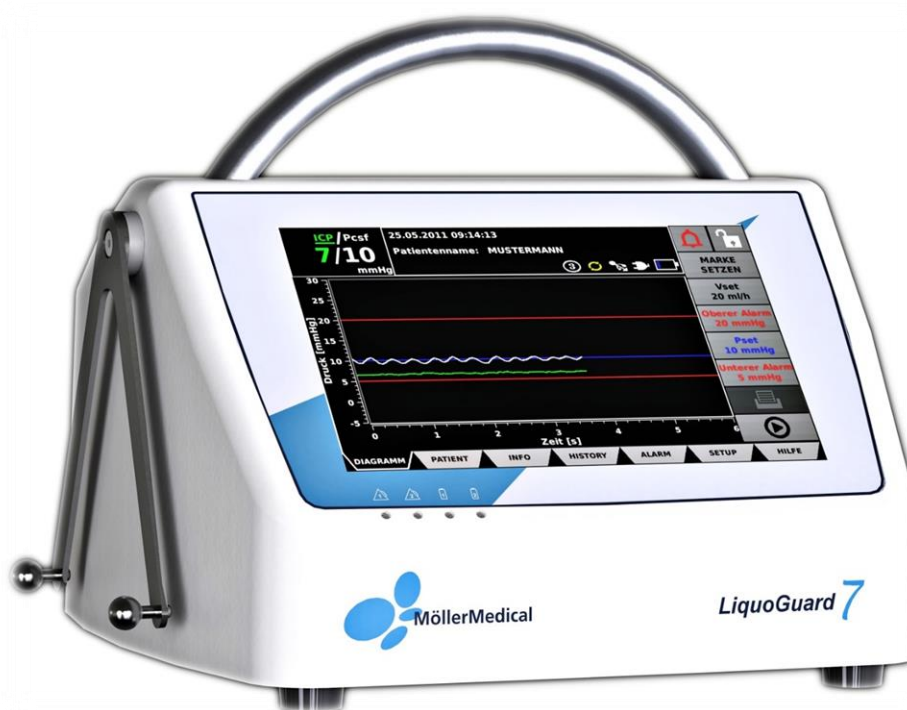


en

# LiquoGuard<sup>®</sup> 7

## CSF drainage pump

# Instruction Manual



# **IMPORTANT**

**READ CAREFULLY BEFORE USE**

**KEEP THESE INSTRUCTIONS FOR FUTURE CONSULTATION**

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## General safety instructions

# 1 General safety instructions

## 1.1 Explanation of the safety symbols used

In this instruction manual, visual symbols are used to highlight important instructions. These references are prerequisites for preventing hazards to patients and operating personnel, as well for avoiding damages or malfunctioning of the device.

### 1.1.1 Symbols used in instruction manual



Caution



Information or help

### 1.1.2 Symbols appearing on the device



Type BF applied part



Defibrillation-proof type CF applied part



Serial number (the 4 digits indicate the year and month of manufacture in YYMM format)



Consult instructions for use



Follow instructions for use



Complies with ANSI/AAMI ES 60601-1  
CAN/CSA 22.2 No. 60601-1-08



Alternating current



Return and disposal according to WEEE Directive



Main alarm











Backup alarm








Main battery

**General safety instructions**



















	Backup battery
<b>ICP</b>	Parenchymal or tip sensor connection (compatible with Philips M1006B invasive pressure module connection).
	Patient monitor output (compatible with Edwards TruWave)
	“ON” for a part of equipment
	“OFF” for a part of equipment
Pcsf	Tubing set connection
In/Out	Connection for I/O connector
	Only the <b>LiquoGuard® 7</b> Multi-Hub accessory may be attached to this connection!
	USB host
	RJ45 network connection
	Connection to the nurse call system

The BF application parts (Pcsf and ICP) are specified as an application part.

**1.1.3 Symbols appearing on the *LiquoGuard® 7* display**

















	Pump is in Pause mode
	Pump is in Application running mode
	All alarms are displayed and emitted
 10:00	One or more alarms have been actively paused by the operator. Alarms are not emitted. The remaining time until the alarms are displayed again is shown.
 off	Drainage quantity counter off

General safety instructions

	Drainage quantity counter active. Message when the set drainage quantity is reached.
	All physiological alarms displayed and emitted.
	All physiological alarms are suppressed, with the remaining time displayed until the alarm sounds again
	Keypad lock inactive
	Keypad lock active
	Main battery charge
	Presentation mode ready
	Softkey: press or save a screenshot Info bar: Printer is connected
	Set a marker for documenting events
	One or two USB memory sticks are connected
	Presetting is active (instead of X, the number of the presetting is indicated)
	<b>LiquoGuard® 7</b> connected to main power supply
	Scale in/out of the time axis in HISTORY dialog field
	Selection of curves to be displayed
	Scaling of the axes to optimum
	Scaling the axes to maximum
	Clear history (graph, volume, alarms, patient data)
	Move back and forth on the time axis in the History dialog field

**General safety instructions**

**1.1.4 Symbols indicated on the retail packaging**

	Consult instructions for use
	Catalog number
	Batch code
	Serial number (the 4 digits indicate the year and month of manufacture in YYMM format)
	Use by date YYYY-MM-DD
	Sterilized using ethylene oxide
	Not suitable for use with MRI
	Limited suitability of tubing set for use with MRI. See details under symbol for the condition.
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Stacking restriction, stack may consist of max. 4 packages
	Keep dry
	Humidity, limitation
	Temperature limit
	Manufacturer

**General safety instructions**



Date of manufacture  
YYYY-MM-DD



Total length



Blood pressure, invasive measurement



Follow the instructions for use



Quantity



Type BF applied part



Keep away from sunlight



Caution! Observe transport and storage conditions.

**Rx ONLY**

Attention:

Under US Federal law, this device may be sold only to a physician or ordered by a physician.

For further information about symbols used please refer to our homepage:

[www.moeller-medical.com/glossary-symbols](http://www.moeller-medical.com/glossary-symbols).

The use of the **LiquoGuard®7** CSF drainage pump is subject to thorough knowledge and observance of this instruction manual which is an integral part of the delivered product. Store this instruction manual carefully. The present instructions are not a substitute for training of the owner/operator by a medical device consultant approved by the manufacturer. The device must be used only by persons who have the required training or knowledge and experience.



If components are used that do not correspond to the original equipment manufacturer parts, the performance, safety and EMC behaviour may be impaired.

## 1.2 Explanation of the conventions applied

Various typefaces are used in these instructions for easier reference.

Typeface	Application
<b><i>Bold and italics</i></b>	Buttons used in operating procedures
SMALL CAPITALS	Dialog fields and submenus in running text.
<i>Italics</i>	Device options, buttons and references to chapters and sections in running text.

## 1.3 Manufacturer's responsibility

The manufacturer is responsible for the safety, reliability and serviceability of the device in the following cases:

- Where assembly, upgrades, adjustments, changes or repairs are performed only by persons authorized by the manufacturer.
- Where the electrical installation of the area used for medical purposes complies with the applicable requirements and regulations (e.g. VDE 0100, VDE 0107 or IEC specifications).
- Where the device is used in accordance with the user manual.
- Where the regulations specific to a region or country are observed.

The manufacturer undertakes to accept returned old devices according to the Electronic Equipment Act.

## 1.4 Equipotential bonding

It is important to limit potential variances between the different parts of a system within the patient's environment. In limiting this potential variance by using a system of protective earth conductors, the quality of the connection is of utmost importance. It is, therefore, essential to avoid a failure in the protective devices in each part of the system.



In the case of failure of the protective earth conductors of a device, a potential variance can occur at the housing of the device and present a danger for the operator and the patient. Do not touch the patient and the device simultaneously.

**General safety instructions****1.5 Owner's duty of care**

The owner of the device must accept responsibility for the proper operation of the medical device. The user is obliged to fulfill all duties in accordance with the regulatory requirements and is fully responsible for all activities when using medical devices. Only qualified personnel may operate the **LiquoGuard®7**. This instruction manual does not replace training of the user by the medical device consultant. The training is carried out when the product is delivered by a medical device consultant authorized by the manufacturer with the aid of all products necessary for use. The operator must ensure that staff are trained on a regular basis by a qualified person (ideally a medical device consultant authorized by the manufacturer) if the safe use of the product on the patient cannot be guaranteed due to inadequate training. Clinical application may be only according to instructions of qualified personnel.

Any modifications to the **LiquoGuard®7** are prohibited. Liquids must not penetrate parts of the device which carry electrical voltage.

Ensure that no cleaning spray enters the connector socket.

Before cleaning, unplug the **LiquoGuard®7** connector plug and turn the device off.

Do not turn the pump rotor opposite to the flow direction indicated if the tube is already connected to the pump. This may present a danger to the patient.

To obtain an accurate pressure measurement, do not use any other accessories except a suitable extension tube with a maximum length of 30 cm, fitted between the catheter and the tubing set.

Never attach filters (e.g. bacteria filter) between the catheter and drainage bag.

**Application on computer tomographs**

The tubing set may remain attached to the patient during computer tomography (CT). The **LiquoGuard®7** must be disconnected.

**Application on magnetic resonance tomographs**

The tubing set may remain attached to the patient during MRI imaging exams. The **LiquoGuard®7** must be disconnected and must be located outside the magnetic field (another room, screened).

It is essential to observe the further measures for use in an MRI environment from *page 126* and in the instruction manual of the respective tubing sets.

Use the device only on a mains power supply fitted with a protective earth conductor. The mains voltage must conform with the indications provided on the identification plate on the back.

Replace any connecting cable in the case of even minor damage and take care not to roll over the cables.

## General safety instructions

Keep cables away from sources of heat. This is to prevent the insulation from melting, potentially causing a fire or electrocution.

Do not force the connector plug into the socket.

Do not pull on the cable when removing the plug. If necessary, loosen the plug interlock to remove it.



Position the **LiquoGuard®7** so that it can be easily disconnected from the mains power supply.

Do not subject the **LiquoGuard®7** to strong heat or fire.

Do not subject the **LiquoGuard®7** to strong impacts.

If heat, fumes or smoke are emitted from the **LiquoGuard®7**, disconnect the mains plug of the device immediately.

Do not extinguish the **LiquoGuard®7** with water in the event of fire.

Also observe the safety instructions in the instruction manuals of the devices used in conjunction with the **LiquoGuard®7**.



Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

### 1.6 Additional accessories

Additional accessories, which are beyond the scope of delivery of the present device and are connected to the analog and digital interfaces of the device, must be proven to comply with the relevant IEC specifications (e.g. IEC 60601 for electrical medical devices). Furthermore, all configurations must satisfy the current version of the system requirements according to standard IEC 60601-1. Any operator connecting the additional devices is responsible for configuring the system and for ensuring that the current version of the system requirements satisfy standard IEC 60601-1.

### 1.7 Single use

The re-use of a single-use product presents a potential risk of infection for the patient or operator. Contaminated products can damage health, and cause illness or even death of the patient. Cleaning, disinfection and sterilization can adversely affect essential material properties and product parameters and thus result in product failure.

Dispose of the used single-use product according to your hygiene requirements. To prevent leakage from the tubing set, ensure that all stopcocks are closed when disposing of the drainage and infusion set.



**General safety instructions****1.8 Declaration on DEHP**

The **LiquoGuard®7** tubing sets do not contain any bis (2-ethylhexyl) phthalate (DEHP).

**1.9 Application during defibrillation and for electrosurgical devices**

Do not touch the patient, table or instruments during defibrillation. The measurement accuracy can be impaired during defibrillation. The recovery time of the device is less than 10 seconds. The recovery time has no effect on patient or device safety. During defibrillation, use only accessories stated in this instruction manual.

When using electrosurgical devices, the **LiquoGuard®7**, the **LiquoGuard®7** Multi-Hub and the transducers used do not include any protective measures against burning.

The **LiquoGuard®7** can be used in combination with electrosurgical devices.

Nevertheless, the strong electromagnetic faults which occur in the direct vicinity of electric motors, power lines, PCs, monitors or other, possibly faulty, electrical devices can, in individual cases, impair the functionality of the device.

Consider such faults when observing inexplicable phenomena on the device. The proper operation of the device can be restored as follows:

- Position the pressure sensor housing as far away as possible from the electrosurgical electrodes.
- Set up the devices at a safe distance from each other, check their functionality and test them for plausibility.
- Make sure that the laid patient cables do not touch as electromagnetic coupling is possible during energy input via the electrosurgical device.
- Make sure that no cables are in contact with the patient.
- Take all the necessary precautions to avoid malfunctioning.
- Note the instructions and recommendations from the manufacturer of the electrosurgical device.

## 2 Purpose

The Möller Medical GmbH **LiquoGuard®7** CSF drainage pump is a pressure-controlled peristaltic pump. The **LiquoGuard®7 Drainage Set** is a sterile single-use accessory designed to be used only with the **LiquoGuard®7** CSF drainage pump. The **LiquoGuard®7** CSF drainage pump with the **LiquoGuard®7 Drainage Set** are specifically designed to pump CSF from the ventricular system and the lumbar area of the patient on the basis of CSF pressure, or when the *Parenchymal/Tip sensor* and a suitable parenchymal sensor is used, from the ventricular system of the patient on the basis of parenchymal or CSF pressure. The **LiquoGuard®7 Drainage Set** is compatible with all conventional ventricle catheters with an internal diameter greater than/equal to 1 mm and length less than/equal to 350 mm, as well as lumbar drainage catheters with an internal diameter greater than/equal to 0.7 mm and length less than/equal to 800 mm.

The **LiquoGuard®7 Infusion Test Set** is a sterile single-use accessory and must be used only in conjunction with the **LiquoGuard®7** CSF drainage pump. The **LiquoGuard®7** CSF drainage pump, together with the **LiquoGuard®7 Infusion Test Set** and the *Lumbar Infusion Test* function, are designed to ensure the flow of up to 100 ml of infusion solution (physiological saline solution or CSF replacement fluid) at a consistent volume into the spinal canal, with simultaneous pressure measurement (see *page 108*).



The **LiquoGuard®7** may be used only in monitored medical areas in hospitals.

The purpose of the **LiquoGuard®7** not to form a diagnosis, but to support in forming a diagnosis.

### 2.1 Indications of temporary intrathecal CSF drainage

Generally, the **LiquoGuard®7** does not change the indication for intrathecal CSF drainage in any patient, nor does it influence the therapeutic concept, type of treatment, therapy objectives, or therapy duration.

The most fundamental characteristics of the **LiquoGuard®7** system are comparable with those of other CSF drainage systems on the market. Therefore, the listed indications for CSF drainage must be understood in the broadest sense, without presupposing the use of the **LiquoGuard®7** system or any specific comparable CSF drainage system, as these systems are interchangeable with each other at all times without the need for a change in therapy or further surgery.

#### Communicating hydrocephalus

This condition includes all clinical pictures in which CSF production is temporarily in disproportion to CSF resorption, usually during cerebral hemorrhage (subarachnoid hemorrhage, intraventricular hemorrhage), encephalitis and cranial-cerebral injuries. In most cases, the cause is resorption dysfunction by obstruction of the Paccioni granulation. There is no alternative treatment to intrathecal CSF drainage for these clinical pictures.

## Purpose

### **Non-communicating hydrocephalus**

CSF drainage is temporarily impaired by a partial or complete occlusion of the CSF draining paths. This case can arise with masses (tumors, cysts, hemorrhage, congenital malformation) near the foramen of Monro, of the 3rd ventricle, the aqueduct, the 4th ventricle or the foramen of Monro and the foramina of Luschka.

### **Therapy-resistant cerebral swelling**

CSF drainage may be indicated in therapy-resistant cerebral swelling caused, for example, by cranial-cerebral injury, cerebral hemorrhage or subarachnoid hemorrhage or by cerebral swelling due to tumors, inflammation or hypoxia, in order to reduce intracranial pressure, and to bypass trepanation (the removal of a cranial bone).

### **Forced CSF pressure reduction**

In cases of endovascular or open surgical procedures such as in aortic aneurysms, the CSF pressure is forcibly lowered so as to achieve better arterial perfusion of distal spinal segments and thus to reduce the risk of paraplegia, for example.

Lumbar CSF drainage and pressure-controlled drainage may be indicated both intra- and postoperatively.

## **2.2 Indications for permanent CSF drainage**

If permanent CSF drainage is indicated (e.g. in normal-pressure hydrocephalus), temporary CSF drainage would be indicated only for diagnostic purposes (e.g. b-wave diagnostics), but not for continuous therapy. This would indicate a CSF shunt system, usually a ventriculoperitoneal shunt or a ventriculoatrial shunt.

## **2.3 Contraindications**

### **Absolute contraindications**

- Coagulation dysfunction
- Thrombocytopenia

### **Relative operative contraindications**

Superficial or deep infections of skin, bone, meninges, or brain. Especially in infections of the brain, meninges, or cerebral chambers (encephalitis, meningitis and ventriculitis), dysfunctional CSF resorption indicates relief, as does simultaneous intake of intrathecal antibiotics in the case of ventriculitis.

## **2.4 Complications**

- Meningitis
- Encephalitis
- Ventriculitis

### Purpose

- Myelitis
- Nosocomial infection
- Cerebral hemorrhage
- Epidural hematoma
- Spinal cord injury
- Nerve injury
- Cone and cauda injury
- Back pain
- Cerebral swelling
- Slit ventricles
- Overdrainage
- Underdrainage
- Disconnection
- Bent tubes
- Interrupted tube flow (bent tube, occluded tube system (blood clots or detritus))
- Death

### 2.5 Combination with other products, catheters and cannulas

The **LiquoGuard® 7** may be used only with the application parts **LiquoGuard® 7 Drainage Set REF. No.: 00003497 (1600 mm) or REF. No.: 00003501 (2000 mm)**, equivalent versions, see Appendix 10.6 or **LiquoGuard® 7 Infusion Test Set REF. No.: 00003499 (2000 mm)** of Möller Medical GmbH.

The **LiquoGuard® 7 Drainage Set** is connected to a surgically implanted CSF draining catheter and does not come into contact with the body.



The **LiquoGuard® 7 Drainage Set** may be connected only to a ventricle drainage catheter with internal diameter  $\geq 1$  mm and length  $\leq 350$  mm or lumbar drainage catheter with internal diameter  $\geq 0.7$  mm and length  $\leq 800$  mm.

The **LiquoGuard® 7 Tubing Set** may be used only with the *Möller Medical CSF bag* provided.

To make an extension, all the usual extension tubes may be connected to the **LiquoGuard® 7 Drainage Set** that are suitable for arterial pressure measurement (sufficient rigidity of the tube), not longer than 30 cm, and have an inner diameter greater than or equal to 2 mm.

**Purpose****2.6 Patient population & residual risk**

There are no restrictions with regard to the patient population. The device can be used on patients from any age group, with any health condition, and from any ethnic group.

The patient does not operate the device.

The **LiquoGuard®7** is designed to ensure at least one alarm trigger between pressure measurement and alarm generation during an error. The residual risk for the patient exists mainly in the selection of parameters unsuitable for the patient or other application errors. The operator must be aware of this risk.

**2.7 Essential performance**

The essential performance of **LiquoGuard®7** is the measurement of the pressure of cerebrospinal fluid (CSF) and the drainage of CSF until the default pressure value (Pset) is reached.

### 3 Product description

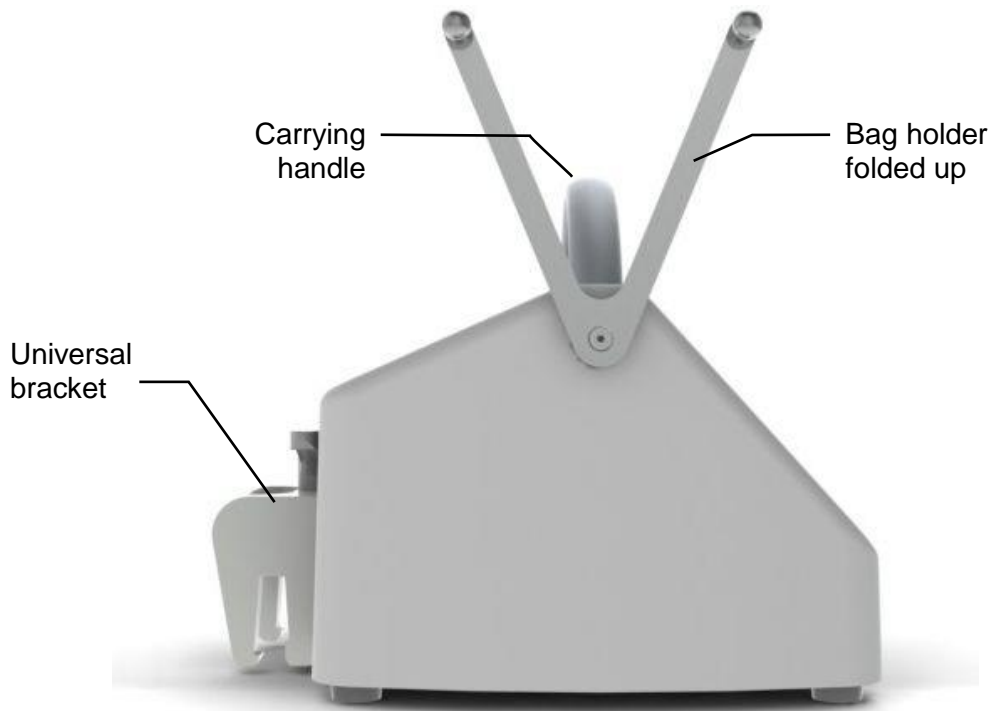


Figure 1: View of the **LiquoGuard®7** from the left.

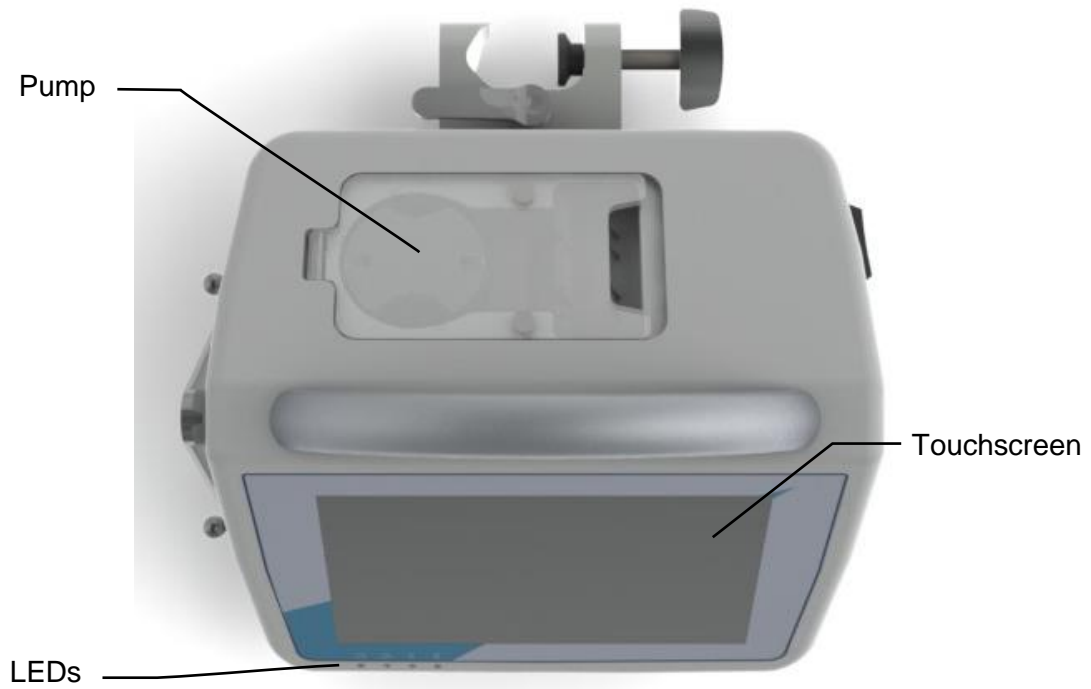


Figure 2: View of the **LiquoGuard®7** from above

## Product description

### 3.1 Touchscreen

User input in the **LiquoGuard®7** is performed via the touch-sensitive, resistive surface (*Touchscreen*, see *Figure 2*) of the display. Use a finger or suitable input pen to make entries. To select a button on the screen, apply light pressure on the touchscreen in the area of the button.

Wearing standard examination gloves does not usually limit the response of the display.

### 3.2 Bag holder

The V-shaped holder located on the side (see *Figure 1*) is used to support the *CSF drainage bag (CSF bag)*. Pull one of the holder ends in the direction of the display and turn upwards until the holder engages.

### 3.3 Universal bracket

The **LiquoGuard®7** can be hung by means of the *universal bracket* located on the back of the device (see *Figure 1*), onto a standard rail or a bar (diameter 18 mm to 25mm).

### 3.4 Pump

The integrated peristaltic pump located on the upper part of the **LiquoGuard®7** (see *Figure 2*) ensures the mechanical deformation of the fitted tube, and seals it at all times, allows the flow of CSF through the tube, and the tubing is never open to the atmosphere.

### 3.5 LEDs

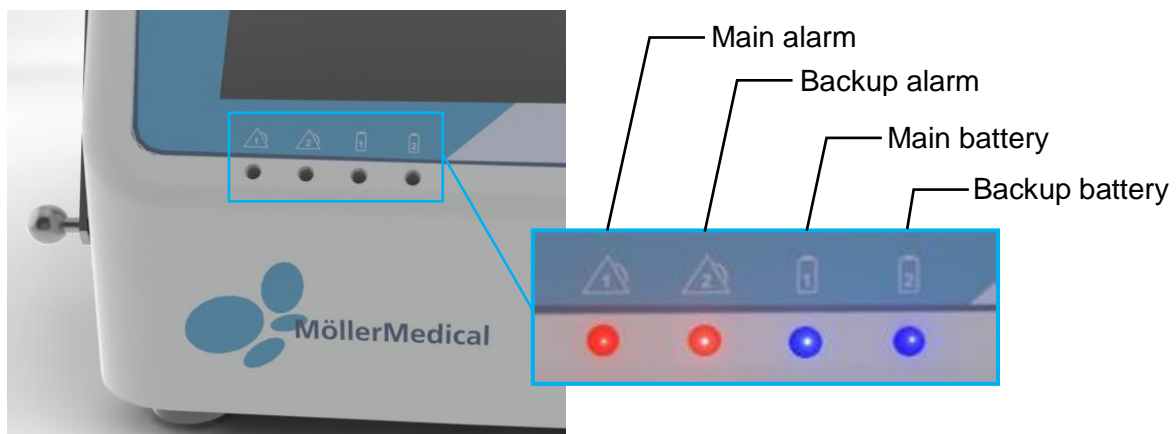






Figure 3: LEDs located on the front of the **LiquoGuard®7** indicate alarm conditions and battery charge.

The LEDs of the **LiquoGuard®7** provide information on active alarm conditions and charge status of the internal battery (see *Figure 3*).

**Product description**

Symbol	Function	Description
	Main alarm	This LED flashes red as soon as an alarm condition or system failure is detected (see <i>page 69</i> ) or when the battery charge is lower than 20%. Even if <i>Alarm Pause</i> is activated, the LED indicates the presence of a valid alarm condition.
	Backup alarm	If the <b>LiquoGuard® 7</b> main controls cannot emit the normal alarm signal (horn) due to a fault, an alternative alarm signal will sound and the backup alarm LED will flash red.
	Main battery	The main battery supplies the <b>LiquoGuard® 7</b> with power when in battery operation mode. The LED lights up permanently in blue when the main battery is being charged.
	Backup battery	If the internal power supply of the <b>LiquoGuard® 7</b> is interrupted, the backup battery will emit an alarm signal. The LED lights up permanently in blue while the backup battery is being charged.

**3.6 Connection options**

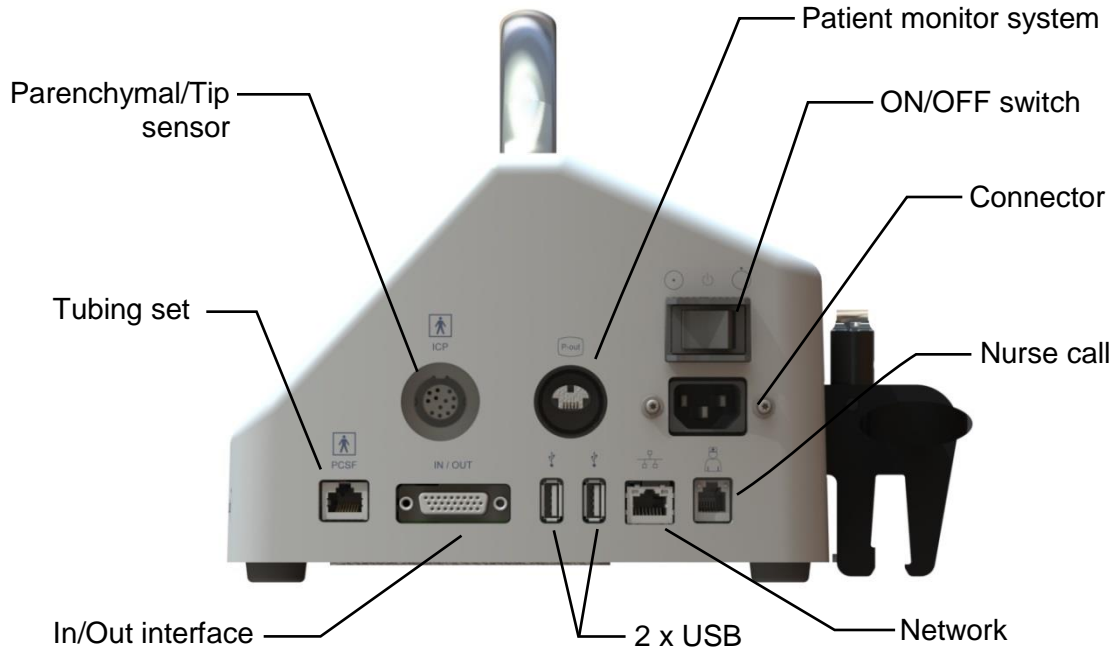


Figure 4: Connection options on the right hand side of the **LiquoGuard® 7**.



## Product description

In addition to the On/Off switch (I O), which is used to switch the **LiquoGuard®7** on and off, the following connection options are also located on the right-hand side of the housing (see *Figure 4*):

- Parenchymal or tip sensor connection (compatible with the Philips M1006B Invasive Pressure Module connection; for connection specifications see *Input and output* on page 119).
- Patient monitor output (compatible with Edwards TruWave; for specifications see *Input and output* on page 119).
- Connector socket for three-pole mains cable Type F connected to mains power supply (mains cable must comply with standard IEC 60320).
- Tubing set connection (drainage and infusion)
- Connection for In/Out connector (used to connect the **LiquoGuard®7** Multi-Hub to use an arterial blood pressure sensor)
- 2 x USB (host)
- RJ45 network connection (not functional in regular clinical operation, for service purposes and demonstrations only)
- Nurse call system connection (for specifications, see page 119).

### 3.7 User interface

This section provides an overview of the **LiquoGuard®7** user interface. For information on *Settings* see page 51.

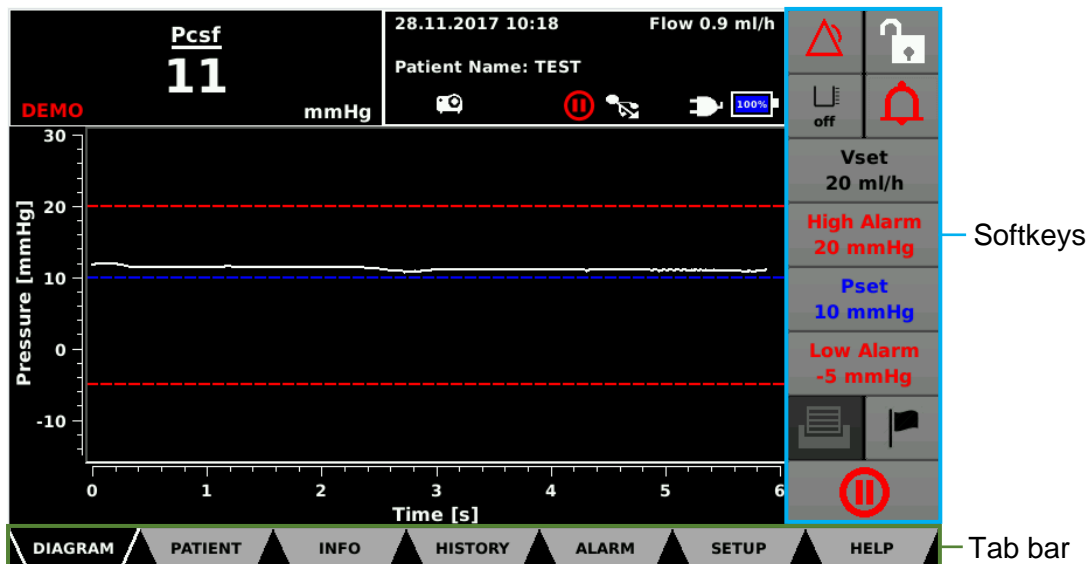


Figure 5: User interface in the DIAGRAM dialog field

**3.7.1 Tab bar**

All information and input fields for the **LiquoGuard®7** can be found under several multi-level dialog fields. Access dialog fields by selecting the relevant button on the tab bar (see *Figure 5*). The active dialog field appears in black on the tab bar. If no entry is made in the selected dialog field within one minute, the **LiquoGuard®7** reverts to the standard dialog field **DIAGRAM**.

The range of functions of the **LiquoGuard®7** can be extended through various device options. Therefore, not all dialog fields and submenus can be selected by the user in the standard **LiquoGuard®7** configuration.

The following table provides an overview of the dialog fields, submenus and their features.

<b>Dialog field</b>	<b>Features</b>	<b>Submenus</b>	<b>Page</b>
DIAGRAM	Pressure curve of the current application Current information on drainage and the equipment Drainage settings Pressure alarms limits Drainage control	None	29
PATIENT	Patient data entry	None	91
INFO	Alarms of the current application Battery status	<ul style="list-style-type: none"> <li>• ALARMS</li> <li>• BATTERY</li> </ul>	49
HISTORY	Statistics. Pressure and flow curves of the current application in table and diagram form.	<ul style="list-style-type: none"> <li>• GRAPH</li> <li>• VOLUME</li> </ul>	95
ALARM	Alarm settings Accessories	<ul style="list-style-type: none"> <li>• GENERAL</li> <li>• FLOW</li> <li>• PULSATION</li> <li>• PARENCHYMAL / TIP SENSOR</li> <li>• MONITOR / NURSE CALL</li> <li>• CPP / CMAP SENSOR</li> </ul>	54

Product description

SETUP	Device settings	<ul style="list-style-type: none"> <li>• LANGUAGE</li> <li>• DISPLAY</li> <li>• CONFIG</li> <li>• OPERATION</li> <li>• SERVICE</li> <li>• PRESETTINGS</li> <li>• NETWORK</li> </ul>	59
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3.7.2 Softkeys

Use the softkeys in the right-hand margin of the screen (see Figure 5) to change the relevant values in the **DIAGRAM** dialog field. Navigate in the other dialog fields using the softkeys provided in the submenu. When a softkey is selected and activated, it will be highlighted in white.

3.7.3 Keyboard screen

A keyboard screen will automatically appear as soon as an entry is required if you click on the input line. Depending on the specific field properties, the function controls on the keyboard screen will vary between alphanumeric and numeric. A calendar screen will appear to change the date.

3.7.3.1 Alphanumeric keyboard screen

Letters and numbers can be entered using an alphanumeric keyboard screen (see Figure 6).

1. Enter the required value via the keys on the alphanumeric keyboard screen. To delete characters, press the **<=** button.
2. End and save the entry by pressing the **ENTER** button. Reject the changes by pressing the **ESC** button.

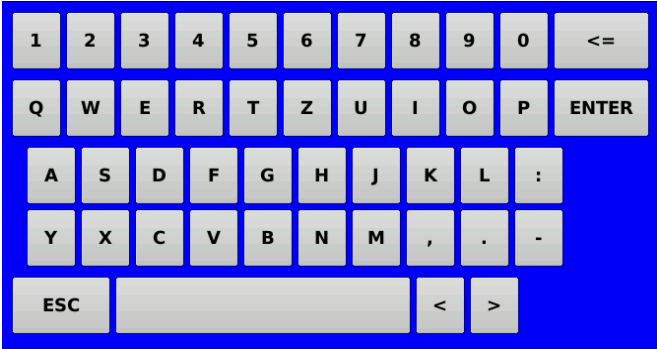


Figure 6: Alphanumeric keyboard screen for entering letters and numbers.

### 3.7.3.2 Numeric keyboard screen

Use the numeric keyboard screen (see *Figure 7*) to enter numeric values. Make sure that a point is used to separate hours and minutes when entering the time.

1. Enter the required value via the digits on the numeric keyboard screen. To delete numbers, press the **<=** button.
2. To save the entry, press the **ENTER** button.

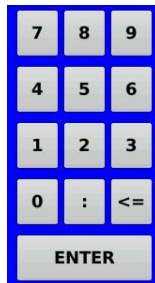


Figure 7: Numeric keyboard screen for entering number values.

### 3.7.3.3 Calendar

Dates can be changed by using the calendar screen (see *Figure 8*). The current year and month appear in the top line of the calendar. The day is shown in a yellow block. To accept changes made, select the calendar day required.

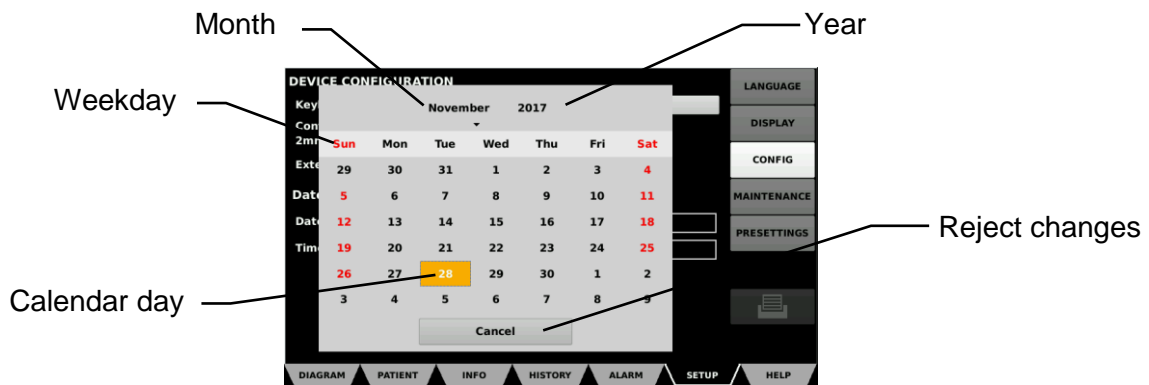


Figure 8: Calendar screen of the *LiquoGuard®7* to change date.

#### Changing the year

1. Select the **Year** indicated at the top of the calendar. Two black arrows will appear next to the year (see *Figure 9*).
2. Press the **arrows** to increase or decrease the year.
3. To save the entry, select the calendar day required. To reject the changes, select **Cancel**.

## Product description



Figure 9: Changing the year on the calendar.

### Changing the month

1. Select the **Month** appearing at the top of the calendar. A drop-out menu will appear on the calendar (see *Figure 10*).
2. Select the month required from the drop-out menu.
3. To save the entry, select the desired **calendar day**. To reject the changes, select **Cancel**.



Figure 10: Changing the month by opening the drop-out menu in the calendar.

### Changing the day

1. Select the required **calendar day** on the calendar.
2. Once the calendar day has been entered, the change will be accepted without needing any further confirmation.

## 3.8 Diagram dialog field

The **DIAGRAM** dialog field is the **LiquoGuard®7** default screen. In addition to the diagram, this screen provides current information on drainage and the device itself. Use the softkeys to operate the **LiquoGuard®7** and to enter the basic drainage settings.

Product description

3.8.1 Diagram

The diagram shows the current measurement curves (see Figure 11)

Curve description	Curve color	Explanation
Pcsf	White	CSF pressure measured on the pressure sensor on the <b>LiquoGuard® 7</b> tubing set.
ICP	Green	CSF pressure, measured at an additional pressure sensor
Lower alarm limit	Lower red dotted line	Lower pressure alarm limit
Upper alarm limit	Upper red dotted line	Upper pressure alarm limit
Pset	Blue dotted line	Target CSF pressure that has been set
CPP	Yellow	When an arterial blood pressure sensor is connected.

The ICP indicator is part of the *Parenchymal/Tip sensor* option. For more detailed information, see page 102.



The CPP indicator is part of the *CPP* option. For more detailed information, see page 107.

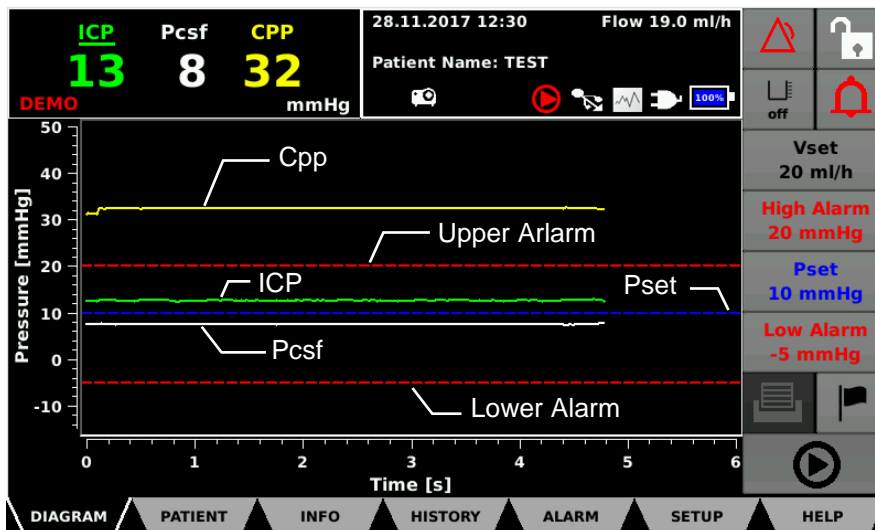


Figure 11: Limit values and curves shown in the diagram.

## Product description

- **Time (x-axis):** Time progression of the pressure curve in seconds. The scale is set automatically.  
The scale can be adjusted as described in chapter 6.3.2.2 (page 60).
- **Pressure (y-axis):** Pressure expressed optionally in [mmHg] or [cmH2O]. The scale is set automatically.
- **White curve:** Progress of the filtered Pcsf pressure value that is measured by the pressure sensor in the tubing set of the **LiquoGuard®7**.
- **Green curve:** Progress of the ICP pressure value that was measured by an external sensor (parenchymal or catheter tip = ventricular).
- **Yellow curve:** Calculated progression of the cerebral perfusion pressure (CPP).  
Calculation method used:  $CPP = cMAP - ICP$  if the ICP value is selected for the calculation, or  
 $CPP = cMAP - Pcsf$  if the Pcsf value is selected for the calculation. cMAP corresponds to the cerebral mean arterial pressure measured at the level of the foramen of Monro.  
Whether ICP or Pcsf is used for the calculation can be set. See *CPP/cMAP* on this from page 107.
- **Blue dotted line:** *Pset* (set pressure)  
When the CSF pressure (ICP or Pcsf) is higher than Pset, and the application is not paused, the pump turns (drainage) to reduce the CSF pressure to Pset.
- **Top red dotted line:** *Upper Alarm* (upper pressure alarm limit)  
When exceeded, an alarm is triggered.
- **Lower red dotted line:** *Lower Alarm* (lower pressure alarm limit)  
An alarm is triggered if too low.

**Product description**

**3.8.2 Info bar**

The Info Bar (see *Figure 12*) provides current information on drainage and the device.

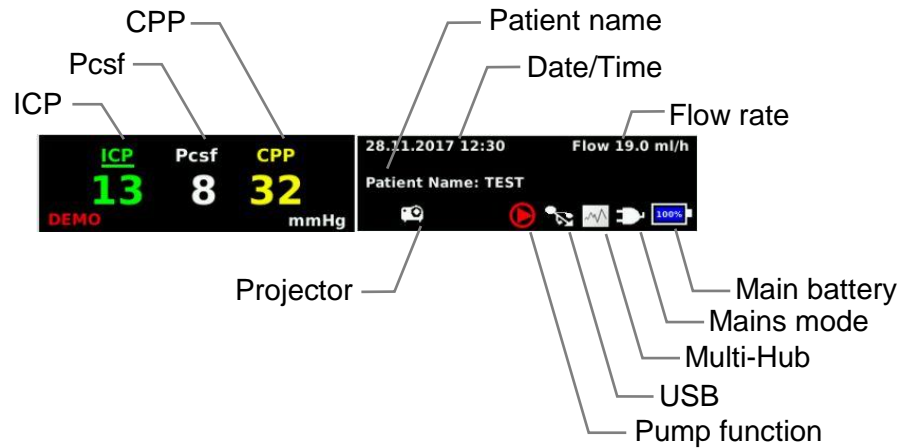


Figure 12: Elements of the Info Bar in the DIAGRAM dialog field.

**Pcsf (pressure of the cerebrospinal fluid)**

The Pcsf field indicates the current pressure value measured by the tubing set pressure sensor. The color of the text and flashing of the pressure value indicates whether the pressure is within or outside the pressure limits set.

Text color	Example	Description
White		The pressure currently measured is within the pressure alarm limits set.
Red flashing		The pressure currently measured is outside the pressure alarm limits set.

If **--/--** appears in the **Pcsf/ICP** field instead of the pressure value, no pressure sensor is currently connected to the **LiquoGuard®7**.

**Date/Time**

This field shows the date and time set on the device.

**USB**

The USB symbol appears when a USB memory stick is connected to the **LiquoGuard®7** and this was recognized correctly by the device.

**Mains operating mode**

If the **LiquoGuard®7** is powered by a mains cable, the plug connector symbol confirms this operating mode.



## Product description

### Battery operating mode

The current charge state of the main battery is indicated by the bar in the battery symbol. The **LiquoGuard® 7** is designed to operate independently of the mains power supply via the battery for up to max. 2 hours, with a delivery rate of 20 ml/h. If the battery charge falls below 20%, the colour of the charge indicator bar will change to red. An alarm is also emitted by the device. The **LiquoGuard® 7** must be connected to the mains power supply at this moment at the latest, in order to prevent the device from turning off due to insufficient battery charge.



The total discharge of a battery can result in permanent damage to the battery and should therefore be avoided.

### Pump function

The pump symbol (play symbol) indicates that the pump is in operation. If the pause function of the **LiquoGuard® 7** is being used, this symbol will not appear. Instead, the Pause symbol appears in the same location on the display.

### Presetting

When the *Presetting* option on the **LiquoGuard® 7** is activated, the number of the current selected presetting will be shown. Information on this option can be found in the relevant section on *page 99*.

### Printer

The printer symbol appears when a printer is connected to the USB port of the **LiquoGuard® 7**.

### Drainage volume

This shows how much volume (CSF) was drained (actual volume) and at which volume a message is issued (target volume), see *Drainage Volume* on *page 33*.

### Flow rate

This value shows the average volume (CSF) per hour.

### 3.8.3 Softkeys

The softkeys in the right-hand margin of the screen (see *Figure 13*) are used to operate the **LiquoGuard® 7** and to make changes to the drainage settings. The parameters form the basis for a controlled drainage.

Product description

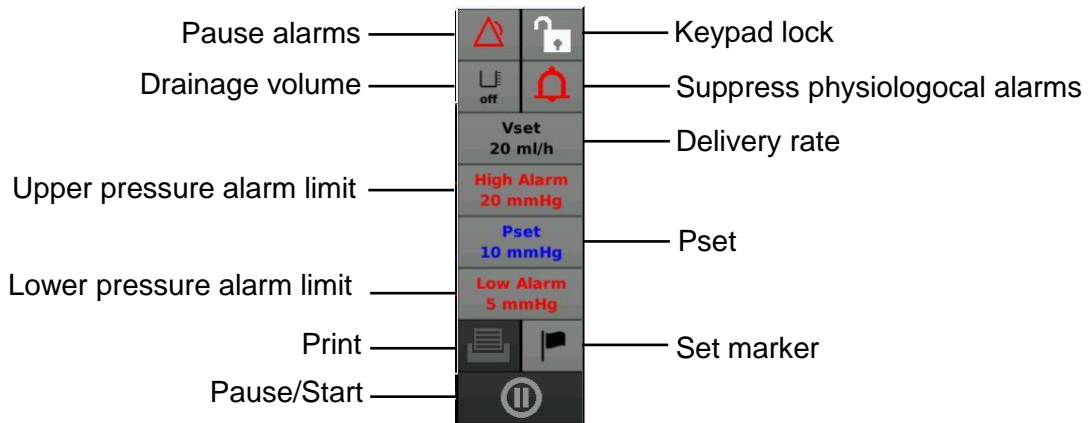


Figure 13: Softkeys in the Diagram dialog field

**Suppress physiological alarms (bell symbol)**

A distinction is made between physiological alarms and technical alarms.

- Physiological alarms, for example, relate to the patient or their readings.
- Technical alarms refer to the condition of device functions.

Use the *Suppress the physiological alarms* button to suppress the audible alarm of all physiological alarms.

If alarms were suppressed, this is indicated by the crossed-out bell. The amount of time remaining before the alarms are automatically reactivated is displayed.

The displayed time is always initially 5 minutes and counts down.

This function refers only to the acoustic output of an alarm. Display of the alarm message in the display is not suppressed.

Alarm messages are shown in the display. Only the alarm sound is suppressed. This alarm suppression can for example, be used when nursing measures are carried out on patients. After 5 minutes, all pending alarms are automatically output again acoustically.

To reactivate the alarms, press the softkey again to **Suppress physiological alarms**. The bell will be shown normally again. Information on the **LiquoGuard® 7** alarm system can be found on *page 69*.

**Pause alarm (triangular symbol)**

The *An alarm was paused* button indicates that one or several alarms have been paused for the indicated period.

If an alarm is paused, this is indicated by the crossed-out symbol. The amount of time remaining before the alarm is reactivated automatically is displayed.

The displayed period of time depends on the selection made in the alarm window (see *Pause alarm signal, page 70*) and counts down.

This function refers to the acoustic output of one or more alarms and also to the display of the alarm messages in the display.

## Product description

If you would like to reactivate the alarm function before expiry of the displayed time, press the softkey **An alarm was paused**. The symbol will be shown normally again. Information on the **LiquoGuard® 7** alarm system can be found on *page 69*.

### Drainage volume

Using the *Drainage volume* button, set the desired amount of CSF (target volume) that the **LiquoGuard® 7** should deliver. Reaching the set drainage volume is indicated by a corresponding message window and an advisory tone.

Use this function to drain a defined amount of CSF and to receive feedback when the desired volume has been reached.

The drainage will NOT be interrupted when the set target volume has been reached and there is no acoustic signal. This function is for information purposes only, not for limiting the amount of drainage, and is not an alarm.

How long it takes until the set drainage volume is reached depends on the speed of the pump (see *Vset*, *page 33*) and how often the pump rotates. In drainage mode, the pump rotates only if the pressure (ICP or Pcsf) is above Pset (blue dotted line).

### Keypad lock

This function activates and deactivates the **LiquoGuard® 7** keypad lock. If the keypad lock is active, the softkey indicates a closed lock symbol and the other buttons on the display are grayed out. In this mode, all buttons other than the *Keypad Lock* softkey (and optionally, *Printing*, if available) are inactive.

### Vset

The *Vset* button can be used to change the delivery rate of the **LiquoGuard® 7** pump.

The pump always delivers (drainage or infusion, depending on the type of the connected tubing set) with the set flow rate *Vset* when the pressure is above *Pset* (blue dotted line) (drainage) or when the pressure is below the maximum pressure alarm limit (infusion). This affects the drainage quantity that is delivered per unit time.

Example: At a flow rate (*Vset*) of 20 ml/h, it may be that after an hour 20 ml has still not been drained, since the pressure (Pcsf or ICP) is not permanently above Pset.

### Upper alarm

The *Upper Alarm* button adjusts the upper alarm limit for the pressure measured. If the pressure measured exceeds the *Upper Alarm* limit, an alarm will be generated.

Choose expedient alarm limits by taking into consideration the degree of mobility of the patient and the nursing effort.

The more mobile the patient is, the more generous you can be in selecting the alarm limit, if necessary, since a change of position always leads to pressure fluctuations (this is physiological).

Please note that the measured pressure may be physiologically relatively high during lumbar drainage the more upright the patient lies, sits or stands.

### Pset

Use the *Pset* button to change the set pressure value.

The **LiquoGuard®7** drains whenever the pressure is above *Pset*.

*Pset* cannot be lower than the lower alarm limit (lower dotted red line). If necessary, lower the lower alarm limit to select a lower *Pset*.

### Lower Alarm

This function changes the lower alarm limit of the measured pressure. If the pressure measured is below the *Lower Alarm* value, an alarm will be generated.

Choose expedient alarm limits by taking into consideration the degree of mobility of the patient and the nursing effort.

The more mobile the patient is, the more generous you can be in selecting the alarm limit, if necessary, since a change of position always leads to pressure fluctuations (this is physiological).

### Print

*Printing* is a function option. Information on this function can be found in the relevant section on *page 101*.



### Set marker



If the option *Documentation* on the **LiquoGuard®7** is active, this button can be used to insert a bookmark in the saved application data. Information on this option can be found in the relevant section on *page 94*.

### Pause/Start

This pause and restarts the drainage (*Pause* mode or *Play* mode).

If drainage is in *Pause* mode, the diagram indicates a large, flashing pause symbol for several seconds. After a few seconds, the symbol is reduced to the small flashing *Pause*

symbol  in the upper part of the display. The softkey *Pause/Start* also shows this symbol .

If drainage is started by selecting the softkey *Pause/Start*, the flashing symbol will go out and the softkey *Pause/Start* will show the start symbol . Similarly, the *Play* symbol  is displayed in the upper part of the display.

## Installation and startup

### 4 Installation and startup



Ensure that the packaging is delivered undamaged. Check the **LiquoGuard®7** for damages. In the event that the product indicates defects, it may not be used, and the supplier must be informed accordingly.

#### 4.1 Transport and storage instructions

Temperature:	-10 °C to +50 °C
Humidity:	less than 90 % rel. humidity
Weight with packaging:	approx. 5.3 kg
Dimension of the <b>LiquoGuard®7</b> with packaging:	Width x Height x Depth 300 mm x 320 mm x 345 mm

#### 4.2 Unpacking the device and inspecting delivery

Delivery of the **LiquoGuard®7** consists of one carton. When unpacking the **LiquoGuard®7** ensure that no parts remain in the package.

The delivery of the **LiquoGuard®7** consists of (1 item each):

- **LiquoGuard®7**
- Mains cable
- Instruction Manual

It is advisable to keep the packaging and use it again for any service required.



Ship the **LiquoGuard®7** only in its original packaging in order to avoid damage during transport.

The subsequent provision of transport packaging is subject to charges.

#### 4.3 Operating the LiquoGuard®7

All handling of the **LiquoGuard®7** is subject to precise knowledge of and compliance with this instruction manual. These instructions do not replace proper user training. Only qualified personnel may operate this unit.

Begin by removing the **LiquoGuard®7** from its packaging. The **LiquoGuard®7** must be prepared according to hygiene guidelines prior to first application. When cleaning, use a mild detergent/disinfectant according to the hygiene instructions on *page 86*.

The **LiquoGuard® 7** can be:

- set up in a suitable place.
- hung onto a standard rail.
- installed on standard infusion stands (ensure that the device is securely fastened onto the infusion stand).

The device is optimally positioned if the user can stand in front of it and view the operating interface vertically.

**When setting up the *LiquoGuard® 7*, please ensure:**

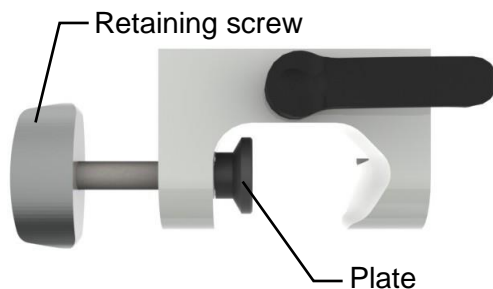


- a sufficient distance from other devices is maintained. The **LiquoGuard® 7** requires a space of at least 34 cm in height and width.
- the device can be turned off via the ON/OFF switch and disconnected from the mains by unplugging the mains cable.
- the **LiquoGuard® 7** is not operated in the direct proximity of or stacked with other devices, as this could result in faulty operation. If operation as described above cannot be avoided, monitor the **LiquoGuard® 7** and other devices to verify specified normal operation.

### 4.3.1 Hanging onto a standard rail

Lift the **LiquoGuard® 7** from its handle and hang it onto a standard rail by means of the universal bracket located on the back. Before releasing the **LiquoGuard® 7**, check that the universal bracket is securely positioned on the rail. Activate the safety clip by turning the lever on the universal bracket by 90° (see *Figure 14*) until it engages. The safety clip prevents the **LiquoGuard® 7** from inadvertently being lifted off the rail.

#### Unsafe fitting of the safety clip



#### Safe fitting of the safety clip

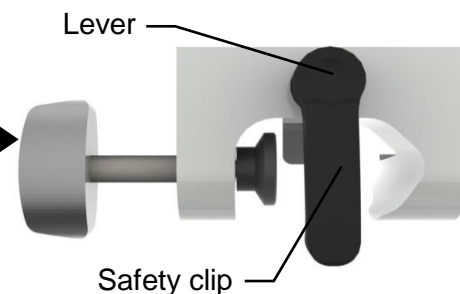


Figure 14: Unsafe and safe positioning of the safety clip.

### 4.3.2 Installation on an infusion stand

Open fully the retaining screw (see *Figure 14*) of the universal bracket. Lift the **LiquoGuard® 7** by its handle and place onto the infusion stand, fitting the opening of the universal bracket onto the stand. Turn the retaining screw until the **LiquoGuard® 7** is safely and stably installed.

## Installation and startup

Do not use the universal bracket for mounting on a stand if the plate for the retaining screw is missing, which is located between the retaining screw and stand (see *Figure 14*).

### 4.3.3 Connecting and turning the device on

Once the device has been installed in the correct place and position, connect the mains cable to the right-hand side of the housing of the **LiquoGuard® 7**. Insert the other end of the mains cable into the power socket with a protective earth conductor. Observe the voltage indicated on the identification plate of the device. The plate is located on the back of the device. The self-test starts by placing the ON/OFF switch of the **LiquoGuard® 7** in the ON (☉) position. The basic functions of the electronic components are tested during the self-test. The device is ready for operation once the self-test is completed.

Testing the elements such as the LEDs on the front of the device and the built-in speaker are not subject to the self-test. In order to guarantee the functioning of these components during an alarm, ensure during the device test and particularly the self-test that both left LEDs flash red briefly and that the speaker emits an audible signal. If problems are encountered, contact the manufacturer's service team.



Use the mains cable provided to connect the **LiquoGuard® 7** to the mains power supply.

To avoid the risk of electrical shock, this device may be connected only to a power supply with a protective earth conductor.



To avoid false alarms, users should be familiar with the alarm concept of the **LiquoGuard® 7** (see *page 69*), as well as the *settings* (see *page 51*) before the first start-up.

To further commission the **LiquoGuard® 7**, you need a **LiquoGuard® 7 Drainage Set REF. No.: 00003497 (1600 mm) or REF. No.: 00003501 (2000 mm)**. The Drainage Set with REF. No.: 00003501 is available in various versions in terms of application duration, service life, and MRI capability, as described in the Appendix.

Observe the maximum tube length between the catheter and the **LiquoGuard® 7**.

The option *Monitor/Nurse Call* allows for the **LiquoGuard® 7** to be connected with a patient monitoring or nurse call system. Further information on this option can be found on *page 89*.

#### **4.4 Suitable operating environment**

The ***LiquoGuard®7*** is suitable for environments in the following areas:

- Professional healthcare facilities with specific requirements  
Clinics (rooms in A+E, hospital rooms, intensive care, operating theatres, except for in the proximity of active facilities of electrosurgical devices or outside of the RF-shielded room for magnetic resonance imaging, first aid facilities).

The ***LiquoGuard®7*** is not approved for use in aircrafts or military applications. The appropriate EMC requirements for these environments have not been tested.



## 5 Application and Operation

### 5.1 Installation and startup

Remove the **LiquoGuard® 7** from the packaging. Place it on an appropriate level surface or install it onto an infusion stand or rail (see *page 37*). Connect the mains cable to the **LiquoGuard® 7** and then to the mains power socket.



When restarted, the **LiquoGuard® 7** will revert to the standard settings (use the option *Presettings* to save the settings). For more detailed information, see *page 99*).

The **LiquoGuard® 7** can operate as a pressure or volume-controlled pump. The sections below describe the basic operating procedures for these two processes.

### 5.2 Switching on the **LiquoGuard® 7**

Place the ON/OFF switch located on the side to the ON position (☉). The **LiquoGuard® 7** starts. It is possible that at the start of the boot process, the screen displays undefined patterns and colors. This is normal and does not indicate a malfunction.

The **LiquoGuard® 7** performs a comprehensive self-test during startup. This process takes several seconds. Once completed, the **LiquoGuard® 7** will be in Pause mode (see *Figure 15*).



Testing the elements such as the LEDs on the front of the device and the built-in speaker are not subject to the self-test. In order to guarantee the functioning of these components during an alarm, ensure when the device starts and particularly during the self-test that both left LEDs flash red briefly and that the speaker emits an audible signal. If problems are encountered, contact the manufacturer's service team.

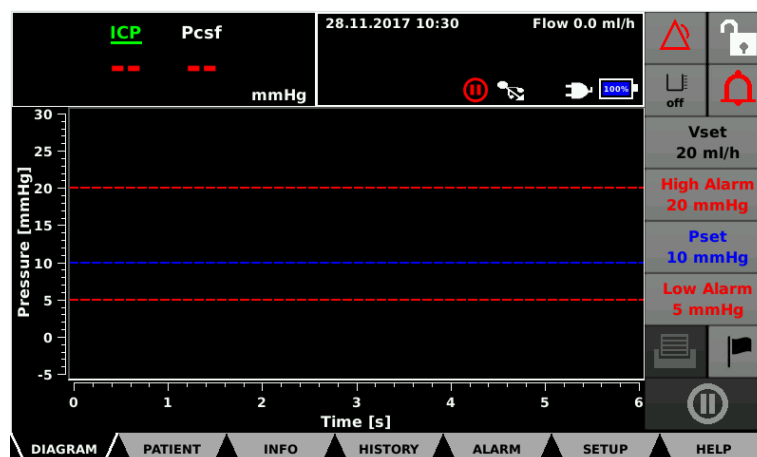


Figure 15: **LiquoGuard® 7** display in Pause mode

### 5.3 Preparing the tubing set

Prepare the tubing set according to the sequence described below.

1. Prepare the patient, insert the catheter (not part of this product), vent the catheter, and check that it is functioning properly.
2. Remove the tubing set from its sterile packaging in accordance with hygiene guidelines.
3. Attach the adhesive electrode to the pressure sensor housing.
4. Connect the tubing set with the CSF bag and fasten it to the bracket provided at the back of the device (see *page 22*).

Ensure that the valve position is open between the tubing set and CSF bag.

### 5.4 Connecting the sensor cable

The sensor cable is part of the tubing set and transmits the measured signals from the pressure sensor to the **LiquoGuard®7**. The sensor cable connection is located on the right side of the device (see *page 24*).

1. Connect the sensor cable of the prepared tubing set to the **LiquoGuard®7** (see *Figure 16*).
2. As soon as the tubing set is recognized by the **LiquoGuard®7**, one or several green windows will appear on the screen with the instruction to insert the tubing set.
3. Select the button **Start Application** in the message window.



Figure 16: Connecting the tubing cable set to the **LiquoGuard®7**

### 5.5 Inserting the tube

The **LiquoGuard®7** tubing set has two pump adapters: Adapter 1 and Adapter 2 (see *Figure 17*). The input points for Adapter 1 and Adapter 2 (see *Figure 18*) in the **LiquoGuard®7** pump are designed so that they cannot be confused. The arrows on the adapter, as well as on the pump, indicate the direction of the CSF flow.

## Application and Operation

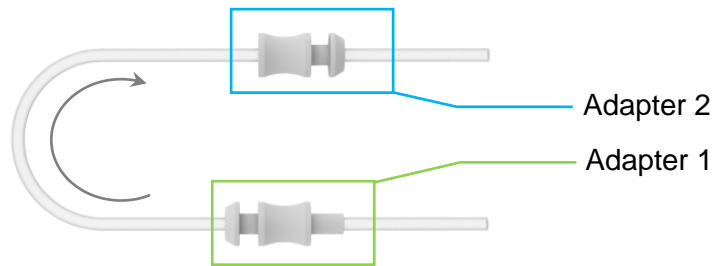


Figure 17: Adapter 1 and Adapter 2 of the **LiquoGuard®7** tubing set

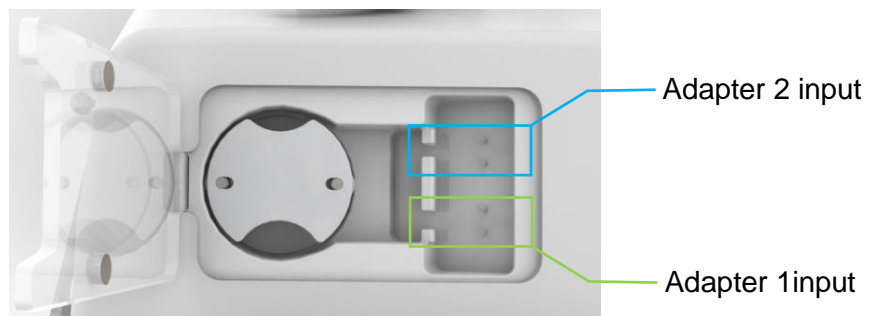


Figure 18: Adapter 1 and Adapter 2 inputs located on the pump housing.  
The two black arrows indicate the CSF flow direction.

1. Use your fingers to reach into the opening of the pump cover and lift until it engages.
2. The **LiquoGuard®7** display indicates a green message window with the softkey *Turn rotor*. Use this button to turn the pump rotor and feed the tube into the pump.
3. Insert Adapter 1 into the **LiquoGuard®7** Adapter 1 input.
4. Hold **Adapter 2** with one hand.
5. Select the softkey **Turn rotor** on the display and keep it pressed.
6. Feed the tube into the semi-circular opening of the rotor up to the **Adapter 2 input**.
7. Now insert Adapter 2 into the Adapter 2 input.
8. Close the front cover of the pump.

Ensure that the entire tube is inserted correctly in the pump; refit it if necessary. Do not allow the tube to be longer than 20 mm. Lay the sensor cable along the device so that it does not lie on the handle or come into contact with it.

### 5.6 Connecting the catheter

Observe the instructions provided in the section *Combination with other products*, catheters and on *page 20*.

Connect the catheter to the **four-way stopcock** of the tubing system. Turn the T-handle of the four-way stopcock by 180° as shown in *Figure 19* to allow drainage. In order to prevent infection, ensure here that the stopcock position does not enable any opening to the atmosphere.

Once the tube has been inserted in the pump and the catheter has been connected, the pump rotor may not turn in the direction opposite to the flow (see *Figure 18*) as this presents a danger for the patient.



The tubing set must always be sufficiently vented.

There may be no air between the patient and the pressure sensor housing.

If there is air between the patient and the pressure sensor housing, the pressure measurement may be erroneous.



To vent the tube, put the pump in Pause mode, open the pump cover, press the softkey Turn Rotor and aspirate CSF until no more air can be detected between the patient and the pressure sensor housing and no more air can be detected in the pressure sensor housing.

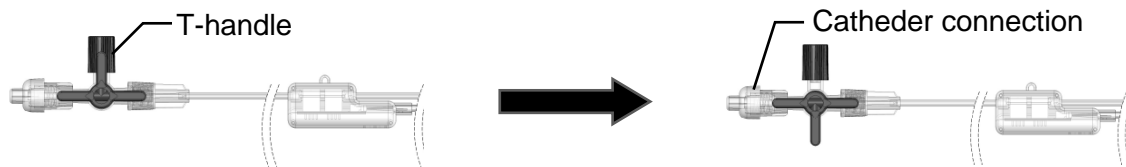


Figure 19: Tubing system four-way stopcock. The picture on the left shows the four-way stopcock in delivery mode. The picture on the right shows the four-way stopcock in operating mode.

## 5.7 Pressure sensor housing – Positioning and fastening

By selecting the sensor position, specify at what level the CSF pressure is measured. "Level" always means the height above the floor.

Literature usually indicates intracranial pressure values that are defined at the level of the foramen of Monro. The level of the pressure sensor housing above the floor should therefore always correspond to the level of the foramen of Monro, if no other levels are specifically defined.

### Ventricular drainage

If the patient's head moves, the measured pressure values may deviate depending on head positioning. The position of the sensor on the head should, therefore, be considered when evaluating the pressure values (adjust sensor position if necessary, to always keep this at the level of the foramen of Monro).

Secure the tubing set pressure sensor housing at the level of the foramen of Monro during ventricular drainage.

## Application and Operation

### Lumbar drainage

For the lumbar measurement, the same (level above the floor) applies, only the location of the measurement is different (spinal canal). The position of the pressure sensor housing is again obtained at the level of the foramen of Monro.

When the patient is lying down (supine or lateral position), the level of the spinal canal above the floor corresponds approximately to the level of the foramen of Monro, which allows the level of the pressure sensor housing to be easily determined (everything on the same level → exact measuring point is not primarily relevant, the important thing is at the level of the foramen of Monro).

Inquire about the patient's sleeping habits. For patients who lie on their sides, tape the pressure sensor housing on their backs; for those who lie on their backs, tape the housing on their sides. A safety cushion (available as an accessory) can be applied to avoid pressure pain (see *page 125*). If the patient moves his/her head, the measured pressure values may deviate depending on head movements. Ensure that the patient does not lie on the side on which the sensor is taped.

### Pressure measurement in mobile patients

The **LiquoGuard®7** is suitable for measuring CSF pressures in partially or completely mobilized patients and to drain CSF.



With standing, sitting or lying patients, misleading pressures can be displayed if the following principles are not observed.

A patient who stands up from a lying position or is placed in an erect position can show strong CSF pressure fluctuations and the CSF pressure readings can vary greatly.

During lumbar measurements, the CSF pressure increases and may fluctuate because cerebrospinal fluid pushes into the caudal regions of the subarachnoid spaces due to gravity and induces a higher CSF pressure there.

In ventricular measurement, the CSF pressure will fall and possibly fluctuate because CSF pushes caudally and therefore less CSF remains in the ventricular system.



Depending on the patient, their degree of mobility, and medical indications, a measurement location which takes into account these circumstances is to be selected.

If applicable, the location of the pressure measurement (position of the pressure sensor housing) is to be changed according to the patient's position, so that the pressure is always measured at the level of the foramen of Monro (level of the pressure sensor above the floor).

Depending on the degree of mobility of the patient, consideration should also be given to selecting the alarm corridor accordingly to avoid frequent false alarms (pressure too high or too low).

For mobile patients, the **LiquoGuard®7** must be attached to an infusion stand. The **LiquoGuard®7** must always be within hearing range of trained medical staff.



If the adhesive electrode is not sufficient to firmly secure the pressure sensor, use an appropriate dressing, net bandage or adhesive tape.

Secure fixation can be crucial, especially when used with mobile patients and children. Attach the drainage catheter, the three-way stopcock, the pressure sensor, and the tubes between them securely. Otherwise, patients may damage the product.

If the position of the pressure sensor housing must be changed regularly (head turning, positioning, patient mobility), more adhesive electrodes can be used so the pressure sensor housing is always attached at the level of the foramen of Monro. In this case, stick several electrodes in the periphery of the head and attach the pressure sensor housing to the electrode located at the level of foramen of Monro (level above the floor). If an extension of the tubing set is required, only use extensions in accordance with *Chapter 2.5 Combination with other products, catheters and cannulas (page 20)*. Ensure that the extension is firmly secured.



### 5.8 Changing drainage settings

Changes to the drainage settings can be made via the softkeys in the right-hand margin of the screen in the **DIAGRAM** dialog field. The parameters form the basis for every controlled drainage.



Inappropriate value settings for *Pset*, *Upper Alarm*, *Lower Alarm* and *Vset* may present a danger to the patient. Ensure that the values are adjusted to the needs of the individual patient prior to each drainage procedure.

#### 5.8.1 Pressure controlled drainage

The set pressure *Pset* is the control parameter for pressure-controlled drainage.

Pressure controlled drainage means that CSF does not flow at a continuous rate and rarely at a constant volume.

- Determine the set pressure *Pset*, the *Upper Alarm* and *Lower Alarm*, as well as the pump flow rate *Vset*.
- Determine the set pressure *Pset* so that it corresponds to the pressure that you think is appropriate for the patient.
- If the measured CSF pressure exceeds the *Pset* set value, CSF is delivered to maintain the *Pset* set pressure.
- Further information on the above and other settings can be found in the section *Settings* on page 51.

## Application and Operation

### 5.8.2 Volume controlled drainage

Volume controlled drainage means that CSF flows at a continuous rate and at a specific volume. The *Vset* value is the control parameter.


- Adjust the volume rate *Vset* and the *Upper* and *Lower Alarms* to the requirements of the individual patient.
- For a continuous CSF flow, now reduce the *Pset* set pressure as far as maintainable (*Lower Alarm* + 1 mmHg) to prevent the drainage from being interrupted when *Pset* is achieved.
- Also reduce the *Vset* volume flow to a sufficiently low level to prevent the patient from being overdrained.
- Further information on the above and other settings can be found in the section *Settings* on page 51.

### 5.9 Starting the application




Check before you start using it



- that the valves on the tubing set are in the correct position (see *Figure 19*).
- that there is no air in the tubing set (between patient and pressure sensor housing)
- that you detect pressure fluctuations in the display when you wiggle the pressure sensor housing
- that a pulsating pressure curve is detected when ventricular pressure is measured (pulsation is not always detectable with a lumbar or parenchymal pressure measurement)

- Press the **Pause/Start**  softkey in the **DIAGRAM** dialog field in the right-hand margin of the screen, in order to start the application.

The pump is activated only when the application is started. An active application is shown by the following display indications:

- The flashing Pause symbol in the upper part of the diagram is replaced by the  symbol.
- The Pause/Start softkey changes from  to .

### 5.10 Pausing the application, only pressure monitoring

Only the pump is inactive in Pause mode. All pressures are still shown. All alarm conditions are active and are signaled in the case of an alarm. The Pause mode is also used for patient pressure monitoring without simultaneous CSF delivery.

- Press the softkey  to pause the application.

### 5.11 Interrupting the application

During treatment, it may be necessary to interrupt drainage for a period of time (e.g. transporting the patient, imaging exams, consultation). The procedure described below ensures that the **LiquoGuard®7** settings and currently collected data are not lost due to the interruption.

1. While in application mode, remove the tubing set sensor cable from the device.
2. Press the **Interrupt Application** button in the alarm message window. The alarm will be deactivated and the device will be set in Pause mode.
3. Close the four-way stopcock between the tubing set and the catheter.
4. Open the pump cover and remove **Adapter 1** from its input point.
5. Press the softkey **Turn Rotor** in the message window.
6. Feed the tube into the semi-circular rotor opening up to **Adapter 2 input**; then remove **Adapter 2** from its input.
7. Close the pump cover.



Ensure that the **LiquoGuard®7** is turned off at this stage.

8. Following the interruption, connect the tubing set to the **LiquoGuard®7** as described in *Points 5.4 to 5.8* and open the four-way stopcock between the tubing set and the catheter. When the **LiquoGuard®7** recognizes the tubing set once again, the current pressure value appears on the display.
9. Press the softkey **Pause/Start** to continue the application.



Ensure that the tubing set is not disconnected from the **LiquoGuard®7** for longer than 8 hours. If this period is exceeded, the **LiquoGuard®7** will no longer accept the tubing set. In this case, connect a new tubing set and adjust the settings.



When the tubing set is removed from the pump or replaced, always first close the four-way stopcock between the tubing set and the catheter in order to prevent any CSF backflow.

During personal hygiene of the patient, ensure that no liquid penetrates the pressure sensor housing of the **LiquoGuard®7 Tubing Set**.

Showering is not permitted.



## Application and Operation

### 5.12 Changing the drainage set

1. Interrupt the application as described in *Point 5.11* and remove the tubing set used. Do not switch off the **LiquoGuard®7**.
2. Follow the instructions in *Points 5.3 to 5.4* to prepare and connect the tubing set.
3. If the tubing set is identified as new, a green message window will appear on the display.
4. If the settings and statistical data of the previous application are to be maintained, press the **Start Application** button in the message window. If the settings and statistics of the previous application are no longer required or a new patient is being treated with the **LiquoGuard®7**, press the button **New Application**.
5. Follow the steps in *Points 5.5 to 5.9* in order to fit the tubing set and start the application.

### 5.13 Displaying drainage information

Information and statistics on the current application are found in the dialog field Info. Use the softkeys in the right-hand margin of the screen to access the submenus **ALARMS** and **BATTERY**.



If the **LiquoGuard®7** has been restarted or the power supply interrupted due to low battery charge, the data saved under the **ALARMS** submenu will be deleted.

#### 5.13.1 Alarms

A chronological list of the alarms and alarm conditions occurring during the current application, is located under the submenu **ALARMS**.

#### 5.13.2 Battery

The current charge of the main and backup batteries of the **LiquoGuard®7** is indicated in the **BATTERY** submenu. Ensure that both batteries are fully charged when the device is disconnected from the mains power supply. Also observe the battery indicator in the **DIAGRAM** dialog field during battery operation (see *page 32*).

### 5.14 Turning off the device

The **LiquoGuard®7** can be turned off via the ON/OFF switch located on the side . If the device is still connected to the mains power supply through the mains cable, the batteries will be charged. If disconnecting the device from the mains, unplug the mains cable from the mains socket.



Dispose of the used single-use product according to your hygiene requirements. In order to prevent leakage from the tubing set, ensure that the stopcocks are closed when disposing of the drainage and infusion sets.

### **5.15 Storage**

After the application, store the **LiquoGuard®7** in accordance with hygiene regulations. In addition, observe the *Storage Conditions* on page 119.

## Settings

## 6 Settings

The default values may be changed only by qualified personnel. The user must check prior to every application and on a regular basis that the current settings are suitable for a specific patient.



Particular attention should be given to the alarm parameters and that these satisfy the current requirements of the individual patient. Inappropriate and extreme values will prevent the **LiquoGuard® 7** alarm system from functioning.

### 6.1 Drainage

In the **DIAGRAM** dialog field, change the drainage settings of the **LiquoGuard® 7** by using the softkeys on the right-hand side.



Inappropriate value settings for *Pset*, *Upper Alarm*, *Lower Alarm* and *Vset* may present a danger to the patient. Ensure that the values are adjusted to the needs of the individual patient prior to each drainage procedure.

Select the appropriate softkey to change a value. When entering a value, a + and - button will appear next to the selected softkey. Press the + or - button until the required value is shown (the softkeys can also be kept pressed). The changed values are automatically accepted without the need for confirmation. To deactivate the + and - buttons, press the highlighted softkey again or wait one minute until the buttons automatically deactivate.

#### 6.1.1 Pset (set pressure value)

This setting determines the set value for the measured CSF pressure. In other words, this is the desired CSF pressure that a connected patient should have.

If the measured CSF pressure exceeds the *Pset* value, CSF will be pumped to reduce the pressure by turning the pump. The pump delivers according to the delivery rate *Vset* until the measured pressure reaches the *Pset*.



Setting the *Pset* value to < 2 mmHg can present a serious danger to the patient. For safety reasons, the system requests confirmation of the setting. To confirm, press the button *Yes, I want to set Pset < 2 mmHg*. This function can be deactivated as described in the section *Config* from page 62.

1. Tab bar **DIAGRAM** → Softkey **Pset**
2. Press the + and - buttons to change the value.

The change is accepted directly.

## Settings

- Default value: 10 mmHg
- Minimum value: limited by Lower Alarm
- Maximum value: limited by Upper Alarm

### 6.1.2 Upper Alarm

Use the softkey *Upper Alarm* to set the upper alarm limit for the CSF pressure. If the measured CSF pressure exceeds the *Upper Alarm* value, an alarm will be generated after a preset delay (default value = 45 seconds, see *page 54*).

If the *Upper Alarm* value for the period set under *delay of emergency drainage* (see *page 56*) is exceeded, the **LiquoGuard® 7** performs an emergency drainage. During emergency drainage the pump delivers 250 ml/h until the pressure measured by the tubing set has dropped to or below the *Upper Alarm* value.

1. Tab bar **DIAGRAM** → Softkey **Upper Alarm**.
2. Press the + and - buttons to change the value.

The change is accepted directly.

- Default value: 20 mmHg
- Minimum value: limited by Pset
- Maximum value: 75 mmHg



Choose expedient alarm limits by taking into consideration the degree of mobility of the patient and the nursing effort.

The more mobile the patient is, the more generous the selected alarm limits can be. Changes in position cause pressure fluctuations (this is physiological) and can result in more frequent unnecessary alarms.

### 6.1.3 Lower Alarm

Use the softkey *Lower Alarm* to set the lower alarm limit. If the measured CSF pressure falls below the *Lower Alarm* limit, an alarm will be generated after a preset delay (default value = 45 seconds, see *page 54*).



Setting the Lower Alarm value to < 2 mmHg can present a serious danger to the patient. For safety reasons, the system requests confirmation of the setting. To confirm, press the button **Yes, I want to set the Lower Alarm below 2 mmHg**. This function can be deactivated as described in the section Config on *page 62*.

## Settings

1. Tab bar **DIAGRAM** → Softkey **Lower Alarm**.
2. Press the **+** and **-** buttons to change the value.

The change is accepted directly.

- Default value: 5 mmHg
- Minimum value: -15 mmHg
- Maximum value: limited by Pset



Choose expedient alarm limits by taking into consideration the degree of mobility of the patient and the nursing effort.

The more mobile the patient is, the more generous the selected alarm limits can be. Changes in position cause pressure fluctuations (this is physiological) and can result in more frequent unnecessary alarms.

### 6.1.4 Vset

This setting changes the delivery rate of the **LiquoGuard®7** pump. The pump delivers according to the *Vset* delivery rate if the measured CSF pressure exceeds the *Pset* (blue line) value. The pump delivers until the measured pressure corresponds to the *Pset* value (blue line).

1. Tab bar **DIAGRAM** → Softkey **Vset**.
2. Press the **+** and **-** buttons to change the value.

The change is accepted directly.

- Default value: 20 ml/h
- Minimum value: 1 ml/h
- Maximum value: 150 ml/h

The pump delivers whenever the CSF pressure is greater than *Pset* (blue dotted line). Often, the CSF pressure of the patient is not continuously above *Pset* (blue dotted line) but fluctuates, which is why the pump does not always have to deliver.



For example, this means that at a set flow rate of 20 ml/h, less than 20 ml was drained after one hour.

This can definitely be a physiological condition. It can be normal for the CSF pressure to fluctuate if observed over the course of a day.

If you would like to achieve an absolutely constant flow rate (e.g. 20 ml/h), carry out a volume controlled drainage (see *Volume controlled drainage*, page 47).

### 6.2 Alarm

Go to dialog field Alarm in the tab bar. The following alarm-related settings for the **LiquoGuard®7** are found in the submenu.

#### 6.2.1 General

##### 6.2.1.1 Alarm delay

This setting is used to determine the time period from the moment a specific physiological alarm condition occurs to the emission of an alarm signal. This avoids generating an alarm with temporary pressure fluctuations (e.g. by coughing, sneezing, patient movements or nursing measures).

An alarm delay applies only to the following alarm conditions:

- Upper Alarm
- Lower Alarm
- ICP differs from Pcsf

1. Tab bar **ALARM** → Softkey **GENERAL** → Subitem **Alarm delay**
2. Press the **+** and **-** buttons to change the value.
3. To save the changes, press the **Confirm changes** button.

- Default value: 45 seconds
- Minimum value: 5 seconds
- Maximum value: 1 minute

##### 6.2.1.2 Sound level

This function determines the volume of the acoustic alarm signal.

1. Tab bar **ALARM** → Softkey **GENERAL** → Subitem **Sound level**
2. Press the **+** and **-** buttons to change the value.
3. To save the changes, press the **Confirm changes** button.

- Default value: 40%
- Minimum value: 20%
- Maximum value: 100%



Reducing the alarm volume below the surrounding volume may result in the user not hearing the alarm signals.

## Settings

## 6.2.2 Flow

## 6.2.2.1 Lower Flow Alarm

This function sets the minimum time-averaged flow rate for the application. The average value is set according to the averaging time. If the average flow is lower than the *Lower Flow Alarm* value, an alarm is generated.

1. Tab bar **ALARM** → Softkey **FLOW** → Subitem **Lower Flow Alarm**.
2. Press the **+** and **-** buttons to change the value.
3. To save the changes, press the **Confirm changes** button.

- Default value: OFF (function deactivated)
- Minimum value: OFF (function deactivated)
- Maximum value: 20 ml/h, limited by *Upper Flow Alarm* function

Example: You would like to be informed (alarm) if less than 5 ml CSF/h is drained.



The default value of this alarm is OFF, since it is physiologically possible that no CSF is drained over a specific period of time. Reasons are, for example, the existing auto drainage of the patient via their venous vascular bundle or a fluctuating, but not necessarily pathological CSF production rate.

## 6.2.2.2 Upper Flow Alarm

The upper flow alarm limit sets the maximum time-averaged flow rate for the application. The average value is set according to the *averaging time*. If the average flow over the *averaging time* is higher than the *Upper Flow Alarm* value, an alarm is generated.

1. Tab bar **ALARM** → Softkey **FLOW** → Subitem **Upper Flow Alarm**.
2. Press the **+** and **-** buttons to change the value.
3. To save the changes, press the **Confirm changes** button.

- Default value: OFF (function deactivated), limited by *Lower Flow Alarm*
- Minimum value: OFF (function deactivated), limited by *Lower Flow Alarm*
- Maximum value: 150 ml/h

Example: You would like to be informed (alarm) if more CSF than 30 ml/h is drained.

Please activate the alarm “**Upper Flow Alarm**” if this is required for your application.

### 6.2.2.3 Averaging time

This function sets the time frame for averaging the flow rate in relation to the flow alarm limits. This setting is visible only when the advanced settings are displayed. See *chapter Advanced Settings* on page 63.

1. Tab bar **ALARM** → Softkey **FLOW** → Subitem **Averaging time**.
2. Press the **+** and **-** buttons to change the value.
3. To save the changes, press the **Confirm changes** button.

- Default value: 30 minutes
- Minimum value: 5 minutes
- Maximum value: 60 minutes



The shorter the averaging time is, the more frequently the **LiquoGuard®7** checks if one of the two flow alarm limits has been exceeded.

### 6.2.2.4 Delay of emergency drainage

This value defines the time that elapses between the appearance of the *upper pressure alarm* (see page 52) and the beginning of emergency drainage. This function is typically active if the flow rate *Vset* is not sufficient for relieving the CSF pressure because the patient, for example, has developed a cerebral hemorrhage that cannot be sufficiently drained with the selected flow rate (*Vset*, see page 53), which is why the intracranial pressure steadily increases. The flow rate during emergency drainage is 250 ml/h. This maximum flow rate is maintained until the CSF pressure has dropped to or below the *Upper Alarm* value (see page 52).

1. Tab bar **ALARM** → Softkey **FLOW** → Subitem **Delay of emergency drainage**.
2. Press the **+** and **-** buttons to change the value.
3. To save the changes, press the **Confirm changes** button.

- Default value: "Off"
- Minimum value: 0 seconds
- Maximum value: "Off" (no emergency drainage)



## Settings

## 6.2.3 Pulsation

## 6.2.3.1 Pulsation alarm

This function changes the alarm conditions for CSF pulsation. Pulsation is a monitoring parameter intended to increase patient safety in ventricular pressure measurement. With a good connection (CSF communication) between patient and pressure sensor, the pulsation frequency corresponds to approximately the patient's pulse and is easy to identify. The poorer the communication is, the less clear the pulsation can be identified. If pulsation fails, this indicates, for example, an occlusion of the catheter.

During lumbar pressure measurement, the pulsation can be very weak, despite a good connection. In patients after craniectomy, pulsation may no longer be measurable at all.

If CSF pulsation fails or is too weak, the **LiquoGuard®7** triggers an alarm.

In certain circumstances, the alarm can be deactivated (e.g. in the case of craniectomy / operative decompression (surgical removal of part of the cranium)).

Also, with continuous lumbar drainage, reliable pulsation detection is sometimes not always possible, and it may be necessary to disable the pulsations alarm.

Using the pulsation alarm, the **LiquoGuard®7** recognizes whether the catheter is blocked.



Deactivating the pulsation alarm means that an alarm function for catheter occlusions or collapsed ventricles is not present.


1. Tab bar **ALARM** → Softkey **PULSATION** → Subitem "**Pulsation lost**" alarm (**only tested in the tubing set!**)
2. Select the required option. The selected option is indicated by a black dot in the options field .
3. To save the changes, press the **Confirm changes** button.

- No alarm: Alarm is deactivated
- As soon as pulsation fails: Alarm when pulsation frequency  $f \leq 30/\text{min}$  or frequency cannot be measured
- If pulsation fails and a problem is suspected: Alarm when pulsation frequency  $f \leq 30/\text{min}$  or frequency cannot be measured, and pulsation test recognizes a problem.

## 6.2.3.2 No amplitude alarm

This setting determines whether an alarm will be generated due to a sustained constant pressure (no pressure fluctuations = amplitude). Independently of the CSF pulsation, CSF pressure is subject to minor pressure fluctuations. If these pressure fluctuations do not occur over a specific period of time, it is possible that the tube is bent, occluded or disconnected.

## Settings

1. Tab bar **ALARM** → Softkey **PULSATION** → Subitem **Alarm "Pressure constant for too long" (only tested in the tubing set!)**
2. Select the required option. The selected option is indicated by a black dot in the options field .
3. To save the changes, press the **Confirm changes** button

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>• No plausibility test:</li> </ul>  | No alarm   |
| <ul style="list-style-type: none"> <li>• As soon as pressure amplitude seems implausible:</li> </ul>                         | Alarm, when the pressure fluctuations over a specific period of time are smaller than the value set under <i>Min. Amplitude</i> .  |
| <ul style="list-style-type: none"> <li>• If there is no pressure amplitude recognized and a problem is suspected:</li> </ul> | If the CSF pressure fluctuations averaged over a specific time period are less than the value set under <i>Min. Amplitude</i> (see below), the drop-in pressure resulting from the very small quantity of CSF delivered will be tested. If the pressure drop exceeds 5 mmHg, it is possible that the tube is bent, occluded or disconnected, and an alarm will be generated. |

### 6.2.3.3 Minimum amplitude

This setting is visible only when the advanced settings are displayed. See *chapter Advanced Settings* on page 63.

This function establishes the pressure difference for the setting "*Pressure constant for too long*" alarm. The CSF pressure fluctuations can vary depending on the patient and the application. If the CSF pressure fluctuation over a specific time period (see *Observation period* on page 58) is less than the value set, an alarm is generated.

1. Tab bar **ALARM** → Softkey **PULSATION** → Subitem **Min. Amplitude**
2. Press the **+** and **-** buttons to change the value.
3. To save the changes, press the **Confirm changes** button.

- Default value: 0.5 mmHg
- Minimum value: 0.1 mmHg
- Maximum value: 0.5 mmHg

### 6.2.3.4 Observation period

This setting is visible only when the advanced settings are displayed. See *chapter Advanced Settings* on page 63.

## Settings

The *Observation period* setting changes the time period for the setting "Pressure constant for too long" alarm. If the CSF pressure fluctuation over this time period is less than the value set under *Min Amplitude*, an alarm is generated.

1. Tab bar **ALARM** → Softkey **PULSATION** → Subitem **Observation period**
  2. Press the **+** and **-** buttons to change the value.
  3. To save the changes, press the **Confirm changes** button.
- Default value: 10 minutes
  - Minimum value: 2 minutes
  - Maximum value: 30 minutes

### 6.2.4 Parenchymal/Tip sensor

The *Parenchymal/Tip sensor* option allows a parenchymal/tip sensor or a catheter with tip sensor to be connected to the **LiquoGuard®7** in addition to the drainage set. Further information on this *device option* can be found on page 102.

### 6.2.5 Monitor/Nurse Call

*Monitor/Nurse Call* is an option which allows a patient monitor and diagnostic call system to be connected to the **LiquoGuard®7**. Further information on this *device option* can be found on page 89.

### 6.2.6 CPP/cMAP Sensor

*CPP/cMAP* is a device option for connecting an arterial blood pressure sensor to the **LiquoGuard®7** and displaying the cerebral perfusion pressure (CPP) together with the CSF pressure (Pcsf or ICP). Further information on this *device option* can be found on page 107.

## 6.3 Setup

Go to the Setup dialog field in the tab bar. The system settings for the **LiquoGuard®7** can be established in the submenus of the dialog field.

### 6.3.1 Language

#### Language settings

Select the language settings for the **LiquoGuard®7** in the Language submenu.

1. Tab bar **SETUP** → Softkey **LANGUAGE** → Subitem **Language Settings**
2. Select one of the languages indicated. The selected language is indicated by a black dot in the options field .

3. Press the button **Load new language** at the bottom of the screen to accept the changes.
4. Restart the **LiquoGuard®7**.

### 6.3.2 Display

#### 6.3.2.1 Pressure unit

Use this selection to set the unit of measure used for pressure.

1. Tab bar **SETUP** → Softkey **DISPLAY** → Subitem **Pressure unit**
2. To change, press the button indicating the unit of measure required.

The change is accepted directly.

Units of measure available:

- mmHg (default value)
- cmH<sub>2</sub>O

#### 6.3.2.2 Time axis scaling

Change the value of the setting *Time Axis Scale* in accordance with the scale used on the time axis in the Diagram dialog field.

1. Tab bar **SETUP** → Softkey **DISPLAY** → Subitem **Time axis scaling**
2. Press the **+** and **-** buttons to change the scale.

The change is accepted directly.

- Default value: 6 seconds
- Minimum value: 6 seconds
- Maximum value: 60 seconds

#### 6.3.2.3 Timeout backlight when on battery

This function determines the period from the last time the display was touched until the background lighting is dimmed. Dimming the lighting reduces battery consumption. This function is possible only in battery operation mode. If the **LiquoGuard®7** touchscreen is touched while the lighting is dimmed, full lighting will be restored.

1. Tab bar **SETUP** → Softkey **DISPLAY** → Subitem **Timeout backlight when on battery**
2. Press the **+** and **-** buttons to change the duration.

The change is accepted directly.

## Settings

- Default value: 10 minutes
- Minimum value: 2 minutes
- Maximum value: ALWAYS ON

### 6.3.2.4 Display brightness

This setting adjusts the brightness of the display.

1. Tab bar **SETUP** → Softkey **DISPLAY** → Subitem **Display brightness**
2. Press the **+** and **-** buttons to change the brightness.

The change is accepted directly.

- Default value: 100%
- Minimum value: 50%
- Maximum value: 100%



The display brightness setting is limited to a minimum value so as to guarantee the operability of the *LiquoGuard®7* at any setting.

### 6.3.2.5 Display contrast

This setting determines the contrast of the display.

1. Tab bar **SETUP** → Softkey **DISPLAY** → Subitem **Display contrast**
2. Press the **+** and **-** buttons to change the contrast.

The change is accepted directly.

- Default value: 100%
- Minimum value: 50%
- Maximum value: 100%

### 6.3.2.6 Date – Time format

This function sets the date and time format for the **DIAGRAM** dialog field.

1. Tab bar **SETUP** → Softkey **DISPLAY** → Subitem **Date-Time format**
2. Press repeatedly on the adjacent button until the required format is indicated.

The change is accepted directly.

Three formats are available (the examples are based the seventh day of the first month of the year 2012 at the time 15:17):

- DD.MM.YYYY HH:MM (default) (e.g. 07.01.2012 15:17)
- MM/DD/YYYY HH:MM am/pm (e.g. 01/07/2012 03:17 pm)
- YYYY-MM-DD HH:MM (e.g. 2012-01-07 15:17)

### 6.3.2.7 Display flow rate

This function allows you to specify whether the *flow rate* is displayed in the main **DIAGRAM** window. The value indicates the average flow rate per hour and is expressed in ml/h. On delivery of the **LiquoGuard®7**, the display is activated, however it can be deactivated at any time.

1. Tab bar **SETUP** → Softkey **DISPLAY** → Subitem **Display flow rate**

- Flow rate visible (default value)
- Flow rate not visible

### 6.3.3 Config

The **Config** dialog field is used to change the **LiquoGuard®7** device settings.

#### 6.3.3.1 Keyboard format

This setting changes the format of the keyboard screen.

1. Tab bar **SETUP** → Softkey **CONFIG** → Subitem **Keyboard format**
2. Press repeatedly on the adjacent button until the required format is indicated.

The change is accepted directly.

Formats available:

- QWERTZ (default)  
This corresponds to keyboards (e.g. German) in which the first five keys on the top row of letters are the letters Q, W, E, R, T, Z.
- QWERTY  
This corresponds to keyboards (e.g. English) in which the first five keys on the top row of letters are the letters Q, W, E, R, T, Y.

#### 6.3.3.2 Confirm Lower Alarm below 2 mmHg

This function determines whether a warning message with confirmation will appear if the user attempts to set the *Lower Alarm* or *Pset* to a value less than 2 mmHg or 2 cmH<sub>2</sub>O.

1. Tab bar **SETUP** → Softkey **CONFIG** → Subitem **Confirm Lower Alarm below 2 mmHg**

- Acknowledgment message active (default)
- Acknowledgment message deactivated

## Settings

**6.3.3.3 Advanced Settings**

This function allows you to specify whether *advanced settings* are displayed. These settings are not required for normal operation and mainly intended for experts.

1. Tab bar **SETUP** → Softkey **CONFIG** → Subitem **Advanced settings**

- Advanced settings visible
- Advanced settings not visible (default value)

**6.3.3.4 Date – Time settings**

Use this setting to change the system time of the *LiquoGuard®7*.



Before changing the date and time, the tubing set must first be disconnected for safety reasons and the *LiquoGuard®7* restarted.

**Change date**

1. Remove the tubing set if this has not yet been done and restart the *LiquoGuard®7*.
2. Tab bar **SETUP** → Softkey **CONFIG** → Subitem **Date-Time settings**
3. Select the box containing the current date.
4. Select another date in the **Screen Calendar** (see *page 28*).

The change is accepted directly.

**Change time**

1. Remove the tubing set if this has not yet been done and restart the *LiquoGuard®7*.
2. Tab bar **SETUP** → Softkey **CONFIG** → Subitem **Date-Time settings**
3. Press the **field** showing the current time.
4. Clear the time to be modified by pressing the button **<=** on the **numeric keypad screen** (see *page 28*) if this is not automatically deleted.
5. Enter the new time. Make sure that a double point is used to separate hours and minutes when entering the time.
6. To save the entry, press the **ENTER** button.

The change is accepted directly.

### 6.3.4 Operation

The **OPERATION** dialog field is used to make changes to the *pump controller* of the **LiquoGuard® 7**.

This setting is visible only when the advanced settings are displayed. See *chapter Advanced Settings* on page 63.

#### 6.3.4.1 Tubing set flow resistance

This function is used to adjust flow resistance parameters.

This setting is visible only when the advanced settings are displayed. See *chapter Advanced Settings* on page 63.



Pressure losses occur when pumping liquids through a tube. If you want to determine the CSF pressure during drainage in the same tubing set, one must know what the pressure losses are and take them into account during the CSF delivery.

The flow resistance measurement is used to record these pressure losses.

#### Repetition rate

This setting is used to determine the interval for the automatic measurement of flow resistance.

1. Tab bar **SETUP** → Softkey **OPERATION** → Subitem **Repetition rate**
2. Press the **+** and **-** buttons to change the measurement frequency.
3. To save the changes, press the **Confirm changes** button.

- Default value: 30 minutes
- Minimum value: 2 minutes
- Maximum value: 24 hours / Manual



If the **Manual** mode is selected, the **LiquoGuard® 7** will not perform any automatic flow measurement. The use of this mode assumes detailed knowledge of the accessories used.

#### Vtest

The parameter *Vtest* determines the flow volume which is used in the calculation of the flow resistance.

1. Tab bar **SETUP** → Softkey **OPERATION** → Subitem **Vtest**
2. Press the **+** and **-** buttons to change the *Vtest*.
3. To save the changes, press the **Confirm changes** button.



## Settings

- Default value: 20 ml/h
- Minimum value: 5 ml/h
- Maximum value: 20ml/h

### Manual

In manual mode the user enters the flow resistance value. Changes are made by first selecting *Manual* in the frequency rate setting.

1. Tab bar **SETUP** → Softkey **OPERATION** → Subitem **Manual**
2. Press the **+** and **-** buttons to change the flow resistance.
3. To save the changes, press the **Confirm changes** button.

- Default value: 0.0
- Minimum value: 0.0
- Maximum value: 0.1

### 6.3.5 Service

#### 6.3.5.1 Registering device options (Activating the software key)

The range of functions of the **LiquoGuard®7** can be extended through various device options. For information on the available *device options*, see from *page 88*. Device options that you can already use with your **LiquoGuard®7** are marked with the message **Active** (with unlimited duration) or the available remaining period (example 23 days) is displayed when using time-limited device options.

To register new device options, a valid key for the specific option and the specific **LiquoGuard®7** is required. You can import the key to enable the device options via the USB interface or enter them directly via the keyboard screen.

#### LOADING KEYS FROM USB

1. Save the file containing the registration key to a USB memory stick. Save the file in its original condition without making any changes to it. Do not save the file in a subfolder but at the top level of the USB stick instead. They will otherwise not be found.
2. Connect the USB memory stick to a free USB port on the **LiquoGuard®7** (see *Connection options on page 24*).
3. Tab bar **SETUP** → Softkey **SERVICE**
4. Press the button **LOAD KEYS FROM USB**.

If the registration key is recognized and accepted by the device, the message *Active* will appear behind the enabled device option.

If the registration key allows time-limited access to the respective device option, the message e.g. 30 days will appear behind the enabled device option. The device will display the remaining days. The device option is disabled automatically once the remaining time has elapsed.

### ENTER KEY

1. Tab bar **SETUP** → Softkey **SERVICE**
2. Press the **ENTER KEY** button.
3. Press into the empty input field
4. Enter the key directly via the **keyboard screen**. Also include all the dashes with your entry. If the key supplied ends with "&", do not enter this.
5. Confirm your entry by using the **Enter key**.

If the registration key is recognized and accepted by the device, the message *Active* will appear behind the enabled device option.

If the registration key allows time-limited access to the respective device option, the message e.g. 30 days will appear behind the enabled device option. The device will display the remaining days. After this period, the device option is disabled automatically.

If you have problems when entering keys and these do not enable the desired device options, you can delete all the active keys first and then enable them again. It is essential to ensure with the supplier of the key beforehand that your key contains all device options to be activated (any previously activated ones and the newly activated ones)

To delete all the active keys, enter "*remove keys*" and then restart the device. All device options are now *inactive*. Now enter the key again and check that the desired device options are *active*.

It is possible to activate keys for limited periods of time. In this case, the remaining time (e.g. 12 days) will be displayed in the overview of the device options. Activation of software options is possible only once their remaining time has elapsed. A valid key will be accepted by the device before this, but the duration of the device options does not change.

## Settings

The key for activating the device options can be ordered through your local LiquoGuard dealer or directly from the manufacturer:

### **Möller Medical GmbH**

Wasserkuppenstrasse 29-31

36043 Fulda, Germany

Tel. +49 (0) 661 / 94 19 5 – 0

Fax +49 (0) 661 / 94 19 5 – 850

info@moeller-medical.com



Make a note of the serial number of the **LiquoGuard®7** when placing an order. This can be found at:

1. Tab bar **SETUP** → Softkey **SERVICE**
2. Press the button **LiquoGuard Information**.

The key applies only to the device indicated in the order and has limited validity of 30 days. If the key is not imported into the device within that time, it will no longer be accepted.

### **6.3.5.2 LiquoGuard Information**

The information on the **LiquoGuard®7** described below is available under *LiquoGuard Information*.

- Device ID
- Software version installed
- Technical safety check date (date of the next device check)
- Contact information (address and contact details of the device manufacturer)

1. Tab bar **SETUP** → Softkey **SERVICE**
2. Press the button **LiquoGuard Information**.

### **6.3.5.3 Reset device settings**

This function resets ALL **LiquoGuard®7** settings to the factory settings.

1. Tab bar **SETUP** → Softkey **SERVICE**
2. Press the **Reset all device settings to factory default** button.
3. Press the button **Yes, I want to set default settings** in the green message window.

### **6.3.6 Presettings**

Use the device function *Presettings* to save different application profiles on the ***LiquoGuard®7***. The drainage settings for the tubing set are also saved. This facilitates changing between different ***LiquoGuard®7*** devices and interrupting drainage. Further information on this option can be found on *page 99*.

## 7 Alarm signals and corrective measures

### 7.1 Presence of an alarm condition

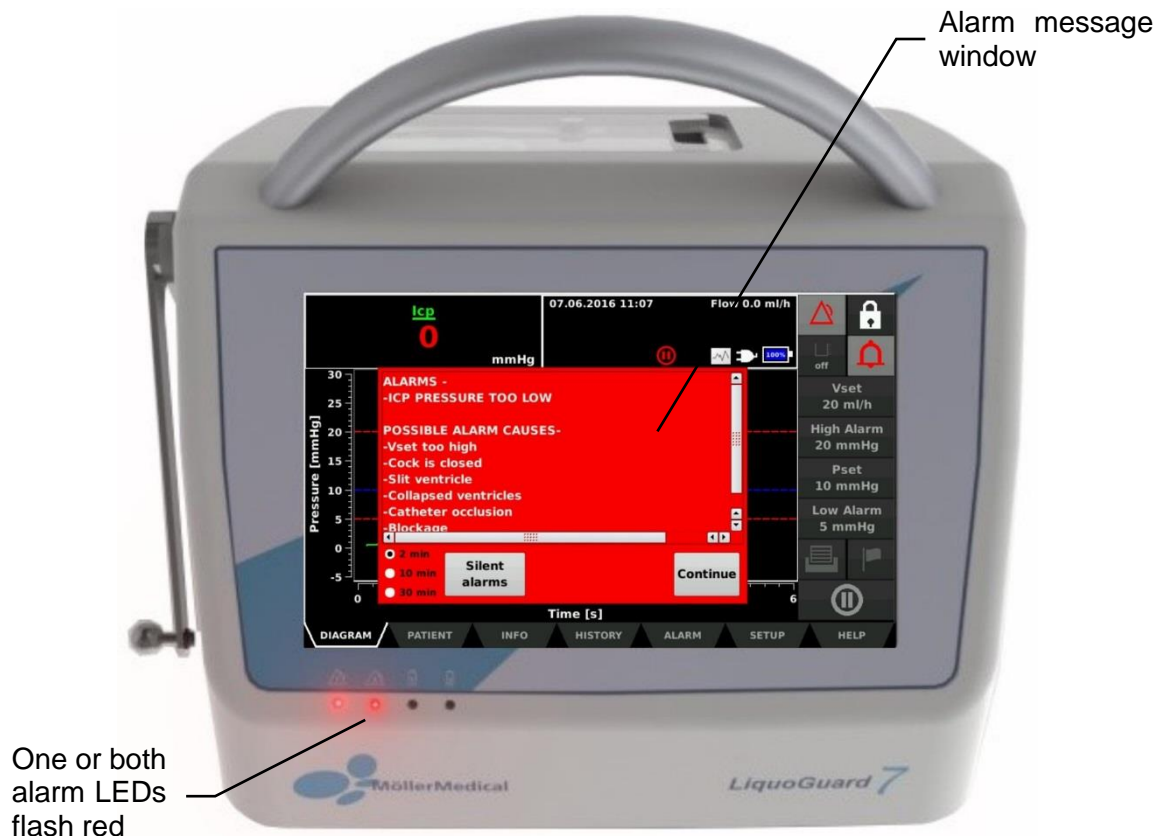


Figure 20: Visual alarm signals of the **LiquoGuard®7**, if an alarm condition exists.

#### 7.1.1 Technical and physiological alarm conditions

In the case of a technical or physiological alarm condition, the **LiquoGuard®7** will generate the following alarm signals (see *Figure 20*):

- The main alarm LED (first from left) on the front of the housing flashes red.
- A red window indicating the alarm condition and possible causes appears on the display.
- An acoustic alarm signal (horn) is emitted by the device.
- In the case of a pressure alarm, the pressure in question is displayed in red.



If an acoustic signal cannot be emitted due to a failure of the main control unit, an alternative alarm signal will be generated and the backup LED (second from left) will flash red.

**Alarm signals and corrective measures**

If various alarm conditions are present simultaneously, they will be displayed together in the same alarm message window. It is the responsibility of the medical personnel or physician to identify the exact cause for the alarm condition. Once the cause is eliminated, the alarm signals will deactivate automatically after a short delay.

An alarm can also be paused for a limited time in order to remedy the alarm condition.

Alarm signals for physiological and technical alarms are generated after a given delay. This delay period can be partly changed (see page 54).

**7.1.2 Pause alarm signal**

In the event of an alarm condition, the **LiquoGuard® 7** offers various options to pause the alarm for a limited time. It is not possible to fully deactivate the alarm.

**Pause alarm in alarm message window**

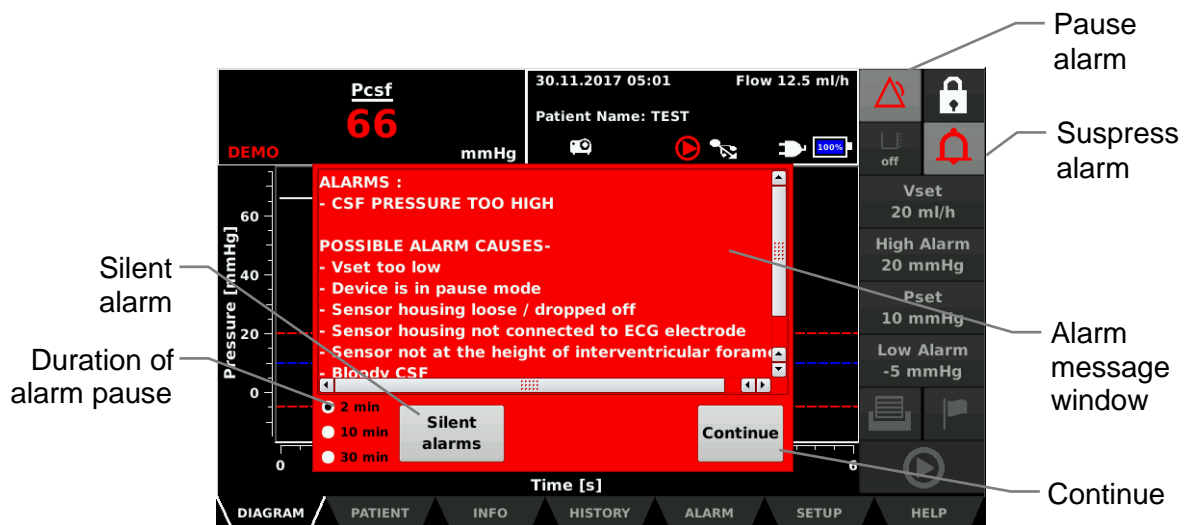


Figure 21: Configuration of the alarm message window in the presence of a technical or physiological alarm condition

The alarm can be paused for 2, 10 or 30 minutes via the alarm message window (see Figure 21).

1. Select the duration required from the **message window**.
2. Press the **Silent alarm** button to pause the acoustic alarm signal for the set period of time. The alarm message window remains visible until the alarm condition is removed.

**or**

Press the **Continue** button to pause the alarm for the required period and hide the alarm message window. Press the button **Pause alarm** to show the alarm message window once again.

## Alarm signals and corrective measures

### Suppressing alarms in the DIAGRAM dialog field

The **DIAGRAM** dialog field gives you the option of suppressing physiological alarms acoustically for 5 minutes.

1. Go to the **DIAGRAM** dialog field in the tab bar.
2. Press the softkey **Suppress alarm**.



In the case of various alarm conditions occurring at different times, each individual alarm condition must be separately suppressed.

### Deactivating Suppress alarm

The crossed-through symbol indicates that an alarm has been suppressed due to an alarm condition. To reactivate the alarm, press the softkey **Suppress alarm** once again.



The removal of the cause of an alarm condition does not mean that the function *Suppress alarm* is deactivated. If the same alarm condition occurs after the cause for suppressing the alarm condition has been removed, neither the acoustic alarm signal nor the alarm message window will be activated. The only indication of an alarm will be the flashing of the red main LED.

### 7.1.3 System error

In the event of an alarm condition due to internal hardware and software tests, the **LiquoGuard® 7** will generate the following alarm signals:

- The main alarm LED (first from left) on the front of the housing flashes red.
- A red window with an error code will appear on the display (see *Figure 22*)
- An acoustic alarm signal (horn) is emitted by the device.



If the usual acoustic signal is not possible due to a failure of the main control unit, an alternative alarm signal will be generated and the backup LED (second from left) will flash red.

Alarms resulting from system errors cannot be deactivated or paused by the user. In this case, restart the device via the On/Off switch (see *Connection* options on *page 24*). If the device returns to this condition repeatedly, the device should be checked by a Service Technician.

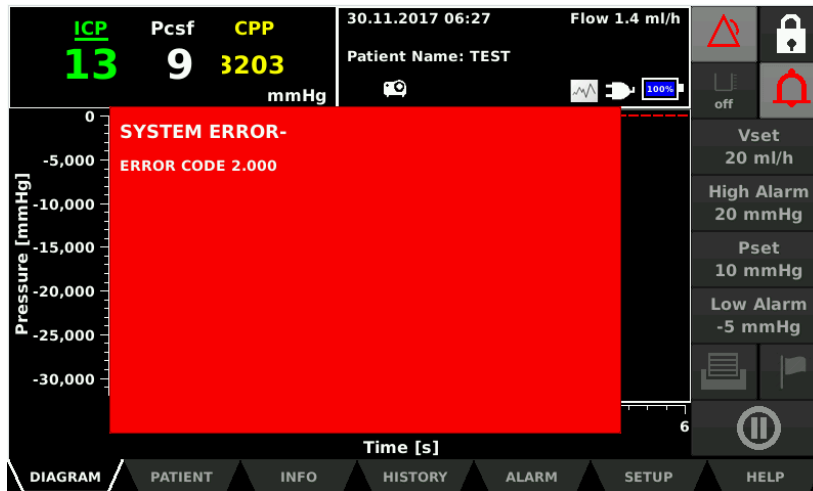


Figure 22: Configuration of the alarm message window in the event of a system error.

## 7.2 Testing alarm functions

When the **LiquoGuard®7** is turned on via the On/Off switch, a brief alarm sound will be emitted during the self-test. A function test will also be performed. Elements such as the LEDs on the front of the device and the built-in speaker are not subject to the function test. In order to guarantee the functioning of these components during an alarm, ensure that both left LEDs flash red briefly during the device start-up and that the speaker emits an audible signal. If problems are encountered, contact the Möller Medical GmbH Service Team.

The **LiquoGuard®7** alarm concept is as described below from a risk perspective. When an alarm condition occurs during proper use of the device, the user is always warned by means of visible or audible alarm signals (i.e. the user must always be within auditory and/or visual range of the device).



The **LiquoGuard®7** is equipped to detect physiological and technical alarm conditions.

The alarm conditions priority is set on HIGH priority for all alarm conditions. The **LiquoGuard®7** generates visible and audible alarm signals. The alarm system is designed for physiological alarm conditions with non-recurring alarms and technical alarm conditions with recurring alarms.

## 7.3 Alarm system, dual safety

The link between pressure measurement of the **LiquoGuard®7** and alarm generation is designed based on the concept of dual safety. This entails two sensors in the tubing set, dual measurement value recording and processing, as well as various means of alarm emission.



**Alarm signals and corrective measures**



If, during the start-up self-test, the monitoring system detects that the backup battery charge is below 50%, the **LiquoGuard® 7** will not be turned on and the battery must first be recharged.

If, during operation, the system detects a problem with the backup battery, the **LiquoGuard® 7** must be tested by a Service Technician and cannot be used.

The red LED (first from left) on the housing is activated by the **LiquoGuard® 7** main control unit. This alarm signal is supported by indications on the display. The acoustic signal of the main control unit is a horn sound.

If the monitoring system determines an error at the main control unit, it issues an acoustic alarm in the form of a rhythmic alarm sound with a fixed frequency. This condition is termed a backup alarm. Restart the device via the On/Off switch. If the device returns to this condition repeatedly, the device should be checked by a Service Technician.



The alarm system refers only to the **LiquoGuard® 7** itself. Any signals from an external connected system do not release the operator from the duty to promptly and appropriately react to alarm situations signaled by the **LiquoGuard® 7**. This is also applicable when an external system does not signal an alarm condition.

**7.4 Alarm system overview**

**Upper Pcsf pressure limit value exceeded**

Physiological alarm condition	Measured pressure in tubing set too high
Technical alarm condition	N/A
Alarm limit	Upper Alarm Adjustable by user
Alarm condition delay	1 ± 0.5 second
Delay of alarm signal generation	Adjustable by user (see page 54)
Alarm signal	Audible/visible
Alarm signal description on display	CSF PRESSURE TOO HIGH
Audio paused	Yes

**Alarm signals and corrective measures**

**Lower Pcsf pressure limit value exceeded**

Physiological alarm condition	Measured pressure in tubing set too low
Technical alarm condition	N/A
Alarm limit	Lower Alarm Adjustable by user
Alarm condition delay	1 ± 0.5 second
Delay of alarm signal generation	Adjustable by user (see page 54)
Alarm signal	Audible/visible
Alarm signal description on display	CSF PRESSURE TOO LOW
Audio paused	Yes

**Upper ICP pressure limit value exceeded**

Physiological alarm condition	Pressure measured by parenchymal or tip sensor too high
Technical alarm condition	N/A
Alarm limit	Upper Alarm Adjustable by user
Alarm condition delay	1 ± 0.5 second
Delay of alarm signal generation	Adjustable by user (see page 54)
Alarm signal	Audible/visible
Alarm signal description on display	ICP TOO HIGH
Audio paused	Yes

**Lower ICP pressure limit value exceeded**

Physiological alarm condition	Pressure measured by parenchymal or tip sensor too low
Technical alarm condition	N/A
Alarm limit	Lower Alarm Adjustable by user
Alarm condition delay	1 ± 0.5 second
Delay of alarm signal generation	Adjustable by user (see page 54)
Alarm signal	Audible/visible
Alarm signal description on display	ICP TOO LOW
Audio paused	Yes

## Alarm signals and corrective measures

### Upper flow limit value exceeded

Physiological alarm condition	Average flow volume too high
Technical alarm condition	N/A
Alarm limit	Upper Flow Alarm Adjustable by user
Alarm condition delay	1 ± 0.5 second
Delay of alarm signal generation	Adjustable by user (see page 54)
Alarm signal	Audible/visible
Alarm signal description on display	CSF FLOW RATE TOO HIGH
Audio paused	Yes

### Lower flow limit value exceeded

Physiological alarm condition	Average flow volume too low
Technical alarm condition	N/A
Alarm limit	Lower Flow Alarm Adjustable by user
Alarm condition delay	1 ± 0.5 second
Delay of alarm signal generation	Adjustable by user (see page 55)
Alarm signal	Audible/visible
Alarm signal description on display	CSF FLOW RATE TOO LOW
Audio paused	Yes

### Pulsation error

Physiological alarm condition	Pulsation frequency too low
Technical alarm condition	N/A
Alarm limit	Pulsation frequency < 30/min (in the event that the function If pulsation fails and Suspicion of problem is active, the alarm is emitted only if the pressure drop due to the flow of a very small quantity of CSF is > 5 mmHg).
Alarm condition delay	30 ± 0.5 seconds
Delay of alarm signal generation	1 second
Alarm signal	Audible/visible
Alarm signal description on display	PULSATION LOST
Audio paused	Yes

**Alarm signals and corrective measures**

**Amplitude constant**

Physiological alarm condition	Measured pressure not plausible (constant)
Technical alarm condition	N/A
Alarm limit	Adjustable by user In the event that the function If pulsation fails and Suspicion of problem is active, the alarm is emitted only if the pressure drop due to the flow of a very small quantity of CSF is > 5 mmHg.
Alarm condition delay	1 ± 0.5 seconds
Delay of alarm signal generation	None Not adjustable by user
Alarm signal	Audible/visible
Alarm signal description on display	CSF PRESSURE CONSTANT FOR TOO LONG
Audio paused	Yes

**Pressure difference between tubing set and parenchymal or tip sensor is too great**

Physiological alarm condition	Measured pressure difference too large between ICP and Pcsf
Technical alarm condition	N/A
Alarm limit	ICP differs from Pcsf Adjustable by user
Alarm condition delay	1 ± 0.5 seconds
Delay of alarm signal generation	Adjustable by user (see page 54)
Alarm signal	Audible/visible
Alarm signal description on display	ICP - Pcsf VALUE DIFFERENCE IS TOO HIGH
Audio paused	Yes

## Alarm signals and corrective measures

### Main battery charge too low

Physiological alarm condition	N/A
Technical alarm condition	Battery charge less than 20%
Alarm limit	Main battery charge < 20%
Alarm condition delay	20 ± 0.5 seconds
Delay of alarm signal generation	1 second
Alarm signal	Audible/visible
Alarm signal description on display	BATTERY LOW
Audio paused	Yes

### End of tubing set useful life

Physiological alarm condition	N/A
Technical alarm condition	Tubing set has reached the end of its expected useful life
Alarm limit	N/A
Alarm condition delay	300 ± 0.5 seconds
Delay of alarm signal generation	1 second
Alarm signal	Audible/visible
Alarm signal description on display	TUBASET USAGE LIMIT EXPIRED
Audio paused	Yes

### Tubing set disconnected

Physiological alarm condition	N/A
Technical alarm condition	Sensor cable no longer detected
Alarm limit	Internal device setting
Alarm condition delay	1 ± 0.5 seconds
Delay of alarm signal generation	1 second
Alarm signal	Audible/visible
Alarm signal description on display	TUBING SET DISCONNECTED
Audio paused	Yes

**Alarm signals and corrective measures**

**Parenchymal or tip sensor disconnected**

Physiological alarm condition	N/A
Technical alarm condition	Sensor cable no longer detected
Alarm limit	Internal device setting
Alarm condition delay	1 ± 0.5 seconds
Delay of alarm signal generation	1 second
Alarm signal	Audible/visible
Alarm signal description on display	PARENCHYMAL/TIP SENSOR DISCONNECTED
Audio paused	Yes

**Tubing set sensor difference**

Physiological alarm condition	N/A
Technical alarm condition	Difference between the two sensors of the tubing set is too great
Alarm limit	Difference between the two sensors is > 4 mmHg
Alarm condition delay	10 ± 0.5 seconds
Delay of alarm signal generation	1 second
Alarm signal	Audible/visible
Alarm signal description on display	TUBASET SENSOR DIFFERENCE
Audio paused	No

**Pump cover open**

Physiological alarm condition	N/A
Technical alarm condition	The pump cover is open or not properly closed
Alarm limit	Internal device setting
Alarm condition delay	3 ± 0.5 seconds
Delay of alarm signal generation	1 second
Alarm signal	Audible/visible
Alarm signal description on display	COVER FLAP OPENED
Audio paused	Yes

## Alarm signals and corrective measures

### Pump fault

Physiological alarm condition	N/A
Technical alarm condition	The <b>LiquoGuard® 7</b> is in Application run mode but the pump does not function due to obstruction.
Alarm limit	Internal device setting
Alarm condition delay	1 ± 0.5 seconds
Delay of alarm signal generation	1 second
Alarm signal	Audible/visible
Alarm signal description on display	ROTOR IS BLOCKED
Audio paused	Yes

### Tubing set defective

Physiological alarm condition	N/A
Technical alarm condition	The tubing set does not function properly
Alarm limit	N/A
Alarm condition delay	1 ± 0.5 seconds
Delay of alarm signal generation	1 second
Alarm signal	Audible/visible
Alarm signal description on display	TUBESSET MALFUNCTION
Audio paused	Yes

### Parenchymal or tip sensor defective

Physiological alarm condition	N/A
Technical alarm condition	Parenchymal or tip sensor not functioning properly
Alarm limit	N/A
Alarm condition delay	1 ± 0.5 seconds
Delay of alarm signal generation	1 second
Alarm signal	Audible/visible
Alarm signal description on display	ICP SENSOR MALFUNCTION
Audio paused	Yes

**Alarm signals and corrective measures**

**Internal safety measures from hardware and software tests**

**-dual safety-**



In the presence of the following alarm condition, restart the **LiquoGuard®7** via the On/Off switch. If the device returns to this condition repeatedly, the device should be checked by a Service Technician.

Physiological alarm condition	N/A
Technical alarm condition	Internal device assessments
Alarm limit	Internal device specification
Alarm condition delay	1 - 10 seconds
Delay of alarm signal generation	Not adjustable by user Set at 3 seconds
Alarm signal	Audible/visible
Alarm signal description on display	Device error XXXX
Audio paused or audio off	Yes

**7.5 Alarm system description**

<b>Terms</b>	<b>Definitions</b>	<b>Use on <i>LiquoGuard®7</i></b>	<b>Explanation</b>
Alarm condition	Condition of the alarm system once it has determined a possible or real threat.	<ul style="list-style-type: none"> <li>• technical alarm conditions</li> <li>• physiological alarm conditions</li> <li>• Internal safety measures from hardware and software tests</li> </ul>	
Alarm condition delay	Time between the occurrence of an alarm condition either on the patient side (PHYSIOLOGICAL ALARM CONDITION), or on the device side (TECHNICAL ALARM CONDITION), up to system determination of an existing threat.	See <i>Alarm system overview on page 73</i>	
Alarm limit	Limit value used by an alarm system to determine an alarm condition.	See <i>Alarm system overview on page 73</i>	Operator panel



## Alarm signals and corrective measures

Terms	Definitions	Use on <i>LiquoGuard</i> ®7	Explanation
Alarm inactive	Condition of indefinite duration in which an alarm system or a part of an alarm system does not generate alarm signals.	The user can render individual alarm conditions inactive if these are not appropriate to the patient's situation. The user is responsible for consciously disabling these conditions. See Pulsation on <i>page 57</i>	
Pause alarm	Condition of limited duration, in which an alarm system or a part thereof does not issue alarm signals.	Settable to 2, 10 and 30 minutes.	
Suppress alarm	Condition of limited duration, in which an alarm system or a part thereof does not issue alarm signals.	The duration is limited to 5 minutes. Only physiological alarms are suppressed.	
Alarm preset	Set of stored configuration parameters, including the selection of algorithms and initial values for use by algorithms that can influence or modify the effect of the alarm system.	See Device options <i>Presettings</i> from <i>page 88</i> .	
Alarm settings	Alarm system configuration including but not restricted to: <ul style="list-style-type: none"> <li>• Alarm limits</li> <li>• Properties of all conditions of the alarm signal inactive circuit</li> <li>• Values of parameter variables that determine the function of the alarm system.</li> </ul>	Partly adjustable by the user See <i>Alarm system overview</i> on <i>page 73</i>	
Alarm signal	Signal type created by the alarm system to display the existence (or the occurrence) of an alarm condition.	<ul style="list-style-type: none"> <li>• Visual alarm signal via two red LEDs on the housing</li> <li>• Visual alarm signal via alarm message window on display</li> <li>• Acoustic alarm signal, speaker is adjustable by user (see <i>page 54</i>).</li> </ul>	
Delay of alarm signal generation	Time from start of alarm condition to emittance of alarm signal.	Partly adjustable by the user See <i>Alarm delay</i> on <i>page 54</i> and <i>Alarm system overview</i> on <i>page 73</i>	

**Alarm signals and corrective measures**

<b>Terms</b>	<b>Definitions</b>	<b>Use on <i>LiquoGuard</i>®7</b>	<b>Explanation</b>
De-escalation	Process which the alarm system uses to lower the priority of an alarm condition or the urgency of an alarm signal.	N/A	
Escalation	Process which the alarm system uses to raise the priority of an alarm condition or the urgency of an alarm signal.	N/A	
False negative alarm conditions	Lack of an alarm condition when a valid triggering event for the patient has occurred in the device or the alarm system.	Double safety measure	
False positive alarm conditions	Presence of an alarm condition when no valid triggering event for the patient has occurred in the device or the alarm system.	Results in safe condition of the device.	
Information signal	Every signal, which is not an alarm or reminder signal.	Applies.	
Recurring alarm signal	Alarm signal which continues to emit after its triggering occurrence has been eliminated, until it is stopped with a deliberate operator action.	System error	
Non-recurring alarm signal	Alarm signal that ceases to be automatically generated when the corresponding triggering event no longer exists.	Physiological and technical alarm conditions	
Physiological alarm condition	Alarm condition originating from a monitored, patient-related variable.	Applies.	
Technical alarm condition	Alarm condition originating from a monitored alarm-system or device-related variable.	Applies.	

### Alarm signals and corrective measures

Terms	Definitions	Use on <i>LiquoGuard</i> ®7	Explanation
Alarm reset	Action performed by operator to cancel an alarm signal for which there is no currently associated alarm condition.	N/A	

## 7.6 Troubleshooting

This chapter identifies possible faults which may occur in connection with the *LiquoGuard*®7.

Several solutions may be possible for each fault. The solutions proposed should be executed in the order provided until the fault is remedied. In the case that the solutions presented below do not remedy the fault, contact the Möller Medical Service Center.

Faults	Solution
Not functional, the display is switched off. or The <i>LiquoGuard</i> ®7 cannot be turned on.	Start the <i>LiquoGuard</i> ®7 via the On/Off switch. Check the power supply lead. Try a different plug connector. Check the leads. Charge the <i>LiquoGuard</i> ®7 batteries.
The pump does not function although Pcsf (or ICP) > Pset.	Pump is in <i>Pause</i> mode. Press the softkey <b>Pause/Start</b> to start drainage. or Flow resistance measurement is being performed. or Pump functions only when the measured CSF pressure (Pcsf (or ICP)) is higher than Pset.
The touchscreen does not respond.	If you are wearing gloves, remove these and try to operate the <i>LiquoGuard</i> ®7 again via the touchscreen. or Restart the <i>LiquoGuard</i> ®7 via the On/Off switch. If the device returns to this condition repeatedly, the device should be checked by a Service Technician.
The incorrect fields are selected when making entries via the touchscreen.	Restart the <i>LiquoGuard</i> ®7 via the On/Off switch. The touchscreen will then be calibrated. If the device returns to this condition repeatedly, the device should be checked by a Service Technician.

## Alarm signals and corrective measures

Faults	Solution
Fault due to moisture penetrating into the plug connection.	Remove mains plug. Allow plug connector to dry.
The device repeatedly emits an alarm sound with regular frequency.	Restart the <b>LiquoGuard®7</b> via the On/Off switch. If the device returns to this condition repeatedly, the device should be checked by a Service Technician.



The **LiquoGuard®7** must not be opened by the user!

### 7.7 Service

If you cannot resolve the fault yourself, please contact your **Möller Medical GmbH** Service Center.

Service Center contact details:

Tel.: +49 (0) 661 - 9 41 95 0

Fax: +49 (0) 661 - 9 41 95 850

Hotline: +49 (0) 661 - 9 41 95 82

E-mail: [service@moeller-medical.com](mailto:service@moeller-medical.com)

Whenever the **LiquoGuard®7** is returned, a suitable disinfection process must be carried out in order to rule out the possible risk of infection.

Consumable materials should be disposed of in accordance with hygiene guidelines. In order to prevent leakage from the tubing set, ensure that the stopcocks are closed when disposing of the drainage and infusion sets.



Never open the device while it is connected to the mains power supply as internal parts may still be energized.

When changing the main battery (type 4S2P CGR-18650CG Block), ensure that the backup battery (type PA-L154.KO2.R002) is fully charged.

The backup battery must be fully charged for a technical safety check.

**Alarm signals and corrective measures****System Log**

In order to systematically remove a fault in the **LiquoGuard®7**, it is sometimes necessary to transmit data from the saved *System Log* to the Service Team.

1. Connect a USB memory stick to your computer.
2. Go to the top directory of the USB memory stick, not in a subfolder.
3. Open the context menu by right clicking the mouse and select **New** → **Text document (.txt file)**.
4. Rename the new file to **export\_logs**.
5. a. Change to the TAB "*INFO*" with the **LiquoGuard®7** switched on. Connect the prepared USB memory stick into one of the **LiquoGuard®7** USB connections (see *Connection options* on page 24). Press the button „Files“ and wait until the file manager appears on the display.  
**or**  
b. Turn the **LiquoGuard®7** off and connect the prepared USB memory stick into one of the **LiquoGuard®7** USB connections (see *Connection options* on page 24). Start the **LiquoGuard®7** and wait until the file manager appears on the display.
6. Go to the dialog field **System Log** in the tab bar.
7. Click on the required files to select them. The selected files will be highlighted in blue. The file name consists of the date in the format Year-Month-Day, and the time in Hours-Minutes-Seconds-Milliseconds.
8. Select the button **Copy** to transfer the data to the USB memory stick. A green message window will inform you once the data has been copied.
9. Select the **End** button on the right of the screen.

You can send the system log file via e-mail to the Service Team.

## 8 Care

### 8.1 Cleaning and disinfection



No moisture must be allowed to enter into the device.

Before cleaning and disinfecting the device surfaces, disconnect the mains plug. Use a soft, lint-free cloth for cleaning and disinfecting.

Cleaning is done with a wet cloth in the form of a "scrub-wipe disinfection". Simply spraying the device is NOT suitable for cleaning. Always follow the manufacturer's instructions regarding the concentration and application time of the cleaning agent/disinfectant.

The following substances are permitted for cleaning the surfaces of the **LiquoGuard®7**:

Manufacturer	Product	Application time	Method
--	Isopropanol 70% aqueous solution	Until fully evaporated	Scrub-wipe
B. Braun	Meliseptol	According to manufacturer information	Scrub-wipe
B. Braun	Meliseptol rapid	According to manufacturer information	Scrub-wipe
Ecolab	Incidin Active	According to manufacturer information	Scrub-wipe
Ecolab	Incidin Liquid	According to manufacturer information	Scrub-wipe
Ecolab	Incidin Rapid	According to manufacturer information	Scrub-wipe
Ecolab	Sani-Cloth Active	According to manufacturer information	Scrub-wipe
Ecolab	Sekusept Aktiv	According to manufacturer information	Scrub-wipe
Lysoform	Lysoformin 3000	According to manufacturer information	Scrub-wipe
Metrex	CaviCide	According to manufacturer information	Scrub-wipe
Metrex	CaviCide1	According to manufacturer information	Scrub-wipe
Schülke	Acryl Des	According to manufacturer information	Scrub-wipe
Schülke	Mikrozid AF Liquid	According to manufacturer information	Scrub-wipe
Schülke	Terralin protect	According to manufacturer information	Scrub-wipe
Schülke	TPH protect	According to manufacturer information	Scrub-wipe

Ensure that the cleaning agents and disinfectants have completely evaporated before using the **LiquoGuard®7**.

Visual inspection: The sockets of all connections and cable plugs must be free of all dirt and moisture.

## Care

## 8.2 Service



The **LiquoGuard®7** will remind you of the impending date for a technical safety check during the booting process.

The service, upgrade or modification of the **LiquoGuard®7** CSF drainage system must only be performed by Möller Medical GmbH or by a person specifically authorized by the manufacturer.

All correspondingly trained persons have an appropriate certificate from the manufacturer which must be valid, as the certificates do expire. Have them show the appropriate certificate if necessary.

Modifications by third parties are not permitted. A technical safety check (TSC) according to the Medical Devices Operator Ordinance must be performed at least every 12 months. Only use the **LiquoGuard®7** if the device functions properly and/or is safe. In cases to the contrary, the device must be immediately repaired by the Service Center.

## 8.3 Replacing the battery

The **LiquoGuard®7** must not be opened by the user. All services, including the replacement of lithium batteries may only be carried out by staff who have received appropriate training from the manufacturer.

## 8.4 Disposal



The present device contains material which must be disposed in accordance with environmental regulations. This device is subject to the European Directive 2012/19/EEC on Waste Electric and Electronic Equipment (WEEE2). The identification plate of the device bears the symbol of the crossed through garbage bin.

Return devices that are no longer used to Möller Medical GmbH. This ensures that the device is disposed in compliance with the national requirements of the WEEE Directive.

## 9 Device options

Various useful device functions are available for extending the functional range the **LiquoGuard® 7**. The functions are as follows:

1. Monitor/Nurse call
  - Connecting the **LiquoGuard® 7** to a patient monitor system
  - Alarm transmission via diagnostic call system
2. Documentation
  - Entry of patient data (name, date of birth, height / weight, other comments)
  - Application data copied onto USB memory stick
  - Insertion of a bookmark to facilitate subsequent search for important points in time in the application data
  - Representation of the maximum and minimum pressure values and average volume flow in the History dialog field
  - Saving of screenshots and values entered in the Alarm and Setup dialog fields, in the internal device memory (only possible in conjunction with device function *Printing*)
3. Presettings
  - Saving different user profiles on the **LiquoGuard® 7**
  - Saving of current drainage setting of tubing set
4. Printing
  - Printing of screenshots and settings in the dialog fields ALARM and SETUP with a printer
  - Saving of screenshots and settings in the dialog fields ALARM and SETUP on a USB memory stick
5. Parenchymal/Tip sensor
  - Connecting a parenchymal pressure sensor (with or without CSF drainage channel)
  - Connecting a catheter with tip sensor (with or without CSF drainage channel)
6. CPP
  - Connecting a cMAP sensor to the **LiquoGuard® 7** drainage pump using the **LiquoGuard® 7** Multi-Hub for invasive blood pressure measurement
  - Calculation of the cerebral perfusion pressure (CPP) by subtracting the ICP or the Pcsf value from the cMAP value



## Device options

### 7. Infusion test

- Indirect measurement of the CSF absorption capability in patients suspected of or confirmed to be suffering from normal pressure hydrocephalus

Specific device functions of the **LiquoGuard®7** can be enabled if required (see 6.3.5.1), Registering device options (Activating the software key). In this case, please contact the manufacturer or a local authorized distributor.

The following sections will provide an overview and setting options of the available **LiquoGuard®7** device options.

Not all device options are available in all markets.

### 9.1 Monitor/Nurse call

The *Monitor/Nurse call* function allows you to connect the **LiquoGuard®7** to a patient monitoring or diagnostic call system.

#### 9.1.1 Patient monitor system

Using an adapter cable (see *Accessories* on page 129), the **LiquoGuard®7** can be connected to a patient monitor system (see *Connection options* on page 24) and transmit the pressure value indicated by the **LiquoGuard®7** to the monitor system. Before connecting, first read the prerequisites under Additional accessories on page 16.

It is essential to check whether the patient monitoring system is compatible with the requirements of the **LiquoGuard®7**, as specified under *Input and output signals* on page 121.



The monitor system cannot be used for monitoring. Only the value indicated on the **LiquoGuard®7** display is to be taken into consideration!

Operate the **LiquoGuard®7** in such a manner that a response to an acoustic alarm is guaranteed at all times.

Ensure that calibration is always performed when connecting the **LiquoGuard®7** to a monitor system.

1. Connect the **Monitor cable** to the Patient monitoring output of the **LiquoGuard®7**
2. Connect the other end of the **monitor cable** to the **analogue pressure input** of the monitor system. The **LiquoGuard®7** detects the connection and displays a selection window with setting options and the calibration function.
3. Select **Simulate pressure with following values [mmHg]**.
4. Select the value **0** to perform zero adjustment between the monitor system and the **LiquoGuard®7**.
5. Perform zero adjustment of the monitor system according to its operating manual.

## Device options

6. Select the other values on the **LiquoGuard®7** under **Simulate pressure with following values** and check that they are correctly displayed on the monitor system.
  7. If the simulated values are indicated correctly, select on the **LiquoGuard®7** the item **Tubing Set** or if available, **Parenchymal/Tip sensor** as a source for the pressure value output on the monitor system (*Parenchymal/Tip sensor* is a device function. Further information can be found on *page 102*).
  8. The selected pressure value is then transmitted to the monitor system and displayed.
- Simulate pressure with following values (default values): -20 mmHg, 0 mmHg, 20 mmHg, 50 mmHg, 100 mmHg
  - Tubing set: Pcsf is indicated on the patient monitor.
  - Parenchymal/Tip sensor: ICP is indicated on the patient monitor (*Parenchymal/Tip sensor* is a device function). For more detailed information, see *page 102*).

To call up the calibration once again at a later stage, select the submenu MONITOR/NURSE CALL in the ALARM dialog field. Alternatively, disconnect the connecting cable and then reconnect it once again.

### 9.1.2 Nurse call system

The **LiquoGuard®7** can be connected to a diagnostic call system (often also referred to as nurse call) using an appropriate cable in order to transfer an alarm (see *Connection options* on *page 24*). The function of this connection must be checked and validated in each individual case. Before connecting, first read the prerequisites under *Additional accessories* on *page 16*.



It is essential to check whether the diagnostic call system is compatible with the requirements of the **LiquoGuard®7**, as specified under *Input and output signals* on *page 121*.



The alarm transfer does not affect the supervision of the patient. In any event, always pay attention to alarm signals of the **LiquoGuard®7**.

Nurse call systems in clinical facilities differ in their response to the relay circuits in the device. Identify in advance which settings are suitable for the diagnostic call system used. If you are not certain which relay circuit your diagnostic call system uses, you can find the correct setting on your own. Proceed as described below.

## Device options

1. Connect the **LiquoGuard®7** to the nurse call system. The **LiquoGuard®7** detects the connection and displays a selection window with setting options.
2. Under **Nurse call** select the setting Close on alarm.
3. Then select the button **Test nurse call**.

If the alarm is transferred via the nurse call system, keep the setting. If not, conduct the same test but this time with the setting *Open on alarm*.

- Close on alarm (default): Transfer of the alarm via the nurse call system with a closed relay in the **LiquoGuard®7**.
- Open on alarm: Transfer of the alarm via the nurse call system with an open relay in the **LiquoGuard®7**.

To call up the setting once again at a later stage, select the submenu **MONITOR/NURSE CALL** in the Alarm dialog field. Alternatively, disconnect the connecting cable and then reconnect it once again.

## 9.2 Documentation

The device function *Documentation* provides for comprehensive records of the entire drainage process through the functions *Patient Data*, *Application Data* and *History*.

### 9.2.1 Patient data

The *Patient Data* function saves data such as name, date of birth, height/weight and other comments directly into the **LiquoGuard®7**. The saved patient data is displayed in the DIAGRAM dialog field.

**EDIT PATIENT DATA**

Name (m/f)

Birth date

Height-Weight

Remarks

DIAGRAM PATIENT INFO HISTORY ALARM SETUP HELP

Figure 23: Patient Data

## Device options

1. Go to dialog field **PATIENT** in the tab bar.
2. Select one of the fields available and enter the data via the keyboard screen (see *page 27*).
3. To save the changes, press the **Confirm changes** button.

### 9.2.2 Application data

This device function documents and saves the entire drainage process. The **LiquoGuard®7** has several gigabyte of internal data memory. The recorded application data can be exported from the **LiquoGuard®7** using a USB memory stick.



When the **LiquoGuard®7** is started, the memory of the **LiquoGuard®7** is cleared so that 500MB is always available to store patient data. This may result in the deletion of patient data if the memory becomes too full.

The function *Application Data* is also available as a function under *Infusion test* in the *Documentation* function list.

The following *Application Data* are collected during drainage:

- TIME STAMP: Time of measurement in the format YYYY-MM-DD\_HH:MM:SS
- Pcsf: Pcsf pressure value in mmHg
- ICP: ICP pressure value in mmHg
- cMAP: Mean arterial pressure measured at the level of the foramen of Monro
- CPP: Cerebral perfusion pressure
- PSET: Set pressure entered in mmHg
- VSET: Flow rate (of the drainage pump in ml/h set in the **LiquoGuard®7**)
- VCURRENT: Current flow rate in ml/h
- MODE: Operating mode of the **LiquoGuard®7**  
0 = Pause  
20 = Operation
- FLAGS: Binary code display of the alarms
- DRAINED: Total drained CSF volume
- PMIN: Lower pressure alarm limit
- PMAX: Upper pressure alarm limit
- VMIN: Low Flow Alarm

## Device options

- VMAX: Upper pressure alarm limit

The following *Application Data* are collected during Infusion:

- TIME STAMP: Time of measurement in the format  
YYYY-MM-DD\_HH:MM:SS
- Pcsf: Pcsf pressure value in mmHg
- PLATEAU: Stabilized pressure value during the infusion
- PSTART: Pressure before the infusion
- ROF: Resistance to outflow
- VSET: Flow rate (of the drainage pump in ml/h set in the  
**LiquoGuard®7**)
- VCURRENT: Current flow rate in ml/h
- VOLUME: Current infused volume  
Operating mode of the **LiquoGuard®7**
- DEVICE\_STATUS: 0 = Pause  
20 = Operation
- ALARM\_STATUS: Binary code display of the alarms

### 9.2.2.1 Application data transferred to USB memory stick

To retrieve the saved data from the **LiquoGuard®7**, a USB memory stick must first be prepared.

Preparation of the USB memory stick:

1. Connect the USB memory stick to a computer.
2. Now go to the top directory of the USB memory stick, not in a subfolder.
3. Open the context menu by **right-clicking** the mouse and select **New → Text document (.txt file)**.
4. Rename the new file **export\_logs**.

Once the USB memory stick has been prepared, the **LiquoGuard®7** file manager can be accessed and the saved data copied to the USB memory stick.

Copying data onto USB memory stick:

1. If the **LiquoGuard®7** is on, turn it on.
2. Change to the TAB "INFO". Connect the prepared USB memory stick into one of the **LiquoGuard®7** USB connections (see *Connection options* on page 24).
3. Press the button "Files" and wait until the file manager appears on the display.

Device options

4. Go to the **HISTORY** dialog field in the tab bar of the file manager.
5. Select the files to be copied by clicking on them. The selected files will be highlighted in blue (see *Figure 24*). The file name consists of the combined details of the patient's name (if saved in the dialog field **PATIENT**), the date and the start time of the application (Name\_Year-Month-Day\_Hours-Minutes-Seconds-Milliseconds.txt).

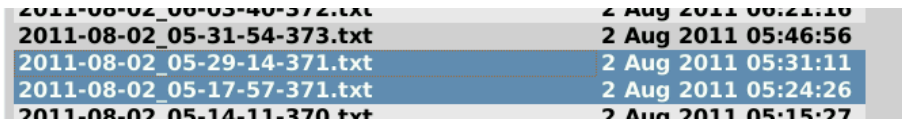


Figure 24: Extract from the HISTORY dialog field. The selected files are highlighted in blue.

6. Once the data records have been selected, press the **Copy** button. A green message window on the display will indicate that the data has been successfully transferred to the USB memory stick.
7. Select the **End** button on the right of the screen to close the file manager.
8. Confirm in the green message window that you want to exit the file manager.

The data saved on the USB memory stick is stored in the folder *userlogs* → *logs*. These can now be viewed with the computer's text editor (see *Figure 25*) or imported into a spreadsheet program. Consult the software operating instructions to learn how to import the data into the spreadsheet program used.



When data are copied from the **LiquoGuard® 7** in the future onto the same USB memory stick, the syslog and userlogs folders will be overwritten. The files contained on the USB memory stick will be deleted. Do not forget to back up the data on your computer.

TIMESTAMP	PCSF	ICP	cMAP	CPP	PSET	VSET	VCURRENT	MODE	FLAGS
2020-06-03_20:03:28	+0	NA	NA	NA	-3	+20	+0	20	0
2020-06-03_20:03:48	+0	NA	NA	NA	-3	+20	+0	20	0
2020-06-03_20:04:08	+0	NA	NA	NA	-3	+20	+0	20	0
2020-06-03_20:04:11	+0	NA	NA	NA	-3	+20	+0	0	0
2020-06-03_20:04:13	+0	NA	NA	NA	-3	+20	+0	0	0
2020-06-03_20:04:16	+0	NA	NA	NA	-3	+20	+0	0	0
2020-06-03_20:04:20	+0	NA	NA	NA	-3	+20	+0	0	0

Figure 25: Abstract of a text document recorded by the *Application Data* function.

### 9.2.3 Set marker

*Set marker* facilitates searches for important points in time in the application data. The inserted bookmarks are represented in the application data with *Marker: this is the name of the bookmark you entered*.

1. Tab bar **DIAGRAM**
2. Press the softkey **SET MARKER**.

## Device options

3. Access the empty field below SET MARKER AT.
4. Use the keyboard screen to enter the name of the bookmark and confirm by selecting **ENTER**.
5. Select the button **Confirm changes** to insert the bookmark. To reject the changes, select **Cancel**.

### 9.2.4 History



To use the History option, it is essential that a tubing set is connected to the **LiquoGuard® 7**.

With the *History* function, you have the possibility to look at the progression of the pressure and flow values, as well as displaying volume balancing.

#### 9.2.4.1 Graph

In the GRAPH submenu the curves of the pressure and flow values of the current application are shown in diagram form (see *Figure 26*).

##### Pressure curve (top diagram)

- White curve: Maximum and minimum Pcsf values
- Green curve: Maximum and minimum ICP values (the green curve is displayed only if the parenchymal or tip sensor is connected.). More detailed information on this function can be found in the section *Parenchymal/Tip sensor* on *page 102*.)
- Yellow curve: Maximum and minimum CPP values (the yellow curve is displayed only when a MAP sensor and a tubing set are connected). Details on this option can be found under *CPP/cMAP* on *page 107*
- x-axis: variable time scale in the format Days:Hours:Minutes
- y-axis: Pressure in mmHg

##### Flow curve (bottom diagram)

- White curve: average CSF quantity delivered
- x-axis: variable time scale in the format Month/Day Hours: Minutes
- y-axis: Flow in ml/h
  - Use the **forward** and **back** arrow keys to navigate the time axis.
  - Use the **scale-down** softkey to reduce the time scale (x-axis) and the **scale-up** softkey to increase it.
  
- Default value: 3 hours
- Minimum value: 2 hours
- Maximum value: 30 days

Device options

- The Selection of curves to be displayed button allows you to select or deselect the display of the different pressure measurements.
- The y-axis of the pressure curve is scaled using the softkey Scaling of the axis to optimum, or Scaling of the axes to maximum.

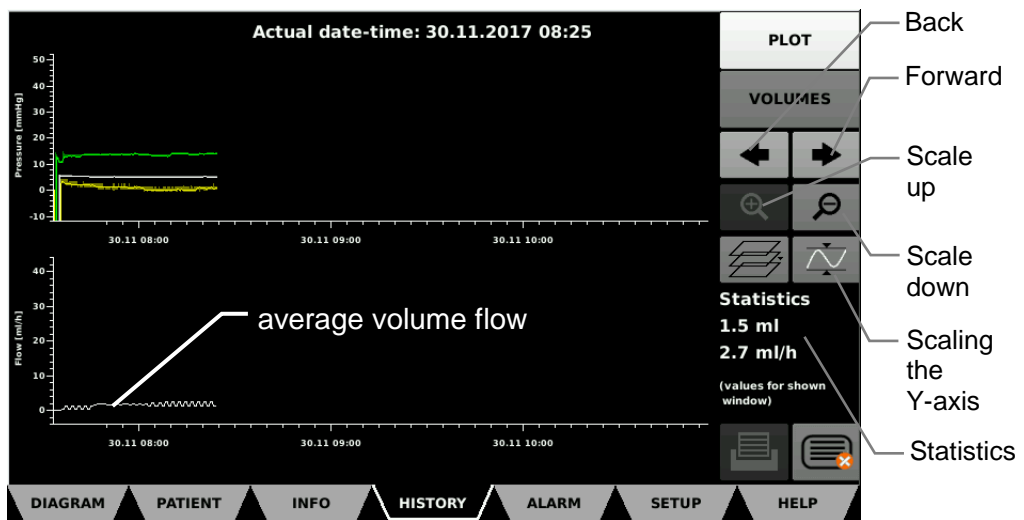
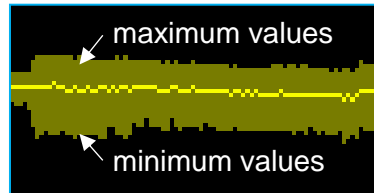


Figure 26: Diagrams in the HISTORY dialog field.

**Statistics**

The volume statistics are found in the right-hand window margin of the dialog field. The volume delivered [ml] and average volume flow [ml/h] for the set time period are shown in the diagram.

**9.2.4.2 Volumes**

The volume balance of the current application is calculated and displayed under the submenu **VOLUME** (see Figure 27). The values always reflect the actual volume balance for a specific time period. If the variable or fixed time periods have not yet been reached, the actual quantity delivered thus far is indicated.



In the event the tubing set is changed several times for the same patient during one application without turning the device off, the balance will be carried over to the end of the application. This means that the total drainage quantity can be read at the end of the process.



## Device options

INFORMATION AND STATISTICS		ml	ml/h
<b>CSF drainage statistics:</b>			
Last hour		1.50	1.80
Last <input type="text" value="24"/> hours		1.50	1.80
This application		1.50	1.80
(running since 30.11.2017 07:35)			
Select time frame below		1.50	1.80
From	Date <input type="text" value="30.11.2017"/>	Time <input type="text" value="07:35"/>	
To	Date <input type="text" value="30.11.2017"/>	Time <input type="text" value="08:25"/>	

Figure 27: Overview of the VOLUME submenu in the HISTORY dialog field.

- Past hour:** Indicates the delivered volume (ml) and the average flow rate (ml/h) during the last 60 minutes.
- The past "X" hours:** Access the input field and use the **numeric keyboard screen** to enter the time period in whole hours (1 - 99). The volume (ml) pumped and average flow rate (ml/h) for this time period will be calculated and displayed.
- Current application:** Indicates the volume delivered (ml) and the average flow rate (ml/h) of the total application.
- Selected time period:** Enter a starting time in the *FROM* field and an end time in the *TO* field. Then press the softkey **Calculate**. The volume (ml) delivered and the average flow rate (ml/h) will be calculated for this time period.

### 9.2.4.3 Clear history

To delete the data saved in the History dialog field, select the softkey **Clear history**. In addition to the volume and flow values, the alarm history and patient data will also be deleted. Alternatively, the history of the volume and flow values will be automatically deleted when a new application is started or when the device is restarted.

### 9.2.5 Printing



This function can be used under the device function *Documentation* only if *Printing* is also enabled.

If, in addition to *Documentation*, the device function *Printing* is also activated, all screenshots and set values in the dialog fields Alarm and Setup, will also be internally stored in the device (see *Printing* option on page 101). The screenshots and data can be transferred to a USB memory stick at a later stage.

To retrieve the saved images and data from the **LiquoGuard®7**, a USB memory stick must first be prepared. If the USB memory stick is already prepared for the transfer, proceed with the instruction *Copy LiquoGuard®7 data to USB memory stick*.

#### Preparation of the USB memory stick

1. Connect the USB memory stick to a computer before retrieving the data.
2. Now go to the top directory of the USB memory stick, not in a subfolder.
3. Open the context menu by **right clicking** the mouse and select **New → Text document (.txt file)**.
4. Rename the new file **export\_logs**.

Once the USB memory stick has been prepared, the **LiquoGuard®7** file manager can be accessed, and the saved data copied to the USB memory stick.

#### Copy screenshots to USB memory stick

1. If the **LiquoGuard®7** is on, turn it on.
2. Connect the prepared USB memory stick to one of the USB inputs on the Change to the TAB "INFO". Connect the prepared USB memory stick into one of the **LiquoGuard®7** USB connections (see *Connection options* on page 24).
3. Press the button "Files" and wait until the file manager appears on the display.
4. Go to the **screenshots** dialog field in the tab bar of the file manager.
5. Select the files to be copied by clicking on them. The selected files will be highlighted in blue. The file name consists of the combination of date and start time of the application and the name of the dialog field from which the screenshot is taken (Year-Month-Day\_Hours-Minutes-Seconds-Milliseconds\_Name\_Dialogfield.png).
6. Once the data records have been selected, press the **Copy** button. A green message window on the display will indicate that the data has been successfully transferred to the USB memory stick.
7. Select the End button on the right of the screen to close the file manager.
8. Confirm in the green message window that you want to exit the file manager.

The data saved on the USB memory stick can now be viewed on the computer. The files are stored in the userlogs folder → snapshot.



When data are copied from the **LiquoGuard®7** in the future onto the same USB memory stick, the syslog and userlog folders will be overwritten. The files contained on the USB memory stick will be deleted. Do not forget to back up the data on your computer.

## Device options

## 9.3 Presettings

Use the device function *Presettings* to save up to eight different application profiles on the *LiquoGuard®7* (see *Figure 28*). The drainage settings for the tubing set are also saved. This facilitates changing between different *LiquoGuard®7* devices and interrupting drainage.



Please note that the selection of presettings may affect the ability to hear the alarms due to the change in environment and its volume.

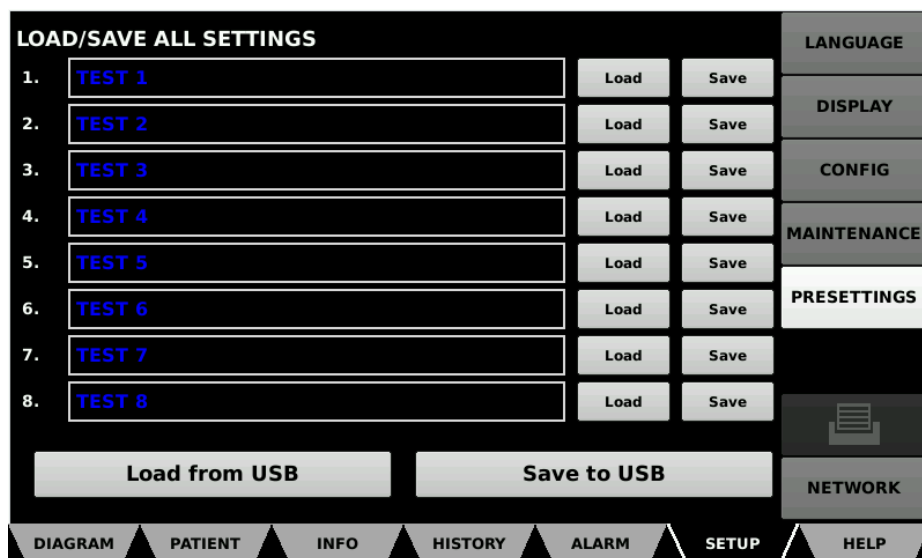


Figure 28: Screen display of Presettings function.

For safety reasons, entering Presettings is password protected.

The password which you used when first accessing the device function *Presettings*, is valid for all functions in the Presettings dialog field.



If you forget this password and enter an incorrect one, the *LiquoGuard®7* will ask whether a new password must be created. Note that when a new password is saved, all current presets are deleted.

The presettings must be reloaded each time the *LiquoGuard®7* is started or when connecting the tubing set with the enabled software option.

9.3.1 Editing the *LiquoGuard®7* presettings

## 9.3.1.1 Saving presettings

1. Adjust the *LiquoGuard®7* settings to the requirements of the patient.
2. Go to the **SETUP** dialog field in the tab bar and open the **PRESETTINGS** submenu.
3. Access a free field and enter a name for the new configuration via the keyboard screen displayed.

4. Enter the password chosen for the presets and confirm with **OK**. If a password has not been assigned yet for the *Presettings* option, the **LiquoGuard®7** will prompt you to do so.

### 9.3.1.2 Changing/overwriting presets

1. Apply the required settings to the **LiquoGuard®7**.
2. Go to the **SETUP** dialog field in the tab bar and open the **PRESETTINGS** submenu.
3. Select the **Save** button next to the changed settings.
4. Enter the password for the presets and confirm with **OK**.

### 9.3.1.3 Loading the Presettings

A preset must be loaded before it is used in the current application. Go to the **Setup** dialog field in the tab bar and open the **PRESETTINGS** submenu.

1. Click on the **Load** button next to the required preset.

Information on the presettings which are active in the current operation can be found in the Info bar of the **DIAGRAM** dialog field (see on *page 29*).

### 9.3.1.4 Saving to USB memory stick

This function allows the presettings indicated in the **LiquoGuard®7** submenu **PRESETTINGS** to be saved on a USB memory stick.

1. Connect a USB memory stick to the USB port on the **LiquoGuard®7** (see *Connection* options on *page 24*).
2. Go to the **SETUP** dialog field in the tab bar and open the **PRESETTINGS** submenu.
3. Press the **Save to USB** button.

### 9.3.1.5 Loading from USB

Presettings saved on a USB memory stick can be transferred to a **LiquoGuard®7**.



Presets loaded from a USB memory stick will replace all presets saved on the device. To avoid this, a backup of the presets onto another USB memory stick should be made before loading.

1. Connect a USB memory stick to the USB port on the **LiquoGuard®7** (see *Connection* options on *page 24*).
2. Go to the **SETUP** dialog field in the tab bar and open the **PRESETTINGS** submenu.
3. Press the **Load from USB** button.
4. Enter the password for the presets and confirm with **OK**.

## Device options

### 9.3.2 Copy drainage settings to tubing set

This function allows the automatic saving of all **LiquoGuard®7** settings in the connected tubing set. Following an interruption during which the tubing set is removed, reconnect the tubing set to the same **LiquoGuard®7** or to another **LiquoGuard®7**. The option *Presettings* on the device must be enabled. The previous settings can then be restored.



Ensure that a used tubing set is not disconnected from the **LiquoGuard®7** for longer than 8 hours. If this period is exceeded, the **LiquoGuard®7** will no longer accept the tubing set. In this case, connect a new tubing set.

1. Reconnect the sensor cable of the tubing set previously disconnected from the **LiquoGuard®7** to the **LiquoGuard®7** (see *Application and Operation* on page 41).
2. A green message window will signal if there are differences in patient data between the tubing set and the **LiquoGuard®7** (this function is part of the *Documentation* option. For more detailed information, see page 91).
3. If you wish to transfer the patient data saved in the tubing set to the **LiquoGuard®7**, select the **Apply** button in the message window. If you want to keep the existing patient data in the **LiquoGuard®7**, press the **Cancel** button.
4. Another green message window will appear in the case of differences between the settings saved in the tubing set and the current settings of the **LiquoGuard®7**. Select the **Apply** button to replace the settings in the **LiquoGuard®7** with the settings in the tubing set. Select the **Cancel** button if you wish to use the tubing set with the current device settings instead.

### 9.4 Printing

Use the *Printing* option to obtain screenshots of the current display. This function is available in all **LiquoGuard®7** dialog fields. When the *Printing* button in the dialog fields **Alarm** and **SETUP** is selected, a copy of the settings will be generated in the respective dialog field, in addition to the screenshot. Depending on whether a printer or USB memory stick is connected to the **LiquoGuard®7**, the data will be automatically printed or saved.



Since a conventional printer is not a medical device, a USB isolator (certified according to IEC 60601-1) must be used as galvanic isolation between the printer and the **LiquoGuard®7** (e.g. USB-GT MED-D Interface, manufactured by Meilhaus Electronic GmbH).

If a USB memory stick and a printer are simultaneously connected to the **LiquoGuard® 7**, the data will be saved and printed.



If, in addition to the *Printing* option, the *Documentation* option is also activated, screenshots and settings will also be internally stored in the device and can be transferred to a USB memory stick at a later stage. More detailed information can be found under the device function *Documentation* on page 91.

### Printer

1. Connect a printer to a free USB port on the **LiquoGuard® 7**. Information on suitable printers can be found in the Appendix on page 119.
2. The printer symbol in the *Info bar* indicates that the printer has been detected by the device. The printer is now ready for operation.
3. Select the softkey **Print** to print the screen content.



### USB memory stick

1. Connect a USB memory stick to a free USB port on the **LiquoGuard® 7**.
2. The USB symbol in the *Info bar* indicates that the USB memory stick has been detected by the device. The USB memory stick is now ready for operation.
3. Select the softkey **Print** to save a screenshot of the current screen content.

## 9.5 Parenchymal/Tip sensor

Only parenchymal and tip sensors should be used which comply with the specifications provided on page 121 under *Input and output signals*.

Since parenchymal and tip sensors are normally not fail-safe, these should be used only with a **LiquoGuard® 7 Drainage Set**.

If you wish to use a parenchymal sensor to control drainage, a **LiquoGuard® 7 Drainage Set** must be used. In all other cases, the parenchymal sensor may be used only for monitoring.



In the event that you disconnect the parenchymal or tip sensor from the **LiquoGuard® 7**, but wish to continue drainage using the **LiquoGuard® 7 Drainage Set**, first also disconnect the *Drainage Set* from the **LiquoGuard® 7**. Select the **Interrupt Application** button in the alarm message window. Then reconnect the **LiquoGuard® 7 Drainage Set** to the **LiquoGuard® 7** and select the **Pause/Start** softkey in the **DIAGRAM** dialog field. Drainage will now continue without the parenchymal or tip sensor.

## Device options

When using the parenchymal sensor, use the **LiquoGuard®7** for monitoring intraparenchymal pressure (see *Figure 29*). When using the connected tubing set, the ICP value can also be used to control drainage.

You can also connect a suitable catheter with a tip sensor to the **LiquoGuard®7** for CSF drainage. Connect the catheter to the **LiquoGuard®7 Drainage Set** (see *Application and Operation* on page 41).

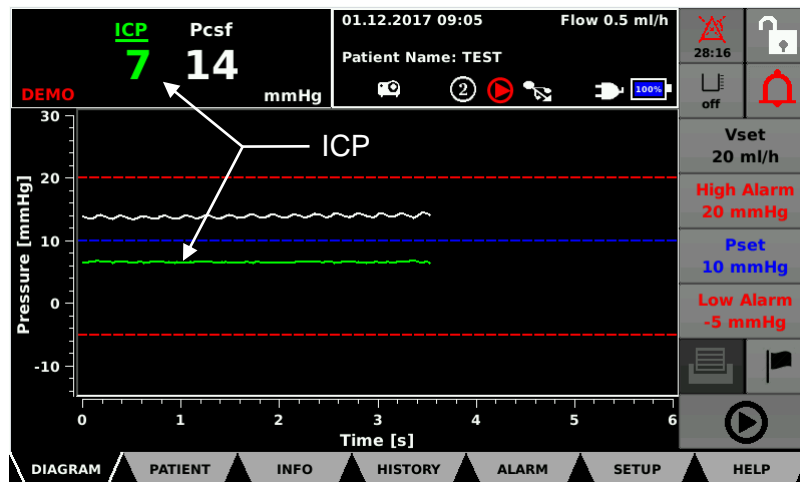


Figure 29: In the "Diagram" dialog field, the ICP is indicated as a green value in the Info bar and as a green curve in the diagram.

The ICP indicated on the display is the filtered pressure value which is transmitted to the **LiquoGuard®7** from the parenchymal or tip sensor. This value is shown only when a parenchymal or tip sensor is connected to the **LiquoGuard®7**. The curve progression of the pressure values is shown in green in the diagram.

- ICP pressure value is green (numerical value on the info display, not the curve directly): The currently measured value is within the alarm limits set.
- ICP pressure value flashes red: The currently measured value is outside the alarm limits set.
- ICP is underlined: The pressure at the parenchymal or tip sensor is used to control drainage.
- Pcsf is underlined: The pressure at the **LiquoGuard®7 Drainage Set** is used to control drainage.

If neither a **LiquoGuard®7 Drainage Set** nor a parenchymal or tip sensor is connected to the **LiquoGuard®7**, two red lines replace the pressure values.

### 9.5.1 Connecting the Parenchymal/Tip sensor



Use an adapter cable to connect the **LiquoGuard®7** to the parenchymal or tip sensor. The **LiquoGuard®7** has a socket for connecting the adapter cable (see *Connection options* on page 24).

### Device options

1. Connect the end of the adapter cable to the pressure sensor cable of the parenchymal or tip sensor.
2. Connect the other end of the cable to the ICP input of the **LiquoGuard®7**. If the **LiquoGuard®7** detects the parenchymal or tip sensor, the ICP value will appear on the display, together with a green message window with calibration setting options and sensor functions.

When measuring pressures in liquids (CSF), the level of the pressure sensor (measured from floor level) is decisive. When using two pressure sensors (for example, pressure sensor in the **LiquoGuard®7** tubing set and another parenchymal pressure sensor), it is often not possible for both sensors to be at the same level. As a result, different pressures are measured regularly, even though the same patient is measured.

The same problem can arise due to the fact that measurements are taken in different compartments of the patient (e.g. CSF and brain tissue).

For this reason, you have the following options for calibrating the sensors to each other:

- **Calibrate to Pcsf:** Select this setting to calibrate the ICP currently indicated by the parenchymal or tip sensor with the Pcsf currently measured by the **LiquoGuard®7** drainage set. Before performing the calibration, connect the parenchymal or tip sensor to the patient. This function can be selected only if the **LiquoGuard®7 Drainage Set** is connected to the **LiquoGuard®7**.
- **Calibrate to zero:** Select this setting to perform a zero adjustment. Ensure that the parenchymal or tip sensor is not yet connected to the patient during zero adjustment. Information on zero adjustment of the sensor with the **LiquoGuard®7** can be found in the operating instructions of the parenchymal or tip sensor used.
- **Ignore calibration (keep current values):** Select this setting if you wish to keep the ICP value indicated by the parenchymal or tip sensor.

The following sensor function options are available:

- **Control CSF drainage:** Select this setting if the ICP value is to be used to control drainage while the Pcsf value (**LiquoGuard®7 Drainage Set**) is used for monitoring.
- **Monitor alarms:** Select this setting if the ICP value of the parenchymal or tip sensor is used for monitoring, while the Pcsf value (**LiquoGuard®7 Drainage Set**) is used for controlling drainage.

#### 9.5.2 Settings



The default values may be changed only by qualified personnel. The user should check prior to every application that the current settings are suitable for a specific patient.

#### ICP differs from Pcsf

This function changes the permitted pressure difference between ICP (parenchymal or tip sensor) and Pcsf (**LiquoGuard®7 Drainage Set**). If this difference is exceeded, an alarm is emitted.



## Device options

1. Tab Bar **ALARM** → Softkey **PARENCHYMAL/TIP SENSOR** → Subitem **CP differs from Pcsf / alarm sensitivity**
2. Press the **+** and **-** buttons to change the value.
3. To save the changes, press the **Confirm changes** button.

- Default value: 5 mmHg
- Minimum value: OFF (function deactivated)
- Maximum value: 15 mmHg

### Use parenchymal/tip sensor (if connected)

This function establishes the settings for the parenchymal or tip sensor functions. The following options are available.

1. to control CSF drainage (default value): Select this setting if the ICP is used to control the **LiquoGuard®7** pump. If the ICP exceeds the *Pset* value in the **DIAGRAM** dialog field, CSF will flow through the tubing set until the ICP is less than the *Pset*. The alarm and Pcsf data are active in this setting. The setting is possible only if the tubing set is connected.
2. for monitoring / recording / alarms only: Select this setting if the ICP value is used for monitoring and the Pcsf value for drainage. The alarm and ICP data are active in this setting.

### Pset (set pressure value)

If the parenchymal or tip sensor are selected *to control CSF drainage*, this function changes the set value of the ICP measured. If the ICP value exceeds the *Pset* value, CSF will be drawn to reduce the pressure. The threshold for exceeding the *Pset* depends on a hysteresis defined in the device. The pump delivers according to the delivery rate *Vset* until the measured ICP reaches the *Pset*.



Setting the *Pset* value to < 2 mmHg can present a serious danger to the patient. For safety reasons, the system requests confirmation of the setting. To confirm, press the button **Yes, I want to set Pset < 2 mmHg**. This function can be deactivated as described in the section *Config* from page 62.

1. Tab bar **DIAGRAM** → Softkey **Pset**
2. Press the **+** and **-** buttons to change the value.

The change is accepted directly.

## Device options

- Default value: 10 mmHg
- Minimum value: limited by Lower Alarm
- Maximum value: limited by Upper Alarm

### Upper Alarm

Use the softkey *Upper Alarm* to set the upper alarm limit. If the measured ICP exceeds the *Upper Alarm* value, an alarm will be generated after a preset delay (default value = 45 seconds, see page 54). If a tubing set (Pcsf) is also connected to the **LiquoGuard®7**, the *Upper Alarm* limit will apply to both values.

If the *Upper Alarm* value for the period set under *Delay of emergency drainage* (see page 56) is exceeded, the **LiquoGuard®7** performs an emergency drainage. During emergency drainage, the pump delivers 250 ml/h until the pressure measured by the tubing set has dropped to the *Lower Alarm* value.

1. Tab bar **DIAGRAM** → Softkey **Upper Alarm**.
2. Press the + and - buttons to change the value.

The change is accepted directly.

- Default value: 20 mmHg
- Minimum value: limited by Pset
- Maximum value: 75 mmHg

### Lower Alarm

Use the softkey *Lower Alarm* to set the lower alarm limit. If the measured ICP exceeds the *Lower Alarm* limit, an alarm will be generated after a preset delay (default value = 45 seconds, see page 54). If a tubing set (Pcsf) is also connected to the **LiquoGuard®7**, the *Lower Alarm* limit will apply to both values.

1. Tab bar **DIAGRAM** → Softkey **Lower Alarm**.
2. Press the + and - buttons to change the value.

The change is accepted directly.



Setting the *Lower Alarm* value to < 2 mmHg can present a serious danger to the patient. For safety reasons, the system requests confirmation of the setting. To confirm, press the button **Yes, I want to set the Lower Alarm below 2 mmHg**. This function can be deactivated as described in the section *Config* from page 62.

- Default value: 5 mmHg
- Minimum value: -15 mmHg
- Maximum value: limited by Pset

## 9.6 CPP/cMAP

### 9.6.1 Basic principles

The cerebral perfusion pressure (CPP) is calculated easily from the difference of mean arterial blood pressure (MAP) and the intracranial pressure (ICP):  $CPP = MAP - ICP$ .

The mean arterial blood pressure (MAP) is calculated from the systolic and diastolic blood pressure and is calculated by the **LiquoGuard®7** automatically.

The **LiquoGuard®7** can measure the ICP as well as the Pcsf, which means the following is also true:  $CPP = MAP - Pcsf$ .

This calculation is also carried out automatically and continuously by the **LiquoGuard®7** as soon as values for ICP and MAP or Pcsf and MAP are present.

To do this, an ICP or Pcsf sensor and a MAP sensor must be connected.

To connect the ICP pressure sensor, see *page 103*

To connect the Pcsf pressure sensor, see *page 42*

To connect the MAP pressure sensor, see *page 108*

### 9.6.2 Positioning the MAP sensor

For the **LiquoGuard®7** to calculate the CPP, it is physically essential that both pressures (MAP and ICP, or MAP and Pcsf) are measured at the same level. This means that the level above the floor must be the same. Because the ICP, or Pcsf is usually measured at the level of the foramen of Monro (see *Pressure sensor housing – Positioning and fastening on page 44*), the MAP must also be measured at the same level. To help the user always keep this in mind, the MAP is named as cMAP (cerebral mean arterial pressure) in the case of **LiquoGuard®7**.



In the conventional measurement method in which the MAP is measured at the level of the right atrium (heart), the CPP is generally calculated incorrectly when the ICP or Pcsf sensor is not located at the same level above the floor.

Other possible sources of errors (non-exhaustive list):

- Incorrect zero-point calibration of the ICP sensor (the Pcsf value does not need to be zeroed for the **LiquoGuard®7**)
- Incorrect zero-point calibration of the MAP sensor
- Insufficient purging/venting of the **LiquoGuard®7** tubing system
- Insufficient purging/venting of the tubing system for the MAP measurement
- Closed valves (no connection between the sensor and the artery/ CSF)

For details on using ICP and MAP sensors, please always refer to the documents of the respective manufacturer that supplies the product in each case.

**9.6.3 Connecting the MAP sensor**

The CPP function is a **LiquoGuard®7** device option. This device option must be enabled to display CPP values (see *Registering device options (Activating the software key)* from page 65).

Connect the cMAP sensor to the bloodstream as described in the corresponding operating manual. If necessary, zero the sensor, vent the sensor cable and connect the sensor via the **LiquoGuard®7** Multi-Hub (REF. No.: 00003817) on the In/Out connector to the **LiquoGuard®7** drainage pump

After connecting the sensor to the **LiquoGuard®7** Multi-Hub and the **LiquoGuard®7**, it automatically shows the corresponding configuration menu (see *Figure 30*)

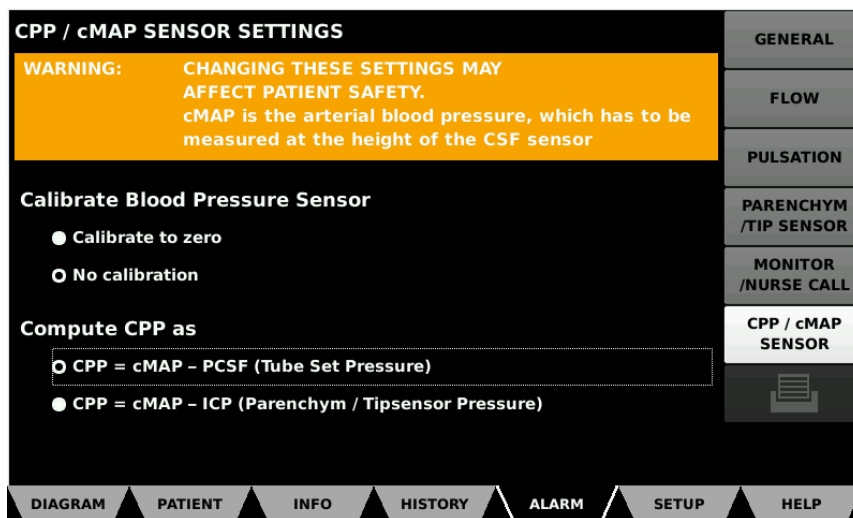


Figure 30: CPP/cMAP sensor configuration menu.

**9.6.4 cMap sensor settings**

- **Calibrate to zero:** Select this setting to perform a zero adjustment. Make sure that the blood pressure sensor is open to the atmosphere during zero adjustment and that the sensor is not exposed to liquids or similar. Information on zero adjustment of the sensor with the **LiquoGuard®7** can also be found in the instructions for use of the blood pressure sensor used.
- **No adjustment** (current value retained): Select this setting if you wish to retain the value indicated by the blood pressure sensor.

Calculation and display of the CPP value based on the two measured variables cMAP and ICP or Pcsf (see 9.6.1).

Set whether the cMAP is to be determined using the Pcsf or the ICP.



Depending on whether a Pcsf or ICP sensor is connected, the setting options may be restricted.

## Device options

### 9.7 Lumbar infusion test

Unlike CSF drainage, the lumbar infusion test application consists of an infusion of CSF substitute in the spinal canal.

For delivering physiological saline solution or CSF substitute, a suitable epidural needle with Tuohy-cut (not available in the Möller Medical product line) is required in addition to the lumbar infusion test set.

Möller Medical recommends:



An epidural needle with a Luer connector and Tuohy-cut incl. mandrel

- Inner diameter 18G (1.3 mm) or larger
- Length approx. 80 mm (depending on patient)



A prerequisite for the *lumbar infusion test* is that the operator is familiar with the regular use of the **LiquoGuard®7**, has received extensive training on the device and has read and understood the instruction manual in its entirety.

With the exception of the *Parenchymal/Tip sensor* option, all enabled device functions can also be used in *Lumbar infusion test* mode.

#### 9.7.1 General description

The lumbar infusion test is an established clinical method for indirect measurement of the CSF absorption capability of patients suffering from normal pressure hydrocephalus. The procedure involves an appropriate infusion system after puncture of the intrathecal space, accompanied by pressure measurement. A fluid is pumped into the subarachnoid space of the patient through the infusion system at a specific flow rate and the CSF pressure is measured simultaneously. The user determines the flow rate and detects the initial and final liquid pressure values.

During the lumbar infusion test with the **LiquoGuard®7**, an *infusion solution* (saline solution or CSF substitute) is infused into the patient at a specific flow rate  $V_{set}$ . The pressure value prior to infusion ( $P_{start}$ ) and the stabilized pressure value during infusion ( $P_{plateau}$ ) are required to calculate the ROF (Resistance to Outflow). The ROF is calculated as follows:

$$ROF = \frac{P_{plateau} [\text{mmHg}] - P_{start} [\text{mmHg}]}{V_{set} \left[ \frac{\text{ml}}{\text{min}} \right]}$$

This value is indicated on the **LiquoGuard®7** display. The ROF dimension is [mmHg / (ml/min)]. The display indicates this in the same manner although  $V_{set}$  is expressed in [ml/h]. The patient must lie down for the duration of the application to avoid excess pressure. Qualified personnel must be present for the duration of application. The measured value depends directly on the initial pressure and the plateau pressure set by the physician. The physician is therefore directly responsible for the measurement results.

## Device options



The attainment of the plateau value depends on the health of the patient. The physician must constantly monitor the patient and interrupt or stop the test via the Pause/Start softkey if the patient indicates dangerously high-pressure values. The physician alone is responsible for evaluating the pressure values. The **LiquoGuard®7** is merely an aid.

The **LiquoGuard®7 Lumbar Infusion test** option can only be used in conjunction with the **LiquoGuard®7 Infusion Test Set REF. No.: 00003499**. Epidural needle with Tuohy-cut required for the infusion test is not included in the set and must be ordered separately.

The **LiquoGuard®7 infusion test set tubing set REF. No.: 00003499** is designed to ensure the flow of up to 100 ml of infusion solution (physiological saline solution or CSF substitute) at a consistent volume flow into the spinal canal, with simultaneous pressure measurement. Device and tubing set together have the purpose of: Performing the lumbar infusion tests.

The appropriate location for its application includes monitored medical hospital rooms or neurosurgical practices.

Qualified personnel must stay with the device/patient for the entire duration of the application.

The **LiquoGuard®7 Infusion Test Set REF. No.: 00003499** is intended only for use in combination with and for connecting to the **LiquoGuard®7** system. Separate application without the **LiquoGuard®7** does not comply with the purpose of the system.



The device has been designed exclusively for the infusion of CSF-like liquid into the subarachnoid space and must not be used for the infusion of drug solutions or other constituents.

The lumbar infusion test serves only to obtain the diagnostics for the evaluation method indicated in specialist literature as the *lumbar infusion test* for normal-pressure hydrocephalus.

The withdrawal of CSF or the connection to other body systems (e.g. blood system) are incompatible with its intended use.

The lumbar infusion test must not be the only means of diagnosis resulting in measures taken on the patient.

The **LiquoGuard®7** may be used specifically for the infusion of fluid (saline solution or CSF substitute) into the spinal canal. It is, however, not an infusion pump because the lumbar infusion test serves diagnostic purposes and is continuously monitored by the operator.



The **LiquoGuard®7** may be used for the infusion of fluids (CSF substitute) into the spinal canal exclusively in the case of the *Lumbar Infusion Test*. The **LiquoGuard®7** must not be considered as an infusion pump since the *Lumbar Infusion Test* option is performed for diagnostic purposes and the operator is present for the entire duration of the application.

## Device options

### 9.7.2 Indications

Indications for the lumbar infusion test

The nervous system (brain, spinal cord) is surrounded by cerebrospinal fluid (CSF). The production and absorption of CSF are in a stable balance. Normal-pressure hydrocephalus disorder (hereinafter referred to as NPH) causes an imbalance between the production and absorption of CSF. Patients with this clinical picture may suffer from several symptoms. The most common are gait abnormalities (magnet gait), memory disorders and micturition disorder (incontinence). These symptoms are typical of NPH but can also be diagnosed in individuals with other cerebral disorders (such as Alzheimer's disease or other dementia disorders).

The treatment of NPH involves the continuous drainage of CSF from the ventricles of the brain into another body cavity, usually intraperitoneal (ventriculo-peritoneal shunt = VP shunt) or into the blood system (usually into the atrium, i.e. ventriculoarterial shunt = VA shunt). In order to determine whether and how a shunt system can contribute towards successful therapy, meticulous diagnosis must be performed in order to ascertain whether a patient actually suffers from NPH. Besides the determination of clinical symptoms, imaging diagnosis is required in order to check for typical NPH symptoms (extension/disproportion of ventricles, effacement of the cerebral sulci, etc.). Since, however, the combination of clinical and imaging exams is not sufficient for safe diagnosis, further examination methods must be applied.

Besides continuous lumbar drainage, the lumbar infusion test represents an additional method for NPH diagnosis verification.

### 9.7.3 Contraindications

- Coagulation dysfunction
- Thrombocytopenia
- Infectious diseases
- Manifest cramp attacks
- Acute central nervous system disorders (cerebral hemorrhage, cerebral infarct, cranial-cerebral injury, subarachnoid hemorrhage)
- Tumorous disease of the central nervous system (intracranial and spinal)
- CSF obstructions (in particular, syringomyelitis, arachnopathy)
- Low CSF pressure syndrome
- Increased cerebral pressure
- Upper articular constriction (herniation)

### 9.7.4 Complications

- Meningitis, encephalitis, ventriculitis, myelitis, nosocomial infection
- CSF depletion syndrome (catheter disconnection, persistent dural defects after puncture) resulting in cerebral hemorrhage, epidural hematoma, slit ventricles, headaches
- Spinal cord injury, nerve injury, cone or cauda injury, back pain

- Increase in CSF pressure resulting in headaches, neurological disorders (impaired vision, reduced consciousness, cramp attacks, loss of consciousness)
- Interrupted tube flow (bent tube, occluded tube system (blood clots or detritus))
- Death

#### **9.7.5 Combination with other products**

The **LiquoGuard®7 Lumbar Infusion Test** option can be implemented only if used in conjunction with the **LiquoGuard®7 Infusion Test Set REF. No.: 00003499** from Möller Medical.

Accordingly, the **LiquoGuard®7 Infusion Test Set REF No.: 00003499** may be used only for the **LiquoGuard®7 Lumbar Infusion Test** option.

#### **9.7.6 Patient population**

This application is to be used exclusively on patients suspected of suffering from normal-pressure hydrocephalus (age group: mostly middle to advanced age).

#### **9.7.7 Residual risk**

The use of the **LiquoGuard®7** with the lumbar infusion test option poses the following risks when carrying out this test:

- Increased CSF pressure
- Infusion of the fluid outside the subarachnoid space due to incorrect positioning of the spinal cannula
- Infection of the cerebrospinal fluid

#### **9.7.8 Execution of the lumbar infusion test**

The puncture of the intrathecal space is an essential element of the lumbar infusion test. The patient is usually placed in the lateral position, the skin in the centerline of the lumbar spine is disinfected, and the subarachnoid space is punctured using a suitably dimensioned cannula (Touhy needle) under sterile conditions. After ensuring the CSF flow, a tubing system is connected to the positioned needle. This tubing system is in turn connected to a pressure measuring device. Using an infusion pump, sterile, CSF-like liquid can be infused via the tube system. Before starting infusion, the initial pressure is measured. Then the liquid is infused at a defined rate (in most cases 1 to 2 ml/min) while continuously measuring the pressure until a specific plateau pressure has been reached, or until a critical pressure value forces the attending physician to abort the test. If the ROF exceeds the critical value (in most cases 12-18 mmHg/ml/min), an NPH is diagnosed. However, the application of the lumbar infusion test as a single method for NPH diagnosis is neither described in expert literature nor is it found to be suitable for this specific purpose.

##### **9.7.8.1 Puncture of the subarachnoid space**

The subarachnoid space is punctured by means of an Epidural needle with Tuohy-cut.



## Device options

### 9.7.8.2 Intrathecal CSF drainage

The withdrawal of CSF requires the surgical installation of an approved cannula into the intrathecal space. This surgical intervention is indicated in case of suspicion of NPH.

### 9.7.9 Application and operation

The **LiquoGuard®7** displays only the filtered pressure values. The diagram shows two horizontal green lines with which the initial and end pressures can be set. The ROF of the CSF is calculated by using these two pressure limit values and the volume rate set. In order to calculate the ROF, it is important that the measured pressure has actually reached the upper plateau.



In *Lumbar Infusion Test* mode, the pump turns off if the Upper Alarm limit is exceeded. If the Lower Alarm limit is exceeded, further CSF substitute will flow.

The alarm "*Pressure constant for too long*" does not exist in the infusion test. Therefore, this parameter is not indicated in the menu.

As the lumbar infusion test is a diagnostic procedure during which small pressure differences are decisive, qualified personnel must stay with the patient throughout the entire process and attend the application. This is important as changes in the position of the patient would more significantly affect the measurement than the additional infiltration.

The operator must manually start and finish the procedure as the automatic mode is risky for the same reasons. In this way the operator specifies the initial pressure as well as the changed final pressure.

In order to perform the lumbar infusion test, the sensor cable of the tubing set must already be connected to the **LiquoGuard®7** when the device is turned on.

#### Preparation of the tubing set

1. Firstly, remove a tubing set suitable for the *lumbar infusion test* from its packaging and connect the sensor cable to the turned off **LiquoGuard®7** (see *Connection options on page 24*).
2. Restart the **LiquoGuard®7** via the **On/Off switch**.
3. As soon as the tubing set is recognized by the **LiquoGuard®7**, a green window will appear on the screen with the instruction to insert the tubing set.
4. Select the button **Start Application** in the message window. The device is now in lumbar infusion test mode.

#### Preparation of the lumbar infusion test

The **LiquoGuard®7** supports the operator in further preparatory procedures. Each measure is indicated in the Info bar of the display. Use the arrow keys in the dialog window **DIAGRAM** to follow the installation procedure step by step.

## Device options

1. *Attach (ECG) electrode to sensor housing*  
Attach the adhesive electrode to the pressure sensor housing.
2. *Insert tubing set into pump*  
Insert the tubing set into the pump (see *Installation and startup* on page 41) but do not close the **LiquoGuard® 7** pump cover yet.
3. *Connect spike to container with infusion solution*  
Remove the protective cap from the spike of the tubing set and prick the container with the CSF substitute.
4. *Fill tubing until completely full*



Ensure that no air remains in the tubing set. This will avoid inaccurate measurements and prevent air from being pumped into the patient.

If the pump cover is closed, open it now. Remove the protective cover on the through valve. Keep the **Turn Rotor** button in the message window pressed until the CSF substitute drips from the tubing set. Close the pump cover.

5. *Puncture the patient with Epidural needle with Tuohy-cut, wait until CSF comes out*  
Remove the Epidural needle with Tuohy-cut from its packaging and puncture the patient. Wait for the cannula to fill with CSF.
6. *Connect cannula and tubing*  
Connect the cannula to the tubing set.
7. *Attach pressure sensor to patient*  
Attach the pressure sensor to the patient at the level of the puncture in order to avoid inaccurate measurements.
8. *Set Vset (e.g. 120 ml/h)*  
Press the softkey **Vset** and change the value for the infiltration flow by using the **+** and **-** buttons. The change is accepted directly.
9. *Adjust Pstart*  
Check whether the current pressure (white line) is relatively constant. Align the start curve (lower green curve) to the pressure curve. Press the **Pstart** button and change the value by using the **+** and **-** buttons until the start curve lies on the pressure curve. If the pressure is not constant, check whether the sensor was attached correctly. The patient must remain still, otherwise fluctuations in pressure may occur.
10. When plateau is reached, adjust the plateau value and read ROF
11. This instruction serves only for information at this stage and can be skipped.
12. Press **>(II)<** to start infusion test.

## Device options

13. On the **LiquoGuard®7** display, press the softkey **Pause/Start** to start the lumbar infusion test.

Once preparations are completed, proceed with measurement.

### Measurement

1. After pressing on the softkey **Pause/Start** to activate the pump, the pressure increases until a new stable pressure plateau is reached. This constant pressure that corresponds to the set speed *Vset* of the pump is required to calculate the ROF.
2. Once it is certain that the plateau value is stable and will no longer increase, enter the plateau pressure in the **LiquoGuard®7**. To do this, press the softkey **Plateau** and change the value using the **+** and **-** buttons until it shows the same value as the stable *Pcsf*.
3. The *ROF* for the application is indicated in the Info bar subject to *Pstart* and the *plateau*.



The *ROF* is always calculated on the basis of the currently set values. If the *Vset* is changed during the application, it is necessary to wait for a new stable pressure plateau.

$$\text{ROF} = \frac{\text{Plateau [mmHg]} - \text{Pstart [mmHg]}}{\text{Vset} \left[ \frac{\text{ml}}{\text{min}} \right]}$$

The start curve (*Pstart*) can be adjusted throughout the application.

If the current pressure and the start curve are identical, only the start curve will be visible.

When the **LiquoGuard®7** is in pump mode, the pump operates for 8 seconds, then pauses for 2 seconds in order to measure the pressure. Then it resumes operation. After every 10 seconds, therefore, the diagram indicates the new measurement values.



In practice it is often difficult to reach a stable plateau value. The final value is subject to strong variation. It must be ensured that the pressure does not increase any further. The attending physician is responsible for setting the correct plateau pressure value.

In the event that the infusion set is disconnected from the **LiquoGuard®7** during the application, the measurement curve is deleted. The indicator of the already dispensed volume is retained.

The following options are available to reset the volume counter and the measurement curve in the **DIAGRAM** dialog field:

- If the *History* device function is enabled, go to the HISTORY dialog field and press the **Clear History** button. In addition to the volume counters and measurement curves, ensure that the alarm history and patient data are deleted.
- If the *History* function is not available, the values can be reset by restarting the **LiquoGuard® 7**.

### 9.7.10 Settings

The setting options in *Lumber Infusion Test* mode differ only in the dialog fields Diagram and Alarm from those available for drainage. The setting options for the Setup dialog field can be found on *page 59*. In the *Lumbar Infusion Test* mode, you can change the unit used to show pressure (mmHg, cmH2O) only before the start of the application.

#### 9.7.10.1 Diagram

##### Upper Alarm

Use the *Upper Alarm* softkey to change the upper pressure alarm limit. If the measured pressure exceeds the *Upper Alarm* limit, an alarm will be generated after a preset delay (default value = 45 seconds, see *page 54*).

1. Tab bar **DIAGRAM** → Softkey **Upper Alarm**.
2. Press the **+** and **-** buttons to change the value.

The change is accepted directly.

- Default value: 40 mmHg
- Minimum value: limited by Plateau
- Maximum value: 75 mmHg

##### Plateau

Use the softkey *Plateau* to set the plateau value at the end of the Pcsf measurement in order to determine the *ROF*.

1. Tab bar **DIAGRAM** → Softkey **Plateau**.
2. Press the **+** and **-** buttons to change the value.

The change is accepted directly.

- Default value: 30 mmHg
- Minimum value: limited by Pstart
- Maximum value: limited by Upper Alarm

## Device options

### Pstart

Before starting measurement, press the softkey *Pstart* to adjust the value to the measured Pcsf pressure.

1. Tab bar **DIAGRAM** → Softkey **Pstart**.
2. Press the **+** and **-** buttons to change the value.

The change is accepted directly.

- Default value: 12 mmHg
- Minimum value: -14 mmHg
- Maximum value: limited by Plateau

### Vset

Using the softkey *Vset*, adjust the volume flow of the infusion solution in ml/h.

1. Tab bar **DIAGRAM** → Softkey **Vset**.
2. Press the **+** and **-** buttons to change the value.

The change is accepted directly.

- Default value: 120 ml/h
- Minimum value: 0 ml/h
- Maximum value: 250 ml/h

### Lower Alarm

Use the softkey *Lower Alarm* to change the lower pressure alarm limit. If the measured pressure exceeds the *Lower Alarm* limit, an alarm will be generated after a preset delay (default value = 20 seconds, see *page 54*).

1. Tab bar **DIAGRAM** → Softkey **Lower Alarm**.
2. Press the **+** and **-** buttons to change the value.

The change is accepted directly.

- Default value: 5mmHg
- Minimum value: -15 mmHg
- Maximum value: limited by Pstart

**9.7.10.2 Alarm****Alarm delay**

This setting is used to determine the time period from the moment a specific physiological alarm condition occurs to the emission of an alarm signal. This avoids an alarm being generated by temporary pressure fluctuations (e.g. after coughing or sneezing).

1. Tab bar **ALARM** → Softkey **GENERAL** → Subitem **Alarm Delay**
  2. Press the **+** and **-** buttons to change the value.
  3. To save the changes, press the **Confirm changes** button.
- Default value: 45 seconds
  - Minimum value: 5 seconds
  - Maximum value: 1 minute

**Sound level**

This function determines the volume of the acoustic alarm signal.

1. Tab bar **ALARM** → Softkey **GENERAL** → Subitem **Sound level**
  2. Press the **+** and **-** buttons to change the value.
  3. To save the changes, press the **Confirm changes** button.
- Default value: 40%
  - Minimum value: 20%
  - Maximum value: 100%

**9.7.11 Alarms**

During the infusion test, alarms may be generated due to values exceeding the *Upper Alarm* limit or *Lower Alarm* limit. Similarly to the drainage mode, these alarms can be silenced for a set period of time (see *Technical and physiological alarm conditions* on page 69).

## Appendix

## 10 Appendix

## 10.1 Technical data

**General characteristics**

Order number REF:	00003500
Dimensions of the <b>LiquoGuard® 7</b> :	Width x Height x Depth [mm] 238.1 x 145 x 212.8
Weight [kg]:	3.7 kg
Operating temperature application side:	42 °C at adhesive electrode
Noise pressure level Pump:	< 38 dB(A) at a flow of 30 ml/h
Noise pressure level Alarm signal :	> 85 dB (A), from speaker setting 80%
Minimum operating life:	8 years
Applicable standard:	IEC 60601-1 + A1:2012

**Electrical connection**

Voltage:	100 – 240 VAC (alternating voltage)
Frequency:	50 – 60 Hz
Current consumption:	1.0 – 0.4 A
Power consumption:	100 VA
Fuse:	T 3.15 A / 250 V
Protection class:	I
Protection rating:	IP 20
Li-Ion battery pack:	Art. No. 93 004 733
Li-Ion cell:	Art. No. 93 004 732
Application part BF:	<b>LiquoGuard® 7 Drainage Set</b> REF. No. 00003497 (1600 mm) or REF. No. 00003501 (2000 mm) <b>LiquoGuard® 7 Infusion Test Set</b> REF. No.: 00003499 <i>ICP interface on LiquoGuard® 7</i>
Application parts CF:	<i>MAP interface on LiquoGuard® 7 Multi-Hub (REF. No.: 00003817)</i>

**Appendix****Fuses**

F1:	Manufacturer: Littlefuse Current 5 A Voltage: 125 VDC Tripping characteristic: Flink Breaking capacity: 50 A @ 125 VAC/ VDC
F2:	Manufacturer: Littlefuse Current 1 A Voltage: 125 VDC Tripping characteristic: Flink Breaking capacity: 50 A @ 125 VAC/ VDC

**Transport and storage instructions**

Temperature:	-10°C to +50°C
Humidity:	less than 90% rel. humidity
Weight with packaging:	approx. 5.3 kg
Dimensions of packaging:	Width x Height x Depth [mm] 300 x 320 x 345

**Operating conditions**

Temperature:	+15 °C to +40 °C
Humidity:	30 to 75% rel. humidity
Pressure:	70 kPa - 101,3 kPa maximum operating altitude < 3000 m above sea level.

**Specific features**

Delivery rate of the <b>LiquoGuard® 7</b> :	1 ml/h to 250 ml/h
Operating pressure range:	- 75 mmHg to + 100 mmHg
Delivery rate accuracy:	± 10% * * including material variations of the tubing set +/- 15%



## Appendix

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### Input and output signals

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#### Patient monitor system

Operating pressure range:	-75 mmHg to +100 mmHg
Impedance:	1.5 kOhm
Sensitivity:	5.0 $\mu\text{V}/\text{V}/\text{mmHg}$ with a tolerance of $\pm 5\%$ or $\pm 2$ mmHg, whereby the higher value is decisive
Power supply:	4 V to 10 V

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#### Nurse call system

Output:	NO / NC
Rated voltage:	250 V/1 A

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#### Parenchymal/Tip sensor

Operating pressure range:	- 75 mmHg to +100 mmHg
Impedance:	300 Ohm – 3 kOhm
Sensitivity:	5.0 $\mu\text{V}/\text{V}/\text{mmHg} \pm 1\%$
Non-linearity and hysteresis:	$\pm 1.5\%$ display accuracy or $\pm 1$ mm Hg, whereby the higher value is decisive
Operating temperature:	min. 15 °C to 40 °C
Certified sensors, catheter and devices:	Neurovent (RAUMEDIC) Neurovent-P (RAUMEDIC) Brain Pressure Monitor HDM 26.1 (Spiegelberg)

---

#### USB

Features:	USB 2.0 and USB 1.1 File system FAT32
Printer:	HP Deskjet 3320, HP Deskjet 3000 Printers may be used only in conjunction with a USB isolator (certified according to DIN IEC 60601-1) (e.g. USB-GT MED-D Interface, manufactured by Meilhaus Electronic GmbH).

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**10.2 Electromagnetic emission**

The **LiquoGuard® 7** is intended for operation in the stipulated electromagnetic environment. The customer and/or operator of the **LiquoGuard® 7** should ensure that it is used in one of the electromagnetic environments described below.

<b>Measurement of emitted interference</b>	<b>Level of conformity</b>	<b>Guidelines for the electromagnetic environment</b>
Emitted high-frequency interference acc. to CISPR 11	Group 1	To satisfy its intended function, the <b>LiquoGuard® 7</b> must emit electromagnetic energy. Electronic devices in the vicinity could be influenced.
Emitted high-frequency interference acc. to CISPR 11	Class B	For areas of application, see <i>chapter 4.4</i>
Harmonic emission acc. to IEC 61000-3-2	Class A	
Voltage fluctuation/flicker emission acc. to IEC 61000-3-3	Complies	

Appendix

10.3 Electromagnetic resistance

Immunity test	IEC 60601 – testing level	Level of conformity	Electromagnetic environment / Guidelines
Discharge of static electricity (ESD) IEC 61000-4-2	±8 kV contact discharge	±8 kV contact discharge	Floors should be made of wood or concrete or fitted with ceramic tiles. If the floor is provided with a synthetic material, relative humidity must be at least 30%.
	±15 kV air discharge	±15 kV air discharge	
Electrical fast transients/Bursts IEC 61000-4-4	±2 kV for power lines	±2 kV for power lines	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment.
	±1 kV for input/output lines	±1 kV for input/output lines	
Impulse voltage (surges) IEC 61000-4-5	±1 kV normal mode voltage	±1 kV normal mode voltage	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment.
	±2 kV common mode voltage	±2 kV common mode voltage	
Voltage dips, temporary interruptions and fluctuations of the supply voltage IEC 61000-4-11	< 5% $U_T$ (> 95% dip in $U_T$ ) for 1/2 period	< 5% $U_T$ (> 95% dip in $U_T$ ) for 1/2 period	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment. We recommend an uninterrupted power supply or battery for operators of the product demanding continuous function even during an interrupted power supply.
	40% $U_T$ (60% dip in $U_T$ ) for 5 periods	40% $U_T$ (60% dip in $U_T$ ) for 5 periods	
	70% $U_T$ (30% dip in $U_T$ ) for 25 periods	70% $U_T$ (30% dip in $U_T$ ) for 25 periods	
	< 5% $U_T$ (> 95% dip in $U_T$ ) for 5 seconds	< 5% $U_T$ (> 95% dip in $U_T$ ) for 5 seconds	

**Appendix**

Immunity test	IEC 60601 – testing level	Level of conformity	Electromagnetic environment / Guidelines
Magnetic field of supply frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields of the supply frequency should conform with the typical values found in commercial or hospital environments.
Note: $U_T$ is the alternating mains voltage prior to the application of the testing level.			

The **LiquoGuard® 7** satisfies all test levels in accordance with IEC60601-1-2 Edition 4 (table 4 to 9).



As a result of the presence of electromagnetic disturbances, it is possible that the key performance features of the **LiquoGuard® 7** are impaired. In this case there may, for example, be a temporary pressure difference. This is indicated by an alarm message from **LiquoGuard® 7** and control of the peristaltic pump is interrupted. For assistance with alarm messages see *chapter 7*.




Portable RF communication devices (radio devices) (including their accessories such as antenna cables and external antennas) should not be used closer than 30 cm (or 12 inches) from the parts and cables of the **LiquoGuard® 7** indicated by the manufacturer. Non-observance may result in a reduction of the device's performance.



Operation of the **LiquoGuard® 7** with additional accessories such as transducers or cables, which are not defined for the intended use with the device, may result in increased electromagnetic emissions, reduced immunity to interference or faulty operation.

The requirements for use in aviation, transportation and military fields have not been taken into account as they have not been tested.

**Appendix**

Immunity tests/standard	IEC 60601 testing level	Level of conformity	Electromagnetic environment / Guidelines
Conducted HF disturbances in accordance with IEC 61000-4-6	<p>3 V<sub>eff</sub> 150 kHz to 30 MHz</p> <p>6 V<sub>eff</sub> in ISM and amateur radio frequency bands between 150 kHz and 80 MHz</p>	<p>3 V<sub>eff</sub></p> <p>6 V<sub>eff</sub></p>	<p>Portable and mobile radio transmitting devices, including the cables, should be used in proximity of the <b>LiquoGuard®7</b> within the recommended safety distance calculated according to the applicable transmission frequency equation.</p> <p>Recommended safety distance:</p> <p><math>d=1,2\sqrt{P}</math> for 80 MHz to 800 MHz</p> <p><math>d=2,3\sqrt{P}</math> for 800 MHz to 2.5 GHz</p> <p>with P as nominal transmitter power in Watt (W) according to transmitter manufacturer stipulations and d as recommended safety distance in meters (m).</p>
Radiated HF disturbance value acc. to IEC 61000-4-3	<p>3 V/m 80 MHz to 2.7 GHz</p> <p>Table 9 of IEC 60601-1-2 Ed. 4</p>	<p>3 V/m 80 MHz to 2.7 GHz</p> <p>Table 9 of IEC 60601-1-2 Ed. 4</p>	<p>According to an on-site examination, the field intensity of stationary radio transmitters ought to be lower than the compliance levelb).</p> <p>Disturbances may occur in the environment of devices carrying the following symbol.</p> 
<p>Note:</p> <p>NOTE 1: The higher frequency range applies to 80 MHz and 800 MHz.</p> <p>NOTE 2: These guidelines may not be applicable to all cases. The diffusion of nominal electromagnetic factors is influenced by absorption and reflection of buildings, objects and people.</p>			
<p>a) The field strength of stationary emitters, such as base stations for mobile phones and mobile terrestrial radio systems, amateur radio stations, AM and FM radio and television emitters, cannot be theoretically accurately predicted. To determine the electromagnetic environment in terms of the stationary emitters, a study of the site should be considered. If the measured field strength in the location in which the <b>LiquoGuard®7</b> is used exceeds the applicable RF compliance level above, the <b>LiquoGuard®7</b> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the <b>LiquoGuard®7</b>.</p> <p>b) Above the frequency range of 150 kHz to 80 MHz the field strength should be lower than 3 V/m.</p>			

**10.4 Recommended safety distances**

See chapter 10.3.

**10.5 Use in a CT and MRI environment**

Non-clinical testing has demonstrated the **LiquoGuard® 7** tubing sets are MR conditional. A patient with this tubing set can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3 T
- Maximum spatial field gradient magnetic field of 45 mT/m
- Maximum MR system reported; whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).
- Following the additional MRI Safety instructions as specified in Sections 10.5.1, 10.5.2 and **Fehler! Verweisquelle konnte nicht gefunden werden..**

Under the scanning conditions defined above, no temperature increase will be detected in the **LiquoGuard® 7** Drainage Set even after 15 minutes of continuous scanning.

**10.5.1 Important safety instructions**

Some **LiquoGuard® 7** products may be used in an MRI environment, some not.



The **LiquoGuard® 7** devices (monitors) may **not** be used in an MRI environment. They contain ferromagnetic materials, and the device function can be **disrupted** by the field load. **LiquoGuard® 7** devices can be attracted by the magnetic field of the MRI and cause collision damage.



**LiquoGuard® 7** tubing sets with the appropriate identification on the label of the package **can** be used in an MRI environment up to the maximum field strength indicated on the label of the product itself.

CSF drainage, infiltration or pressure measurements during MRI imaging are not possible. Tubing sets may remain connected to the catheter (lumbar or ventricular) during an MRI examination. The valve between the tubing set and the catheter must be closed in order to avoid, for example, unintentional drainage.

Keeping the tubing set connected to the patient during an MRI helps to reduce the risk of infection which could be increased when the catheter or tubing lines are opened. Unnecessary disconnection or unnecessary opening of the tubing sets is to be avoided.

**Preparation before MRI imaging:**

The following safety measures must be taken by the user when using the **LiquoGuard® 7** tubing sets during an MRI:

Tubing sets may not be connected to the **LiquoGuard® 7** device (monitor) during MRI examinations.

**LiquoGuard® 7** devices (monitors) must be located outside the MRI room. They may remain switched on in order not to change settings (note the maximum allowable time that the tubing set may be separated from the device; see *page 48*), but may not be exposed at any time to the MRI's magnetic field.

## Appendix

Proceed as follows:

1. While in application mode, remove the tubing set sensor cable from the device.
2. Press the **Interrupt Application** button in the alarm message window. The alarm will be deactivated, and the device will be set in Pause mode.
3. Close the four-way stopcock between the tubing set and the catheter (patient protection).
4. Open the pump cover.
5. Remove **Adapter 1** from the pump.
6. Press the softkey **Turn Rotor** in the message window.
7. Feed the tube into the semi-circular rotor opening to **Adapter 2 input**; so that it is guided out of the rotor area.
8. Remove **Adapter 2** from the pump and close the pump cover.
9. Take the drainage bag from the bag stand but do not disconnect it from the tubing set. Do not close the 2-way stopcock between the bag and the tubing set.
10. Lay the tubing set and the drainage bag next to the patient on the MRI bed. Do not separate the tubing set from the drainage catheter.
11. Detach the pressure sensor housing from the adhesive electrode.
12. Detach the adhesive electrodes from the patient and discard them.
13. Reconnect the tubing set to the **LiquoGuard®7** within 8 hours (see *After MRI imaging, page 128*).

### 10.5.2 Measures to avoid image artifacts in MRI

The tubing sets must not be attached with the sensor housing directly to the patient. The tubing set and the drainage bag should not be left on or below the patient, and not lie directly next to the patient but rather should be stored as far as possible away from the patient in order to avoid artifacts in the imaging. The adhesive electrode with which the pressure sensor housing is fixed to the patient must be removed.



**Since the *LiquoGuard®7* devices (monitor) may not be connected to the tubing set during MRI imaging, and the tubing set attached to the patient must be closed, no intracranial pressure readings may be taken during the MRI imaging, and no drainage or infusion may take place.**

**10.5.3 After MRI imaging**

After MRI imaging, the patient is reconnected to the **LiquoGuard®7**.

Proceed as follows:

1. Reconnect the sensor cable of the tubing set to the **LiquoGuard®7** within 8 hours (see *Figure 16, page 42*). The unit is still in Pause mode.
2. Connect the tubing set to the pump:
  - a. Open the pump cover, use your fingers to reach into the opening of the panel and lift until the panel engages.
  - b. The **LiquoGuard®7** display indicates a green message window with the softkey Turn rotor . Use this button to turn the pump rotor and feed the tube into the pump.
  - c. Insert **Adapter 1** into the **LiquoGuard®7 Adapter 1 input**.
  - d. Hold **Adapter 2** with one hand.
  - e. Select the softkey **Turn rotor** on the display and keep it pressed.
  - f. Feed the tube into the semi-circular opening of the rotor up to the **Adapter 2 input**.
  - g. Now insert **Adapter 2** into the **Adapter 2 input**.
3. Attach the **drainage bag** to the holder provided on the device side (see *page 22*).
4. Clip the **pressure sensor housing** to the **adhesive electrode** and attach it to the patient (see *Pressure sensor housing – Positioning and fastening, page 44*)
5. Open the 4-way stopcock between the patient (catheter) and tubing set, but not to the atmosphere, in order to prevent infection (see *Figure 19, page 44*).
6. Check if there is air in the tubing set. If so, press the softkey **Turn rotor** and aspirate CSF until no more air can be detected between the patient and the pressure sensor housing and no more air can be detected in the pressure sensor housing.
7. Close the front cover of the pump.
8. Press the **Pause** softkey to use to start again.
9. Check the display,
  - a. whether the patient's slight head movements create print changes that are visible on the display to ensure that the pressure sensor measures CSF pressure.
  - b. whether the CSF pulsation of the patient is indicated by a pulsation of the pressure curve (often less pronounced for lumbar pressure measurement)
10. Check the device settings



## Appendix

Always make sure that all valves are set correctly (especially between the tubing set and drainage bag).



Always check whether the patient's movements create corresponding print changes within the pressure curve to ensure that there is a connection between the pressure sensor and CSF.

Make sure there are no air bubbles between the catheter tip and pressure sensor in the tubing set, and whether the patient's CSF pulsation can be seen on the display.

### 10.6 Accessories

#### Ordering accessories:

##### Möller Medical GmbH

Wasserkuppenstrasse 29-31

36043 Fulda, Germany

Tel. +49 (0) 661 / 94 19 5 – 0

Fax +49 (0) 661 / 94 19 5 – 850

E-mail: [info@moeller-medical.com](mailto:info@moeller-medical.com)



Please make a note of the device ID of the **LiquoGuard®7** when placing an order.

1. Tab bar **SETUP** → Softkey **SERVICE**
2. Press the **LiquoGuard Information** button.

The key to enable the device functions applies only to the device indicated in the order and has a limited validity of 30 days. If the key is not imported into the device within that time, it will no longer be accepted.

Not all device options are available in all markets.

**Device options for *LiquoGuard®* 7:**

- Monitor/Nurse call  
**REF. No. 00003580**
- Documentation  
**REF. No. 00003567**
- Presettings  
**REF. No. 00003568**
- Printing  
**REF. No. 00003569**
- Parenchymal/Tip sensor  
**REF. No. 00003570**
- CPP/Cmap  
**REF. No. 00003653**
- Infusion test  
**REF. No. 00003571**

**Appendix**

**Tubing sets for *LiquoGuard*®7:**

- 1 x *LiquoGuard*®7 Drainage Set (1600 mm)  
REF.-No. 00003497
- 1 x *LiquoGuard*®7 Drainage Set (2000 mm)

REF. No. CE market	MRI use	Application time	Shelf Life	Comment
00003501 / 1470	No	7 days	4 years	
00003501 / 1411	Yes	10 days	4 years	

REF. No. US market	MRI use	Application time	Shelf Life
00003501 / 2471	Yes	7 days	4 years
00003501 / 2411	Yes	10 days	4 years

REF. No. China market	MRI use	Application time	Shelf Life	Comment
00003501 / 3471	Yes	7 days	4 years	
00003501 / 3411	Yes	10 days	4 years	

- 1 x *LiquoGuard*®7 Infusion Test Set  
REF. No. 00003499

#### **Demonstration tubing sets for *LiquoGuard® 7*:**

- 1 x *LiquoGuard® 7* Demo Drainage Set  
REF. No. 00003553
- 1 x *LiquoGuard® 7* Demo Infusion Test Set  
REF. No. 00003554

#### **Connecting cable for patient monitor system:**

- *LiquoGuard®* connecting cable Datex-Ohmeda S5 Monitor System  
REF. No. 00003012
- *LiquoGuard®* connecting cable Maquette Hellige Solar8000 Monitor System  
REF. No. 00003013
- *LiquoGuard®* connecting cable Phillips Intelliview MP 30, MP50, MP70  
REF. No. 00003174
- *LiquoGuard®* connecting cable Infinity Dräger (Siemens) Brücke Hemomed  
REF. No. 00003128
- *LiquoGuard®* connecting cable Nihon Kodan  
REF. No. 00003172
- *LiquoGuard®* connecting cable Hellige Servocad 904 5Th. Gen.  
REF. No. 00003193
- *LiquoGuard®* connecting cable Siemens 9000 XL Monitor  
REF. No. 00003065

#### **MAP sensors:**

- EdWards pressure sensor  
REF. No. 00003650

#### **MAP connection cable**

- EdWards pressure sensor connection cable  
REF. No. 00003174

**Appendix**

**Other accessories:**

- CSF Bag for the *LiquoGuard*<sup>®</sup> (drainage bag)  
REF. No. 00003194
- Safety cushion for *LiquoGuard*<sup>®</sup>  
REF. No. 00002701
- *LiquoGuard*<sup>®</sup>7 Multi-Hub  
REF. No. 00003817

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