INSTRUCTIONS FOR USE

Aquarius System

Blood Purification
with Regional Citrate and/or
Heparin Anticoagulation

NIKKISO

Information

These Instructions for Use are valid for the Aquarius hemofiltration system with Aquarius^{+} software (RCA) and Platinum software (Regular). The Aquarius^{+} software provides the highest level of extension including the Regional Citrate Anticoagulation functionality.

This document provides instructions necessary for the proper operation of the Aquarius system. It is not a guide to the administration of the therapies provided.

Safe and effective treatment using the Aquarius system depends primarily upon the medical skills and knowledge of the attending physician and nurses. Consequently, technical competence in operation of the Aquarius system control unit must be supplemented by a thorough understanding of the associated medical procedures.

The operator must use the Aquarius system in accordance with the information detailed in the present Instructions for Use and after adequate training by the manufacturer. Patient treatment must be in accordance with specific procedures prescribed by a qualified physician.

The Aquarius system must be installed by a manufacturer certified technician.

Aquarius^{TM}, Accusol^{TM}, Aquamax^{TM} and Aquaset^{TM} are trademarks of NIKKISO Co. Ltd.

Table of contents

1 How to use the Instructions for Use

The Aquarius system must only be operated in accordance with the procedures contained in these Instructions for Use, by trained and qualified personnel.

The use of operating procedures, maintenance procedures, or accessory devices other than those published or recommended by the manufacturer can result in patient injury or death.

Within the general continuous text of this IfU, the Aquarius device is called "Aquarius system". This implies the Aquarius hemofiltration system with Aquarius^{+} software (RCA) and Platinum software (Regular).

Specific descriptions of the device variants will be indicated by the terms "RCA/Aquarius^{+}" and "Regular/Platinum", respectively.

1.1 Organization

The material in these Instructions for Use is organized in 12 sections.

Section Title	Content
1 – How to use the Instructions for Use	This section describes the organization and content of this document.
2 – Intended purpose	This section describes the intended purpose, indications, contraindication, and general warnings of Aquarius system.
3 – Getting started with the Aquarius system	This section provides the precautions and instructions needed to set up the Aquarius system.
4 – Introducing the Aquarius system	This section describes the Aquarius system.
5 – Performing a treatment with the Aquarius system	This section describes the steps necessary to turn on the Aquarius system, prime the system, connect to a patient, perform a treatment and end a treatment.
6 – Alarms and messages	The alarms and messages generated by the Aquarius system are described. For each alarm, potential causes and corrective actions are listed.
7 – Cleaning and disinfection	Cleaning and disinfection instructions for the Aquarius system are listed in this section.
8 – Guidance and manufacturer declaration – Electromagnetic emissions	Describes compliance with EMC norms.
9 – Technical data	Lists the technical specifications of the Aquarius system.
10 – Waste management	Information related to dispose of the Aquarius system and its components.
11 – Warranty and liability	Information related to warranty and liabilities are described in this section.
12 – References	References used to generate this document.

1.2 Symbols

The following symbols are used to highlight warnings and cautions as well as additional information:

Symbol	Meaning
	This symbol is used to draw your attention to a "**Warning**". "**Warnings**" are used to alert the reader about a situation which, if not avoided, could result in death or serious injury.
	This symbol draws attention to a "**Caution**". "**Cautions**" are used to warn the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the operator or patient or damage to the equipment or other property.
	This symbol indicates that the text to the right is necessary information to fully understand the procedures that follow.
	This symbol indicates supplementary information.

The following symbols are used in the text to increase the comprehensibility of this document:

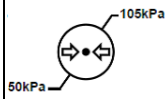
Symbol	Meaning
⇨	This symbol indicates an independent action request.
Step 1: **1.** **2.** **3.** ***Step 2:*** ***Step 3:***	These symbols indicate a numbered action request. The actions follow one after the other.
▶	This symbol indicates the result of the action request.

The following representation of the tubing lines are used in the flow diagrams:

Symbol	Meaning
	Solid line indicates an active tubing line.
	Dashed line indicates a not active tubing line.

The following symbols are used on/in the Aquarius system:

Symbol	Meaning
	Mute key (Audio paused)
	Clamp LED/key. This key is used to reset air detector or to open the return line clamp.
	Treatment LED/key. This key is used to start or stop the treatment.
	Blood pump LED/key. This key is used to start or stop the blood pump.
	Filtrate scale (Yellow dot)
	Substitution scale (Green dot)
	Citrate scale (Black dot)
	Calcium scale (White dot)
~	Alternating current
	Potential equalization conductor
	Protective earth conductor
	Degree of protection against shock: Type B
	Year of manufacture
	Manufacturer
	Separate collection for electrical and electronic equipment
	Product conforms to a particular directive of the European Union (European Medical Device Directive 93/42/EEC) 0123 is the identification number of the Notified Body TÜV SÜD Product Service
	Device is a medical device
	Non-condensing
	Humidity range for transportation and storage of product (from 30 to 80%)

Symbol	Meaning
	Temperature range for transportation and storage (from -5 to 45 °C)
	Pressure range for transportation and storage (from 50 to 105 kPa)
IPX1	**IP**: Ingress protection **X**: Protection against accidental contact with electrical or moving parts, no protection against ingress of solid foreign bodies **1**: Degree of water ingress protection: Protection against vertically falling water drops
	Follow the Instructions for Use
	Indicates compliance with both Canadian and U.S. requirements with respect to electrical shock, fire and mechanical hazards in accordance with UL 60601-1 in its currently released version and CAN/CSA-C22.2 No. 601.1-M90.
	Interference may occur in the vicinity of equipment marked with this symbol
	Up (Package labeling)
	Fragile (Package labeling)
	Keep dry (Package labeling)
	Do not remove from pallet
	Installation by authorized technician before use
	Pollution control symbol (China)
Hemofiltration system	Generic device name according Global Medical Device Nomenclature (GMDN)

1.3 Abbreviations and terms

1.3.1 Organizations

Abbreviation	Definition
AAMI	Association for the Advancement of Medical Instrumentation.
CSA	Canadian Standards Association. This designation indicates that a product conforms to the standards of the Canadian Standards Association.
TÜV	Technische Überwachungs-Vereine (Notified Body and Testing laboratories).
UL	Underwriters' Laboratories. This designation indicates that a product conforms to the standards set by Underwriters' Laboratories.

1.3.2 Units of measure

Abbreviation	Definition
A	Ampere (unit of electric current)
°C	Degrees Celsius
cm	Centimeters
°F	Degrees Fahrenheit
h	Hour
Hz	Hertz (unit of frequency)
kg	Kilogram
kPa	Kilo Pascale
l	Liter
min	Minute
ml/h	Milliliters per hour
ml/min	Milliliters per minute
mmHg	Millimeter of mercury (unit of pressure)
mmol/l	Millimol per liter
s	Second
V	Volt

1.3.3 Special terms

Expression	Definition
Access	The tubing line supplying blood from the patient
ACD-A	Acid Citrate Dextrose formula A
ADU	Automatic Degassing Unit
Balance pumps	Pre- and post-dilution pumps, filtration pump
BLD	Blood Leak Detector
CE	Conformité Européenne. This designation indicates that a product conforms to a particular directive of the European Union.
Citrate dose	Concentration of citrate in blood
CRRT	Continuous Renal Replacement Therapies
CVVH	Continuous Veno-Venous Hemofiltration
CVVHD	Continuous Veno-Venous Hemodialysis
CVVHDF	Continuous Veno-Venous Hemodiafiltration
ECG	Electrocardiograph
EP	European Pharmacopoeia
FFP	Fresh Frozen Plasma
Filtration fraction	Relation between fluid removal and blood flow rate
Fluid loss total	Amount of fluid removed from the patient
Hemofilter	Filter used in hemofiltration for its practical impermeability to albumin.
Hemoperfusion (HP)	Blood filtration using adsorption
Hypervolemia	Name of the medical state caused by excessive fluid in the blood
Hypovolemia	Name of the medical state caused by a decrease in blood plasma
IFU	Instructions for Use
I.V.	Intravenous
K_{Uf}	Ultrafiltration coefficient
Operator	Trained medical personnel using Aquarius system
PD	Pressure drop
POST	Pre-operational System Test
RCA	Regional Citrate Anticoagulant
Renal dose	Dose of treatment related to the patient's blood weight
Return	The tubing line returning blood to the patient
SCUF	Slow Continuous Ultrafiltration
TMP	Transmembrane pressure

Expression	Definition
TPE	Therapeutic Plasma Exchange
Turnover rate	The sum of the programmed loss rate, the pre-dilution and the post-dilution substitution fluid rates
UF	Ultrafiltration

1.4 Related publications

Aquarius system Service Manual: Information on the configuration of the instrument, testing and calibration of all systems (including safety systems), required periodic maintenance, necessary diagrams and replacement parts are all contained in the Service Manual.

To determine if a more recent version of the Aquarius system Instructions for Use is available, contact your service representative.

2 Intended purpose

2.1 Intended use

The Aquarius system is indicated for Continuous Renal Replacement Therapies (CRRT) in patients with acute renal failure or fluid overload.

The Aquarius system may also be used in Therapeutic Plasma Exchange (TPE) and Hemoperfusion therapies.

2.1.1 Benefit of using the Aquarius hemofiltration system

The following benefits are identified:

- Reduction of bleeding risk for RCA in comparison to the use of standard heparin
- Reduction of blood transfusions for RCA in comparison to the use of standard heparin
- Reduction in the use of heparin
- Progression of renal recovery for CRRT in comparison to SLED (sustained low-efficiency dialysis)
- No accumulation of LMWH (low molecular weight heparin) during CVVH
- Decline in the level of procalcitonin, hs-CRP (high sensitive c-reactive protein) and TXB2 (Thromboxane B2)
- Elimination of plasma lactate by CVVH
- Prolongation of filter runtime

2.2 Area of application – Indications

The Aquarius system controls and monitors the extracorporeal blood circuit and the fluid balance circuit. The fluid balance circuit is defined as a filtrate/substitution system in hemofiltration, a filtrate/dialysate system in hemodialysis, a filtrate/dialysate-substitution system in hemodiafiltration, a plasma/substitution system in therapeutic plasma exchange, and a filtrate system only in slow continuous ultrafiltration. The fluid balance circuit is inactive in hemoperfusion. The fluid balance is controlled by pumps and scales.

Toxins are removed from the blood and the blood composition is corrected by means of filters and solutions, using filtration and/or adsorption in the extracorporeal circuit. The blood is then returned to the patient.

Details of treatment procedures are described in section *4.2 Fields of application – Overview (Page 4-8)* of the present Instructions for Use.

All therapies using the Aquarius system must be prescribed by and performed under the responsibility of a physician who is familiar and well informed about the therapies. The prescribed treatment must be performed by trained medical personnel in medical facilities.

The citrate anticoagulation is intended for:

- CVVH with post-dilution using calcium containing replacement fluid and for TPE in adult patients only.
- CVVH with pre-dilution citrate-containing replacement fluid (available in specified countries).
- CVVHD with calcium free dialysate fluid.

The Aquarius heparin syringe pump is intended to deliver heparin into the extracorporeal circuit.

The Aquarius citrate pump is intended to deliver citrate anticoagulation solution conforming to the national drug regulations into the extracorporeal circuit.

The Aquarius calcium pump is intended to deliver calcium supplementation solution conforming to the national drug regulations into the return line of the extracorporeal circuit.

The Aquarius system is intended to enable anticoagulation with heparin by using the integrated heparin syringe pump in all treatment procedures. The Aquarius system heparin syringe pump is intended to deliver heparin into the extracorporeal circuit.

The use of the Aquarius system is limited to patients weighing a minimum of 20 kg and the extracorporeal blood volume, including tubing set and filter (in ml), should not exceed 10% of the patient's blood volume.

2.3 Contraindications

No contraindications associated specifically to the Aquarius system are currently known when it is used according to Indications.

General

All generally applicable side effects and contraindications for extracorporeal therapies must be observed.

An extracorporeal treatment procedure with the Aquarius system should be performed after careful consideration of the risks and benefits by the responsible physician, in patients;

- incapable to tolerate an extracorporeal treatment procedure because of their age and their physical development or their clinical condition,
- with known hypersensitivity to the substances used in the extracorporeal circuit,
- with severe anemia,
- with hemorrhagic diathesis (bleeding tendencies),
- with coagulopathy (blood clotting disorders).

Disposables

The contraindications for the disposable medical devices/medicinal product used as accessories with the Aquarius system must be considered. It is essential to observe the Instructions for Use supplied with the medical device/medicinal product, as these contain updated information on areas of use, side effects, and contraindications for the respective disposable product.

Citrate Anticoagulation

A regional citrate anticoagulation with the Aquarius system should be performed after careful consideration of the risks and benefits by the responsible physician, in patients:

- with liver insufficiency
- known citrate metabolism disturbance
- hypersensitivity against citrate.

2.4 Side effects

No side effects associated specifically with the Aquarius system are currently known.

Side effects associated with the extracorporeal circuit

General side effect associated to extracorporeal procedures are the following:

Stress from extracorporeal circuit

Extracorporeal treatment procedures are always linked to individual stress for each patient, possibly leading to non-specific side effects, such as tiredness, nausea, sweating, dizziness, headache, reduction in blood pressure, change in pulse rate, arrhythmia, shock, chills, fever, systematic inflammatory syndrome or bleeding.

Vascular access

Extracorporeal treatment procedures require a high volume central vein catheter (e.g. Shaldon catheter) when performing a vein puncture. If a vein puncture is performed incorrectly, it may lead to hematoma, thrombosis, hemato- or pneumothorax, arrhythmia, nerve injury, vasovagal reaction and/or inflammation of the vascular area.

Blood loss

Extracorporeal treatment procedures may result in blood loss caused by circuit leaks or clotting. When the therapy prescription supposes using a blood flow rate below 150 ml/min, we recommend to use an Aquaset containing an Aqualine S.

Circulatory complications

Extracorporeal treatment procedures may result in circulatory complications, such as hypertension and hypotension from temporary fluid displacement within or from the extracorporeal circuit.

Anaphylactic reaction

Extracorporeal treatment procedures may result in anaphylactic reaction from intolerance to the accessories, exchange fluid, dialysate solution, or anticoagulants.

Side effects associated to administration of heparin anticoagulant

The heparin administration can lead to side effects. Bleeding, heparin induced thrombocytopenia as well as further general side effects must be considered, such as: hypersensitivity reactions, osteoporosis, eosinophilia, alopecia, hyperkalemia, hypoaldosteronism.

Side effects associated to the administration of citrate anticoagulant

Citrate administration can lead to side effects e.g:

Disturbance of calcium homeostasis

Calcium homeostasis may be disturbed by the administration of citrate as an anticoagulant. A temporary decrease in systemic ionized calcium in the blood can occur.

Citrate toxicity

The signs and symptoms of citrate toxicity begin with paresthesia, a “tingling” sensation around the mouth or in the extremities, followed by severe reactions that are characterized by chills, stomach cramps, or pressure in the chest, followed by more severe reactions that are characterized by hypotension and possible cardiac arrhythmia. Citrate toxicity may occur more frequently in patients that are hypothermic, have impaired liver or renal function, or have low calcium levels because of an underlying disease.

Hypocalcaemia

Hypocalcaemia is defined as serum calcium level lower than 8.2 mg/dl (2.05 mmol/l) or an ionized calcium level lower than 4.4 mg/dl (1.1 mmol/l) and severe hypocalcaemia as serum calcium level lower than 1.8 mmol or an ionized calcium level lower than 0.9 mmol/l.

Hypokalemia

Hypokalemia is defined as an electrolyte imbalance characterized by a low level of potassium (<3.6 mmol/l) in the blood serum.

Hyperkalemia

Hyperkalemia is defined as an electrolyte imbalance characterized by an elevated level of potassium (>5.0 mmol/l and >5.4 mmol/l in children) in the blood serum.

Hypernatremia

Hypernatremia can result from the presence of high non-physiological sodium concentration in the citrate solution.

Acidosis

Acidosis under citrate anticoagulation can be caused by:

- citrate accumulation
- imbalance between blood flow and filtrate flow (high blood flow, low filtrate flow)
- high citrate dose (high citrate flow, low blood flow)
- high blood flow

Metabolic Alkalosis

Sodium citrate is metabolized to bicarbonate and carbon dioxide and can lead to metabolic alkalosis.

Side effects associated to the electrolyte supplementation

Electrolyte supplementation can lead to side effects e.g.:

Hypocalceamia

Inadequate calcium supplementation can lead to hypocalcaemia as described above.

Hypokalemia

Inadequate potassium supplementation can lead to hypokalemia as described above.

Hypercalceamia

An over dosage of calcium supplementation fluid by an excessive or highly concentrated calcium infusion can lead to:

- symptoms like heat feeling, nausea, vomiting, vasodilation and blood pressure drop, bradycardia and arrhythmia up to cardiac arrest.
- hypercalcemia (total plasma calcium concentration > 3 mmol/l or ionized calcium amount > 1.1 mmol/l). Symptoms of hypercalcemia can be:
  - cerebral disturbances (e.g. weariness, lethargy, confuses)
  - gastrointestinal disturbances (e.g. nausea, vomiting, constipation, inclination to ulceration)
  - cardiac disturbances (e.g. tachycardia and arrhythmia inclination, high blood pressure, ECG changes (QT shortening))
  - renal disturbance (increased urination, increased thirst, reduction of the power of concentration, inclination to calcium salts deposit in the kidney)
  - reflex drop
- hypercalcemic crisis (plasma concentration > 4 mmol/l) characterizes by the followings quickly developing symptoms:
  - vomiting
  - colic's, in-acoustic up to the intestinal obstruction results of paralysis of the intestines musculature, general muscle weakness
  - consciousness disturbances, at first increased, later, frequently reduced till complete missing urine ejection

Hyperkalemia

Inadequate potassium supplementation can lead to hyperkalemia as described above.

Side effects associated to the plasma and albumin supplementation in TPE

Plasma and albumin supplementation in TPE can lead to hypotension, tingling, nausea, vomiting, arrhythmia, syncope, urticaria, chills, fever, bronchospasm, hypo- or hyperproteinemia.

2.5 Warnings

Read all warnings, precautions and instructions carefully before using the Aquarius system.

This summary does not contain all the safety statements in this Instruction for Use. Other cautions and warnings exist within this Instruction for Use.

The following warnings must be observed in order to avoid possible dangers associated with a high risk of death or severe injury for patients, operators, or third parties.

Installation and connection, moving of the device

The installation of the Aquarius system at the place of operation according to the technical service manual must be performed by trained personnel authorized by the manufacturer.

Connecting additional devices may result in exceeding the permissible leakage currents. If the system is used in parallel operations (according to open heart surgery standards), the equipotential bonding conductor must be connected.

To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

Position the Aquarius system in such a way that it is difficult to disconnect the device from mains.

When using a device of safety class I, like the Aquarius system, the quality of the protective conductor of the installation is important. It should be noted that it is officially specified by the authorities in many countries.

The Aquarius system may only be operated with connection of the potential equalization to insure electromagnetic immunity.

Release the brakes of all wheels before moving the device! Move the device carefully over steps or crevice.

Do not modify this equipment without authorization of the manufacturer.

If this equipment is modified according the information from the manufacturer, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

Treatment environment

Do not operate devices emitting electromagnetic energy near the Aquarius system, e.g. cellular phones.

Do not operate the Aquarius system close to areas where explosive gasses or flammable anesthetics are or have been used.

The Aquarius system must not be operated simultaneously with or near any system whose emission compromises the immunity level of the Aquarius system as specified in the section *8.3 Emission class, group and immunity test level (Page 8-5)* of these Instructions for Use. Emissions outside the specified electromagnetic energy may impact the accuracy of the balance system.

Ensure that no electrical equipment with touch currents and patient leakage currents above the respective limits for type CF applied parts is used in the patient environment in combination with central venous catheters with atrial location.

Accessories, disposable products, drugs and replacement fluids

For disposables which are approved and validated by NIKKISO Europe GmbH (e.g. hemoperfusion cartridge and tubing sets) follow the Instructions for Use from the relevant manufacturer.

During priming and treatment, all active fluid line clamps must be open. Remove all line occlusions and kinks.

Do not use replacement solutions of different compositions simultaneously on the Aquarius system.

All solutions used must be sterile, of appropriate composition and prescribed by a physician. Inapropriate composition of the solutions can lead to hyper- or hypocalcaemia, hyper- or hyponatremia, hyper- or hypokalemia, hyper- or hypomagnesemia, hyper- or hypoglycaemia.

Use of incorrect solutions can result in toxic shock, endotoxin shock, patient injury or death.

If a commercially available replacement solution is used, it must be labeled as intended for intravenous injection.

The operator must ensure that the correct substitution solutions and dialysate solutions prescribed by a physician are used appropriately for all therapies.

Only use an anticoagulant that complies with the requirements of national drug regulations and observe the information contained in its package insert.

No electrical equipment with touch currents and patient leakage currents above the limits for type CF applied parts are allowed to be used in the patient environment in combination with central venous catheters with atrial location.

If a central venous catheter with atrial location is used, the potential equalization cable shall be connected.

It is recommended that the filters and the Aqualine tubing sets be changed after 24 hours of use.

The Aqualine and Aqualine RCA tubing set (adult) have been tested under the following high end conditions without adverse effect:

- Duration = 72 h/100 h configurable
- Pre-filter pressure = 450–500 mmHg
- Return pressure = 300–350 mmHg
- Blood flow = 450 ml/min (for 72 h configuration)
- Blood flow = 300 ml/min (for 100 h configuration)
- Infusion flow = 10 l/h
- Citrate flow = 650 ml/h
- Calcium flow = 300 ml/h
- Temperature = 37 °C

The Aqualine S and Aqualine S RCA tubing set have been tested under the following high end conditions without adverse effect:

- Duration = 72 h/100 h configurable
- Pre-filter pressure = 450–500 mmHg
- Return pressure = 300–350 mmHg
- Blood flow = 200 ml/min (for 72 h configuration)
- Blood flow = 100 ml/min (for 100 h configuration)
- Infusion flow = 4 l/h
- Citrate flow = 650 ml/h
- Calcium flow = 300 ml/h
- Temperature = 37 °C

Operation and use

Only staff trained by the manufacturer shall operate the Aquarius system.

During the system test, the operator must wait for the visual and audible alarm signals to be generated.

If there are errors during the initial functional system test the Aquarius system must not be used. Refer to on-screen help and repeat. Notify Technical Service if the system test continues to fail on the same error.

When entering the parameters the operator must compare the entered value with the displayed value.

The patient parameters must be entered and adjusted in accordance with the instructions of the prescribing physician.

Ensure that the patient's blood access (usually a central venous catheter) is secured properly.

During priming and treatment, all active fluid line clamps must be open. Remove all line occlusions and kinks.

Connecting or disconnecting the patient to or from the Aquarius system requires aseptic technique and continuous monitoring to prevent air from entering the system (air infusion) or blood from escaping from the system (blood loss). All system connections must be checked at regular intervals. All blood and fluid paths are sterile and non-pyrogenic.

Always follow hospital policy for standard precautions. Gloves, mask and a face shield should be worn when connecting or disconnecting blood lines from patients and removing tubing sets from the Aquarius system.

In case of negative return pressure, air may enter into the extracorporeal circuit downstream the air detector and may not be detected.

Improper functioning of an ultrasonic air detector may be caused by a coagulum or the application of ultrasound gel.

The operator must make sure that the heparin syringe used has been configured in service mode by a technician. Use only Luer lock syringes designed for syringe pumps (ISO 7886-2).

The blood flow and thus the treatment efficacy may be reduced when the pre-pump access pressure is extremely negative.

A physician must prescribe the anticoagulation application.

Low delivery rates of heparin (e.g. use of undiluted anticoagulation solution) can lead to delayed and non-continuous delivery due to compliance in the syringe with output pressure changes in the extracorporeal circuit.

When *No anticoagulant* is selected, constantly monitor the TMP and pressure drop values to reduce or avoid the risk of clotting of the extracorporeal circuit (filter and lines).

The operator must make sure that the pressure domes integrated in the tubing sets are clipped on properly to the pressure sensors and the dome clamps are closed securely on the Aquarius system.

Do not open the dome clamps or remove the pressure domes during treatment.

Do not move the Aquarius system during treatment: movement of the device while the Balance system is active can cause false balance alarms and may lead to undesired automatic fluid compensation.

The Aquarius system must be placed on a horizontal plane during its normal use. Angle discrepancies from the horizontal plane may cause device instability and inaccurate functioning.

Before removing the Aqualine tubing set or disconnecting domes after ending treatment, make sure that pressure level inside tubes are below 400 mmHg. The end treatment screen displays all four pressures from the system. Use a syringe or Aquasafe bag to decrease the pressure level before removing a dome from a pressure sensor. When domes are removed from pressure sensors in over pressure conditions, there is high risk of burst and leakage of dome membranes.

Negative ultrafiltration: Excessive negative ultrafiltration (a positive balance) may result in patient hazard. The prescribing physician must make this indication.

When treatment with low volume blood line is used, the patient must be physiologically capable to accept the minimum extracorporeal blood flow of 10 ml/ min.

The I.V. pole may only carry a maximum weight of 2.5 kg.

The Aquarius system is not intended to be a substitute for monitoring the patient's condition.

Treatment data sent by the Aquarius system from the optical ports are intended for documentation purpose only. They are not intended for diagnostic purposes.

All connecting points on the system must be regularly and carefully checked to protect against blood loss. Particular care should be taken to ensure that the venous access site catheter/needle is secure and does not slip out from the vessel.

Complete monitoring of the extracorporeal system to avoid blood losses is practically impossible with the current state of technology.

The Aquarius system monitors the return pressure in order to detect disconnections in the extracorporeal system. The system triggers an alarm if it detects a pressure drop of 30 mmHg below the working value measured 90 seconds after the start of the blood pump or a measured pressure lower than +20 mmHg and stops the blood pump.

In case of a continuously negative access pressure, the accuracy of the blood pump flow rate as well as the accuracy of the inlet and outlet pressure ranges may be reduced; thus also the treatment efficacy may be decreased.

Ensure that the filtrate bags and substitution bags do not touch the cart frame. Ensure that the tubing lines are not supported by and are not resting on the cart frame. Do not touch the filtrate or substitution solution bags while the balance system is active.

Observe this warning to avoid patient fluid balance errors.

Fluid leaks lead to a patient fluid balance error and can harm the patient seriously.

Ensure that all connectors are closed properly to prevent any potential fluid leak.

Ensure that unused fingers of the multi-way connectors manifolds are properly clamped.

Alarm and system

If for some reason the operator interface is compromised, the machine will normally stop automatically. In rare instances, the machine will continue with a black screen (for example if the back light is broken). In such instances, the machine should be stopped manually and the blood returned to the patient. This is possible by removing the return line from the automatic clamp and manually turning the blood pump with the hand-crank. The hand-crank is located at the back of the scale system. Be careful during manual blood return to patient, as the return line is not automatically clamped if air is present.

When bypassing one or more of the safety controls the operator is responsible for monitoring the patient.

If power is restored after a power outage the operator is responsible for monitoring the patient.

Interference to the Electrocardiograph (ECG) monitor

Electrically isolated peristaltic pumps such as those used on the Aquarius system can produce electrostatic charges in the disposable set that are not hazardous to the patient, but can appear as an artifact on cardiac monitors. When starting treatment, observe the cardiac monitor before and after starting the blood pump to verify that the artifact is not present.

Citrate anticoagulation

Use only citrate anticoagulant solutions that allow citrate pump within its intended operation range to reach a citrate concentration between 2.5 and 5 mmol/l in the patient´s blood.

If a citrate anticoagulant is used, pay special attention to the sodium balance of the patient. Citrate anticoagulant administration has potential risk of hypernatremia. The citrate concentration of the preferred citrate solution must be defined within the setup. If 4% trisodium citrate is used, only adapted replacement fluid should be used.

If a citrate anticoagulant is used, pay special attention to the acid base index of the patient. Citrate anticoagulant administration has potential risk of metabolic alkalosis.

The sodium and glucose concentration in the patient blood must be monitored regularly.

Only use citrate and calcium line sets approved for use with Aquarius system.

Check the composition of the citrate and calcium bags before use.

If necessary control frequently the glucose and magnesium concentration in the blood of the patient.

Make sure that the citrate bag is on the citrate scale (black label) before beginning a treatment.

Make sure that the calcium bag is on the calcium scale (white label) before beginning a treatment.

Check that the citrate and calcium bags are connected to their respective lines before beginning the treatment. Lines are colour coded (black for citrate and white for calcium).

The anticoagulant process needs to be prescribed under the control of a physician. When citrate anticoagulant is used, blood samples should be taken as often as necessary, given the protocol used and the physician's prescription, in order to carefully monitor the concentration of blood electrolytes, citrate, ionized calcium, magnesium, sodium and bicarbonate.

Side effects can occur if monitoring is not performed as prescribed.

Patients with liver failure may have impaired citrate metabolism. Citrate anticoagulation should be used with caution in patients with liver failure.

Ensure the adequate calcium supplementation considering both the calcium concentration in the replacement or dialysate fluid and in the calcium supplementation solution.

A risk of hypocalcemia is given if citrate anticoagulant is administered with inadequate citrate dose and/or no adapted calcium supplementation.

The acid base index in systemic blood must be monitored regularly and adequate medical measures should be performed if a metabolic acidosis or alkalosis occurs.

The reduction of blood flow and corresponding citrate flow reduces the citrate infusion as the source of metabolized bicarbonate.

The calcium concentration in the extracorporeal circuit and the systemic total calcium concentration of the patient have to be monitored regularly. Adequate medical measures have to be performed if calcium homeostasis is disturbed.

- The ionized calcium concentration after the hemofilter shall be monitored after the start of treatment to ensure that a correct citrate dose is used. The ionized calcium concentration after the hemofilter (before the return drip chamber) should be approx. 0.2 mmol/l to 0.4 mmol/l.
- The ionized calcium concentration of blood inside the extracorporeal circuit shall be monitored:
  - before treatment,
  - directly after the start of the treatment (5 to 10 min), or
  - after reprogramming blood flow, citrate flow, turnover or calcium flow, and
  - at regular time intervals defined by the physician depending on the patient (ex. every 6 hours) if the programmed treatment parameters are unchanged.
- Systemic total calcium and ionized calcium concentration shall be monitored at treatment start and at regular time intervals defined by the physician depending on the patient (ex. every 6 hours) thereafter. The systemic ionized calcium concentration shall be approximately 1.2 mmol/l.

Use only diluted calcium supplementation solutions.

It is strongly recommended that the calcium concentration of the supplementation fluid is between 10 and 20 mmol of calcium per liter.

Do not use calcium free replacement fluids.

Adapt the blood flow rate to the turnover/gross filtration rate. It is recommended to ensure a gross filtration rate from 20% to 33% of the blood flow programmed rate.

The increase of the blood/filtrate flow ratio results in a higher citrate dose for the patient due to lower citrate clearance levels.

Program the citrate flow rate so that the citrate dose is between 2.5 and 5 mmol citrate per liter blood.

Control the citrate flow rate every time the blood flow rate is changed to maintain the prescribed citrate/blood flow ratio. Reprogram the citrate flow rate if necessary.

3 Getting started with the Aquarius system

3.1 Setting up

Personnel authorized by the manufacturer must perform set up and installation of the Aquarius system, according to the requirements.

When setting up the Aquarius system, the room and the necessary power installations must comply with the currently valid standards. Line voltage must conform to the data specified on the data plate of the Aquarius system.

Before putting the Aquarius system into operation carefully read the complete Instructions for Use.

3.2 Installation

Before operating the Aquarius system for the first time, ensure that the system is complete and that all parts have been delivered with it. If the Aquarius system is damaged, do not put it into operation. In this case, notify the service technician responsible for this system.

The Aquarius system should only be set up and installed by qualified staff authorized by the manufacturer.

Only authorized staff together with the prescribing physician should do basic modifications of particular settings that do not change the safety concept of the Aquarius system.

3.3 Equipment: disposables

The Aquarius system is designed to operate exclusively with the standard disposables intended for the indicated treatments. Follow the Instructions for Use provided by the manufacturer.

All disposables (tubing sets, filters, waste bags, solution bags, accessories) used with the Aquarius system are single use only and must be disposed of after use.

Use only the tubing sets stated below to ensure the proper operation of the Aquarius system.

The Aquarius system level test was performed with the following disposables:

Item	Description	Legal manufacturer/ MAH***
Citraset RCA 12	REF: Citraset RCA 12 Set containing all required lines for RCA (Aqualine RCA with citrate and calcium tubing) and a hemofilter (Aquamax HF12) Use only for Aquarius RCA devices when RCA treatments are prescribed.	Haemotronic
Citraset RCA 19	REF: Citraset RCA 19 Set containing all required lines for RCA (Aqualine RCA with citrate and calcium tubing) and a hemofilter (Aquamax HF19) Use only for Aquarius RCA devices when RCA treatments are prescribed.	Haemotronic
Tubing set	REF: Aqualine tubing Adult line set Extracorporeal volume (Blood circuit) = 111 ml*	Haemotronic
Tubing set	REF: Aqualine RCA tubing Adult line set for RCA Extracorporeal volume (Blood circuit) = 96 ml* Use only for Aquarius RCA devices when RCA treatments are prescribed.	Haemotronic
Tubing set	REF: Aqualine S tubing Low volume blood line set Extracorporeal volume (Blood circuit) = 65 ml*	Haemotronic
Tubing set	REF: Aqualine S RCA tubing Low volume blood line set for RCA Extracorporeal volume (Blood circuit) = 70 ml* Use only for Aquarius RCA devices when RCA treatments are prescribed.	Haemotronic
Hemofilter	REF: HF03, HF07+, HF12, HF19 Aquamax hemofilters	Bellco/Nikkiso Belgium
Plasma filter	REF: MPS05 Plasma filter, 0.5 m^2	Medtronic
Solution	Accusol 35 Replacement solution for CRRT, 5L	Nikkiso Belgium

Item	Description	Legal manufacturer/ MAH***
Disposable	REF: Aquasafe bags For use with Aqualine and Aqualine S tubing sets, prior to their removal from the machine, to decrease internal pressure	Haemotronic
Disposable	REF: Aquaspike 2 manifolds Manifolds for connecting up to four solution or waste bags	Haemotronic
Disposable	REF: B3052 Waste bag	Haemotronic
Syringe**	REF: BD Plastipak 50 ml Syringe for Heparin pump	Becton Dickinson
Syringe**	REF: Fresenius Injektomat Syringe 50 ml Syringe for Heparin pump	Fresenius
Syringe**	REF: Original Braun Perfusor Syringe 50 ml Syringe for Heparin pump	BBraun

* These values assume that the drip chamber is full.

** **Important: Use only with max. 50 ml, even if the max. volume of the syringe is 60 ml**

*** Marketing authorisation holder

Hemofilters, plasma filters, hemoperfusion cartridges and solutions to be used with the Aquarius system must conform to applicable standards. Use only products with blood port connections compatible with ISO 594 (Part 1+2) female Luer lock connectors, and connections of dialysate filtrate and plasma ports compatible with male Luer lock connectors.

Use catheters according to the instructions provided by the manufacturer; the catheter connector has to be compatible with male Luer lock connectors.

The use of needles imposes a higher risk of needle dislodging. Control the patient connection regularly. The patient connection has to be visible during the complete treatment.

Use only filters and cartridges that are CE marked, according to the Medical Device Directive (93/42/EWG) and are registered for the indications CVVH, CVVHD, CVVHDF, SCUF, TPE or hemoperfusion.

Use only hemofilters which can stand a TMP of 400 mmHg or plasmafilters which have a working range of 50 to 100 mmHg. For both the max. pre-filter pressure is limited to 450 mmHg.

The use of an inappropriate filter for a selected therapy can result in a patient injury or death.

Always ensure that the appropriate filter is used for the intended therapy:

- **Hemofilter for SCUF, CVVH, CVVHD, CVVHDF**
- **Plasma filter for TPE**
- **Hemoperfusion cartridge for Hemoperfusion**

Risk of hemolysis and haemolytic anemia. For plasma filters do not exceed the transmembrane pressure indicated in the Instructions for Use of the filter. This alarm limit is preset to 100 mmHg in TPE therapy mode.

Replacement solutions and dialysate have to be sterile and must meet European Pharmacopoeia requirements or local drug regulations. Use only bags with female Luer lock connectors or a sterile adapter to male Luer lock connectors.

Citrate and calcium solutions have to be sterile and must meet European Pharmacopoeia requirements or local drug regulations. Use container with no more than 2 l, with female Luer lock connectors for citrate and calcium.

The prescribing physician must define concentration and composition requirements.

Never use substitution solutions of different compositions simultaneously with the Aquarius system.

To protect patients from cross-infection, use only tubing sets equipped with pressure measurement with hydrophobic 0.2 µm filters to exclude bacteria.

To avoid false *No bag* alarms during *Priming* or *Treatment* modes, do not use empty bags with a weight less than 80 g.

For further information on disposables and consumables supplied and recommended for Aquarius system, please contact your Official Representative or call Customer Service.

3.4 Disposables overview

3.4.1 Aqualine RCA / Aqualine S RCA tubing line

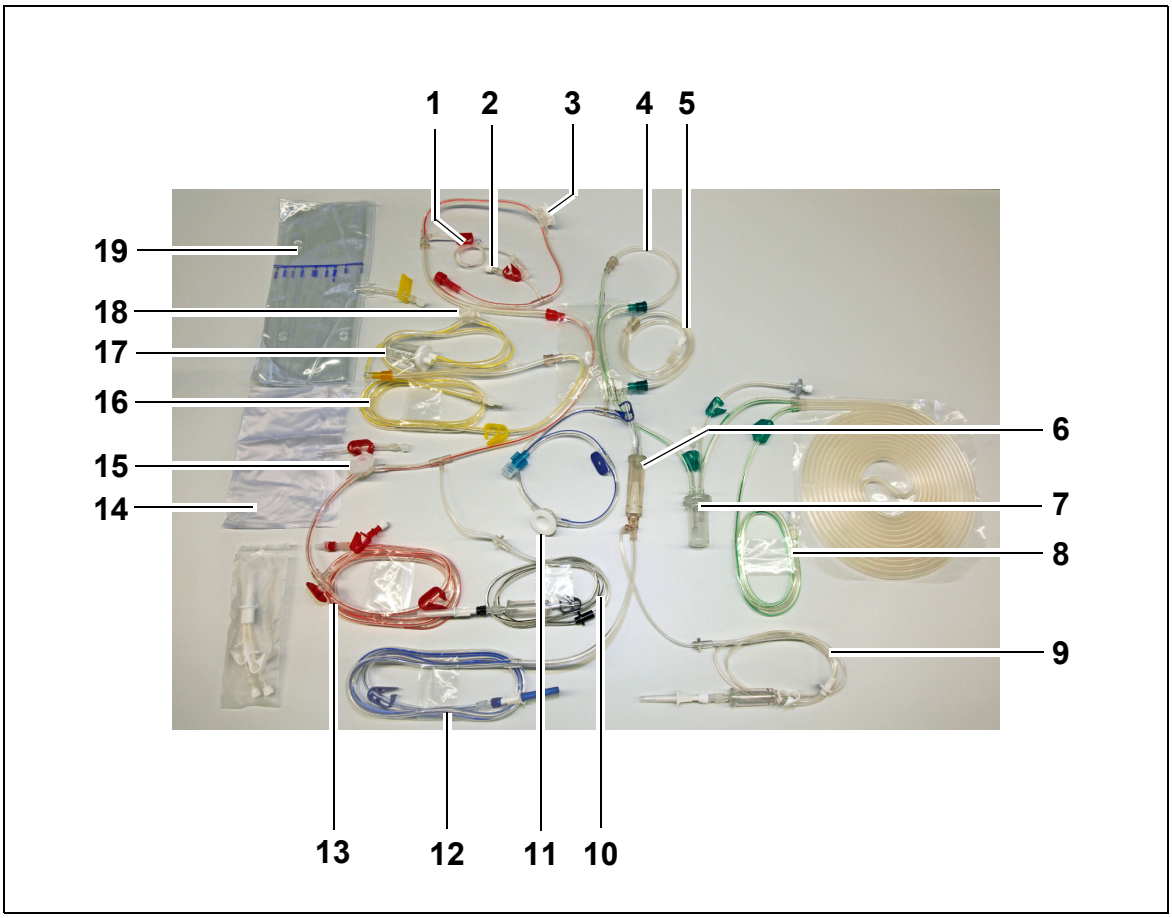


Fig. 1

No.	Description	No.	Description
1	Heparin line	11	Return pressure dome
2	Substitution pre-dilution port	12	Return line
3	Pre-filter pressure dome	13	Access line
4	Post-dilution line	14	Empty priming bag
5	Pre-dilution or dialysate line	15	Access pressure dome
6	Bubble air trap with filter	16	Filtrate line
7	Automatic degassing chamber system line	17	Filtration BLD chamber
8	Substitution or dialysate line	18	Filtrate pressure dome
9	Calcium line	19	Filtrate bag
10	Citrate line		

3.4.2 Aqualine / Aqualine S tubing line

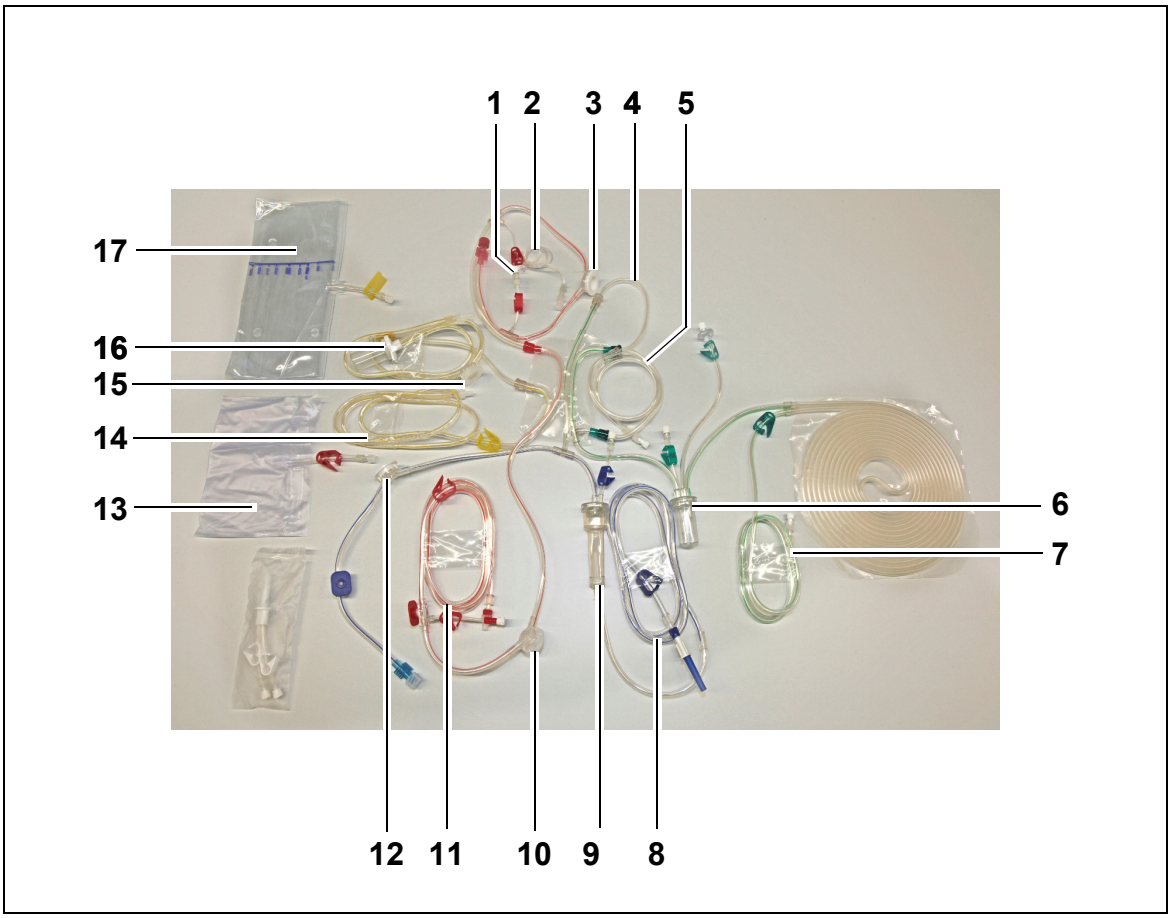


Fig. 2

No.	Description	No.	Description
1	Substitution pre-dilution port	10	Access pressure dome
2	Heparin line	11	Access line
3	Pre-filter pressure dome	12	Return pressure dome
4	Post-dilution line	13	Empty priming bag
5	Pre-dilution or dialysate line	14	Filtrate line
6	Automatic degassing chamber system line	15	Filtrate pressure dome
7	Substitution or dialysate line	16	Filtration BLD chamber
8	Return line	17	Filtrate bag
9	Bubble air trap with filter		

3.5 Materials used

The patient's blood does not have contact with the components of the Aquarius system, thus there is no danger of infection for patients, operators or other persons dealing with the system and there are no special requirements regarding the biocompatibility of the materials used for manufacturing this system.

All disposables (tubing sets, filters, waste bags, solution bags, accessories) used with the Aquarius system are single use only and must be disposed of after use.

This is also true for the integrated transducers that separate and protect the pressure sensors of the Aquarius system by means of an impermeable membrane.

3.6 Transport and storage

To move or transport the Aquarius system it is necessary to release the locking tabs on the wheels. The Aquarius system can then be rotated and freely moved about.

To move the Aquarius system over steps or stairs the locking tabs must be released. The system should be tilted, lifted and carried by at least three people.

Never carry the Aquarius system holding on to the display, the I.V. pole, the scales or the pump doors.

Do not push the Aquarius system over uneven floors and transport it on floors with an angle >10°.

Side hooks for priming bags

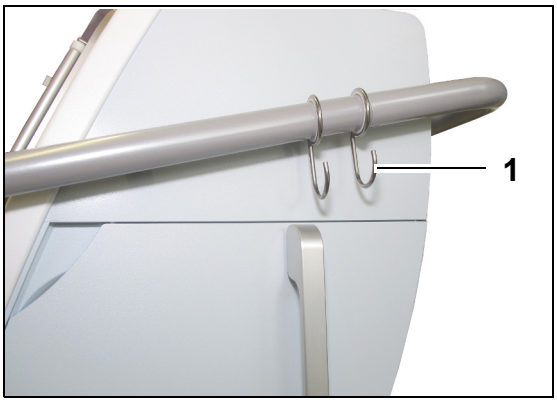


Fig. 3

To avoid the risk of tipping over during transport do not hang any weights on the side hooks (1) of the Aquarius system. These hooks shall be used for priming bags only.

Environmental conditions for the Aquarius system:

Environmental conditions	Transport and storage	Operation
Relative humidity	30 to 80%, non-condensing	10 to 90%, non-condensing
Ambient temperature	-5 to +45 °C (23 to 113 °F)	+17 to +35 °C (61 to 95 °F)
Ambient air pressure	50 to 105 kPa	80 to 105 kPa

3.7 Packing

At the end of manufacturing the Aquarius system is packed in special packaging including a pallet. If the Aquarius system needs to be transported, use special packaging with all relevant safety labels.

3.8 Service and maintenance

The Aquarius system is subject to technical safety checks and maintenance at least once a year. Only qualified service staff, authorized by the manufacturer, must carry out this maintenance and any other repair work. Any work done by non-qualified and non-authorized personnel immediately voids all warranties.

Disconnect the power supply cord before servicing the Aquarius system.

More detailed information on the safety check and maintenance can be obtained from Technical Service.

The expected service lifetime of the Aquarius system is 8 years.

4 Introducing the Aquarius system

4.1 General machine description

The Aquarius system is an Automated Fluid Balance Monitor, designed to be used with various extracorporeal treatments in the field of renal replacement therapies or plasma therapies. All therapies must be prescribed by a physician.

The Aquarius system is divided into three circuits: the extracorporeal (blood) circuit, the substitution/dialysate circuit and the filtrate circuit. The Aquarius RCA adds citrate and calcium anticoagulant circuits.

Toxic substances are removed by filters and clean blood is returned to the patient.

The Aquarius system uses scales to accurately measure and precisely balance fluid volumes.

The Aquarius system has an integrated heater system which may be used to warm the substitution/dialysate fluid before it is given to the patient.

Heparin anticoagulant may be supplied to the extracorporeal circuit via an integrated heparin anticoagulant pump. The prescribing physician may select continuous or intermittent options.

A blood leak detector and an air detector are provided to ensure patient safety.

The Aquarius system protective system is designed as a 2-channel system to protect the patient from foreseeable danger.

At the back of the scale system, a removable hand-crank is mounted. This can be used to manually turn the blood pump.

The Aquarius system has two optical ports at the rear, which can be used for data transfer from the machine.

The Aquarius system is portable. It has a wheeled base connected with a handle to move or carry the Aquarius system.

A transparent protective cover adequately guards against inadvertent contact with the pump's powered roller assemblies.

The Aquarius system contains a filter holder system designed to allow correct positioning of the filter and to facilitate handling and installation of the line set.

The Aquarius system design allows the patient to be positioned left or right of the instrument.

The operator is expected to stand in front of the machine when interacting with the Aquarius system.

Differences overview:

Aquarius Regular (Platinum software)	Aquarius RCA (Aquarius^{+} software)
4 pumps: • Blood pump • Pre-dilution pump • Postdilution pump • Filtration pump • Heparin syringe pump	6 pumps: • Blood pump • Pre-dilution pump • Postdilution pump • Filtration pump • Heparin syringe pump • Calcium pump • Citrate pump
2 scales: • Substitution fluid scale • Filtration fluid scale	4 scales: • Substitution fluid scale • Filtration fluid scale • Citrate scale • Calcium scale

4.1.1 Configurations of the Aquarius system

Aquarius system RCA – Front view

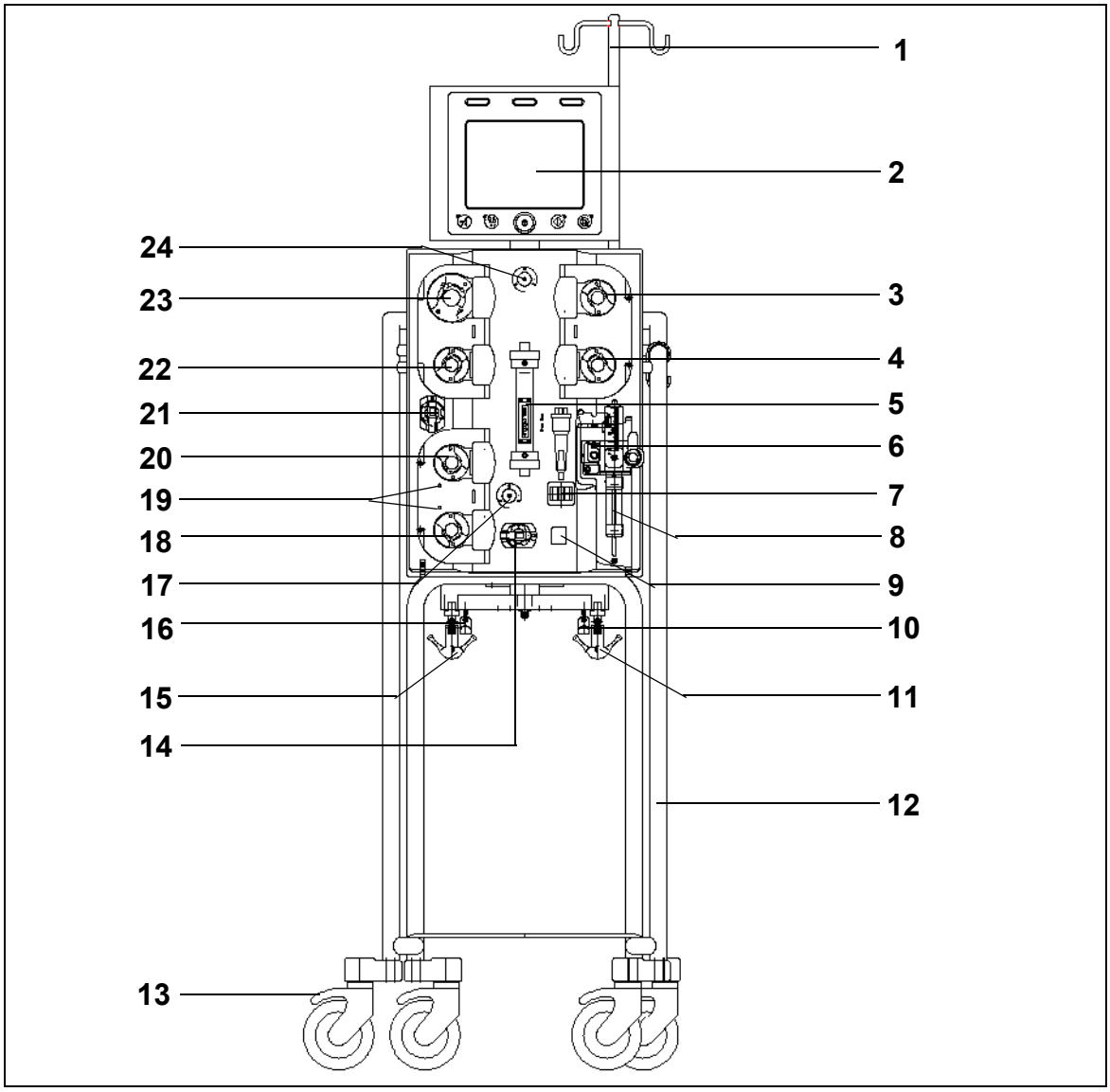


Fig. 4

No.	Mechanical component	No.	Mechanical component
1	I. V. pole	13	Wheel lock
2	Display	14	Pressure sensor: Access pressure
3	Post-dilution pump	15	Filtration fluid scale
4	Pre-dilution pump	16	Citrate scale
5	Filter	17	Pressure sensor: Return pressure
6	Degassing unit (Temperature sensor)	18	Calcium pump
7	Air detector	19	Indication LEDs
8	Heparin pump	20	Citrate pump
9	Return line clamp	21	Pressure sensor: Filtrate pressure
10	Calcium scale	22	Filtration pump
11	Substitution fluid scale	23	Blood pump
12	Wheeled base	24	Pressure sensor: Pre-filter pressure

Aquarius system RCA – Side view (left)

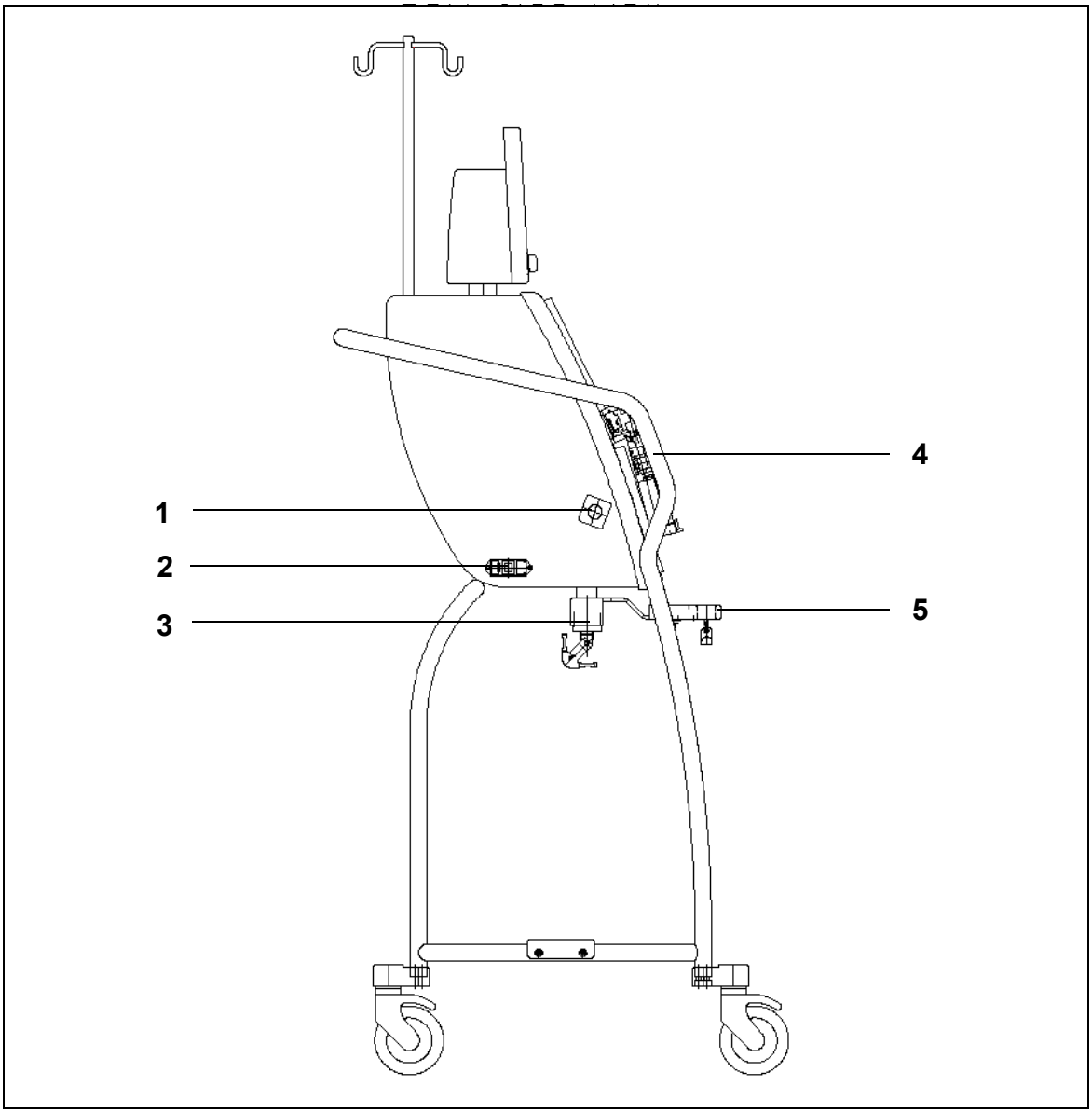


Fig. 5

No.	Mechanical component	No.	Mechanical component
1	Blood leak detector	4	Handle
2	Power supply and power switch	5	Citrate and calcium scales
3	Balancing scales		

Aquarius system RCA – Side view (right)

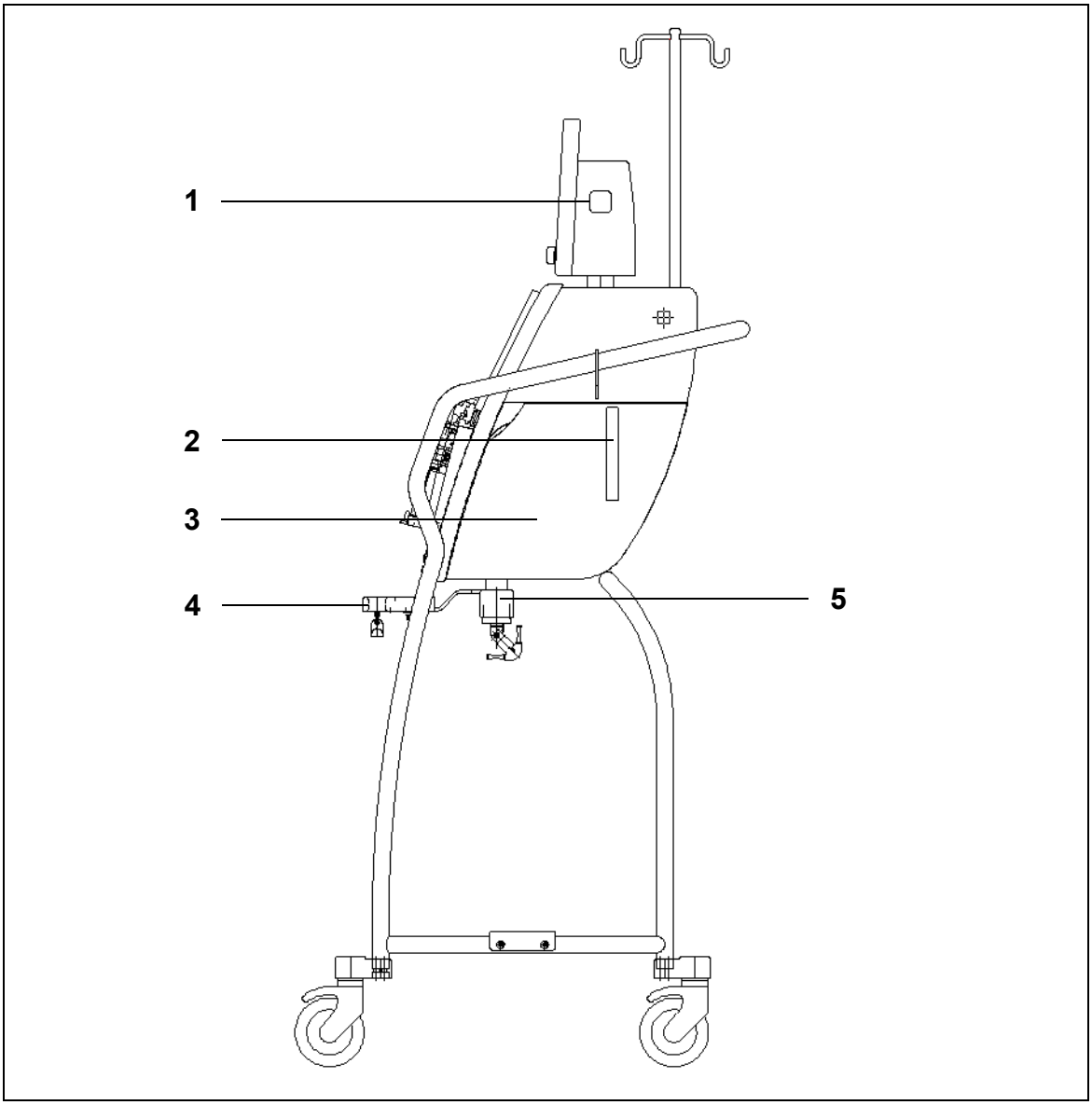


Fig. 6

No.	Mechanical component	No.	Mechanical component
1	ON/OFF key	4	Citrate and calcium scales
2	Lever for opening heating unit door	5	Balancing scales
3	Heating unit door		

Aquarius system Regular – Front view

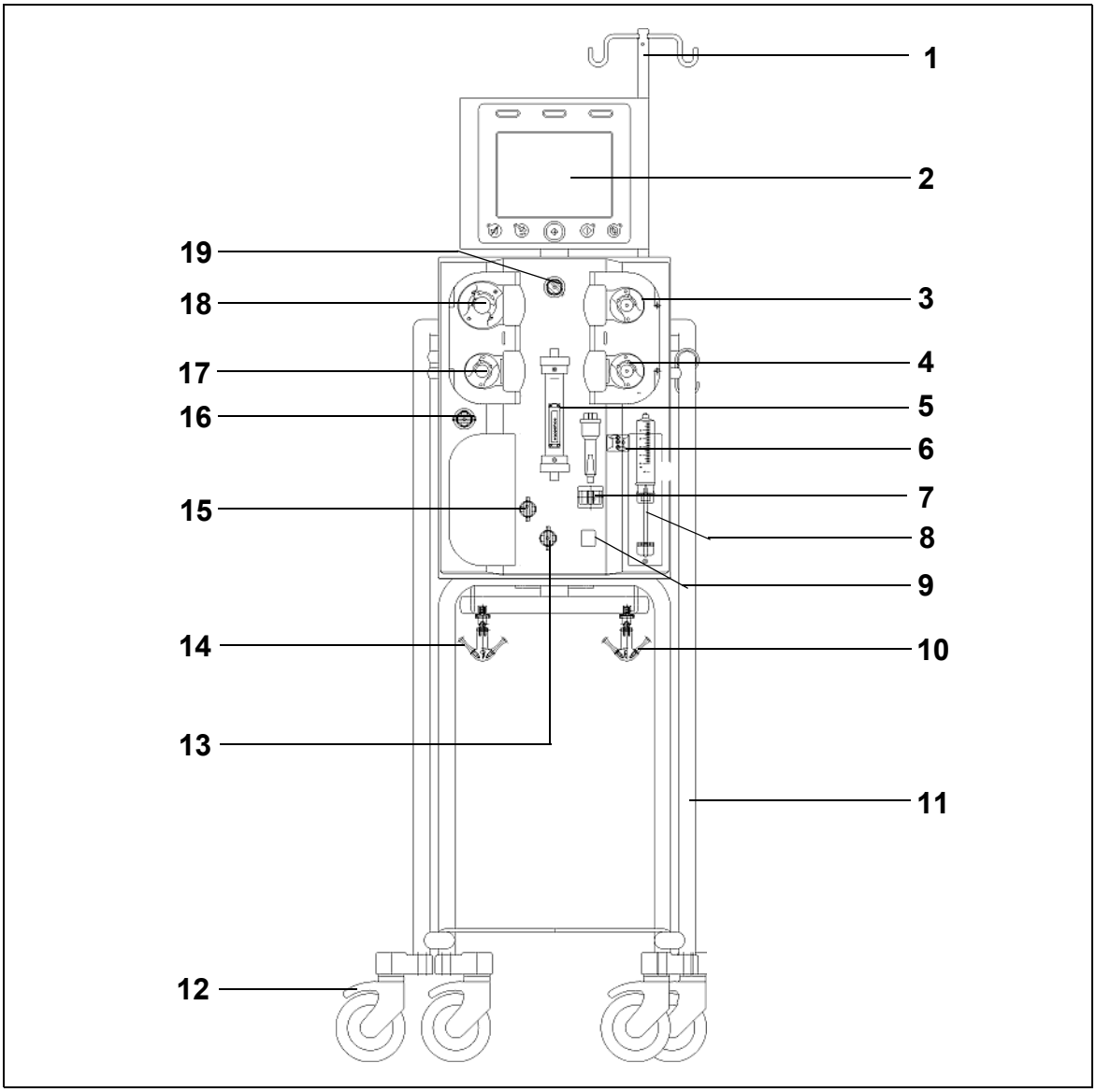


Fig. 7

No.	Mechanical component	No.	Mechanical component
1	I. V. pole	11	Wheeled base
2	Display	12	Wheel lock
3	Post-dilution pump	13	Pressure sensor: Access pressure
4	Pre-dilution pump	14	Filtration fluid scale
5	Filter	15	Pressure sensor: Return pressure
6	Degassing unit (Temperature Sensor)	16	Pressure sensor: Filtrate pressure
7	Air detector	17	Filtration pump
8	Heparin pump	18	Blood pump
9	Return line clamp	19	Pressure sensor: Pre-filter pressure
10	Substitution fluid scale		

Aquarius system Regular – Side view (left)

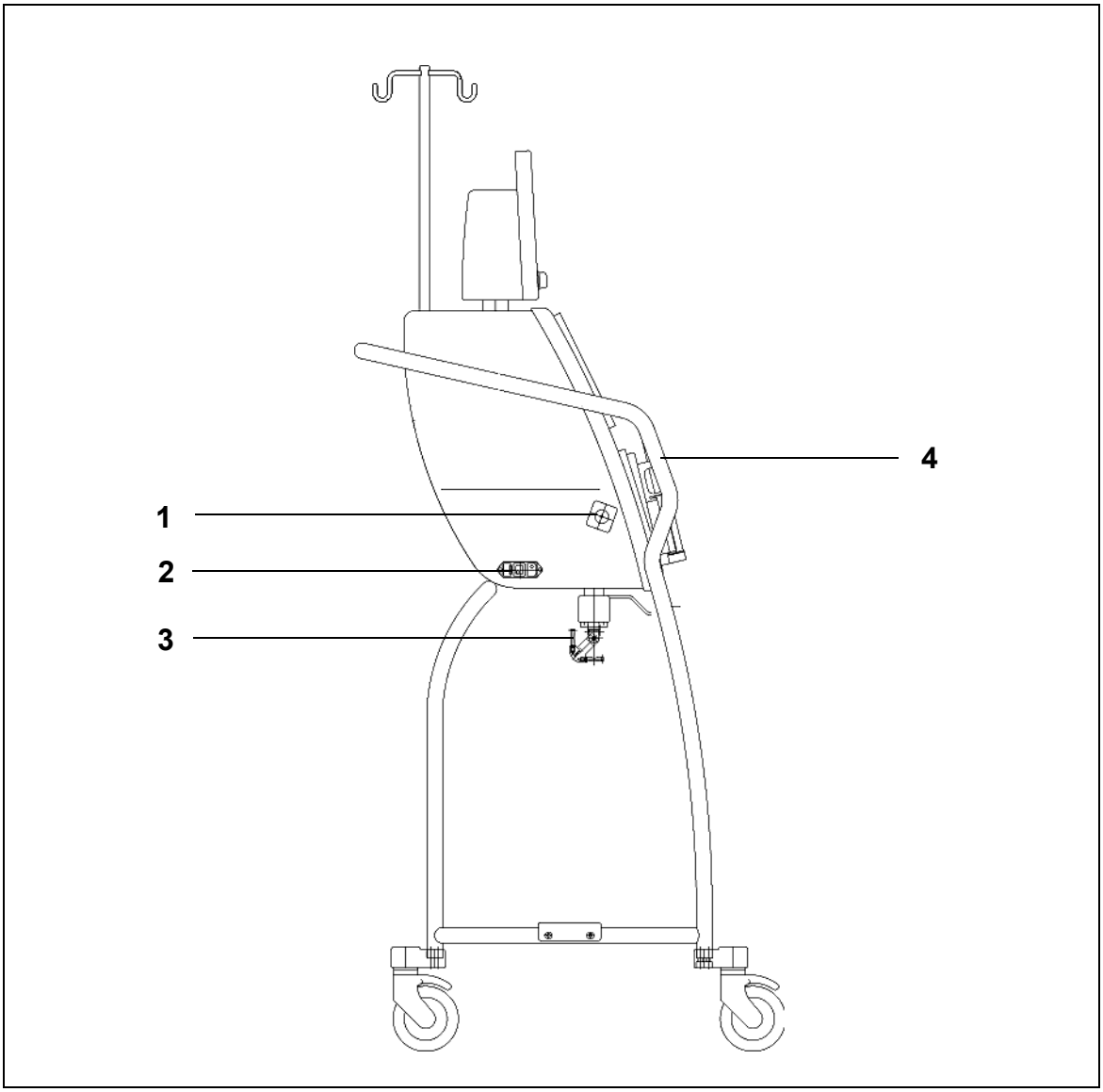


Fig. 8

No.	Mechanical component	No.	Mechanical component
1	Blood leak detector	3	Balancing scales
2	Power supply and power ON/OFF switch	4	Handle

Aquarius system Regular – Side view (right)

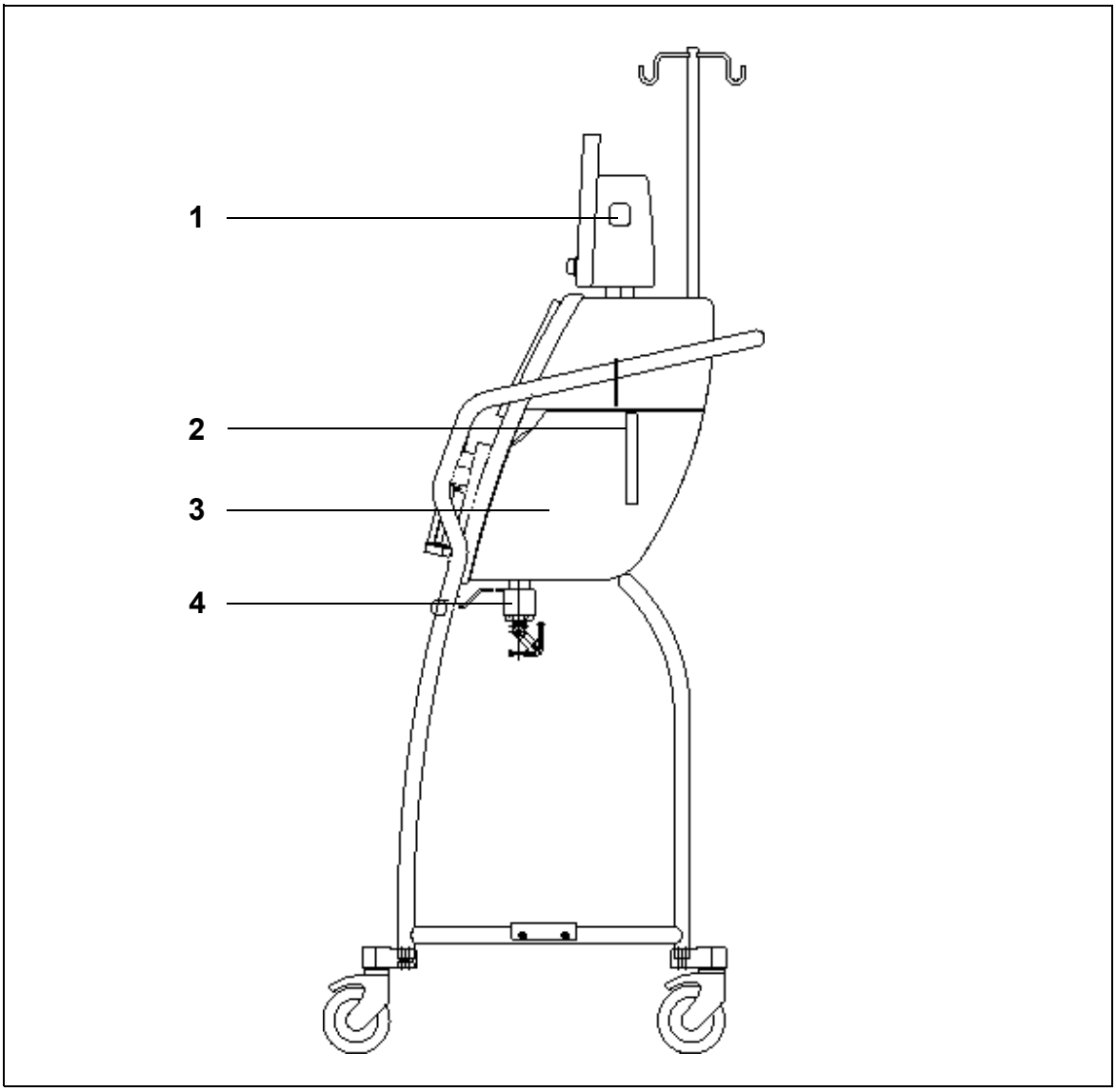


Fig. 9

No.	Mechanical component	No.	Mechanical component
1	ON/OFF key	3	Heating unit door
2	Lever for opening heating unit door	4	Balancing scales

4.2 Fields of application – Overview

The Aquarius system is an Automated Fluid Balance Monitor. It is only designed for the following treatments:

- Regular GE-F096-00, GE-F097-00

Treatment overview	Anticoagulation	Reference for detailed treatment description
SCUF Slow Continuous Ultrafiltration	Heparin anticoagulation	Section *5.11.1 (Page 5-78)*
CVVH Continuous Veno-Venous Hemofiltration		
• CVVH pre-dilution	Heparin anticoagulation	Section *5.11.2.1 (Page 5-80)*
• CVVH post-dilution	Heparin anticoagulation	Section *5.11.2.2 (Page 5-82)*
• CVVH pre- and post-dilution	Heparin anticoagulation	Section *5.11.2.3 (Page 5-83)*
CVVHD Continuous Veno-Venous Hemodialysis	Heparin anticoagulation	Section *5.11.3.1 (Page 5-91)*
CVVHDF Continuous Veno-Venous Hemodiafiltration	Heparin anticoagulation	Section *5.11.4 (Page 5-96)*
TPE Therapeutic Plasma Exchange	Heparin anticoagulation	Section *5.11.5.1 (Page 5-99)*
Hemoperfusion	Heparin anticoagulation	Section *5.11.6 (Page 5-104)*

- GE-F095-00 and GE-F096-00, GE-F097-00 with RCA Option

Treatment overview	Anticoagulation	Reference for detailed treatment description
SCUF Slow Continuous Ultrafiltration	Heparin anticoagulation	Section *5.11.1 (Page 5-78)*
CVVH Continuous Veno-Venous Hemofiltration		
• CVVH pre-dilution	Heparin anticoagulation	Section *5.11.2.1 (Page 5-80)*
	RCA	Section *5.11.2.4 (Page 5-84)*
• CVVH post-dilution	Heparin anticoagulation	Section *5.11.2.2 (Page 5-82)*
	RCA	Section *5.11.2.5 (Page 5-85)*
• CVVH pre- and post-dilution	Heparin anticoagulation	Section *5.11.2.3 (Page 5-83)*
CVVHD Continuous Veno-Venous Hemodialysis	Heparin anticoagulation	Section *5.11.3.1 (Page 5-91)*
	RCA*	Section *5.11.3.2 (Page 5-93)*
CVVHDF Continuous Veno-Venous Hemodiafiltration	Heparin anticoagulation	Section *5.11.4 (Page 5-96)*
TPE Therapeutic Plasma Exchange	Heparin anticoagulation	Section *5.11.5.1 (Page 5-99)*
	RCA	Section *5.11.5.2 (Page 5-100)*
Hemoperfusion	Heparin anticoagulation	Section *5.11.6 (Page 5-104)*

* Available only in selected countries

4.3 Labeling

The following labels are on the Aquarius system:

4.3.1 Data plate

Data plate for GE-F095-00 with RCA option:

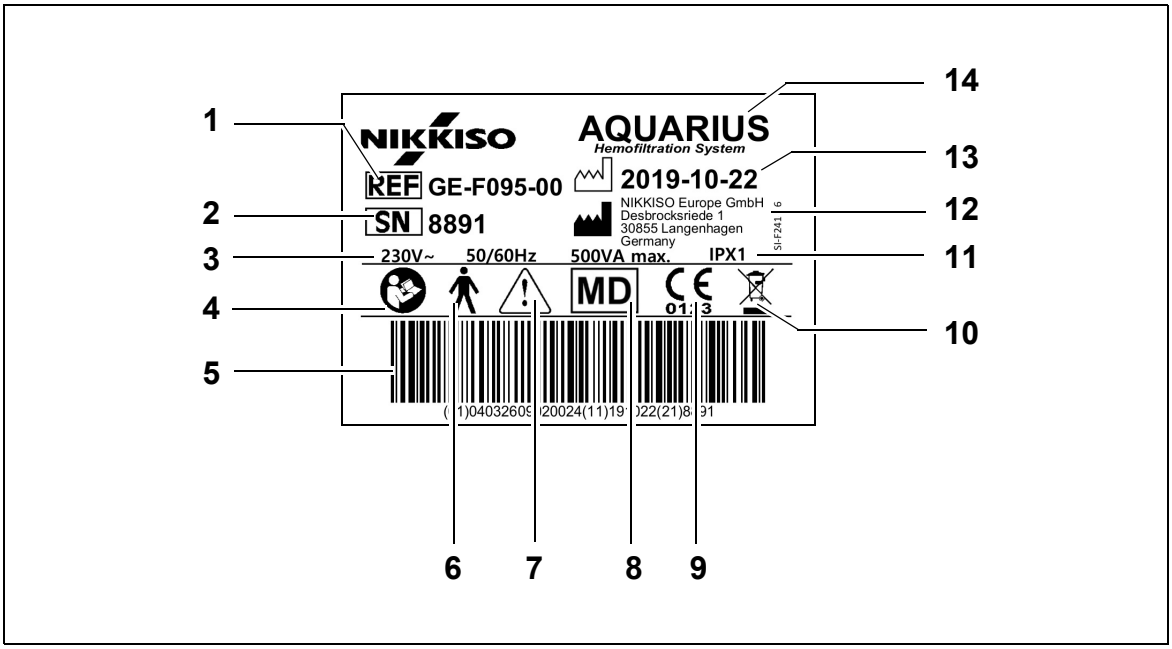


Fig. 10

No.	Description	No.	Description
1	Reference code: In case of GE-F096-00 with RCA option REF GE-F096-00 is referenced	8	Device is a medical device
2	Serial No.	9	CE mark + ID of the notified body
3	Electrical specification	10	Separate collection for waste of electrical and electronic equipment
4	Follow the Instructions for Use	11	Ingress protection rating
5	Barcode: In case of GE-F096-00 with RCA option the bar code for GE-F096-00 is referenced	12	Manufacturer
6	Type of the applied part (Type body)	13	Date of manufacture
7	General warning	14	Name of device

Data plate for GE-F096-00 with RCA option:

Fig. 11

Data plate for GE-F097-00 with RCA option:

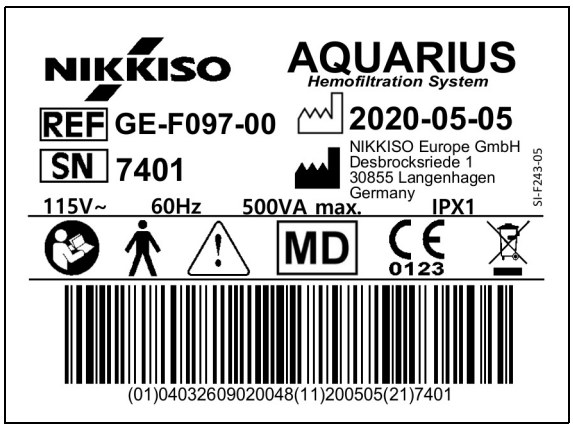


Fig. 12

4.3.2 Filtrate scale

Yellow

The filtrate scale is marked yellow

4.3.3 Substitution fluid scale

Green

The dialysate/substitution fluid scale is marked green.

4.3.4 Citrate scale/pump

Black

The citrate scale and pump are marked black.

In addition the citrate scale has the label below.

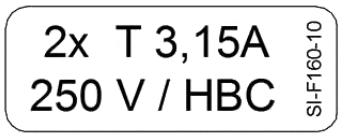
4.3.5 Calcium scale/pump

White

The calcium scale and pump are marked white.

In addition the calcium scale has the label below.

4.3.6 Fuses

Device	Label
GE-F095-00 GE-F096-00	
GE-F097-00	

4.3.7 Potential equalization conductor

4.3.8 Protective earth conductor

4.3.9 Package labeling

Fig. 13

The symbols used for the package labeling are defined in section *1.2 Symbols (Page 1-2)*. The REF number in the package label varies between the different Aquarius models.

4.3.10 Optical data output/RS232 port

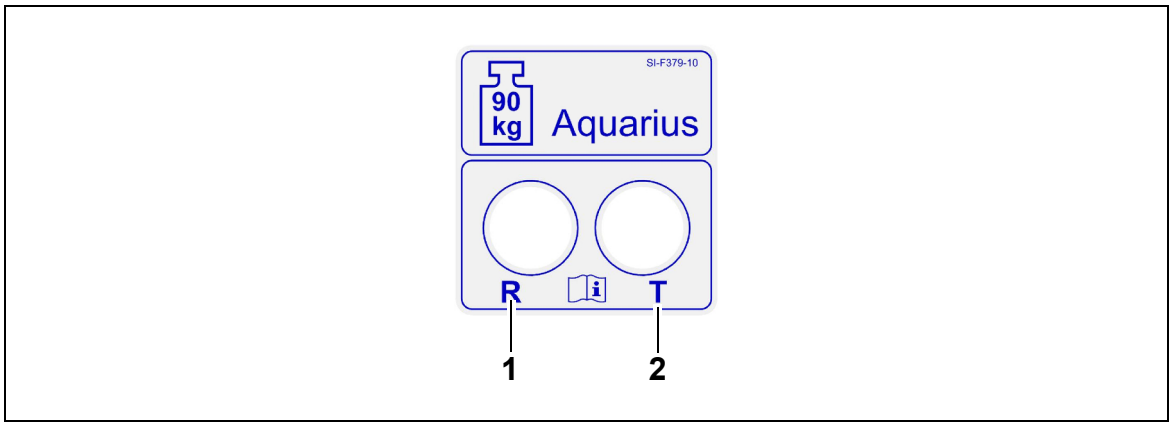


Fig. 14

No.	Description	No.	Description
1	R-connector: Receive data	2	T-connector: Transmit data

To use the optical data output, connect the R-connector to the R-connector on the converter and the T-connector to the T-connector on the converter (see Service Manual). For further information please contact the legal manufacturer of the Aquarius system.

4.3.11 Aqualine tubing set colour code

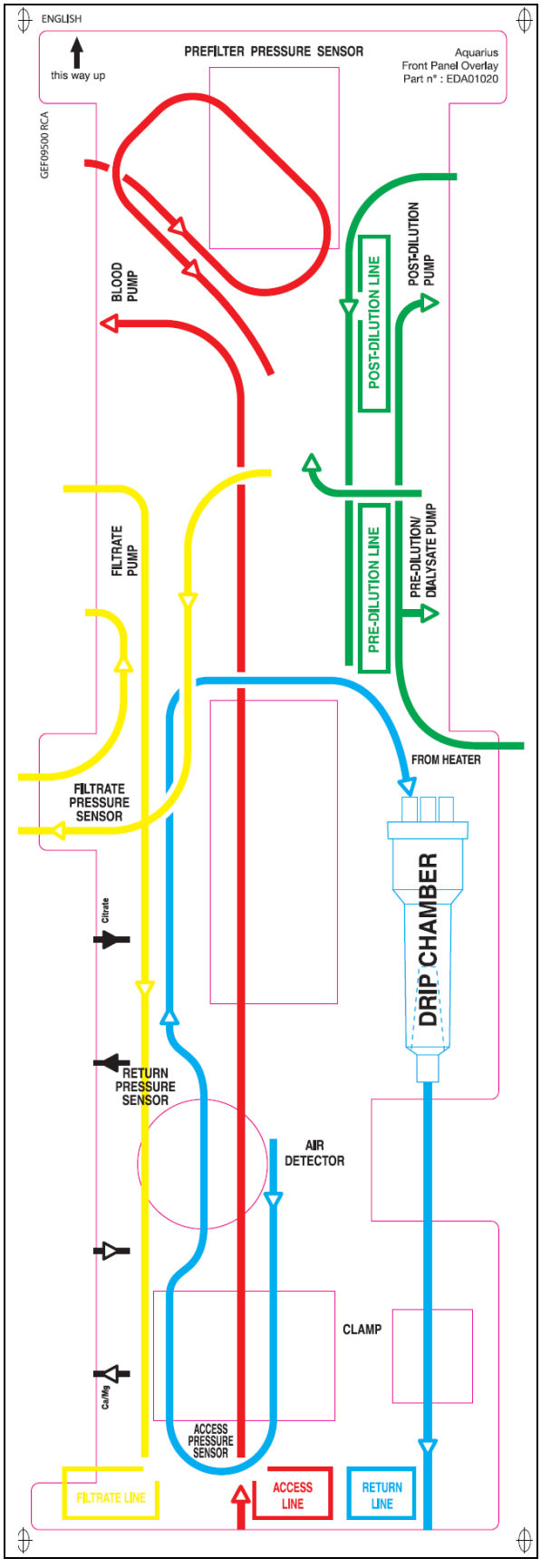
The Aqualine RCA / Aqualine S RCA tubing set is colour coded:

- Access line = Red
- Return line = Blue
- Filtrate line = Yellow
- Substitution line = Green
- Citrate line = Black
- Calcium line = White

The Aqualine and Aqualine S tubing sets are colour coded:

- Access line = Red
- Return line = Blue
- Filtrate line = Yellow
- Substitution line = Green

4.3.12 Front panel – Overlay label for Aquarius RCA



A colour coded front panel overlay is available for the Aquarius RCA. Its function is to help the operator correctly install the Aqualine RCA / Aqualine S RCA tubing set.

Fig. 15

4.3.13 Front panel – Overlay label for Aquarius Regular

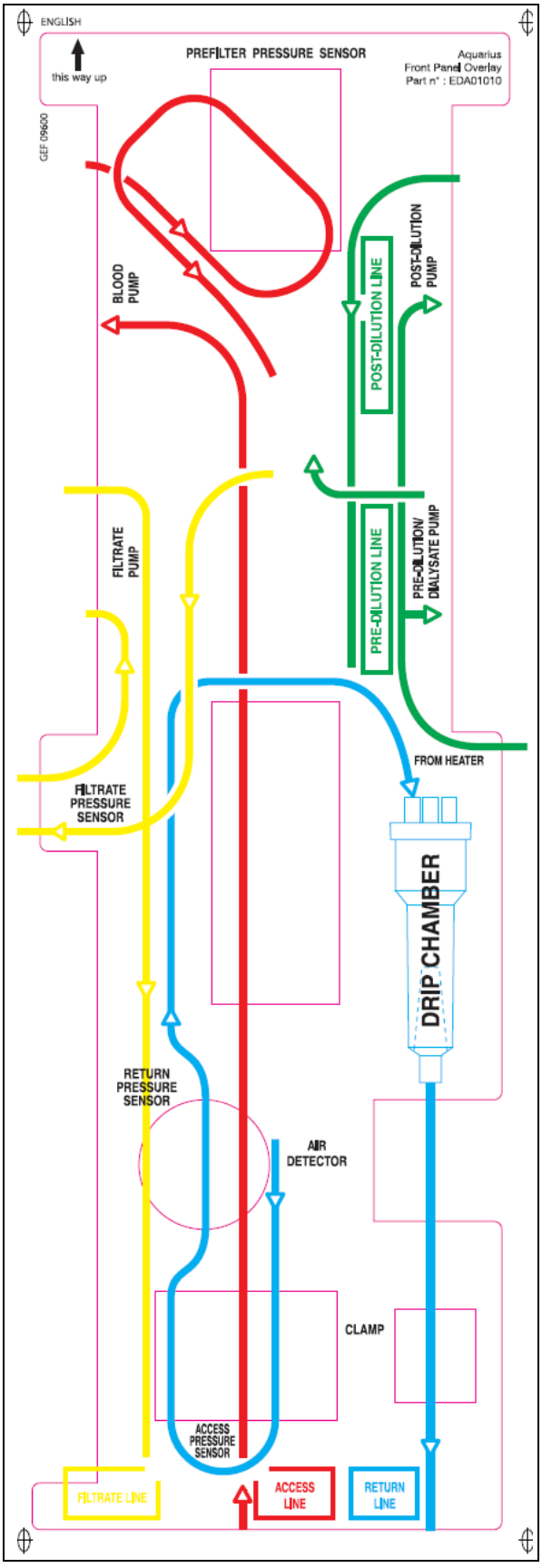


Fig. 16

A colour coded front panel overlay is available for the Aquarius Regular. Its function is to help the operator correctly install the Aqualine and Aqualine S tubing sets.

4.4 Operational sequence (modes)

The operational sequence for the Aquarius system is fixed. It is impossible for the operator to accidentally change the sequence.

4.4.1 System test

When the power is switched on, the Aquarius system is initialized. A system test is performed to verify the system´s main functions. The system test must be performed before the tubing set is attached to the machine. The current software version is displayed during the test.

4.4.2 System test failed

The system test must be repeated if it fails. The on-screen *Help* function will provide further information to assist with troubleshooting any failure. Follow all suggested corrective actions and retry system test. If alarm messages continue, inform Technical Service. The device can be used only if the system test passes.

4.4.3 Preparation

The operator can select one of the following therapies in the *Preparation* mode:

- SCUF
- CVVH
- CVVHD
- CVVHDF
- TPE
- Hemoperfusion

In case of Aquarius Regular, only regular treatments can be performed, treatments with RCA are not possible.

In case of Aquarius RCA, when SCUF, CVVHDF or Hemoperfusion are selected, citrate anticoagulation cannot be selected.

For treatments with RCA select Aqualine RCA or Aqualine S RCA respectively.

Refer to section *5.1 (Page 5-1)* for detailed instructions.

Selection of the tubing set to be used (Aqualine RCA or Aqualine tubing set for adult and Aqualine S or Aqualine S RCA tubing set for low volume) is made during *Preparation* mode.

The tubing set selected has to be installed on the Aquarius system before priming.

4.4.4 Priming

A test compares the tubing set selected (adult or low volume) and the tubing set in-situ at the beginning of priming.

In the *Priming* mode the blood and all fluid circuits are rinsed and filled.

At the end of the priming procedure the operator can select *Reprime* or *Next* to proceed.

Refer to section *5.2 (Page 5-27)* and *5.3 (Page 5-30)* for detailed instructions.

4.4.5 Clamp and pressure test

During this test phase, the return clamp occlusion function, the access pressure function, the return pressure function, the pre-filter pressure function and the filtrate pressure function are tested. This test is only possible if, after priming, the air detector has determined that the extracorporeal circuit is free from air which will be indicated by a steady green light in the *Clamp* key  . The access pressure, return pressure and transmembrane pressure are displayed during the test.

After a successful test, the system goes to *Start connection* mode. The operator may select from the following options: *Go to programming, Go to recirculation, Single connection* or *Double connection.*

Refer to section *5.4 (Page 5-38)* for detailed instructions.

4.4.6 Recirculation

During *Recirculation* mode the extracorporeal circuit is flushed until the operator is ready to connect the patient to the Aquarius system. This mode is started and stopped manually by the operator. During *Recirculation* mode only the blood flow rate can be modified. The patient parameters **must** be entered within *Start connection* mode.

To leave *Recirculation* mode the operator selects the *Go to connection* key to connect the patient to the Aquarius system or the *End treatment remove tube system* key to switch off the device.

Refer to section *5.5 (Page 5-41)* for detailed instructions.

4.4.7 Connecting the patient

Parameters must be programmed within *Start connection* mode.

During *Single connection* mode, the operator is asked to connect the Aqualine access line (red) to the access limb (red) of the patient's catheter. After pressing the *Blood pump* key, the Aqualine tubing set is filled with blood up to the air detector. The blood pump automatically stops when the air detector detects blood. The operator is asked to connect the return segment of the Aqualine tubing set to the return limb (blue) of the patient's catheter during the *Start treatment* mode. Treatment can then commence.

During *Double connection* mode, the operator is asked to connect the Aqualine access (red) and return (blue) lines to the access (red) and return (blue) limbs of the patient's catheter at the same time. After pressing the *Blood pump* key, the Aqualine tubing set is filled with blood. The Aqualine RCA also receives anticoagulant as the circuit is filled with blood. Once blood is detected by the air detector system, the blood pump stops automatically. The user may access treatment after confirming safe and secure connection of the catheter to the Aqualine tubing set. Treatment can then commence.

Refer to section *5.6 (Page 5-43)* and *5.7 (Page 5-46)* for detailed instruction.

If the operator has not already programmed the patient parameters, this must be done before starting treatment.

4.4.8 Regulated start

The *Regulated start* mode is optional for Aquarius system with Aquarius^{+} software, in case of RCA treatments. During regulated start the blood flow rate increases slowly step by step every 30 s by 10 ml/min from the default setting determined during calibration up to the programmed blood flow rate (e. g. from 80 ml/min default setting to 150 ml/min programmed blood flow rate).

Anticoagulation is adjusted according to the blood flow rate and increases according to the blood flow rate. The substitution rate, including calcium and filtration rate, increase according to the blood flow rate. The treatment parameters can be set or adjusted.

When the programmed blood flow rate is reached, the system switches automatically from *Regulated start* mode to *Treatment* mode. The blood pump as well as all other pump flow rates, increase without delay up to the programmed flow rate.

Exit function terminates the *Regulated start* mode. The Aquarius system then automatically starts the treatment.

The *Regulated start* mode is also terminated when the blood flow rate programming window is opened and the actual displayed blood flow rate is set and confirmed. This new programmed blood flow rate is then validated on *Exit* to treatment. The citrate pump is set according to the validated blood flow rate and citrate ratio.

For Regular start the blood pump starts directly after the treatment start. The blood flow rate increases step by step every 3 s by 10 ml/min or by 2 ml/min for low volume RCA from the default setting to the programmed blood flow rate. All other pump flow rates increase without delay up to the programmed flow rate. Regular start allows full independent manual control of all flow rates.

4.4.9 Treatment

Treatment begins after selecting the *Treatment* key  (blood pump must run to start treatment). The patient parameters are displayed on the screen and may be modified during treatment.

During treatment it may be necessary to change fluid bags and heparin syringe:

Heparin syringe

The operator can exchange the heparin syringe at any time during a treatment. If the heparin syringe is empty, the heparin pump stops automatically with notification. The operator can now exchange the empty heparin syringe.

Substitution (TPE: plasma bag) and filtration bag

The operator may stop filtrate/substitution solution circulation to exchange bags.

The balance system stops automatically with notification when the substitution bag is empty or the filtrate bag is full. The operator can now exchange the corresponding bag(s).

Dialysate (CVVHDF: dialysate and substitution bag) and effluent bag

The operator may stop effluent/dialysate solution circulation to exchange bags.

The balance system stops automatically with notification when the dialysate bag is empty or the effluent bag is full. The operator can now exchange the corresponding bag(s).

Citrate and calcium bag (Aquarius^{+} only)

The operator may stop the blood pump to exchange citrate or calcium bag.

The balance system stops automatically with notification when the calcium bag is empty. The operator can now exchange the calcium bag.

The blood pump and the balance system are automatically stopped when the citrate bag is empty. The operator can now exchange the citrate bag.

Citrate pump only runs when blood pump is active.

Calcium pump only runs when balance pumps are active during normal treatment conditions.

When *Therapy target achieved by time* or *Therapy target achieved by fluid loss* are displayed on the screen, the time target or the fluid loss target respectively have been achieved. The operator may now reprogram to continue treatment or may move into disconnection phase.

Refer to section *5.8 (Page 5-54)* for detailed instructions.

4.4.10 Disconnecting the patient

During *Disconnection* mode the operator is asked to disconnect the patient's blood access and to connect it to a saline solution bag. The system re-infuses the blood contained in the system to the patient. The blood pump stops when the air detector unit detects saline solution. By selecting the *Next* key the operator moves to the *Treatment end* mode.

Refer to section *5.9 (Page 5-69)* for detailed instructions.

4.4.11 Terminating the treatment

During *Treatment end* mode the operator is requested to remove all tubing from the machine. The operator has to select the *Aquarius Off* key to switch off the Aquarius system.

Refer to section *5.10 (Page 5-73)* for detailed instructions.

4.5 Operating concept

Only trained and qualified personnel should operate the Aquarius system.

Operator's position: For being able to operate the device in the most practical and effective way, the operator has to be in front of the device.

To check the functionality of the indication lights and the audible alarm signals, the operator has to observe the Aquarius during system test.

During *Preparation* mode a *Zoom graphic* key allows a step by step guide to the complete installation of the device with visual assistance.

Instructions displayed on the screen provide the operating staff with information about subsequent treatment steps. *Help* function will provide further information on screen at all stages.

Alarms and messages are colour coded and displayed in separate windows on the screen.

Alarms, messages and the end of the respective mode are also indicated to the operating staff by an audible signal.

Selected screen pages close 5 min after last key press and lead back to the main menu page.

The *Main selector button* is a rotary switch, located below the display screen. It is used to select and confirm different functions and to modify treatment parameters.

4.5.1 Display screen – Aquarius system with Aquarius+ software

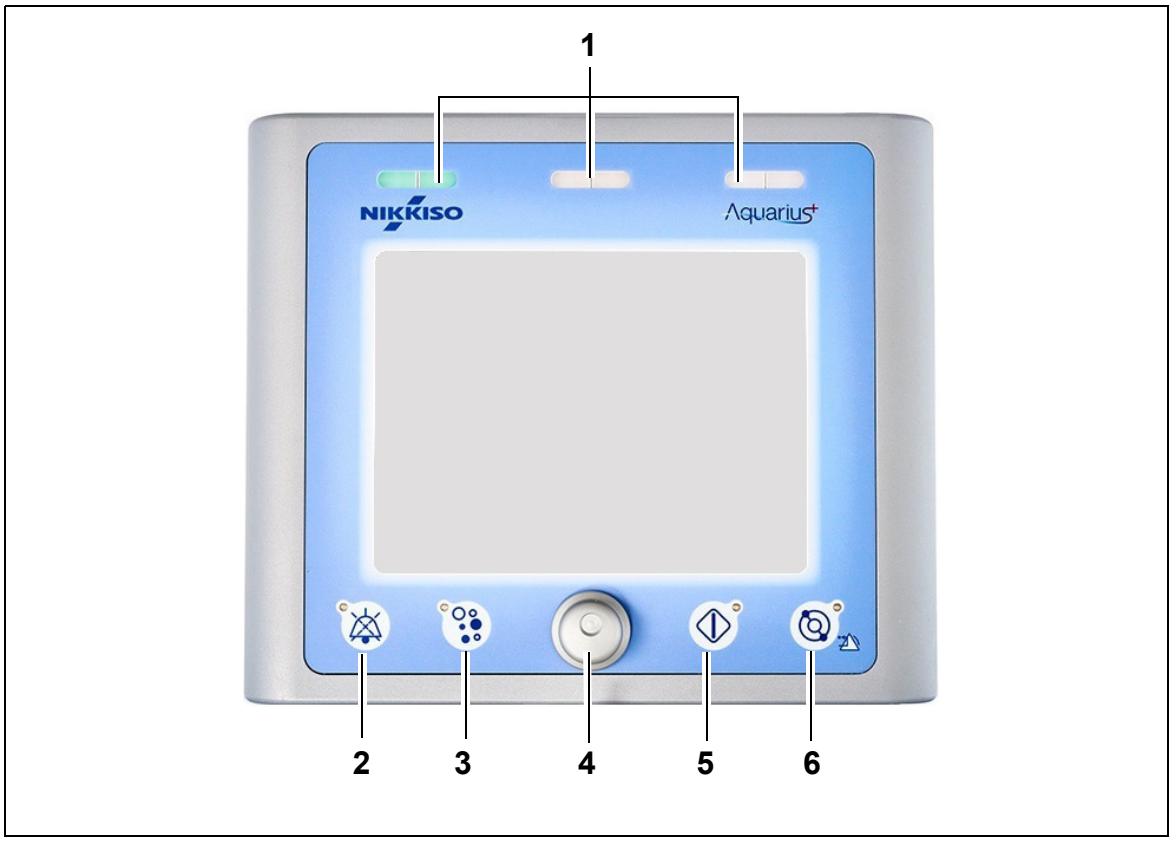


Fig. 17

No.	Description	No.	Description
1	Operation status display	4	Main selector button
2	Mute key (Audio paused)	5	Treatment key
3	Clamp key	6	Blood pump key with reset function

The individual function keys and their displayed functions are explained below.

4.5.2 Display screen – Aquarius system with Platinum software

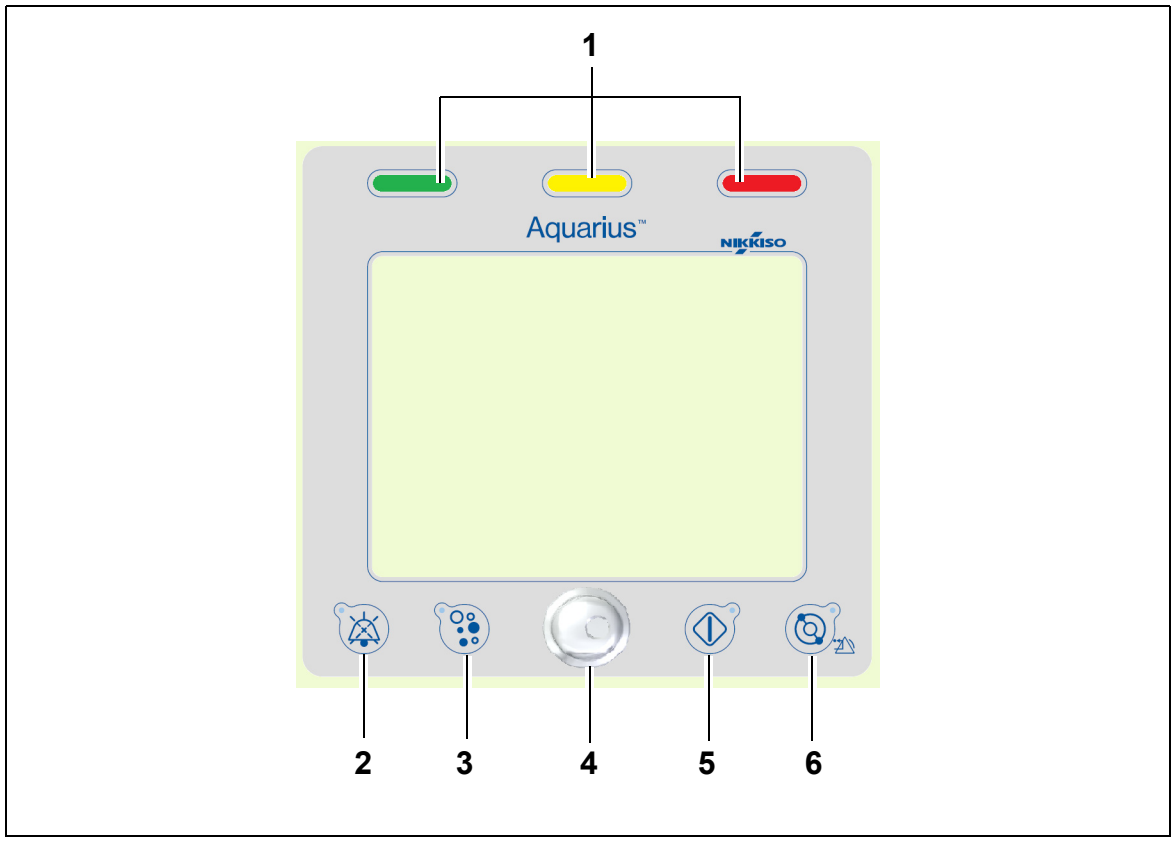


Fig. 18

No.	Description	No.	Description
1	Operation status display	4	Main selector button
2	Mute key (Audio paused)	5	Treatment key
3	Clamp key	6	Blood pump key with reset function

The individual function keys and their displayed functions are explained below.

4.5.3 Operation status display

Three status lights indicate the different operation modes. They are visible from the front and the back of the machine.

Operation indication:

Illuminated status light	Meaning of the status indicators
	The treatment is running. No alarms are active.
no light	The treatment is interrupted but no alarm is active.
	The machine is performing system test. All indication lights are functional.

Optical alarm indication:

Alarm category	Alarm meaning	Colour	Frequency	Operator's reaction
High priority	Can lead to death or irreversible injury.	Red LED	1.67 Hz	Immediate reaction required. Measures are mandatory.
Medium priority	Can lead to reversible injury.	Yellow LED	0.5 Hz	Adequate response required. Measures are necessary.
Low priority	Can lead to injury or discomfort.	Yellow LED	Constantly	Message needs to be acknowledged. Eventually, measures are required.

4.5.4 Mute function key (Audio paused)

Pressing the *Mute* key enables the operator to silence the alarm signal for a period of 2 min. The LED integrated into the key flashes. If the cause of the alarm cannot be removed within the given time period, the audible alarm is reactivated. If another alarm occurs during this time period, the audible alarm is reactivated and generated at once. The *Mute* key does not reset alarms. During the 2 minutes of audio paused, no reminder signal is given.

4.5.5 Clamp function key

Pressing the *Clamp* key opens the return line clamp during an air detected alarm, when the return pressure is below 50 mmHg, to allow removal of air bubbles from within the tubing set. The LED integrated into the key flashes. The return line clamp is automatically reactivated after 1 min. When the air is removed, treatment may be resumed by pressing the *Blood pump* key  .

The red indicator of the return line clamp is illuminated when the clamp is closed and extinguished when the clamp is open.

4.5.6 Main selector button

The *Main selector button* is a multi-function rotary button. These functions include:

- Selecting function windows by turning the *Main selector button*.
- Confirming selected functions by pressing the *Main selector button*.
- Selecting input parameters by turning the *Main selector button* and having the corresponding parameter highlighted.
- Opening the input window for the selected parameter by pressing the *Main selector button*.
- Raising the parameter input for the selected parameter by turning the *Main selector button* to the right.
- Lowering the parameter input for the selected parameter by turning the *Main selector button* to the left.

Confirming the entered parameter by pressing the *Main selector button*. The modified parameter is displayed on the screen.

4.5.7 Treatment function key

Pressing the *Treatment* key starts the selected treatment whilst maintaining the selected parameters as programmed by the operator.

Pressing the *Treatment* key stops the filtrate and substitution pumps. This can be used to temporarily stop treatment, for example, to exchange bags.

When citrate anticoagulation is used, pressing the *Treatment* key all treatment pumps and calcium pump will stop. Blood pump and citrate pump will continue running at their programmed speed until a maximum delivery of 50 ml of citrate has been reached. The amount of citrate volume injected will be removed after restart of the treatment pumps.

If an alarm occurs in the filtrate and/or the substitution circuits, the pumps stop and the LED integrated into the key starts flashing. After correcting the cause of the alarm the pumps may be restarted by pressing the *Treatment* key. The treatment restarts with the parameters previously programmed by the operator.

When therapy is running and no filtrate or substitution alarm is active, the *Treatment* key´s indicator is green.

During pre- and post-treatment, the *Treatment key's* indicator is extinguished.

4.5.8 Blood pump function key with reset function

Pressing the *Blood pump* key starts or stops the flow of blood through the blood circuit. If the pumps are running, pressing the *Blood pump* key stops all pumps and the *Blood pump* indicator flashes. If an alarm occurs in the blood circuit, all pumps stop and the LED integrated in the *Blood pump* key starts flashing. After correcting the cause of the alarm the alarm is cleared by pressing the *Blood pump* key. The system is restarted by pressing the *Blood pump* key again. The filtrate, pre-dilution and post-dilution pumps start after the blood pump. The citrate pump starts with the blood pump and calcium pump starts with the balance pumps.

The *Blood pump* key is also used to immediately stop all pumps in case of an unpredictable occurrence.

The *Blood pump* key also serves as an alarm reset key. In this case, the blood pump will not start. To start the blood pump, the key has to be pressed a second time. The *Blood pump* key in its reset function cannot switch off the alarm system. If the alarm cause is not removed, it will be retriggered after its defined alarm delay time.

4.5.9 Citrate and calcium status indicators (LEDs)

The green LEDs on the citrate and calcium pumps indicate the status of the pumps:

- the LED is OFF when the pump is inactive (no citrate anticoagulation is selected)
- the LED is FLASHING when the pump is active and stopped (citrate anticoagulation is selected)
- the LED is ON when the pump runs

4.6 Safety concept

The Aquarius system has a safety concept based on three independent processors, which are the control system, the protective system and the display system. Figure *19* shows the basic principle.

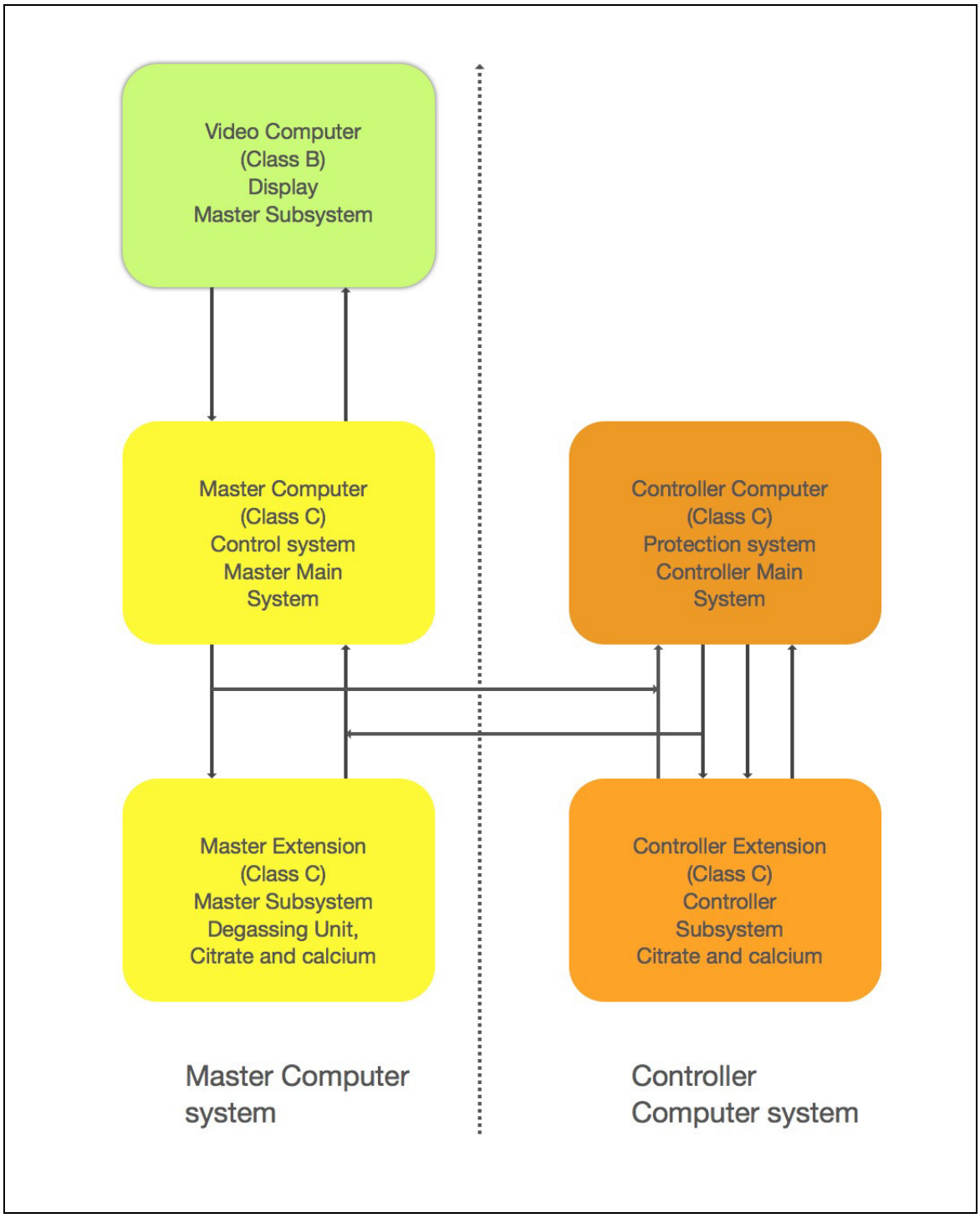


Fig. 19

The safety mode of the Aquarius system is determined by the type of the occurring alarm:

Alarm type	Aquarius system safety mode
Alarms in blood circuit	• Visual and audible signals will be generated. • The return line clamp will close if air or micro-foam is detected or the return pressure drops below the lower alarm limit. • All pumps will stop. NOTE When citrate anticoagulation is used, the blood and citrate pumps will continue running at their programmed speed until a maximum delivery of 50 ml citrate has been reached for specific alarms.
Alarms in filtrate/dialysate circuit	• Visual and audible signals will be generated. • The filtrate, pre-dilution and post-dilution pumps will stop. NOTE When citrate anticoagulation is used, the blood and citrate pumps will continue running at their programmed speed until a maximum delivery of 50 ml citrate has been reached. • After TFL fluid deviation compensation, the calcium pump starts running and all pumps speed up to their programmed rate.
Alarms in citrate/calcium circuit	• Visual and audible signals will be generated. • The filtrate and post-dilution pumps will stop. • In case of a citrate circuit alarm, the blood and citrate pumps will stop immediately. • In case of a calcium circuit alarm, the blood and citrate pumps will continue running at their programmed speed until a maximum delivery of 50 ml citrate has been reached. • When restarting the blood pump after a citrate alarm, all pumps will start turning at the programmed speed.
System error	• Visual and audible signals will be generated. • All pumps will stop. • The return line clamp will close.

The **control system** regulates, controls and monitors the operation of the Aquarius system. If an out-of-range condition occurs, either a system error or an alarm is generated and the Aquarius system switches to safety mode.

The **protective system** monitors all control system processes. If the protective system detects an alarm or a system error, this alarm or system error will be generated independently of the control system and the Aquarius system switches to safety mode.

The **display system** is responsible for communication between the protective system, the control system and the operator. The information coming from the protective system and the control system is displayed on the screen and the operator's input is communicated to both systems.

5 Performing a treatment with the Aquarius system

5.1 Preparing the Aquarius system

5.1.1 Switch ON

The Aquarius system test must be performed before tubing, bags, pressure sensors and solutions are placed on the machine. The pump doors must be closed.

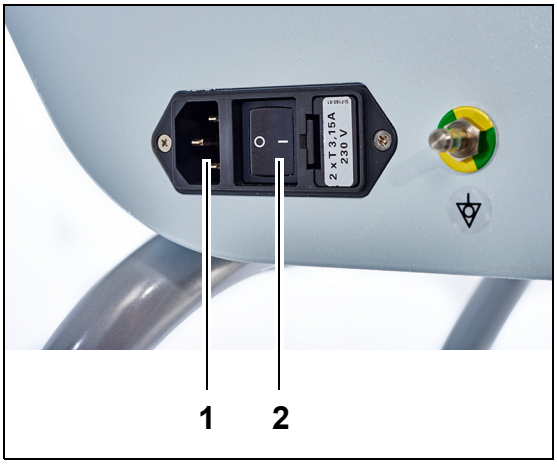


Fig. 20

Step 1:

1. Plug the power cable into the socket (1) and turn socket on.
2. Set the main switch (2) on the power input module to the I position. This is located on the left side of the Aquarius system.
   ▶ The green LED in the *On/Off* key lights up.

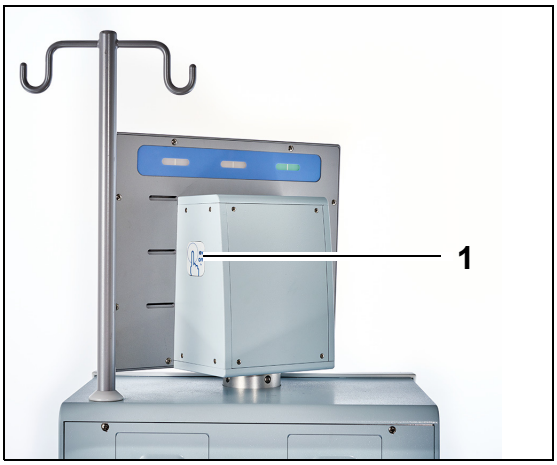


Fig. 21

3. Before proceeding, ensure no tubing set or bags are installed on the Aquarius system.
4. Press the *On/Off* key (1) located on the right side of the display screen.

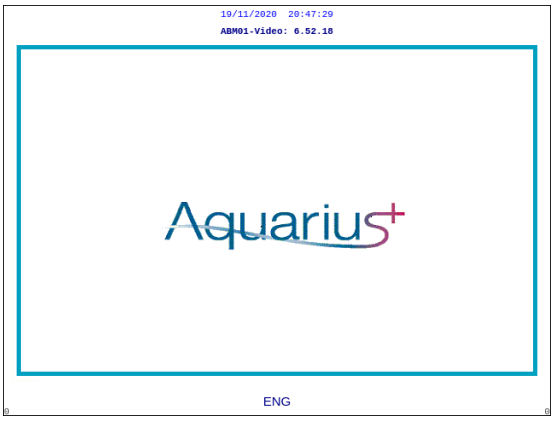


Fig. 22

▶ The system turns on and starts the system test.

- Start screen of the Aquarius System with the Aquarius^{+} software (RCA).

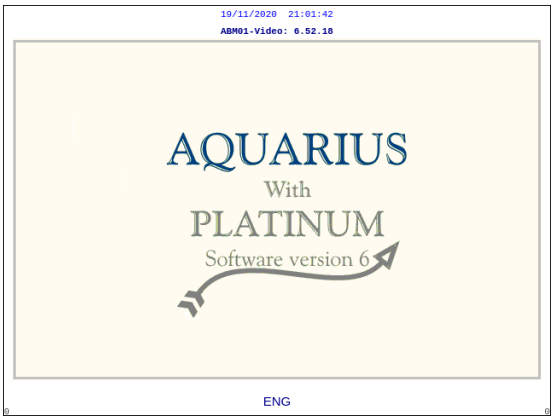


Fig. 23

- Start screen of the Aquarius System with the Platinum software (Regular).

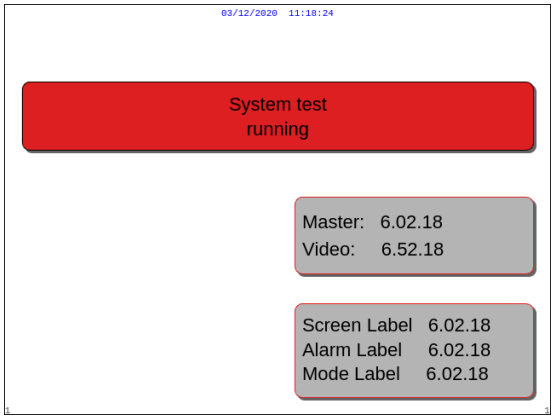


Fig. 24

Step 2: Wait until the system test is completed.

▶ The system checks the main system functions as well as safety control functions.

▶ During this process, the three status lights of the operation status display, located above the screen, illuminate one after the other until the system test is finished.

▶ The screen displays *System test running*.

NOTE

The software version number displayed by the Aquarius system may change in revision.

When the system test is finished, an audible alarm is generated and the green status light is illuminated.

The pumps stop in the correct position for the tubing set to be installed.

If the green status light is still flashing after the system test is finished, the heater self-test is still running. Entering the priming process before the heater self-test is finished is not possible. The green light stops flashing when the heater self-test is finished.

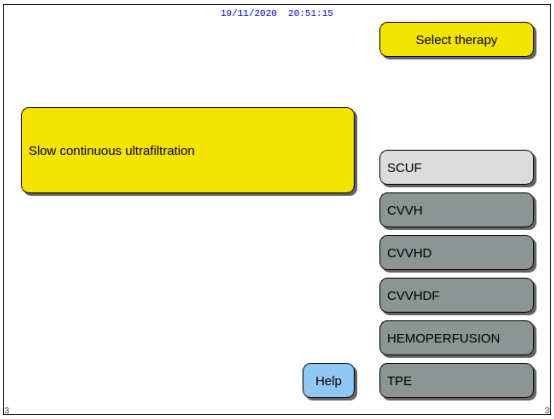


Fig. 25

Step 3: When the system test passed, select a therapy, refer to section *5.1.3 (Page 5-5)* for more details.
OR
If necessary, select *Help* to go to *Clock* mode. Refer to section *5.1.2 (Page 5-3)* for more details.

- **System test failure**

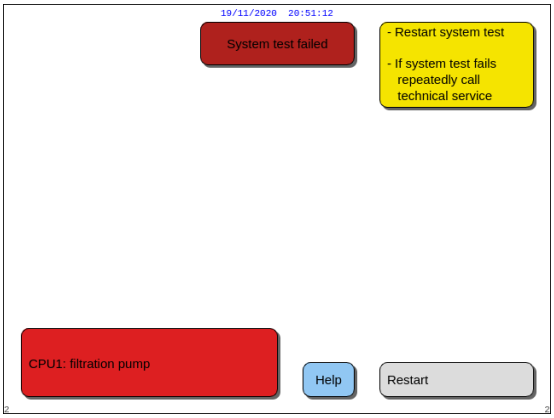


Fig. 26

Step 1: Read the on-screen information to understand what has failed.

Step 2: Follow the suggested corrective action.

Step 3: Select and confirm the *Help* function.

Step 4: Further select and confirm the *Error Help* function.

Step 5: If the system test fails select *Restart* to run the system test again. If the system test continues to fail, please contact Technical Service.

5.1.2 Set date and time

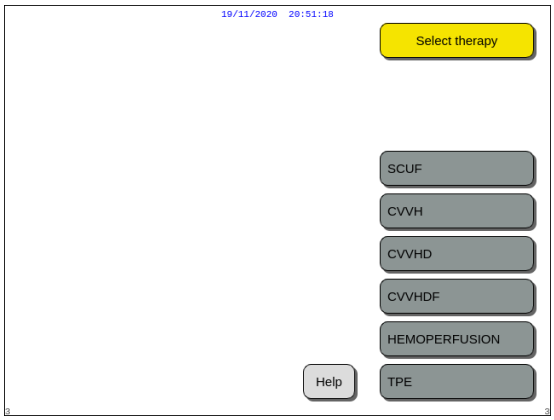


Fig. 27

Step 1: Select the *Help* key by turning the *Main selector button* .

Step 2: Press the *Main selector button* to confirm.

▶ The *Help* mode window appears.

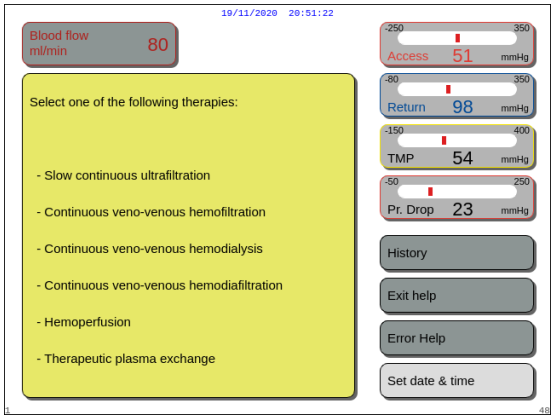


Fig. 28

Step 3: Select and confirm the *Set date and time* key.

- ▶ The *Clock* mode window appears.
- ▶ The hour indicator is highlighted.

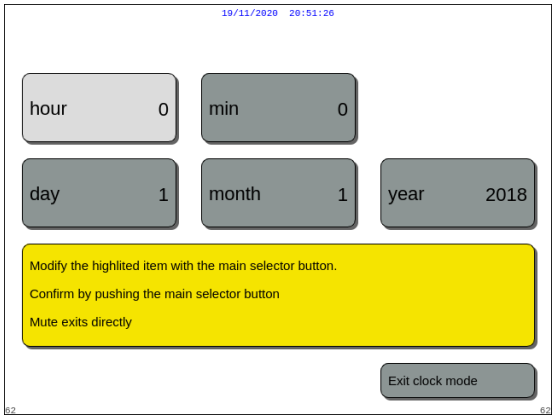


Fig. 29

Step 4: Rotate the *Main selector button* to modify the hour adjustment.

Step 5: Press the *Main selector button* to confirm.

- ▶ The hour value is set.
- ▶ The next indicator is highlighted.

Step 6: Continue until all time items are set.

Step 7: To exit the *Clock* mode select and confirm the *Exit clock mode* key.

- ▶ The *Help* screen appears.

OR
Press the *Mute* key to return to the main menu.

NOTE

If another time or date adjustments are necessary select the *Help* screen in any running mode and then select the *Set date and time* key.

Accessible values for change are:

For time	For date
Hour	Day
Minute	Month
	Year

NOTE The Aquarius system does not automatically compensate for Daylight Saving Time (DST). The operator will need to adjust the time manually, as described above. Patient treatment is based on an elapsed-time system and will not be affected by this manual adjustment.

5.1.3 Preparation mode – Selecting a therapy

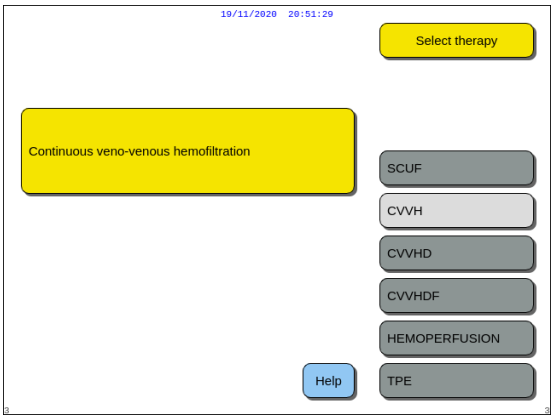


Fig. 30

Step 1: Press the *Main selector button* to confirm the selected therapy.

Step 2: Select the desired therapy by turning the *Main selector button* until the chosen therapy is highlighted.

▶ The system switches to the *Preparation* mode.

Step 3: If a different therapy is desired select and confirm the *Previous* function to return to the previous screen.

NOTE

When displayed, the *Previous* function simply takes the operator back one screen.

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

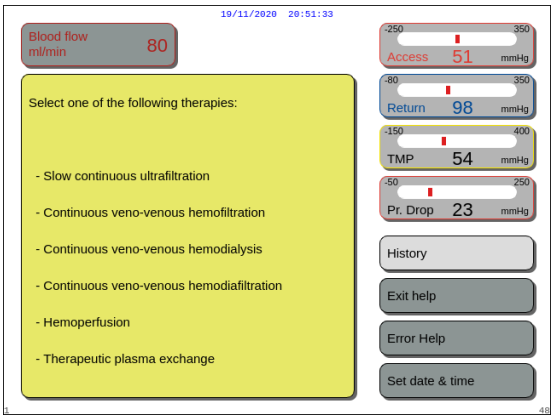


Fig. 31

When SCUF, CVVHDF or Hemoperfusion are selected, only Heparin or No anticoagulant can be selected. Citrate anticoagulation is disabled.

Citrate anticoagulation is only enabled if CVVH, CVVHD or TPE is configured and selected.

When the Regional Citrate Anticoagulation (RCA) option is not configured and displayed, use an Aqualine tubing set and not an Aqualine RCA tubing set.

5.1.4 Preparation mode – Selecting the tubing set

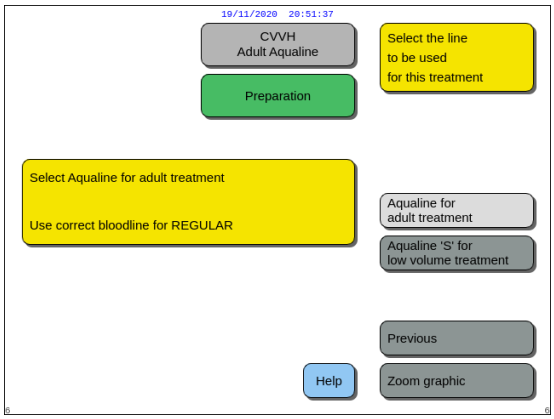


Fig. 32

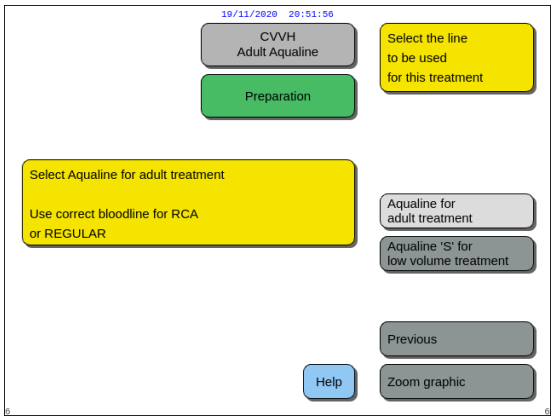


Fig. 33

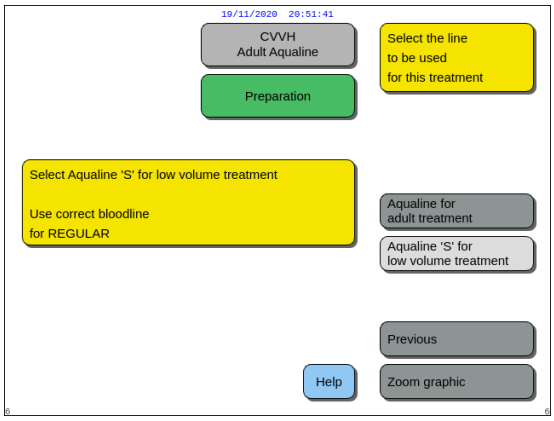


Fig. 34

Step 1: Select the tubing set by turning the *Main selector button* until the chosen tubing set is highlighted.

Aqualine RCA, Aqualine tubing set for adult treatment (RCA or Regular):

- Blood flow rates from 30–450 ml/min (30–300 ml/min when citrate anticoagulation is used).
  Optional: For 100 h treatments blood flow rates from 30–300 ml/min for RCA or Regular.

Aqualine S RCA, Aqualine S tubing set for low volume treatment:

- Blood flow rates from 10–200 ml/min
  Optional: For 100 h treatments blood flow rates from 10–100 ml/min for RCA or Regular.

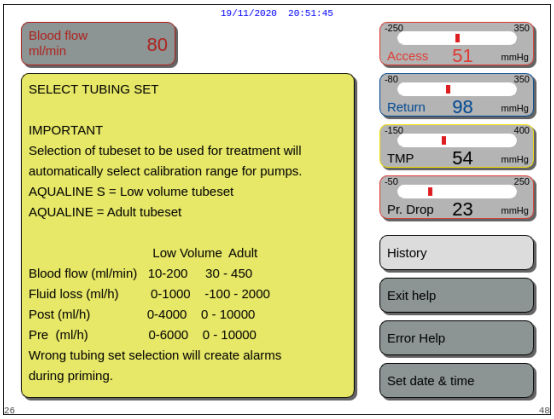


Fig. 35

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

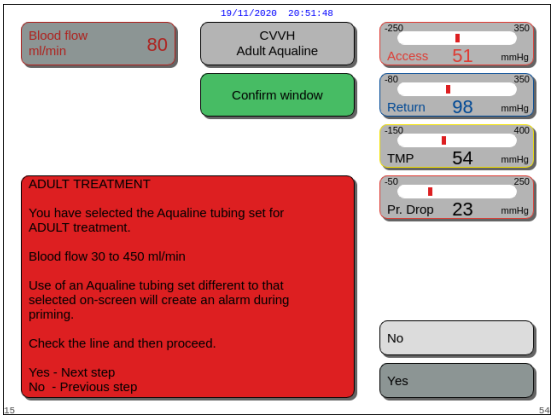


Fig. 36

▶ Depending on which tubing set was chosen the following *Confirm* window appears: see Fig. *36* or *37*.

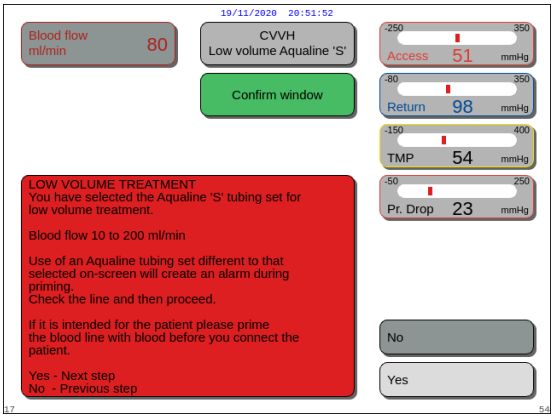


Fig. 37

Step 2: IMPORTANT! Follow the on-screen instructions.

Step 3: Select and confirm *Yes* to confirm the tubing set selection.
OR
Select and confirm *No* to return to the previous step (Tubing set selection screen).

5.1.5 Preparation mode – Installing the tubing set and empty bags

In case of Aquarius Regular, the citrate and calcium pump as well as the corresponding scales are not available.

NEVER use any type of fluid or gel on the tubing or the air detector sensor. Any foreign substance applied to the air detector sensor could result in patient injury or death.

Use only bloodlines approved for use with Aquarius system.

To prevent fingers from getting pinched in the pump chamber, keep fingers out of the pump chamber while rotating the pump heads.

The pump rotors are placed in the load position at the end of system test (horizontal) to enable correct installation of the tubing. Always ensure the rotors are in the load position before starting to wrap the pump segments into the pumps.

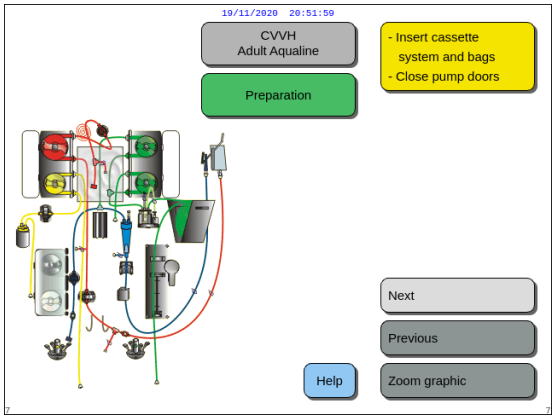


Fig. 38

The user can get the detailed description of all necessary actions on the machine using the *Help* function or *Zoom graphic* key.

The user can fulfill all necessary actions as described in this chapter below without the on-screen assistance and then select *Next* to get to the filter and bags installation.

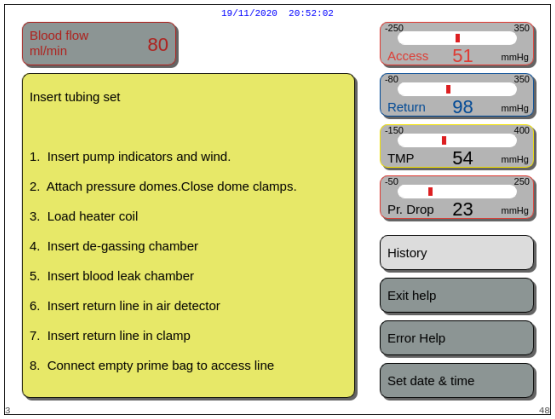


Fig. 39

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

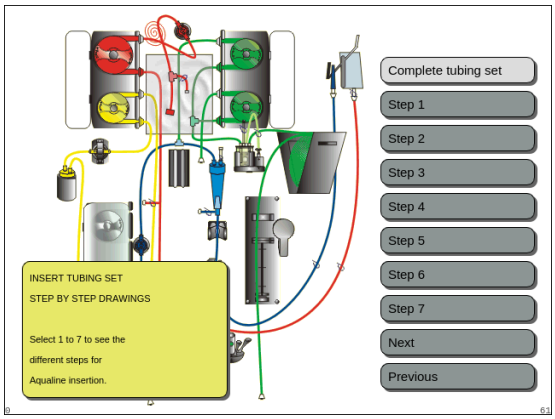


Fig. 40

⇨ If you need detailed step-by-step visual help with graphics, select *Zoom graphic* key.

▶ A window with the list of all steps necessary for the installation of the tubing set and empty bags appears.

⇨ Choose step after step and follow instructions on the screen. When all steps are completed, select *Next*, to get to the filter and bags installation.

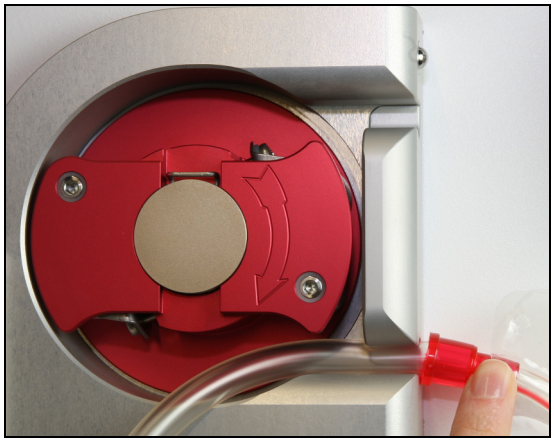


Fig. 41

Step 1: Install pump segments:

1. Open both pump doors.
2. Install the ***blood pump*** segment by pressing the softer tubing, near the red marker, into the bottom of the blood pump housing.

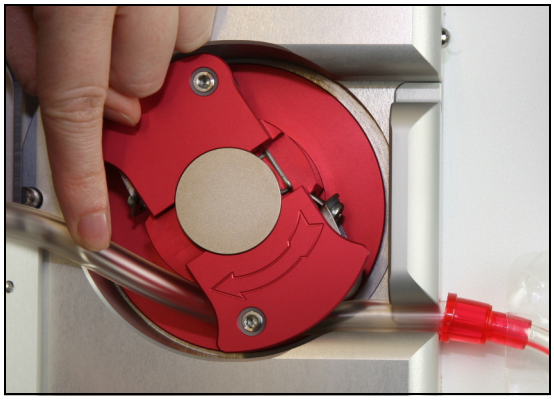


Fig. 42

3. ***Carefully*** wrap the segment around the pump by turning the rotor ***clockwise***.

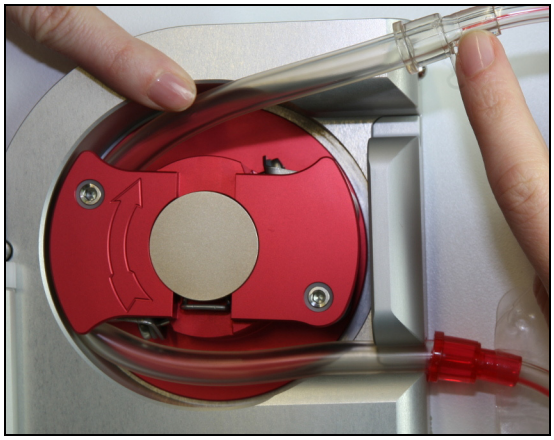


Fig. 43

4. Press the tubing into the holder at the pump outlet.

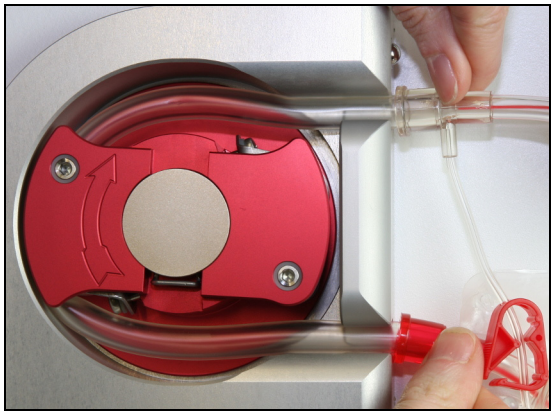


Fig. 44

▶ A tubing segment is properly inserted when it is seated all the way in the chamber.

The operator must make sure that the tubing set is not pinched between the rotor and the housing or twisted in the pump chamber.

If the tubing is not installed in the pump chamber correctly, the pump segment may leak or rupture. If the tubing is pinched or twisted during installation of the pump segments, discard the tubing and do not use it for treatment.

5. Install the ***filtration pump*** segment by pressing the tubing, located near the yellow marker, into the bottom of the filtration pump housing.
6. ***Carefully*** wrap the segment around the pump by turning the rotor ***clockwise***.
7. Press the tubing into the holder at the pump outlet.
8. Install the ***post-dilution pump*** segment (top segment with green marker) by pressing the tubing into the inlet (bottom) of the post-dilution pump housing.
9. ***Carefully*** wrap the segment around the pump by turning the rotor ***counter-clockwise*.**
10. Press the tubing into the holder at the pump outlet (top).
11. Install the ***pre-dilution pump*** segment (lower segment with green marker) by pressing the tubing into the inlet (bottom) of the pre-dilution pump housing.
12. ***Carefully*** wrap the segment around the pump by turning the rotor ***counter-clockwise***.
13. Press the tubing into the holder at the pump outlet (top).

Step 2: Close both pump doors.

If the pump doors do not close easily, open the doors and re-check the pump segments for proper position. The doors should close easily when the tubing is properly inserted.

The operator must make sure that all pressure domes are properly in place.

The tubing from the top of the blood pump should project outward and form a loop to prevent kinking of the tubing set.

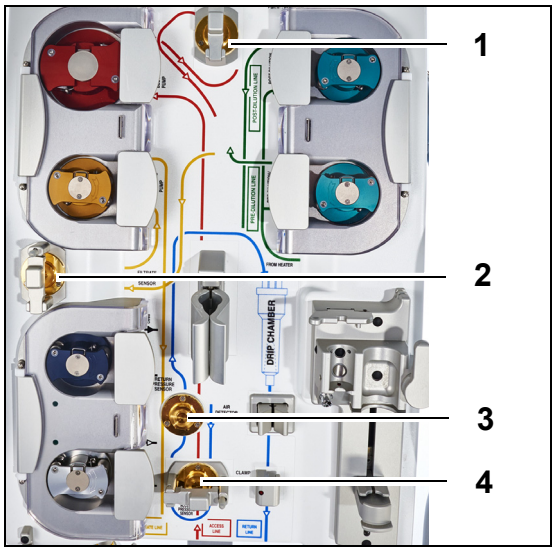


Fig. 45

Step 3:

1. Attach the pre-filter pressure dome to the pre-filter pressure sensor (1) and close the dome clamp.
2. Attach the filtrate pressure dome to the filtrate pressure sensor (2) and close the dome clamp.
3. Attach the return pressure dome to the return pressure sensor (3).
4. Attach the access pressure dome to the access pressure sensor (4) and close the dome clamp.
5. Verify all pressure domes are attached and the dome clamps are correctly closed.

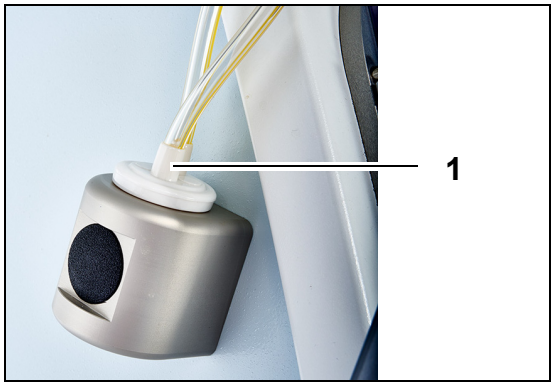


Fig. 46

Step 4: Place the blood leak detector chamber (1) in the holder on the left side of the cabinet.

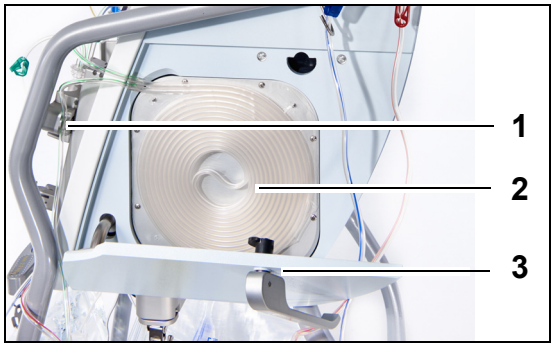


Fig. 47

Step 5: Insert the tubing coil (2) into the heater and close the door (3).

Step 6:

1. Place the degassing chamber in the automatic degassing unit holder, see section *5.2 Automatic degassing unit (ADU) – Priming and use (Page 5-27)*.
2. Place the substitution/dialysate line into the line tidy (1), on upper right side of the automatic degassing unit.

NOTE

Take care to place the substitution/dialysate line into the line tidy. This avoids contact between the line and the bag.

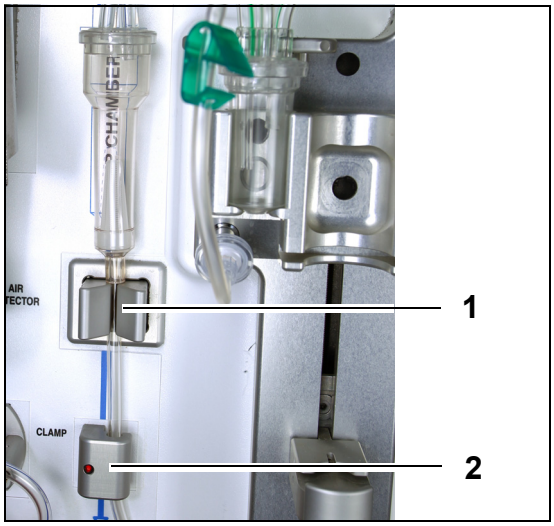


Fig. 48

3. Install the return line in the air detector tube holder (1).
4. Ensure the return tubing is located securely within the groove of the air detector.
5. Press the unit together and push back to hold the return line in place.
6. Install the return line in the return line clamp (2).

Step 7: Connect the empty collection bag for priming to the access line and hang it on the I.V. pole.

The operator must make sure that the tubing in the pump segments are not dislodged or twisted by installation of the filter.

Any time the tubing has been manipulated, visually verify that the pump segment is properly inserted into the pump chamber.

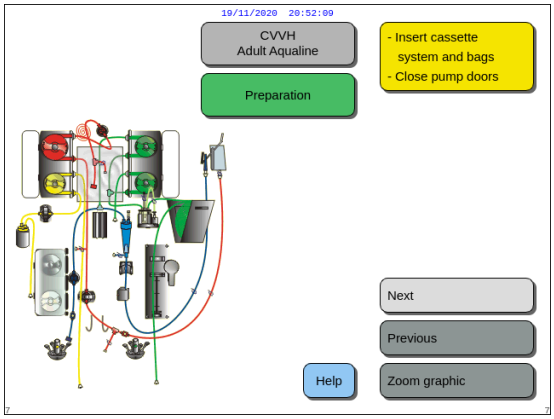


Fig. 49

Step 8: Select *Next* to proceed with the filter and bags installation.

5.1.6 Preparation mode – Installing the filter and bags, and connecting the lines

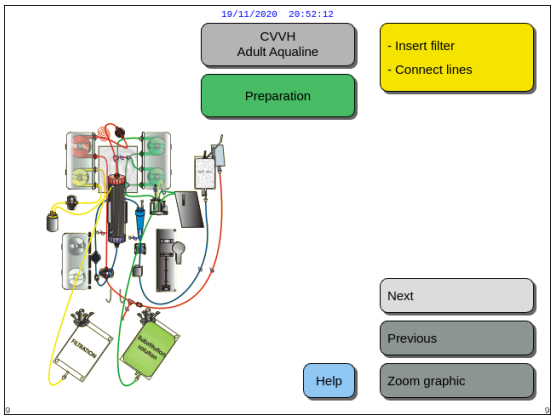


Fig. 50

The user can get the detailed description of all necessary actions on the machine using the *Help* function or *Zoom graphic* key.

The user can fulfill all necessary actions as described in this chapter below without the on-screen assistance and then select *Next* to get to the anticoagulant selection.

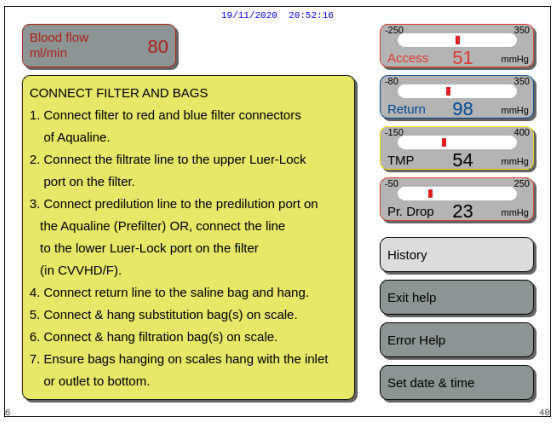


Fig. 51

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

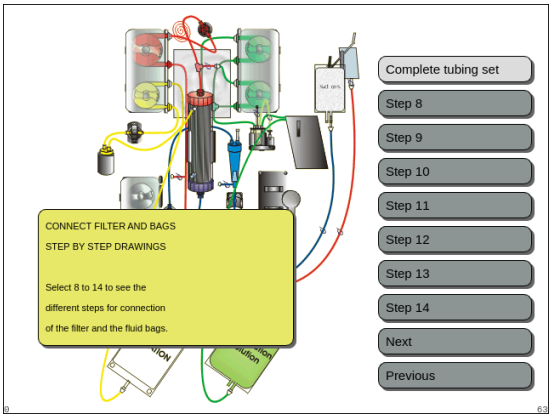


Fig. 52

- ⇨ If you need detailed step-by-step visual help with graphics, select *Zoom graphic* key.
  - ▶ A window with the list of all steps necessary for the installation of the tubing set and empty bags appears.
- ⇨ Choose step after step and follow instructions on the screen. When all steps are completed, select *Next*, to get to the filter and bags installation.

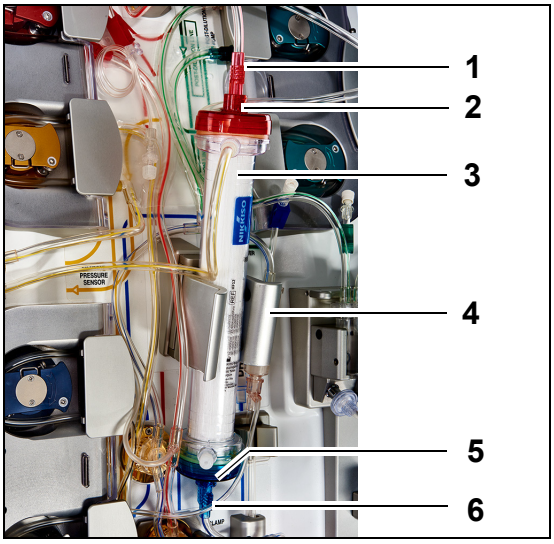


Fig. 53

Step 1:

1. Place the prescribed hemofilter (3) in the filter holder (4).
2. Attach the red connector of the tubing set (1) to the red connector of the filter (2).
3. Attach the blue connector of the tubing set (6) to the blue connector of the filter (5).

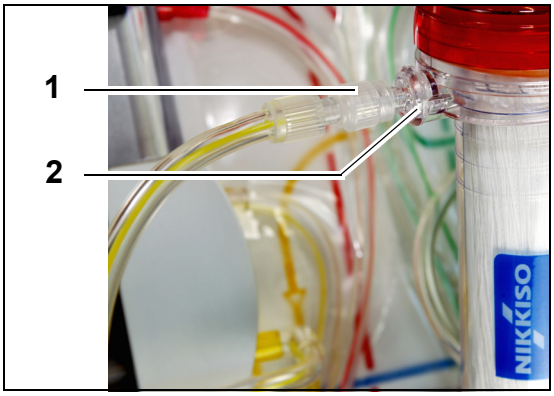


Fig. 54

Step 2: Attach the filtrate line (short line from the blood leak detector) (1) to the clear Luer lock filtrate port (2) at the top of the filter.

Fig. 55

Step 3: Attach the free line (1) depending on the treatment required.

For hemoperfusion treatments, the filtrate tubing line is not used and should not be connected to the blood circuit.

The “free line” is the colorless line exiting the pre-dilution pump (bottom green pump).

The free line can be connected to the access line prior to the filter (SCUF, CVVH, TPE and Hemoperfusion) or to the dialysate port at the bottom of the filter (CVVHD and CVVHDF).

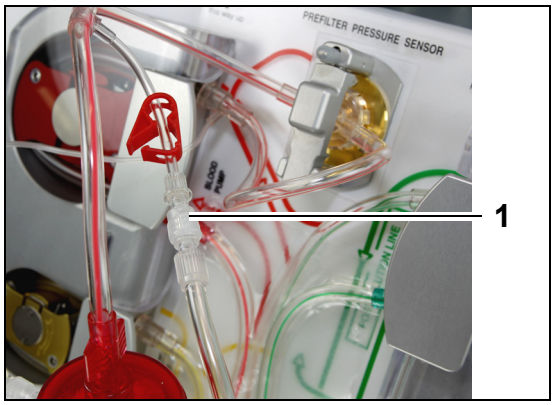


Fig. 56

- For **SCUF**, **CVVH**, **TPE**, **Hemoperfusion** attach the free line to the access line prior to the filter (1).

Fig. 57

- For **CVVHD** or **CVVHDF** attach the free line to the dialysate port (1) at the bottom of the filter.

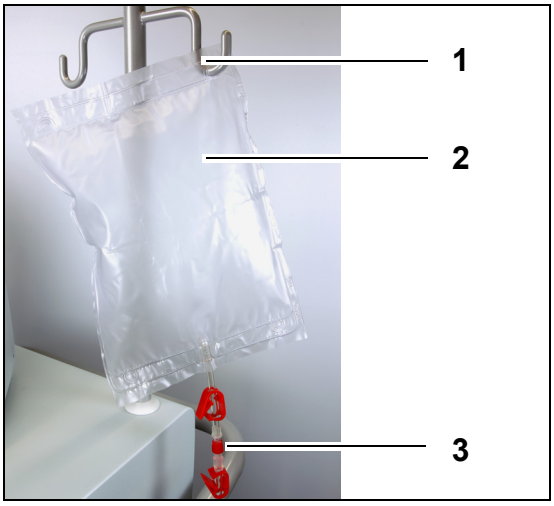


Fig. 58

Step 4:

1. Hang the empty collection bag (2) for priming on the I.V. pole (1).
2. Connect the red end (3) of the Aqualine tubing set (access line) to the bag.

To avoid leakage or the entrance of air, ensure that the citrate and calcium lines are clamped during CVVHDF on an Aquarius system when using Aqualine RCA.

The I.V. pole may only carry a maximum weight of 2.5 kg.

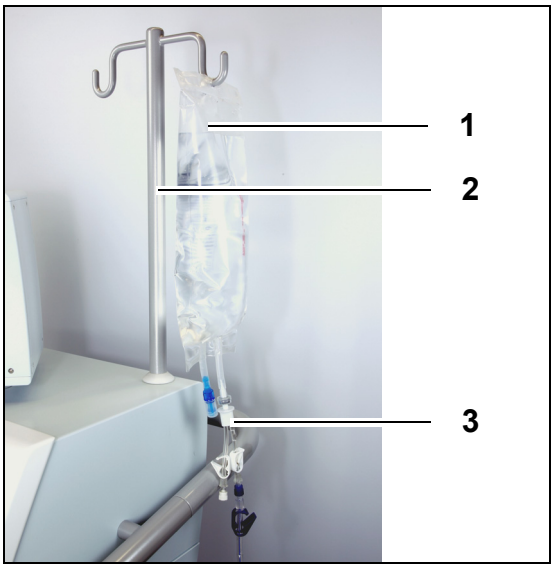


Fig. 59

Step 5:

1. Hang a 1 l bag of priming solution (1) (usually heparinized saline) on the I.V. pole (2).
2. Insert the spike of the Y-connector (3) provided with the Aqualine tubing set into the priming solution bag.
3. Remove the cap at the end of the return line (blue line of the Aqualine tubing set).
4. Clamp the return line, and connect the blue Luer lock end of the return line to the Y-connector.
5. Break the frangible pin of the priming solution bag if needed.

Step 6:

Connect the empty, 5 l collection bag(s) to the filtrate tubing and hang it on the filtrate scale. Be sure to open all clamps on the bags and manifold set.

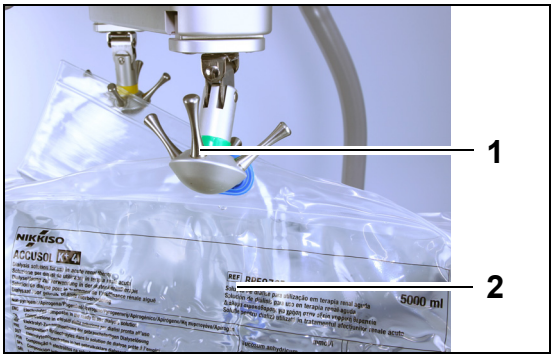


Fig. 60

Step 7:

1. Hang the substitution solution bag(s) (2) on the substitution scale (1) and connect it to the heater tubing.
2. Open all clamps on the bags and manifold set.

If using 2.5 l substitution or dialysate bags, in order to detect empty bags properly, enter the number to be used and use the appropriate number of 5 l filtrate bags. One 5 l filtrate bag will be needed for two 2.5 l fluid bags.

To prevent overfilling or rupturing of the filtrate bags, please ensure that an equal number of bags of the same size are used on the substitution and filtrate scales. At the start of treatment, if three 5 l substitution bags are placed on the substitution scale, then three empty 5 l filtrate bags must be placed on the filtrate scale.

Do not hang anything except soft plastic fluid bags on the balancing scale hooks located at the base of the Aquarius system. Foreign objects on the scale hooks can significantly alter fluid balance, resulting in patient injury or death.

Ensure that the filtrate bags and substitution bags do not touch the cart frame. Ensure that the tubing lines are not supported by and are not resting on the cart frame. Do not touch the filtrate or substitution solution bags while the balance system is active.
Observe this warning to avoid patient fluid balance errors.

When using a manifold with multiple bags, all applicable clamps must be opened to allow the fluid to move freely.
If a substitution bag is kinked or remains clamped, air may be pumped into the substitution lines and balance alarms may occur due to the unbalanced load hanging on the scale.

To prevent misdirection of substitution solution or extracorporeal blood loss, be sure that all lines are properly installed and correctly connected.

Step 8: Connect the ADU hydrophobic sensor to prevent a positive pressure within the tubing. See section *5.2 (Page 5-27)* for how to proceed.

Step 9: Verify that the output of the dialysate/pre-dilution pump (lower green pump) is connected to the bottom of the filter for CVVHD and CVVHDF therapies.
The output of the pre-dilution pump (lower green pump) should be connected to the pre-dilution Luer connector of the pre-filter blood line leading to the top of the hemofilter, for all other therapies.

Step 10: Verify that all tubing clamps are open for the access, return, filtrate and substitution/dialysate tubing lines. If the substitution line is connected to the pre-dilution Luer connector, open the pre-dilution line clamp.

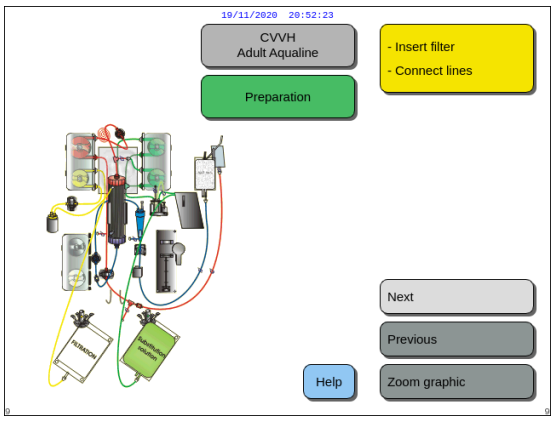


Fig. 61

Step 11: Select and confirm *Next* to prepare the heparin syringe.

5.1.7 Preparation mode – Selecting the anticoagulant

In case of Aquarius Regular, the citrate and calcium pump as well as the corresponding scales are not available.

Use only the heparin syringe type that the Aquarius system has been calibrated to use (see also section *3.3 Equipment: disposables (Page 3-1)*).

The Aquarius system must be calibrated for the particular type of syringe you are using by a certified technician. The syringe size is shown at the right of the *Prepare syringe* screen.

Use only Luer lock syringes and ensure that the heparin line is not clamped prior to the start of heparin infusion.

Use of non-Luer lock syringes or failing to unclamp the heparin line can result in patient blood loss due to coagulation.

When no anticoagulant is used, there is a risk of blood clotting in the extracorporeal circuit. Clotting may result in blood loss.

When no heparin is used the heparin line should be clamped.

Citrate and calcium pump light indicators (Aquarius^{+} only):

- Light indicators are off if citrate or citrate and heparin anticoagulation has not been selected before connecting the patient.
- Light indicators are flashing if the pumps are off when citrate anticoagulation is selected.
- Light indicators are on if citrate and calcium pumps are running.

The operator has the choice between the following anticoagulation modes:

- No anticoagulant (in all therapies)
- Heparin (in all therapies)
- Citrate (in CVVH, CVVHD and TPE) (Aquarius^{+} only)
- Citrate + heparin (in CVVH, CVVHD and TPE) (Aquarius^{+} only)

Use only Aqualine and Aqualine S line sets when the treatment shall be performed with heparin anticoagulation or without anticoagulation.

In CVVH, CVVHD and TPE adult therapies:

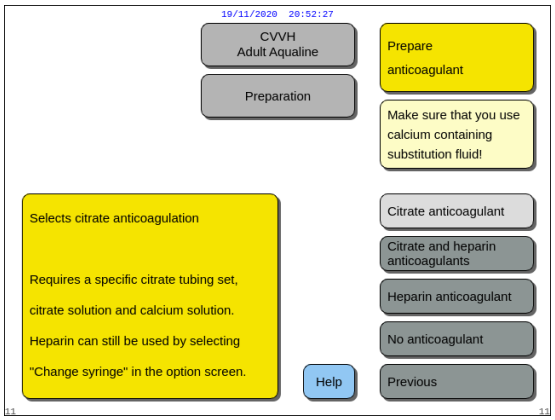


Fig. 62

Step 1: Select between:

- Citrate anticoagulant
- Citrate and heparin anticoagulant
- Heparin anticoagulant
- No anticoagulant.

Step 2: Confirm the selected anticoagulant by pressing the *Main selector button*.

Step 3: Select and confirm the *Previous* function to return to the previous screen (Install filter and bags).

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

If heparin anticoagulation is selected:

- in all therapies on Aquarius Regular devices
- in SCUF, CVVHDF, and Hemoperfusion therapies on Aquarius RCA devices
- in all therapies on Aquarius RCA devices where Heparin anticoagulation is selected

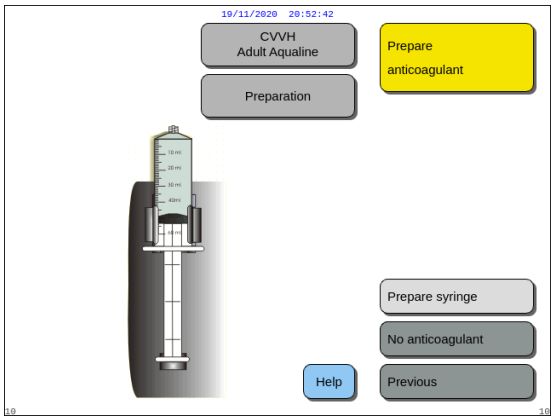


Fig. 63

Step 1: Select between:

- Prepare syringe
- No anticoagulant.

Step 2: Confirm the selection by pressing the *Main selector button*.

Step 3: Select and confirm the *Previous* function to return to the previous screen (Install filter and bags).

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

5.1.8 Preparation mode – HEPARIN anticoagulation

Step 1: Select *Heparin anticoagulant*.

Step 2: Fill the syringe with the concentration and volume prescribed by the physician.

Step 3:

1. Confirm *Select volume in syringe* by pressing the *Main selector button*.
2. Adjust the heparin volume by turning the *Main selector button* left or right as required.
3. Confirm the volume input by pressing the *Main selector button*.

▶ The syringe driver moves to the correct position.

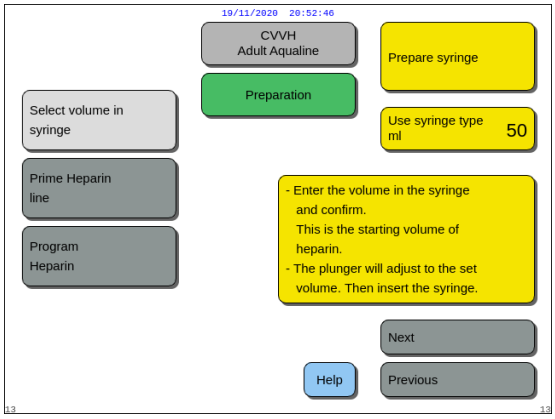


Fig. 64

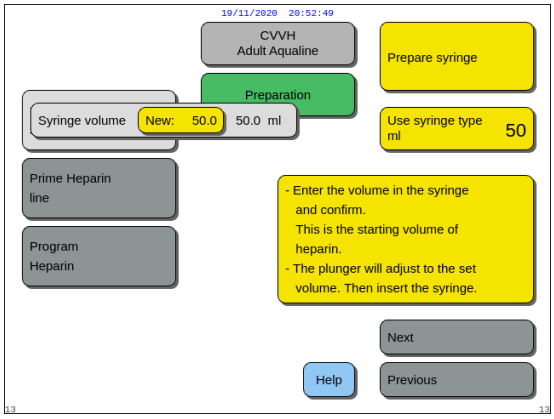


Fig. 65

Fig. 66

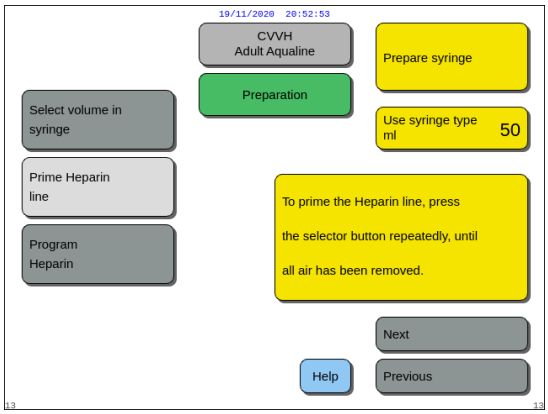


Fig. 67

Step 4:

1. Clamp the heparin line.
2. Connect the heparin syringe to the heparin line (1).
3. Place heparin syringe in heparin pump.

NOTE

Ensure the syringe body and plunger flanges are engaged correctly into the pump.

4. Unclamp the heparin line.

Step 5:

1. Select *Prime heparin line* by turning the *Main selector button* .
2. Press *Main selector button* as many times as necessary until all air is removed from the line (Fig. *67*).

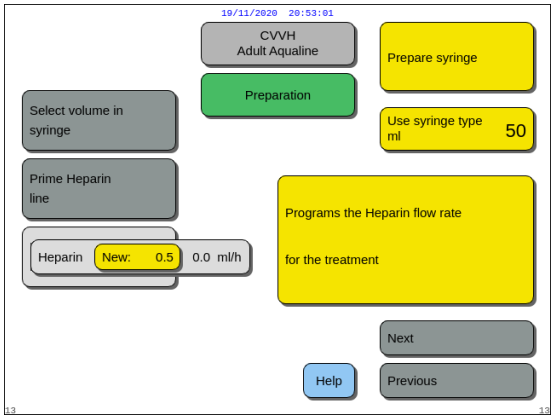


Fig. 68

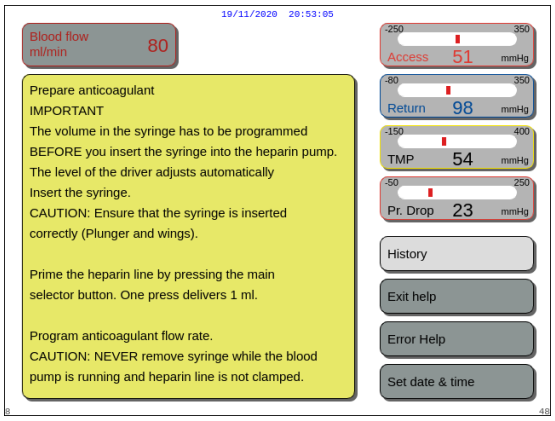


Fig. 69

Step 6:

1. Select *Program Heparin* by turning the *Main selector button* .
2. Adjust heparin flow rate by turning the *Main selector button* left or right as required (Fig. *68*).
3. Confirm flow rate input by pressing the *Main selector button* .
4. Select and confirm *Next* to proceed with *Start priming* screen.
5. Select and confirm *Start priming* to enter *Priming* mode.
   OR
   Return to preparing an anticoagulant. To do this select and confirm *Prepare anticoagulant*.

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

When Heparin only is selected as the anticoagulant, it will not be possible to use citrate anticoagulation for the actual treatment.

When the Regional Citrate Anticoagulation (RCA) option is not chosen, use an Aqualine tubing set and not an Aqualine RCA tubing set.

In case an Aqualine RCA tubing set is used, insert the citrate and calcium line as described in section *5.1.9 (Page 5-21)*. Then clamp the citrate line close to the access line with a tubing clamp and clamp the calcium line close to the return chamber with a tubing clamp.

5.1.9 Preparation mode – CITRATE anticoagulation (Aquarius+ only)

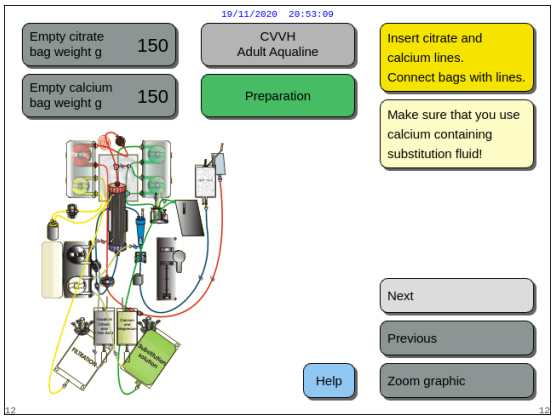


Fig. 70

Step 1:

1. Select *Citrate anticoagulant*, see section *5.1.7 Preparation mode – Selecting the anticoagulant (Page 5-17)*.
2. Install citrate and calcium lines and bags, use *Help* function or *Zoom graphic* key for detailed instructions.
3. Select and confirm *Next* to proceed.
   OR
   If anticoagulant choice needs to be changed select and confirm *Previous*.

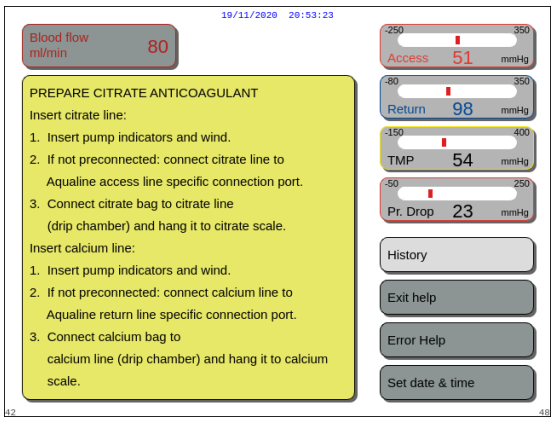


Fig. 71

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

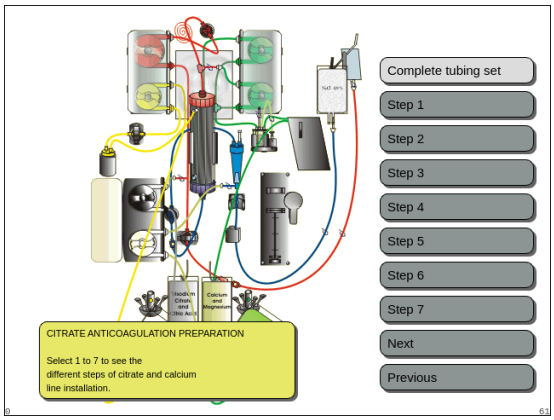


Fig. 72

⇨ If you need detailed step-by-step visual help with graphics, select *Zoom graphic* key. See also description of this key in this section below.

▶ A window with the list of all steps necessary for the installation of citrate and calcium lines and bags appears.

⇨ Choose step after step and follow instructions on the screen. When all steps are completed, select *Next*, to open the *Start priming* screen.

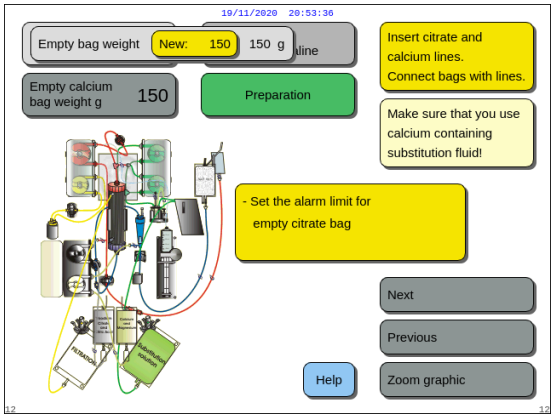


Fig. 73

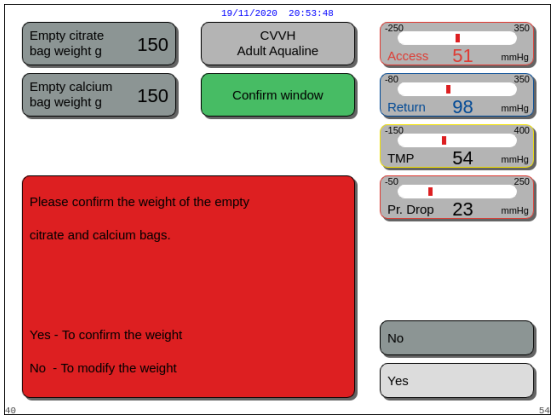


Fig. 74

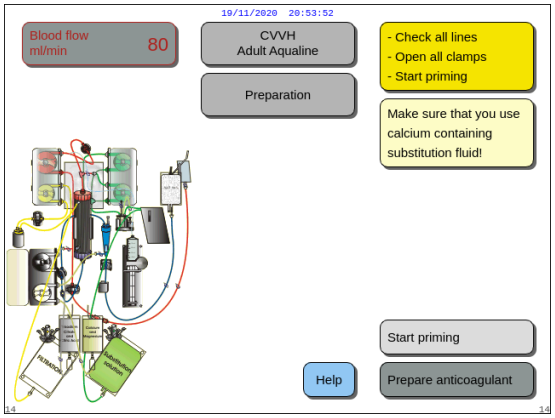


Fig. 75

Step 2:

1. Select empty citrate and calcium bag weight by turning the *Main selector button*.
2. Adjust the new weight by turning the *Main selector button* left or right as required (Fig. *73*).
3. Confirm the new weight by pressing the *Main selector button*.
   ▶ With the new bag weight the machine can calculate the time until the next bag change.
4. Select *Next* to proceed.

   ▶ A *Confirm* window appears.
5. Press *Yes* if satisfied with the weight of the citrate and calcium bags entered.
   OR
   Press *No* to modify.

6. Select and confirm *Start priming* to enter *Priming* mode.
   OR
   Select and confirm *Prepare anticoagulant* to return to preparing an anticoagulant.

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

During treatment the heparin syringe may be optionally added using *Change syringe* function.

Verify the contents of each specific anticoagulant, replacement or dialysate bag correctly against the prescribed therapy selected.

The default value of the *Change citrate bag* and *Change calcium bag* alarm is 150 g. This value is the weight of the empty citrate and calcium bags. When inserting the citrate and calcium line, it is possible to set this value in the range 50 g–300 g. Different weight values may be set for fluids presented in sterile bags and glass bottles.

- **Zoom graphic key – installation of citrate and calcium lines**

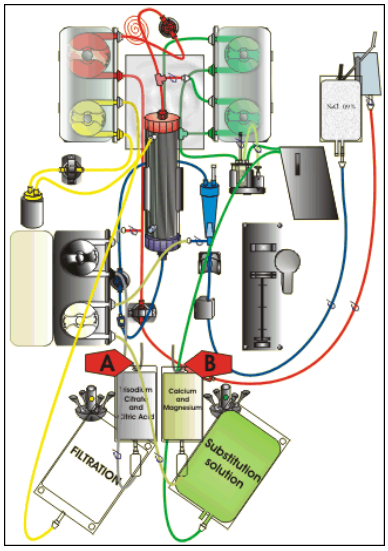


Fig. 76

Step 1: Hang citrate and calcium bag:

1. **A** – Hang citrate solution bags up to 2.2 kg on the citrate scale. This scale is on the left and has a small black hook.
2. **B** – Hang only one calcium (+ magnesium) solution bag on the calcium scale. This scale is on the right and has a small white hook.

NOTE

In case of using Aqualine S RCA hang only a one litre bag or bottle of calcium (+ magnesium) solution on the calcium scale.

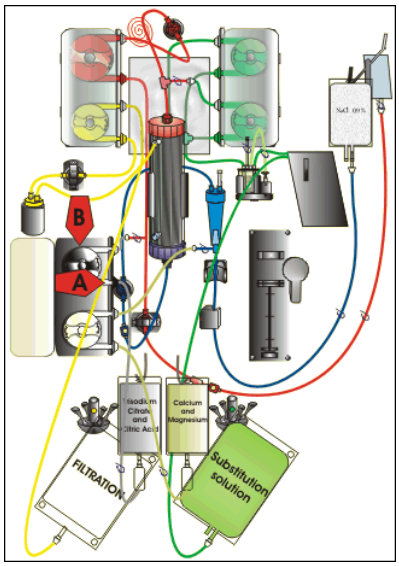


Fig. 77

Step 2: Insert the citrate pump segment:

1. Open the citrate and calcium pump door.
2. Place the citrate line (black line and clamp) into the pump housing with the drip chamber to the bottom.
3. **A** – Insert the citrate pump segment by pressing the tubing into the bottom of the pump housing.
4. **B** – Wrap the citrate pump segment around the citrate pump (black) by manually turning the pump rotor.

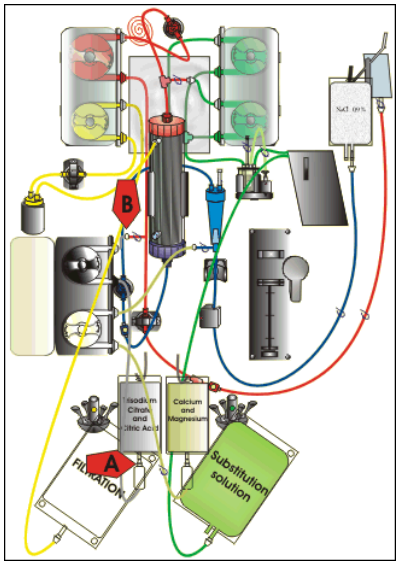


Fig. 78

Step 3: Connect citrate line:

1. **A** – Connect the drip chamber of the citrate line (bottom) to the citrate bag.

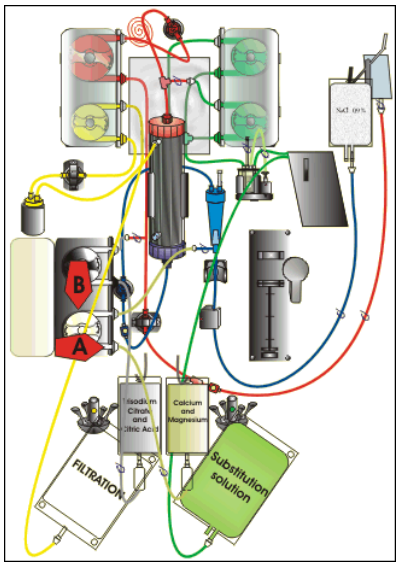


Fig. 79

Step 4: Insert the calcium pump segment:

1. Place the calcium line (white line and clamp) into the pump housing with the drip chamber to the bottom.
2. **A** – Insert the calcium pump segment by pressing the tubing into the bottom of the pump housing.
3. **B** – Wrap the calcium pump segment around the calcium pump (silver) by manually turning the pump rotor.

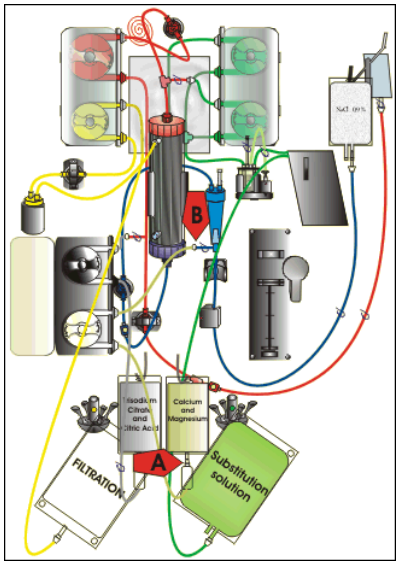


Fig. 80

Step 5: Connect calcium line:

1. **A** – Connect the drip chamber of calcium line (bottom) to the calcium bag.
2. Open the clamps on the citrate and calcium lines.
3. Make sure that the citrate and calcium bags do not touch the tubing lines or solution bags to prevent a fluid balance deviation.

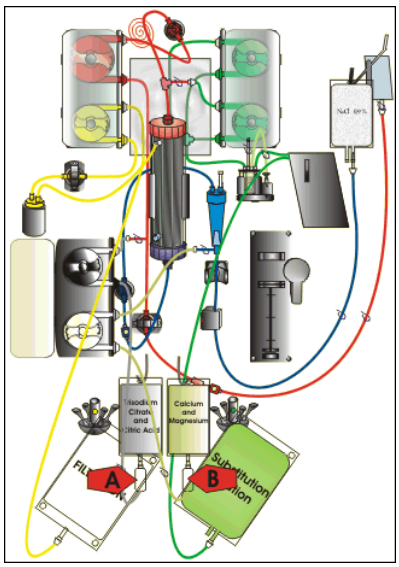


Fig. 81

Step 6: Fill the drip chambers:

1. **A** – Squeeze the drip chamber of the citrate line until the chamber is half-full.
2. **B** – Squeeze the drip chamber of the calcium line until the chamber is half-full.
3. Make sure that all clamps are open.

Step 7: Close pump doors.

5.1.10 Preparation mode – CITRATE and HEPARIN anticoagulation (Aquarius+ only)

The syringe pump is designed for heparin only.

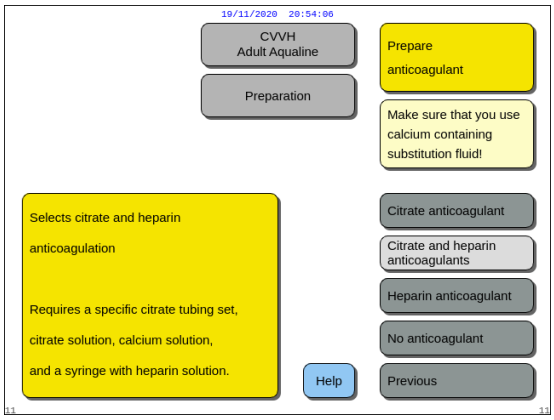


Fig. 82

Step 1: Select and confirm *Previous* to change the anticoagulant.

Step 2: Follow steps for *Heparin anticoagulation* (see section *5.1.8 (Page 5-18)*) and *Citrate anticoagulation* (see section *5.1.9 (Page 5-21)*).

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

When *Citrate anticoagulant* or *Citrate and heparin anticoagulants* are selected, citrate use can be switched off by programming both Citrate flow and Calcium flow to 0 ml/h in the *Programming* screen.

Heparin use is still available when only *Citrate anticoagulant* is selected. To start heparin infusion, go to *Options* screen and select *Change syringe*.

Heparin use can be switched off by programming the Heparin flow rate to 0 ml/h in the *Programming* screen.

When a programming value is set to 0 ml/h a *Confirm* window validates the choice.

5.1.11 Preparation mode – No anticoagulant

When *No anticoagulant* is selected, TMP and Pressure drop should be regularly monitored to reduce or avoid the risk of clotting in the filter and tubing set.

When *No anticoagulant* is selected as the anticoagulation method, it will not be possible to use citrate anticoagulant for the actual treatment.

In case of Aquarius Regular devices, *Citrate anticoagulant* as well as *Citrate and heparin anticoagulants* are not selectable, citrate and calcium bags are not indicated.

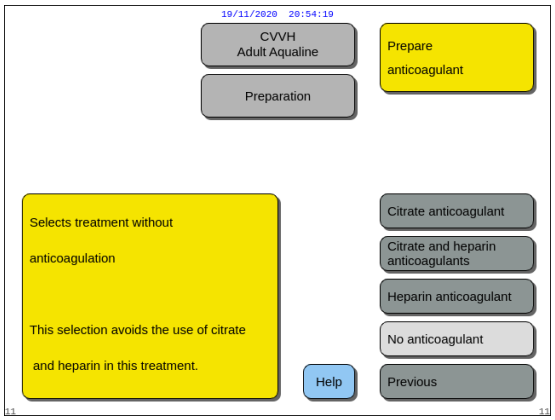


Fig. 83

Step 1: Select and confirm *No anticoagulant*.

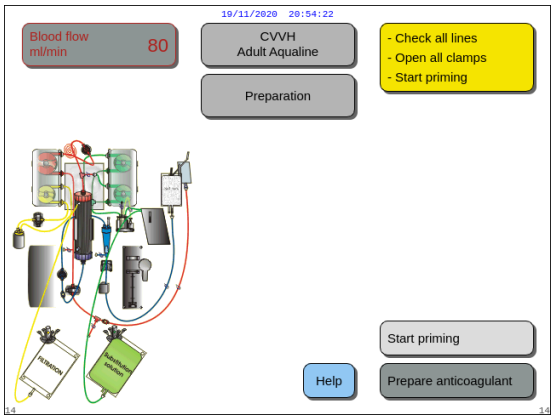


Fig. 84

Step 2: Select and confirm *Start priming* to enter *Priming* mode.
OR
Select and confirm *Prepare anticoagulant* to return to preparing an anticoagulant if needed.

In case an Aqualine RCA tubing set is used, insert the citrate and calcium line as described in section *5.1.9 (Page 5-21)*. Then clamp the citrate line close to the access line and clamp the calcium line close to the return chamber.

Priming the Aquarius system may be delayed due to high heater plate temperature from the previous treatment. The message *Wait! Heater self-test running* will be displayed until the *Start priming* key is available.

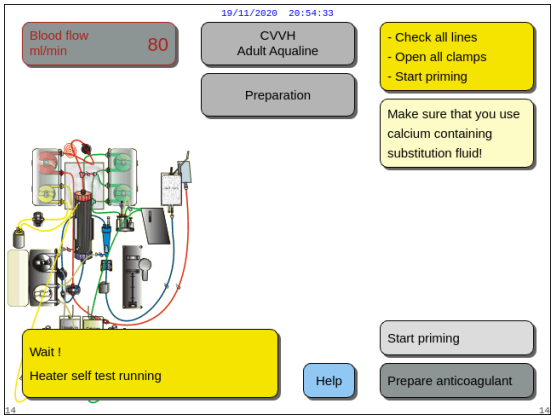


Fig. 85

The message disappears automatically when the heater self-test is completed.

➪ If necessary, use *Help* function for further on-screen information.

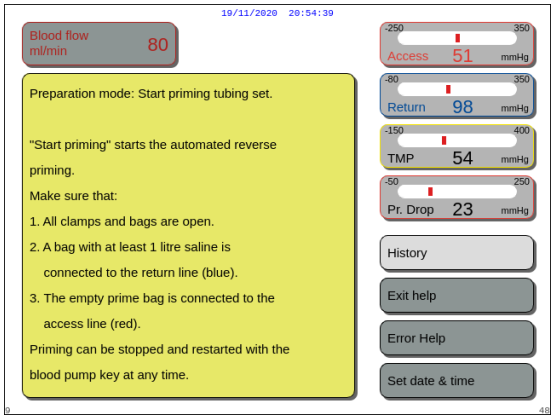


Fig. 86

▶ A window with short instructions appears.

5.2 Automatic degassing unit (ADU) – Priming and use

5.2.1 General description of the ADU

Fig. 87

The Aquarius system automatic degassing unit sets the level in the degassing chamber automatically (±1 cm around the light beam). Gas inside the substitution chamber, caused by degassing from substitution/ dialysate fluid, is removed by a small pump inside the ADU box (placed inside the Aquarius system).

Two hydrophobic filters prevent the ADU from contaminating the substitution fluid. One hydrophobic filter is located outside, on the degassing tubing. A second filter is located inside the Aquarius system before the pressure unit. The level is controlled by an infra-red light beam and pressure.

The Aquarius system ADU is a microprocessor-controlled system. The ADU works independently from the Aquarius system, except for the power supply and the alarm display.

5.2.2 Aqualine tubing installation

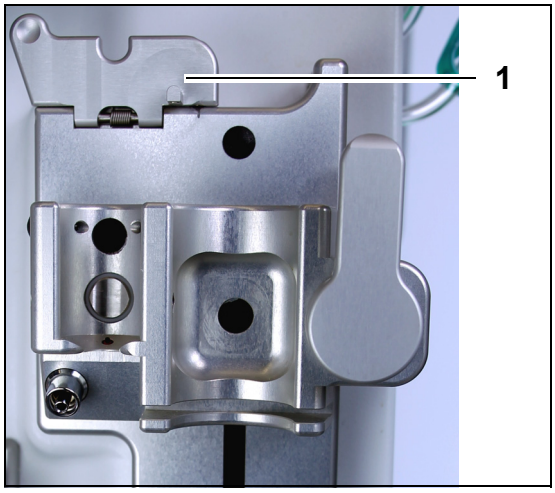


Fig. 88

Step 1: Move the ADU fixation clip (1) into the vertical position.

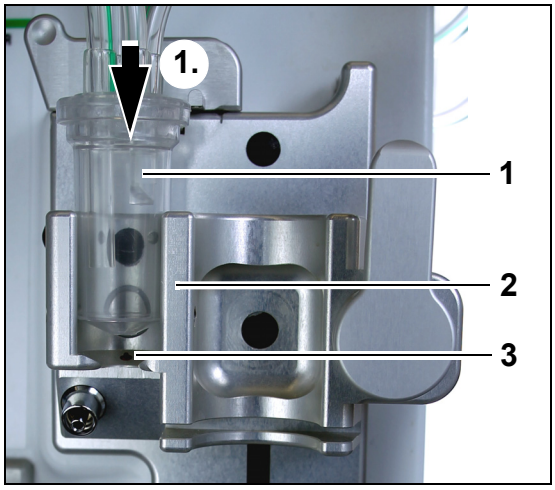


Fig. 89

Step 2:

1. Place the degassing chamber (1) into the holder (2).
2. Move the degassing chamber from top to the bottom of the holder (1.)
3. Make sure that the holder switch is pressed ON (3) by the chamber.

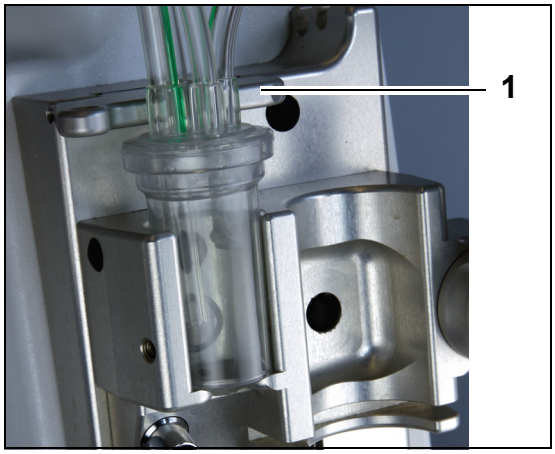


Fig. 90

4. Move the fixation clip (1) to its horizontal position.
   - ▶ The degassing chamber is fixed into its functional position.
   - ▶ The small line with clamp is inserted into fixation clip housing.

NOTE

In case the fixation clip is not well closed, the alarm *Degassing chamber missing* appears at the end of priming.

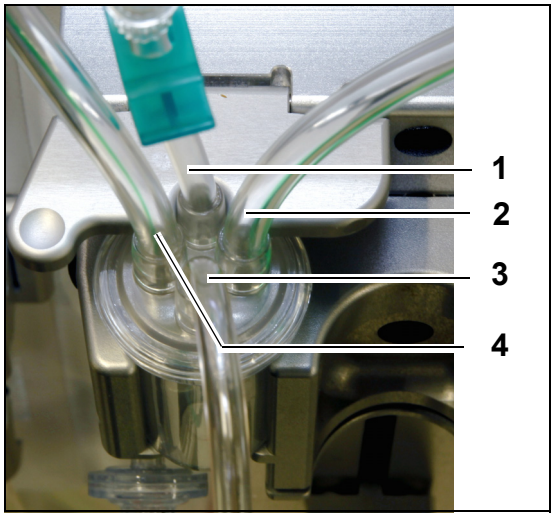


Fig. 91

5. Check the correct position of the degassing chamber:

- The short tubing (1) is placed at the back of the fixation clip.
- The longer clamped tube (3) on the degassing chamber is placed at the front of the holder. The tube (2) connects the line from heater with the ADU chamber.
- The tube (4) connects the green tubing line with the green pumps.

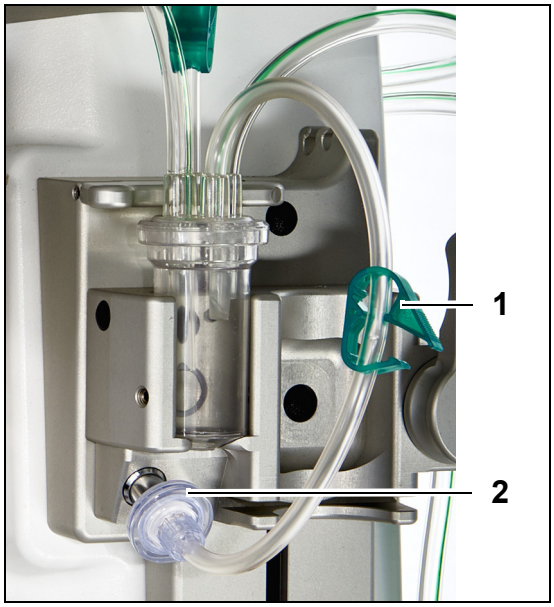


Fig. 92

Step 3:

1. Connect the Luer lock (2) hydrophobic filter from the ADU pressure line to the ADU pressure sensor.
2. Leave the clamp (1) of the hydrophobic filter tubing open, as shown in the Fig. *92*.

5.2.3 Priming

The ADU starts working during *Priming* mode. When the ADU pressure sensor detects less than -30 mmHg (post-dilution pump is running) it will automatically prime the degassing chamber **after** 10 seconds **for** 10 seconds.

If the infrared sensor does not detect water after the initial prime, the pump will start again **after** 2 minutes. For the second prime, the motor stops priming when liquid is detected at the infra-red sensor (second priming cannot run more than 25 seconds).

If the degassing line (with hydrophobic filter) is not connected to the pressure sensor, the message *Check degassing chamber* will appear after approximately 60 seconds with an audible signal. Priming is stopped and needs to be restarted.

Once priming is completed, inspect the chamber to ensure it is filled!

5.2.4 Operational mode

During operational mode, if the fluid level in the ADU falls below the level of the light-sensor, the ADU will remove air, thus refilling the chamber with fluid for up to 3.5 seconds. If the chamber is not filled after this time, the pump will pause for 10 seconds and then automatically repeat this cycle until fluid is detected.

5.2.5 ADU alarms and controls

The ADU unit generates audible and visible alarms (*Check degassing chamber* alarm is displayed on screen in a yellow window) under the following conditions:

- If the motor works for more than 25 s without detecting a filled chamber.
- If the hydrophobic filter is blocked (measured pressure less than -300 mmHg).
- If the system detects a positive pressure higher than +30 mmHg.
- If the system detects degassing line disconnection (measured pressure between -30 mmHg and +30 mmHg)
- If the ADU system test fails.

In case of an alarm where the balance pumps stop, the cause of the alarm should be identified taking into account the substitution fluid flow obstructions. If the balance pumps do not stop after an alarm, check connection of the substitution bag, Treatment continues after the problem resolves.

In case of fluid in the ADU sensor line, proceed as follows:

Step 1: Clamp the ADU sensor line and remove the chamber from the holder.

Step 2: Connect an air filled 10 ml syringe and inject 5 -10 ml air gently down the sensor line until there is no fluid left in the line.

Step 3: Replace the ADU chamber and sensor line, and unclamp the line.

When the ADU detects "normal conditions" (no blocked hydrophobic filter and a set level) the alarm can be cleared by pressing the *Mute* key. The balance pumps will restart.

During treatment the ADU system will keep the fluid level constant inside the degassing chamber (±1 cm around the light beam). In case the fixation clip is not in the horizontal functional position, *No degassing chamber detected* or *Degassing chamber missing* alarm occurs at the end of *Priming* and during *Treatment* mode.

When an ADU alarm (*Check degassing chamber, No degassing chamber detected* or *Degassing chamber missing*) cannot be cleared anytime during self-test, setup, priming or treatment, remove the Aquarius system from service and call Technical Service.

5.3 Priming mode – Priming the Aquarius system

5.3.1 Regular priming

Before starting regular priming ensure that:

- All line clamps are open.
- A bag with at least 1 l of saline is connected to the return (blue) line.
- The supplied prime collection bag is connected to the access (red) line.
- The substitution tubing connector is connected to a bag of substitution/dialysate solution on the substitution scale.
- All access, return, replacement and filtration tubing clamps are open.
- The substitution degassing chamber and return drip chamber clamps are closed.

Priming the Aquarius system may be delayed due to high heater plate temperature from the previous treatment. The message *Wait! Heater self test running* will be displayed until the *Start priming* key is available.

Use only Aqualine and Aqualine S bloodlines approved for use for regular treatments.

If TPE or Hemoperfusion therapy is selected, saline solution may be used in place of substitution/dialysate solution.

The *Blood pump* key and the *Mute* key are active during *Priming* mode.
The *Clamp* key and the *Treatment* key are inactive during *Priming* mode.

The priming procedure requires 800 ml of saline. The pre- and post-dilution lines are primed with fluid from the substitution/dialysate bag(s). The extracorporeal circuit and the filtrate lines are primed with fluid from the saline bag.

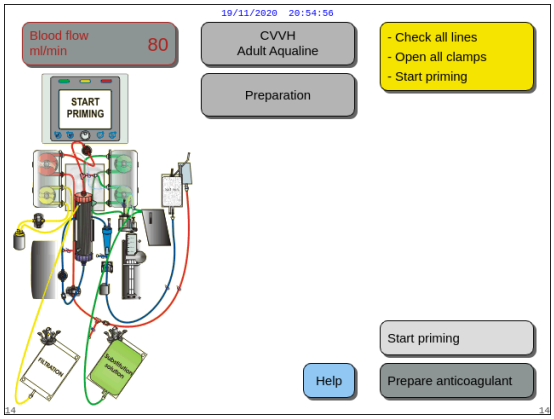


Fig. 93

Step 1:

1. Select *Start priming* by turning the *Main selector button* .
2. Press the *Main selector button* to start the priming procedure.

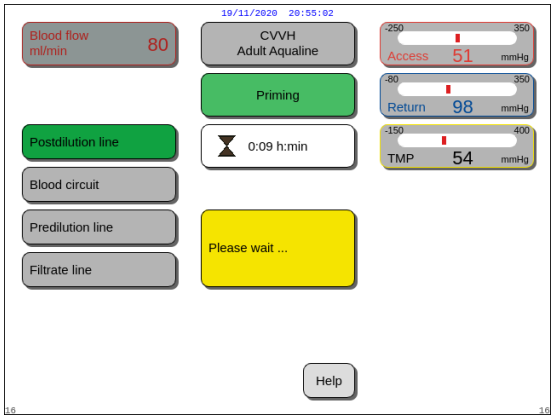


Fig. 94

- ▶ The screen displays *Access*, *Return* and *TMP* pressures.
- ▶ In the left part of the screen, the components of the circuit that are currently being primed are highlighted.
- ▶ The displayed clock indicates the remaining priming time.

⇨ If necessary, use *Help* function for further on-screen information.

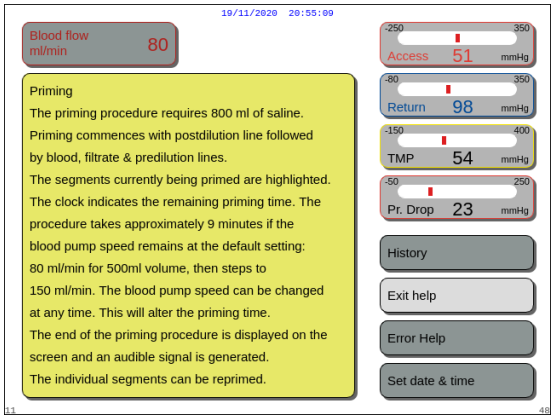


Fig. 95

▶ A window with short instructions appears.

Step 2:

The automated priming procedure takes approximately 9 min if the blood pump speed remains at the default setting determined during calibration. During this time, the operator can increase the blood pump flow rate to reduce priming time. The blood pump flow rate field is highlighted.

The prime sequence increases the blood pump speed during the last 3 minutes to 150 ml/min to facilitate adequate filter and tubing set degassing. Should additional filter degassing be required, the Reprime function permits degassing of the blood circuit and filter.

Any air remaining in the degassing chamber can be removed by either inversion of the chamber during priming or aspiration via a syringe after priming.

1. Press the *Main selector button* to modify the blood pump flow rate.
2. Turn the *Main selector button* to the left or right to enter the new flow rate.
3. Press the *Main selector button* to confirm.
   ▶ The new blood pump flow rate is displayed on the screen.
   ▶ The pump speed changes.
   ▶ The clock recalculates the remaining time.

If a *Check degassing chamber* alarm occurs during the first two minutes of priming (post-dilution line) and fluid is in the heater line, up to 120 ml of dialysate or substitution fluid may be pumped into the saline bag when the alarm is cleared and priming restarts.

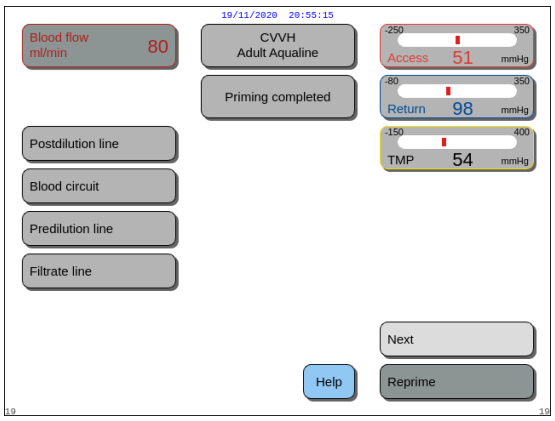


Fig. 96

▶ The priming procedure is completed.
▶ The *Priming completed* message is displayed on the screen.
▶ An audible signal is generated.

Step 3: Select and confirm *Next* to open the *Clamp and pressure test* screen.
If the *Next* function is disabled, check if the filtrate line and the blood leak detector line are correctly filled.
If they are not, restart priming.

⇨ If necessary, use *Help* function for further on-screen information.

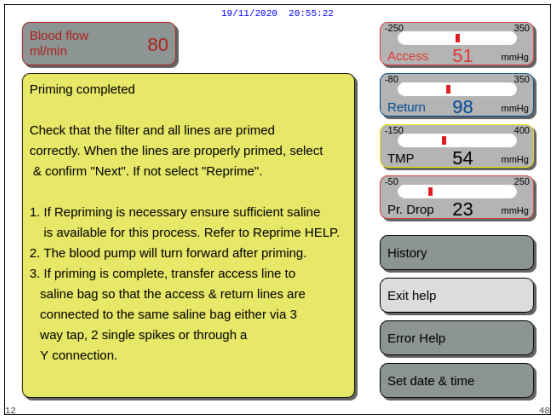


Fig. 97

▶ A window with short instructions appears.

5.3.2 Priming when RCA is selected

Before starting priming ensure that:

- All line clamps are open.
- A bag with at least 1 l of saline is connected to the return (blue) line.
- The supplied prime collection bag is connected to the access (red) line.
- The substitution tubing connector is connected to a bag of substitution/dialysate solution on the substitution scale.
- Citrate and calcium lines and prescribed solution are correctly installed.
- All access, return, replacement and filtration tubing clamps are open.
- The substitution degassing chamber and return drip chamber clamps are closed.

Priming the Aquarius system may be delayed due to high heater plate temperature from the previous treatment. The message *Wait! Heater self test running* will be displayed until the *Start priming* key is available.

Use only Aqualine RCA and Aqualine S RCA bloodlines approved for use for RCA treatments.

If TPE or Hemoperfusion therapy is selected, saline solution may be used in place of substitution/dialysate solution.

The *Blood pump* key and the *Mute* key are active during *Priming* mode.
The *Clamp* key and the *Treatment* key are inactive during *Priming* mode.

The priming procedure requires 800 ml of saline. The pre- and post-dilution lines are primed with fluid from the substitution/dialysate bag(s). The extracorporeal circuit and the filtrate lines are primed with fluid from the saline bag. The citrate line is primed with fluid from the citrate bag and the calcium line with fluid from the calcium bag.

Citrate anticoagulation system priming process:

a) Calcium pump starts, delivers a minimum of 15 ml of fluid;

b) Citrate pump follows, delivers a minimum of 15 ml of fluid.

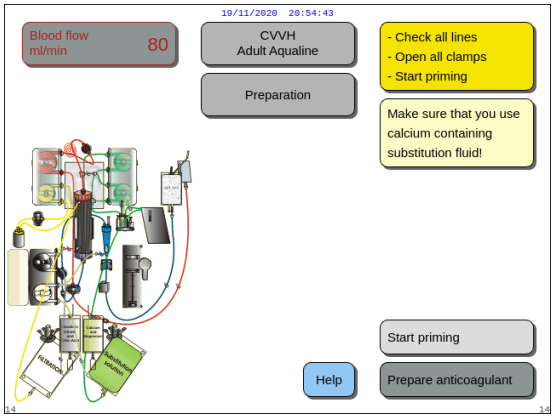


Fig. 98

Step 1:

1. Select *Start priming* by turning the *Main selector button*.
2. Press the *Main selector button* to start the priming procedure.

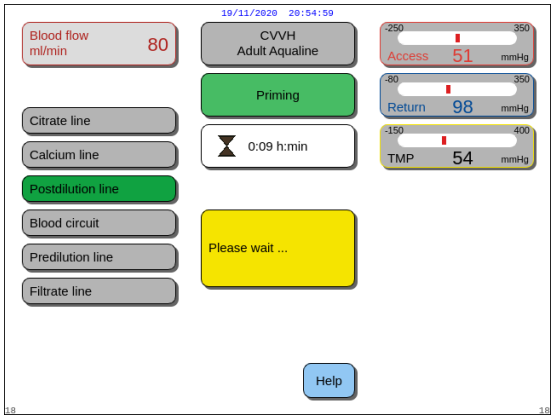


Fig. 99

- ▶ The screen displays *Access*, *Return* and *TMP* pressures.
- ▶ In the left part of the screen, the components of the circuit that are currently being primed are highlighted.
- ▶ The displayed clock indicates the remaining priming time.

⇨ If necessary, use *Help* function for further on-screen information.

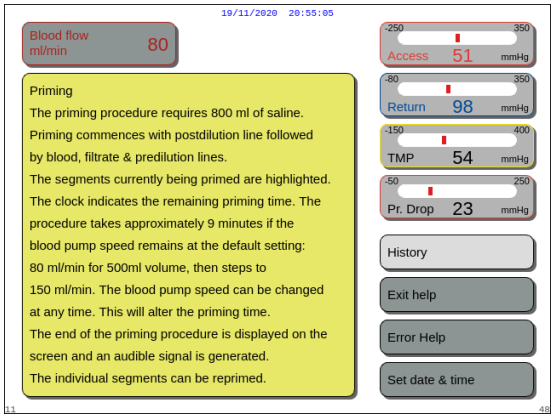


Fig. 100

- ▶ A window with short instructions appears.

Step 2:

The automated priming procedure takes approximately 9 min if the blood pump speed remains at the default setting determined during calibration. During this time, the operator can increase the blood pump flow rate to reduce priming time. The blood pump flow rate field is highlighted.

The prime sequence increases the blood pump during the last 3 minutes to 150 ml/min to facilitate adequate filter and tubing set degassing. Should additional filter degassing be required, the Reprime function permits degassing of the blood circuit and filter.

Any air remaining in the degassing chamber can be removed by either inversion of the chamber during priming or aspiration via a syringe after priming.

1. Press the *Main selector button* to modify the blood pump flow rate.
2. Turn the *Main selector button* to the left or right to enter the new flow rate.
3. Press the *Main selector button* to confirm.
   - ▶ The new blood pump flow rate is displayed on the screen.
   - ▶ The pump speed changes.
   - ▶ The clock recalculates the remaining time.

If a *Check degassing chamber* alarm occurs during the first two minutes of priming (post-dilution line) and fluid is in the heater line, up to 120 ml of dialysate or substitution fluid may be pumped into the saline bag when the alarm is cleared and priming restarts.

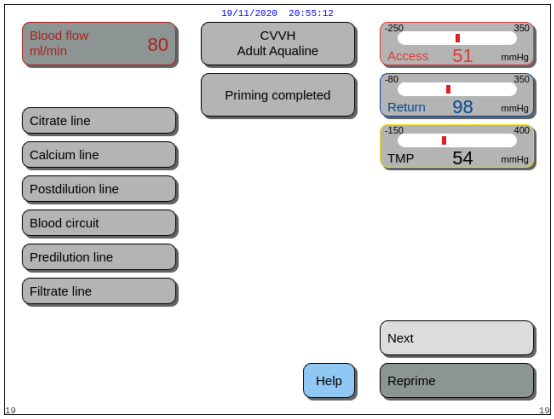


Fig. 101

- ▶ The priming procedure is completed.
- ▶ The *Priming completed* message is displayed on the screen.
- ▶ An audible signal is generated.

Step 3: Select and confirm *Next* to open the *Clamp and pressure test* screen.
If the *Next* function is disabled, check if the filtrate line and the blood leak detector line are correctly filled.
If they are not, restart priming.

⇨ If necessary, use *Help* function for further on-screen information.

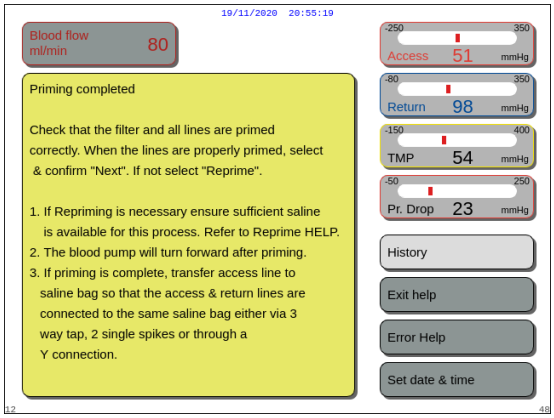


Fig. 102

- ▶ A window with short instructions appears.

5.3.3 Priming mode – Wrong tubing set selected or clamp closed message

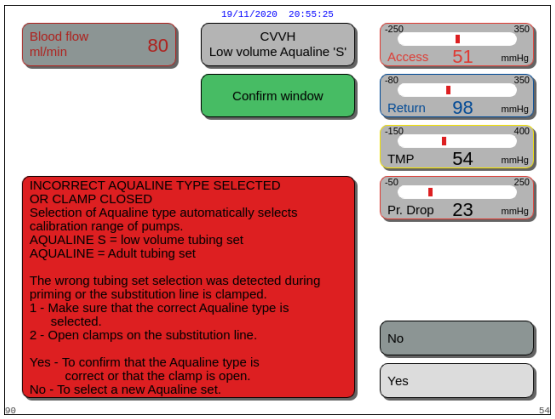


Fig. 103

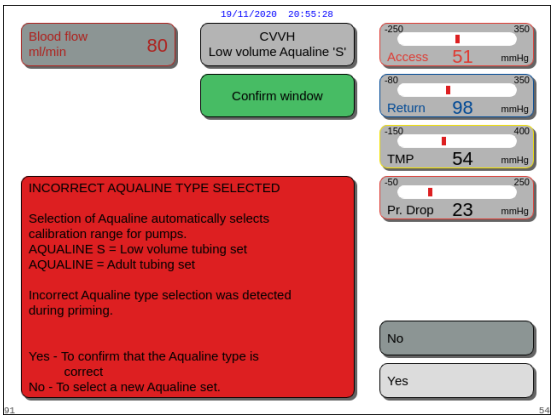


Fig. 104

If the message *Incorrect Aqualine type selected* or *Clamp closed* appears within the first 2 minutes of priming, this could be due to:

- one clamp is closed on the substitution line or the substitution bag(s) are not open.
- the selected line (Aqualine tubing set for adult or Aqualine S tubing set for low volume treatment) is not the one which has been installed on the Aquarius system by the operator.

Step 1: Open all clamps on the substitution line.

Step 2: Position the substitution bag(s) correctly on the substitution scale and open them.

Step 3: If the selected tubing set and used tubing set correspond, select *Yes* to confirm the selected line. Turn and press the *Main selector button* .
OR
If the selected tubing set and used tubing set are different, select *No* to change selection. Turn and press the *Main selector button* .

If an *Incorrect Aqualine type* confirm window appears and fluid is in the heater line, up to 120 ml of dialysate or substitution fluid may be pumped into the saline bag when *Yes* is selected to confirm the correct tubing set. When priming completes, replace the saline bag and reprime the blood circuit if the dialysate or substitution fluid is not indicated for infusion.

5.3.4 Priming mode – Reprime mode

In case of Aquarius Regular devices, citrate and calcium lines are not indicated.

Reprime mode allows you to select an individual or multiple lines/circuit to be reprimed.

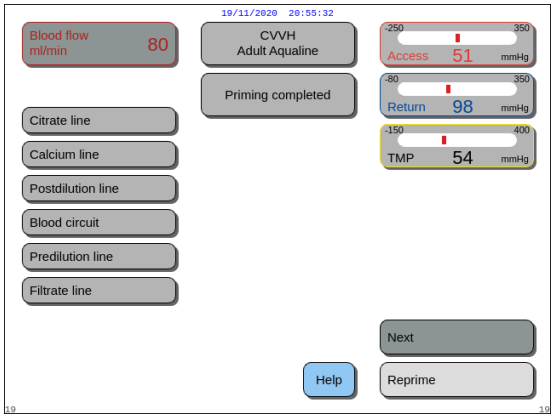


Fig. 105

Step 1: Select and confirm the *Reprime* function.
OR
Select *Next* function to go to the *Clamp and pressure test* function.

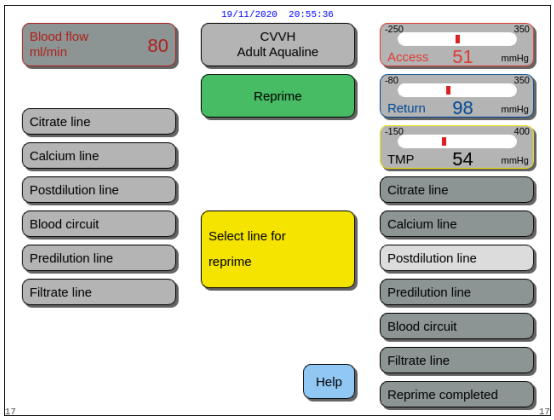


Fig. 106

- ▶ The *Reprime* mode screen is displayed.
- ▶ All selectable lines/circuit are displayed on the right side of the screen: Post-dilution line, Blood circuit, Pre-dilution line and Filtrate line. When the blood line is reprimed, the filtrate line is reprimed. When the filtrate line is reprimed, the blood line is not reprimed.

Step 2: Select the line(s) requiring reprime and confirm to start.

- ▶ The circuit or the tubing set currently being primed is highlighted on the left side of the screen.

Step 3: Stop *Reprime* mode manually by selecting and confirming *Reprime completed*.
OR
Wait until *Reprime* mode stops automatically after the following volumes are pumped:

- Blood circuit + filtration pump: 800 ml
- Post-dilution pump: 160 ml
- Pre-dilution/Dialysate pump: 20 ml for SCUF, CVVH, TPE, HP
  500 ml for CVVHD, CVVHDF
- Citrate pump: 15 ml
- Calcium pump: 15 ml

NOTE If a complete system reprime is required, a minimum of 1 l of saline solution and a new priming collecting bag must be attached before the reprime procedure is started.

To prevent overfilling or rupturing of the priming collection bag, please ensure that the capacity of the priming collection bag is sufficient to allow a safe reprime or replace the priming collection bag with a new one.

NOTE In Hemoperfusion, the filtration pump is always disabled during repriming.

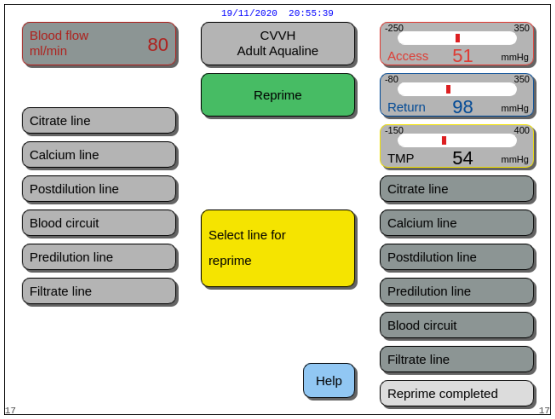


Fig. 107

Step 4: Select and confirm *Reprime completed* to return to *Priming completed* mode.

⇨ If necessary, select *Help* function for further on-screen information.

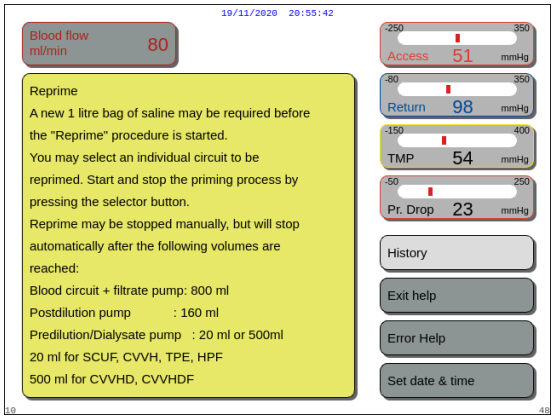


Fig. 108

▶ A window with short instructions appears.

5.4 Clamp and pressure test

The *Blood pump* key and the *Mute* key are active during the *Clamp and pressure test*.
The *Clamp* key and the *Treatment* key are inactive during the *Clamp and pressure test*.

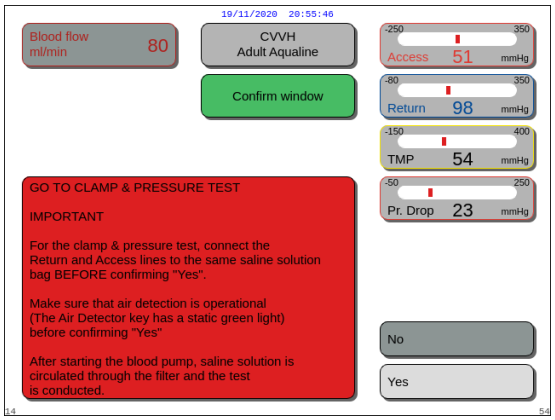


Fig. 109

Step 1:

1. If the priming procedure is satisfactory, select and confirm *Next*.
   ▶ A *Confirm* window appears.
2. Follow the on-screen instructions.
3. Select and confirm *Yes* to move to the *Clamp and pressure test*.
   OR
   Confirm *No* to return to the previous step.

Before proceeding, ensure return and access lines have been connected to the same saline bag.

Using Aqualine S or Aqualine S RCA verify before proceeding:

- Substitution/dialysate line is retained with the tube holder on the upper right side of the automatic degassing unit (ADU).
- Filtration/dialysate line is retained with the tube holder on the lower left side of Aquarius front panel.
- If the patient is on the left side of Aquarius, insert the blood lines into the tube holder first, then the filtrate/effluent line. Use the tube holder on the lower left side of Aquarius front panel.

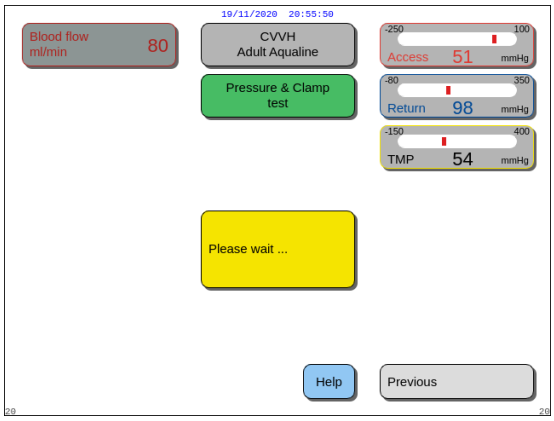


Fig. 110

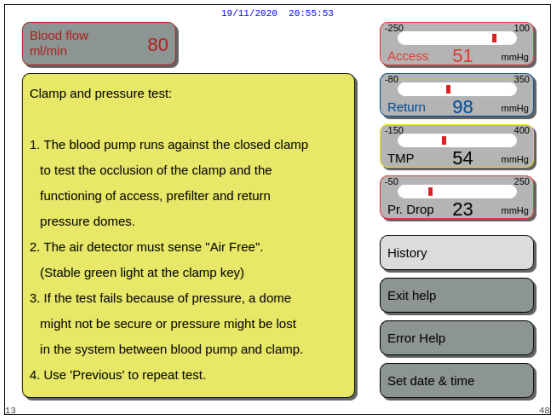


Fig. 111

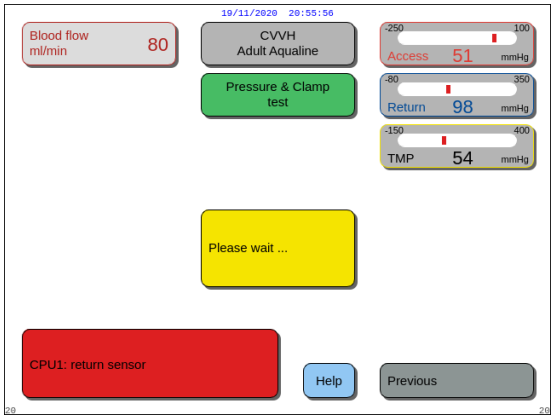


Fig. 112

Step 2:

1. Ensure that the extracorporeal circuit is free from air.
   ▶ A yellow message *Insert tube to air detector* is displayed at the end of priming if air is detected or if the tube is not correctly inserted into the air detection system.
2. Perform the *Clamp and pressure test* before the Aquarius system proceeds to the *Start Connection* mode.
   ▶ An air free circuit is indicated by a steady green light in the *Clamp* key.

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

▶ If the *Clamp and pressure test* is successfully completed, the air detector and the blood leak detector are active.

▶ If the *Clamp and pressure test* failed, a red window with the description of the reason appears (Fig. *112*).

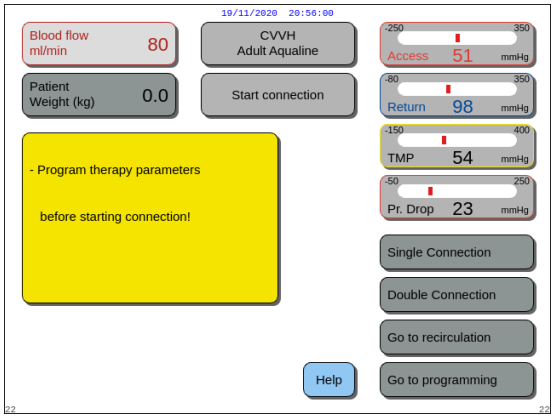


Fig. 113

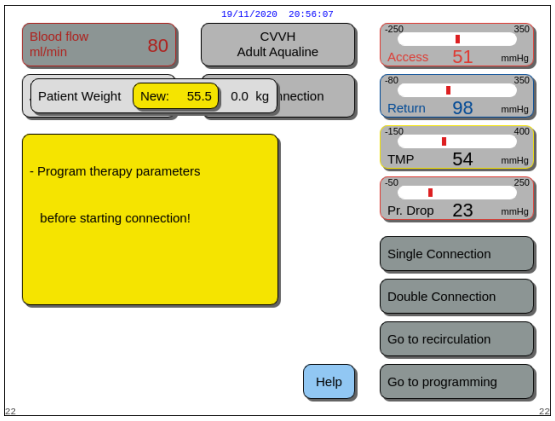


Fig. 114

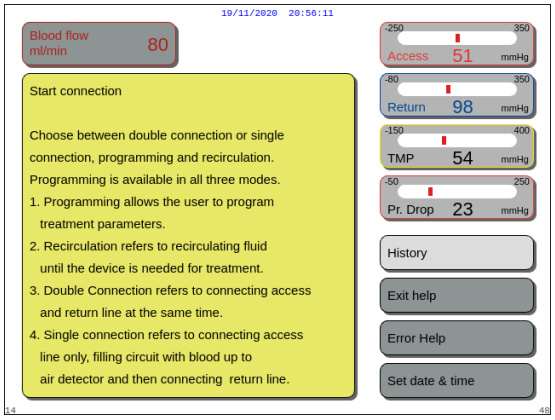


Fig. 115

Step 3:

Condition: the *Clamp and pressure test* was completed successfully.

1. Use the *Main selector button* to select and confirm one of the following functions: *Go to programming, Go to recirculation, Single connection or Double connection*.
   These functions are listed in the lower right side of the screen.
2. If citrate is used as anticoagulant, program prescribed treatment parameters for the chosen RCA therapy and anticoagulant fluids.
3. Select the *Patient Weight* window to enter the patient body weight. This data will be taken into account in the Renal dose calculation for CVVH, CVVHD, and CVVHDF therapy modes.

If patient body weight is not entered at this time, the Renal dose calculation will not be displayed on the screen during the treatment.

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

At the end of priming, always check that the lines have been correctly primed and that the filter has been correctly rinsed. Check that the waste volume is more than 500 ml.

5.5 Recirculation mode – Recirculating saline solution

Recirculation can be used after priming OR during a treatment when a patient needs to be disconnected temporarily (e.g. CAT scan).

During *Recirculation* mode, the *Blood pump* key, the *Mute* key and the *Clamp* key are active. During *Recirculation* mode only the blood flow can be modified.

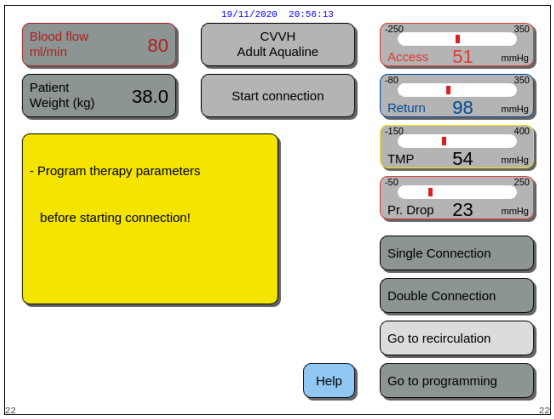


Fig. 116

Step 1:

1. To start recirculation after priming, select and confirm *Go to recirculation*.
   OR

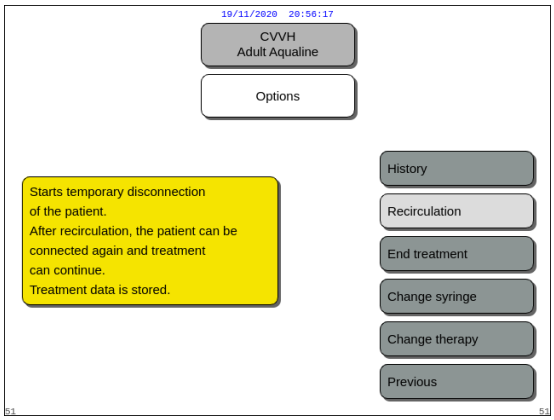


Fig. 117

To use recirculation during a therapy, select and confirm *Recirculation* from the *Options* screen.

Recirculation cannot be selected if Aqualine S or Aqualine S RCA is in use.

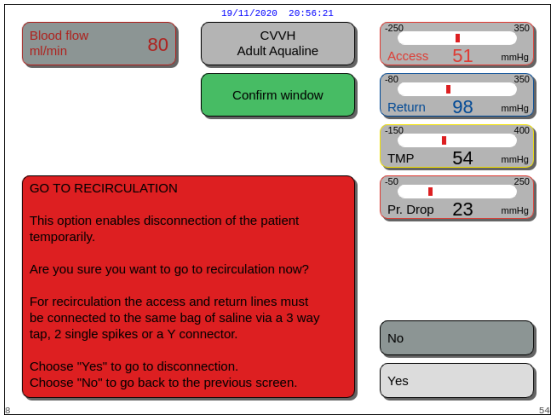


Fig. 118

▶ A *Confirm* window appears.

2. Follow the on-screen instructions.
3. Select and confirm *Yes* to move into *Recirculation* mode.
   OR
   Confirm *No* to return to the previous step.
4. Press the *Blood pump* key to begin recirculation.
   ▶ While the system is recirculating the saline solution, the patient parameters may be entered. The blood pump runs at the programmed speed until turned off by the operator, or until a blood circuit alarm condition is detected or until *Connect patient* is selected.

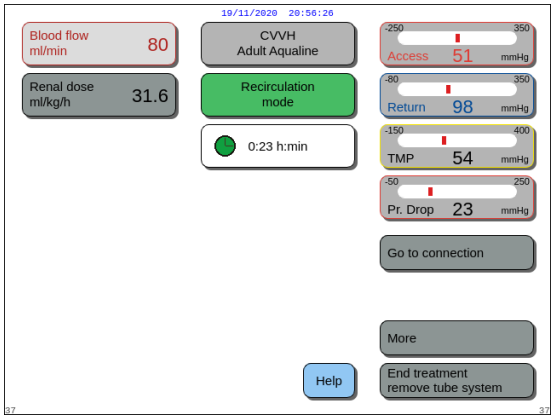


Fig. 119

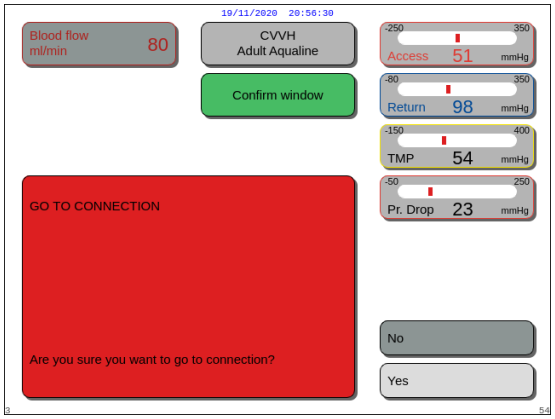


Fig. 120

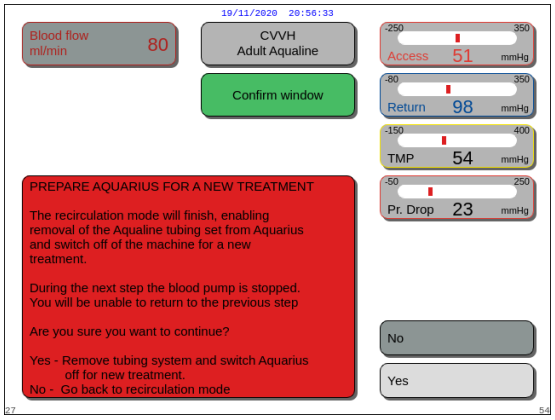


Fig. 121

▶ The recirculation time is displayed on the main screen.

▶ During recirculation only the blood pump circuit is active, i.e. the balance system will not operate.

5. Use the *Main selector button* to select and confirm one of the following functions: *Go to connection*, *More* or *End treatment remove tube system* if needed.
   These functions are listed in the lower right side of the screen.

Step 2:

To proceed with the *Connection* mode:

1. Select and confirm *Go to connection* (Fig. *119*).
   ▶ A *Confirm* window appears.
2. Select and confirm *Yes* to move into *Connection* mode.
   OR
   Confirm *No* to return to the previous step.
3. Use *Help* function for further on-screen information.

To end the treatment:

1. Select and confirm *End treatment remove tube system* (Fig. *119*).
   ▶ A *Confirm* window appears.
2. Follow the on-screen instructions.
3. Select and confirm *Yes* to move into *End treatment* mode.
   OR
   Confirm *No* to return to the previous step.
4. Use *Help* function for further on-screen information.

5.6 Programming – Entering patient parameters

The programming function can be accessed after *Priming* mode when *Clamp and pressure* test is completed during *Start connection* and during *Treatment* mode. Verify prescribed therapy, all replacement/dialysate fluid and anticoagulant solutions are correct for the patient prescription. Programming allows the operator to change program parameters.

In case of Aquarius Regular devices and for therapy modes without RCA, blood, citrate and calcium flow rates are not indicated.

To set the values:

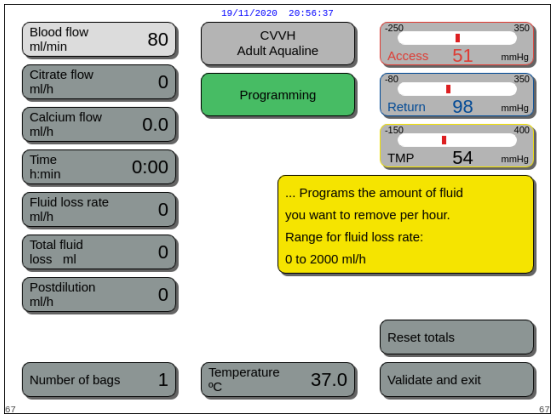


Fig. 122

Step 1:

1. Select and confirm *Go to programming* to commence programming.
   ▶ The active parameter available for input is highlighted.
2. Scroll to the parameter to program.
3. Press the *Main selector button* to confirm.
   ▶ A short definition of the parameter appears in a yellow box to the right of the screen.

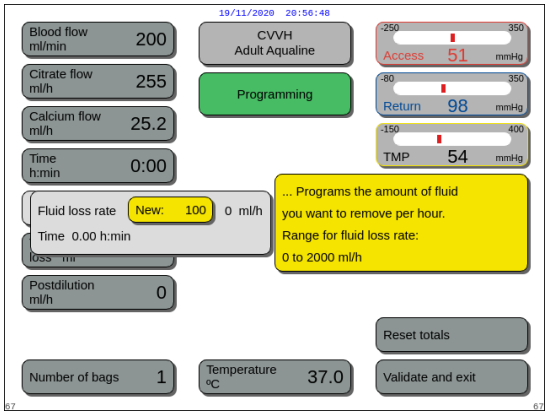


Fig. 123

4. Press the *Main selector button* to open the input window.
   ▶ The current set value is displayed on the right.
   ▶ A small input window with the word *New* appears inside the parameter selected.
5. Turn the *Main selector button* to the left or to the right to adjust the new set value.

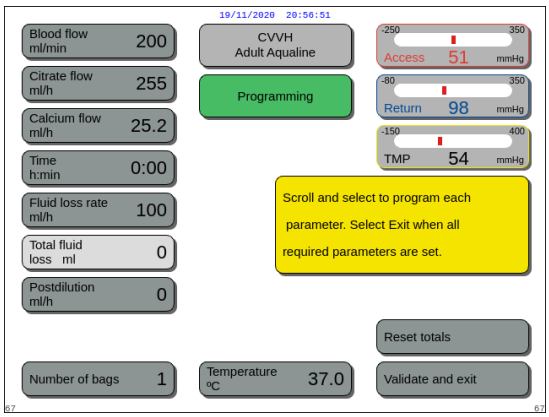


Fig. 124

6. Press the *Main selector button* to confirm the input value.
   ▶ The new value is displayed.
   ▶ The next parameter is highlighted.
7. Change the desired parameters as described in the Step 1 points 2-6.

Step 2: Select *Validate and exit* to return to the *Start connection* screen or *Treatment* screen.

▶ All parameters are confirmed and saved for further treatment.

To program the patient parameters:

Step 1: In the *Start connection* mode program the initial patient parameters in the **same order** as they are shown on the screen. The settings for blood flow rate and citrate flow rate become active after *Validate and Exit* from the *Programming* screen. Please keep the order of parameter setting.

1. Program blood flow rate. Set the blood flow rate goal for the treatment (Aquarius^{+} only).
2. Program citrate flow rate. Set the citrate flow rate goal (Aquarius^{+} only).

Citrate link – automatic connection of the citrate flow rate to the blood flow rate.

Citrate link is ON: the citrate flow rate is linked to the above set blood flow rate. If the blood flow rate is modified during the treatment, the citrate flow rate is automatically adjusted to the blood flow rate in the same ratio. Adjustment of the citrate flow rate may be used to store a new blood/citrate ratio.

Example 1: Citrate adjustment

Initial:	Blood flow rate is 200 ml/min;
	Citrate flow rate is 300 ml/h;
	Calculated blood/citrate ratio is stored 1:40;
Modified:	Blood flow rate is reduced to 150 ml/min during treatment.
	Citrate flow rate is automatically reduced to 225 ml/h to keep the ratio of 1:40

Example 2: New citrate ratio

Initial:	Blood flow rate is 200 ml/min;
	Citrate flow rate is 300 ml/h
Modified:	Citrate flow rate is set to 320 ml/h.
	New blood/citrate ratio is stored.
	Blood/citrate ratio is stored 1:37.5

Citrate link is OFF: the citrate flow rate has to be adjusted manually with each blood flow rate modification.

3. Program calcium flow rate. Set the calcium flow rate goal (Aquarius^{+} only).
4. Program time. Set the time goal for the treatment.
   The time goal does not need to be set when both the fluid loss rate and the total fluid loss are prescribed.
   The time goal setting can be used as a treatment record timer.
   The treatment will be temporarily terminated if the time goal is reached before the fluid loss goal.
5. Program fluid loss rate. Set the fluid loss rate of the prescribed net fluid loss rate that has to be removed from the patient.
6. Program total fluid loss. Set the total fluid volume that is prescribed to be removed from the patient.
   The treatment will be temporarily terminated if the total fluid loss is achieved.
7. Program substitution/dialysate flow rate. Set the substitution/dialysate flow rate goal for the treatment.

Calcium link – automatic connection of the calcium flow rate to the dialysate flow rate in the CVVHD mode and to the filtration flow rate in the CVVH mode.

Calcium link is ON in the CVVHD mode: automatic connection of the calcium flow rate to the dialysate flow rate.

Calcium link is ON in the CVVH mode: modification to the programmed fluid loss rate, the substitution flow rate and the citrate flow rate will automatically adapt the calcium flow rate.

If the calcium link is ON the link is active after 10 minutes of therapy.

Calcium link is OFF: the calcium flow rate has to be manually adapted to the dialysate flow rate.

8. Program the number of bags. Set the number of bags that are used on the substitution scale and respectively on the filtration scale. On both scales the same number of bags should be used, but never less bags on the filtration scale than on the substitution scale.
   The number of bags sets the trigger for bag change message.
9. Program heparin flow rate. Set the heparin flow rate goal for the treatment.
   The function is only available if *Citrate and heparin anticoagulation* is selected.
10. Program heparin bolus. This parameter activates a single heparin bolus with the selected volume.
    The function is only available if *Citrate and heparin anticoagulation* is selected.
11. Program the temperature. Set the substitution/dialysate fluid temperature goal.

Step 2: Adjust only the blood flow rate in the *Connection* mode.

NOTE The citrate pump is automatically adjusted to the ratio stored from the programming already made during *Start connection* mode.

Step 3: Modify the patient parameters during *Regulated start* mode or *Treatment* mode, if necessary:

1. Select the *Programming* screen.
2. Modify the parameter and select *Validate & Exit* to confirm the modification.

To reset the achieved parameters:

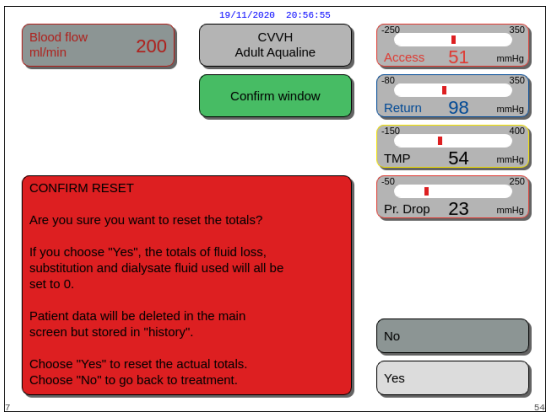


Fig. 125

Step 1:

1. Use the *Main selector button* to select and confirm the *Reset totals* function.
   ▶ A *Confirm* window appears.
2. Confirm the window.
   ▶ The following parameters in the *Treatment* and *More* screens are set to zero:
   - fluid loss total,
   - substitution fluid total,
   - treatment clocks,
   - pre- and post-dilution,
   - blood volumes pumped since last reset or commencement of therapy,
   - citrate and calcium fluid total (Aquarius^{+} only).
3. Set and store a new value.

Step 2: Select *Validate and exit* to confirm and activate the new flow rates, to return to the *Start connection* screen, *Recirculation* mode or *Treatment* screen.

NOTE Parameters displayed on the *Programming* screen depend on the substitution/dialysate fluid choice. Verify programmed parameters, therapy selection, actual anticoagulant and fluid bags in use are correct for the patient prescription.

When citrate anticoagulation is used, selecting the *Blood flow* key in the main screen automatically opens the *Programming* screen. When the blood flow rate is modified, check that all other flow rate parameters are still appropriate, especially the citrate flow rate.

5.6.1 Caution for anticoagulant flow rates programmed to 0 ml/h

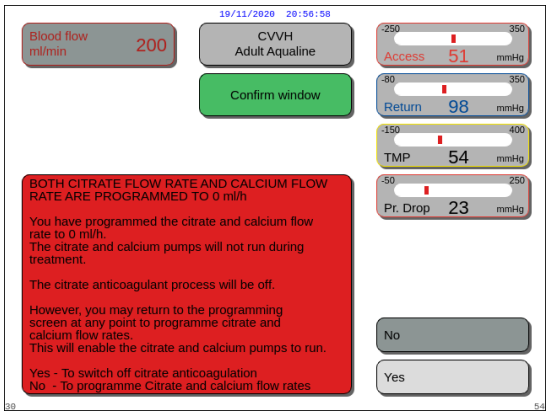


Fig. 126

- If one of the anticoagulant flow rates (Citrate, Calcium or Heparin) has been set to 0 ml/h:

1. Select and confirm *Exit* key.
   ▶ A *Confirm* window opens to validate this choice.
2. Select and confirm *Yes* to validate.
   OR
   Confirm *No* to return to the *Programming* screen.

- If both citrate and calcium flow rates are set to 0 ml/h, the citrate anticoagulant process is off. This is notified by the display of a message on the screen. *Heparin* or *No anticoagulant* appears on the main screen.
- If the heparin flow rate is set to 0 ml/h, the Heparin anticoagulant process is off. *Citrate* or *No anticoagulant* appears on the main screen.
- If both anticoagulant processes are off, *No anticoagulant* appears on the main screen.
- If both citrate and heparin anticoagulant processes are running, *Citrate + Heparin* appears on the main screen.

5.7 Start connection – Connecting the patient

The use of the Aquarius system is limited to patients weighing a minimum of 20 kg. In addition, the extracorporeal blood volume, including tubing set, filter and maximal fluid deviation (in ml), should not exceed 10% of the patient's blood volume.

For this reason, in some cases the minimum weight limit for the patient can be above 20 kg. The minimum patient body weight should be calculated for each tubing set and filter chosen, as follows:

Extracorporeal blood volume (ml) = Tubing priming volume (ml) + Filter priming volume (ml) + Maximal fluid deviation (ml)

Patient minimum blood volume (ml) = $10^{(*)}$ × Extracorporeal blood volume (ml)

(*) Being: Extracorporeal blood volume (ml) =10% × Patient minimum blood volume (ml)

$$\text{Patient minimum weight (kg)} = \frac{\text{Patient minimum blood volume (ml)}}{\text{Blood volume per kilogram (ml/kg)}}$$

To avoid hemorrhagic shock clinicians may indicate to prime the blood line of the tubing set Aqualine S and the filter with donated blood.

Example 1:
Aqualine RCA tubing priming volume = 96 ml (This value assumes that the drip chamber is full)
Filter priming volume = 54 ml (in this example the Aquamax filter HF07 is used)
Maximal fluid deviation without alarm = 50 ml
Blood volume per kilogram chosen for this example = 80 ml/kg
Extracorporeal blood volume = (96 ml + 54 ml + 50 ml) = 200 ml
Patient minimum blood volume = 10 × 200 ml = 2000 ml
Patient minimum weight = (2000 ml) / (80 ml/kg) = 25 kg
In this example the minimum patient body weight that should be used with the Aquarius system must be 25 kg.

Example 2:
Aqualine S RCA tubing priming volume = 65 ml (This value assumes that the drip chamber is full)
Filter priming volume = 54 ml (in this example the Aquamax filter HF07 is used)
Maximal fluid deviation without alarm = 20 ml
Blood volume per kilogram chosen for this example = 80 ml/kg
Extracorporeal blood volume = (65 ml + 54 ml + 20 ml) =139 ml
Patient minimum blood volume = 10 × 139 ml = 1390 ml
Patient minimum weight = (1390 ml) / (80 ml/kg) ~ 20 kg
In this example the minimum patient body weight that should be used with the Aquarius system must be 20 kg.

Using Aqualine S or Aqualine S RCA would allow a patient minimum blood volume of 1650 ml: or about 20 kg patient weight.

Be sure the patient blood access and connections are secured properly. Keep access connections uncovered and visible to allow immediate identification of any leakage. Careful monitoring of the patient for any evidence of extracorporeal blood loss is required to prevent serious injury or death.

Air entering the extracorporeal blood circuit can cause a fatal air embolism.

If the air detected alarm cannot be cleared, discontinue treatment and do not return the extracorporeal blood to the patient.

Be sure the patient blood access and connections are secured properly. As defined by the Association for the Advancement of Medical Instrumentation (AAMI), the return Pressure Monitor provides for the detection of bloodline separations. The return Pressure Monitor will trigger an alarm when the pressure decrease is greater than the limit. However, if the needle or cannula becomes dislodged from the return access and remains attached to the bloodline tubing, at typical blood access pressures and usual blood flow rates, the decrease in pressure from the dislodgment will not be sufficient to trigger an alarm condition. This is due to the resistance in the return needle or cannula which will maintain pressures above the recommended set limits of -75 to +25 mmHg.

Pressure monitoring technology should not be relied upon as the sole method for detecting a breach in the system. The healthcare professional attending the patient must be vigilant in securing the blood access needle or cannula. Careful monitoring of the patient for any evidence of extracorporeal blood loss is required to prevent serious injury or death.

Connecting or disconnecting the patient to or from the Aquarius system requires aseptic technique and continuous monitoring of all connections to prevent air from entering the system (air infusion) or blood from escaping from the system (blood loss). All system connections must be visually observed for security of connection at regular intervals. All blood and fluid paths are sterile and non-pyrogenic.

Before connecting the patient and at regular intervals, ensure that the blood lines are not kinked. Kinked blood tubing may cause hemolysis (patient injury). It may be that kinked lines are not detected by the protective system.

Make sure that the patient's needle has no direct contact to the vessel. When the patient's needle has direct contact to the vessel, failure in access pressure measurement can occur.

When citrate anticoagulation is in process, the citrate pump will start running with the blood pump during *Connection* mode.

If *Regulated start* is configured, all pumps increase their flow rates concurrently until the programmed target rate is achieved.

When the *Treatment* key is pressed after *Connection* mode, the blood pump does not stop unless a related alarm is detected.

During the *Start connection* mode you can select *Go to recirculation* and *Go to programming*.

During *Single connection* mode, the operator is asked to connect the access segment of the tubing set to the access limb (red) of the patient's catheter. After selecting the *Blood pump* key the access and return segments of the tubing set are filled with blood, up to the air detector. The blood pump automatically stops when the air detector detects blood.

During *Double connection* mode, the operator is asked to connect the access and return segments of the tubing set to the access (red) and return (blue) limbs of the patient's catheter at the same time. After selecting the *Blood pump* key, the access and return segments of the tubing set are filled with blood, up to the air detector. The blood pump automatically stops when the air detector detects blood. Treatment can then commence after confirming safe and secure connection of the Aqualine tubing set to the patient catheter.

After the *Connection* mode is started, only blood flow can be accessed. The patient parameters set during *Programming* mode are kept for the treatment as well as the blood flow rate. The blood flow rate programmed during *Connection* mode is only used temporarily.

5.7.1 Single connection

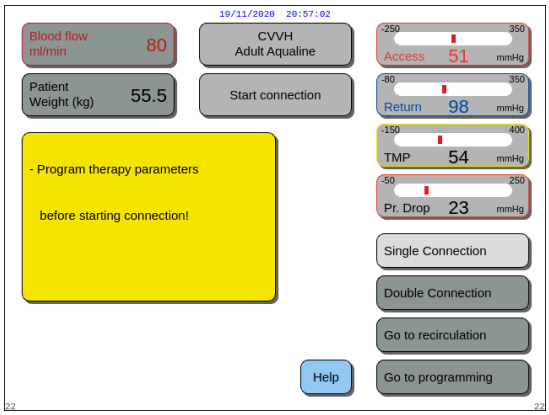


Fig. 127

Step 1:

1. Select and confirm *Single connection*.

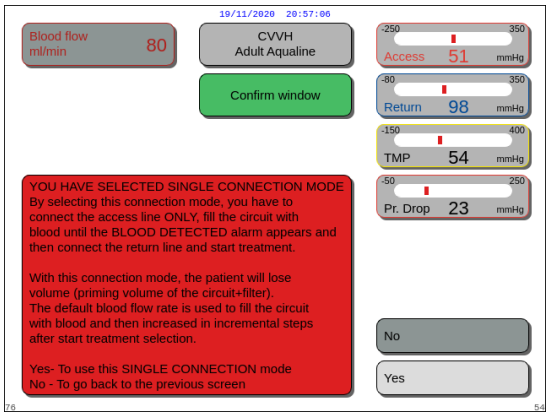


Fig. 128

▶ A *Confirm* window appears.

2. Follow the on-screen instructions.
3. Select and confirm *Yes*.

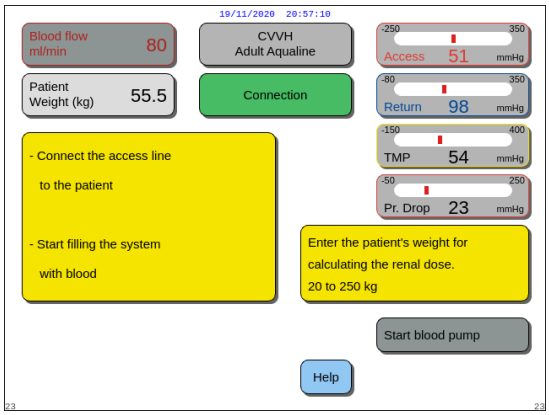


Fig. 129

▶ The screen *Connection* appears.

4. Follow the on-screen instructions to proceed with patient connection:
   - enter the patient's weight,
   - connect the access line to the patient (if necessary, use *Help* function for further information),
   - start filling the system with blood.
5. Select and confirm *Start blood pump* function or press the *Blood pump* key  .

▶ The extracorporeal circuit is now being filled with blood.

The blood pump stops and an audible signal is generated when the air detector detects blood.

NOTE

During calibration of the machine you can choose:

- a default blood flow rate between 50 and 80 ml/min for regular treatment;
- a default blood flow rate between10 and 50 ml/min for low volume treatment.

It is used to fill the circuit with blood. The blood flow rate can be increased in incremental steps after *Start treatment* selection.

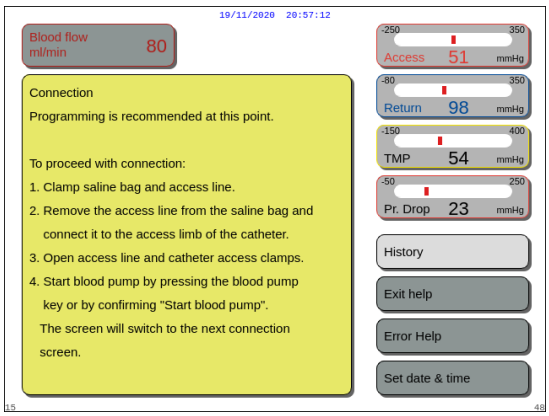


Fig. 130

⇨ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

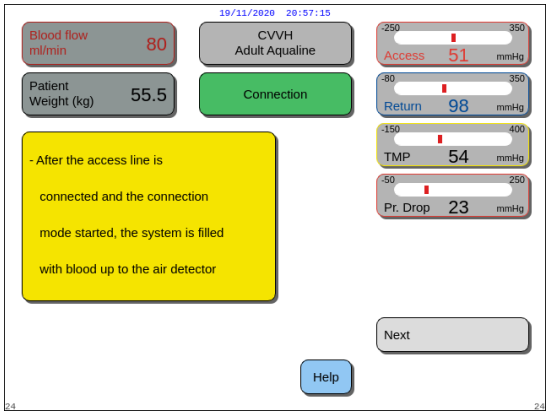


Fig. 131

6. Select and confirm *Next* to start the treatment.

⇨ If necessary, select *Help* function for further on-screen information.

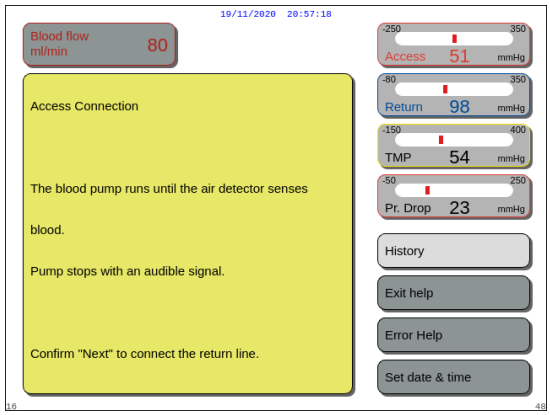


Fig. 132

▶ A window with short instructions appears.

Enter patient parameters before starting treatment!

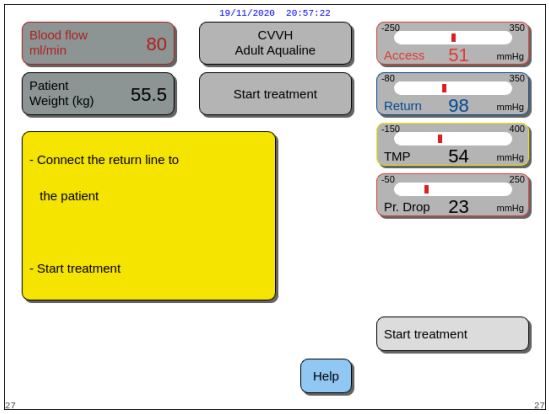


Fig. 133

Step 2: Select and confirm *Start treatment* to proceed.

⇨ If necessary, select *Help* function for further on-screen information.

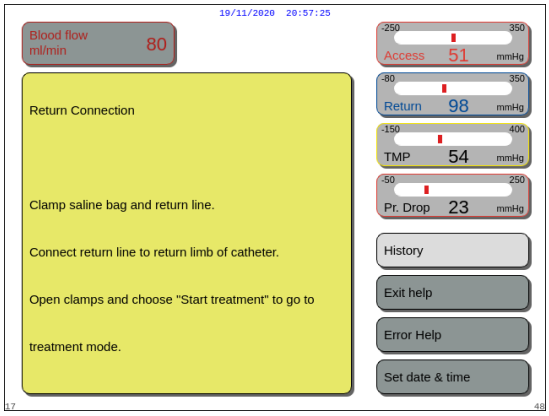


Fig. 134

▶ A window with short instructions appears.

NOTE During *Patient connection* mode the air detector and the blood leak detector are active.

5.7.2 Double connection

For low volume treatments the *Double connection* mode can be disabled in *Service* mode.

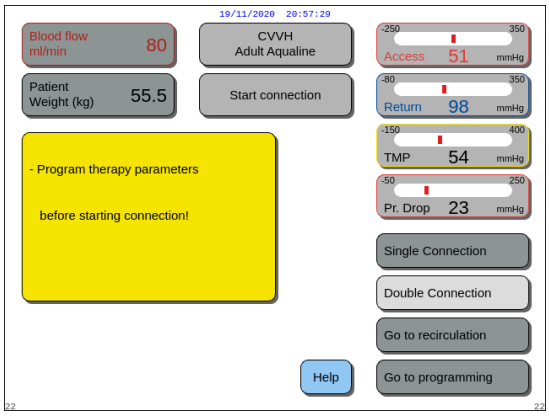


Fig. 135

Step 1:

1. Select and confirm *Double connection*.

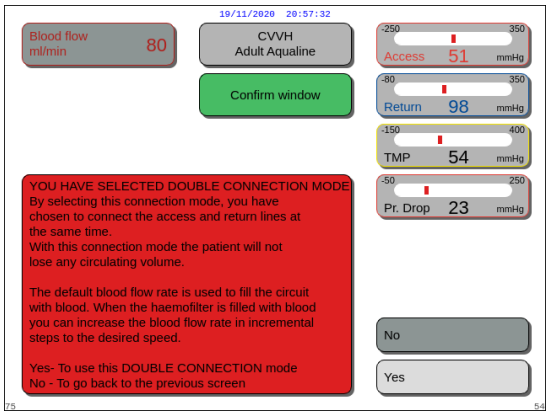


Fig. 136

▶ A *Confirm* window appears.

2. Follow the on-screen instructions.
3. Select and confirm *Yes*.

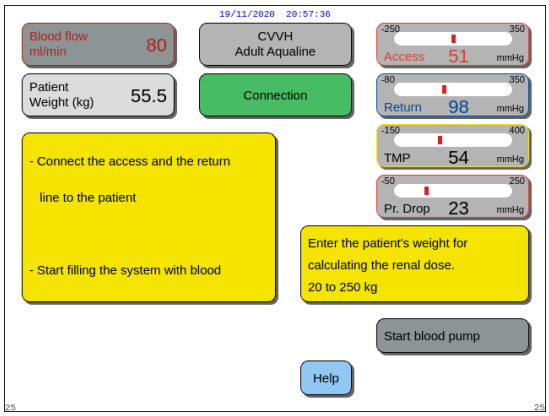


Fig. 137

▶ The screen *Connection* appears.

4. Follow the on-screen instructions to proceed with patient connection:
   - enter the patient's weight,
   - connect the access and the return line to the patient (if necessary, use *Help* function for further information),
   - start filling the system with blood.
5. Select and confirm *Start blood pump* or press *Blood pump* key .

▶ The extracorporeal circuit is now being filled with blood.

▶ The blood pump stops and an audible signal is generated when the air detector detects blood.

NOTE

During calibration of the machine you can choose:

- a default blood flow rate between 50 and 80 ml/min for regular treatment;
- a default blood flow rate between 10 and 50 ml/min for low volume treatment.

It is used to fill the circuit with blood. The blood flow rate can be increased in incremental steps after *Start treatment* selection.

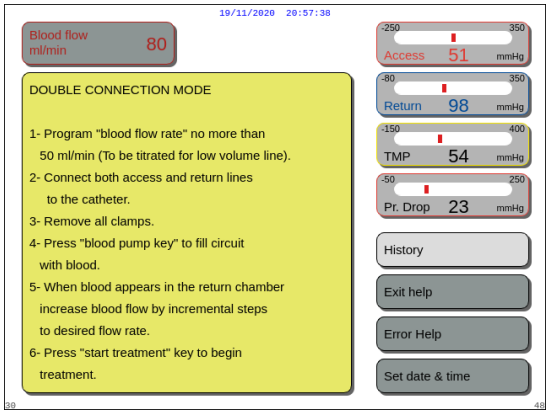


Fig. 138

➪ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

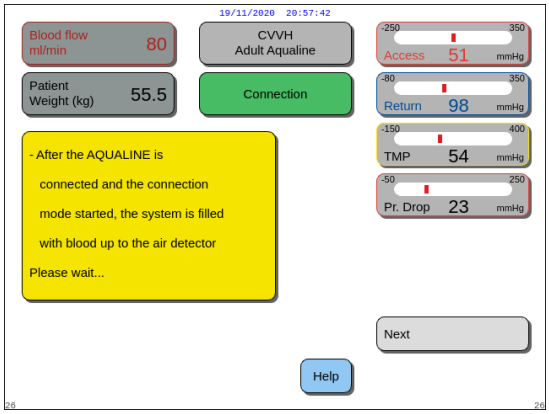


Fig. 139

Step 2: Select and confirm *Next* to start the treatment.

➪ If necessary, select *Help* function for further on-screen information.

▶ A window with short instructions appears.

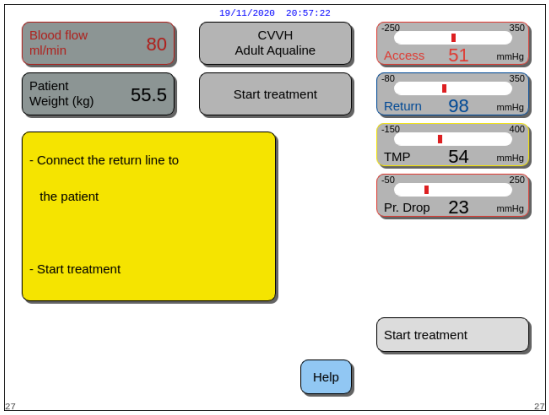


Fig. 140

Step 3: Select and confirm *Start treatment* to proceed.

➪ If necessary, select *Help* function for further on-screen information.

NOTE

During *Patient connection* mode, the air detector and the blood leak detector are active.

5.8 Treatment mode – Description of functions throughout the treatment

Enter patient parameters before starting treatment!
Program the blood flow rate to the prescribed value before starting the treatment.

5.8.1 Regulated start mode – Description (Aquarius+ only)

This occurs only in *Treatment* mode when adult treatment is selected, the therapy selected is not *SCUF* or *Hemoperfusion* and *Citrate* or *Citrate* + *Heparin* anticoagulant is selected. The *Regulated start* mode must be enabled in the *Service* mode.
If *Regulated start* is disabled in *Service* mode, *Treatment* mode is automatically started.

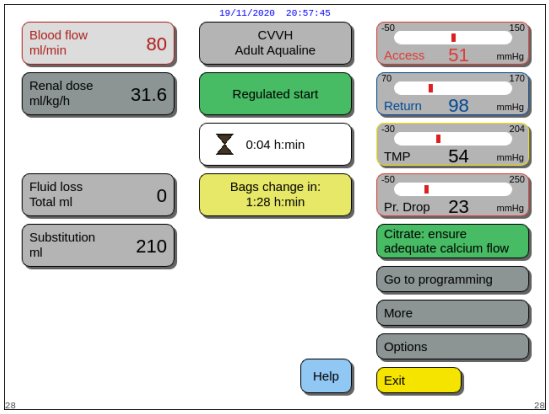


Fig. 141

After return line connection, and blood is detected, the blood pump stops. To enter the *Regulated start* mode, select *Start treatment*. The blood pump starts, the *Treatment* key flashes, and must be pressed to start the balance system.

Help function provides further on-screen information.

When ***Regulated start*** mode runs, balance (post-dilution and filtrate), citrate and calcium pumps will run with an automatic adjusted flow rate adapted to the blood flow rate and their own programming values. The starting value is at the default setting determined during calibration and will increase by 10 ml/min every 30 s up to the programmed blood flow rate. When the programmed blood flow rate is reached, the system switches automatically from *Regulated start* mode to *Treatment* mode.

Example: If the programmed blood flow rate is 200 ml/min, the actual blood flow rate is 80 ml/min and the programmed citrate pump flow rate is 150 ml/h, when *Regulated start* mode begins, the actual citrate pump flow rate will be 150 (ml/h) x 80 ml/min / 200 (ml/min) = 60 ml/h.

NOTE It is recommended to wait until the *Regulated start* mode is completed before going to *Treatment* mode.

NOTE *Exit* key allows the user to go directly to *Treatment* mode.

5.8.2 Treatment mode

The blood pump stops after the *Treatment* key starts flashing and 50 ml (Aqualine RCA) or 25 ml (Aqualine S RCA) of citrate are infused (Aquarius$^+$ only).

Do not perform a citrate bag change before the *Blood pump* key flashes (Aquarius$^+$ only). All other bags can be changed when the *Treatment* key flashes.

When the treatment is stopped and the blood pump is not running, the treatment must be restarted by pressing the *Blood pump* key.

When the treatment is stopped and only the *Treatment* key is flashing, restart the treatment by pressing it.

If the blood pump is off and an alarm is pending, press the *Blood pump* key twice to restart the blood pump.

The *Treatment* screen displays the main patient parameters. The timer shows the remaining treatment time and bags change in box shows the remaining time before bag(s) require changing. All safety controls and functions are active.

During the treatment the operator has three main choices:

- *Go to programming* – enables changes to programmed parameters.
- *More* – provides additional information to that available on the main treatment screen.
- *Options* – activates another screen with 5 further information and function screens: *History, Recirculation, End treatment, Change syringe* or *Change therapy*. If CVVH post -dilution treatment is performed, it is possible to change an anticoagulant instead of changing the therapy. See next sections for more details.

Suspend a treatment

It may be necessary to suspend a treatment, for example, in order to change a bag on the scales. When the Aquarius system detects a full or empty bag it produces a bag change alert. This automatically stops the pre-dilution pump, the post-dilution pump, the filtration pump, and the calcium pump. The blood pump and citrate pump continue to run until 50 ml of citrate solution are infused (20 ml for Aqualine S). The treatment bags may be changed while the blood and citrate pumps continue to run.

Step 1: Press the *Treatment* key to suspend the treatment.

Step 2: Change the relevant bags.

Step 3: Press *Treatment* key to resume the treatment.

In case the Aquarius system detects an empty citrate bag on the scale, a bag change alarm is triggered. This automatically stops all pumps: blood pump, post-dilution pump, filtrate pump, citrate and calcium pump.

Step 1: Change the citrate bag(s).

Step 2: Press the *Blood pump* key to resume the treatment.

Air detected alarm

When air is detected in the return line during *Treatment* mode, the blood pump is automatically stopped, the return clamp closes and an air detected alarm is indicated.

5.8.3 History

In this menu the Aquarius stores data logs and event logs of the last three treatments. This information is also kept after the machine has been switched off.

Data log

The history of the last three treatments is available in this menu.

The data is visible as a list or as graphs. Pressures, programmed parameters, patient data, events (alarms) are stored at 1 min intervals. This list of alarms is recorded and updated when a new alarm occurs. Treatment 1 is the current treatment with Treatment 2 as the previous treatment and so on.

Event log

The inspection of the events (alarms and messages) of the last three treatments is selectable in this menu. The events represented in a list and sorted following their appearance including date and time. These event data are not volatile and kept in case of a power fail and a short brown-out, even if the battery is completely discharged. When the power is returned, all event data can be inspected.

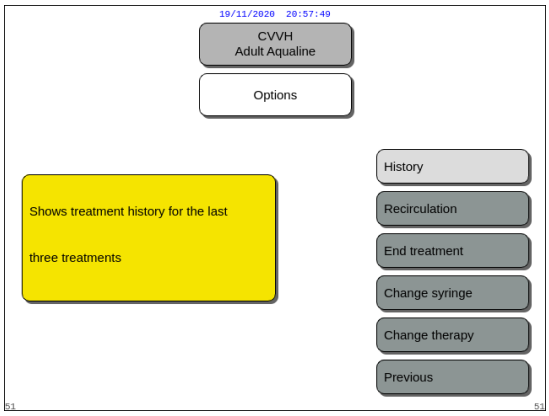


Fig. 142

Step 1: Select and confirm the *History* screen.

▶ The last three (3) treatments are available.

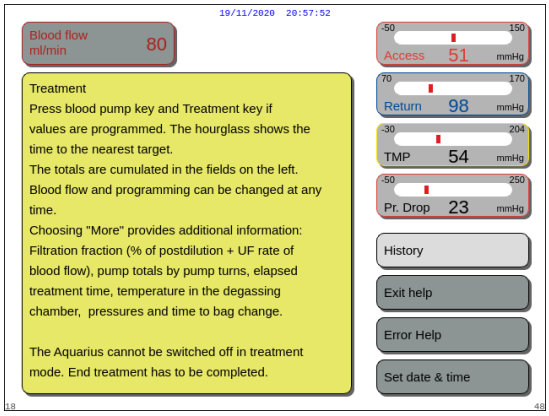


Fig. 143

NOTE

Using the *Help* screen you can access the *History* screens in any running mode.

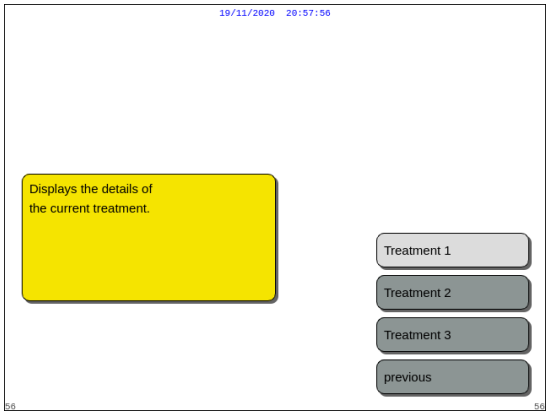


Fig. 144

Step 2: Select and confirm one of the following treatments:

- Treatment 1 (current treatment),
- Treatment 2 (last treatment),
- Treatment 3 (second last treatment),
- Previous

OR

Select and confirm *Previous* key to return to the previous screen.

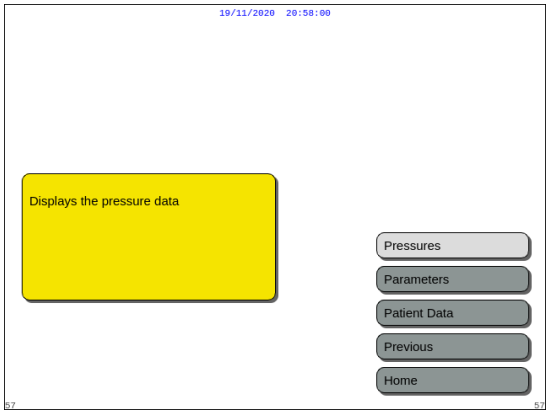


Fig. 145

▶ When one of the treatments is selected, the following functions are displayed:

- Pressures,
- Parameters,
- Patient data,
- Previous (i.e. previous screen),
- Home (i.e. main screen).

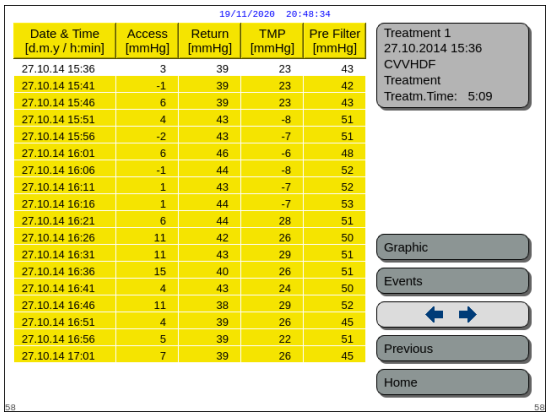


Fig. 146

Example: Treatment 1, Pressure data

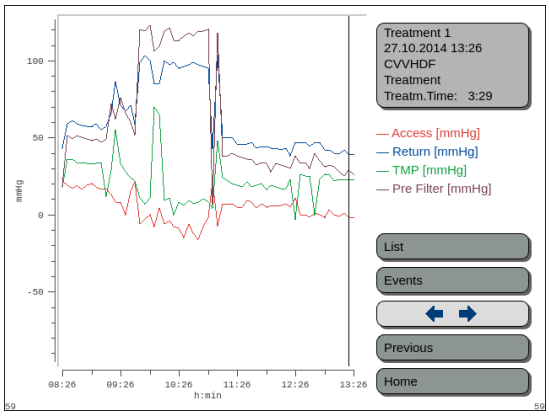


Fig. 147

Example: Treatment 1, Pressure graph

5.8.4 Recirculation

Recirculation mode can be accessed before connecting the patient, just after the *Clamp and pressure test*. In this case there is no disconnection phase before accessing the *Recirculation* mode.

Recirculation mode can be accessed as a temporary disconnection of the patient. The screen menu guides the operator through this disconnection procedure.

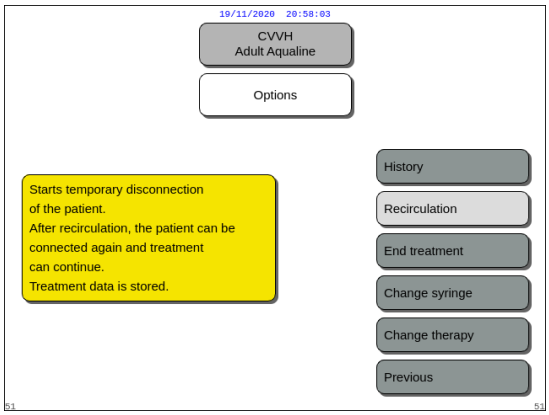


Fig. 148

Step 1:

1. Select and confirm *Recirculation* to access the *Recirculation* mode.

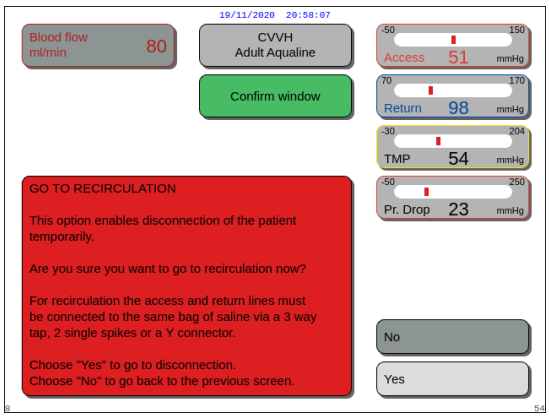


Fig. 149

▶ A *Confirm* window appears.

2. Follow the on-screen instructions.

Step 2:

If a patient is connected, follow the points in Step 2. If there is no patient connected, then go to Step 3.

1. Select and confirm *Yes* to interrupt the treatment temporarily.
   ▶ All data is stored.
   ▶ *Disconnection* mode for recirculation opens.

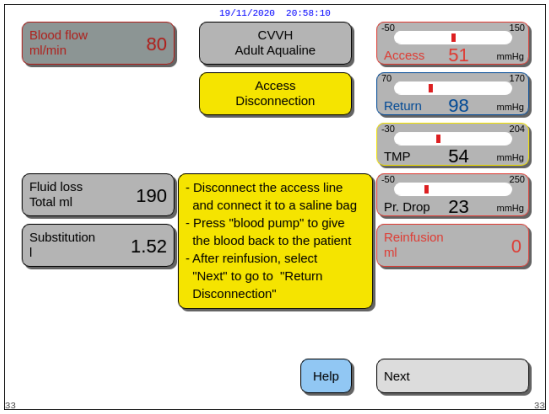


Fig. 150

2. Disconnect the access line. See section *5.9 (Page 5-69)* for more information.
3. If necessary, use *Help* function for further on-screen information.

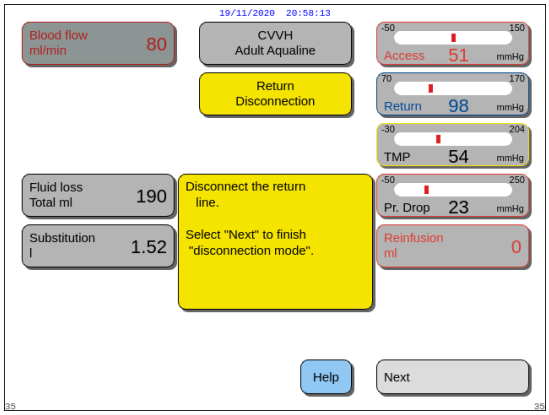


Fig. 151

4. Disconnect the return line. See section *5.9 (Page 5-69)* for more information.
5. If necessary, use *Help* function for further on-screen information.

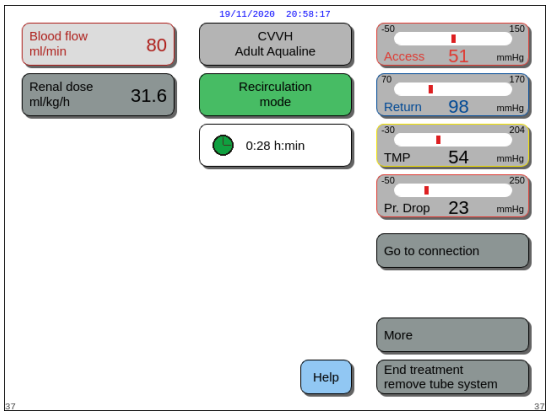


Fig. 152

Step 3:

1. Press *Blood pump* key to start the blood pump.
   ▶ Time in recirculation is displayed on the screen. This is a cumulative total of all recirculation.
2. If necessary, use *Help* function for further on-screen information.

Step 4:

Select and confirm *Go to connection*
OR
End treatment to exit the recirculation.

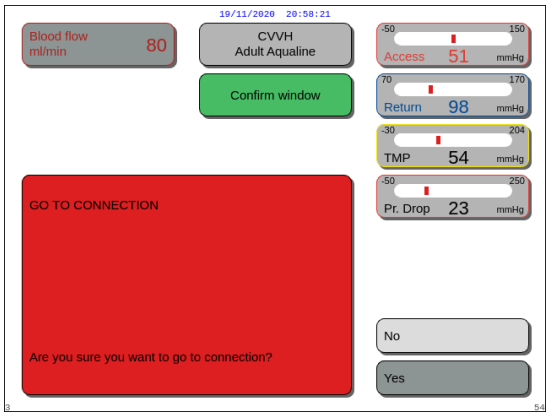


Fig. 153

▶ If *Go to connection* is selected, a *Confirm* window appears.

Step 5:

1. Follow the on-screen instructions.
2. Select and confirm *Yes* to open the *Connection* mode.
3. Follow the on-screen instructions.
4. Connect the patient again. See section *5.7 (Page 5-46)* for more information.
5. Continue the treatment.

Step 6:

Confirm the blood flow or program a new value.

5.8.5 End treatment

This option terminates the treatment immediately.

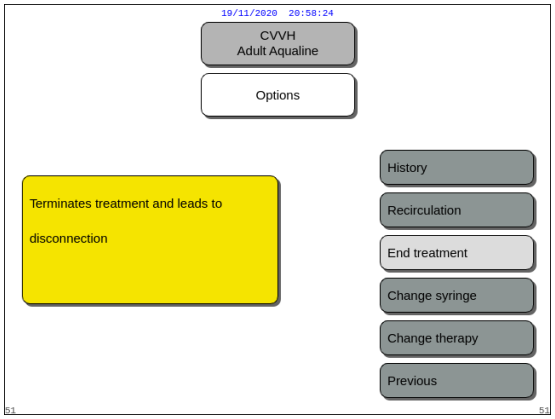


Fig. 154

Step 1: Select and confirm *End treatment* to end the treatment.

▶ A *Confirm* window appears.

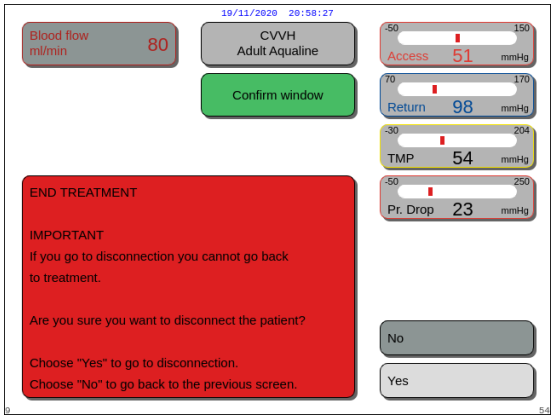


Fig. 155

Step 2: Follow the on-screen instructions.

Step 3: Select and confirm *Yes*.

▶ All pumps stop.
▶ The *Disconnection* mode window opens .
▶ IMPORTANT! No return to treatment is possible.

5.8.6 Change syringe

This option enables the operator to change the syringe or to stop anticoagulation.
If initially *No anticoagulant* was chosen anticoagulation can be started with this option.

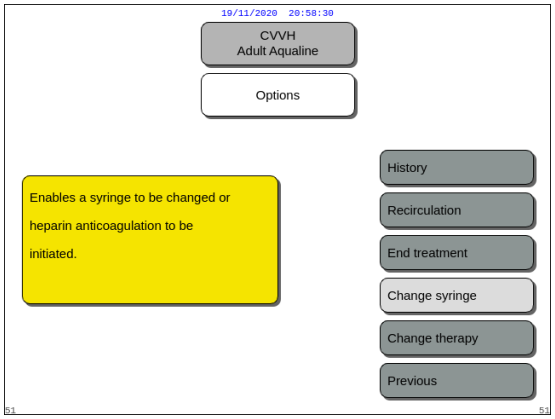


Fig. 156

Step 1:

1. Select and confirm *Change syringe*.

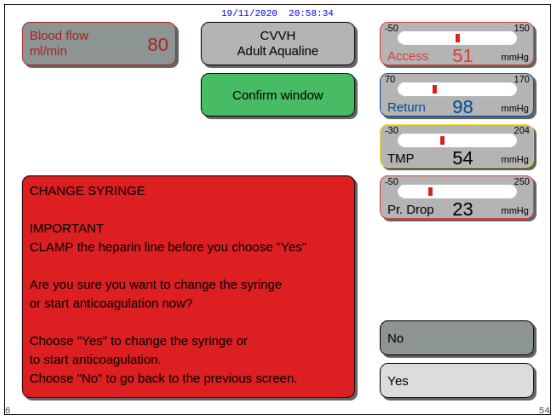


Fig. 157

▶ A *Confirm* window appears.

2. Follow the on-screen instructions.
3. Before proceeding, clamp the heparin line.
4. Select and confirm *Yes* to move to the second *Confirm* window.

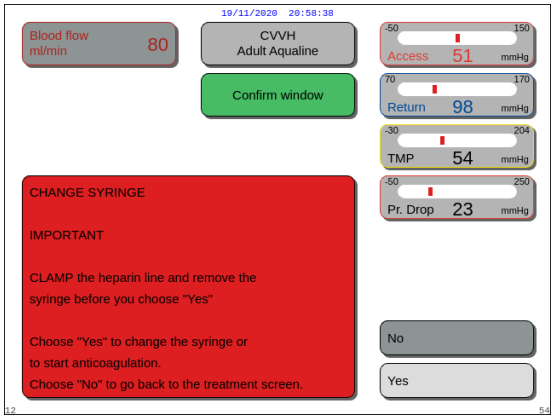


Fig. 158

▶ A Confirm window appears.

▶ Reminder to clamp the heparin line and then to remove the syringe before confirming appears.

OR

Select and confirm No to return to the previous step.

Step 2: Reprogram the heparin rate, as it is reset to zero.

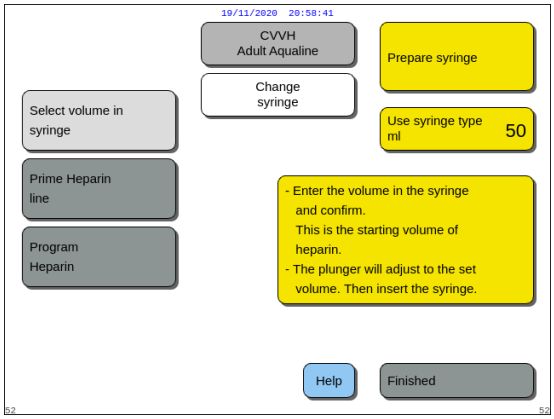


Fig. 159

Step 3:

1. Prepare the syringe as described in section *5.1.7 (Page 5-17)*.
2. Follow the on-screen instructions.

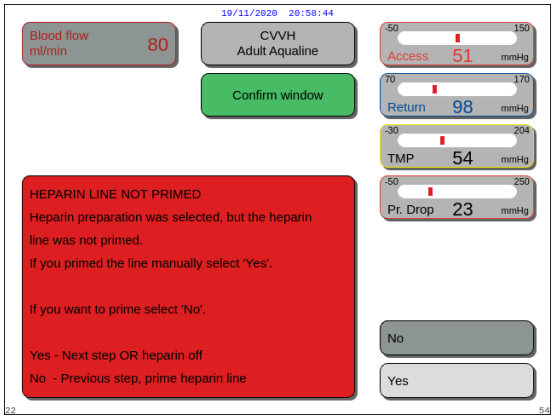


Fig. 160

In case one step is missed in the syringe preparation, a *Confirm* window appears. The content of the window depends on the missing step.

5.8.7 Change therapy

This option enables the operator to switch between SCUF, CVVH, CVVHD and CVVHDF. This option is disabled for treatments with citrate anticoagulation.

For CVVH RCA it is possible to change the anticoagulant to heparin and vice versa (see section *5.11.2.8 (Page 5-90)*).

The anticoagulant change is possible when CVVH treatment is started in RCA mode.

In case of CVVHD and using solutions that are not indicated as infusion solutions, it is strictly recommended not to change therapy to CVVH or CVVHDF.

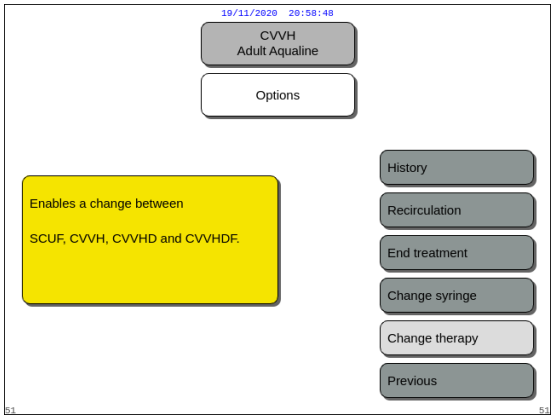


Fig. 161

Step 1:

1. Select and confirm *Change therapy*.

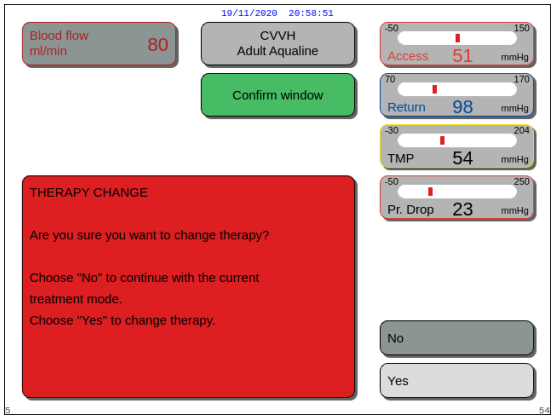


Fig. 162

▶ A *Confirm* window appears when the operator attempts any modality change.

2. Select and confirm *Yes* to go to the therapy list.

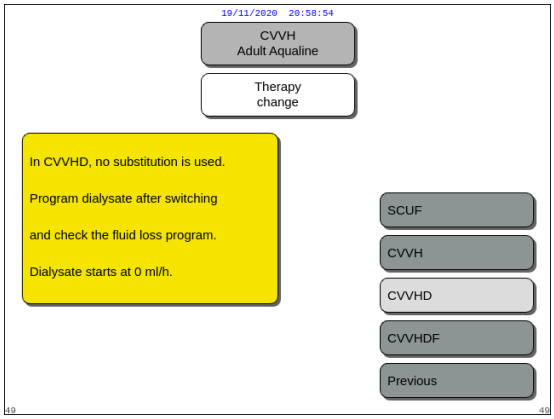


Fig. 163

3. Select and confirm the new therapy.

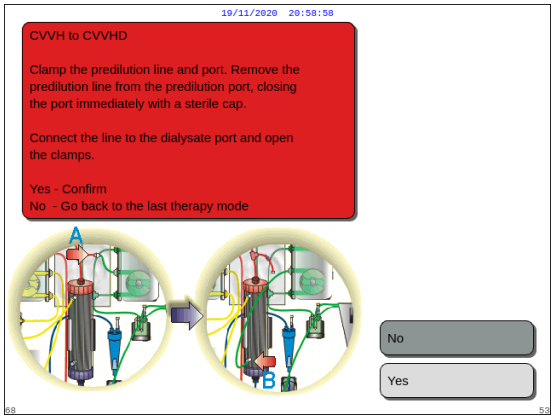


Fig. 164

Step 2:

1. Follow the on-screen instructions to reconnect the pre-dilution/dialysate line to fit the new treatment modality.
2. Select and confirm *Yes* to validate therapy change and new line positioning.

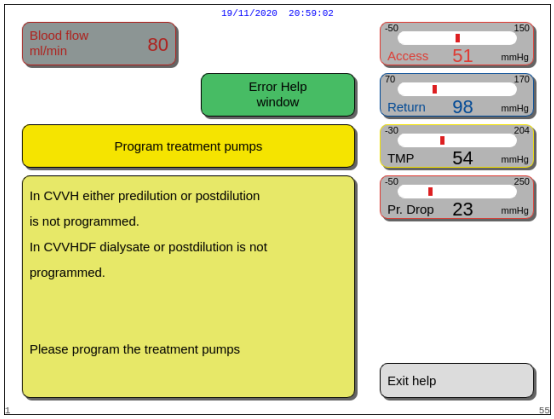


Fig. 165

3. Review the programmed parameters to ensure they meet the requirements of the new therapy. All totals are at 0 when the new treatment mode is started.

If the programming of the parameters is not completed, a message is generated. The message content depends on the missing programming parameter.

Step 3:

Press the *Treatment* key to start a new treatment mode.

5.8.8 More screen

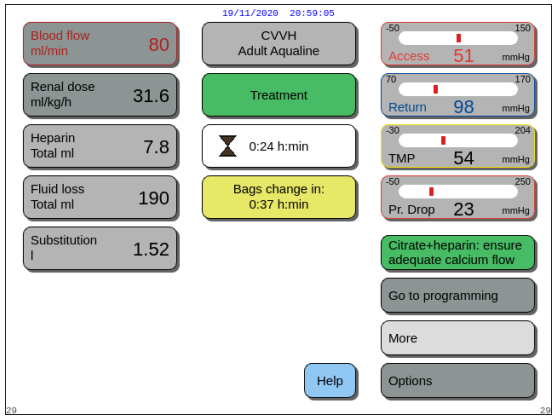


Fig. 166

➪ Select and confirm *More* at the main screen for additional information.

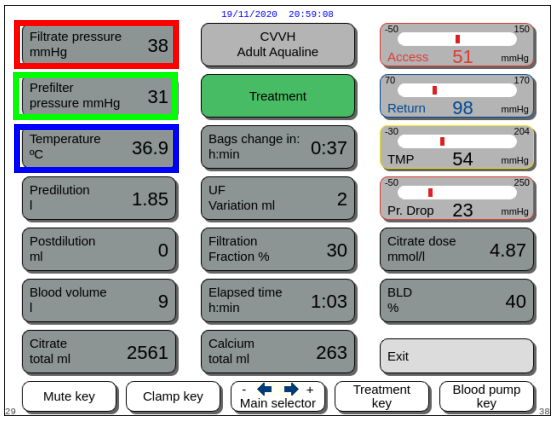


Fig. 167

➪ Select and confirm *More* at the main screen for the following information:

- *Filtrate pressure (mmHg)* (red frame Fig. *167*)
  The actual pressure is displayed.
- *Pre-filter pressure (mmHg)* (green frame Fig. *167*)
  The actual pressure is displayed.
- *Temperature (°C)* (blue frame Fig. *167*)
  The temperature displayed corresponds to the calculated temperature of the fluid inside the degassing chamber.

Do not rely on the temperature displayed as a basis for clinical assessment of hypothermia or hyperthermia. The Aquarius device is not designed to monitor the patient's body temperature. The patient body temperature should be closely monitored to detect potential patient hypothermia or hyperthermia.

The temperature displayed on the *More* screen is **not** the temperature of the fluid infused into the blood and/or dialysate circuit.

The temperature of the fluid infused into the blood and/or dialysate circuit will be lower than the temperature of the fluid inside the degassing chamber due to heat energy loss in the tubing between the degassing chamber and infusion site(s) (refer to section *9.6 (Page 9-9)*).

The temperature displayed on the *More* screen is **not** the patient's body temperature or the temperature of the patient's blood. The accuracy of the calculated temperature displayed on the *More* screen is affected by the ambient temperature.

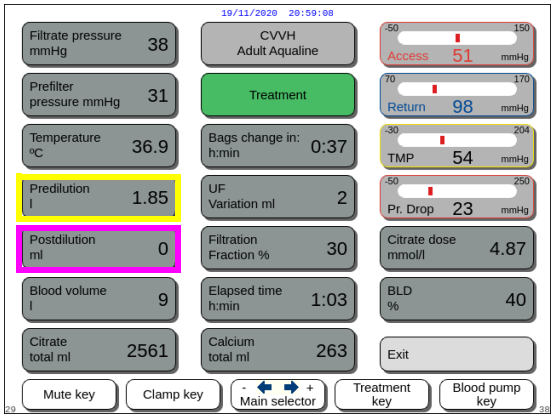


Fig. 168

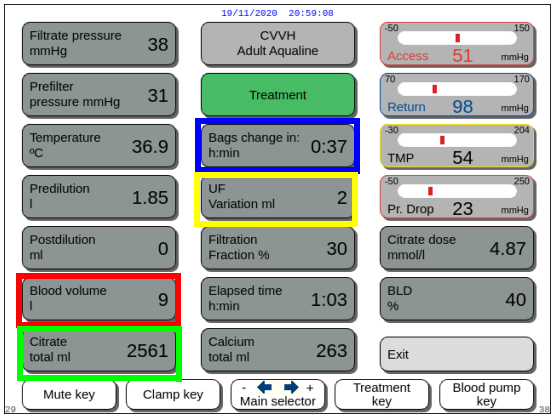


Fig. 169

- *Pre-dilution (ml)* (yellow frame Fig. *168*)
  This shows the amount of fluid that was delivered by the pre-dilution/dialysate pump. This is the value the pump estimates it has delivered, and may differ from the total in the treatment screen that shows the actual value detected by the scales. The scales regulate the pumps to cover any deviation caused by the differences in line sets. It is normal to see intermittent stoppage of the fluid pumps, as the scales regulate the fluid deviations.
- *Post-dilution (ml)* (magenta frame Fig. *168*)
  This shows the amount of fluid that was delivered by the post-dilution pump. This is the value the pump estimates it has delivered, and may differ from the total in the treatment screen that shows the actual value detected by the scales. The scales regulate the pumps to cover any deviation caused by the differences in line sets. It is normal to see intermittent stoppage of the fluid pumps, as the scales regulate the fluid deviations.
- *Blood volume (l)* (red frame Fig. *169*)
  The cumulative amount of blood pumped through the circuit during treatment.
- *Citrate total volume (ml)* (green frame Fig. *169*)
  This shows the amount of citrate solution pumped by the citrate pump controlled by the citrate scale.
- *Bags change in (h:min)* (blue frame Fig. *169*)
  The time remaining until the next bag change. This is calculated by the mass sensed on the scales.
- *UF variation (ml)* (yellow frame Fig. *169*)
  The variation of the actual patient fluid loss versus the expected fluid loss is displayed. A variation >50 g for adult, and >20 g for low volume treatments will cause a balance alarm.

The UF variation is calculated as follows:

UF variation = Expected fluid loss – (Fluid volume OUT – Fluid volume IN)

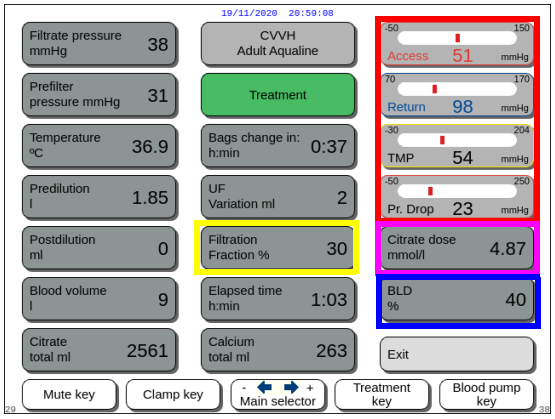


Fig. 170

- *Filtration fraction* (%) (yellow frame Fig. *170*).
  The filtration fraction is affected by the pre-dilution flow rate, post-dilution flow rate, blood flow rate, citrate flow rate, and calcium flow rate.
- *Access*, *Return*, *TMP* and *pressure drop* (red frame Fig. *170*)
  Access and return pressure, and TMP and pressure drop are displayed.
- *Citrate dose* (mmol/l) (magenta frame Fig. *170*).
  This dose is displayed, when in *Service* mode the used citrate solution is programmed. If no citrate solution is programmed, the value displayed is citrate/blood flow ratio in percent.
  Attention: This display is accurate if the relevant citrate solution is programmed.
- *BLD* (%) (blue frame Fig. *170*)
  Over 100% *Blood leak* alarm is activated.

The Filtration fraction (%) is calculated as the sum of all infusion fluids divided by the sum of blood flow plus all pre-dilution fluids. If no RCA treatment is performed, citrate and calcium flow rates are zero. The filtration fraction for CVVH is calculated as:

$$\text{Filtration fraction (\%)} = \frac{\text{Pre-dilution flow rate + Citrate flow rate + Post-dilution flow rate + + Calcium flow rate + Fluid loss rate}}{\text{Pre-dilution flow rate + Citrate flow rate + (Blood flow rate x 60)}}$$

BLD is the measurement of clouding and is calculated as follows:

$$\text{BLD (\%)} = \frac{\text{Optical\_calibration\_value} - \text{Actual\_optical\_value}}{\text{Optical\_calibration\_value} - \text{Optical\_alarm\_limit\_value}}$$

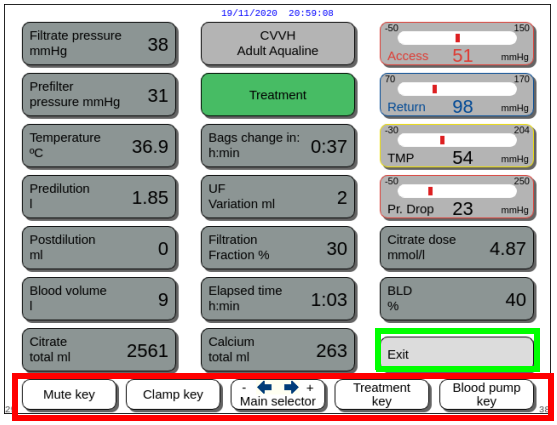


Fig. 171

- *Exit* key (green frame Fig. *171*) to go back to main screen.
- All control buttons (red frame Fig. *171*):
  Mute key, *Clamp* key, *Main selector*, *Treatment* key, *Blood pump* key.

5.8.9 Therapy target achieved

The treatment will proceed until it achieves a programmed target. This may be time or fluid loss. If both targets are set, the time goal is typically the primary target achieved. At this point the *Therapy target achieved by time* (Fig.*172*) or *Therapy target achieved by fluid loss* (Fig. *173*) is displayed and an audible alert is generated.

Throughout the *Therapy target achieved* phase the blood pump continues to transport blood through the extracorporeal circuit during the blood pump stop program. If the Heparin anticoagulation mode is selected, the blood pump is running until it is stopped manually. With RCA, the blood pump stop program is performed. The blood pump and the citrate pump flow rates are automatically reduced. When 25 ml of citrate are infused, both pumps stop.

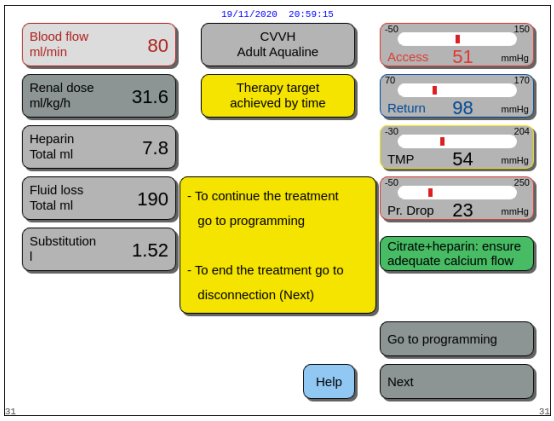


Fig. 172

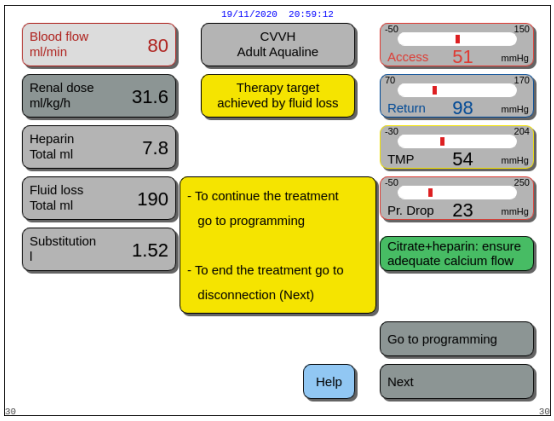


Fig. 173

➪ Select and confirm *Go to programming* to set a new target.
If the target is achieved by fluid loss, the total fluid loss has to be increased for a new target.
If the target is achieved by time, the new time to the next target has to be programmed.
OR
Select and confirm *Next* to go to *Access disconnection* mode.

➪ If necessary, select *Help* function for further on-screen information.

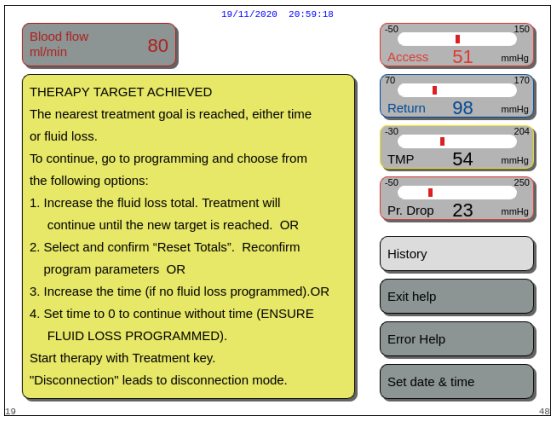


Fig. 174

▶ A window with short instructions appears.

5.8.10 Treatment termination due to maximum operation time

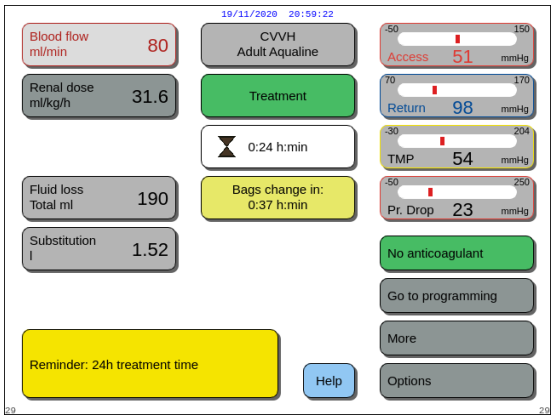


Fig. 175

A yellow message is displayed notifying the operator that the machine has been running for 24 h. An equivalent message appears for 48 h and 72 h.

⇨ Press the *Mute* key.

▶ The message disappears.

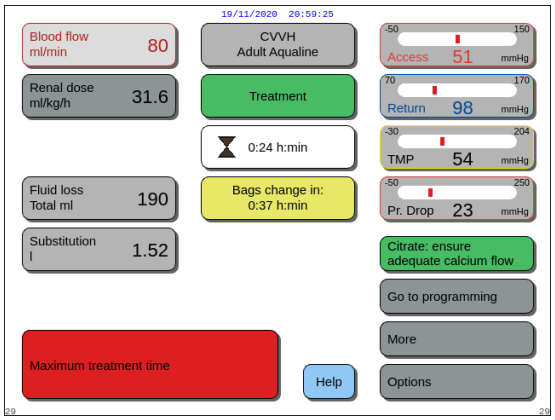


Fig. 176

A red warning is displayed when the maximum treatment time is reached. The warning can be silenced 8 times for 1 h.

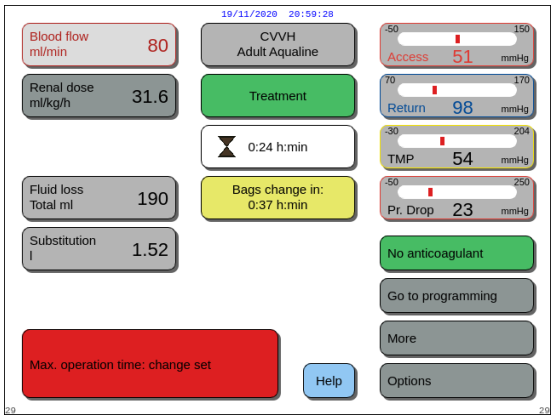


Fig. 177

An alarm is displayed when the red warning (Fig. *176*) was silenced 8 times. The balance system cannot be operated.

Step 1: Terminate the treatment.

Step 2: Disconnect the patient.

Step 3: Replace the tubing sets and the filter by the new ones.

5.9 Access disconnection and return disconnection – Disconnecting the patient

Always follow hospital policy for standard precautions. Gloves, mask and a face shield should be worn when connecting or disconnecting blood lines from patients and removing tubing lines from the Aquarius system.

In case the blood line of the tubing set Aqualine S has been primed with donated blood, it may be indicated not to return the blood to the patient.

Before to proceed, check, if the following conditions are fulfilled:

- The therapy target is achieved.
- *Next* is selected.
- The operator is directed to *Access disconnection* mode.

Fig. 178

Step 1:

1. Select and confirm *Yes*.
   ▶ A *Confirm* window appears.
2. Follow the on-screen instructions.
3. Select and confirm *Yes* to proceed.

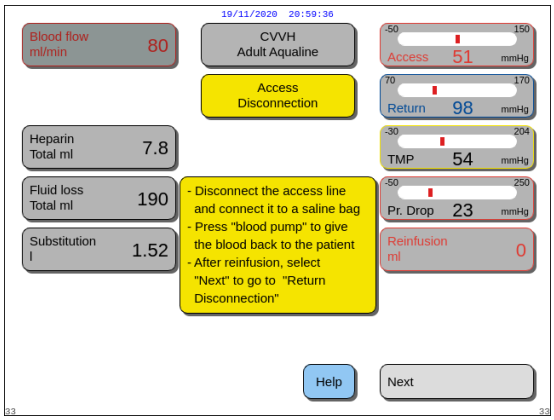


Fig. 179

▶ *Access disconnection* is displayed on the screen.

Step 2: Disconnect the access line. Follow the on-screen instructions:

1. Clamp catheter access port and access line (red).
2. Disconnect the access line from the access port (red) of the patient's blood access and connect it to a saline solution bag by using a 2-way connector.
3. Unclamp access line and saline bag.
4. Press *Blood pump* key .
   ▶ The blood in the extracorporeal circuit is sent back to the patient.
   ▶ The blood flow rate is reduced to the default value if the programmed value at the start of the *Disconnect patient* mode is higher. When the air detector detects saline solution instead of blood, the blood pump stops.
   ▶ An audible signal is generated.

NOTE

Reinfusion value on-screen is the volume of saline solution used to return blood to the patient during disconnection.

5. If necessary, select *Help* function for further on-screen information.

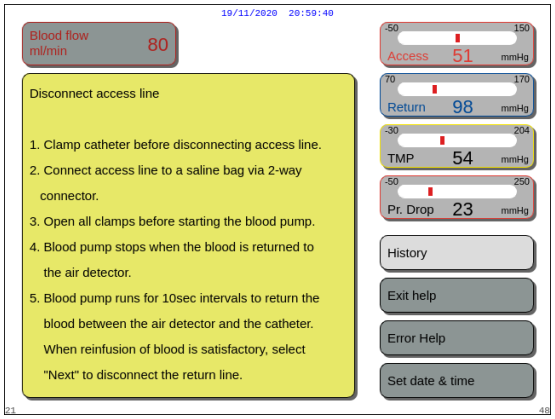


Fig. 180

▶ A window with short instructions appears.

6. When satisfied with the *Reinfusion*, select and confirm the *Next* function (Fig. *179*).
   ▶ When clear fluid is detected in the air detection system, the next screen *Return disconnection* opens automatically.

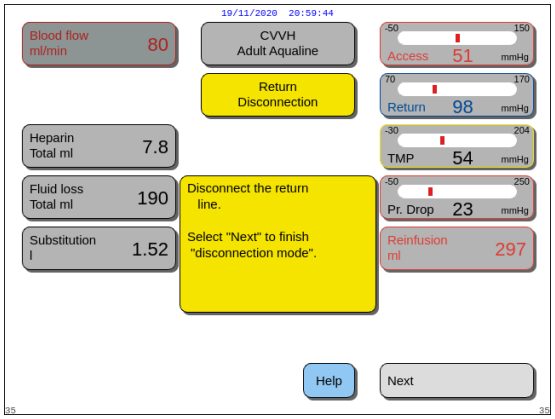


Fig. 181

Step 3: Disconnect the return line. Follow the on-screen instructions:

1. Clamp catheter return port and return line (blue).
2. Disconnect return line from return port (blue) of the patient blood access.
3. Connect return line to the saline solution bag or to the Luer lock fitting on degassing chamber.
4. Unclamp the return line and the saline bag.
5. Select and confirm *Next* to finish *Disconnection* mode.

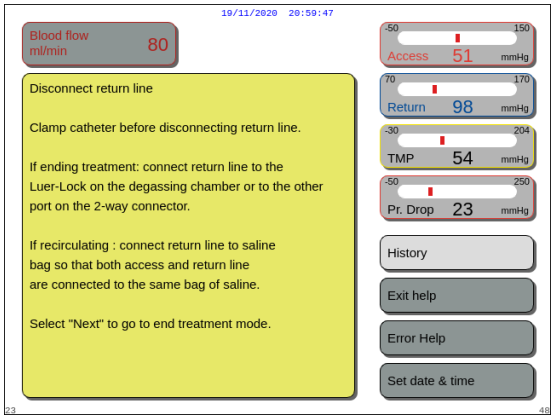


Fig. 182

6. If necessary, select *Help* function for further on-screen information.
   ▶ A window with short instructions appears.

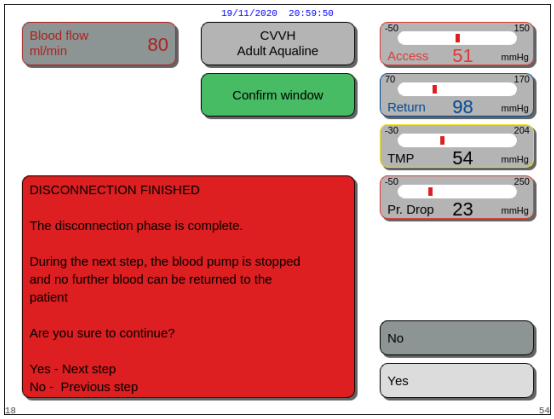


Fig. 183

▶ If *Next* was selected, a *Confirm* window appears.

7. Select and confirm *Yes* to proceed.

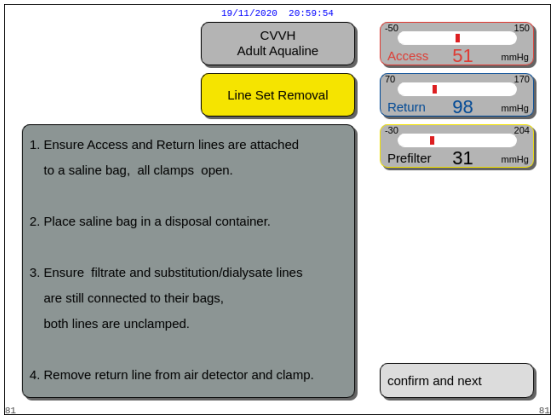


Fig. 184

▶ A window with instructions appears.

8. To remove the tube, follow the on-screen information.
9. Follow the instructions step by step.
10. Select and confirm *Confirm and next* to proceed.

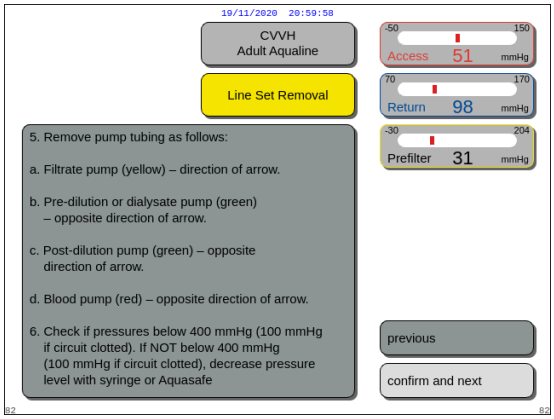


Fig. 185

▶ A window with instructions appears.

11. Follow the instructions step by step.
12. Select and confirm *Confirm and next* to proceed.

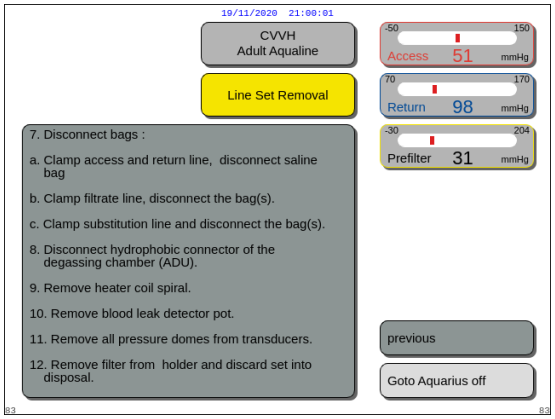


Fig. 186

▶ A window with instructions appears.

13. Follow the instructions step by step.
14. Select and confirm *Go to Aquarius off* to proceed.

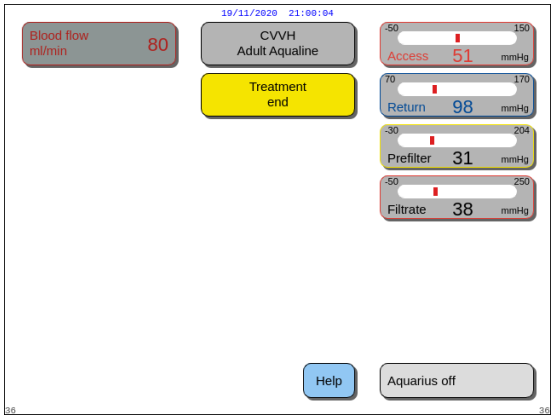


Fig. 187

▶ A *Treatment end* window appears.

15. Select and confirm *Aquarius off* to switch off the Aquarius system.
16. If necessary, select *Help* function for further on-screen information.

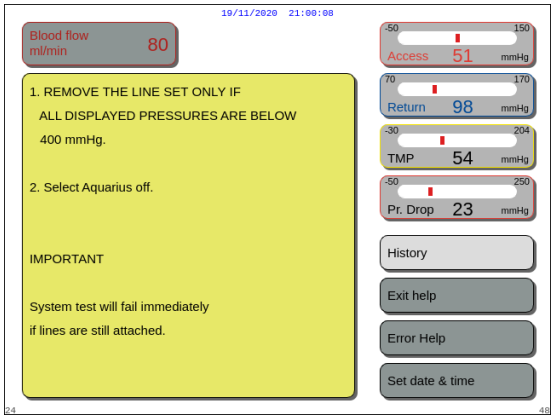


Fig. 188

▶ A window with short instructions appears.

Before removing the pressure domes from the Aquarius system during Aqualine tubing set disconnection, make sure that all four pressure levels (filtrate, pre-filter, access, and return pressures) are below 400 mmHg. If necessary, use a 50 ml syringe or an Aquasafe bag to decrease the pressure before removing a pressure dome from a pressure sensor. When pressure domes are removed from pressure sensors in over-pressure conditions, there is a risk that the pressure dome membrane may burst which could result in a blood leak from the extracorporeal circuit. (See *5.10 Safe removal of the Aqualine tubing set (Page 5-73)*).

To avoid membrane burst, all clamps must be opened and all pump segments must be removed from their respective pump housings before the removal of the pressure domes of the Aqualine tubing set.

5.10 Safe removal of the Aqualine tubing set

This section contains guidelines and recommendations to remove the Aqualine tubing set safely from the Aquarius system at the end of a treatment.

Follow and apply these instructions at the end of each treatment, with special care when treatment termination is caused by clotting and when (for any other reason) there is blood remaining in the extracorporeal circuit after the patient's disconnection.

Never switch off the Aquarius system before complete removal of the Aqualine tubing set, in order to allow pressure monitoring during treatment termination.

To avoid membrane burst, all clamps must be opened and all pump segments must be removed from their respective pump housings before the removal of the pressure domes of the Aqualine tubing set.

Before removing the pressure domes from the Aquarius system during Aqualine tubing set disconnection, make sure that all four pressure levels (filtrate, pre-filter, access, and return pressures) are below 400 mmHg.

In the event of clotting in the filter (or in other parts of the extracorporeal circuit), the *High pre-filter pressure* alarm, *High TMP* alarm and *High return pressure* alarm will not permit the re-infusion of blood to the patient. In this case do not remove Aqualine tubing pressure domes from Aquarius pressure sensors without first reducing the pressure level inside the tubing set below 100 mmHg for this procedure.

If the above warnings are not followed, the risk of pressure dome bursting and the operator being contaminated with biological fluid increases.

After patient disconnection from the Aquarius system, the operator has to remove the Aqualine tubing set from the Aquarius system according to the following steps:

Step 1:

1. Ensure that the return line is connected to the saline bag (or to the degassing chamber) and all clamps are open along the return line path.
2. Ensure that the access line is connected to the saline solution bag and all clamps are open along the access line path. Place the saline bag on the floor in a disposal container.
3. Ensure that the filtrate and the substitution or dialysate lines are connected to the corresponding filtrate and substitution or dialysate bags and that both lines are unclamped.

Step 2: Remove the return line from the air detector and from the return line clamp.

Step 3: Remove the pump tubing segments from the pumps in the following order:

1. Filtration pump (yellow)
2. Pre-dilution or dialysate pump (green)
3. Post-dilution pump (green)
4. Blood pump (red)

Step 4:

1. Check if pressures are below 400 mmHg.

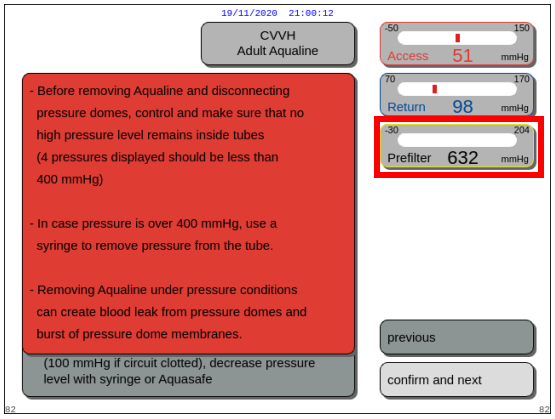


Fig. 189

NOTE

A *Warning* screen is displayed if at least one of the four pressures (filtrate, pre-filter, access, and return) is over 400 mmHg.

2. Remove all pressure domes from the Aquarius system **only if** all pressures (pre-filter pressure, filtrate, return pressure and access pressure) are below 400 mmHg.
   If not all pressures are below 400 mmHg, refer to section *5.10.1 Instructions to decrease pressure level (Page 5-75)*.

Step 5: Disconnect the bags as follows:

1. Clamp the access line and disconnect the saline solution bag.
2. Clamp the filtrate line and disconnect the filtrate bag(s).
3. Clamp the substitution or dialysate line and disconnect the substitution or dialysate bag(s).

Step 6: Disconnect the hydrophobic connector line of the degassing chamber from the ADU unit.

Step 7: Remove the heater coil line spiral from the heating unit.

Step 8: Remove completely the Aqualine tubing set from the Aquarius system.

Step 9: Switch off the Aquarius system as follows:

1. Select and confirm *Aquarius off* to switch off the Aquarius system
   OR
   press the *ON/OFF* key located on the right side of the display screen.

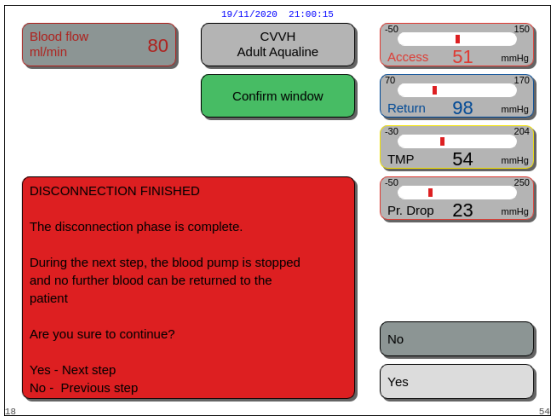


Fig. 190

▶ If *Aquarius off* is selected and confirmed, a *Confirm* window appears.

2. Select the *Confirm* window and confirm again.

   ▶ The Aquarius system shuts down.

Step 10: Discard the tubing set according to the local regulation (refer to section *3.5 Materials used (Page 3-7)*).

Ensure that the Aquarius system is switched off by confirming *Aquarius off* or pressing the *ON/OFF* key located on the right side of the display screen before disconnecting the Aquarius system from main power (unplugging the cable or switching off the main switch) to avoid battery discharging.

5.10.1 Instructions to decrease pressure level

Use gloves and goggles as per ward protocol.

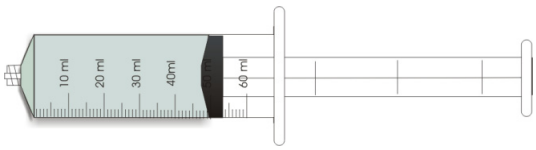


Fig. 191

Step 1: Prepare an empty 50 ml syringe or an Aquasafe bag.

Fig. 192

NOTE

- The Aquasafe bag is an empty bag with 25 ml capacity used to release excessive pressure from the Aqualine tubing set.
- The Aquasafe bag has been successfully tested on the Aquarius system.
- See the Aquasafe bag instructions for use.

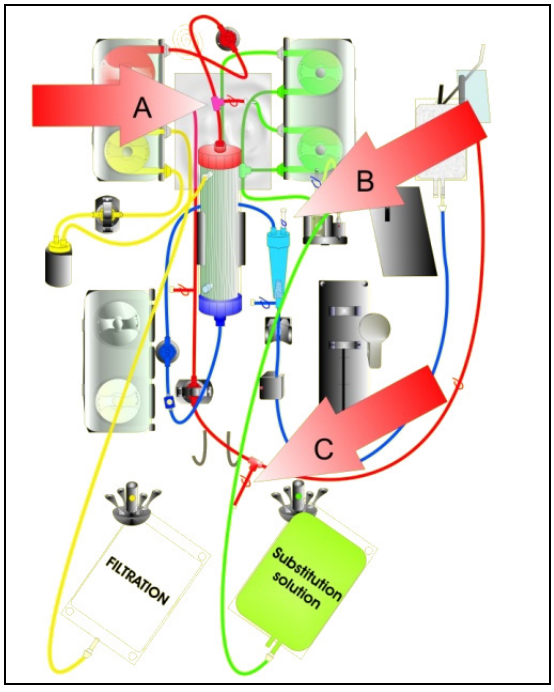


Fig. 193

In case of high pre-filter pressure:

Step 2: Close the clamp (red) on the pre-dilution line (A).

Step 3: Connect an empty syringe or Aquasafe bag to the pre-dilution access port (A) and open the line clamp.

In case of high return pressure:

Step 2: Close the clamp (blue) on the Luer lock connector fitting on the drip chamber (B).

Step 3: Connect an empty syringe or Aquasafe bag to the Luer lock connector fitting on the drip chamber (B) and open the line clamp.

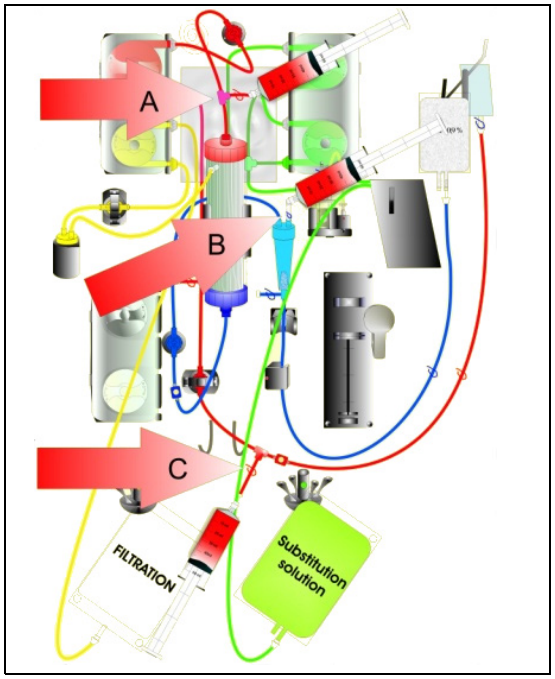


Fig. 194

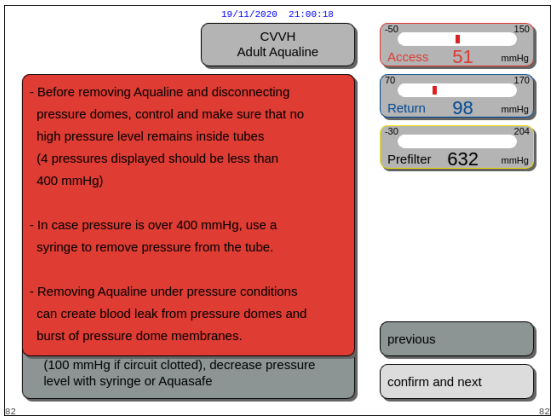


Fig. 195

In case of high access pressure:

Step 2: Close the clamp (red) on the access port line (C).

Step 3: Connect an empty syringe or Aquasafe bag to the access port (C) and open the line clamp.

Step 4: Fill the syringe(s) or Aquasafe bag(s) with fluid until the pressures value displayed on the screen is below 100 mmHg.

Step 5: If any pressure is above 100 mmHg, go back to Step 2 and reduce it to a level below 100 mmHg.

5.11 Therapy modes of Aquarius system

This section describes the therapies possible on the Aquarius system. It may only be operated within the given specifications and limits detailed in these Instructions for Use. For each therapy, a diagram illustrates how the tubing set should be installed.

The main differences between the therapies are as follows:

- All pumps are **not** always operated.
- Depending on the treatment, the patient parameters to be entered are different.
- The displayed patient parameters are different.
- During CVVH pre-dilution the pre-dilution/dialysate line segment is connected to the pre-filter access line.
- During CVVHD or CVVHDF the pre-dilution/dialysate line segment is connected to the dialysate in-flow port.
- During TPE the pre-dilution/dialysate line segment should be connected to the pre-filter access line.
- Regional Citrate Anticoagulant is available with the following therapies: CVVH, CVVHD and TPE. Please contact your local representative for options.

CVVH pre-dilution or CVVH post-dilution can be configured depending on the prescription. Only calcium-free or citrate containing solutions should be administered at the clinicians discretion for these therapy modes.

All pump segments must be loaded in the pump chambers and primed prior to treatment.

When priming the Aquarius system for SCUF, TPE and Hemoperfusion, the substitution line should be connected to a 1 l bag of saline solution.

When running SCUF or when not using the replacement solution heater, ensure that the patient's temperature is maintained. Cold solutions or operation in very cold environments can cause hypothermia.

If temperature is set to 0 °C (Off), do not rely on the Aquarius system to detect substitution fluid that is outside of physiological range. An external heater device should be used to monitor and control the substitution fluid temperature.

In the following diagrams:

- Red shows the unfiltered blood path;
- Blue shows the blood path after the filter;
- Yellow shows the filtrate path;
- Green shows the substitution solution and dialysate path.
- Dotted lines indicate that these pumps are not operating during the respective treatment.

The default therapy mode configuration for RCA is CVVH post-dilution. It can only be changed by personnel authorized by the manufacturer.

Therapy modes with RCA are available for adult patients.

5.11.1 SCUF (Slow Continuous Ultrafiltration)

During Slow Continuous Ultrafiltration blood is driven through a hemofilter via an extracorporeal circuit.

SCUF is used primarily to manage fluid overload. The underlying principle of water removal is ultrafiltration. The underlying principle of clearance is convection.

Fluid removal is controlled and balanced by the filtration pump and the filtration scale.

The filtrate is not replaced by substitution solution.

During Slow Continuous Ultrafiltration the pre-dilution pump and the post-dilution pump are inactive. The blood is pumped through a hemofilter and reinfused to the patient. The filtrate is collected in an empty bag hanging on the filtrate scale.

Citrate anticoagulation cannot be used with SCUF. If citrate anticoagulation is selected, SCUF cannot be used.

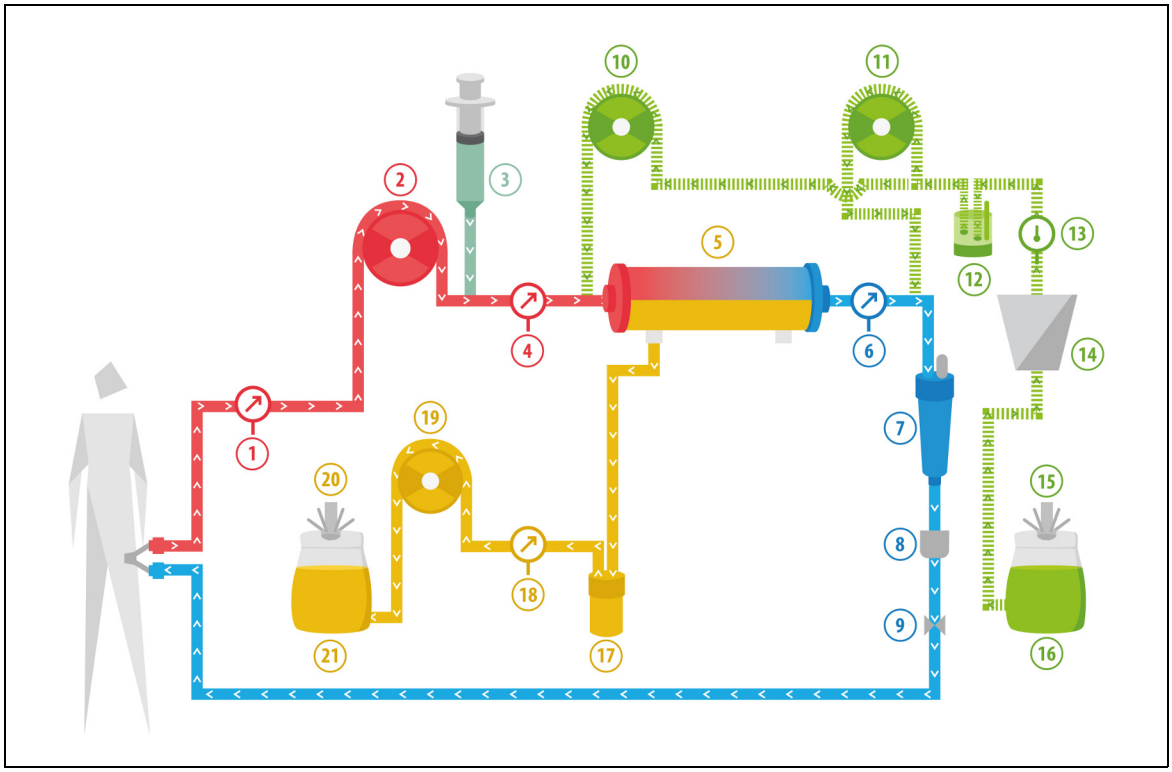


Fig. 196

No	Component	No	Component
1	Access pressure	12	Automatic degassing unit
2	Blood pump	13	Temperature control
3	Heparin pump	14	Heater
4	Pre-filter pressure	15	Substitution scale
5	Filter	16	Priming solution
6	Return pressure	17	Blood leak detector
7	Air bubble trap	18	Filtrate pressure
8	Air bubble detector	19	Filtrate pump
9	Automatic clamp	20	Filtrate scale
10	Pre-dilution substitution pump (not running)	21	Filtrate
11	Post-dilution substitution pump (not running)		

The following patient parameters are entered for a SCUF treatment:

Parameter	Range		Units	Increment	
	Adult	Low volume		Adult	Low volume
Blood flow rate	30 to 450	10 to 200	ml/min	10 ml/min	2 ml/min
Time	0 to 99:59	0 to 99:59	h:min	10 min	10 min
Fluid loss rate	0 to 2,000	0 to 1,000	ml/h	10/100 ml/h	10/100 ml/h
Total fluid loss	0 to 32,000	0 to 15,000	ml	100 ml	10 ml
Number of bags	1 to 4	1 to 2	5 l	1 bag	1 bag
Heparin flow rate	0 to 15	0 to 15	ml/h	0.1 ml/h	0.1 ml/h
Heparin bolus	0 to 2.5	0 to 2.5	ml	0.5 ml	0.5 ml

The following patient parameters are displayed on the main screen during SCUF:

- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- Blood flow (ml/min)
- Anticoagulant Total (ml)
- Total fluid loss (ml)
- Remaining time (h:min)
- Bag change in (h:min)

The following patient parameters are displayed on the *More* screen during SCUF:

- Temperature (°C)
- Pre-filter pressure (mmHg)
- Filtrate pressure (mmHg)
- Pre-dilution (ml)
- Post-dilution (ml)
- Blood volume (l)
- Next bag change in (h:min)
- UF variation (ml)
- Filtration fraction (%)
- Elapsed time (h:min)
- Citrate dose (mmol/l)
- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- BLD (%)
- Pressure drop (mmHg)

5.11.2 CVVH (Continuous Veno-Venous Hemofiltration)

During Continuous Veno-Venous Hemofiltration, blood is driven through a hemofilter via an extracorporeal circuit.

Sterile, physiological substitution solution is infused into the blood circuit before (pre-dilution) and/or after the filter (post-dilution). Filtrate is removed simultaneously at an equal or greater rate.

CVVH is used to achieve solute removal (small, medium and large sized molecules) and fluid balance. The principle of clearance is convection.

The substitution solution and filtrate are controlled and balanced by the substitution pumps, the filtration pump and the scales.

During this treatment, the output of the *pre-dilution* pump **must** be connected to the *pre-filter* Luer connection before the filter.

Patient hazard because of use of incorrect or outdated solutions.

⇨ **Use only substitution solutions labeled for intravenous injection, of appropriate composition and prescribed by a physician.**

5.11.2.1 CVVH pre-dilution Regular

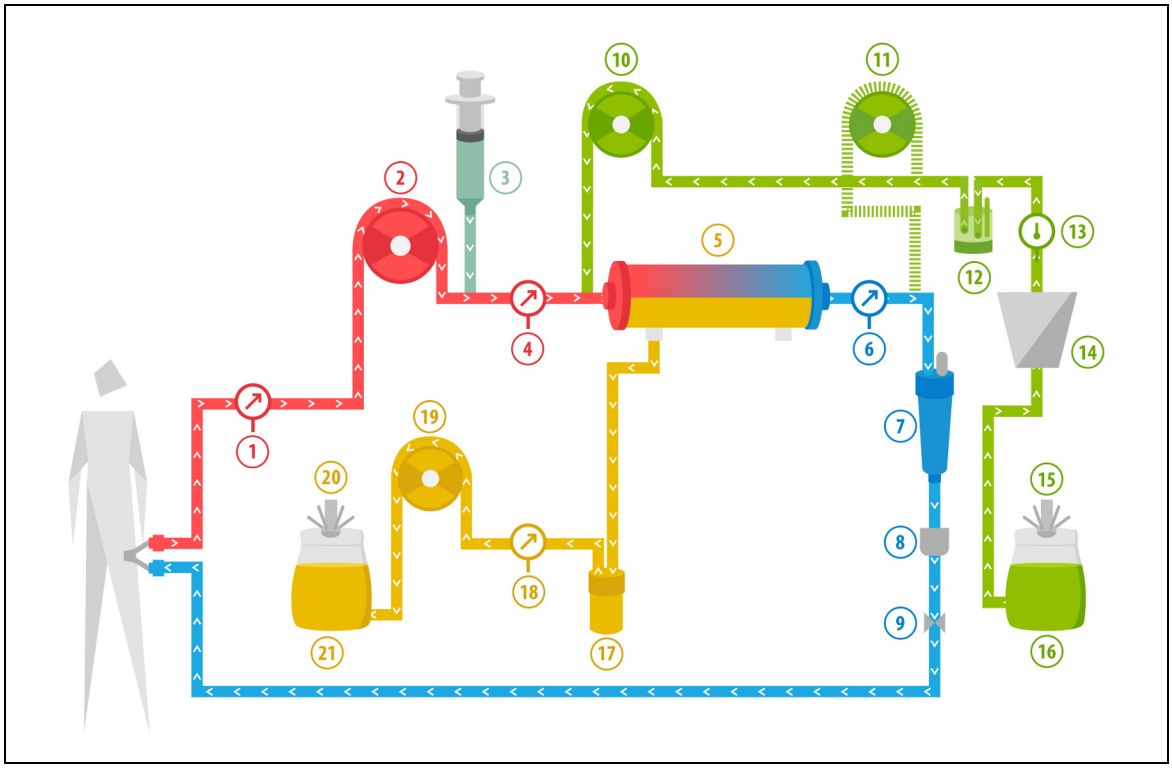


Fig. 197

No	Component	No	Component
1	Access pressure	12	Automatic degassing unit
2	Blood pump	13	Temperature control
3	Heparin pump	14	Heater
4	Pre-filter pressure	15	Substitution scale
5	Filter	16	Priming solution
6	Return pressure	17	Blood leak detector
7	Air bubble trap	18	Filtrate pressure
8	Air bubble detector	19	Filtrate pump
9	Automatic clamp	20	Filtrate scale
10	Pre-dilution substitution pump	21	Filtrate
11	Post-dilution substitution pump (not running)		

- During this treatment the free line of the pre-dilution pump is connected to the pre-filter access line connection before the filter.
- During CVVH, blood is pumped through a hemofilter and reinfused to the patient.
- During pre-dilution CVVH it is recommended to inactivate the post-dilution pump by setting the flow rate to 0 ml/h (default).
- During pre-dilution, the substitution solution is administered immediately before the filter.
- The substitution fluid is hung on the substitution scale.
- The filtrate is collected in an empty bag hanging on the filtrate scale.

If a regular treatment is performed on the Aquarius system, it is strongly recommended to use a regular Aqualine tubing set. Please don't use a RCA tubing set for regular treatments.

5.11.2.2 CVVH post-dilution Regular

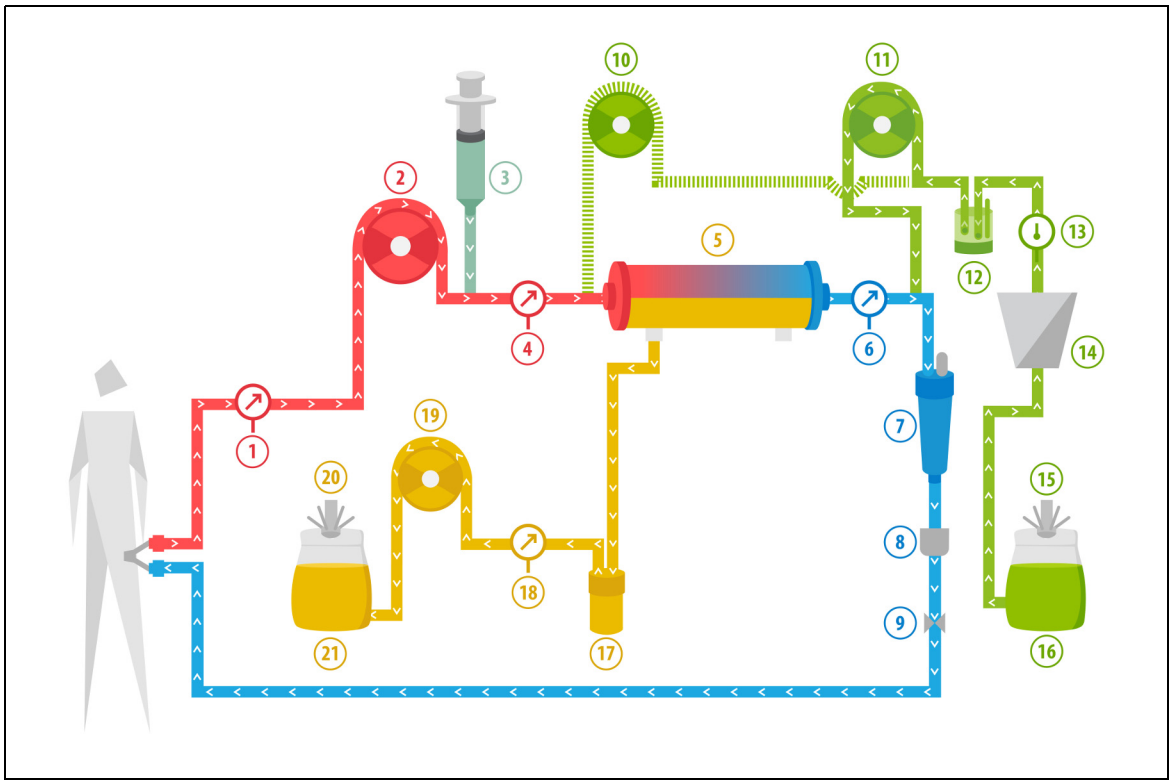


Fig. 198

No	Component	No	Component
1	Access pressure	12	Automatic degassing unit
2	Blood pump	13	Temperature control
3	Heparin pump	14	Heater
4	Pre-filter pressure	15	Substitution scale
5	Filter	16	Priming solution
6	Return pressure	17	Blood leak detector
7	Air bubble trap	18	Filtrate pressure
8	Air bubble detector	19	Filtrate pump
9	Automatic clamp	20	Filtrate scale
10	Pre-dilution substitution pump (not running)	21	Filtrate
11	Post-dilution substitution pump		

- During post-dilution CVVH, the pre-dilution pump is not active.
- Blood is pumped through a hemofilter and reinfused to the patient.
- During post-dilution the substitution solution is administered after the filter at the return drip chamber.
- The substitution fluid is hung on the substitution scale.
- The filtrate is collected in an empty bag hanging on the filtrate scale.

If a regular treatment is performed on the Aquarius system, it is strongly recommended to use a regular Aqualine tubing set. Please don't use a RCA tubing set for regular treatments.

5.11.2.3 CVVH pre- and post-dilution Regular

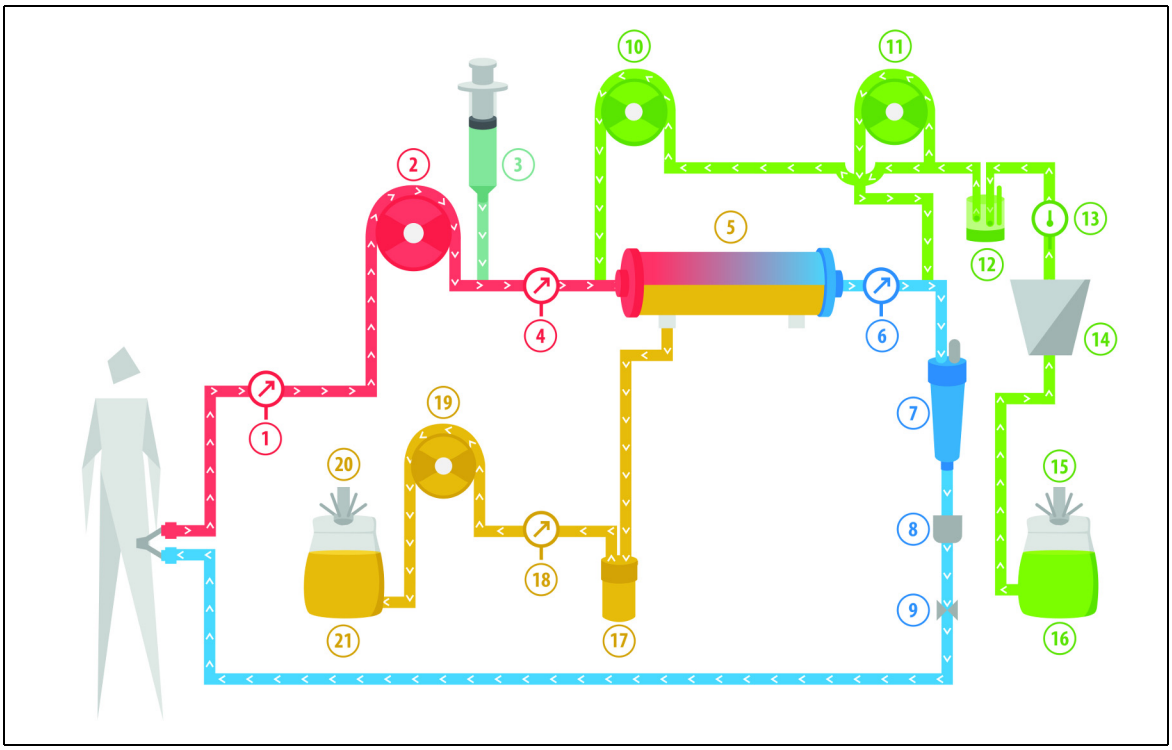


Fig. 199

No	Component	No	Component
1	Access pressure	12	Automatic degassing unit
2	Blood pump	13	Temperature control
3	Heparin pump	14	Heater
4	Pre-filter pressure	15	Substitution scale
5	Filter	16	Priming solution
6	Return pressure	17	Blood leak detector
7	Air bubble trap	18	Filtrate pressure
8	Air bubble detector	19	Filtrate pump
9	Automatic clamp	20	Filtrate scale
10	Pre-dilution substitution pump	21	Filtrate
11	Post-dilution substitution pump		

- During post- and pre-dilution CVVH the post- and pre-dilution pumps can be activated separately by setting the flow rate.
- Blood is pumped through a hemofilter and reinfused to the patient.
- The post-dilution pump administers the substitution solution after the filter at the return drip chamber, if it is activated
- The pre-dilution pump administers the substitution solution between blood pump and filter, if it is activated.
- The substitution fluid, for both post- and pre-dilution, is hung on the substitution scale.
- The filtrate is collected in empty bags hanging on the filtrate scale.

If a regular treatment is performed on the Aquarius system, it is strongly recommended to use a regular Aqualine tubing set. Please don't use an RCA tubing set for regular treatments.

5.11.2.4 CVVH pre-dilution with RCA

This treatment is not accessible in case CVVHD with RCA is configured.

In case the Aquarius device is configured for the therapy mode CVVH pre-dilution RCA, the following set-up is applicable.

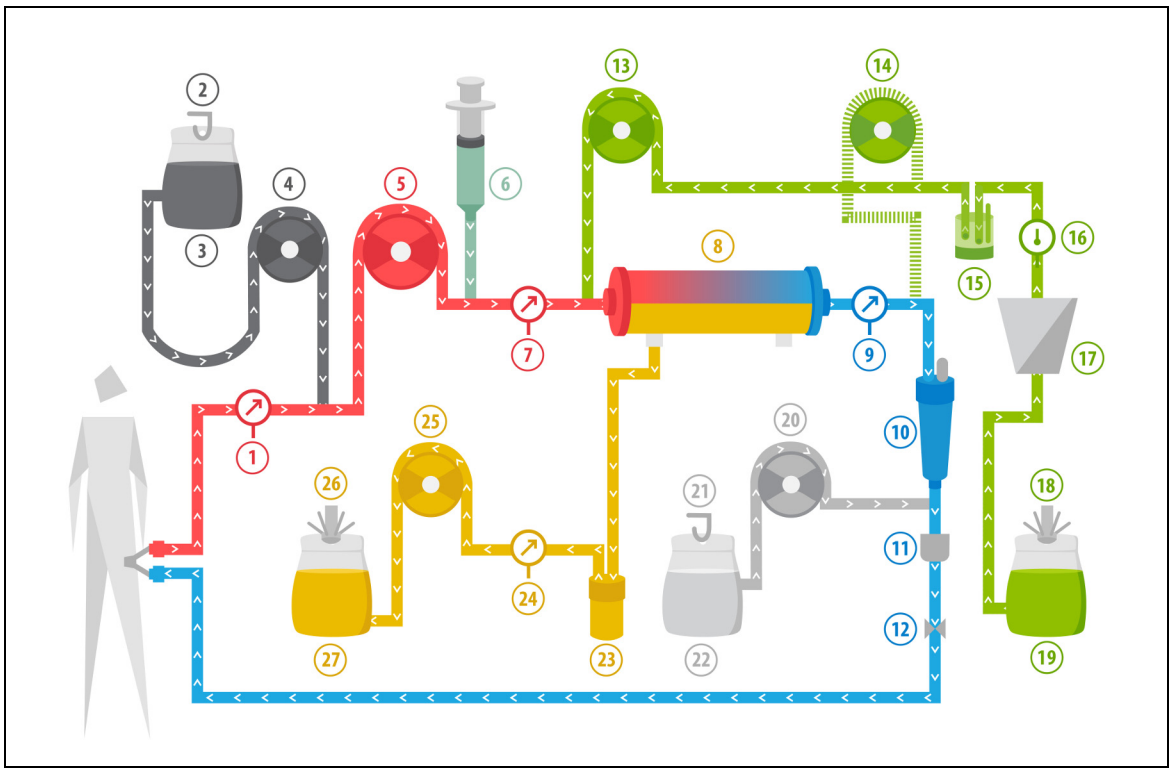


Fig. 200

No	Component	No	Component
1	Access pressure	15	Automatic degassing unit
2	Citrate scale	16	Temperature control
3	Citrate	17	Heater
4	Citrate pump	18	Substitution scale
5	Blood pump	19	Substitution fluid
6	Heparin pump	20	Calcium pump
7	Pre-filter pressure	21	Calcium scale
8	Filter	22	Calcium
9	Return pressure	23	Blood leak detector
10	Air bubble trap	24	Filtrate pressure
11	Air bubble detector	25	Filtrate pump
12	Automatic clamp	26	Filtrate scale
13	Pre-dilution substitution pump	27	Filtrate
14	Post-dilution substitution pump (not running)		

- During this treatment the free line of the pre-dilution pump is connected to the pre-filter access line connection before the filter.
- During CVVH, blood is pumped through a hemofilter and reinfused to the patient.

- During pre-dilution CVVH, the post-dilution pump is not active.
- During pre-dilution, the substitution solution is administered immediately before the filter.
- The substitution fluid is hung on the substitution scale.
- The filtrate is collected in an empty bag hanging on the filtrate scale.
- The citrate pump administers the citrate solution from the citrate scale to the access blood line. If citrate-containing predilution substitution fluid is chosen, the citrate pump may be switched off.
- The calcium pump administers the calcium solution from the calcium scale to the return blood line after the drip chamber.

For the therapy mode CVVH pre-dilution with RCA only calcium-free or citrate-containing replacement solutions are applicable.

5.11.2.5 CVVH post-dilution with RCA

This treatment is not accessible in case CVVHD with RCA is configured.

In CVVH post-dilution with RCA, citrate solution is infused into the blood circuit before the blood pump and a calcium supplementation solution is infused into the blood circuit between the drip chamber and the air detector system.

Citrate and calcium solutions are controlled and balanced by the citrate and calcium pumps and their respective scales.

Citrate and calcium bags should not touch substitution and filtrate bags.

If the citrate and calcium bags touch the substitution and filtrate bags while the balance system is active, calcium and citrate flow alarms can occur.

To avoid bags touching each other, the number of substitution and filtrate bags per scale needs to be reduced.

Patient hazard because of use of incorrect or outdated solutions.

⇨ **Use only substitution solutions labeled for intravenous injection, of appropriate composition and prescribed by a physician.**

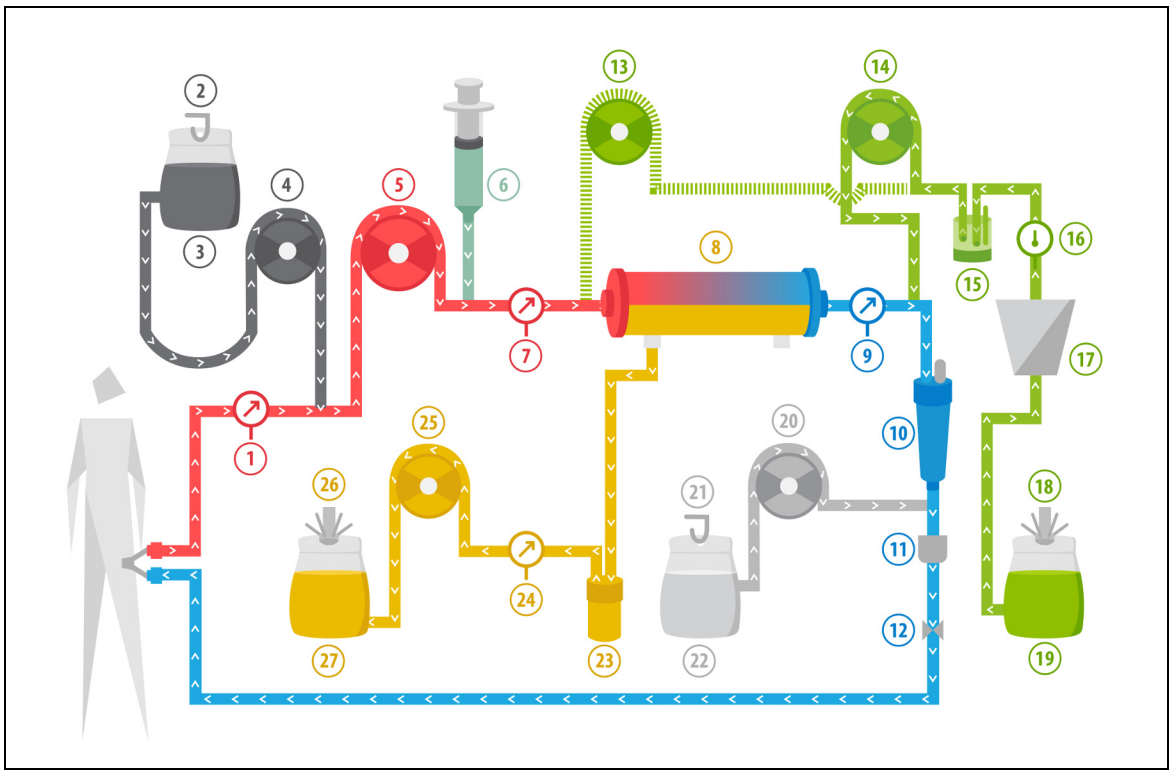


Fig. 201

No	Component	No	Component
1	Access pressure	15	Automatic degassing unit
2	Citrate scale	16	Temperature control
3	Citrate	17	Heater
4	Citrate pump	18	Substitution scale
5	Blood pump	19	Substitution fluid
6	Heparin pump	20	Calcium pump
7	Pre-filter pressure	21	Calcium scale
8	Filter	22	Calcium
9	Return pressure	23	Blood leak detector
10	Air bubble trap	24	Filtrate pressure
11	Air bubble detector	25	Filtrate pump
12	Automatic clamp	26	Filtrate scale
13	Pre-dilution substitution pump (not running)	27	Filtrate
14	Post-dilution substitution pump		

- During post-dilution CVVH, the pre-dilution pump is not active. The predilution line may be clamped after priming is completed.
- Blood is pumped through a hemofilter and reinfused to the patient.
- During post-dilution the substitution solution is administered after the filter before the return drip chamber.
- The substitution fluid is hung on the substitution scale.
- The filtrate is collected in an empty bag hanging on the filtrate scale.
- The citrate pump administers the citrate solution from the citrate scale to the access blood line.

The calcium pump administers the calcium solution from the calcium scale to the return blood line after the drip chamber.

5.11.2.6 Patient parameters for CVVH treatments

The following patient parameters are entered for a CVVH treatment without citrate anticoagulation:

Parameter	Range		Units	Increment	
	Adult	Low volume		Adult	Low volume
Blood flow rate	30 to 450	10 to 200	ml/min	10 ml/min	2 ml/min
Time	0 to 99:59	0 to 99:59	h:min	10 min	10 min
Fluid loss rate	-100 to 2,000	0 to 1,000	ml/h	10/100 ml/h	10/100 ml/h
Total fluid loss	-1000 to 32,000	0 to 15,000	ml	100 ml	10 ml
Pre-dilution rate	0; 100 to 10,000 - post-dilution rate	0; 100 to 6,000 - post-dilution rate	ml/h	100 ml/h	10 ml/h
Post-dilution rate	0; 100 to 10,000 - pre-dilution rate	0; 100 to 6,000 - pre-dilution rate	ml/h	100 ml/h	10 ml/h
Number of bags	1 to 4	1 to 2	5 l	1 bag	1 bag
Heparin flow rate	0 to 15	0 to 15	ml/h	0.1 ml/h	0.1 ml/h
Heparin bolus	0 to 2.5	0 to 2.5	ml	0.5 ml	0.5 ml
Temperature	0 (off) or 35 to 39	0 (off) or 35 to 39	°C	0.5 °C	0.5 °C

The following patient parameters are displayed on the main screen during CVVH:

- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- Blood flow (ml/min)
- Anticoagulant total (ml)
- Fluid Loss Total (ml)
- Substitution (ml and l)
- Remaining time (h:min)
- Bag change in (h:min)
- Renal dose (ml/kg/h)

NOTE

The Renal dose is defined as the dose of treatment related to the patient's body weight (refer to section *5.4 Clamp and pressure test (Page 5-38)*), the fluid loss rate and the pre- and post-dilution volumes.

At the start of treatment or after a programmed value change for blood flow rate, pre-dilution flow rate, post-dilution flow rate, citrate flow, calcium flow, fluid loss rate, or patient body weight, the programmed Renal dose is displayed for the first 2 minutes after starting the balance system. After 2/10 minutes of uninterrupted therapy, the calculated Renal dose achieved is displayed, based on the actual pump rates and the set patient weight.

The following patient parameters are displayed on the *More* screen during CVVH:

- Pre-filter pressure (mmHg)
- Filtrate pressure (mmHg)
- Temperature (°C)
- Pre-dilution (ml and l)
- Post-dilution (ml and l)
- Blood volume (l)
- Next bag change in (h:min)
- UF variation (ml)
- Filtration fraction (%)
- Elapsed time (h:min)
- Citrate dose (mmol/l)
- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- BLD (%)

The following patient parameters are entered for a CVVH treatment with citrate anticoagulation:

Parameter	Range		Units	Increment	
	Adult	Low volume		Adult	Low volume
Blood flow rate	30 to 300	10 to 200	ml/min	10 ml/min	2 ml/min
Citrate flow rate	0; 20 to 650	0; 20 to 650	ml/h	1 ml/h	1 ml/h
Calcium flow rate	0; 2, to 300	0; 2, to 300	ml/h	from 2 to 30 ml in 0.2 ml/h steps from 30 to 300 ml in 1 ml/h steps	from 2 to 30 ml in 0.2 ml/h steps from 30 to 300 ml in 1 ml/h steps
Fluid loss rate	0 to 2,000	0 to 1,000	ml/h	10/100 ml/h	10 ml/h
Total fluid loss	0 to 32,000	0 to 15,000	ml	100 ml	10 ml
Post-dilution flow rate	0; 500 to 6,000	0; 100 to 4,000	ml/h	100 ml/h	10 ml/h
Pre-dilution flow rate	Option: please contact your local representative	Option: please contact your local representative	ml/h	100 ml/h	100 ml/h
Number of bags	1 to 4	1 to 2	5 l	1 bag	1 bag
Temperature	0 (off) or 35 to 39	0 (off) or 35 to 39	°C	0.5 °C	0.5 °C
Time	0 to 99:59	0 to 99:59	h	10 min	10 min
Heparin flow rate	0 or 0.5 to 15	0 or 0.5 to 15	ml/h	0.1 ml/h	0.1 ml/h
Heparin bolus	0 to 2.5	0 to 2.5	ml	0.5 ml	0.5 ml

The following patient parameters are displayed on the *More* screen during CVVH with citrate anticoagulation:

- UF variation (ml)
- Filtration fraction (%)
- Elapsed time (h:min)
- Citrate dose (mmol/l)
- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- BLD (%)
- Pre-filter pressure (mmHg)
- Filtrate pressure (mmHg)
- Temperature (°C)
- Pre-dilution (ml and l)
- Post-dilution (ml and l)
- Blood volume (l)
- Citrate total (ml)
- Calcium total (ml)
- Next bag in (h:min)
- Pressure drop (mmHg)

5.11.2.7 Bag change

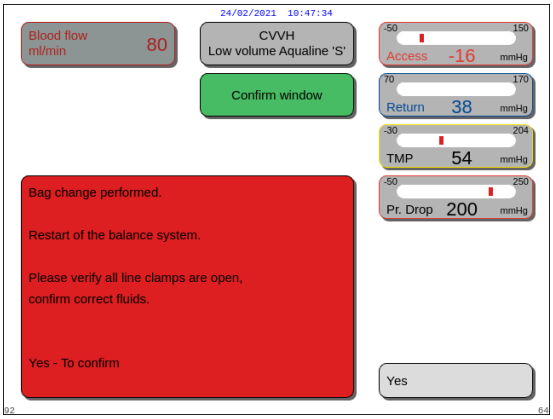


Fig. 202

Using Aqualine S or Aqualine S RCA:

Step 1: Change the bag if necessary.

▶ A *Confirm* window appears.

Step 2: Check if all lines are open, without clamps, and the correct solutions are in use. This avoids coagulation, electrolyte dysfunction and hyper- or hypovolemia.

Step 3: Select *Yes* to confirm the change.

▶ The confirm window is closed.
▶ The course of the treatment is not impacted.

5.11.2.8 Anticoagulant change

The anticoagulant change is possible when the treatment started in RCA mode.

During a CVVH RCA treatment it may be indicated to change the anticoagulant from RCA to heparin.

Step 1: Select *Options* on the main screen to change the anticoagulant.

Step 2: Select *Anticoagulant change*.

- ▶ A *Confirm* window appears.

Step 3: Select and confirm *Yes* to confirm the change.

- ▶ The citrate and calcium pumps are disabled and the machine switches to CVVH with heparin anticoagulation, see section *5.11.2.3 (Page 5-83)*. In this mode, it is possible to activate the pre-dilution pump additionally using appropriate substitution fluid.
- ▶ If a syringe is inserted into the heparin pump, the Aquarius system will automatically start the CVVH treatment with heparin. If no syringe is inserted and this has been confirmed, a message requires the operator to prepare and to install a heparin syringe.

Step 4: Verify and confirm all flow rates against the patient prescription after each anticoagulant change.

If the change of the predilution pump after the aticoagulant change is planned, make sure that the clamp on the predilution line is open.

If during the course of that treatment, a change from heparin anticoagulation back to RCA mode is indicated and the Aqualine RCA is installed, it is possible to return to CVVH with RCA.

5.11.3 CVVHD (Continuous Veno-Venous Hemodialysis)

5.11.3.1 CVVHD Regular

During Continuous Veno-Venous Hemodialysis, blood is driven through a hemofilter/dialyzer via an extracorporeal circuit. Dialysate solution flows through the dialysate compartment of the hemofilter/dialyzer, counter-current to the blood flow.

CVVHD is used to achieve solute removal (small and medium sized molecules) and fluid balance. Filtrate should correspond to the desired net weight loss. No substitution solution is used. The principle of clearance is diffusion.

The dialysate solution and filtrate are controlled by the dialysate pump (otherwise known as the pre-dilution pump), the filtration pump and the scales.

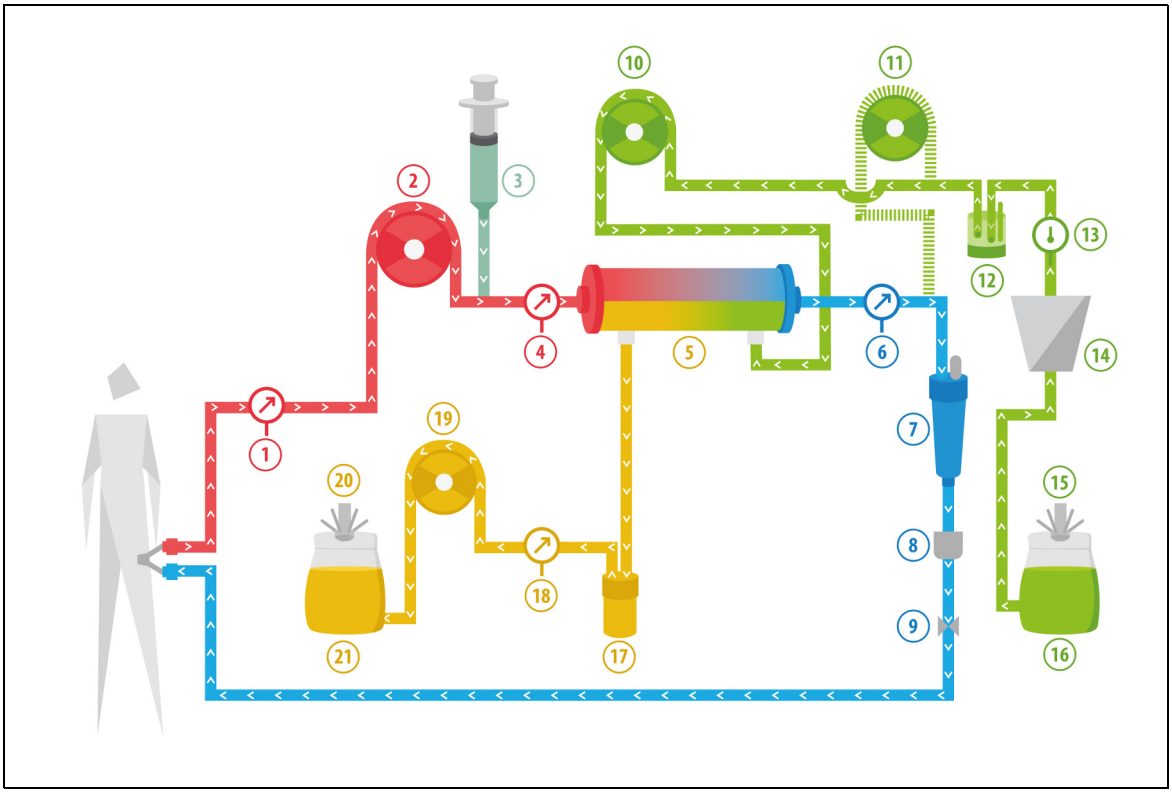


Fig. 203

No	Component	No	Component
1	Access pressure	12	Automatic degassing unit
2	Blood pump	13	Temperature control
3	Heparin pump	14	Heater
4	Pre-filter pressure	15	Dialysate scale
5	Filter	16	Dialysate solution
6	Return pressure	17	Blood leak detector
7	Air bubble trap	18	Filtrate pressure
8	Air bubble detector	19	Filtrate pump
9	Automatic clamp	20	Filtrate scale
10	Dialysate pump	21	Filtrate/Effluent
11	Post-dilution substitution pump (not running)		

- During CVVHD the post-dilution pump is not active.

- Blood is pumped through a semi-permeable dialyzer and reinfused to the patient.
- The filtrate is collected in an empty bag hanging on the filtrate scale.
- The dialysate pump delivers the dialysate to the dialyzer, countercurrent to the blood flow.

The following patient parameters are entered for a CVVHD treatment:

Parameter	Range		Units	Increment	
	Adult	Low volume		Adult	Low volume
Blood flow rate	30 to 450	1 to 200	ml/min	10 ml/min	2 ml/min
Time	0 to 99:59	0 to 99:59	h:min	10 min	10 min
Fluid loss rate	-100 to 2,000	0 to 1,000	ml/h	10/100 ml/h	10/100 ml/h
Total fluid loss	-1000 to 32,000	0 to 15,000	ml	100 ml	10 ml
Dialysate rate	0 to 10,000	0; 100 to 10,000	ml/h	100 ml/h	10 ml/h
Number of bags	1 to 4	1 to 2	5 l	1 bag	1 bag
Heparin flow rate	0 to 15	0 to 15	ml/h	0.1 ml/h	0.1 ml/h
Heparin bolus	0 to 2.5	0 to 2.5	ml	0.5 ml	0.5 ml
Temperature	0 (off) or 35 to 39	0 (off) or 35 to 39	°C	0.5 °C	0.5 °C

The following patient parameters are displayed on the main screen during CVVHD:

- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- Blood flow (ml/min)
- Anticoagulant Total (ml)
- Fluid Loss Total (ml)
- Dialysate (ml and l)
- Remaining time (h: min)
- Bag change in (h: min)
- Renal dose (ml/kg/h)

NOTE The Renal dose is defined as the dose of treatment related to the patient's body weight (refer to section *5.4 Clamp and pressure test (Page 5-38)*), fluid loss rate and the pre- and post-dilution volumes.

At the start of treatment or after a programmed value change for blood flow rate, pre-dilution flow rate, post-dilution flow rate, citrate flow, calcium flow, fluid loss rate, or patient body weight, the programmed Renal dose is displayed for the first 2 minutes after starting the balance system. After 2/10 minutes of uninterrupted therapy, the calculated Renal dose achieved is displayed based on the actual pump rates and the set patient weight.

The following patient parameters are displayed on the *More* screen during CVVHD:

- Pre-filter pressure (mmHg)
- Filtrate pressure (mmHg)
- Temperature (°C)
- Dialysate (ml and l)
- Blood volume (l)
- Next bag change in (h:min)
- UF variation (ml)
- Filtration fraction (%)
- Elapsed time (h:min)
- Citrate dose (mmol/l)
- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- BLD (%)

5.11.3.2 CVVHD with RCA

This treatment is not accessible if CVVH with RCA is configured.

Fig. 204

For **CVVHD** treatment with RCA attach the free line to the dialysate port (1) at the bottom of the filter.

All pump segments must be loaded in the pump chambers and primed prior to treatment.

For the therapy mode CVVHD with RCA only calcium-free replacement solutions are applicable.

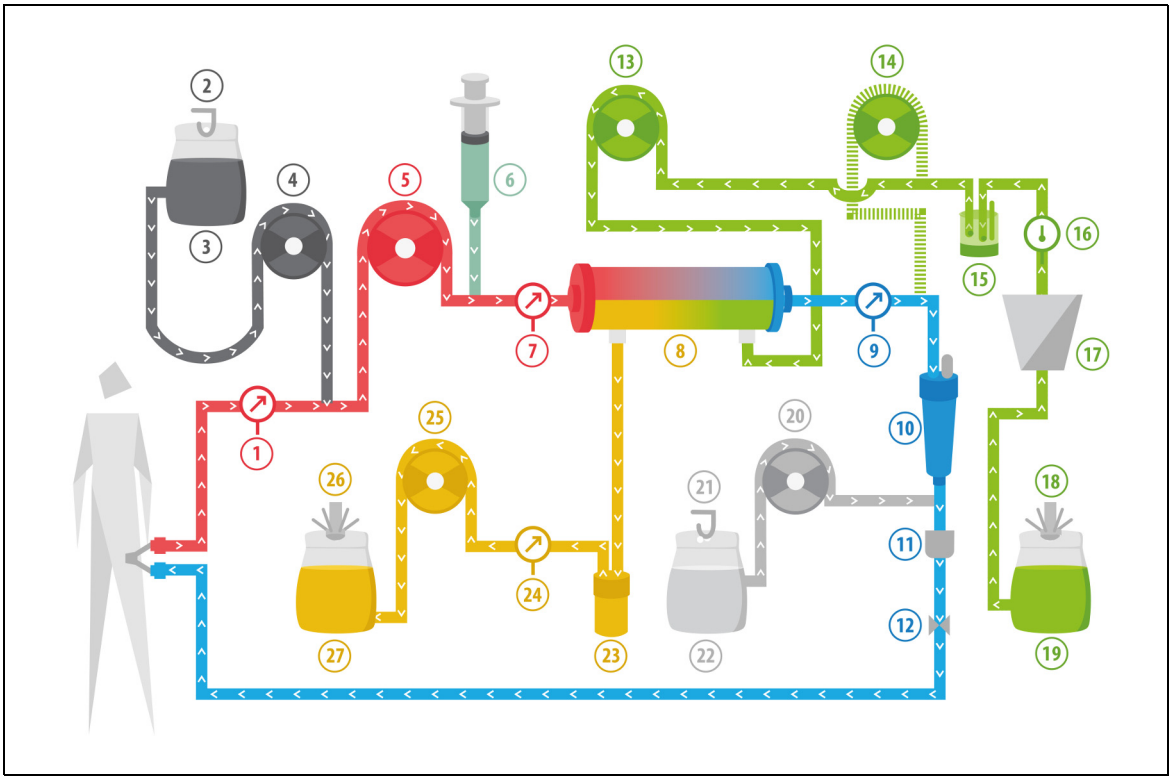


Fig. 205

No	Component	No	Component
1	Access pressure	15	Automatic degassing unit
2	Citrate scale	16	Temperature control
3	Citrate	17	Heater
4	Citrate pump	18	Dialysate scale
5	Blood pump	19	Dialysate solution
6	Heparin pump	20	Calcium pump
7	Pre-filter pressure	21	Calcium scale
8	Filter	22	Calcium
9	Return pressure	23	Blood leak detector
10	Air bubble trap	24	Effluent pressure
11	Air bubble detector	25	Effluent pump
12	Automatic clamp	26	Effluent scale
13	Dialysate pump	27	Effluent
14	Post-dilution substitution pump (not running)		

- During continuous veno-venous hemodialysis the postdilution pump is not active.
- Blood is pumped through a semi-permeable dialyser and reinfused to the patient.
- The filtrate is collected in an empty bag hanging on the filtrate scale.
- The dialysate pump delivers the dialysate to the dialyser, countercurrent to the blood flow.

The following patient parameters are entered for a CVVHD treatment with RCA:

Parameter	Range		Units	Increment	
	Adult	Low volume		Adult	Low volume
Blood flow rate	30 to 300	10 to 200	ml/min	10 ml/min	2 ml/min
Citrate flow rate	0; 20 to 650	0; 20 to 650	ml/h	1 ml/h	1 ml/h
Calcium flow rate	0; 2, to 300	0; 2, to 300	ml/h	from 2 to 30 ml in 0.2 ml/h steps from 30 to 300 ml in 1 ml/h steps	from 2 to 30 ml in 0.2 ml/h steps from 30 to 300 ml in 1 ml/h steps
Time	0 to 99:59	0 to 99:59	h:min	10 min	10 min
Fluid loss rate	0; 10 to 2,000	0 to 1,000	ml/h	10 ml/h	10 ml/h
Total fluid loss	0; 100 to 32,000	0 to 15,000	ml	100 ml	10 ml
Dialysate flow rate	0; 500 to 6,000	0; 100 to 4,000	ml/h	100 ml/h	10 ml/h
Number of bags	1 to 4	1 to 2	5 l	1 bag	1 bag
Heparin flow rate	0 or 0.5 to 15	0 or 0.5 to 15	ml/h	0.1 ml/h	0.1 ml/h
Heparin bolus	0 to 2.5	0 to 2.5	ml	0.5 ml	0.5 ml
Temperature	0 (off) or 35 to 39	0 (off) or 35 to 39	°C	0.5 °C	0.5 °C

The following patient parameters are displayed on the main screen during CVVHD with RCA:

- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- Blood flow (ml/min)
- Anticoagulant Total (ml)
- Fluid Loss Total (ml)
- Dialysate (ml and l)
- Remaining time (h:min)
- Bag change in (h:min)
- Renal dose (ml/kg/h)

NOTE The Renal dose is defined as the dose of treatment related to the patient's body weight (refer to section *5.4 Clamp and pressure test (Page 5-38)*), fluid loss rate and the pre- and post-dilution volumes.

At the start of a treatment or after a programmed value change for blood flow rate, pre-dilution flow rate, post-dilution flow rate, citrate flow, calcium flow, fluid loss rate, or patient body weight, the programmed Renal dose is displayed for the first 2 minutes after starting the balance system. After 2/10 minutes of uninterrupted therapy, the calculated Renal dose achieved is displayed based on the actual pump rates and the set patient weight.

The following patient parameters are displayed on the *More* screen during CVVHD with RCA:

- Pre-filter pressure (mmHg)
- Filtrate pressure (mmHg)
- Temperature (°C)
- Dialysate (ml and l)
- Blood volume (l)
- Next bag change in (h:min)
- UF variation (ml)
- Filtration fraction (%)
- Elapsed time (h:min)
- Citrate dose (mmol/l)
- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- BLD (%)

5.11.3.3 Bag change

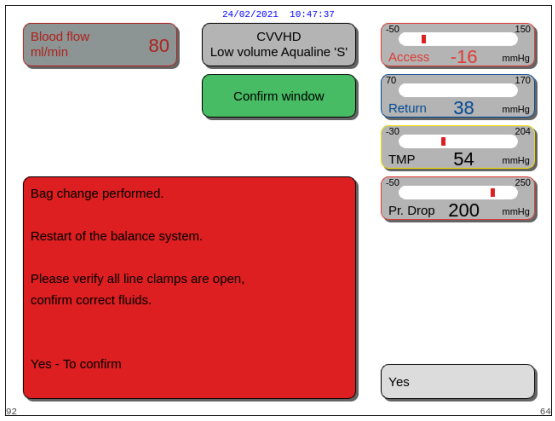


Fig. 206

Using Aqualine S or Aqualine S RCA:

Step 1: Change the bag if necessary.

▶ A *Confirm* window appears.

Step 2: Check if all lines are open, without clamps, and the correct solutions are in use. This avoids coagulation, electrolyte dysfunction and hyper- or hypovolemia.

Step 3: Select *Yes* to confirm the change.

▶ The confirm window is closed.
▶ The course of the treatment is not impacted.

5.11.4 CVVHDF (Continuous Veno-Venous Hemodiafiltration)

During Continuous Veno-Venous Hemodiafiltration, blood is driven through a hemofilter via an extracorporeal blood circuit.

Sterile, physiological substitution solution is infused into the blood circuit after the filter. Filtrate is removed simultaneously at an equal or greater rate.

Dialysate solution flows through the dialysate compartment of the filter, counter-current to the blood flow.

CVVHDF is used to achieve solute removal (small, medium and large sized molecules) and fluid balance.

The principles of clearance are convection and diffusion.

The substitution solution, dialysate solution and filtrate are controlled and balanced by the post-dilution pump, dialysate pump, the filtration pump and the scales.

Citrate anticoagulation cannot be used with CVVHDF.

Patient hazard because of use of incorrect or outdated solutions.

⇨ **Use only substitution solutions labeled for intravenous injection, of appropriate composition and prescribed by a physician.**

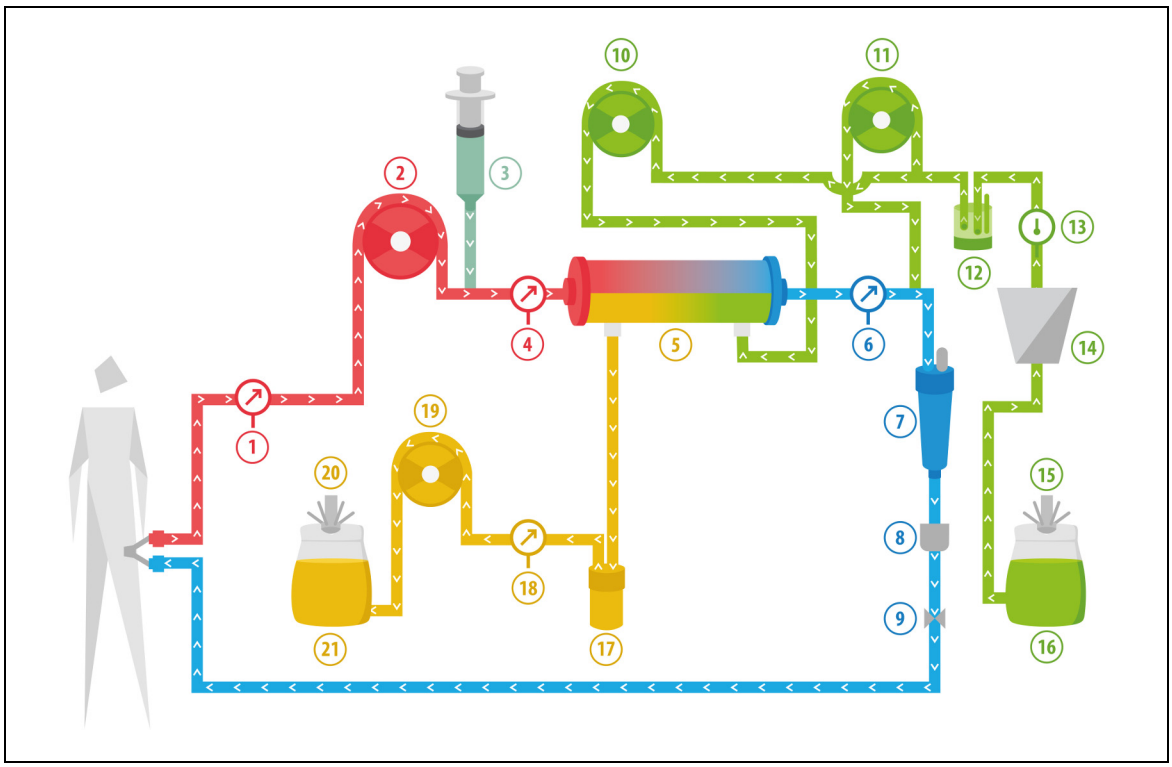


Fig. 207

No	Component	No	Component
1	Access pressure	12	Automatic degassing unit
2	Blood pump	13	Temperature control
3	Heparin pump	14	Heater
4	Pre-filter pressure	15	Dialysate and substitution scale
5	Filter	16	Dialysate and substitution solution
6	Return pressure	17	Blood leak detector
7	Air bubble trap	18	Filtrate pressure

No	Component	No	Component
8	Air bubble detector	19	Filtrate pump
9	Automatic clamp	20	Filtrate scale
10	Dialysate pump	21	Filtrate and effluent
11	Post-dilution substitution pump		

- Substitution solution and dialysate solution are administered during CVVHDF.
- All pumps are in operation.
- Blood is pumped through a hemofilter and reinfused to the patient.
- The post-dilution pump is used to administer the substitution fluid.
- The pre-dilution pump transports the dialysate to the dialyzer.
- The filtrate is collected in an empty bag hanging on the filtrate scale.

CVVHDF cannot be used if citrate anticoagulation is selected.

The following patient parameters are entered for a CVVHDF:

Parameter	Range		Units	Increment	
	Adult	Low volume		Adult	Low volume
Blood flow rate	30 to 450	10 to 200	ml/min	10 ml/min	2 ml/min
Time	0 to 99:59	0 to 99:59	h:min	10 min	10 min
Fluid loss rate	-100 to 2,000	0 to 1,000	ml/h	10/100 ml/h	10/100 ml/h
Total fluid loss	-1000 to 32,000	0 to 15,000	ml	100 ml	10 ml
Dialysate rate	0; 100 to 10,000 – post-dilution rate	0; 100 to 6,000 – post-dilution	ml/h	100 ml/h	100 ml/h
Post-dilution rate	0; 100 to 10,000 – dialysate rate	0; 100 to 4,000 – dialysate rate	ml/h	100 ml/h	100 ml/h
Number of bags	1 to 4	1 to 2	5 l	1 bag	1 bag
Heparin flow rate	0 to 15	0 to 15	ml/h	0.1 ml/h	0.1 ml/h
Heparin bolus	0 to 2.5	0 to 2.5	ml	0.5 ml	0.5 ml
Temperature	0 (off) or 35 to 39	0 (off) or 35 to 39	°C	0.5 °C	0.5 °C

The following patient parameters are displayed on the main screen during CVVHDF:

- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- Blood flow (ml/min)
- Anticoagulant total (ml)
- Total fluid loss (ml)
- Substitution (ml and l)
- Dialysate (ml and l)
- Remaining time (h:min)
- Bag change in (h:min)
- Renal dose (ml/(kg x h))

NOTE The Renal dose is defined as the dose of treatment related to the patient's body weight (refer to section *5.4 Clamp and pressure test (Page 5-38)*), fluid loss rate and the pre- and post-dilution volumes.

At the start of treatment or after a programmed value change for blood flow rate, pre-dilution flow rate, post-dilution flow rate, citrate flow, calcium flow, fluid loss rate, or patient body weight, the programmed renal dose is displayed for the first 2 minutes after starting the balance system. After 2/10 minutes of uninterrupted therapy, the calculated Renal dose achieved is displayed based on the actual pump rates and the set patient weight.

The following patient parameters are displayed on the *More* screen during CVVHDF:

- Pre-filter pressure (mmHg)
- Filtrate pressure (mmHg)
- Temperature (°C)
- Dialysate (ml and l)
- Post-dilution (ml and l)
- Blood volume (l)
- Next bag change in (h:min)
- UF variation (ml)
- Filtration fraction (%)
- Elapsed time (h:min)
- Citrate dose (mmol/l)
- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- BLD (%)

5.11.4.1 Bag change

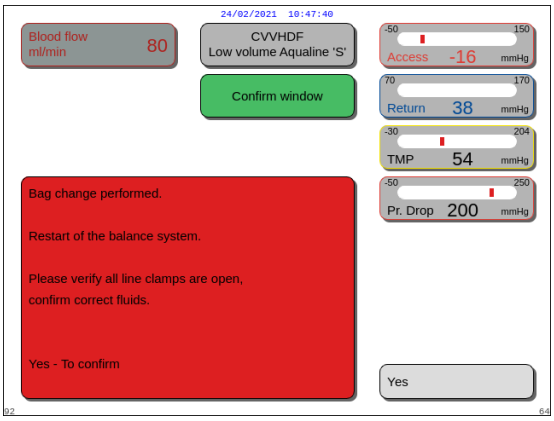


Fig. 208

Using Aqualine S:

Step 1: Change the bag if necessary.

▶ A *Confirm* window appears.

Step 2: Check if all lines are open, without clamps, and the correct solutions are in use. This avoids coagulation, electrolyte dysfunction and hyper- or hypovolemia.

Step 3: Select *Yes* to confirm the change.

▶ The confirm window is closed.
▶ The course of the treatment is not impacted.

5.11.5 TPE (Therapeutic Plasma Exchange)

During TPE, blood is driven through a plasma filter via an extracorporeal blood circuit.

Plasma is separated from the blood components and replaced by plasma replacement fluid, typically albumins or Fresh Frozen Plasma (FFP).

TPE is used to achieve the removal of toxic substances (large molecules). Fluid balance usually remains unchanged.

Plasma exchange is controlled and balanced by the plasma pump (otherwise known as the post-dilution pump), the filtration pump and the scales.

5.11.5.1 TPE Regular

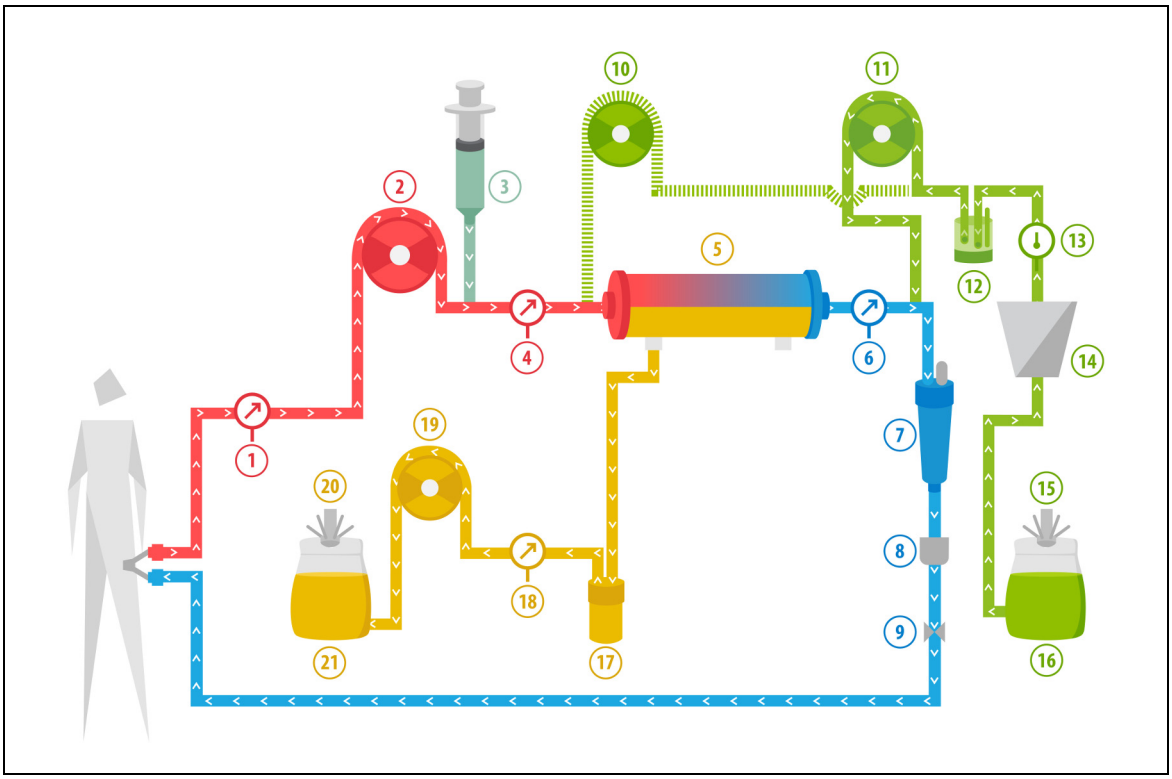


Fig. 209

No	Component	No	Component
1	Access pressure	12	Automatic degassing unit
2	Blood pump	13	Temperature control
3	Heparin pump	14	Heater
4	Pre-filter pressure	15	Substitution scale
5	Filter	16	Fresh frozen plasma or serum albumin
6	Return pressure	17	Blood leak detector
7	Air bubble trap	18	Filtrate pressure
8	Air bubble detector	19	Filtrate pump
9	Automatic clamp	20	Filtrate scale
10	Pre-dilution substitution pump (not running)	21	Waste plasma
11	Plasma pump		

- During TPE blood is pumped through a plasma filter. The corpuscular blood components are sent back to the patient.

- FFP (Fresh Frozen Plasma) or albumin solution is delivered to the patient via the post-dilution pump.
- The plasma is collected in an empty bag hanging on the filtrate scale.
- The pre-dilution pump is not operational during this treatment.

5.11.5.2 TPE with RCA

In TPE with RCA citrate solution is infused into the blood circuit before the blood pump. Calcium solution is infused into the blood circuit after the drip chamber. In TPE calcium solution could be used at the discretion of the physician.

Citrate and calcium solution volumes are controlled and balanced by citrate and calcium pumps and their respective scales. The citrate and calcium volume is taken into consideration for the patient balance.

The TPE modality can be configured to end treatment either with a substitution goal, anticoagulant fluid volume excluded, or filtration goal, anticoagulant fluid volume included. The goal of the treatment can be selected in the *Service* mode. Filtration goal: The treatment stops when the programmed fluid (citrate + calcium + plasma) has been achieved at the filtration scale. Substitution goal: The treatment stops when the programmed fluid has been achieved at the substitution scale.

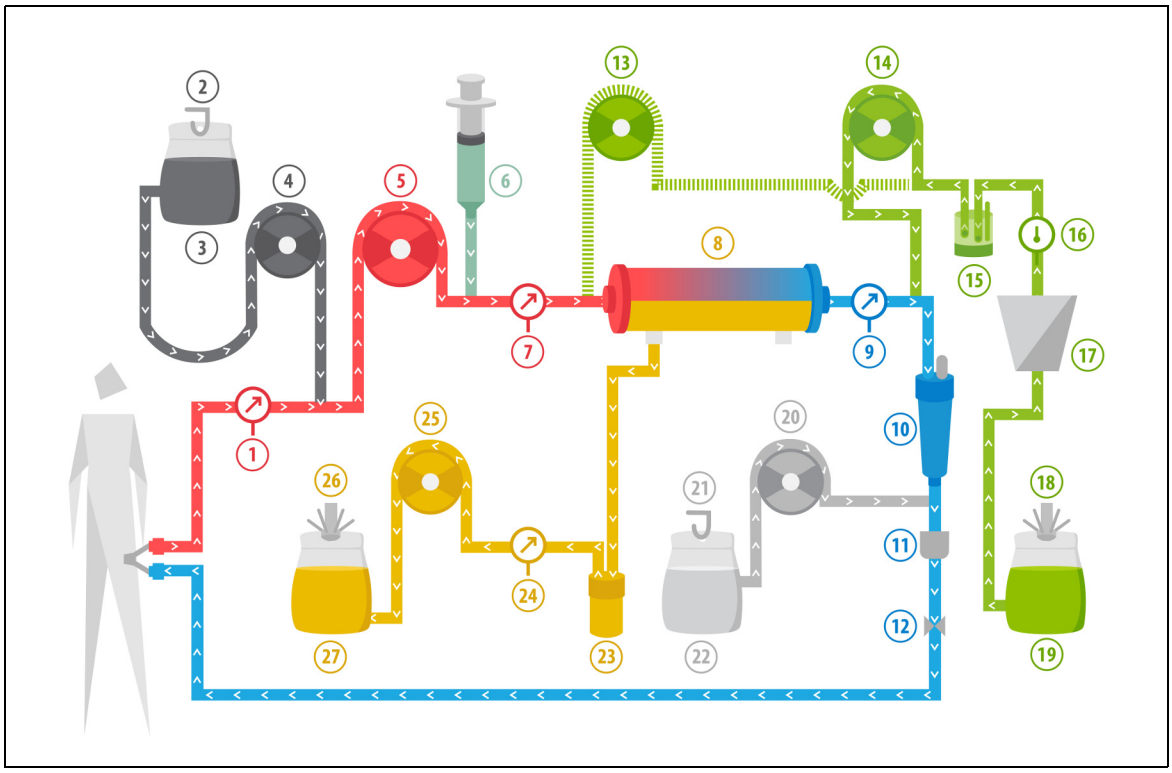


Fig. 210

No	Component	No	Component
1	Access pressure	15	Automatic degassing unit
2	Citrate scale	16	Temperature control
3	Citrate	17	Heater
4	Citrate pump	18	Substitution scale
5	Blood pump	19	Fresh frozen plasma or serum albumin
6	Heparin pump	20	Calcium pump
7	Pre-filter pressure	21	Calcium scale
8	Filter	22	Calcium
9	Return pressure	23	Blood leak detector
10	Air bubble trap	24	Filtrate pressure

No	Component	No	Component
11	Air bubble detector	25	Filtrate pump
12	Automatic clamp	26	Filtrate scale
13	Pre-dilution substitution pump (not running)	27	Waste plasma
14	Plasma pump		

5.11.5.3 Patient parameters for TPE treatments

The following patient parameters are entered for a TPE treatment without citrate anticoagulation:

Parameter	Range		Units	Increment	
	Adult	Low volume		Adult	Low volume
Blood flow rate	30 to 250	10 to 200	ml/min	10 ml/min	2 ml/min
Time	0 to 99:59	0 to 99:59	h:min	10 min	10 min
Plasma flow rate	0; 100 to 3,000	0; 10 to 1,200	ml/h	10 ml/h	10 ml/h
Total plasma volume	0 to 10,000	0 to 10,000	ml	10 ml	10 ml
Container weight	0; 30 to 5,000	0; 30 to 5,000	g	10g	10g
Heparin flow rate	0 to 15	0 to 15	ml/h	0.1 ml/h	0.1 ml/h
Heparin bolus	0 to 2.5	0 to 2.5	ml	0.5 ml	0.5 ml
Temperature	0 (off) or 35 to 39	0 (off) or 35 to 39	°C	0.5 °C	0.5 °C

The following patient parameters are displayed on the main screen during TPE:

- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- Blood flow (ml/min)
- Anticoagulant total (ml)
- Total plasma (ml)
- Remaining time (h:min)
- Bag change in (h:min)

The following patient parameters are displayed on the *More* screen during TPE:

- Pre-filter pressure (mmHg)
- Filtrate pressure (mmHg)
- Temperature (°C)
- Pre-dilution (ml)
- Post-dilution (ml and l)
- Blood volume (l)
- Next bag change in (h:min)
- UF variation (ml
- Filtration fraction (%)
- Elapsed time (h:min)
- Citrate dose (mmol/l)
- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- BLD (%)

The following patient parameters are entered for a TPE treatment with citrate anticoagulation:

Parameter	Range		Units	Increment	
	Adult	Low volume		Adult	Low volume
Blood flow rate	30 to 300	10 to 200	ml/min	10 ml/min	2 ml/min
Citrate flow rate	0; 20 to 650	0; 20 to 650	ml/h	1 ml/h	1 ml/h
Calcium flow rate	0; 2 to 300	0; 2 to 300	ml/h	from 2 to 30 ml in 0.2 ml/h steps from 30 to 300 ml in 1 ml/h steps	from 2 to 30 ml in 0.2 ml/h steps from 30 to 300 ml in 1 ml/h steps
Total plasma volume	0 to 10,000	0 to 10,000	ml/h	10 ml/h	10 ml/h
Plasma flow rate	0; 500 to 3,000	0; 100 to 1,200	ml	100 ml/h	10 ml/h
Container weight	0; 30 to 5,000	0; 30 to 5,000	g	10 g	10 g
Temperature	0 (off) or 35 to 39	0 (off) or 35 to 39	°C	0.5°C	0.5°C
Time	0 to 99:59	0 to 99:59	h:min	10 min	10 min
Heparin flow rate	0 or 0.5 to 15	0 or 0.5 to 15	ml/h	0.1 ml/h	0.1 ml/h
Heparin bolus	0 to 2.5	0 to 2.5	ml	0.5 ml	0.5 ml

The following patient parameters are displayed on the *More* screen during TPE with citrate anticoagulation:

- UF variation (ml)
- Filtration fraction (%)
- Elapsed time (h:min)
- Citrate dose (mmol/l)
- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- BLD (%)
- Pre-filter pressure (mmHg)
- Filtrate pressure (mmHg)
- Temperature (°C)
- Plasma volume (ml and l)
- Post-dilution volume (ml and l)
- Citrate total (ml)
- Calcium total (ml)
- Next bag change in (h:min)

Option filtration goal: The treatment continues until the filtration equals the programmed plasma volume (removed plasma + citrate + calcium). It may be necessary to continue the treatment to exchange the full plasma volume.

Option substitution goal: The treatment continues until all plasma is exchanged. The filtration bag contains the complete plasma exchanged including citrate and calcium infusions.

In case of *Therapy target achieved by time* or *Therapy target achieved* all treatment pumps (post-dilution and filtrate pumps) and the calcium pump will stop. The blood and citrate pumps will continue running at their programmed speed until a maximum delivery of 50 ml citrate has been reached. After 50 ml of delivered citrate, blood pump and citrate pump will stop. The citrate volume injected during this time will not be removed from the patient.

5.11.5.4 Bag change

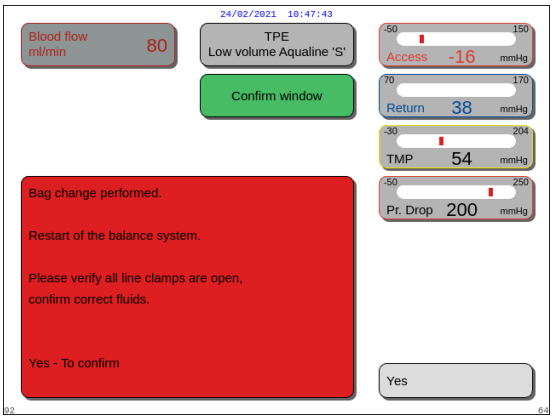


Fig. 211

Using Aqualine S or Aqualine S RCA:

Step 1: Change the bag if necessary.

▶ A *Confirm* window appears.

Step 2: Check if all lines are open, without clamps, and the correct solutions are in use. This avoids coagulation, electrolyte dysfunction and hyper- or hypovolemia.

Step 3: Select *Yes* to confirm the change.

▶ The confirm window is closed.
▶ The course of the treatment is not impacted.

5.11.6 Hemoperfusion (Blood Detoxification)

During hemoperfusion blood is driven through a hemoperfusion cartridge via an extracorporeal circuit.

Hemoperfusion is intended to remove toxic substances from the blood using a hemoperfusion cartridge.

The principle of clearance is adsorption. Substitution solutions are not used in this therapy and no filtrate is produced.

Citrate anticoagulation cannot be used with hemoperfusion.

Patient hazard because of use of incorrect disposables.

- ⇨ **Always use a hemoperfusion cartridge when performing a hemoperfusion therapy.**
- ⇨ **For all disposables which are approved and validated by NIKKISO Europe GmbH (e.g. hemoperfusion cartridge and tubing sets) follow the Instructions for Use from the relevant manufacturer.**

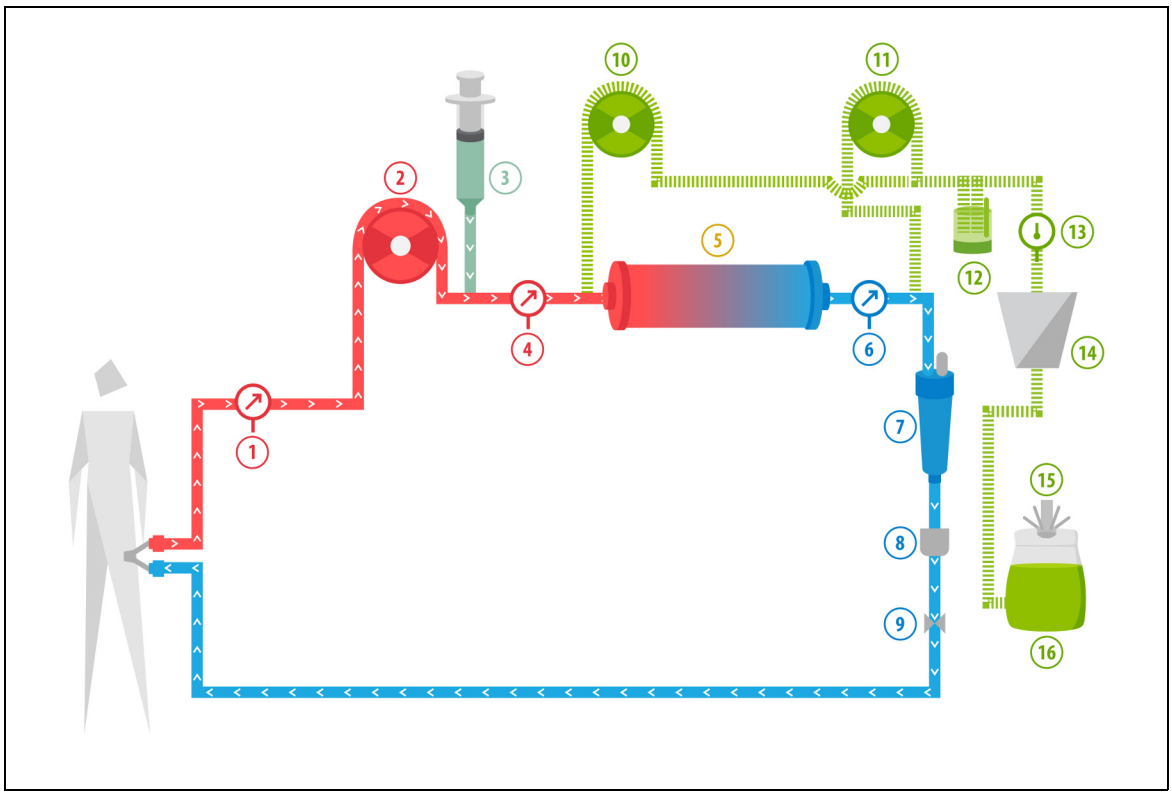


Fig. 212

No	Component	No	Component
1	Access pressure	9	Automatic clamp
2	Blood pump	10	Pre-dilution substitution pump (not running)
3	Heparin pump	11	Post-dilution substitution pump (not running)
4	Pre-filter pressure	12	Automatic degassing unit
5	Cartridge	13	Temperature control
6	Return pressure	14	Heater
7	Air bubble trap	15	Substitution scale
8	Air bubble detector	16	Priming solution

- During hemoperfusion blood is pumped through a hemoperfusion cartridge.

- Certain substances (e. g. toxins) are adsorbed and the cleansed blood is reinfused to the patient.
- Only the blood pump is in operation.

Hemoperfusion cannot be used if citrate anticoagulation is selected.

The following patient parameters are entered for a hemoperfusion treatment:

Parameter	Range		Units	Increment	
	Adult	Low volume		Adult	Low volume
Blood flow rate	30 to 450	10 to 200	ml/min	10 ml/min	2 ml/min
Time	0 to 99:59	0 to 99:59	h:min	10 min	10 min
Heparin flow rate	0 to 15	0 to 15	ml/h	0.1 ml/h	0.1 ml/h
Heparin bolus	0 to 2.5	0 to 2.5	ml	0.5 ml	0.5 ml

The following patient parameters are displayed on the main screen during a hemoperfusion treatment:

- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Blood flow (ml/min)
- Anticoagulant total (ml)
- Pressure drop (mmHg)
- Remaining time (h:min)
- Bag change in (h:min)

The following patient parameters are displayed on the *More* screen during a hemoperfusion treatment:

- Pre-filter pressure (mmHg)
- Filtrate pressure (mmHg)
- Temperature (°C)
- Pre-dilution (ml)
- Post-dilution (ml)
- Blood volume (l)
- Next bag change in (h:min)
- UF variation (ml)
- Filtration fraction (%)
- Elapsed time (h:min)
- Citrate dose (mmol/l)
- Access pressure (mmHg)
- Return pressure (mmHg)
- TMP (mmHg)
- Pressure drop (mmHg)
- BLD (%)

The TMP value displayed in hemoperfusion therapy is not transmembrane pressure. It is the pressure inside the cartridge. The hemoperfusion principle is based on adsorption. The cartridge does not have a membrane. TMP does not exist for hemoperfusion therapy.

6 Alarms and messages

6.1 Description of alarm operation

In the event of an alarm or system error:

- Visual and audible signals will be generated. Audible signals can be muted for 2 min by pressing the *Mute* key *(Audio paused)*  . However, if the alarm is not corrected after 2 min, the audible signal will start again. In addition, if another alarm or system error occurs during the mute period, an audible signal will be given immediately.
- The corresponding status light located in the operation status display (red or yellow light) will be illuminated.
- The main screen will be displayed, except when in programming screen.
- The cause of the alarm or system error will be shown in a window on the screen. With respect to multiple alarms, the alarm with the highest priority will be displayed first.
- The *Help* function will provide further information on-screen about the alarm. In the case of multiple alarms, the *Help* screen will only display information about the highest priority one.

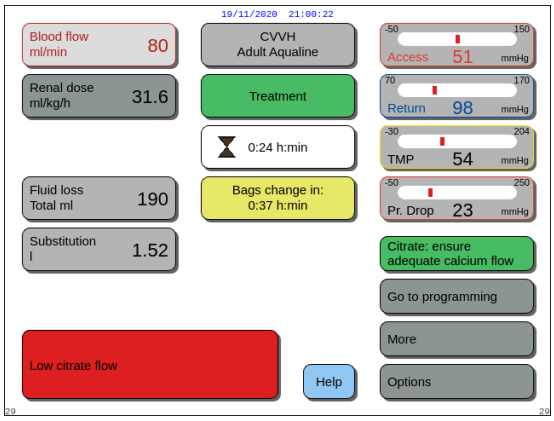


Fig. 213

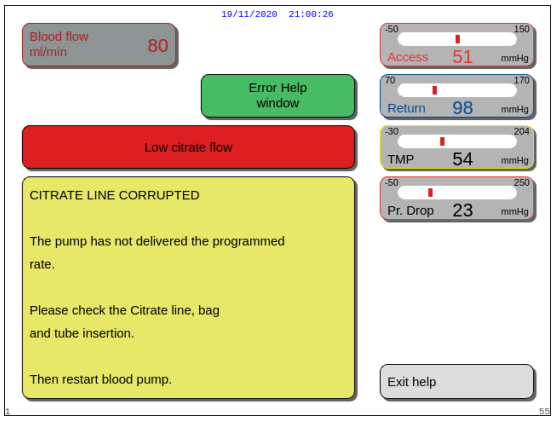


Fig. 214

- Once the alarm cause has been corrected, the treatment can be resumed by pressing either the *Treatment* key  or the *Blood pump* key  . For more details please refer to section *6.2 Alarms, messages, system errors and removal options (Page 6-5)*.

In the event of a message:

- Visual and audible signals will be generated.
- The corresponding status lights located in the operation status display will be illuminated.
- The main screen will be displayed.
- The cause of the message will be shown in a window on the screen.
- The *Help* function will provide further information on-screen about the alarm.

Should an unresolvable alarm, unresolvable failure or defect of the Aquarius system prevent controlled blood return, blood may be returned to the patient by hand. Aquarius includes a manual blood pump crank to turn the blood pump rotor. Aquarius system does not represent a life sustaining system, after replacement of the device, a chosen treatment can be continued.

6.1.1 Alarm classification

Alarms, system errors and messages are classified according to their priority.

Priority	Alarms/System Errors/Messages
High priority	System errors, *Air detected* alarm, *Return pressure low* alarm, *Blood pump off*
Medium priority	All alarms except high priority alarms
Low priority	All messages

System errors are technical alarms, all other alarms are physiologically based, messages are notifications to the operator.

6.1.2 Blood circuit alarms

In the event of a blood circuit alarm:

- Visual and audible signals will be generated.
- All pumps will stop.
- The LEDs in the *Blood pump* and *Treatment* keys will flash.
- If air or micro-foam is detected or the return pressure drops below the lower alarm limit, the return line clamp will close.

In the event of a filtrate or dialysate circuit alarm, the calcium pump stops, the blood pumpand citrate pump continue to run until a maximum of 50 ml of citrate is infused, then both pumps stop.

To reset a blood circuit alarm:

Step 1: Correct the cause of the alarm.

Step 2: Press the *Blood pump* and *Treatment* keys to resume treatment.

Alarm limit setting:

All alarm limits in the Aquarius are preset and cannot be modified by the user. After a power fail or a short brown-out, the alarm presets are unchanged.

6.1.3 Aquarius Solution Heater

The Aquarius system has an integrated heater which may be used to warm the substitution fluid before it is given to the patient.

When the treatment pumps stop for more than15 seconds and the plate temperature is above 43 °C, the fluid temperature in the heater coil can rise. In this case, the Aquarius system starts the Heater Cool Down management: the plate temperature is reduced to the programmed temperature and a yellow message *Heater cools down* is displayed on the screen.

Heater Cool Down management may take up to 10 minutes. When the temperature of the heater plate is below 42 °C, the *Heater cools down* message disappears and the treatment restarts automatically. In the case when the *Heater cools down* message was preceded by a Balance alarm, the Fluid Loss management is activated.

Heater Cool Down management: The treatment is paused until the temperature is in a safe condition (below 42 ° C). Substitution pumps will run at a slow rate to help cooling (Exception: during TFL compensation balance substitution pumps will not run).

If the temperature value on the *More* screen exceeds 40 °C and/or the heater plate temperature exceeds 57 °C at any time, a red *High temperature* alarm is generated. The fluid pumps stop until the temperature displayed on the *More* screen is below 40 °C and the heater plate temperature is below 57 °C. During this time, the red *High temperature* alarm is displayed on the screen.

When the *High temperature* alarm disappears, the treatment pumps restart automatically.

6.1.4 Fluid (filtrate, substitution, dialysate) circuit alarms

In the event of a fluid circuit alarm:

- Visual and audible signals will be generated.
- The filtrate, pre-dilution and post-dilution pumps will stop.
- The LED in the *Treatment* key will flash.

In addition, if citrate anticoagulation is used:

- The calcium pump will stop.
- The blood pump and the citrate pump will run at their relevant flow rates until maximum 50 ml of citrate is infused. The rates are specific to the activation of the blood and citrate pump links.
- The filtration pump runs at the citrate pump flow rate. If the UF variation is negative, the filtration pump will stop.

In the event of a red *High temperature* or *Balance alarm* followed by a yellow *Heater cools down* message, the citrate pump runs at a reduced speed and the calcium pump is stopped resulting in an infusion of citrate without calcium while the *Heater cools down* message is displayed. The filtration pump speed is automatically set to zero if the UF deviation is negative.

To reset a fluid circuit alarm:

Step 1: Correct the cause of the alarm.

Step 2: Press the *Treatment* key to resume treatment.

6.1.5 Total Fluid Loss (TFL) management

Treatment pumps run to achieve the programmed ultrafiltration volume (or fluid loss volume). The balance scales measure the difference between the substitution volume and the filtration volume, which is the ultrafiltration volume. A balance alarm occurs in an adult case when a 50 g (20 g for low volume) difference is detected between the programmed ultrafiltration volume and the actual ultrafiltration volume. When the pumps are reactivated by pressing the *Treatment* key, the volume discrepancies are automatically compensated for by the system. This function is Total Fluid Loss (TFL) management.

When a balance alarm occurs, a yellow box will indicate the number of counted balance alarms detected during a 20 minute period. If within 20 minutes 5 counted balance alarms are detected, a red box will be displayed to inform the operator that the treatment has stopped. Only the blood pump continues. At this time press the *Next* button, to go to *Disconnection* mode. Follow the instructions in section *5.9 (Page 5-69)*.

The balance alarm count will reset to zero only after the Aquarius system operates for 20 minutes continuously without stopping the pumps. An alarm that stops the balancing system or the operator manually stopping the balancing system, will re-start the 20 minute period.

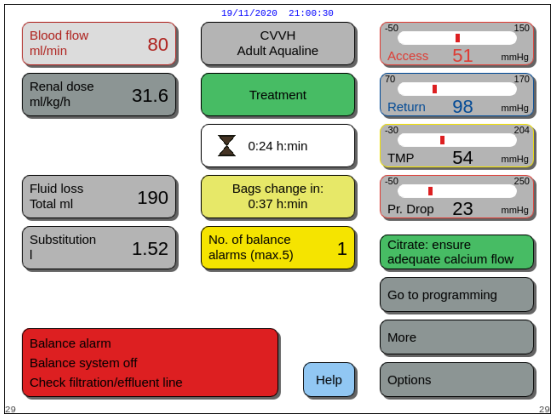


Fig. 215

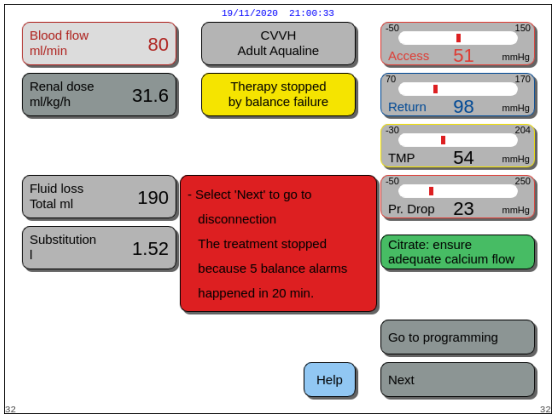


Fig. 216

TFL volume compensation may be delayed if a *Heater cools down* message is displayed. When the *Heater cools down* message disappears, the balance alarm fluid discrepancy will be automatically compensated for by the system.

Risk of hyper- or hypovolemia by the weight deviations greater than ±120 g.

If the weight deviations generate a balance alarm but its count does not increase, the UF variation will be reset to the value displayed before the deviation occurred. The weight deviation will not be compensated when the treatment is restarted because it is not related to the patient fluid deviation.

- ⇨ **Always stop the balance system when adding or removing a bag from the scale during the treatment.**
- ⇨ **Repair all fluid leaks immediately.**
- ⇨ **Do not move the Aquarius system while the balance system is active.**

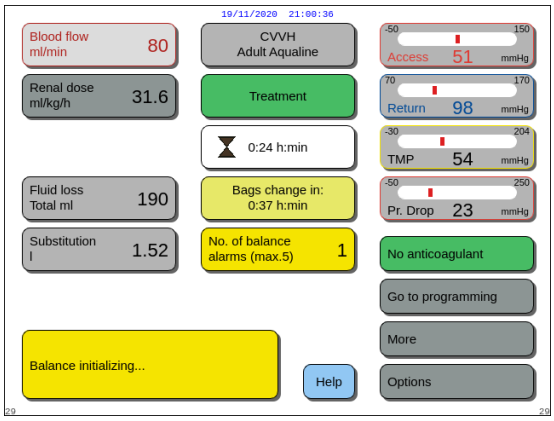


Fig. 217

NOTE

During TFL compensation, the message *Balance initializing…* is displayed.

6.1.6 Citrate/calcium circuit alarms

In the event of citrate/calcium circuit alarms when using citrate anticoagulation:

- Visual and audible signals will be generated.
- The treatment pumps and the calcium pump will stop.

In addition, for alarms other than *Citrate pump failure*, *Citrate turnover failure*, *Clamp on citrate line* and *Citrate bag missing*:

- The LED in the *Blood pump* key  and the *Treatment* key  will flash.
- The blood, treatment and citrate pumps will stop.

For the alarm *Citrate bag change*:

- 20 seconds before the *Citrate bag change* alarm occurs, the balance pumps and the calcium pump stop. When the alarm occurs also the blood and citrate pumps stop.
- The LEDs in the *Treatment* key  and the *Blood pump* key  will flash.

To reset a citrate/calcium circuit alarm:

Step 1: Correct the cause of the alarm.

Step 2: Press the *Blood pump* key  to resume treatment.

6.1.7 Blood pump stop program

When citrate anticoagulation is used, the blood and citrate pumps will continue running until the maximum volume of 50 ml of citrate is infused. After 50 ml of delivered citrate, blood pump and citrate pump will stop. The amount of citrate volume injected will be removed after restart of the treatment pumps.

6.2 Alarms, messages, system errors and removal options

6.2.1 Alarms

If the Aquarius system detects an out-of-range condition during the system test or during operation or if parameters exceed or drop below the respective limits, an alarm message is generated and the Aquarius system switches to the safety mode. The alarm is accompanied by an audible alert. Please note that some alarms require a manual restart of the blood pump.

All alarms lead to the defined alarm reaction on the Aquarius system. No alarm can be suppressed by an alarm of higher priority. The plain text on the screen displays the alarm reason for the alarms with the highest priorities. In maximum, four alarm reasons can be displayed on the screen in parallel.

Do not repeatedly clear alarms and restart the treatment without having identified and solved the alarm cause.

Alarm delay times consist of maximum alarm condition and alarm signal generation delay time. The alarm signal generation delay time can be at maximum 3 s, so that the indicated alarm times vary in a range of +0/-3 s. The mean alarm delay time is the indicated maximum alarm delay time minus 0.5 s. The Aquarius does not delay the alarm condition.

* L (Latched) – Alarm is NOT reset if an alarm condition is no longer present

**NL (Non-latched) – Alarm is reset if an alarm condition is no longer present

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Air detected	64	≤1 s	L	• Return tubing line contains air or micro-foam. • The return line is not properly positioned. • The blood level is too low in the return chamber. • The detector is malfunctioning.	⇨ Make sure that the tubing line does not contain air. ⇨ Check access and filter connections for sources of air leaks. ⇨ When you clear the *Air detected* alarm, make sure there is no air or foam trapped in the line between the drip chamber and the patient end. To remove air from the tubing line: **1.** Attach syringe to the top of the return chamber after carefully releasing the pressure from the line. **2.** Press the *Clamp* key  to open the ***return*** line clamp. **3.** Remove all air from the return chamber with the syringe. **4.** Place the tubing back into the air detector and put it back in place. **5.** If level in the drip chamber is correct and the bubbles are out of the tubing, press the *Clamp* key to close the return line clamp. **6.** Resume treatment by pressing the *Blood pump* key. **If the *Air detected* alarm does not clear and air is visible in the return drip chamber, disconnect the patient from the instrument and recirculate per your centre's procedure.** NOTE You may see microbubbles smaller than the air detector sensitivity.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Balance alarm **Check substitution /dialysate line** or **Balance alarm** **Check filtration/ effluent line**	70 99 70 100	≤20 s	L	If the *Balance alarm* is counted (see the alarm counter in the yellow box on the main screen) it indicates that: • The patient's fluid balance deviates more than 50 g in adult treatment or 20 g in low volume treatment for more than 15 s. The deviation is less than 120 g. • The deviation could not be compensated during TFL. Possible causes are: • Fluid lines/manifold set is kinked or clamped. • Snap connection on fluid bag is not broken. • Bags are swinging on scales or touching the cart frame of the Aquarius. • When multiple bags are hung on the scale, if the bags are touching each other or the tubing lines are resting on the cart frame, the draining of the bags can cause them to shift position, resulting in a temporary weight change on the scale. • Tubing lines are supported by and are resting on the cart frame. • Fluid is leaking or a bag is detached from the scale. • Touching the filtrate or substitution bags while the balance system is active. • Adding or removing a bag without stopping the Balance system. • Moving the Aquarius system while the Balance system is active.	**1.** If the *Balance alarm* is counted, ensure that: - All clamps are open. - Lines and bags are hanging freely. - Lines and bags are not kinked or blocked. - Bag connections are correct - Bags and lines are not resting on the cart frame **2.** Restart the balance pumps by pressing the *Treatment* key.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Balance alarm **Check substitution /dialysate line** or **Balance alarm** **Check filtration/ effluent line** (continu-ation)				If the *Balance alarm* is **not** counted (see the alarm counter in the yellow box on the main screen) it indicates that: • The patient's fluid balance deviates more than 120 g for more than 15 seconds. Possible causes are: • Bags are swinging on scales or touching the cart frame of the Aquarius system. • When multiple bags are hung on the scale, if the bags are touching each other or the tubing lines are resting on the cart frame, the draining of the bags can cause them to shift position, resulting in a temporary weight change on the scale. • A bag is detached from the scale. • Adding or removing a bag without stopping the Balance system. • Moving the Aquarius system while the active Balance system.	**1.** If the *Balance alarm* is **not** counted, ensure that: - All bags are hanging on the scale. - All bags are hanging freely and do not move. **2.** Restart the balance pumps by pressing the *Treatment* key.
Balance system off	84	≤305s	L	The balance system has been off for 5 min. All fluid pumps have stopped.	⇨ Correct the cause and switch balance system on again.
Blood flow failure	89	≤10 s revolu-tion direction ≤35 s Flow deviation ≤65 s Blood pump does not rotate	L	The number of revolutions of the blood pump exceeds or falls below the alarm limits by ±5%.	⇨ Check blood flow rate. ⇨ Check blood pump tubing. ⇨ Check tubing set for narrow sections.
Blood leak	69	≤10 s	L	• Filtrate/plasma contains blood. • Filter membrane is damaged/ ruptured.	**1.** Discontinue the treatment. **2.** Exchange the circuit.
				• During treatment the BLD chamber has been removed from its housing. • BLD chamber not filled with fluid.	⇨ Reposition the BLD chamber. ⇨ Go to *Reprime* and choose ultrafiltrate line.
				• Dust on mirror of housing.	**1.** Remove mirror. **2.** Clean it and install at the same position.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Blood pump off	83	≤65 s	L	The blood pump has not been running for 1 min.	⇨ Press *Blood pump* key to switch blood pump on again.
Calcium bag change	171	≤15 s	L	The calcium bag is empty.	**1.** Wait for blood pump to stop. **2.** Exchange empty calcium solution bag for a new one filled with calcium solution.
Calcium bag missing	107/ 169	≤15 s	L	No bag is hung on the calcium scale.	**1.** Hang a calcium solution bag on the calcium scale. **2.** Press the *Blood pump* key to resume the treatment.
Calcium/ Citrate scale overload	165	≤5 s	L	Too much weight is hung on citrate and/or calcium scales (limit = 2.2 kg).	⇨ Hang on calcium/citrate scale only one calcium/citrate bag of less than 2.2 kg.
Check citrate ratio	80	≤65 s	NL	• The citrate concentration in the blood is outside the range of 2.5 mmol/l to 5 mmol/l. • The programmed ratio between blood flow and citrate flow has changed by more than 20%.	⇨ Correct citrate- and blood flow rates to achieve the intended concentration and ratio. ⇨ Press the *Blood pump* key to suppress the alarm for one hour.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Check degassing chamber	157	≤30 s	NL	• The motor works for more than 25 s without detecting a filled chamber.	⇨ Check if all clamps are open. ⇨ Check if the substitution line is kinked. ⇨ Check if the 4 way connector is kinked. ⇨ Check if the frangible pins of the bags are well broken.
				• The hydrophobic filter is blocked (measured pressure less than -300 mmHg).	**1.** Clamp the line to the hydrophobic filter. **2.** Open the clamp to the substitution line or from the 4 way connector. **3.** Disconnect the line with the hydrophobic filter. **4.** Open the clamp and reconnect it. **5.** Press the *Mute* key.
				• The system detects a positive pressure higher than +30 mmHg. • The system test fails.	⇨ After system test: degassing pressure sensor or degassing module defect. Do not use the Aquarius system and call Technical Service. ⇨ During use: pressure sensor detects less than -300 mmHg. Degassing filter is wet. Clamp the pressure line, disconnect filter from sensor and use a syringe to dry it. Reconnect the line and unclamp it.
				• The fluid is detected in the ADU sensor line. **A *Check degassing chamber* alarm occurs during the first two minutes of priming (post-dilution line) and fluid is in the heater line, up to 120 mL of dialysate or substitution fluid may be pumped into the saline bag when the alarm is cleared and priming restarts. When priming completes, replace the saline bag and reprime the blood circuit if the dialysate or substitution fluid is not indicated for infusion.**	⇨ When an ADU alarm (*Check degassing chamber, No degassing chamber detected,* or *Degassing chamber missing*) cannot be cleared anytime during self-test, setup, priming or treatment, remove the Aquarius system from service and call Technical Service.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Check substitution /dialysate line or **Check filtration/ effluent line**	99 100	≤5s	L	Balancing deviates from the set values entered by the operator.	⇨ Check flow rates of the pumps. ⇨ Check fluid removal and turnover input parameters. NOTE Potentially pumps cannot deliver program with very high volume because of pressure peaks. ⇨ Check bag hanging on scale (filtration or substitution). ⇨ Check tubing set for narrow sections (filtration or substitution).
Check the blood for coagulation	104	≤5 s	L	The blood pump is switched off for more than 5 minutes.	Risk of blood clotting in the extracorporeal circuit. ⇨ Check the blood line for clotting.
Check the blood for coagulation and **Replace filter and set**	104 110	≤5 s	L	The blood pump is switched off for more than 15 minutes.	⇨ Check the blood line for clotting. If no clotting detected: **1.** Clear the alarm by pressing the *Blood pump* key. **2.** Restart the blood pump. In case of clotting: **1.** Terminate the treatment. **2.** Disconnect the patient. **3.** To continue, start a new treatment with a new filter and a new tubing system.
Check transducer connections	95	≤20 s	NL	The pressure domes have not detected any pressure change for 15 s.	⇨ Ensure the domes are properly connected. IMPORTANT: do not remove any pressure sensors. ⇨ If domes are in place: increase blood pump speed if return pressure reading is low.
Citrate bag change	170	≤15 s	NL	The citrate bag is empty.	**1.** Wait for blood pump to stop. **2.** Exchange empty citrate solution bag for a new one filled with citrate solution.
Citrate bag missing	106/ 168	≤15 s	L	No bag is hung on the citrate scale.	**1.** Hang a citrate solution bag on the citrate scale. **2.** Press the *Blood pump* key to resume treatment.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Citrate module comm. failure	160	≤5 s	L	No communication between Master and Citrate module.	⇨ Restart the treatment by pressing the *Blood pump* key. ⇨ If the alarm is repeated frequently, terminate the treatment and pass the device over to the Technical Service.
Clamp heparin line	94	≤5 s	L	The heparin syringe has been removed.	⇨ Clamp anticoagulant line.
CPU2: balance alarm	109	≤30 s	L	The Controller detects a balance deviation of more than 75 g.	⇨ Check substitution and filtration line for obstacles or clamps. ⇨ Restart balance system. ⇨ If the alarm is repeated frequently, terminate the treatment and pass the device over to the Technical Service.
Degassing chamber missing	76	≤20 s	NL	The substitution degassing chamber is not inserted or the sensors are defective.	**1.** Insert the substitution chamber properly. **2.** Ensure the chamber is in contact with the sensor of the holder. **3.** Start balance pumps. ⇨ When an ADU alarm (*Check degassing chamber, No degassing chamber detected,* or *Degassing chamber missing*) cannot be cleared anytime during self-test, setup, priming or treatment, remove the Aquarius system from service and call Technical Service.
Filtrate flow failure	90	≤310 s	L	The number of revolutions of the pump exceeded or fell below the alarm limits by ±5%.	⇨ Check filtration flow rate. ⇨ Check filtration tubing. ⇨ Check tubing set for narrow sections.
Filtration fraction too high	111	≤5 s	NL	The filtration fraction is above 43%.	**1.** Increase blood flow. **2.** Reduce the substitution flow
Heparin syringe missing	116	≤5 s	L	• Heparin rate has been programmed and no syringe has been inserted in the plunger. • The syringe is not inserted properly.	**1.** Correctly insert heparin syringe if heparin is needed. **2.** Press the *Blood pump* key to resume treatment. **1.** Set anticoagulant rate to zero if anticoagulant is not required. **2.** Press the *Blood pump* key to resume treatment.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
High access pressure	68	≤5 s	NL	• Access pressure has exceeded the upper alarm limit. • Coagulation in the return drip chamber. • Problem with the catheter. • Lines are kinked.	⇨ Change the Aqualine tubing set. ⇨ Check position of patient access. ⇨ Check access blood line, including access and pre-filter sensors, for kinks or occlusions. ⇨ Press the *Blood pump* key to resume treatment.
High calcium flow	162	Depends on flow: from 60 s to 3330 s	L	• Balancing exceeds the set calcium values entered by the operator more than 5%.	**1.** Reduce the number of substitution and filtrate bags per scale. **2.** Restart the blood pump and continue the treatment. **3.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
				• Calcium pump runs too fast.	**1.** Ensure calcium bag is not moving. **2.** Restart the blood pump and continue the treatment. **3.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
				• Pump segment diameter is out of tolerance.	⇨ Stop treatment and change lines if the alarm occurs repeatedly. Control patient’s systemic calcium.
				• Calcium bag is touching another bag or tubing set line.	**1.** Ensure calcium bag is not moving e. g. after a bag change. **2.** Ensure calcium bag is not touched by another bag or tubing line. **3.** Restart the blood pump and continue the treatment. **4.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
High citrate flow	161	Depends on flow: from 60 s to 330 s	L	• Balancing exceeds the set citrate values entered by the operator more than 5%.	**1.** Reduce the number of substitution and filtrate bags per scale. **2.** Restart the blood pump and continue treatment. **3.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
				• Pump segment is not inserted.	**1.** Ensure pump segment is inserted in citrate pump. **2.** Restart the blood pump and continue treatment. **3.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
				• Citrate pump runs too fast.	**1.** Control patient for citrate intoxication if pump segment was not inserted and citrate rapidly infused by the blood pump. **2.** Restart the blood pump and continue treatment. **3.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
				• Pump segment diameter is out of tolerance.	**1.** Stop treatment and change lines if the alarm occurs repeatedly. **2.** Restart the blood pump and continue treatment. **3.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
High citrate flow (continu-ation)				• Citrate bag is touching another bag or tubing set line.	**1.** Ensure citrate bag is not moving e. g. after a bag change. **2.** Ensure citrate bag is not touched by another bag or tubing line. **3.** Restart the blood pump and continue treatment. **4.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
High filtrate pressure	81	≤5 s	NL	Filtrate pressure exceeds upper alarm limits.	⇨ Check pressure sensor. ⇨ Check tubing set for narrow sections. ⇨ Check filter and exchange circuit if required. ⇨ Check ratio between blood flow and filtration.
High pre-filter pressure	73	≤5 s	NL	• The pre-filter pressure exceeds upper alarm limit. • A rapid increase in pre-filter pressure without any change in parameters indicates membrane clogging, overall filter clotting or coagulation in the return drip chamber.	⇨ Check pressure sensor. ⇨ Check filter and exchange circuit if required. ⇨ Check blood flow. ⇨ Check tubing set for narrow sections. ⇨ Check access line for kinks or occlusions. ⇨ In case of clotting, prepare to end treatment; increase pre-dilution flow rate and blood flow rate on next circuit.
High return pressure	66	≤5 s	NL	• Return line is kinked or clamped. • Return chamber is clotting. • Return line is occluded or clotted.	⇨ Check return line for kinks or occlusions. ⇨ Prepare to end the treatment. ⇨ Check position of patient access. ⇨ Check return pressure transducer. In the case of a faulty transducer, stop treatment and call Technical Service.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
High temperature	77	≤15 s	NL	• Temperature value on the *More* screen exceeds 40 °C. (For more information regarding the temperature displayed on the *More* screen, see section *5.8.8 (Page 5-64)*.) • The Aquarius device detects a plate temperature of the heater above 57 °C.	**1.** Check for air inside the heater coil. **2.** If air is present, remove the air by shaking the heater coil when the pumps have restarted. **3.** Ensure that the heater door is closed after reinsertion of the heater coil. **4.** Wait until the temperature has cooled down. ▶ If the alarm disappears the treatment pumps will start automatically. **In the event of a red *High temperature* alarm followed by a yellow *Heater cools down* message, the citrate pump runs at a reduced speed and the calcium pump is stopped resulting in an infusion of citrate without calcium while the *Heater cools down* message is displayed. The filtration pump speed is automatically set to zero if the UF deviation is negative.**
High TMP	71	≤5 s	NL	• TMP has risen slowly – filter is clogging. • TMP has risen rapidly – filtrate line or bags clamped or kinked. • High TMP from the start.	⇨ Check *More* screen for pressure details. The rate of change over initial TMP (with same filtration and exchange rate) indicates pressure changes in the filter. ⇨ Reduce post-dilution flow rate and increase pre-dilution flow rate. ⇨ Unclamp or remove kink from line. ⇨ Check blood flow/exchange ratio. ⇨ Increase blood flow rate accordingly.
Keyboard failure	85	≤65 s	L	A key press longer than 60 s was detected by the master CPU.	⇨ If alarm does not clear, call Technical Service.
Line/ Substitution failure	96/ 97	≤5 s	NL	A substitution deviation is detected that influences the patient balance.	⇨ Check lines. ⇨ Check clamps. ⇨ Check bags. ⇨ Check for leakages.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Low access pressure	67	≤5 s	NL	• Access pressure has dropped below the lower alarm limit. • Catheter is not in the correct position. • Problem with the catheter. • Lines are kinked.	⇨ Check blood flow rate. NOTE If blood flow rate is changed, check the filtration fraction displayed on the *More* screen. ⇨ Check position of the catheter and of the patient access. ⇨ Reprime catheter or change it. ⇨ Check access blood line, including access and pre-filter sensors, for kinks or occlusions.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Low calcium flow	173	Depends on flow: from 60 s to 3330 s	L	• Balancing deviates from the set calcium values entered by the operator by 5%.	**1.** Reduce the number of substitution and filtrate bags per scale. **2.** Restart the blood pump and continue the treatment. **3.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
				• Calcium pump segment improperly installed into the calcium pump or not installed at all.	**1.** Check calcium pump segment of tubing set for proper installation. **2.** Restart the blood pump and continue the treatment. **3.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
				• Calcium pump segment not correctly primed.	**1.** Check Calcium tubing set including connection to Aqualine for closed clamp or kink. **2.** Control calcium line and calcium bag connection. **3.** Control calcium line and Aqualine tubing set connection. **4.** Restart the blood pump and continue the treatment. Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
				• Pump segment diameter is out of tolerance.	⇨ Stop treatment and change lines if the alarm occurs repeatedly. Control patient’s systemic calcium.
				• Calcium bag is touching another bag or tubing set line.	**1.** Ensure calcium bag is not moving e. g. after a bag change. **2.** Ensure calcium bag is not touched by another bag or tubing line. **3.** Restart the blood pump and continue the treatment. **4.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Low citrate flow	172	Depends on flow: from 60 s to 330 s	L	• Balancing deviates from the set citrate values entered by the operator by 5%.	**1.** Reduce the number of substitution and filtrate bags per scale. **2.** Restart the blood pump and continue treatment. **3.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
				• Citrate pump segment improperly installed into the citrate pump or not installed at all.	**1.** Check citrate pump segment of tubing set for proper installation. **2.** Restart the blood pump and continue treatment. **3.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
				• Citrate pump segment not correctly primed.	**1.** Check citrate tubing set including connection to Aqualine for closed clamp or kink. **2.** Control citrate line and citrate bag connection. **3.** Control citrate line and Aqualine tubing set connection. **4.** Restart the blood pump and continue treatment. Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
				• Pump segment diameter is out of tolerance.	**1.** Stop treatment and change lines if the alarm occurs repeatedly. **2.** Restart the blood pump and continue treatment. **3.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Low citrate flow (continuation)				• Citrate bag is touching another bag or tubing set line.	**1.** Ensure citrate bag is not moving e. g. after a bag change. **2.** Ensure citrate bag is not touched by another bag or tubing line. **3.** Restart the blood pump and continue treatment. **4.** Check the patient's systemic calcium level (see section *2.4 (Page 2-2)*) and, if necessary, reduce or increase the calcium flow.
Low filtrate pressure	82	≤5 s	NL	Filtrate pressure falls below the alarm limits.	⇨ Check pressure sensor. ⇨ Check tubing set for narrow sections. ⇨ Check filter and exchange circuit if required. ⇨ Check ratio between blood flow and filtration.
Low pre-filter pressure	74	≤10 s	NL	The pre-filter pressure falls below the alarm limit.	⇨ Check pressure sensor. ⇨ Check filter and exchange circuit if required. ⇨ Check blood flow. ⇨ Check tubing set for narrow sections. ⇨ Check access line for kinks or occlusions. ⇨ Press the *Blood pump* key to resume treatment (in case of low pre-filter pressure). ⇨ In case of clotting, prepare to end treatment; increase pre-dilution flow rate and blood flow rate on next circuit.
Low return pressure	65	≤5 s	L	• Blood flow rate is too low.	⇨ Increase blood speed.
				• Blood pump has stopped.	⇨ Clear any initial alarm and restart blood pump.
				• Return line is disconnected.	⇨ Reattach the return line to the catheter.
Low temperature	78	≤610 s	NL	The heater plate temperature has been below 33 °C for more than 10 min.	⇨ Check substitution temperature setting. ⇨ Ensure that the substitution solution bags are warm enough (ambient temperature) for infusion.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Low TMP	72	≤20 s	NL	• Filtration pump runs slower than the dialysate pump. • The filtrate line is closed between filter and bag.	⇨ Check *More* screen for pressure details. The rate of change over initial TMP (with same filtration and exchange rate) indicates pressure changes in the filter. ⇨ Modify blood flow rate and/or fluid exchange, this will impact the blood flow-to-fluid removal or blood flow-to-turnover ratio.
Main battery high	88	≤10 s	NL	A high voltage has been detected in the main battery.	⇨ If alarm does not clear, call Technical Service.
Master key transfer	86	≤85 s	L	• A key press longer than 60 s was detected by the master CPU. • Short disturbances in the communication between the master and the controller CPU.	⇨ Clear the alarm by pressing the *Blood pump* key. ▶ The error is automatically cleared by the system; the alarm is to notify the user that an issue occurred only. ⇨ If alarm does not clear, call Technical Service.
Maximum treatment time	117	≤5 s	L	Max. blood pump run time reached.	⇨ Terminate the treatment. ⇨ Disconnect the patient. ⇨ To continue, start a new treatment with new filter and a new tubing system.
Post-dilution failure	91	≤310 s	L	The number of revolutions of the pump exceeded or fell below alarm limits by ±5%.	⇨ Check post-dilution flow rate. ⇨ Check post-dilution tubing. ⇨ Check tubing set for narrow sections.
Pre-dilution failure	92	≤310 s	L	The number of revolutions of the pump exceeded or fell below alarm limits by ±5%.	⇨ Check pre-dilution rate. ⇨ Check pre-dilution tubing. ⇨ Check tubing set for narrow sections.
Pump door, **Pump door open**	75, 118	≤5 s	NL	One of the pump doors is open.	⇨ Close the door.
				During *Preparation* mode, before *Start priming* mode, the Aquarius system did not detect an activated door switch.	⇨ Open and close all pump doors. If the alarm persists, contact Technical Service.
Replace filter and set	110	≤5 s	L	Notifies the operator that the machine has been running for more than the maximum treatment time. The message can be silenced 8 times for 1 h.	⇨ Disconnect and start a new treatment with a new filter and a new tubing system.
Syringe empty: change in Options	119	≤5 s	L	The heparin syringe is empty.	⇨ Select *Options* and replace the empty syringe by a filled one. ⇨ Select *Options* and program heparin flow to zero if no further heparin is used.

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal
Temperature controller	79	≤20 s	NL	High temperature of the heater at the controller.	⇨ Refer to the *Options* for error removal of the error message *High temperature*. ⇨ If the alarm persists, contact Technical Service.
Turn over deviation	98	≥605 s	L	Balance pump speed is consistently higher (or lower) than the programmed speed for more than 20 consecutive minutes to ensure accurate fluid delivery. Possible causes are: • Fluid leakage. • Fluid delivery restrictions due to: - Incorrect line installation (kinked tubes, closed or partially closed clamps, twisted lines). - Incorrect bag installation (incorrect spiking of the substitution bag, spike or frangible pin blocking the fluid path, frangible pin only partially broken, bag not hanging freely, bag swinging). • Pump calibration out of range. • Filter inappropriate for fluid delivery rates.	**1.** Stop the balance pumps. **2.** Check for fluid leakage. **3.** Ensure lines and bags are hanging freely. **4.** Ensure lines and bags are not kinked or blocked. **5.** Check that all clamps are open. **6.** Ensure that the bags are not swinging. **7.** Ensure filter is capable of the prescribed flow rates. If necessary, use a larger surface area filter. **8.** Restart the balance pumps. **9.** If the problem persists, contact Technical Service.

6.2.2 Messages

If the Aquarius system detects out-of-range conditions or reminders that do not conform to the intended use of the system. The message is accompanied by an audible alert. The operator gets detailed information defined for the individual conditions and the system switches to the safety mode.

Do not repeatedly clear messages and restart the treatment without having identified and solved the message cause.

Display	ID	Cause	Options for error removal
Air detected	128	• Air detection system does not detect "air free" tubing. • The *Clamp and pressure test* is disabled.	⇨ Make sure that the tubing set does not contain air. ⇨ Make sure that the return line is properly installed in the clamping system of the air detector. ⇨ Ensure that the return line is not scratched at the contact part.

Display	ID	Cause	Options for error removal
Balance initializing…	126	Scales and fluid pumps initialize: • when the balance system is started • when the balance system is controlled during treatment • during TFL volume compensation.	This is a reminder. No actions are needed.
Balance system off	113	The balance system is off, all fluid pumps are stopped.	⇨ Correct the cause and switch the balance system on again.
Blood detected	122	During the connection or recirculation phase blood is detected in the return line.	⇨ Switch to the *Treatment* mode.
Blood pump off	112	The blood pump was manually switched off.	⇨ Press *Blood pump* key to switch blood pump on again.
Calcium bag change soon	156	The calcium bag will be empty within the next 10 min.	Prepare a new bag with calcium solution. Be ready for the bag change.
Calcium bag missing	107/ 169	No bag is hung on the calcium scale.	⇨ Hang a calcium solution bag on the calcium scale.
Change prime bag	147	• During priming the waste bag is full or the prime bag is empty.	⇨ Change the prime and waste bag and restart the blood pump.
		• A closed clamp is on the access line or on the return line.	⇨ Open the closed clamps on the access or return line.
Change substitution/ dialysate bag or **Change filtrate/ effluent bag**	114 115	• The filtrate bag has reached maximum permissible weight.	**1.** Replace full filtrate bag with empty bag. **2.** Open the bag(s). Ensure the line is not kinked or clamped. **3.** Ensure proper placement of bags on the scale hooks. **4.** Ensure that inlets always hang from the bottom.
		• The substitution solution bags do not contain solution.	**1.** Replace empty substitution solution bag with new bag filled with solution. **2.** Open the bag(s). Ensure the line is not kinked or clamped. **3.** Ensure proper placement of bags on the scale hooks. **4.** Ensure that inlets always hang from the bottom.
			1. If substitution bag is far from empty: check that the number of bags on program screen is equal to bags on scale. If yes, change filtrate bag(s) alone. **2.** Open the bag(s). Ensure the line is not kinked or clamped. **3.** Ensure proper placement of bags on the scale hooks. **4.** Ensure that inlets always hang from the bottom.

Display	ID	Cause	Options for error removal
Check access transducer connections	142	• The access/return transducer does not register a pressure change with the blood pump running. • During Clamp and pressure test no pressure increase is found when the clamp is closed.	⇨ Check dome connection. ⇨ Reconnect dome connection as follows: **1.** Stop blood pump. **2.** Wait for 15 s. **3.** Properly connect the dome. **4.** Start blood pump.
Check degassing chamber	157	⇨ Refer to "Check degassing chamber" causes as stated in the section *6.2.1 (Page 6-5)*.	⇨ Refer to "Check degassing chamber" options for error removal as stated in the section *6.2.1 (Page 6-5)*.
Check lines	137	The post-dilution pump has been stopped for longer than 3 min to regulate the fluid loss.	⇨ Check that the substitution line, the filtrate line and all bags are open, all clamps are removed and the tubes and bag inputs are not kinked.
Citrate and calcium swapped	175	During priming calcium bag is hanging on the citrate scale and citrate bag is hanging on the calcium scale.	⇨ Please hang on the bags correctly.
Citrate bag missing	106/ 168	No bag is hung on the citrate scale	⇨ Hang a citrate solution bag on the citrate scale.
Citrate bag change soon	155	The citrate bag will be empty within the next 10 min.	Prepare a new bag with citrate solution. Be ready for the bag change.
Filt./effluent bag change soon	154	Filtrate/effluent bag change in less than 10 min.	Prepare a new empty filtrate/effluent bag. Be ready for the bag change.
Function not available	138	During treatment the *ON/OFF* key is used.	**1.** Select *End treatment* to switch off the machine. **2.** Perform the disconnection program until the *Aquarius off* mode appears.
Heater cools down	130	Balance system has stopped for more than 15 s and the heater plate temperature is above 43 °C.	This is a notification. No actions are needed. The treatment is paused until the temperature is in a safe condition (below 42 °C). Substitution pumps run at a slow rate to help cooling. (Exception: during TFL compensation balance substitution pumps will not run.) Heater cool down management may take up to 10 minutes. The treatment will restart automatically. **In the event of a red *High temperature* alarm followed by a yellow *Heater cools down* message, the citrate pump runs at a reduced speed and the calcium pump is stopped resulting in an infusion of citrate without calcium while the *Heater cools down* message is displayed. The filtration pump speed is automatically set to zero if the UF deviation is negative.**

Display	ID	Cause	Options for error removal
Heater self test running	159	Heater self test is in progress when the *Start priming* screen is reached.	⇨ Wait until heater self test is completed. ▶ During the heater self test, the green status light is flashing. ▶ When the heater self test is finished, the green status light is illuminated.
Heparin syringe missing	116	• A heparin rate has been programmed and no syringe has been inserted in the plunger. • The heparin syringe is not inserted properly.	⇨ Insert heparin syringe if heparin is needed. ⇨ Set heparin rate to zero if no anticoagulant is required.
High filtration fraction (yellow or red)	120	• The proportion of the removed fluids exceeds the programmed limit (e.g. 33%).	⇨ Decrease fluid removal or plasma exchange rate.
		• Exchange of fluid or plasma across the membrane is too high in comparison to the blood flow rate.	⇨ Increase blood flow rate.
		• The post-dilution substitution rate is higher than acceptable for the current blood flow rate and the programmed limit.	⇨ Evaluate ratio of pre- vs. post-dilution substitution solutions.
Insert BLD chamber	125	The blood leak detector is not properly inserted into the blood leak chamber.	**1.** Insert the chamber correctly. **2.** Reprime to fill up the chamber correctly. **3.** Ensure no scratches or marks are present on the Aqualine tubing set chamber.
Insert tube to air detector	148	The air detection system is not operational after priming.	⇨ Insert correctly the return line into the air detection system. ▶ The green diode of the *Clamp* key is on. ⇨ Make sure that the air detection system is well inserted, if not push it back firmly. ▶ The green diode of the *Clamp* key is on.
Main battery low	133	After a power failure, the main power supply battery must be charged. This message indicates that in the event of a power failure the Aquarius system will run for less than 2 min.	⇨ Go on with this treatment to charge the battery automatically.
Negative UF	124	A negative UF is programmed.	This is a reminder. No actions are needed.

Display	ID	Cause	Options for error removal
No bag	135	• The priming solution bag weighs less than 1000 g.	⇨ Hang a bag weighing more than 1000 g on the substitution scale.
		Less than 45 g are detected on one scale during the treatment. Possible causes are: • No bag installed on filtration scale.	⇨ Ensure that the filtrate bag is hanging on the filtration scale. ⇨ If the problem persists, contact Technical Service.
		• Bag weighs less than 45 g.	⇨ Install an additional bag on each scale as follows: **1.** Go to *Programming* screen. **2.** Program 2 bags. **3.** Ensure that 2 empty effluent bags are hanging on the filtration scale and connect both filtration bags to the filtrate line. **4.** Ensure that 2 substitution bags are hanging on the substitution scale and connect both substitution bags to the substitution line. ⇨ If the problem persists, contact Technical Service.
		• Incorrect bag installation (lines or spike touching the Aquarius cart frame or lines twisted).	⇨ Check the filtrate line and make sure they are not resting on the Aquarius cart frame and that it is not twisted. Make sure the filtration bag hangs freely from the scale. ⇨ If the problem persists, contact Technical Service.
		• Aquarius system test performed with bag(s) hanging on the scales.	⇨ If the above mentioned measures do not solve the issue, start a new treatment and ensure that during the system test there is no weight on the scales. ⇨ If the problem persists, contact Technical Service.
		• Scale calibration out of tolerance.	⇨ Ensure that a correct waste bag is used (refer to section *3.3 (Page 3-1)*). ⇨ If the problem persists, contact Technical Service.
No degassing chamber detected	127	The substitution degassing chamber is not inserted.	⇨ Insert the chamber correctly. ⇨ When an ADU alarm (*Check degassing chamber, No degassing chamber detected,* or *Degassing chamber missing*) cannot be cleared anytime during self-test, setup, priming or treatment, remove the Aquarius system from service and call Technical Service.
Please program	139	Hourly fluid loss or fluid loss total is not programmed.	⇨ Select programming mode and program both hourly fluid loss and fluid loss total. ⇨ In CVVH, CVVHD and CVVHDF, if no fluid loss is required, program the treatment time.

Display	ID	Cause	Options for error removal
Power failure	132	The power supply is interrupted. Depending on the charge status of the main battery the blood pump will run for around 2 min.	⇨ Start blood pump. ⇨ Check power cord connection. ⇨ Use crank handle to manually return blood to the patient if the power failure lasts longer than the battery supports.
Pressure test disabled	131	• Air detection system does not detect "air free" tubing. • The *Clamp and pressure test* is disabled.	⇨ Make sure that the tubing set does not contain air. ⇨ Make sure that the return line is properly installed in the clamping system of the air detector. ⇨ Ensure that the return line is not scratched at the contact part.
Program dialysate	145	In CVVHD, dialysate rate is not programmed.	⇨ Select programming and program a dialysate rate.
Program goal	141	Treatment goal is not programmed.	⇨ Select programming and program time, fluid loss and fluid loss total.
Program treatment pumps	144	In CVVH/CVVHDF pre- and post-dilution/post-dilution and dialysate are not programmed.	⇨ Select programming and program pre- and post-dilution or post-dilution and dialysate rate.
Pump door open	118	One of the pump doors is open.	⇨ Close pump door.
Read error help instructions	143	To solve the alarm further information is needed.	⇨ Further information is available from the *Help* screens.
Reminder: 72h treatment time	117	The treatment is completed.	⇨ Disconnect a patient or reprogram patient parameter.
Reminder: 24h treatment time	140	This message is displayed every 24 h of use of the same filter and line set (including priming, connection, recirculation and treatment time).	⇨ If the filter and line have been used for less than the maximum treatment time, clear this message. ⇨ Disconnect and start a new treatment with a new filter and a new tubing system.
Return pressure low	123	The return pressure is below 20 mmHg.	⇨ During the first minute of treatment this is a reminder.
Subst./dialysate bag change soon	153	Substitution/dialysate bag change in less than 10 min.	⇨ Prepare substitution and/or dialysate bag change.

Display	ID	Cause	Options for error removal
Syringe empty: change in Options	119	The syringe located in the heparin pump is empty.	**1.** Follow instructions on *Change syringe* screens – removing syringe **only** when directed. **2.** Clamp heparin line. **3.** Take syringe out of pump and disconnect from line. **4.** Fill new syringe with heparin. **5.** Enter syringe volume and confirm. **6.** Place syringe in pump and connect line. **7.** Ensure that plunger and wings are inserted. **8.** Open clamp and confirm. NOTE If using BD syringe: ensure the grooves on the plunger are running towards the machine.
Syringe pump off	121	The heparin rate is programmed to zero.	⇨ If heparin is not required proceed to next screen. ⇨ If heparin is required, insert a syringe containing heparin and program the desired heparin rate.
Too much weight	136	• One of the scales has detected more than 20 kg.	⇨ Ensure that the same number of substitution solution and filtrate bags hang on the scale hooks. ⇨ Check if filtration and substitution bags are full. ⇨ Reduce weight: change the filtration bags, reduce the number of substitution bags.
		• The total weight on both scales exceeds the maximum weight.	⇨ Ensure that the substitution/dialisate bags do not touch filtrate/effluent bags. ⇨ Replace filtration bags with empty ones. NOTE The maximum number of bags on each scale is 4 bags of 5 kg each.
Wait!	129	The balance system is stopped.	This is an indication that the system will start automatically after some minutes.

6.2.3 System errors

During the system test (after switching the system on) and also during operation, the Aquarius system automatically performs tests to check the safety-critical components. If errors occur during these tests, the system switches to the safety mode and generates a red system error message as well as an audible alarm. This error message appears with the abbreviation CPU1 (control processor unit1) or CPU2.

If the following system errors cannot be corrected, please call Technical Service.

*L (Latched) – Alarm is NOT reset if an alarm condition is no longer present

**NL (Non-latched) – Alarm is reset if an alarm condition is no longer present

Message/Description		Alarm delay until indication	L* / NL**	Operation mode for detection
CPU1: error1 CPU	Master CPU Register test failed	≤5 s	L	Initial self-test
CPU1: error2 CPU	Master CPU RAM test failed	≤5 s	L	Initial self-test
CPU1: error3 CPU	Master CPU jump test failed	≤5 s	L	Initial self-test
CPU1: XRAM	Master CPU extern RAM failed	≤5 s	L	Initial self-test
CPU1: CODE	Master CPU program code test failed	≤5 s	L	Initial self-test
CPU1: EEPROM	Master CPU calibration data test failed	≤5 s	L	Initial self-test
CPU2: error1 CPU	Controller CPU Register test failed	≤5 s	L	Initial self-test
CPU2: error2 CPU	Controller CPU RAM test failed	≤5 s	L	Initial self-test
CPU2: error3 CPU	Controller CPU jump test failed	≤5 s	L	Initial self-test
CPU2: XRAM	Controller CPU external RAM test failed	≤5 s	L	Initial self-test
CPU2: CODE	Controller CPU program code test failed	≤5 s	L	Initial self-test
CPU2: EEPROM	Controller CPU calibration data test failed	≤5 s	L	Initial self-test
CPU1: program run	Program failure Master CPU	≤15 s	L	All
CPU2: program run	Program failure Controller CPU	≤5 s	L	All
CPU1: ADC/Voltage CPU2	Voltage supply or AD-converter failure	≤5 s	L	All
CPU1: sensor voltage	Voltage supply or AD-converter failure	≤20 s	L	All
CPU2: ADC/Voltage CPU1	Voltage supply or AD-converter failure	≤5 s	L	All

* L (Latched) – Alarm is NOT reset if an alarm condition is no longer present

**NL (Non-latched) – Alarm is reset if an alarm condition is no longer present

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal	Test frequency
CPU1: Access sensor **CPU2: Access sensor**	29 61	≤15 s	L	• Access pressure sensor values deviate from limits.	After system test: ⇨ Ensure that no tubing is on the machine during the system test. ⇨ Repeat the system test. If it fails again, call Technical Service.	Continuous: 2 s^{-1}
				• During clamp/ pressure test no pressure increase is detected.	During clamp and pressure test: **1.** Ensure the access dome is positioned properly. **2.** Press the *Blood pump* key to reset the alarm and to continue the Clamp and pressure test.	
CPU1: ADC/ Voltage CPU2 **CPU2: ADC/ Voltage CPU1**	19 51	≤5 s	L	Voltage supply or AD-converter failure – the master/controller-CPU detects high or low voltage at the power supply for the master/ controller-CPU.	⇨ End the treatment and call Technical Service.	Continuous: < 2 s^{-1}
CPU1: Air detector **CPU2: Air detector**	6 38	≤5 s	L	• Air detector test failed.	⇨ Repeat the system test. If it fails again, call Technical Service.	Continuous: <1 s^{-1} (Master) <3 s^{-1} (Protection)
				• Master-CPU and controller-CPU have different information regarding air alarm.	⇨ Press *Blood pump* key. If error cannot be reset, put system out of operation and notify Technical Service.	
CPU1: Backup	27	≤5 s	L	No dates at the backup.	⇨ Restart system (no tubing may be installed). ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Initial self-test
CPU1: Balance filtration **CPU2: Balance filtration**	26 58	≤5 s	L	• Values between protective and control system deviate from each other (outside of limits). • Actual values are outside of limits.	⇨ Check filtration scale. ⇨ Restart system (no tubing may be installed). ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Initial self-test

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal	Test frequency
CPU1: Balance substitution **CPU2: Balance substitution**	13 45	≤5 s	L	• Values between protective and control system deviate from each other (outside of limits). • Actual values are outside of limits.	⇨ Check substitution scale. ⇨ Restart system (no tubing may be installed). ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Initial self-test
CPU1: BLD **CPU2: BLD**	12 44	≤5 s	L	Blood leak detector (BLD) does not work properly.	⇨ Press the *Blood pump* key. ⇨ If the system error cannot be reset, put system out of operation and notify Technical Service.	Continuous: < 5 s^{-1}
CPU1: Blood pump **CPU2: Blood pump**	7 39	≤5 s	L	• Flow rate test failed. • Blood pump drive defective. • Blood pump did not stop. • Actual value of number of revolutions deviates from set value outside of limits.	⇨ Ensure the pump door is closed. ⇨ Switch system off and on again after approximately 1 min (no tubing must be installed). ⇨ Press *Blood pump* key. ⇨ If the error cannot be removed, notify Technical Service.	Continuous: < 25 s^{-1}
Citrate module function fails	18		L	A failure during the citrate module system test was detected.	⇨ Repeat the test. ⇨ If the problem persists, notify Technical Service.	Initial test
CPU1: Clamp doesn't close **CPU2: Clamp doesn't open**	14 47	≤5 s during POST ≤15 s during treat-ment	L	• Clamp test failed. • Clamp does not close. • Clamp does not open.	⇨ Correct tubing set position in clamp. ⇨ Press *Blood pump* key. If the error cannot be reset, put system out of operation and notify Technical Service.	Continuous: < 1 s^{-1}
CPU1: CODE **CPU2: CODE**	4 36	≤5 s	L	• Controller CPU program code test failed. • Master CPU program code test failed.	⇨ Restart system (no tubing may be installed). ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Initial self-test
CPU2: Commu control system	54	≤10 s	L	• The communication between master and controller failed.	⇨ If the message cannot be reset, turn off the Aquarius system and turn it back on.	Continuous: < 5 s^{-1}

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal	Test frequency
CPU1: Commu front system	23	≤20 s	L	• The communication between the master-CPU and the display failed.	**1.** Set up safety mode for the patient. **2.** Switch system off and on again after approximately 1 min (no tubing must be installed). **3.** If the error cannot be reset, put system out of operation and notify Technical Service.	Continuous: $< 5\ s^{-1}$
CPU1: Commu protection system	22	≤10 s	L	• Error during data transfer. • Power supply for protective system is defective.	⇨ Press *Blood pump* key. ⇨ Switch system off and on again after approximately 1 min. ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Continuous: $< 2\ s^{-1}$
CPU1: EEPROM **CPU2: EEPROM**	5 37	≤5 s	L	• Master CPU calibration data test failed. • Controller CPU calibration data test failed.	⇨ Restart system (no tubing may be installed). ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Initial self-test
CPU1: Error 1 CPU **CPU2: Error 1 CPU**	0 32	≤5 s	L	• Master CPU Register test failed. • Controller CPU Register test failed.	⇨ Restart system (no tubing may be installed). ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Initial self-test
CPU1: Error 2 CPU **CPU2: Error 2 CPU**	1 33	≤5 s	L	• Master CPU RAM test failed. • Controller CPU RAM test failed.	⇨ Restart system (no tubing may be installed). ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Initial self-test
CPU1: Error 3 CPU **CPU2: Error 3 CPU**	2 34	≤5 s	L	• Master CPU jump test failed. • Controller CPU jump test failed.	⇨ Restart system (no tubing may be installed). ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Initial self-test

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal	Test frequency
CPU1: Error blood detection **CPU2: Error blood detection**	16 48	≤5 s	L	Blood at optic sensor (air detector)	⇨ Restart system (no tubing may be installed). ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Initial self-test
CPU1: Filtration pump **CPU2: Filtration pump**	8 40	≤5 s	L	• Flow rate test failed. • Filtration pump drive defective. • Filtration pump did not stop. • Actual value of number of revolutions deviates from set value outside of limits.	⇨ Ensure the pump door is closed. ⇨ Switch system off and on again after approximately 1 min (no tubing must be installed). ⇨ Press *Treatment* key. ⇨ If error cannot be reset, notify Technical Service.	Initial self-test Continuous: $< 30\ s^{-1}$

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal	Test frequency
CPU1: Heater **CPU2: Heater**	25 57	≤5 s	L	During system test: • The heater failed the system test.	⇨ Repeat the system test. ⇨ If message appears again, call Technical Service. ⇨ Do not use the system for treatment.	Initial self-test
				During treatment: • Master and controller detect different values at the temperature sensors.	**1.** Check for air in the heater coil. **2.** If air is present, remove air as follows: **Large amounts of air** (approximately more than 1/3 of the heating coil - or in low volume treatment): ⇨ Remove the air via the access port on the degassing chamber using a syringe. **Small amounts of air** (approximately less than 1/3 of the heating coil): **1.** Remove heater coil from heater. **2.** Clear the alarm. **3.** Wait for treatment pumps to start,. **4.** Shake the heater coil gently while the treatment pumps are running. ▶ The air will be automatically removed by the degassing chamber. **5.** Ensure that the heater door is closed after reinsertion of the heater coil. **6.** If the problem still persists, notify Technical Service.	Continuous $< 1\ s^{-1}$

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal	Test frequency
CPU1: Heparin pump **CPU2: Heparin pump**	11 43	≤5 s	L	• Actual values of control and protective systems deviate from each other (outside of limits). • Actual values deviate from limits. • Pump stall. • The plunger is incorrectly positioned.	After system test: **1.** Restart the system (no tubing must be installed). **2.** If the error cannot be reset, put system out of operation and notify Technical Service. During the treatment: **1.** Check the heparin line is not clamped. **2.** Go to *Options* and then to *Change syringe*. Follow the on-screen text. NOTE It is **not** necessary to remove the syringe during this process. **3.** If problem persists, program the pump to 0, clamp the line and remove the syringe. **4.** If the problem persists, end treatment and call Technical Service.	Continuous: < 2 s^{-1}
CPU1:Operation mode **CPU2:Operation mode**	24 56	≤15 s	L	The data transfer values regarding the operation mode deviate between master- and controller CPU.	**1.** Press *Blood pump* key to start a new check. **2.** If the alarm appears again, call Technical Service.	Continuous: < 2 s^{-1}
CPU1: Post-dilution pump **CPU2: Post-dilution pump**	9 41	≤5 s	L	• Flow rate test failed. • Post-dilution pump drive defective. • Post-dilution pump did not stop. • Actual value of number of revolutions deviates from set value outside of limits.	⇨ Ensure the pump door is closed. ⇨ Switch system off and on again after approximately 1 min (no tubing may be installed). ⇨ Press *Treatment* key. ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Continuous: < 30 s^{-1}

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal	Test frequency
CPU1: Pre-dilution pump **CPU2: Pre-dilution pump**	10 42	≤5 s	L	• Flow rate test failed. • Pre-dilution pump drive defective. • Pre-dilution pump did not stop. • Actual value of number of revolutions deviates from set value outside limits. • The pump is not running at the correct speed.	⇨ Ensure the pump door is closed. ⇨ Switch system off and on again after approximately 1 min (no tubing must be installed). ⇨ Press *Treatment* key. ⇨ If the error cannot be reset, put system out of operation and notify Technical Service.	Continuous: $< 30\ s^{-1}$
CPU1: Program run **CPU2: Program run**	17 49	CPU1: ≤15 s CPU2: ≤5 s	L	• Program failure Master CPU. • Program failure Controller CPU.	⇨ Press the *Blood pump* key to reset the alarm. ⇨ If the message appears repeatedly, end the treatment and notify Technical Service.	Continuous: $< 25\ s^{-1}$
CPU1: Return sensor **CPU2: Return sensor**	30 62	CPU1: ≤15 s CPU2: ≤3 s	L	• Return pressure sensor values deviate from limits.	After system test: **1.** Ensure that no tubing is on the machine during the system test. **2.** Repeat the system test. **3.** If it fails again, call Technical Service.	Continuous: $< 30\ s^{-1}$
				• During Clamp and pressure test no pressure increase is detected.	**1.** Ensure the return and pre-filter domes are positioned properly. **2.** Press *Blood pump* key to reset the alarm and to continue the Clamp and pressure test.	
CPU1: Sensor voltage **CPU2: Sensor voltage**	20 52	≤20 s	L	• High or low voltage is detected at the power supply for the sensors. • Voltage supply or AD-converter failure	**1.** Restart system (no tubing may be installed). **2.** If the error cannot be reset, put system out of operation and notify Technical Service.	Continuous: $< 30\ s^{-1}$
CPU1: Timer **CPU2: Timer**	28 60	≤210 s	L	Timer deviation between master and controller.	**1.** Press *Blood pump* key to clear the message. **2.** If the message appears repeatedly, end the treatment and call Technical Service.	Continuous: $< 25\ s^{-1}$

Display	ID	Max. alarm delay time	L* / NL**	Cause	Options for error removal	Test frequency
CPU1: TMP sensor **CPU2: TMP sensor**	31 63	≤15 s	L	The TMP calculation or the filtrate pressure sensor is out of range.	**1.** Ensure no tubing is on the machine during system test. **2.** Repeat the system test. **3.** If the test fails again, notify Technical Service.	Continuous: < 2 s^{-1}
CPU1: Vcc Master/ communication **CPU2: Vcc Master/ communication**	21 53	≤5 s	L	• A high or low voltage has been detected at the master power supply. • RAM, EPROM or EEPROM are defective. • Values between protective and control system deviate from each other (outside of limits).	**1.** Press the *Blood pump* key to reset the message. **2.** If the error cannot be reset, end the treatment and notify Technical Service.	Continuous: < 2 s^{-1}
CPU1: XRAM **CPU2: XRAM**	3 35	≤5 s	L	During system test the RAM of the controller-CPU was found to be defective.	**1.** Restart system (no tubing may be installed). **2.** If the error cannot be reset, put system out of operation and notify Technical Service.	Initial self-test

7 Cleaning and disinfection

Danger to life from electric voltage. Always switch off the Aquarius system and remove it from the external voltage before cleaning or disinfecting the device.

7.1 Cleaning

The surfaces of the Aquarius system, of the cabinet and the wheeled base may be cleaned with a soft, damp cleaning cloth. For surface cleaning use a mild standard surface cleaning agent diluted with water. Any dirt must be wiped off with special consideration of edges and corners. Follow the instructions of the manufacturer regarding use, concentration, fields of application and safety.

The overlay may be cleaned with a soft, damp cleaning cloth.

Property damage. Do not use cleaning agents containing iodide for the pressure transducers.

7.2 Disinfection

The Aquarius system components do not come into contact with the patient's blood. Therefore, disinfection of internal components is not required. Only the tubing sets and the filters have direct blood contact. These items are disposables that are discarded after every treatment.

For surface disinfection, use the surface disinfection agent that is listed below. Follow the instructions of the manufacturer regarding use, concentration, fields of application and safety.

Property damage. Do not use disinfection agents containing iodide for the pressure transducers.

The following disinfection agent is recommended:

- 70 % Isopropyl alcohol

Before using the disinfection agent, read and follow carefully the instructions for use.

Contamination, for example from blood, blood components and filtrate, must be removed with a disposable paper towel soaked in disinfectant. The surface must then be disinfected again by spraying with disinfectant taking in special consideration edges and corners. The pumps can be disinfected by removing the rotors and spray the disinfection agent into the pump housing. The rotors must then be sprayed separately.

Allow the disinfectant a contact time of ten minutes before drying the surface.

Always check that the areas of the sensors and actuators are clean, otherwise their function may be impaired.

8 Guidance and manufacturer declaration – Electromagnetic emissions

8.1 Safety rules – Electromagnetic compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility. In respect of this, the installation and operating notes must be kept in accordance with the guidance and manufacturer declarations.

The emission and the immunity characteristic of the device are in accordance with the requirements for non life-supporting devices in a typical clinical environment under consideration of normal use.

Electromagnetic disturbances.

Electromagnetic disturbances can influence the Aquarius system. The Essential performance data defined as: blood flow, filtration flow, pre- and post-dilution respectively dialysate flow are not completely maintained. The actual treatment result can deviate from the expected treatment result.

- ⇨ **Do not use portable and mobile radio frequency (RF) communication equipment, such as cellular phones, laptops with W-LAN/Bluetooth and other similar equipment, close to the Aquarius system.**

Degradation of the performance of the Aquarius system.

- ⇨ **Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the Aquarius system.**

Degradation of the performance of the Aquarius system.

- ⇨ **Do not use the device adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.**

Increased emissions and/or decreased immunity of the device.

- ⇨ **Do not fulfill unauthorized variations, modifications, reparations or services.**
- ⇨ **Do not use unregistered equipment with the Aquarius system.**

Loss or degradation of the Essential performance of the Aquarius device.

A loss or degradation of Essential performances may lead to: citrate toxicity, death, hypo-/hyper-coagulopathy, hypo-/hypercalcaemia, hypertonia, hypo-/ hypervolaemia, insufficient treatment, malaise, metabolic acidosis, metabolic alkalosis, shock, anaphylactic shock.

- ⇨ **Avoid the use of the Aquarius device in the following special environments:**
- **military areas (submarines, near radar installations, near weapons control systems),**
- **heavy industrial areas (power plants, steel and paper mills, foundries, automotive and appliance manufacturing, smelting and mining operations, oil and gas refineries),**
- **medical treatment areas with high-powered ME EQUIPMENT (HF SURGICAL EQUIPMENT, SHORT-WAVE THERAPY EQUIPMENT, inside the RF shielded room of an ME SYSTEM for magnetic resonance imaging).**

Increased emissions and/or decreased immunity of the device.

- ⇨ **Avoid to operate the Aquarius device by a power cord with a length of more than 4 m.**

Loss or degradation of the Basic safety and the Essential performance of the Aquarius device.

- ⇨ **To ensure the Basic safety and the Essential performance of the Aquarius system regarding electromagnetic disturbances during the expected service life, perform the maintenance within the defined interval and according to the instructions in the Technical Service Manual.**
- ⇨ **Install only spare parts specified by the legal manufacturer NIKKISO.**

8.2 Guidance and manufacturer declaration – Electromagnetic emissions and immunity

Table 1 – Guidance and manufacturer declaration – Electromagnetic emission

The Aquarius system is intended for use in the electromagnetic environment specified below. The operator of the Aquarius system has to ensure that the device is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – Guidance
RF emissions (CISPR 11)	Group 1	The Aquarius system uses RF energy only for its internal function. Therefore the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission (CISPR 11)	Class A	The emission characteristics of the Aquarius system make it suitable for use in industrial areas and hospitals. If it is used in a residential environment (for which CISPR 11 class B is normally required) the Aquarius system might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orientating the Aquarius system.
Harmonic emissions (IEC 61000-3-2)	Class A	
Voltage fluctuation/ flicker emissions (IEC 61000-3-3)	Complies	

Table 2 – Guidance and manufacturer declaration – EMC Immunity

The Aquarius system is designed for use in the electromagnetic environments specified below. The operator of the Aquarius system has to ensure, that the device is used in such an environment.

Immunity test	IEC 60601-test level	Compliance-Level	Electromagnetic environment – Guidance
EMS-Electrical static discharge (IEC 61000-4-2)	±8 kV contact-discharge ±15 kV air-discharge	±8 kV contact-discharge ±15 kV air-discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
EMS-Bursts (IEC 61000-4-4)	±2 kV power supply input lines and PE ±1 kV for input and output lines	±2 kV power supply input lines n.a.	Mains power quality should be that of a typical commercial or hospital environment.
EMS-Surges (IEC 61000-4-5)	±1 kV pulse amplitude power line sym. ±2 kV pulse amplitude power line unsym.	±1 kV pulse amplitude power line sym. ±2 kV pulse amplitude power line unsym.	Mains power quality should be that of a typical commercial or hospital environment.

Table 2 – Guidance and manufacturer declaration – EMC Immunity

The Aquarius system is designed for use in the electromagnetic environments specified below. The operator of the Aquarius system has to ensure, that the device is used in such an environment.

EMS-Voltage dips, short interruptions and voltage variations on power supply input lines (IEC 61000-4-11)	< 5% U_T (> 95% dip in U_T for ½ cycles) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (> 95% dip in U_T for 5 seconds)	< 5% U_T (> 95% dip in U_T for ½ cycles) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (> 95% dip in U_T for 5 seconds)	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the Aquarius system requires continued operation during power mains interruptions, it is recommended that the Aquarius system be powered from an uninterruptible power supply or a battery.
EMS-Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3 – Guidance and manufacturer declaration – EMC Immunity

The Aquarius system is designed for use in the electromagnetic environments specified below. The operator of the Aquarius system has to ensure, that the device is used in such an environment.

Immunity test	IEC 60601-test level	Compliance-Level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Aquarius system, including cable (power cord with the length of 4 m), than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
EMS-Conducted Disturbances (IEC 61000-4-6)	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms} 150 kHz to 80 MHz	Recommended separation distance: $d = 1.167 \cdot \sqrt{P}$ $d = 1.167 \cdot \sqrt{P}$

Table 3 – Guidance and manufacturer declaration – EMC Immunity

The Aquarius system is designed for use in the electromagnetic environments specified below. The operator of the Aquarius system has to ensure, that the device is used in such an environment.

EMS-Radiation (IEC 61000-4-3)	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	for 80 MHz to 800 MHz $d = 2.33 \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer specifications and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2: The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Aquarius system is used exceeds the applicable RF compliance level above, additional measures may be necessary, such as reorienting or relocating the Aquarius system.

b) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Table 4 – Recommended separation distances between portable and mobile RF communications and the Aquarius system

The Aquarius system is designed to operate in an electromagnetic environment, in which radiated RF disturbances are controlled. The customer or the operator of the Aquarius system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aquarius system as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of the transmitter W	150 kHz to 80 MHz $d = 1.167 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.167 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \cdot \sqrt{P}$
0.01	0.1167	0.1167	0.233
0.1	0.37	0.37	0.74
1	1.167	1.167	2.33

Table 4 – Recommended separation distances between portable and mobile RF communications and the Aquarius system			
10	5.30	5.30	7.4
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitters, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: For 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

8.3 Emission class, group and immunity test level

The following tables are part of the latest version of the EMC standard IEC 60601-1-2. Therefore, the numbering is equivalent to the system provided in the standard. Further on, the references stated within the tables are linked to the IEC 60601-1-2 standard itself or to the indicated specific ones.

Table 4 – Enclosure port			
Phenomenon	**Basic EMC standard or test method**	**Immunity test levels**	
		Professional healthcare facility environment	**Home healthcare environment**
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Radiated RF EM fields [a)]	IEC 61000-4-3	3 V/m [f)] 80 MHz – 2.7 GHz [b)] 80% AM at 1 kHz [c)]	10 V/m [f)] 80 MHz – 2.7 GHz [b)] 80% AM at 1 kHz [c)]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See table 9	
Rated power frequency magnetic fields [d) e)]	IEC 61000-4-8	30 A/m [g)] 50 Hz or 60 Hz	

a) The interface between the patient physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM.

b) ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the Risk Management Process. This test assesses the Basic safety and Essential performance of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

c) Testing may be performed at other modulation frequencies identified by the Risk Management Process.

d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

e) During the test, the ME EQUIPMENT or ME SYSTEM may be powered at any nominal input voltage, but with the same frequency as the test signal (see Table 1 in IEC 60601-1-2).

f) Before modulation is applied.

g) This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the risk analysis shows that the ME EQUIPMENT or ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the immunity test level shall be adjusted as appropriate for the minimum expected distance.

Table 5 – Input a.c. power port			
Phenomenon	**Basic EMC standard**	**Immunity test levels**	
		Professional healthcare facility environment	**Home healthcare environment**
Electrical fast transients/ bursts [a) l) o)]	IEC 61000-4-4	±2 kV 100 kHz repetition frequency	
Surges [a) b) j) o)] Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV	
Surges [a) b) j) k) o)] Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV	
Conducted disturbances induced by RF fields [c) d) o)]	IEC 61000-4-6	3 V [m)] 0.15 MHz – 80 MHz 6 V [m)] in ISM bands between 0.15 MHz and 80 MHz [n)] 80% AM at 1 kHz [e)]	3 V [m)] 0.15 MHz – 80 MHz 6 V [m)] in ISM amateur radio bands between 0.15 MHz and 80 MHz [n)] 80% AM at 1 kHz [e)]
Voltage dips [f) p) r)]	IEC 61000-4-11	0% U_T; 0.5 cycle [g)] At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [q)] 0% U_T; 1 cycle and 70% U_T; 25/30 cycles [h)] Single phase: at 0°	
Voltage interruptions [f) i) o) r)]	IEC 61000-4-11	0% U_T; 250/300 cycle [h)]	

Table 5 – Input a.c. power port			
Phenomenon	**Basic EMC standard**	**Immunity test levels**	
		Professional healthcare facility environment	**Home healthcare environment**

a) The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

b) All ME EQUIPMENT and ME SYSTEM cables are attached during the test.

c) Calibration for current injection clamps shall be performed in a 150 Ω system.

d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e) Testing may be performed at other modulation frequencies identified by the Risk Management Process.

f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the manufacturer of the ME EQUIPMENT or ME SYSTEM. The Immunity test levels are applied to the a.c. power input of the converter.

g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.

h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i) ME EQUIPMENT and ME SYSTEMS with rated input current greater than 16 A/phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

j) ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ±2 kV line(s) to earth and ±1 kV line(s) to line(s).

k) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.

l) Direct coupling shall be used.

m) r.m.s., before modulation is applied.

n) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

o) Applicable to ME EQUIPMENT and ME SYSTEMS with rated input current less than or equal to 16 A/phase and ME EQUIPMENT and ME SYSTEMS with rated input current greater than 16 A/phase.

p) Applicable to ME EQUIPMENT and ME SYSTEMS with rated input current less than or equal to 16 A/phase.

q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide Basic safety during and after the test.

r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum rated input voltage. ME EQUIPMENT and ME SYSTEMS with a rated input voltage range of less than 25% of the highest rated input voltage shall be tested at one rated input voltage within the range. See Table 1 Note c) (IEC 60601-1-2) for examples calculations.

Table 6 – Input d.c. power port

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrical fast transients / bursts [a) g)]	IEC 61000-4-4	±2 kV 100 kHz repetition frequency	
Surges [a) b) g)] Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV	
Surges [a) b) g)] Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV	
Conducted disturbances induced by RF fields [a) c) d) i)]	IEC 61000-4-6	3 V [h)] 0.15 MHz – 80 MHz 6 V [h)] in ISM bands between 0.15 MHz and 80 MHz [j)] 80% AM at 1 kHz [e)]	3 V [h)] 0.15 MHz – 80 MHz 6 V [h)] in ISM amateur radio bands between 0.15 MHz and 80 MHz [j)] 80% AM at 1 kHz [e)]
Electrical transient conduction along supply lines [f)]	ISO 7637-2	Not applicable	As specified in ISO 7637-2

a) The test is applicable to all d.c. power ports intended to be connected permanently to cables longer than 3 m.
b) All ME EQUIPMENT and ME SYSTEM cables shall be attached during the test
c) Internally powered ME EQUIPMENT is exempt from this test if it cannot be used during battery charging, is of less than 0.4 m maximum dimension including the maximum length of all cables specified and has no connection to earth, telecommunications systems, any other equipment or a patient.
d) The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its nominal input voltages.
e) Testing may be performed at other modulation frequencies identified by the Risk Management Process.
f) For ME EQUIPMENT and ME SYSTEMS intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems
g) Direct coupling shall be used.
h) r.m.s., before modulation is applied.
i) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
j) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Table 7 – Patient coupling port

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic discharge [c]	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Conducted disturbances induced by RF fields [a]	IEC 61000-4-6	3 V [b] 0.15 MHz – 80 MHz 6 V [b] in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz [a]	3 V [b] 0.15 MHz – 80 MHz 6 V [b] in ISM amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz [a]

a) The following apply:
- All patient-coupled cables shall be tested, either individually or bundled
- Patient-coupled cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
- No intentional decoupling device shall be used between the injection point and the patient coupling point in any case.
- Testing may be performed at other modulation frequencies identified by the Risk Management Process.
- Tubes that are intentionally filled with conductive liquids and intended to be connected to a patient shall be considered to be patient-coupled cables.
- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

b) r.m.s., before modulation is applied

c) Discharges shall be applied with no connection to an artificial hand and no connection to patient simulation. patient simulation may be connected after the test as needed in order to verify Basic safety and Essential performance.

Table 8 – Signal input/output parts port

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic discharge [e]	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Electrical fast transients/ bursts [b] [f]	IEC 61000-4-4	±1 kV 100 kHz repetition frequency	
Surges Line-to-ground [a]	IEC 61000-4-5	±2 kV	
Conducted disturbances induced by RF fields [a]	IEC 61000-4-6	3 V [h] 0.15 MHz – 80 MHz 6 V [h] in ISM bands between 0.15 MHz and 80 MHz [i] 80% AM at 1 kHz [c]	3 V [h] 0.15 MHz – 80 MHz 6 V [h] in ISM amateur radio bands between 0.15 MHz and 80 MHz [i] 80% AM at 1 kHz [c]

a) This test applies only to output lines intended to connect directly to outdoor cables.
b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.
c) Testing may be performed at other modulation frequencies identified by the Risk Management Process.
d) Calibration for current injection clamps shall be performed in a 150 Ω system.
e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of intended use, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.
f) Capacitive coupling shall be used.
g) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
h) r.m.s., before modulation is applied.
i) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Table 9 – Test specifications for enclosure port immunity to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst case.

9 Technical data

This chapter contains information about individual components and general technical information about the Aquarius system.

For more detailed technical information please contact the Aquarius system manufacturer.

9.1 Dimensions and weight

Height	175 cm (without I.V. pole)
Width	65 cm
Depth	75 cm
Floor space	approx. 65 cm (W) x 75 cm (D)
Weight	approx. 90 kg

9.2 Electrical power supply

Voltage	230 V ~ ± 10% = 207 VAC to 253 VAC, 50/60 Hz for GE-F095-00 230 V ~ ± 10% = 207 VAC to 253 VAC, 50/60 Hz for GE-F096-00 upgraded with RCA option 115 V ~ ± 10% = 103 VAC to 117 VAC, 50/60 Hz for GE-F097-00 upgraded with RCA option
Currents	2.2 A with 230 V~ for GE-F095-00/GE-F096-00 4.4 A with 115 V~ for GE-F097-00
Power consumption	500 VA with 230 V~ and 115 V~

9.3 Electrical safety

Complying with EN 60601-1

Manner of protection against electrical shock

Degree of protection against electrical shock: The Aquarius system is classified in class 1.

The applied parts of Aquarius system are classified as type B (body).

Symbol:

- Degree of protection against harmful ingress of water and particular matter: Non-protected.
- A sterilization process is not required. The method of cleaning and disinfection is indicated in the section *7 Cleaning and disinfection (Page 7-1)*
- Category Non-AP or Non-APG, the equipment is not anaesthetic-proof or anaesthetic-proof category G.
- Mode of operation: Continuous Operation.

The Aquarius system is classified as type B.

Fuses:

Main fuses for GE-F095-00 and GE-F096-00:	2 x T 3.15 A, 20 x 5 mm fine fuse with time delay, high breaking capacity Nominal voltage: 250 V AC max.
Main fuses for GE-F097-00:	2 x mT 4 A, 32 x 6.3 mm fine fuse with time delay, high breaking capacity Nominal voltage: 250 V AC max.
Heater fuse:	1 x T 3.15 A, 20 x 5 mm fine fuse with time delay, high breaking capacity Nominal voltage: 250 V AC max.
Battery fuses:	T 1 A, plastic body soldered on secondary power supply Nominal voltage: 250 V AC max.
	1 x T 3.15 A, plastic body soldered on secondary power supply Nominal voltage: 250 V AC max.

Storage battery:

Maintenance-free lead storage battery, LC-R061R3PG
Capacity: 6 V, 1.3 Ah

9.4 Power outage operation

If the mains power supply fails during a treatment, the Aquarius system automatically switches to storage battery power supply, until the emergency mains power supply is available. Storage battery operation is indicated via an audible signal. On the screen the *Power fail* message is displayed. During this period, the fluid circuit (substitution and filtrate) is stopped. Circulation through the blood circuit is maintained.

The system will operate for a minimum of 2 min during a power failure with a fully charged battery. The Power fail alarm is triggered immediately after the brown-out.

If the power supply is restored, the fluid circuit may be resumed.

If the power supply is not restored before the end of battery operation, after approximately 2 min, the Aquarius system will be switched off (safety mode) and all pumps will stop. The return line clamp is still open to enable manual return of blood from the extracorporeal circuit. At the back of the scale system a removable hand-crank is mounted. This can be used to manually turn the blood pump in case the pump stops.

If the Aquarius system is stored over a longer period the manufacturer recommends connecting the system to the power outlet and charging the storage battery for 15 h every half year. Also charge the storage battery for 15 h before initial set up and installation.

NOTE Change the battery every 2 years.

9.5 Technical data of individual components

Component	Specification	
Access pressure sensor	Measurement method:	Contact measurement
	Measuring range:	-250 to +350 mmHg, step 1 mmHg
	Measuring accuracy:	±5 mmHg Resolution: 1 mmHg
	Upper alarm limit:	automatic setting between -50 and +350 mmHg
	Lower alarm limit:	automatic setting between -250 and +150 mmHg
	Alarm window size during treatment:	200 mmHg around the actual value
ADU pressure working range	-300 mmHg to +30 mmHg	
ADU pressure alarm	Low pressure:	< -300 mmHg
	High pressure:	> +30 mmHg
	Zero pressure/disconnection:	-30 mmHg; +30 mmHg
	ADU pressure alarm accuracy:	±50 mmHg
Air detector	Method:	Ultrasonic air bubble detection at 2.3 MHz
	Sensitivity:	Air bubbles at a volume of 1 µl at a blood flow rate of 200 ml/min
	Alarm trigger:	20 µl air bubble or accumulation of 20 µl of 1 µl air bubbles within 1 min at a blood flow rate of 200 ml/min
Alarm	The alarm signal may be muted for a period of 2 min. The alarm loudness is **>** 65 dB (A) within a distance of 1 m.	
Blood leak detector	Measurement of clouding $\frac{\text{Optical calibration value – Actual optical value}}{\text{Optical calibration value – Optical alarm limit value}} = \text{BLD (\%)}$	
	Sensitivity:	2 ml of blood in 1000 ml (±10%) of filtrate at a filtration pump flow rate of 100 ml/h up to 12000 ml/h (at a hematocrit of 32%)
	Sensitivity for TPE:	4 ml of blood in 1000 ml

Component	Specification	
Blood pump**	Input range adult Regular mode:	SCUF, CVVH, CVVHD, CVVHDF and Hemoperfusion: 30 ml/min–450 ml/min Step-by-step: 10 ml/min TPE: 30 ml/min–250 ml/min Step-by-step: 10 ml/min
	Input range adult RCA mode and 100 h option:	SCUF, CVVH, CVVHD, CVVHDF and Hemoperfusion: 30 ml/min-300 ml/min Step-by-step: 10 ml/min TPE: 30 ml/min-250 ml/min Step-by-step: 10 ml/min
	Input range low volume blood line:	10 ml/min–200 ml/min Step-by-step: 2 ml/min
	Accuracy adult:	-5% ~ +10%
	Accuracy low volume:	-5% ~ +10% or min ±1 ml
	Pressure range for the specified accuracy: see defined values for access pressure and pre-filter pressure	
	Alarm limits:	-10 to +10% from set point
	Aqualine tubing set pump insert size is:	ID x OD: ø6.36 (±0.10) x 9.54 (±0.10) mm/ Length: 24 (±0.50) cm
	Aqualine S tubing set pump insert size is:	ID x OD: ø4.7 (±0.10) x 7.2 (±0.10) mm/ Length: 24 (±0.50) cm
	When RCA module is in use: Blood pump flow rate = Prescribed blood flow rate + Citrate flow rate	
Citrate pump (Aquarius^{+} only)	Input range:	0 to 650 ml/h
	Programming range:	0 or 20 to 650 ml/h, step 1 ml/h
	Accuracy:	±5% at maximum flow rate 650 ml/h
	Accuracy of the system (pumps and scales together):	0.5% related to a maximum flow rate of 650 ml/h The regulation of citrate pump permits flow rates greater than the maximum programmable range.
Calcium pump (Aquarius^{+} only)	Input range:	0 to 300 ml/h
	Programming range:	2–30 ml/h step 0.2 ml/h 30–300 ml/h step 1 ml/h
	Accuracy:	±5% at maximum flow rate 300 ml/h
	Accuracy of the system (pumps and scales together):	0.5% related to a maximum flow rate of 300 ml/h The regulation of calcium pump permits flow rates greater than the maximum programmable range.
Citrate and Calcium solution scale (Aquarius^{+} only)	Measurement method:	via strain gauge
	Max. load:	2.2 kg each
	Working range:	0 to 2.5 kg (Overload alarm 2.3 kg), step 0.1 g
	Accuracy:	±0.2% at maximum weight of 2 kg

Component	Specification	
Dialysate pump**	In CVVHD and CVVHDF, the pre-dilution pump is used as dialysate pump with the following specifications:	
	Input range adult Regular mode:	0 or 100–10,000 ml/h optional: 7,000 ml/h Step-by-step: 100 ml/h
	Input range adult RCA mode:	0 or 500-6,000 ml/h Step-by-step: 100 ml/h
	Input range low volume blood line:	0 or 100–6,000 ml/h Step-by-step: 10 ml/h
	Accuracy:	Accuracy of the pump: ±5% or ±1 ml
		Accuracy of the system: Pump regulated by scales is controlled within a maximum net fluid loss deviation of 50 ml for adults and 20 ml for low volume and a treatment accuracy of ±5% or 50 ml.
	Pressure range for specified accuracy: see specified values for return pressure.	
Display monitor	10.4 " TFT colour monitor	
	Minimum resolution:	640 x 480 pixels
Filtrate and substitution solution scale	Measurement method:	via strain gauge
	Max. load:	0 to 20 kg, max. 4 bags with 5 l of substitution fluid each
	Accuracy of scale:	0.1%
	Patient fluid balance error:	max. ±100 ml or 0.45%
Filtrate pressure sensor	Measurement method:	Contact measurement
	Measuring range:	-450 to +500 mmHg, step 1 mmHg Resolution: 1 mmHg
	Measuring accuracy:	±10 mmHg
	Upper alarm limit:	+450 mmHg
	Lower alarm limit:	-400 mmHg
Filtration pump**	Input range adult:	0 or 100–12,000 ml/h
	Input range low volume blood line:	0 or 100–7,000 ml/h
	Accuracy: Pressure range for the specified accuracy: see defined values for filtrate pressure.	Accuracy of the pump: ±5% or ±1 ml
		Accuracy of the system: Pump regulated by scales is controlled within a maximum net fluid loss deviation of 50 ml for adults and 20 ml for low volume and a treatment accuracy of ±5% or 50 ml.
	Fluid loss adult:	-100 to 2,000 ml/h Step-by-step 10 ml/h Maximum total fluid loss: 32,000 ml
	Fluid loss low volume blood line:	0 or 10–1,000 ml/h Step-by-step 10 ml/h Maximum total fluid loss: 15,000 ml
	NOTE Fluid can be added at a maximum rate of 100 ml/h, a maximum positive balance of 1 l is permissible for adult treatment.	
	Aqualine tubing set pump insert size is:	ID x OD: ø4.7 (±0.10) x 7.2 (±0.10) mm/ Length: 22.5 (±0.50) cm
	Aqualine S tubing set pump insert size is:	ID x OD: ø4.7 (±0.10) x 7.2 (±0.10) mm/ Length: 22.5 (±0.50) cm

Component	Specification	
Heating unit**	Adjustable substitution temperature:	0 (Off) or 35 °C to 39 °C, adjustable in 0.5 °C increments
	Alarm is triggered if temperature displayed on *More* screen is >40 °C.	
	Plate working range for CVVH, CVVHD or CVVHDF:	21 °C to 53 °C Alarm is triggered if heater plate temperature is >57 °C.
	Plate working range for TPE:	21 °C to 42 °C Alarm is triggered if heater plate temperature is >42 °C.
Heparin pump	Syringe pump uses 50 ml syringes (Calibration necessary).	
	Input range:	0 or 0.5–15 ml/h, Steps: 0.1 ml/h
	Flow rate accuracy:	typical: 2% related to 50 ml syringes, worst case scenario (line clamped): 2 ml
	Heparin bolus:	0.5–2.5 ml/bolus via patient parameter function, step 0.5 ml
PD (Pressure Drop)	Pre-filter pressure - Return pressure +35 (35 is the offset value. It is the distance between the pre-filter and the return sensors in cm divided by 1.3)	
	Working range:	-50 mmHg to +250 mmHg, step 1 mmHg
	Measuring accuracy:	±10 mmHg
	Alarm limits:	-50 to +250 mmHg
Plasma pump**	In TPE the post-dilution pump is used as plasma pump with the following specifications:	
	Input range adult:	Regular: 0 or 100–3,000 ml/h Step-by-step: 10 ml/h RCA: 0 or 500 –3,000 ml/h (RCA)
	Input range low volume blood line:	0 or 100–1,200 ml/h Step-by-step: 10 ml/h
	Accuracy:	Accuracy of the pump: ±5% or ±1 ml
		Accuracy of the system: Pump regulated by scales is controlled within a maximum net fluid loss deviation of 50 ml for adults and 20 ml for low volume and a treatment accuracy of ±5% or 50 ml.
	Pressure range for specified accuracy: see specified values for return pressure.	
Post-dilution pump**	Input range adult Regular mode:	0 or 100–10,000 ml/h Step-by-step: 100 ml/h
	Input range adult RCA mode:	0 or 500-6,000 ml/h Step-by-step: 100 ml/h
	Input range low volume blood line:	0 or 100–4,000 ml/h Step-by-step: 10 ml/h
	Accuracy:	Accuracy of the pump: ±5% or ±1 ml
		Accuracy of the system: Pump regulated by scales is controlled within a maximum net fluid loss deviation of 50 ml for adults and 20 ml for low volume and a treatment accuracy of ±5% or 50 ml.
	Pressure range for specified accuracy: see specified values for return pressure.	
	Aqualine tubing set pump insert size is:	ID x OD: ø4.7 (±0.10) x 7.2 (±0.10) mm/ Length: 22.5 (±0.50) cm
	Aqualine S pump insert size is:	ID x OD: ø3.3 (±0.10) x 5.7 (±0.10) mm/ Length: 22.5 (±0.50) cm

Component	Specification	
Pre-dilution pump**	Input range adult Regular mode:	0 or 100–10,000 ml/h
	Input range adult RCA mode:	0 or 500-6,000 ml/h Step-by-step: 100 ml/h
	Input range low volume blood line:	0 or 100–6,000 ml/h Step-by-step: 10 ml/h
	Accuracy:	Accuracy of the pump: ±5% or ±1 ml
		Accuracy of the system: Pump regulated by scales is controlled within a maximum net fluid loss deviation of 50 ml for adults and 20 ml for low volume and a treatment accuracy of ±5% or 50 ml.
	Pressure range for specified accuracy: see specified values for return pressure	
	Aqualine tubing set pump insert size:	ID x OD: ø4.7 (±0.10) x 7.2 (±0.10) mm/ Length: 22.5 (±0.50) cm
	Aqualine S tubing set pump insert size:	ID x OD: ø4.7 (±0.10) x 7.2 (±0.10) mm/ Length: 22.5 (±0.50) cm
Pre-filter pressure sensor	Measurement method:	Contact measurement
	Measuring range:	-400 to +500 mmHg, step 1 mmHg Resolution: 1 mmHg
	Measuring accuracy:	±5 mmHg
	Upper alarm limit:	+450 mmHg
	Lower alarm limit:	-100 mmHg
Processors	2 x CPU 80517 and 1 x Intel	
Return line clamp	With no power applied, the clamp is open	
	Minimum occlusion of the line:	350 mmHg
Return pressure sensor	Measurement method:	Contact measurement
	Measuring range:	-80 to +350 mmHg, step 1 mmHg Resolution: 1 mmHg
	Measuring accuracy:	±5 mmHg
	Upper alarm limit:	automatic setting between 120 and 350 mmHg
	Lower alarm limit:	automatic setting between 20 and 250 mmHg
	Alarm window size during treatment:	100 mmHg

Component	Specification	
TMP	Calculated: $\frac{(\text{Return pressure} + \text{Pre-filter pressure} + 35)}{2} - \text{Filtrate pressure}$ (35 defines the offset value. It represents the distance between the pre-filter and the return pressure sensor in cm divided by 1.3)	
	Working range:	-150 mmHg to +400 mmHg, step 1 mmHg Resolution: 1 mmHg
	Measuring accuracy:	±10 mmHg
	Upper alarm limit:	CVVH, CVVHD, CVVHDF, SCUF: automatic setting between +30 and +400 mmHg TPE (Plasma therapy): automatic setting between +30 and +100 mmHg Hemoperfusion: Alarm off
	Lower alarm limit:	CVVH, CVVHD, CVVHDF, SCUF: -30 mmHg TPE (Plasma therapy): -30 mmHg Hemoperfusion: Alarm off

NOTE The double star symbol (**) used as subscript for a parameter indicates that the correspondent performance data shown in the table, such as blood flow, filtrate flow, pre- and post-dilution flow, are considered as essential performance data.

9.6 Heater performance data

The Aquarius system has a heater system to warm up the substitution fluid. The programmed temperature range is [OFF; 35 °C to 39 °C]. To control the heater system, four temperature sensors are used: two are situated on the housing heater plate and two on the degassing chamber holder.

The resulting temperature of the substitution fluid depends on the following conditions:

- Programmed temperature
- Substitution fluid rate
- Substitution fluid temperature in the bag
- Environment temperature
- Gas in the heater coil

The relationship between substitution flow rate and maximal heating of the substitution fluid is shown in the following figure:

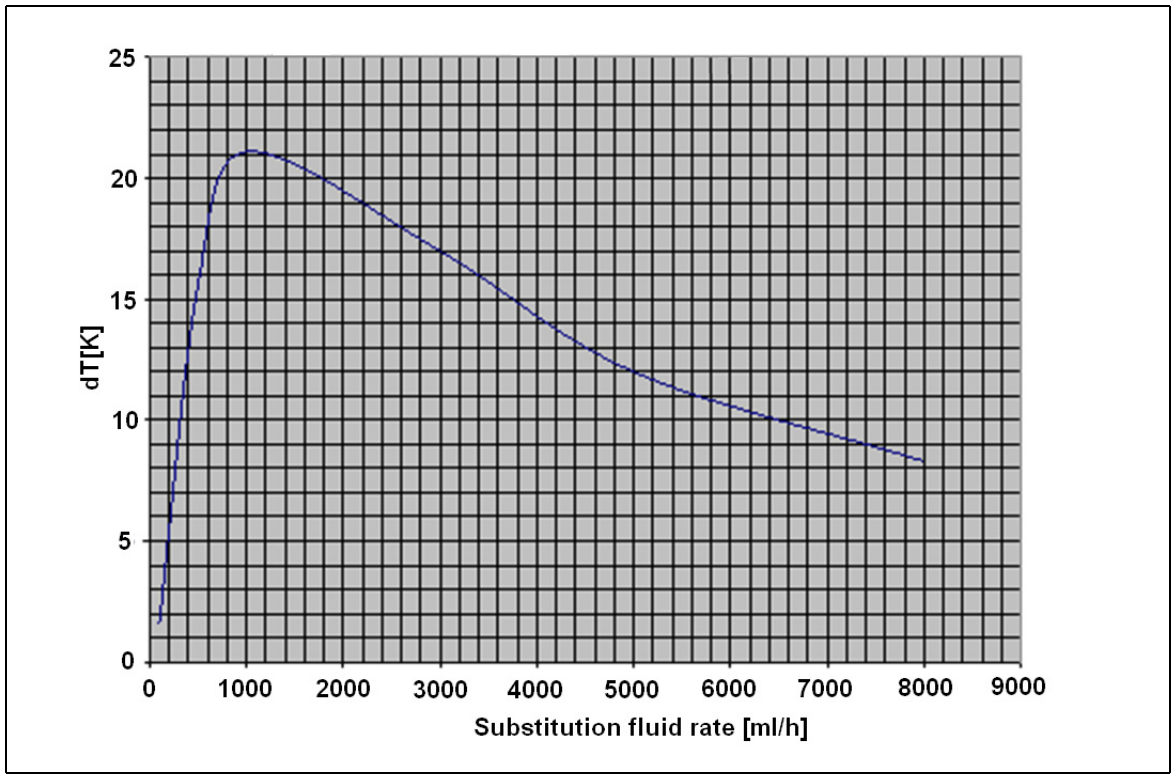


Fig. 218

This curve describes the amount of degrees the Aquarius system can heat up the substitution solution (Accusol) in dependence of the programmed substitution fluid rate.

Y - axis: Maximum heating capacity achievable by the heater (dT K)

X - axis: Substitution fluid rate in ml/h

Example:

Substitution fluid rate	3000 ml/h	3000 ml/h	5000 ml/h
Capacity to heat up	17 °C	17 °C	12 °C
Temperature Accusol	22 °C	19 °C	22 °C
Maximum substitution temperature	39 °C	36 °C	34 °C

The maximum substitution temperature depends on the programmed temperature and it is limited by the heating capacity described in Figure *218*. Due to safeguards designed into the system, the temperature of the fluid infused into the blood and/or dialysate circuit is less than 41 °C.

DO NOT rely on the temperature displayed on the *More* screen as a basis for clinical assessment of hypo- or hyperthermia. The accuracy of the calculated substitution fluid temperature displayed on the *More* screen is affected by the ambient temperature.

In vitro data shows that, under certain conditions, the temperature of the fluid infused into the blood and/or dialysate circuit can vary by as much as 8 °C from the temperature displayed on the *More* screen depending on the ambient temperature and substitution flow rates. However, due to safeguards designed into the system, the temperature of the fluid infused into the blood and/or dialysate circuit is less than 41 °C.

10 Waste management

The Aquarius system and used disposables should be disposed of according to the local provisions. The system must be cleaned before disposal to prevent bio-hazardous risks.

Electronic components of the Aquarius system must be disposed of, according to currently valid regulations for the disposal of electronic components.

Aquarius devices manufactured after the 15 July 2014 comply with RoHS regulations.

For more information on disposal please contact your local Technical Service Representative.

Part name	Toxic or Hazardous Substances and Elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr (VI))	Poly-brominated biphenyls (PBB)	Poly-brominated diphenyl ethers (PBDE)
Housing	X	o	o	o	o	o
TFT-Display	o	o	o	o	o	o
Accumulator	X	o	o	o	o	o
Electronics	o	o	o	o	o	o
Motors	o	o	o	o	o	o
Magnetic Clamp	o	o	o	o	o	o
Front Panel	o	o	o	o	o	o
Wheels	o	o	o	o	o	o
Cabling	o	o	o	o	o	o
Varnishing	o	o	o	o	o	o

o: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006 (Standard of the Electronics Industry of the People's Republic of China)

X: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirements in SJ/T11363-2006.

The environmental protection period for the device is specified in the pollution control symbol displayed above. The product should be stored and operated in accordance with the Instructions for Use, with particular regard to the environmental conditions described for use of the device.

11 Warranty and liability

The manufacturer can only guarantee the safety, reliability and performance of the Aquarius system if the operator follows the instructions contained in these Instructions for Use.

Warranty includes the repair and replacement of defective parts, as long as these are defects due to construction, fabrication and material.

The following actions immediately void the warranty:

- If modifications and repair work of the Aquarius system is done by unauthorized persons.
- If the intended use of the Aquarius system is ignored.
- If the Aquarius system is operated improperly.
- If valid standards regarding electrical installations are not fulfilled.
- If errors or system malfunction is caused by improper operation or normal wear.

12 References

Ahmad S, C. R., Cole JJ, Blagg CR: Dialysate made from dry chemicals using citric acid increases dialysis dose. Am J Kidney Dis 35(3):493-499, 2000

Ahmad S, Y. K., Yensen WM, Landicho D, Gregory B, Moritz JL et al.: Citrate anticoagulation during in vivo simulation of slow haemofiltration. Blood Purif 8(4):177-182, 1990

Anderson BJ, W. G., Bradbury P, Fox T, Stollery DE, Meier MA: Regional anticoagulation using trisodium citrate for continuous venovenous haemodiafiltration in critically ill adults. Blood Purif 16:103-104, 1998

Apsner R, Schwarzenhofer M, Derfler K, Zauner C, Ratheiser K, Kranz A: Impairment of citrate metabolism in acute hepatic failure. Wien Klin Wochenschr 109(4):123-7, 1997

Bellomo R, T. H., Boyce N: Anticoagulant regimens in acute continuous haemodiafiltration: a comparative study. Intensive Care Med 19(6):329-32, 1993

Brophy PD, Sommers MJG, Baum MA, Symons JM, McAfee N, Fortenberry JD, Blowey D, Baker C, Bunchman TE, Glodstein SL: Multi-centre evaluation of anticoagulation in patients receiving continuous renal replacement therapy (CRRT). Nephrol Dial Transplant 20:1416-1421, 2005

NOTE

The Aquarius devices manufactured before 2011 (serial numbers below 5000) are labeled with EDWARDS LIFESCIENCES as the manufacturer.

NIKKISO Europe GmbH acts as manufacturer of the Aquarius devices since 1st October 2010.
NIKKISO Europe GmbH supports all existing Aquarius devices in the market with post market activities.

The Instructions for Use Aquarius System published by NIKKISO Europe GmbH is valid for all Aquarius devices including devices labeled with EDWARDS LIFESCIENCES if the software 6.02.14 or higher is installed.

Manufacturer:
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Local sales contact:	Local technical support contact:
STAMP	STAMP

CE 0123

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REF: GE-F096-00
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Instructions for Use Aquarius System
English, Version 6.02.18 ff, Rev. 7.0
Part No.: DO-F599-00