

## 4 Specifications

### 4.1 Dimensions and weight

#### Dimensions

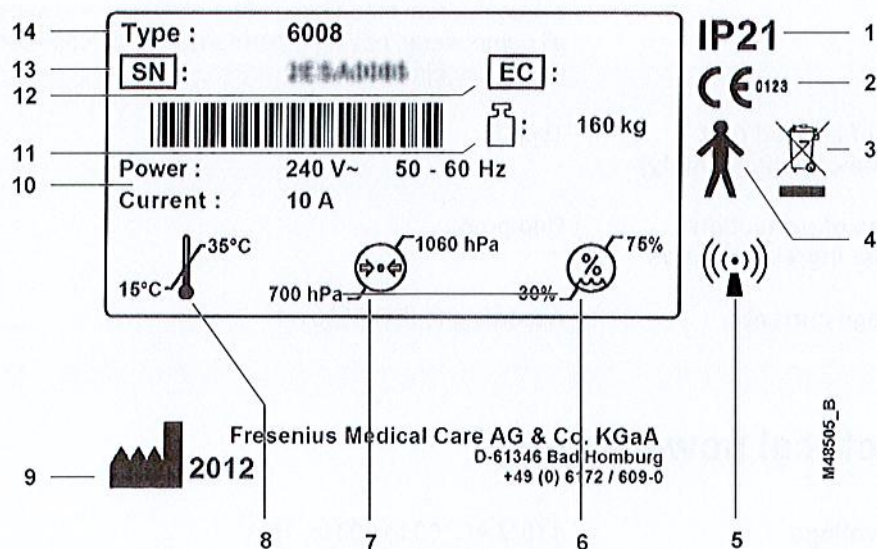
Height: approx. 168 cm (approx. 200 cm incl. IV pole)  
 Width: approx. 52 cm (on base incl. brake)  
 Depth: approx. 78 cm (approx. 90 cm incl. container holder)

#### Weight

Empty weight including all options: approx. 115 kg  
 Safe working load: approx. 45 kg  
 Maximum total weight: approx. 160 kg (empty weight including all options + safe working load = maximum total weight)

### 4.2 Identification label (device marking)

The identification label shown is only an example. Always go by the information shown on the identification label affixed to the device itself.



- 1 Degree of protection against ingress of solid foreign objects and liquids
- 2 CE mark
- 3 Symbol for the marking of electrical and electronic equipment
- 4 Type of applied part (degree of patient safety): Type B
- 5 Non-ionizing electromagnetic interference

- 6 Relative humidity (operating conditions)
- 7 Atmospheric pressure (operating conditions)
- 8 Operating temperature range
- 9 Manufacturer and year of manufacture
- 10 Power requirements (voltage / operating current)
- 11 Maximum total weight (weight empty plus safe working load)
- 12 Equipment code (EC)
- 13 Serial number
- 14 Type identification

### 4.3 Electrical safety

Classification according to IEC 60601-1

Degree of protection against electric shock	Protection class I
Applied part	Depending on the method of treatment, the applied part consists of the extracorporeal blood circuit, the dialysate and substitute circuits, and all components having a permanent electrically conductive connection with these circuits.
Type of applied part (degree of patient safety)	Type B
Degree of protection against ingress of fluids	Drip-proof
Leakage currents	According to IEC 60601-1

### 4.4 Electrical power supply

Line voltage	110 V AC, 50 to 60 Hz, 15 A 120 V AC, 50 to 60 Hz, 14 A 220 to 230 V AC, 50 to 60 Hz, 11 A 240 V AC, 50 to 60 Hz, 10 A (Always go by the line voltage, frequency and operating current information specified on the identification label attached to the device itself.)
Rechargeable battery	Rechargeable lead-acid battery (maintenance-free) 24 V, 7 Ah Power supply for audible alarm output in case of power failure for at least one minute.
PC board battery	Battery (see chapter 10.14.18 on page 475)

PCB LP 1105-1 battery	Battery (see chapter 10.14.2 on page 451)
PCB LP 1186 battery	Battery (see chapter 10.14.16 on page 472)
VenAcc battery (option)	Battery (see chapter 4.20 on page 85)
Power supply cord	Length 3.5 m, unshielded
Power switch	All-pole simultaneous disconnection

## 4.5 Fuses

Power switch	2 x G 16 A (thermal overcurrent circuit breaker), rear of power supply unit
Rechargeable battery	1 x T 10 AL, 250 V; fuse in housing foot (rear)
Power plug fuse, UK version	Fuse (see chapter 10.10.3 on page 321)
PCB LP 1104	Fuses (see chapter 10.14.1 on page 449)
PCB LP 1106	Fuses (see chapter 10.14.3 on page 452)

## 4.6 Information on electromagnetic compatibility (IEC 60601-1-2:2014)

Specifications refer to the requirements of IEC 60601-1-2:2014.

The data are valid for devices manufactured as of 2019.

### 4.6.1 Minimum distances between radiation source and medical electrical equipment

Medical electrical equipment is subject to special precautions with respect to electromagnetic compatibility (EMC).



#### Warning

##### Risk for the patient as a result of a device malfunction

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

- In the case of portable RF communications equipment, always observe a distance of at least 30 cm from the device.



Portable RF communications equipment may include the following radiation sources (examples):  
Cell phone, smartphone, tablet computer, cordless telephone, notebook/laptop, wireless keyboard, wireless mouse, wireless speaker, radio remote control (the device-specific radio remote control by the manufacturer is not affected).



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**Warning**

**Risk for the patient as a result of a device malfunction**

The use of electrical accessories and cables other than those specified in the Instructions for Use can lead to an increase in electromagnetic emissions or a reduction in electromagnetic immunity of the device.

- Only use accessories and cables approved by the manufacturer.
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**Warning**

**Patient hazard through electromagnetic incompatibility with other devices**

Electromagnetic interference from other devices can cause device malfunctions.

- Do not operate the device in the immediate vicinity of other devices.
- If operation in the immediate vicinity of other devices cannot be avoided:
- Monitor the device to verify that it is working properly.
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#### 4.6.2 Guidance and manufacturer's declaration on EMC

##### ● Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The 6008 device is intended for use in the electromagnetic environment specified below. The customer or the user of the 6008 device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1 Class A	<p>The 6008 device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</p> <p>The 6008 device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</p> <p>The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.</p>
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

##### ● Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The 6008 device is intended for use in the electromagnetic environment specified below. The customer or the user of the 6008 device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.



Guidance and manufacturer's declaration – electromagnetic immunity			
The 6008 device is intended for use in the electromagnetic environment specified below. The customer or the user of the 6008 device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % $U_T$ for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees  0 % $U_T$ for 1 cycle  70 % $U_T$ for 25 cycles  0 % $U_T$ for 250 cycles (5 s)	0 % $U_T$ for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees  0 % $U_T$ for 1 cycle  70 % $U_T$ for 25 cycles  0 % $U_T$ for 250 cycles (5 s)	In the event of power supply interruptions, the rechargeable battery of the 6008 device temporarily takes over the supply for parts of the system without delay.  Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<b>Note:</b> $U_T$ is the AC mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 $V_{rms}$ 150 kHz to 80 MHz  6 $V_{rms}$ in ISM bands between 150 kHz and 80 MHz	3 $V_{rms}$  6 $V_{rms}$ in ISM bands	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	
<b>Note:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

## 4.7 Operating conditions

Atmospheric pressure	700 hPa to 1060 hPa
Installation altitude	Maximum installation altitude up to 3000 m
Relative humidity	30 % to 75 %, temporarily 95 %
Stability	Maximum allowed inclination angle 5°
Inclination during operation	Maximum allowed inclination angle 3°
IV pole load capacity	Maximum: 3 kg

<b>Dialysis water inlet pressure</b>	1.5 to 6.0 bar
<b>Dialysis water inlet temperature</b>	<p>5 °C to 30 °C          for "Integrated hot rinse": 85 °C to 95 °C          for "Interface heat disinfection": 78 °C to 85 °C</p> <p>For line voltages between 100 V and 120 V and low dialysis water inlet temperatures, a restriction of the dialysate flow can be expected due to the available power supply.</p> <p>Example:          Line voltage 110 V, heater output 1200 W, dialysis water inlet temperature 10 °C, dialysate temperature (target value) 37 °C,          = flow ≤ 800 ml/min</p>
<b>Dialysis water inlet rate</b>	<p>Maximum 1.5 l/min; with an inlet pressure of 1.5 bar</p> <p>for interface heat disinfection: minimum 500 ml/min at 1.5 bar</p>
<b>Water drain</b>	0 up to 100 cm above floor, separate free fall for each device no less than 2 cm. The water drain must be located at a lower level than the dialyzer.
<b>Temperature at water drain</b>	Maximum temperature at the water drain: 95 °C
<b>Concentrate supply</b>	0 to -100 mbar; maximum suction height 1 m
<b>Central delivery system (option)</b>	<p>Pressure: 0.05 to 2.0 bar</p> <p>Temperature: 15 °C to 35 °C</p> <p>Maximum flow: 35 ml/min</p>
<b>Operating temperature range</b>	15 °C to 35 °C

## 4.8 Consumption and energy data

The consumption and energy data represent the average values during typical operation.

Environmental conditions: dialysis water inlet temperature 15 °C, ambient temperature 22 °C.

For dialysis, the following data is assumed: ONLINE treatment with a blood flow rate of 350 ml/min and an AutoFlow factor of 1.2 including substitute preparation (factor 0.3) corresponding to a dialysate flow of 525 ml/min.

Unless stated otherwise, the consumption values below have been determined for one operating hour each.

Specifications for cleaning programs are based on factory settings and are applicable for each program run.

More data can be obtained from the manufacturer on request.



<b>Mean dialysis water consumption</b>	Dialysis: approx. 31 liters Disinfection / heat disinfection: approx. 14 liters
<b>Mean acid concentrate consumption</b>	Dialysis (ACF, mixing ratio 1+44): approx. 0.7 liters
<b>Mean bicarbonate consumption</b>	Dialysis: approx. 650 g bicarbonate (bibag) every 4 h
<b>Mean energy consumption</b>	Dialysis: approx. 0.68 kWh Heat disinfection: approx. 0.80 kWh
<b>Mean energy loss to the drain</b>	Dialysis: approx. 0.53 kWh Heat disinfection: approx. 0.40 kWh
<b>Mean energy loss to the environment</b>	Dialysis: approx. 0.15 kWh Heat disinfection: approx. 0.40 kWh

## 4.9 Storage conditions

	The device must be stored upright in a well-ventilated room with low variations in temperature.
<b>Temperature</b>	Without antifreeze: +5 °C to +60 °C With antifreeze: -20 °C to +60 °C (new device / decommissioned device)
<b>Relative humidity</b>	30 % to 75 %, temporarily 95 %
<b>Atmospheric pressure</b>	500 hPa to 1060 hPa
<b>Maintenance of the built-in rechargeable battery</b>	<p>The rechargeable battery is maintenance-free.</p> <p>Upon receipt of the system, charge the battery as follows:</p> <ul style="list-style-type: none"> <li>➤ Use the power supply cord to connect the device to the power supply.</li> <li>➤ Switch the main power switch of the device to "on".</li> <li>➤ Leave the device on for 10 hours.</li> </ul> <p>If the device is not used, repeat this procedure every six months.</p>



## 4.10 External connection options



### Warning

#### Risk of injury as a result of an electric shock

There is a risk of electric shock if the patient comes into contact with the pins or contacts of the device's connectors, whether directly or indirectly through the operator.

➤ Avoid touching connector pins or contacts during treatment.

Any additional equipment connected to this device must comply with the relevant IEC or ISO standards (e.g., IEC 60950-1 for information technology equipment).

Furthermore, all device configurations must comply with the requirements for medical electrical systems (see IEC 60601-1 Section 16 and Annex I).

Connecting the device to an IT network that contains components not installed and validated by the device manufacturer can introduce unknown risks for patients, operators or third parties. These risks must be identified, analyzed, evaluated and monitored by the responsible organization. For assistance, consult IEC 80001-1 and Annexes H6 and H7 of IEC 60601-1, for example.

Any modification to an IT network that has been installed and validated by the device manufacturer can introduce new risks and therefore requires a repeat analysis. Especially problematic activities:

- Changes to the IT network configuration
- Connection of additional components and devices to the IT network
- Removal of components and devices from the IT network
- Updating or upgrading components and devices in the IT network

Note that local laws take priority over the above mentioned normative requirements. If you have any questions, please contact your local service support organization.

### LAN

Interface for data exchange.

Electrically isolated by transformer.

Port: RJ 45

Length of network cable: 4 m

Shielded twisted pair cable: CAT5 or better

### Service/diagnostics

(Protected by cover!)

For in-house computer diagnostics.

Interface for data exchange (RS232).

24 V (max. 0.75 A)

Port: DSUB 15-pin

Length of serial cable: max. 3 m, shielded

Connection for AquaUNO/AquaC UNO H (single-station reverse osmosis units)

Length of cables: adapter cable 0.3 m and control cable 3 m or 11 m

**Alarm output**

For the connection of an external alarm indicator (nurse call) (potential-free alarm output, alternating contact, maximum 24 V / 24 W).

Port: 5-pin circular DIN connector

Length of cable: max. 3 m, unshielded

Only the cable from the accessories approved by the manufacturer must be used.

Signal transmissions to external alerting systems (nurse call) are not monitored by the device.

Connecting an external alerting system (nurse call) has no influence on the visual and audible alarms on the device itself.

**Warning****Risk for the patient as a result of ignored alarm signals**

The reliability of alarm signal transmissions to external alarm systems cannot be guaranteed, meaning that alarms can fail to be indicated externally.

- Stay close enough to the device to be able to notice any alarms it emits at all times.

**Equipotential bonding line**

Length 4 m, unshielded

## 4.11 Operating programs

**T1 test**

Automatic test of the operating and safety systems.

The T1 test is mandatory

- After power on (not following a power failure).
- After a cleaning program.

**Preparation**

Defined by the venous optical detector located below the venous bubble catcher.

Preparation is terminated as soon as the venous optical detector detects dark in the cassette system.

**Priming and rinsing the cassette system**

Minimum rinse volume 500 ml; automatic switching to Rinse mode if fluid level detected in the level detector. Automatic raising of the fluid level during the rinse phase.

**Treatment**

Hemodiafiltration (HDF), hemodialysis (HD), hemofiltration (HF), ISO UF

Double-Needle, double-lumen catheter, Single-Needle, single-lumen catheter

Bicarbonate citrate dialysis, bicarbonate acetate dialysis, acetate dialysis

Dialysis time display

Maximum time: 12:00 hours

Resolution: 1 minute

Time base accuracy\*: max.  $\pm 0.6$  seconds per hour



<b>Reinfusion</b>	<p>Reinfusion volume adjustable in the <b>User setup</b>. Return to treatment possible.</p>
<b>Circulation (during the treatment)</b>	<p>The Circulation function allows the patient to be disconnected from the device for a short time during treatment.</p> <p>During the circulation function, the device shows the following behavior:</p> <ul style="list-style-type: none"> <li>– The blood flow rate is set to 100 ml/min.</li> <li>– The heparin pump rate is reduced to 1 ml/h if the specified value exceeds 1 ml/h.</li> <li>– The alarm limits for the arterial and venous pressure are monitored to ensure they cannot be set higher than the end of the scale.</li> <li>– Ultrafiltration, <i>ONLINEplus™</i> and OCM are inactive.</li> <li>– The BTM and BVM control options are inactive.</li> <li>– The interval mode of the BPM option is turned off.</li> <li>– Alarms are not emitted with the VenAcc option.</li> </ul>
<b>Cleaning programs</b>	<p>Free rinse / rinse / mandatory rinse: Time (adjustable in the Service setup) Temperature: approx. 37 °C Flow rate: 600, 700 ml/min (adjustable in the Service setup)</p> <p>Degreasing / cold disinfection, Cold disinfection: Time (adjustable in the Service setup) Temperature: approx. 37 °C Flow rate: 600, 700 ml/min (adjustable in the Service setup)</p> <p>Heat disinfection: Time (adjustable in the Service setup) Temperature: approx. 85 °C Flow rate: 600, 700 ml/min (adjustable in the Service setup)</p> <p>Integrated hot rinse: Time (adjustable in the Service setup) Temperature: approx. 85 °C Flow: max. 600 ml/min Flow rate for cool down rinse: 600, 700 ml/min (adjustable in the Service setup)</p> <p>Interface heat disinfection: Time (adjustable in the Service setup) Temperature (adjustable in the Service setup) Temperature: 78 °C to 85 °C (dialysis water supply) Flow: 400 ml/min; with AquaC UNO H 200 ml/min</p> <p>Endless rinse: Time not adjustable, Temperature: approx. 37 °C Flow rate: 600, 700 ml/min (adjustable in the Service setup)</p> <p>In all programs: Progress of the program (time-counting) is interrupted in the event of a flow alarm. The cleaning programs can be stopped. A mandatory rinse is performed after the following programs:</p> <ul style="list-style-type: none"> <li>– Disinfection</li> <li>– Heat disinfection</li> <li>– Endless rinse</li> </ul>

**Flush (option)**

Rinsing of the water supply area

(\* = essential performance characteristics for IEC 60601-1)

## 4.12 Dialysate circuit and safety systems

**Blood leak detector**

Response threshold  $\leq 0.35$  ml blood loss per minute into the dialysis fluid for a hematocrit of 0.32.  
(flow rate 100 ml/min to 1000 ml/min).

If the dialysis fluid flow is switched off, blood leak alarms will be delayed. The delay depends on the fluid volume in the rinse area between the dialyzer and the blood leak detector (total fluid volume approx. 65 ml) and the size of the membrane rupture in the dialyzer. The initiation of a blood leak alarm also depends on the set UF rate.

**Transmembrane pressure**

Display range:  $-100$  to  $400$  mmHg  
Resolution:  $5$  mmHg

Definition:

$$\text{TMP} = P_{bo} - (P_{di} + P_{do}) / 2 + \text{offset}$$

TMP = transmembrane pressure

 $P_{bo}$  = blood pressure on the outlet side of the dialyzer $P_{di}$  = dialysate pressure on the inlet side of the dialyzer $P_{do}$  = dialysate pressure on the outlet side of the dialyzer

Offset = correction of flow-dependent pressure drops

An alarm is generated if values are outside the display range.

A default value is used for the TMP offset.

**Pressure holding test**

The pressure holding test is initiated as soon as the possibility of a balancing error  $\geq 400$  ml arises, based on the TMP monitoring calculation.

The pressure holding test detects leakages of  $\geq 100$  ml/h  $\pm 25\%$ .

When using the LOW VOLUME option:

The pressure holding test is initiated as soon as the possibility of a balancing error  $\geq 350$  ml arises, based on the TMP monitoring calculation.

In addition, the sensitivity of the pressure holding test is increased at a dry weight  $\leq 25$  kg.

In this case, the detectable leakage is  $0.5\%$  of the dry weight per hour.

**Ultrafiltration\***

Selectable UF rate:  $0$  ml/h to  $4000$  ml/h (in increments of  $10$  ml/h)

Maximum rate can be limited in **User setup** in increments of  $10$  ml/h.

Pump volume accuracy:  $\pm 1\%$  (for  $P_{di} > -500$  mbar)

The ratio of UF rate to effective blood flow is monitored during the treatment. If a discrepancy occurs a warning is displayed after about  $10$  seconds.



<b>UFC measurement</b>	<p>At the beginning of the treatment, a measurement of the ultrafiltration coefficient (UFC) of the connected dialyzer is performed. This value is taken as initial value for different parameters (e.g., TMP monitoring).</p> <p>If this measurement fails to be performed successfully 3 times in a row because of malfunctions, a message will be displayed: <i>TMP: UFC measurement failed. The treatment can be continued! Please read the information!</i> – <b>Repeat</b> together with the corresponding information about possible causes. As long as no current value is measured, a default value is used for the calculation instead of the measured value.</p>
<b>Balancing*</b>	Accuracy: $\pm 0.1\%$ , relative to the total dialysis fluid volume
<b>Maximum balancing error</b>	$F = F_{UF} + F_{Bal}$ <p> <math>F</math> = Maximum balancing error  <math>F_{UF}</math> = Ultrafiltration error  <math>F_{Bal}</math> = Balancing error </p> <p>Example:            Ultrafiltration error at 1000 ml in 1 hour: <math>\pm 1\% = \pm 10</math> ml/h            Balancing error at 30 liters of fluid flow in 1 hour with a dialysis fluid flow rate of 500 ml/min: <math>\pm 0.1\% = \pm 30</math> ml/h            Maximum balancing error:  <math>F = F_{UF} + F_{Bal} = (\pm 10 \text{ ml/h}) + (\pm 30 \text{ ml/h}) = \pm 40 \text{ ml/h}</math> </p>
<b>Degassing</b>	Method: negative pressure
<b>Composition of the dialysis fluid (conductivity)*</b>	<p>The composition of the dialysis fluid results from the volumetric mixing of dialysis water and the concentrates used. This is monitored by conductivity measurement.</p> <p>Display range: 12.8 to 15.7 mS/cm            Resolution: 0.1 mS/cm            Accuracy: 0.1 mS/cm            Method:            Temperature-compensated electronic conductivity meter with adjustable alarm limit window (<math>\pm 5\%</math> around the target value).</p> <p>Separate bicarbonate concentration monitoring using a fixed alarm limit window (<math>\pm 25\%</math> around the target value).</p>
<b>Concentrates</b>	<p>Entering concentration types.            Adjustment range: 125 to 151 mmol/l, depending on the concentrate used, <math>\pm 10\%</math> of the base value.            Bicarbonate adjustment range: corresponds to <math>\pm 8</math> mmol/l</p>
<b>bi bag</b>	<p>Bicarbonate concentrate preparation from the bi bag            Temperature range: 15 to 35 °C</p>
<b>Dialysate temperature*</b>	<p>Adjustment range: (target temperature) 34.0 °C to 39.0 °C            Resolution: 0.5 °C            Measuring accuracy: <math>+0.2\text{ °C} / -0.5\text{ °C}</math></p> <p>If the temperature falls below 33 °C or exceeds 40 °C an alarm is generated.</p>

**Dialysate flow\***

Depending on the ambient conditions, the temperature at the dialysate inlet port may drop by up to 5 °C if the dialysate flow is < 200 ml/min.

Display range: 100 to 1000 ml/min

Resolution: 100 ml/min

Accuracy:  $\pm 20$  ml/min or  $-10\%$

(the smaller value applies)

Target values: 100 to 1000 ml/min

If necessary, the dialysate flow rate will be limited in relation to the current substitution rate. The sum of the dialysate flow rate and the substitution rate will not exceed 1000 ml/min.

Measured by means of time pulse monitoring and balancing chamber volume

AutoFlow: The AutoFlow function automatically regulates the dialysate flow, depending on the blood flow rate.

Entering a specific factor for AutoFlow changes the ratio of the selected blood flow rate to the dialysate flow. The default value of the AutoFlow factor in the **User setup** is 1.2 for HDF and 1.5 for HD.

Example:

Blood flow rate: 350 ml/min, HDF, factor: 1.2

Dialysate flow = 420 ml/min

The factor (AutoFlow) can be modified in the **User setup** and in the **Dialysate** menu.

These particular default values achieve the optimum balance between the dialysis quality (Kt/V) and the resources used (dialysis water, concentrates, energy).

If the default values are exceeded, the use of resources is disproportionately high as compared with the dialysis quality obtained. An entry below the default value in either case will result in a disproportionately poorer dialysis quality, compared with the resources saved.

EcoFlow: Dialysate flow is automatically reduced to 100 ml/min in Preparation.

The following must be observed regarding the dialysate flow:

If the dialysis water inlet rate is not sufficient for achieving the maximum dialysate flow of 1000 ml/min, the permitted adjustment range will be limited accordingly.

**Rinse temperature**

Rinsing:

Target temperature: 37 °C

Resolution: 0.5 °C

Measuring accuracy:  $\pm 0.2$  °C

Integrated hot rinse:

Target temperature: 85 °C

Resolution: 0.5 °C

Measuring accuracy:  $\pm 2.0$  °C

Endless rinse:

Target temperature: 37 °C

Resolution: 0.5 °C

Measuring accuracy:  $\pm 0.2$  °C



<b>Disinfection temperature</b>	Cold disinfection:
	Target temperature: 37 °C
	Resolution: 0.5 °C
	Measuring accuracy: $\pm 0.2$ °C
	Degreasing / cold disinfection:
	Target temperature: 37 °C
	Resolution: 0.5 °C
	Measuring accuracy: $\pm 0.2$ °C
	Heat disinfection:
	Target temperature: 85 °C
	Resolution: 0.5 °C
	Measuring accuracy: $\pm 2.0$ °C
	Interface heat disinfection:
	depends on the dialysis water inlet temperature; temperature not monitored.
<b>Rinse and disinfection flow</b>	Target value: 600 ml/min or 700 ml/min (depending on the settings in the Service setup) (During the recirculation phase in disinfection the flow is always 600 ml/min)
<b>Concentration of disinfectant</b>	Citrosteril, Diasteril, Puristeril 340, Puristeril <i>plus</i> : 4 % Sporotal 100: 3 %
<b>Flow alarm</b>	Depends on the programmed flow (* = essential performance characteristics for IEC 60601-1)

## 4.13 Extracorporeal blood circuit and safety systems

<b>Arterial pressure measurement</b>	Display range: -300 to +300 mmHg
	Resolution: 5 mmHg
	Accuracy: 7 mmHg (typical)
	Venous optical detector is not detecting blood:
	Alarm limits, arterial alarm limit window size: -300 to +300 mmHg
	Venous optical detector is detecting blood:
	Alarm limits, arterial alarm limit window size: +40 to +200 mmHg
	Default value adjustable in the <b>User setup</b> , factory setting 100 mmHg
<b>Blood flow*</b>	Delivery rate: 30 to 600 ml/min
	Resolution: 10 ml/min
	For LOW VOLUME option: resolution 5 ml/min, for delivery rates $\leq 100$ ml/min
	System accuracy of the delivered blood volume: $\pm 10$ % (Single-Needle operation: -10 to +15 %) over the complete duration of the treatment, for typical treatment situations




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**Warning**
**Risk for the patient as a result of insufficient detoxification**

If the arterial pressure before the blood pump reaches extreme negative values, the blood flow may be reduced, which will impair the effectiveness of the treatment.

- Take suitable measures to prevent extremely negative arterial pressures at the access.
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Pump segment diameter: 7.1 mm  
 Blood pump stop alarm: 60 seconds  
 (180 seconds in Single-Needle operation – option).

**Pre-filter pressure monitoring**

Accuracy: 20 mmHg (typical)  
 Venous optical detector is not detecting blood:  
 no monitoring  
 Venous optical detector is detecting blood:  
 limit value monitoring for 950 mmHg, or 600 mmHg after preparation with NaCl solution  
 (not adjustable).

**Venous pressure measurement**

Display range: –100 to +500 mmHg  
 Resolution: 5 mmHg  
 Accuracy: 7 mmHg (typical)  
 Venous optical detector is not detecting blood:  
 Alarm limits, venous alarm limit window size: –100 to +500 mmHg  
 Venous optical detector is detecting blood:  
 Alarm limits, venous alarm limit window size: +40 to +200 mmHg  
 Default value adjustable in the **User setup**,  
 factory setting 100 mmHg  
 adjustable over a range of +20 to +500 mmHg  
 (adjustable in the **User setup** from –100 to 500 mmHg).

**Level detector**

Method:  
 Capacitive measurement

**Optical detector**

Method: infrared transmission  
 Distinguishes between  
 Optical detector is not detecting blood (rinse solution or air in the cassette system)  
 Optical detector is detecting blood (blood in the cassette system)

**Air bubble detector (arterial/venous)**

Method:  
 ultrasonic transmission measurement on the line  
 Sensitivity:  
 – Air bubbles of  $\geq 25 \mu\text{l}$  volume  
 – Blood foam (air/blood mixture)  
 – Microbubbles



## Air alarm:

- Blood flow rate < 100 ml/min:  
Air bubble of  $\geq 25 \mu\text{l}$  volume  
Blood foam  
Microbubbles (venous only)
- Blood flow rate  $\geq 100 \text{ ml/min}$ :  
10 air bubbles (5 for LOW VOLUME) with an air bubble volume of < 100  $\mu\text{l}$  each  
or 1 air bubble with an air bubble volume of  $\geq 100 \mu\text{l}$ ,  
Blood foam  
Microbubbles (venous only)

The specified data is based on a worst-case assumption, at a blood flow rate of 0 to 600 ml/min using the cassette system approved for the device.

**Heparin pump**

Delivery rate: 0.5 to 10 ml/h

Resolution: 0.1 ml/h

Accuracy:  $\pm 1 \text{ ml}$  or  $\pm 7 \%$  of cumulative heparin (the higher value applies) at pressures from 0 to +1.27 bar.

(Applies only to the disposable syringes listed in the Instructions for Use. When using other syringes the tolerance may differ.)

Stop time: 0 min to 9 hrs 59 min

Resolution: 1 min

Bolus administration: 1.0 to 20.0 ml

Resolution: 0.1 ml

**Audible alarm**

Adjustment range of the loudness of the audible alarm:

Loudness range: 50 to 75 dBA ( $\pm 10 \%$ )

(adjustable in the **SYSTEM** menu, in the Loudness submenu).

Factory setting:  $\geq 65 \text{ dBA}$

(\* = essential performance characteristics for IEC 60601-1)

## 4.14 DIASAFE<sup>®</sup> plus

**Life of the filter  
(filter 1 / filter 2)**

No more than 12 weeks and/or 100 treatments

The number of remaining treatments is displayed in the cleaning programs and under **Status** ⇨ **Device info**.

The device monitors filter life and issues a warning when a filter change is necessary.

When ONLINEplus<sup>™</sup> is used, the functions of ONLINEplus<sup>™</sup> will be disabled when the life of the filter has been exceeded.

**Cleaning/disinfection  
(filter 1 / filter 2)**

Up to 11 degreasing programs can be performed during the life of the filters. After that, no more degreasing programs can be performed during the remaining life of the filters. All other cleaning/disinfection programs for the device remain available.

The number of remaining degreasing procedures is displayed in the cleaning programs and under **Status** ⇨ **Device info**.

## 4.15 OCM

Measuring accuracy of the clearance:  $\pm 6$  % standard deviation

Shortest measuring interval: 25 min

Time scale of the display: 10 s

## 4.16 ONLINEplus™

### Sub rate (substitution rate)\*

With AutoSub plus (automatic substitution): 25 to 400 ml/min (automatic control of the sub rate, depends on the continuously calculated utilization of the dialyzer)

With manual substitution: 25 to 600 ml/min (maximum adjustable sub rate, depending on treatment procedure, blood flow rate, UF rate, hematocrit)

Resolution: 1 ml/min

Sub goal (substitution goal): depends on treatment parameters

Accuracy:  $\pm 10$  %

Sub volume (substitution volume):

Resolution: 0.1 liter

Spring-loaded line rollers, fully occluding (with the prescribed cassette system)

### Substitute temperature\*

Adjustment range: see dialysate temperature (see **Dialysate temperature\*** on page 77)

Depending on the ambient temperature, the substitute temperature may be lower than the set dialysate temperature due to cooling along the way. If the dialysate flow rate is less than 200 ml/min or if the substitute flow rate is very low, the drop in temperature may be more than 5 °C.

(\* = essential performance characteristics for IEC 60601-1)

### Bolus rates and blood flow rates with automatic bolus for "Standard" treatment

Set blood flow rate in ml/min	Blood flow rate with bolus in ml/min	Bolus rate in ml/min
600 to 150	50	Blood flow rate – 50
140	50	100
130	50	100
120	50	100
110	50	100
100	50	100
90	50	100
80	50	100
70	50	100



Set blood flow rate in ml/min	Blood flow rate with bolus in ml/min	Bolus rate in ml/min
60	50	100
50	50	100
40	40	100
30	30	100
0	0	100

**Bolus rates and blood flow rates with automatic bolus for "LOW VOLUME" treatment**

Set blood flow rate in ml/min	Blood flow rate with bolus in ml/min	Bolus rate in ml/min
600 to 150	50	Blood flow rate – 50
140	40	100
130	30	100
120	30	90
110	30	80
100	30	70
90	30	60
80	30	50
70	30	40
60	30	30
50	30	30
40	30	30
30	30	30
0	0	30

## 4.17 Network



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### Warning

#### **Risk of blood loss as a result of an unavailable device**

#### **Risk for the patient as a result of insufficient detoxification**

Excessive network loads can cause the device to malfunction or become unavailable.

- The network operator must protect the device from excessive network loads (e.g., caused by accumulation of broadcast messages or port scans). If necessary, the connection to the network must be established via a router or a firewall, for example.



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### Warning

#### **Risk for the patient as a result of corrupted data**

Data corruption or data loss caused by the network and the server software cannot be detected by the device. This can lead to malfunctions.

- The system installer must ensure that device data is processed securely, e.g., in PC software applications.
- The network operator must ensure that any data transferred without encryption is protected.



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### Warning

#### **Risk for the patient as a result of ignored alarm signals**

The reliability of alarm signal transmissions to external alarm systems cannot be guaranteed, meaning that alarms can fail to be indicated externally.

- Stay close enough to the device to be able to notice any alarms it emits at all times.

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Any additional equipment connected to this device must comply with the relevant IEC or ISO standards (e.g., IEC 60950-1 for information technology equipment).

Furthermore, all device configurations must comply with the requirements for medical electrical systems (see IEC 60601-1 Section 16 and Annex I).

Connecting the device to an IT network that contains components not installed and validated by the device manufacturer can introduce unknown risks for patients, operators or third parties. These risks must be identified, analyzed, evaluated and monitored by the responsible organization. For assistance, consult IEC 80001-1 and Annexes H6 and H7 of IEC 60601-1, for example.

Any modification to an IT network that has been installed and validated by the device manufacturer can introduce new risks and therefore requires a repeat analysis. Especially problematic activities:



- Changes to the IT network configuration
- Connection of additional components and devices to the IT network
- Removal of components and devices from the IT network
- Updating or upgrading components and devices in the IT network

Note that local laws take priority over the above mentioned normative requirements. If you have any questions, please contact your local service support organization.

## 4.18 Radio (option) – in monitor

The Radio (wireless) option must be installed in the monitor of the device if the VenAcc option is used.

Radio unit	Radio frequency: 2.46 GHz Transmission power: 0.25 mW (EIRP)
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## 4.19 Single-Needle (option)

Stop alarm Blood pump	180 seconds in Single-Needle operation.
Single-Needle stroke volume	10 to 60 ml in increments of 5 ml
Auto-Single-Needle flow	+20 % (adjustable in the <b>User setup</b> )
Single-Needle flow	Delivery rate: 30 to 600 ml/min Resolution: 10 ml/min

## 4.20 VenAcc (option) monitoring unit

Dimensions and weight	Dimensions: Height: approx. 8.5 cm Width: approx. 5.5 cm Depth: approx. 1.5 cm  Weight: approx. 73 g (with contact protection cover, sensor cable with connector and clamp, fixing clip)
Electrical safety	Type of applied part (degree of patient safety): Type CF
Applied part	The fluid sensor is the applied part of the VenAcc.
Electrical power supply	Lithium battery: CR 2450, 3 V (replaceable), manufacturer: Renata

<b>IP protection</b>	IP22
<b>Radio unit</b>	Radio frequency: 2.46 GHz Transmission power: 0.25 mW (EIRP)
<b>Material (monitoring unit, cable)</b>	PP, TPE-S

## 4.21 BPM (option)

The BPM has been validated in clinical tests in accord with the objectives of ISO 81060-2.

<b>Electrical safety (blood pressure cuff)</b>	Type of applied part (degree of patient safety): Type CF, defibrillator-proof
<b>Blood pressure</b>	Cuff pressure measurement range: 10 to 280 mmHg  Display range – Systolic: 60 to 250 mmHg** – Diastolic: 40 to 200 mmHg** – MAP: 45 to 235 mmHg**  Resolution: 1 mmHg
<b>Accuracy of blood pressure measurement</b>	Mean value deviation: $\leq \pm 5$ mmHg Standard deviation: $\leq 8$ mmHg
<b>Pulse</b>	Display range: 40 to 200 1/min** Resolution: 1/min  (** Values can vary depending on equipment variant.)

## 4.22 BTM (option)

<b>Required blood flow for accurate BTM function</b>	$\geq 250$ ml/min (The measuring and control functions of the BTM are deactivated if blood flow rates are $< 100$ ml/min.)
<b>Typical operation</b>	Blood flow: 250 ml/min to 600 ml/min Blood temperature: 34 °C to 37.5 °C Ambient temperature: 20 °C to 35 °C Recirculation: 5 % to 35 %
<b>Temperature measurement</b>	Accuracy of the fistula temperatures relative to different blood temperatures (33 °C to 39.5 °C) if correct room temperature ( $\pm 1$ °C) is set in User setup: $\pm 0.5$ °C



	<p>Error in fistula temperatures per °C error in the set room temperature  0.08 °C (with a blood flow rate of 100 ml/min)  0.03 °C (with a blood flow rate of 300 ml/min)</p> <p>Measurement accuracy of body temperature changes during typical operation: <math>\pm 0.2</math> °C</p>
<b>Recirculation measurement</b>	<p>Accuracy of recirculation measurement  (during typical operation and at 2.5 °C venous bolus amplitude): <math>\pm 2</math> %</p> <p>Maximum bolus amplitude: <math>-3</math> °C or <math>+3</math> °C</p> <p>Maximum duration of the bolus: up to 10 min</p>
<b>Body temperature control</b>	<p>Permitted range of target values for body temperature change rate:  <math>-0.5</math> °C/h to <math>+0.5</math> °C/h</p> <p>Dialysate temperature range used by the BTM:</p> <ul style="list-style-type: none"> <li>– Minimum dialysate temperature: 35.5 °C</li> <li>– Maximum dialysate temperature: 37.0 °C to 38.0 °C (adjustable in the <b>User setup</b>)</li> </ul>
<b>Recording treatments with control functions</b>	<p>BTM treatments can be recorded as follows (resolution 1 minute):</p> <p>Enable the BTM charts in the <b>User setup</b>.</p> <p>Relevant control parameters: BTM T control</p> <p>Events: BTM events</p> <p>The charts for the last 3 treatments are stored on the PatientCard.</p> <p>In the event of a short-term power failure during treatment, the built-in rechargeable battery protects the current treatment data from loss.</p>

## 4.23 BVM (option)

	<p>The following accuracy information applies after successful calibration of the BVM cuvette during Preparation.</p>
<b>Relative blood volume</b>	<p>55 to 115 %</p> <p>Accuracy within the range 70 to 105 %, <math>\pm 1.7</math> % absolute (standard deviation)</p> <p>(The accuracy of the blood volume measurement can be affected by extremely high lipid concentrations (e.g., triglycerides &gt; 400 mg/dl).)</p>
<b>Hemoglobin</b>	<p>7 to 17 g/dl</p> <p>Accuracy: <math>\pm 0.8</math> g/dl</p> <p>(The accuracy of hemoglobin measurement is valid only for plasma protein concentrations ranging between 60 and 85 g/l.)</p>
<b>Hematocrit</b>	<p>20 to 55 %</p> <p>Accuracy: <math>\pm 2.9</math> % of Hct</p> <p>(The accuracy of hematocrit measurement is valid only for plasma protein concentrations ranging between 60 and 85 g/l.)</p>
<b>Recording treatments with control functions</b>	<p>BVM treatments can be recorded as follows (resolution 1 minute):</p>

➤ Enable the BVM charts in the **User setup**.

Relevant control parameters: RBV, UF rate

Events: BVM events

The charts for the last 3 treatments are stored on the PatientCard.

In the event of a short-term power failure during treatment, the built-in rechargeable battery protects the current treatment data from loss.

## 4.24 Materials used

### ● Materials used – device

Materials shown on the gray background come into contact with dialysis water, dialysis fluid, or dialysis fluid concentrate.

#### Plastics and cast resins

Abbreviation	Material
EPDM	Ethylene propylene diene monomer rubber
FPM (FKM)	Fluorocarbon rubber
PFA	Perfluoroalkoxy alkane
PAEK	Polyaryletherketone
PPSU	Polyphenylsulfone
PVDF	Polyvinylidene difluoride
PTFE	Polytetrafluoroethylene
PP	Polypropylene
PES	Polyethersulfone
PPO	Polyphenylene oxide
PPS	Polyphenylene sulfide
SI	Silicone
TPE	Thermoplastic elastomer
PBT/ABS	Polybutylene terephthalate / acrylonitrile butadiene styrene
ABS	Acrylonitrile butadiene styrene
PA	Polyamide
PC/ABS	Polycarbonate / acrylonitrile butadiene styrene
POM	Polyoxymethylene



**Metals, glass, graphite,  
ceramics**

Abbreviation	Material
EPDM+PP	Ethylene-propylene terpolymer / polypropylene
PC	Polycarbonate
PUR	Polyurethane
PS	Polystyrene

Abbreviation	Material
Glass	Glass
Graphite	Graphite
Ceramics	Ceramics
Stainless steel	Stainless steel
Ti	Titanium
Stainless steel	Stainless steel
St	Steel
Fe	Iron
Al	Aluminum and aluminum alloys
CuZn39	Brass
Magnet	Samarium-cobalt magnet
Magnet	NdFe magnet

**Electrical equipment**

Abbreviation	Material
Motors	Copper
	Connectors
	Tin
Connectors	Copper and tin
	Glass fiber reinforced thermoplastic
Transformers	Potting compound PU
	Polyester, polyurethane
	Copper
	Polyester resin
	Ferrite cores

Abbreviation	Material
Microswitches	Polyacetal
	Glass fiber reinforced polyamide
	Silicone
	Silver, gold
	Brass
	Beryllium copper
Cables	Copper
	PVC
	Teflon
Electronics	PCB base material
	Fiberglass epoxy resin
	Ferrite cores
	Lithium batteries
	Lead-acid rechargeable batteries
	LCD screen

## Equipment

Abbreviation	Material
Adhesives	Loctite 3321
	UHU Plus Endfest
	Scotchweld DP 499
Insulating material	Polyethylene
Lacquers	Acrylic enamel
	Screening lacquer – copper conductive lacquer
	PUR structural lacquer
Grease	Unisilikon