Addendum for DO-F599-00_Aquarius_RCA_Reg_IFU_SW6.02.18ff_R7.0_en

Use of Software 6.02.21

The following changes are applicable for the IfU while operating the Aquarius hemofiltration machine with the SW 6.02.21.

Editorial note: Text changes/supplements are highlighted in yellow: text change/supplement

Aquarius System equipped with the software 6.02.21 and higher provides a *Low return pressure* mode that allows the blood pump to operate with return pressure between 0 and 20 mmHg. *Low return pressure* mode must be enabled in *Service* mode.

After blood pump start in *Regulated Start* or *Treatment* modes, an operating range for return pressure is set. A low alarm limit is set at 0 mmHg, high limit at 100 mmHg. When return pressure is inside operating range, the blood pump runs without audible alarm.

Up to 60 s, a yellow message "Low return pressure" is displayed on-screen as a silent visual reminder. After 60 s, the silent message changes the reminder to "Low return pressure, check patient connection". The blood pump still operates. Both message displays are silent, green status indication light is on.

If monitored return pressure exceeds 30 mmHg for more than 60 s, *Low return pressure* mode is automatically switched off and the alarm limits follow the actual pressure for 90 s.

If within 60 s, monitored return pressure exceeds 70 mmHg, *Low return pressure* mode is switched off immediately.

After blood pump stop, a restart of the blood pump initiates a repetition of the described *Low return pressure* mode process.

The delay time for a *Low return pressure* alarm is set to:

- $60 \times 350\ [ml] \div blood\ flow\ rate\ [ml/min]$ for adult treatments
- $60 \times 150\ [ml] \div blood\ flow\ rate\ [ml/min]$ for low volume treatments.

The delay time for a *Low pre-filter pressure* alarm receives similar settings.

In the context of the changes mentioned above, the following messages were changed:

- *Return pressure low* was replaced by *Low return pressure*
- *Heater self test running* was replaced by *Low return pressure – Check patient connection!*

In the context of the changes mentioned above, the following alarm was changed:

- *Low return pressure* was replaced by *Return pressure drop*

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	**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.** **During the *Low return pressure* mode the blood pump operates with return pressures below 20 mmHg. In this case: pay closer attention to the security and correct connection of the return line, position, and correct fitting of catheter connections. A pressure drop below 0 mmHg return pressure detects a dislodging or disconnection of the return line from the patient. Nevertheless, in this case the risk of undetected dislodging or disconnection is increased.**

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	**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 blood line 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 blood line 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.** **Especially the *Low return pressure* mode requires higher attention for the return line and correct fitting of catheter connections.**

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

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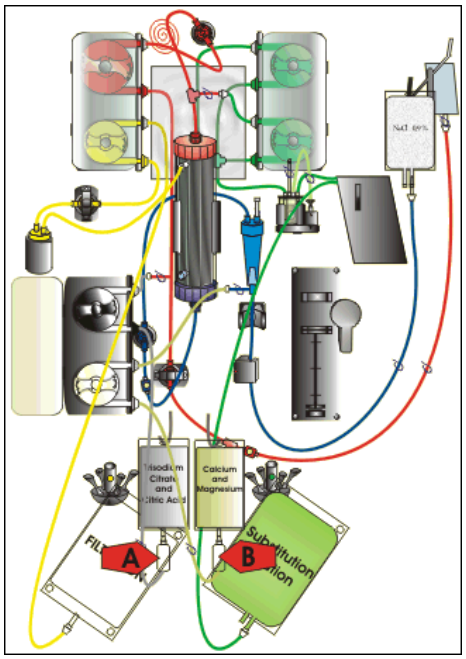

Fig. 81

Step 6: Fill the drip chambers:

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

Step 7: Close pump doors.

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5.8.10 Treatment termination due to maximum operation time

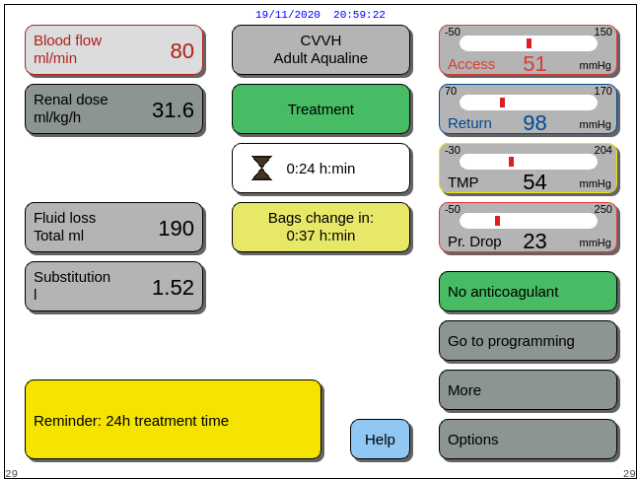

Fig. 175

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.

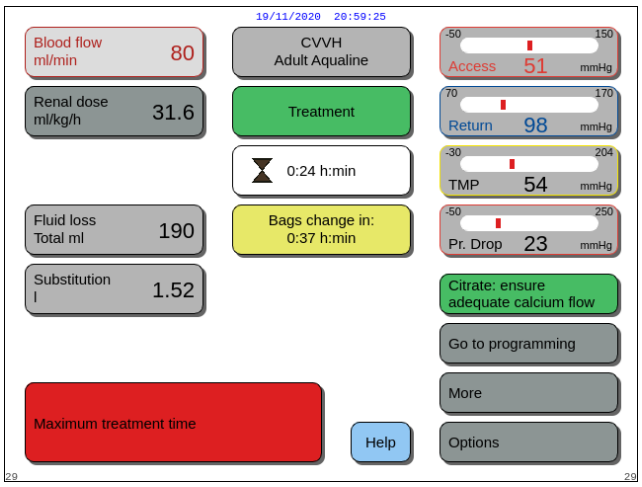

Fig. 176

A red warning is displayed when the maximum treatment time* is reached. The warning can be silenced for 1 h when maximum blood pump operation time** does not exceed 108 h.

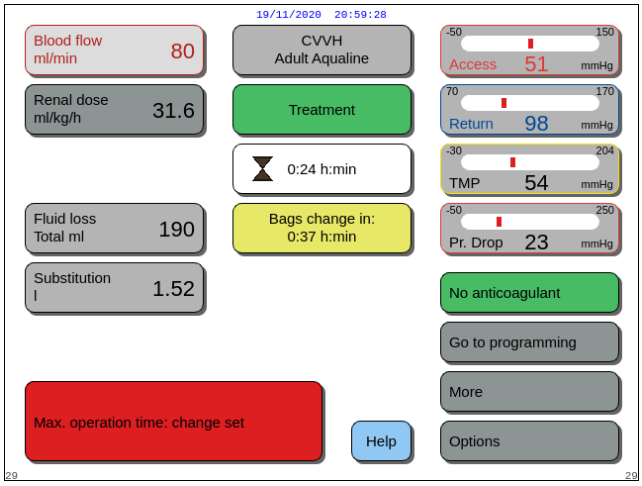

Fig. 177

An alarm is displayed when the blood pump operation time** exceeds 108 h. The balance system cannot be operated. Blood pump operation time during balance system stops or recirculation can show this alarm occurring before maximum treatment time is reached. Blood pump operation time overrides maximum treatment time.

Step 1: Terminate the treatment.

Step 2: Disconnect the patient.

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

*The maximum treatment time takes into consideration time when the balance system is active.

** The blood pump operation time takes into consideration the combined time duration for priming, treatment, and recirculation.

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Display	ID	Max alarm delay time	L*/NL**	Cause	Options for error removal
Return pressure drop	**65**	15 s to 90 s	L	• The return line is disconnected from the patient and the return pressure dropped or fell below the alarm limit.	⇒ Ensure that the return line is connected to the patient. If connected, restart the blood pump.
				• The return pressure dropped or fell below the alarm limit.	⇒ Consider an increased blood flow rate prescription and restart the blood pump. ⇒ Faulty transducer. Stop treatment and call technical service.

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Display	ID	Cause	Options for error removal
Low return pressure – check patient connection	**159**	The return pressure is below 20 mmHg. The blood pump runs with on-screen message. The Aquarius system operates in the *Low return pressure* mode.	⇒ During bag change in RCA mode the on-screen message clears automatically. ⇒ If the return pressure remains less than 20 mmHg, check patient connections are intact. ⇒ Consider an increased blood flow rate prescription.

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Display	ID	Cause	Options for error removal
Low return pressure	**123**	After blood pump start the return pressure is below 20 mmHg.	⇒ The blood pump runs with this temporary message on screen for 2 minutes at the beginning of the treatment or until the pressure is above 20 mmHg. ⇒ The blood pump runs with this temporary message on screen for 1 minute after starting the blood pump in treatment mode. ⇒ Ensure that the return line is connected to the patient.