



## Tourniquet Touch TT15

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## INSTRUCTIONS FOR USE

Read and follow the instructions for use carefully before commissioning and keep them for future reference.

The instructions for use contain important information and directions that must be observed when using the device.

### 1. SIGNAL WORDS AND SYMBOLS

Symbol	Description
	<b>DANGER</b> Indicates an imminent hazard with high risk which, if not avoided, will result in death or serious personal injury.
	<b>WARNING</b> Indicates a potential hazard with moderate risk which, if not avoided, can result in death or serious personal injury.
	<b>CAUTION</b> Indicates a hazard with low risk which, if not avoided, could result in minor or moderate personal injury or property damage.
NOTE	NOTE helps to prevent damage to the device.
EMC	Electromagnetic compatibility
▶	Instruction: Prompt for the user to do something.

### 2. INTENDED USE

The Tourniquet Touch TT15 is an electrically operated surgical tourniquet with additional irrigation channel. It regulates the pressure of a Tourniquet Cuff which temporarily occludes the blood flow of a patient's upper or lower extremity in order to obtain a bloodless field. A Pressure Infusion Cuff for administration of irrigation solutions can be connected to the irrigation channel.

The Tourniquet Touch TT15 is suitable for use with a Single Cuff and a Pressure Infusion Cuff. Clinical benefit: to create a bloodless surgical field during extremity surgery to minimise blood loss and facilitate visualisation and identification of vascular structures.

Patient target group: Patients who require surgery at upper or lower extremities.

Location of use: Rooms suitable for medical purposes.

### 3. INDICATION / CONTRAINDICATION

Indications and contraindications depend on the intervention and therefore on the selected Tourniquet Cuff and Pressure Infusion Cuff.

#### Possible indications for blood arrest:

- Reduction of certain fractures
- Arthroscopy of knee, hand, finger or elbow
- Bone grafting
- Kirschner wire removal
- Traumatic or non-traumatic amputations
- Removal of tumours or cysts
- Subcutaneous fasciotomy
- Nerve injuries
- Tendon repair
- Replacement or revision of joints (knee, wrist or finger)
- Correction of a hammer toe
- Podiatry

No other indications are known.

#### Possible contraindications for blood arrest:

- Open fractures of extremities
- Post-traumatic lengthy hand reconstruction
- Severe crushing
- Elbow surgery where there is excess swelling
- Severe hypertension
- Skin transplant
- Compromised circulation (e.g. peripheral artery disease)
- Diabetes mellitus

No other contraindications are known.

The physician must, in each individual case, assess the indications and contraindications in the light of his or her expert knowledge.

#### Possible indications for irrigation:

- For irrigation during minimally invasive surgery

No other indications are known.

#### Possible contraindications for irrigation:

- None known.


### 4. SAFETY INFORMATION

- The products must be inspected visually for damages (cracks, breakage etc.). Damaged products must not be used.
- If there is a change in ambient temperature (e.g. due to transport), then the device must only be connected to the power supply when it has reached room temperature.
- This product must only be used by a physician, or by medically trained personnel working under the instruction of a physician.
- The user and/or patient must report all serious adverse events that occurred in connection with the product to the manufacturer and competent authorities of the EU member state (or report to the competent authorities of the country if an event occurs outside of the EU) in which the user and/or patient is located.
- The device was designed and tested for use with Tourniquet / Pressure Infusion Cuffs and Coil Connecting Tubing from the manufacturer. If the user uses Tourniquet / Pressure Infusion Cuffs and Coil Connecting Tubing from other manufacturers, then the manufacturer assumes no liability for the device.
- Each time the device is started up, a functional check must first be performed.
- If problems occur, restart the device. If the error occurs again, contact the manufacturer. Protect the device from spray water and moisture. The device must not be operated if liquids have penetrated the device.
- The device is not suitable for MRI.
- The device is not sterile.
- The device is not defibrillation-proof.
- The device must be set up in such a way that it can be quickly disconnected from the power supply.
- The rechargeable battery in the device will bridge brief interruptions of the power supply.
- The device contains a Li-Ion battery. If damage of the battery is suspected, the device must not be used. Damages could cause inflammation of the battery if the device is continued to be plugged-in or used. Contact the manufacturer.
- Due to the risk of explosion, the device must not be used in the immediate proximity (distance < 25 cm (9 7/8 inch)) of flammable anaesthetic gases or in environments with an oxygen concentration > 25%.
- In order to avoid the risk of electric shock, the device must be disconnected from the power supply prior to assembly, cleaning or storage.
- In order to avoid the risk of electric shock, the device must only be connected to a power supply with protective earthing.
- No changes may be made to the device.
- More extensive repairs that are not described in these instructions must only be carried out by the manufacturer.

#### EMC interferences

- When installing the Tourniquet Touch, the EMC requirements (EMC = electromagnetic compatibility) must be considered. The Tourniquet Touch meets the EMC requirements of IEC 60601-1-2. Equipment may possibly be used in the proximity of the Tourniquet Touch that does not have to comply with these EMC requirements during use and may therefore interfere with the Tourniquet Touch.
- If the Tourniquet Touch is in the proximity of a high-frequency surgical unit or a high-frequency shielded room, this may cause the Tourniquet Touch to malfunction. In case of interference with other HF surgical units, proceed as follows:
  1. Increase the distance between the Tourniquet Touch and the HF surgical equipment including the cable.
  2. The cable of the monopolar electrode and the neutral electrode of an HF surgical unit must be guided parallel and close to each other to the patient.
  3. Otherwise, contact the manufacturer of the HF surgical units.
- In case of faults via the in-house power supply network, decoupling must be carried out with the help of qualified personnel, e.g.:
  - Separate supply network for Tourniquet Touch and the other devices
  - Star-shaped wiring of the power supply
  - Star-shaped combination of the reference potentials of several units as well as the protective earth conductor or the earthing system
  - No common return conductor (e.g. PEN conductor)




## 5. SCOPE OF DELIVERY

	Tourniquet Touch TT15
	Coil Connecting Tubing, blue; stretched length 3.0 m; for cuff channel
	Coil Connecting Tubing, black; stretched length 3.0 m; for irrigation channel
	Plug for cuff channel
	Plug for irrigation channel
	Mains plug, Europe (all countries except for Great Britain and Switzerland) Type CEE 7 / XVII Cable label ID: 6051.2183
	Mains plug, Great Britain Type BS 1363 Cable label ID: 6051.2188
	Mains plug, Switzerland Type 12 SEV Cable label ID: 6051.2185
	Mains plug, Australia Type AS 3112 Cable label ID: 6051.2190
	Mains plug, China Type GB 2099 Cable label ID: 3-100-527
	Mains plug, Japan Type JIS 8303 Cable label ID: 6051.2191
	Mains plug, North America Type NEMA 5-15 Cable label ID: 6051.2181

The appropriate mains cable is supplied, depending on the country. Only use the enclosed cable. Other mains cables must not be used.

### Mains cable

The mains cable included in the delivery can be identified via the following features:

<ul style="list-style-type: none"> <li>V-Lock inlet connector for non-heating apparatus for Europe, Great Britain, Switzerland, Australia, China and Japan</li> </ul> 	<ul style="list-style-type: none"> <li>V-Lock inlet connector for non-heating apparatus for North America</li> </ul> 
<ul style="list-style-type: none"> <li>Cable label ID</li> </ul> 	

## 6. PRODUCT DESCRIPTION



- ① Screen with Touch screen function
- ② Optical alarm
- ③ On/Off button
- ④ Loudspeaker for alarm sound
- ⑤ Blue tube connection - cuff channel
- ⑥ Follow instructions for use
- ⑦ Black tube connection - irrigation channel



- ⑧ Handle
- ⑨ USB port
- ⑩ Connection for potential equalisation
- ⑪ Connection for the V-Lock inlet connector for non-heating apparatus
- ⑫ Type plate

**CAUTION**

- The manufacturer prohibits a network installation on the USB port.
- The USB port is for service purposes only.

### Handle

► Only carry the device by the handle intended for this purpose. The device can alternatively be shifted by the handle of the stand if it is mounted on the stand.

### Battery management

The device is equipped with a Li-Ion battery whose charging process is controlled by a battery management system.


The charging process is performed depending on the temperature and the state of charge to increase the shelf life of the battery. This means the charging time can significantly vary.

The battery is designed as a backup system of the device. In the event of a power supply interruption, all functions of the device are available. The device must generally be operated with the power supply.


To ensure a long battery shelf life and to avoid damage to the battery, the following criteria must be met:


- Observe the storage and operating conditions (see chapter „7. Device specifications / technical data“).
- If the device is not used and it has not been connected to the power supply, it must be recharged every 5 months. This prevents deep discharge of the battery. Do not switch on the device during charging.


## Battery status

If the device is connected to the power supply, the battery status of the device can be identified by means of the  button.

The device must generally be operated with the power supply.

 button is permanently lit: The device is ready for operation and has sufficient battery status.

 button flashes five times in succession upon being touched: The device is not ready for operation and has insufficient battery status. Connect the device to the power supply. The charging process can take a few minutes up to one hour.

 button is not lit: The device is not ready for operation and the battery is deeply discharged. Connect the device to the power supply. The charging process can take several hours.

## 7. DEVICE SPECIFICATIONS / TECHNICAL DATA

Weight:	4.5 kg (9.9 lbs) (without accessories included in delivery)		
Dimensions:	Height	186 mm (7 3/8 inch)	
	Width	263 mm (10 3/8 inch)	
	Depth	226 mm (8 7/8 inch)	
Software Version:	1.0		
Supply voltage:	100 - 240 VAC		
Supply frequency:	50 - 60 Hz		
Power consumption:	130 VA		
Mains fuse:	2x Littelfuse 215 Series: T2,5 AH, 250 V		
Battery type:	Lithium ion battery (14.4 V - 93.6 Wh)		
Battery backup runtime:	Approx. 8 h with full charge (battery as good as new) and in normal operation (Tourniquet / Pressure Infusion Cuff without leakage)		
Battery charging time:	Approx. 3 h with an ambient temperature of 20 °C (68 °F)		
Protection class (IEC 60601-1):	1 (Type B applied part *) * Device is defined as Type B applied part in means of IEC 60601-1. All requirements regarding applied parts (e.g. insulation against leakage currents) are implemented within the device.		
Operating pressure:	100 kPa		
Pressure range of cuff channel:	Settable from 80 - 500 mmHg in increments of 5 mmHg		
Pressure range of irrigation channel:	Settable from 50 - 300 mmHg in increments of 10 mmHg		
Pressure control:	0 / +5 mmHg (from target value)		
Display accuracy:	±5 mmHg		
Alarm time:	Adjustable from 15 - 120 min in increments of 5 minutes (acoustic & optic)		
Pressure alarm:	Acoustic and optic		
Alarm volume:	60 - 88 dB (A) at 1 m distance		
Device surface, that are likely to be touched by the user:	Case	t < 1 minute	T <sub>max</sub> = 55 °C (131 °F)
	Display (glass)	t < 10 seconds	T <sub>max</sub> = 52 °C (125.6 °F)
Connection:	Blue Coil Connecting Tubing with positive locking connectors Black Coil Connecting Tubing with male Luer lock and female positive locking connectors		
Display:	8" WVGA (800 x 480 pixel) TFT with LED backlight		
Touch sensor:	capacitive, responds to touch		
Transport conditions:	Temperature:	-20 to +60 °C (-4 to +140 °F)	
	Humidity:	5 to 95% relative humidity, non-condensing	
	Ambient pressure:	70 to 106 kPa	
Storage and operating conditions:	Temperature:	+10 to +35 °C (+50 to +95 °F)	
	Humidity:	30 to 95% relative humidity, non-condensing	
	Ambient pressure:	70 to 106 kPa	
Conversion of pressure units:	1 hPa = 1,01973 cmH <sub>2</sub> O = 0,75006 mmHg		

## 8. MOBILE STAND

A mobile stand with basket is optionally available from the manufacturer.



### CAUTION

- To prevent slipping or tilting of the Mobile Stand during transport, the instruction of use 004-01-0336 - Mobile Stand, chapter "Transport conditions" must be observed.
- If the following instructions are not followed, personal injury or damage to property could result.




























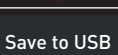
The Mobile Stand with mounted Tourniquet Touch device may only be transported under the following conditions:

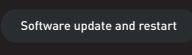



- ▶ The mains cable must be attached to the stacking plate behind the Tourniquet Touch device.
- ▶ The loading of the basket must be arranged evenly.
- ▶ The baskets must not be loaded beyond their top level.
- ▶ The connection tubings of the Tourniquet Touch device must be attached to the lateral openings of the stacking plate.
- ▶ Push the device only by the handle of the mobile stand.
- ▶ To prevent the Mobile Stand from moving, lock all castors. If not all castors are locked, the Mobile Stand can move unintentionally.

## 9. BUTTONS AND SYMBOLS











### Buttons

The button colours vary, depending on session or cuff / irrigation channel. The function of the buttons is not changed thereby.













	On/Off button
	Audio paused (Alarm)
	Settings
	Inflate
	Slider; to deflate, shift the  button to the left within 2 seconds
	History
	Close window
	Up selection button
	Down selection button
	Left selection button
	Right selection button
	Increase / reduce value
	Fast choice button (the values can vary)
	Presetting for pressure and alarm time
	Volume and alarm tone
	Brightness
	Calibration
	Date / Time
	Data Exchange
	System Check
	Language
	Reduce / increase volume
	Set alarm tone
	Reduce / increase brightness
	Confirm
	Close
	Save log file to USB

	Install software update and restart the device
 	Calibration Increase / reduce pressure by 50 mmHg
	Perform self test or leak test

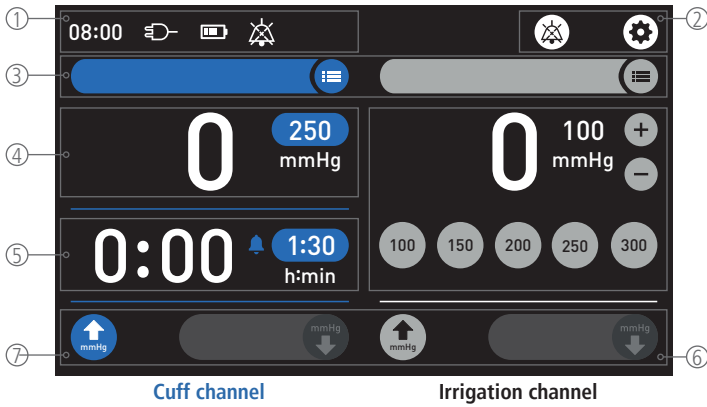
### Status display symbols

	Power supply is on
	Power supply interrupted
	Battery status 80 - 100 %
	Battery status 60 - 80 %
	Battery status 40 - 60 %
	Battery status 20 - 40 %
	Battery status 10 - 20 %
	Battery status 0 - 10 %
	No battery / battery defective
	Audio paused (Alarm) activated

### Further symbols

	Self test
	Manual self test successfully completed
	Warning
	Alarm time
	Log file
	USB
	Saved to USB
	No USB connected
	USB error
	USB full
	Tourniquet Touch
	Tourniquet Touch power supply interruption

## 10. MAIN SCREEN

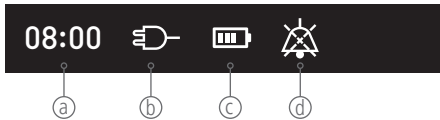













The main screen is divided up into ① status bar, ② control bar, ③ channel bar, ④ pressure display (cuff channel), ⑤ time display (cuff channel), ⑥ pressure display (irrigation channel) and ⑦ inflation / deflation area.

The cuff channel and the irrigation channel each have their own separate compressed air circuit. Both channels can be operated separately from each other.

### ① Status bar

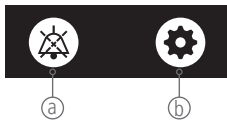
This bar displays information about the device status. No settings are possible.



① Time:	The field displays the current time.
② Power supply:	The field indicates the status of the power supply.  Power supply is on  Power supply interrupted
③ Battery status:	The field indicates the status of the battery.  Battery status 80 - 100 %  Battery status 60 - 80 %  Battery status 40 - 60 %  Battery status 20 - 40 %  Battery status 10 - 20 %  Battery status 0 - 10 %  No battery present or battery defective
④ Audio paused (Alarm):	The field indicates the status Audio paused (Alarm).  is displayed for 30 seconds if the  button was activated during an alarm. The optical alarm remains active.

### ② Control bar

This bar contains buttons, by means of which functions are activated or deactivated, or the window is opened for settings.



① Audio paused (Alarm):	By activating the button, the alarm is switched to paused for 30 seconds. The button is only displayed in the control bar when there is an alarm.
② Settings:	Button opens the window for settings. The button is hidden in the control bar when the Tour-niquet / Pressure Infusion Cuff has been inflated.

### ③ Channel bar

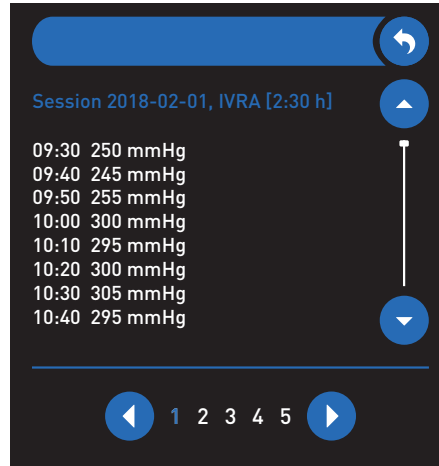
This bar contains buttons which open or close a window.

This bar also displays current error messages (see chapters „14. Alarms“ and „15. Trouble-shooting“). When the window is opened, the respective button is hidden. No settings are possible.








① History:	The button opens the history window. The button is hidden in the control bar when the Tour-niquet / Pressure Infusion Cuff has been inflated.
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- ▶ Select  button for the history.



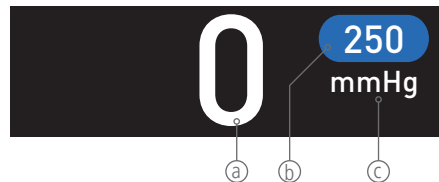
The window is opened.

The last 5 sessions for this cuff / irrigation channel are stored in the history.

- ▶ Use the two  /  buttons to select the session.
- ▶ Within the session, use the  button to scroll up and the  button to scroll down.
- ▶ Use the  button to close the window.

### ④ Pressure display (cuff channel)

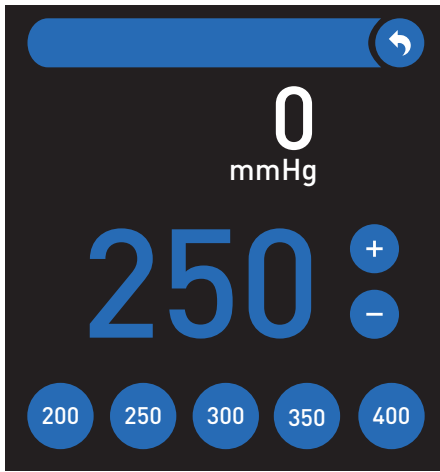
In this operating field, the preset pressure can be adjusted prior to and during the session.



① Actual pressure:	current pressure (control precision +5 mmHg)
② Preset pressure:	preset pressure
③ Unit:	mmHg

- ▶ Select operating field.





The window is opened.

▶ Select a fast choice button in the bottom line.

▶ If necessary, increase the preset pressure in increments of 5 mmHg using the **+** button, or reduce it in increments of 5 mmHg using the **-** button.

The value that has been set is implemented immediately.

If no further entry is made, the operating field is closed automatically after 3 seconds.

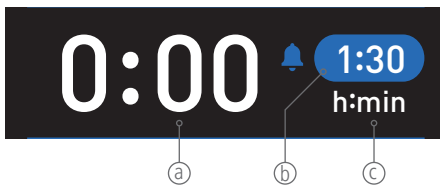
▶ Alternatively, use the **↶** button to close the field.

**NOTE**

If no change is made after opening the operating field, then the window is closed automatically after 5 seconds.

**5 Time display (cuff channel)**

In this operating field, the alarm time can be adjusted prior to and during the session.

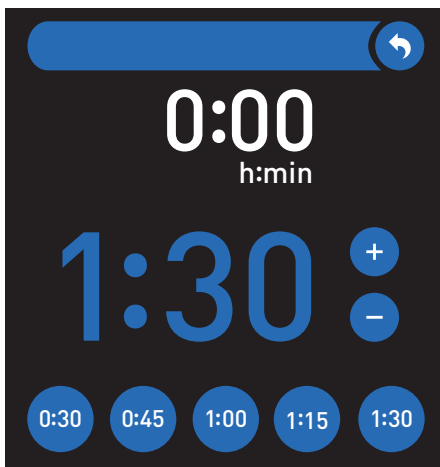


**a** Timer: expired inflation time

**b** Alarm time: planned inflation time

**c** Unit: h:min

▶ Select operating field.



The window is opened.

▶ Select a fast choice button in the bottom line.

▶ If necessary, increase the alarm time in increments of 5 minutes using the **+** button, or reduce it in increments of 5 minutes using the **-** button.

The value that has been set is implemented immediately.

If no further entry is made, the operating field is closed automatically after 3 seconds.

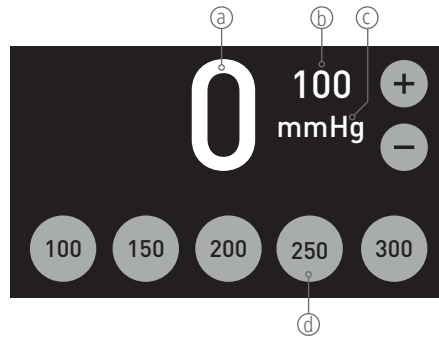
▶ Alternatively, use the **↶** button to close the field.

**NOTE**

If no change is made after opening the operating field, then the window is closed automatically after 5 seconds.

**6 Pressure display (irrigation channel)**

In this operating field, the preset pressure can be adjusted prior to and during the session.



**a** Actual pressure: current pressure

**b** Preset pressure: preset pressure

**c** Unit: mmHg

**d** Fast choice button: -

▶ Select a fast choice button in the bottom line.

▶ If necessary, increase the preset pressure in increments of 10 mmHg using the **+** button, or reduce it in increments of 10 mmHg using the **-** button.

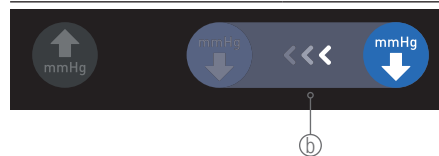
The value that has been set is implemented immediately.

**7 Inflation / deflation area**

In this operating field, the Tourniquet / Pressure Infusion Cuff is inflated or deflated.




**a** Inflation button: Inflates the Tourniquet / Pressure Infusion Cuff.

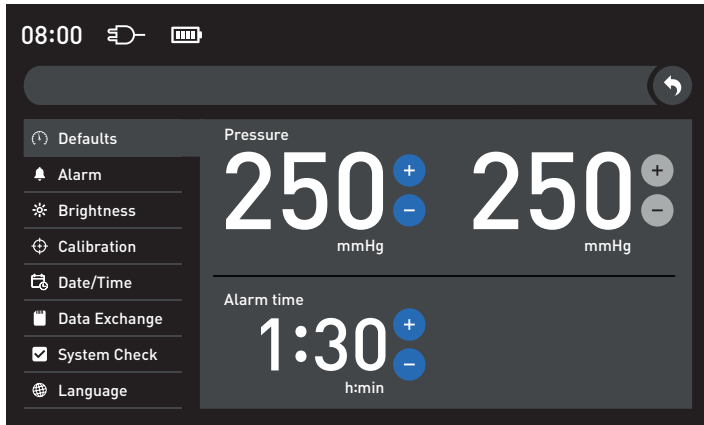


**b** Slider for deflation: Deflates the Tourniquet / Pressure Infusion Cuff.  
▶ Shift the slider completely over to the left within 2 seconds using the **mmHg** button.

## 10.1 SETTINGS

- ▶ Activate the  button to open the window for settings.

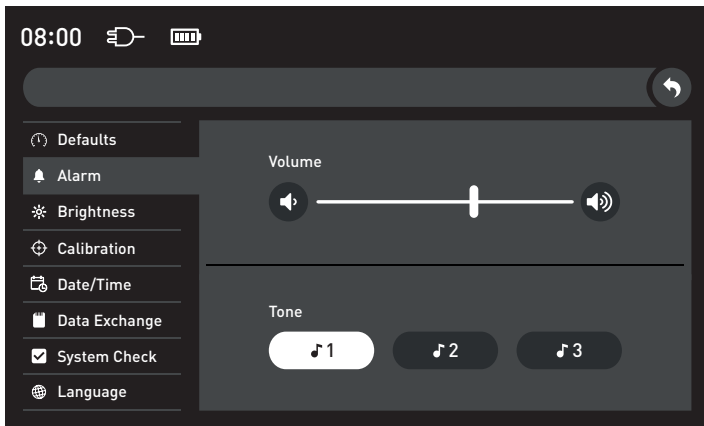
### Presetting for pressure and alarm time



- ▶ Increase the values using the  button, or reduce them using the  button. The values are adopted in the main screen when the device is restarted.

	Setting range
Cuff channel pressure	150 - 400 mmHg in increments of 5 mmHg
Irrigation channel pressure	50 - 300 mmHg in increments of 10 mmHg
Alarm time	00:15 - 1:30 h:min in increments of 5 minutes

### Volume and tone

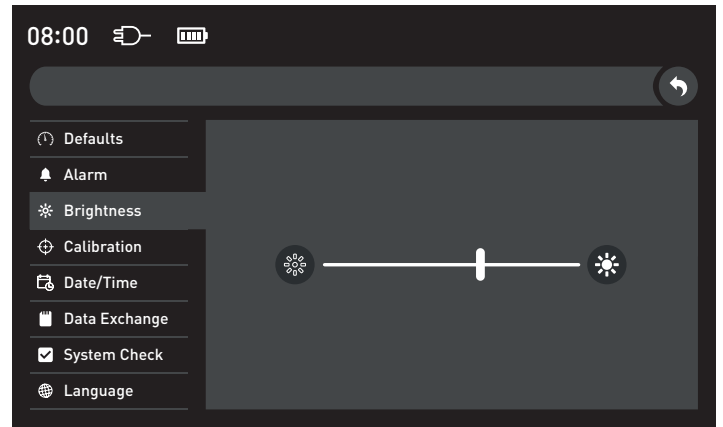





#### WARNING

- Adjust the alarm according to the ambient conditions.
- The alarm must be clearly audible by the user in the room.
- The alarm must be different from the devices of other manufacturers.
- The loudspeaker for the alarm is automatically checked when the device is switched on.

- ▶ Select "Alarm" operating field.
- ▶ Set the volume using the  /  button or the controller.
- ▶ Select the tone using the  /  /  button.

## Brightness



- ▶ Select the "Brightness" operating field.
- ▶ Set the brightness using the  /  button or the controller.
- ▶ Use the  button to close the window.

The "Calibration", "Date/Time", "Data Exchange", "System Check" and "Language" operating fields are described in chapter „17. Maintenance“.

## 11. START-UP



- The device must generally be operated with the power supply. The power supply must be equipped with protective earthing.
- The potential equalisation compensates for the potential of different metal parts which can be touched simultaneously or reduces potential differences which can arise between bodies, electromedical devices and foreign conductive parts in case of use.
  - ▶ Connect the potential equalisation (POAG) ① of the device according to DIN 42801 to the POAG of the room with a POAG connection cable.
  - ▶ If a medical electrical system is installed by the operator, the IEC 60601-1, clause 16. ME systems must be followed.
  - ▶ Insert the mains cable into the socket ② and connect it to the power supply.



### CAUTION

Perform self test without connected Tourniquet / Pressure Infusion Cuff.

- ▶ Switch the device on with the  button. Switch on the device with the button by touching the button until the device starts.
- ▶ Do not touch the screen during the self test.



The device then triggers an optical alarm ③ and an alarm sound ④.



### CAUTION

If the visual alarm and the alarm sound do not go off, restart the device. If the error occurs again, contact the manufacturer.



The device automatically performs a self test when it is switched on. This takes approx. 30 seconds.

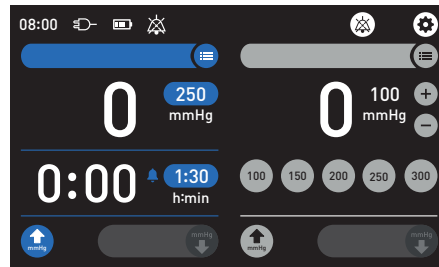
The following functions are checked in the self test:

- Internal safety features
- Voltages and device temperature
- Primary and secondary compressed air supply for cuff channel and irrigation channel
- All data storage devices
- Battery
- Software and hardware versions
- All audible alarm systems



### CAUTION

In the event of non-stop operation, the device must be restarted at least once a day in order to ensure the function and safety of the device.



If the self test was successful, the main screen is shown on the screen.

- ▶ If error messages are displayed, remedy the errors as described in chapter „15. Troubleshooting“.
- ▶ Perform a functional check prior to each session (see chapter „12. Functional Check“).

## 12. FUNCTIONAL CHECK




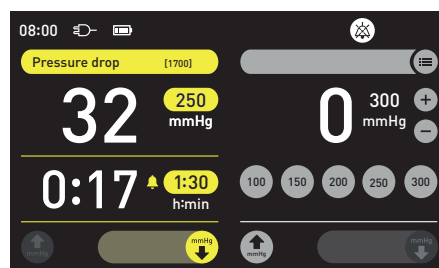
### Cuff channel



### CAUTION


- Do not use any damaged Single Cuffs or Coil Connecting Tubings.
- Do not kink Coil Connecting Tubings or cuff tubes.
- Use the correct cuff size for the respective extremity.
- The cuff tube must always be connected to the device with only **one** Coil Connecting Tubing. All tube connections must snap firmly into place.

- ▶ Connect the blue Coil Connecting Tubing to the cuff channel.
  - ▶ Select the Single Cuff that is required for the session.
  - ▶ Tightly roll-up the Single Cuff to enable a counter-pressure to build up when the Single Cuff is inflated.
  - ▶ Connect the cuff tube to the blue Coil Connecting Tubing.
  - ▶ Inflate the Single Cuff with the button .
- The entire system must be free of any air leakage.
- ▶ If the device signals an error, then the function test must be repeated with another Single Cuff.
  - ▶ To check the alarm system, disconnect the connection between the cuff tube and the cuff channel to be tested.



An error is displayed in the channel bar. The cuff channel alternates between yellow and the channel colour.

The optical alarm is displayed to the left of the main screen and an alarm tone is generated.

- ▶ Reconnect the cuff tube to the blue Coil Connecting Tubing.
- ▶ Deflate the Single Cuff with the slider .



### CAUTION

If the device fails to pass the functional check, restart the device. If the error occurs again, contact the manufacturer. As long as the error has not been corrected, the device must not be put into operation.

### Irrigation channel

#### NOTE

No functional check is required for the irrigation channel.

### 13. APPLICATION



#### CAUTION

- Prior to each session of the device, a functional check must be performed for the entire system (see chapter „12. Functional Check“).
- If problems occur, restart the device. If the error occurs again, contact the manufacturer.
- The user must be at a distance of max. 3 m from the device and the view to the display must not be obstructed by other objects.
- Regarding the duration of the bloodless field, established scientific guidelines must be followed. A max. of 2 hours is normally recommended.
- The use of a pneumatic Tourniquet can increase the risk of post operative distal Deep Vein Thrombosis after Total Knee Arthroplasty. The decision whether to use a Tourniquet for a particular application rests with the physician.
- In order to ensure a safe bloodless field while avoiding exposure of the patient to unnecessary stress, an appropriate Single Cuff preset pressure must be selected, depending on the cuff size, the extremity and the systolic blood pressure.
- The user must check the current pressure of the Single Cuff at regular intervals. If the preset pressure deviates from the current Single Cuff pressure, then appropriate action must be taken in response.
- Use the correct cuff size for the respective extremity.
- Alarms with high priority must be remedied as quickly as possible (see chapter „14. Alarms“).

In case of a system failure of the device, the pressure in the Tourniquet Single Cuff is maintained.

#### NOTE

Various Tourniquet Cuffs (see chapter „22. Article numbers“) are available from the manufacturer for the following use. The instructions for use (G1033 - Tourniquet Cuffs for single use, G1046 - Tourniquet Cuffs reusable or 004-01-0349 - Tourniquet Wipe Cuff) must be observed, in particular the chapters Use, Reprocessing and Disposal.

#### 13.1 BLOODLESS FIELD WITH SINGLE CUFF

- ▶ Follow applied parts (see chapter „22. Article numbers“, column “Applied parts for: chapter “13.1 Use with Single Cuff“”).
- ▶ Apply the Single Cuff to the extremity.

The manufacturer recommends session of padding underneath the Single Cuff.

- ▶ Connect the cuff tube to the blue Coil Connecting Tubing.

If necessary, adjust the preset pressure in the pressure display and the alarm time in the time display.

- ▶ Generate a bloodless field up to the already applied single cuff.

- ▶ Inflate the Single Cuff with the button

The current pressure is displayed in the operating field. If necessary, it can be adjusted in the operating field.

- ▶ Start the procedure. During the procedure, the current pressure must be monitored all the time.

The elapsed inflation time and the planned inflation time are displayed in the time display.



#### NOTE

When the alarm time is reached, the device generates an alarm sound, an optical alarm and a pop-up window with yellow frame opens. The alarm time can be extended in the pop-up window.

- ▶ After the session, completely deflate the Single Cuff with the slider
- ▶ Immediately remove the Single Cuff and the padding underneath it from the extremity in order to prevent the risk of venous congestion.
- ▶ Disconnect the cuff tube from the Coil Connecting Tubing.
- ▶ If desired, switch the device off with the
- ▶ The manufacturer recommends to disinfect the device after each use in order to reduce the risk of contamination (see chapter „19. Wipe disinfection“).

#### 13.2 IRRIGATION WITH PRESSURE INFUSION CUFF

- ▶ Follow applied parts (see chapter „22. Article numbers“, column “Applied parts for: chapter “13.2 Irrigation with Pressure Infusion Cuff“”).
- ▶ Connect the black Coil Connecting Tubing to the irrigation channel.
- ▶ Insert the irrigation solution into the Pressure Infusion Cuff.
- ▶ Connect the cuff tube of the Pressure Infusion Cuff to the black Coil Connecting Tubing. If necessary, adjust the preset pressure in the operating field for the irrigation channel.

- ▶ Inflate the Pressure Infusion Cuff with the button

The current pressure is displayed in the operating field. If necessary, it can be adjusted in the operating field.

- ▶ Start the procedure. During the procedure, the current pressure must be monitored all the time.

- ▶ After the session, completely deflate the Pressure Infusion Cuff with the slider



- ▶ Disconnect the cuff tube of the Pressure Infusion Cuff from the black Coil Connecting Tubing.

- ▶ If desired, switch the device off with the
- If desired, switch off the device with the button by touching the button until the main screen turns black. The device can now be disconnected from the power supply.

- ▶ The manufacturer recommends to disinfect the device after each use in order to reduce the risk of contamination (see chapter „19. Wipe disinfection“).

## 14. ALARMS

The device is equipped with an alarm system. The alarms must be remedied immediately to ensure patient safety.

If an alarm has been corrected or the reason for an alarm no longer exists, the alarm is automatically deleted. In case a further alarm is present, the alarm of the same priority or the next higher priority is displayed.

The battery is designed as a backup system of the device. The alarm system continues to monitor all functions of the device in the event of a power failure. The device must generally be operated with the power supply.



- ① Channel bar
- ② Optical alarm
- ③ Screen with Touch screen function
- ④ Loudspeaker for acoustic alarm
- ⑤ Status for Audio paused (Alarm)
- ⑥ Button for Audio paused (Alarm)

### 14.1 COMPOSITION AND PRIORITY OF THE ALARM

The alarm consists of the following components:

- Alarm sound ④
- Optical alarm ②
- Channel bar ① or pop-up window

If an alarm is present, all components of the alarm are active. In addition, the respective error message is displayed in the channel bar or in the pop-up window. The alarms are classified in priorities according to the severity and urgency of the alarm in priorities (high, medium and low) (see chapter „15. Troubleshooting“).



#### WARNING

- ▶ Adjust the alarm according to the ambient conditions (see chapter „10.1 Settings“).
- ▶ If the alarm is still not audible, the user must constantly monitor the optical alarm ② and the display ③. This is the only way to detect the alarm and take appropriate countermeasures.



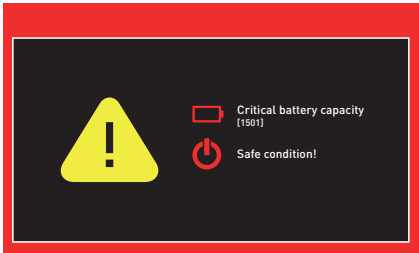





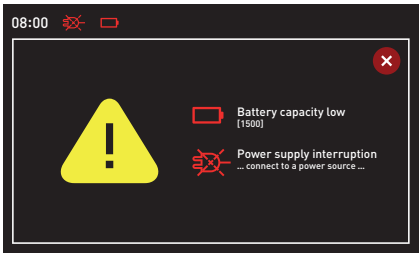


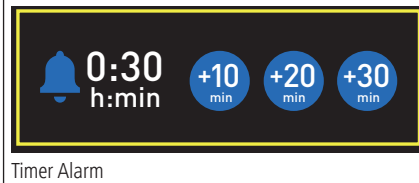
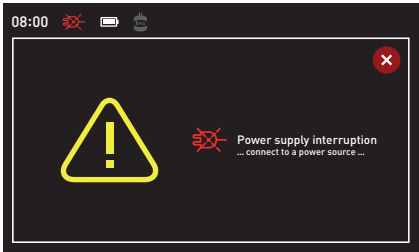

#### CAUTION

Alarms with high priority must be resolved as quickly as possible.

#### NOTE

- The user is shown the alarm on the display with Touch screen function (channel bar ① or pop-up window) and above the optical alarm ②. In addition, the acoustic alarm ④ is activated via the loudspeaker.
- If several alarms occur simultaneously, the alarm tones and visual alarms may overlap.

Priority	Alarm sound	Optical alarm	Additional alarm	
			Channel bar Alarm for one channel or both channels (global alarm)	Pop-up window (example picture)
High	10 alarm tones every 3 seconds	 Red flashing light		
High	Alarm tone every second	 Red permanent light	-	-

Priority	Alarm sound	Optical alarm	Additional alarm	
			Channel bar Alarm for one channel or both channels (global alarm)	Pop-up window (example picture)
Medium	3 alarm tones every 4 seconds	 Yellow flashing light		
Low	2 alarm tones every 16 seconds	 Yellow permanent light		
None, the message is a notice	-	-	-	
Additional information	-	-	The channel switches colour every second (from yellow to the respective channel colour). (a) Error indicator (b) Error description (c) Error number	 Acknowledgeable error

The detailed error description along with error rectification is given in chapter „15. Troubleshooting“.


### 14.2 ALARM TIME EXCEEDED (TIMER ALARM)

If the set alarm time is reached during use, the device creates an alarm sound, an optical alarm and a pop-up window with a yellow frame opens. The alarm time can be extended in the pop-up window.

### 14.3 INTERRUPTING THE ALARM SOUND

The Audio paused (Alarm) button is only activated when there is an alarm.

- ▶ Use the  button to switch the alarm sound to paused.

The alarm sound is switched to paused for 30 seconds. The symbol  is displayed in the status bar for 30 seconds. The optical alarm and the channel bar **or** the pop-up window are continued to be displayed. If the alarm has not been remedied, then the alarm sound is reactivated after 30 seconds.

- If the alarm sound of the first alarm is interrupted and meanwhile another alarm is active, another alarm with a lower priority will be reactivated 30 seconds from the first alarm. If it is an alarm of the same or higher priority alarm, the alarm sound is activated without the 30 second interruption.
- If several alarms are present, the display shows the alarm with the highest priority.
- If an alarm with the highest priority no longer exists, the next with the highest priority is displayed. As soon as no alarm with highest priority is present, the next lowest alarm is displayed.

## 15. TROUBLESHOOTING

### 15.1 SELF TEST

Error message	Fault / failure	Cause	Fault remediation
0x00000001	A leak was detected in the system.	The self test is at the limit of the lower tolerance.	<ul style="list-style-type: none"> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
0x00000008	Maximum pressure check has failed.	Pump does not reach the required pressure.	<ul style="list-style-type: none"> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
0x00400000	Internal device temperature out of range.	Internal device temperature > 55 °C or < 5 °C.	<ul style="list-style-type: none"> <li>▶ Adjust the device to room temperature and disconnect it from the power supply.</li> <li>▶ Connect the device to the power supply and restart.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
0x00000400, 0x00001000, 0x00001400	The device detects that a Tourniquet / Pressure Infusion Cuff is connected.	Tourniquet / Pressure Infusion Cuff is connected to the device.	<ul style="list-style-type: none"> <li>▶ Disconnect the Tourniquet / Pressure Infusion Cuff from the device.</li> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
0x00020000	Unexpected internal device status or internal connection problems.	Internal timing deviations or internal defects.	<ul style="list-style-type: none"> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>


Contact the manufacturer for all other error messages.

### 15.2 USE






Error message (cuff channel / irrigation channel)	Priority	Fault / failure	Cause	Fault remediation
1000 / 1001, 1020 / 1021	Medium	Technical failure	-	<ul style="list-style-type: none"> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1300	High	Device temperature high	Device temperature > 65 °C (+149 °F)	<ul style="list-style-type: none"> <li>▶ Terminate the procedure as quickly as possible while continuously monitoring the device.</li> <li>▶ Switch off the device after the procedure.</li> <li>▶ Allow the device to cool down and disconnect it from the power supply.</li> <li>▶ Connect the device to the power supply and restart.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1301	High	Technical failure	-	<ul style="list-style-type: none"> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1302 / 1303	Low			
1400 - 1413	High			
1500	Medium	State of charge of battery low	The device has insufficient battery status. The remaining operating time is approx. 10 minutes.	<ul style="list-style-type: none"> <li>▶ Connect the device to the power supply.</li> </ul>
1501	High	State of charge of battery critical	The device has insufficient battery status. The remaining operating time is approx. 2 minutes.	<ul style="list-style-type: none"> <li>▶ Connect the device to the power supply.</li> </ul>
1502	Medium	Battery failure	No battery connection.	<ul style="list-style-type: none"> <li>▶ Terminate the procedure as quickly as possible while continuously monitoring the device.</li> <li>▶ Switch off the device after the procedure.</li> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1503	High	Battery temperature too high	Battery temperature > 60 °C (+140 °F)	<ul style="list-style-type: none"> <li>▶ Terminate the procedure as quickly as possible.</li> <li>▶ Switch off the device after the procedure.</li> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1504	High	Technical failure	-	<ul style="list-style-type: none"> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1505	Low			
1600	Medium	Timer expired	Timer exceeds the alarm time and the session is taking longer than 90 minutes.	<ul style="list-style-type: none"> <li>▶ Extend the alarm time and terminate the application as quickly as possible.</li> </ul>
1602	Low	Timer expired	Timer exceeds the alarm time and the session is taking less than 90 minutes.	<ul style="list-style-type: none"> <li>▶ Extend the alarm time.</li> </ul>
1700 / 1701	High	Pressure drop	Pressure drop > 50 mmHg Leakage in the Coil Connecting Tubing, the Tourniquet / Pressure Infusion Cuff or the connections.	<ul style="list-style-type: none"> <li>▶ Check all connections and connect if necessary.</li> <li>▶ If the pressure loss still persists, replace the Coil Connecting Tubing or the Tourniquet / Pressure Infusion Cuff.</li> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1702	High	High pressure	High pressure > 15 mmHg persists since at least 60 seconds. The position of the Tourniquet Cuff has changed during the procedure.	<ul style="list-style-type: none"> <li>▶ Check pressure and position of the Tourniquet Cuff.</li> <li>▶ Monitor pressure.</li> <li>▶ In the event of too high pressure, switch cuff channel or use another device.</li> </ul>
1704	Medium	High pressure	High pressure > 15 mmHg persists since 6 - 60 seconds. The position of the Tourniquet Cuff has changed during the procedure.	<ul style="list-style-type: none"> <li>▶ Check pressure and position of the Tourniquet Cuff.</li> <li>▶ Monitor pressure.</li> </ul>

Error message (cuff channel / irrigation channel)	Priority	Fault / failure	Cause	Fault remediation
1705	Medium	High pressure	High pressure > 15 mmHg persists since 60 seconds. The position of the Pressure Infusion Cuff has changed during the procedure.	<ul style="list-style-type: none"> <li>▶ Check pressure and position of the Pressure Infusion Cuff.</li> <li>▶ Monitor pressure.</li> </ul>
1706	High	Low pressure	Low pressure > 15 mmHg persists since at least 60 seconds. The position of the Tourniquet Cuff has changed during the procedure.	<ul style="list-style-type: none"> <li>▶ Check Tourniquet Cuff and all connections.</li> <li>▶ If the low pressure still persists, replace the Tourniquet Cuff.</li> </ul>
1708	Medium	Low pressure	Low pressure > 15 mmHg persists since 6 - 60 seconds. The position of the Tourniquet Cuff has changed during the procedure.	<ul style="list-style-type: none"> <li>▶ Check Tourniquet Cuff and all connections.</li> </ul>
1709	Medium	Low pressure	Low pressure > 15 mmHg persists since 60 seconds. The position of the Pressure Infusion Cuff has changed during the procedure.	<ul style="list-style-type: none"> <li>▶ Check Pressure Infusion Cuff and all connections.</li> </ul>
1710 / 1711	Low	Leakage	Device has a higher activity than expected. Leakage is larger than expected.	<ul style="list-style-type: none"> <li>▶ Finish the procedure as normal.</li> <li>▶ After completion of the procedure, check the Tourniquet / Pressure Infusion Cuff and the Coil Connecting Tubing.</li> <li>▶ Then perform a leak test on the device.</li> </ul>
1712	Low	No Tourniquet Cuff	Pressure build-up not possible within 20 seconds off inflation.	<ul style="list-style-type: none"> <li>▶ Connect Tourniquet Cuff to the cuff channel via the Coil Connecting Tubing.</li> <li>▶ Check all connections and connect if necessary.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1713	Low	No Pressure Infusion Cuff	Pressure build-up not possible within 70 seconds off inflation.	<ul style="list-style-type: none"> <li>▶ Connect Pressure Infusion Cuff to the irrigation channel via the Coil Connecting Tubing.</li> <li>▶ Check all connections and connect if necessary.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1714 / 1715	Low	Deflate failure	When the Tourniquet / Pressure Infusion Cuff is deflated, the pressure does not drop as quickly as expected.	<ul style="list-style-type: none"> <li>▶ Disconnect the Tourniquet / Pressure Infusion Cuff from the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1800 / 1801	Low	Technical failure	-	<ul style="list-style-type: none"> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1802 / 1803	Low	Technical failure	Internal error of the device.	<ul style="list-style-type: none"> <li>▶ Terminate the procedure as quickly as possible while continuously monitoring the device.</li> <li>▶ Switch off the device after the procedure.</li> <li>▶ Perform the functional check outside the application room (see chapter „12. Functional Check“).</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
			HF surgical equipment including cable (e.g. cable of the monopolar electrode and neutral electrode) were placed too close to or on the Tourniquet Touch.	<ul style="list-style-type: none"> <li>▶ Terminate the procedure as quickly as possible while continuously monitoring the device.</li> <li>▶ Switch off the device after the procedure.</li> <li>▶ Perform the functional check outside the application room (see chapter „12. Functional Check“).</li> <li>▶ In the application room, check the power supply network and increase the distance between the Tourniquet Touch and the HF surgical equipment including the cable. If necessary, use a different connector strip.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
1900	High	Technical failure	-	<ul style="list-style-type: none"> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
2000 / 2001	Low	Sensor error	Sensor deviation	<ul style="list-style-type: none"> <li>▶ Terminate the procedure as quickly as possible while continuously monitoring the device.</li> <li>▶ Switch off the device after the procedure.</li> <li>▶ Perform the calibration outside the application room (see chapter „17.1.1 Calibration“).</li> <li>▶ If the discrepancy is greater than +/- 5 mmHg, immediately label the device as defective and contact the manufacturer.</li> </ul>
2002 / 2003	High			



Optical alarm	Priority	Fault / failure	Cause	Fault remediation
 Red permanent light	High	This error message can be displayed in combination with other error messages in this table (see chapter „14.1 Composition and priority of the alarm“).		
		Technical failure	Internal error of the device.	<ul style="list-style-type: none"> <li>▶ Terminate the procedure as quickly as possible while continuously monitoring the device.</li> <li>▶ Switch off the device after the procedure.</li> <li>▶ Perform the functional check outside the application room (see chapter „12. Functional Check“).</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
		Devices interfere with the Tourniquet Touch (e.g. EMC interference).	HF surgical equipment including cable (e.g. cable of the monopolar electrode and neutral electrode) were placed too close to or on the Tourniquet Touch.	<ul style="list-style-type: none"> <li>▶ Terminate the procedure as quickly as possible while continuously monitoring the device.</li> <li>▶ Process the error messages.</li> <li>▶ Switch off the device after the procedure.</li> <li>▶ Perform the functional check outside the application room (see chapter “12. Functional check”).</li> <li>▶ In the application room, check the power supply network and increase the distance between the Tourniquet Touch and the HF surgical equipment including the cable. If necessary, use a different connector strip.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>

### 15.3 GENERAL ERRORS

Fault / failure	Cause	Fault remediation
The device cannot be operated or the Tourniquet / Pressure Infusion Cuff cannot be deflate.	Defect device	<ul style="list-style-type: none"> <li>▶ Terminate the procedure as quickly as possible.</li> <li>▶ Disconnect the connection between the cuff tube and the cuff / irrigation channel.</li> <li>▶ Switch off the device with the  button.</li> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul>
The device cannot be switched on.	Defective fuse	▶ Replace the fuse (see chapter „17. Maintenance“).
	The device is not connected to the power supply. The battery is deeply discharged.	▶ Connect the device to the power supply. The charging process can take several hours.
 button flashes five times in succession	The device has insufficient battery status. The device is not ready for operation.	▶ Connect the device to the power supply. The charging process can take a few minutes up to one hour.
The device cannot be switched off.	Tourniquet Cuff is inflated.	<ul style="list-style-type: none"> <li>▶ Deflate the Tourniquet Cuff with the slider .</li> <li>▶ Disconnect the Tourniquet Cuff from the device.</li> <li>▶ Switch off the device with the  button.</li> </ul>
The device switches on and off by itself.	The device is located near an HF surgical unit or an HF shielded room.	▶ Observe the safety instructions for EMC interference (see chapter “Safety information”).
The touch screen does not work.	The device is located near an HF surgical unit or an HF shielded room.	▶ Observe the safety instructions for EMC interference (see chapter “Safety information”).
	An object is placed on the touch screen for a long time. The touch screen is being calibrated.	<ul style="list-style-type: none"> <li>▶ Remove the object from the touch screen.</li> <li>▶ Switch off the device with the  button.</li> <li>▶ Restart the device.</li> </ul>
	Touch screen is operated from the side.	▶ Operate the touch screen from the front.

## 16. EMC TABLE

The device complies with the standards specified in the table.

### Emissions test

Phenomenon	Basic EMC standard or test method	Group / Class / Test parameters
Mains terminal interference voltage / current	CISPR-11	Group 1 - Class A 0,15 MHz - 30 MHz
Radiated electromagnetic field	CISPR-11 CISPR-32	Group 1 - Class A 30 MHz - 1000 MHz 1 GHz - 6 GHz
Harmonic interference	IEC 61000-3-2	Class A
Flicker	IEC 61000-3-3	230 V / 50 Hz

### Immunity test

Phenomenon	Basic EMC standard or test method	Immunity test levels
Electrostatic discharge (ESD)	IEC 61000-4-2	Contact discharge: $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV  Air discharge: $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV
Radiated, radio-frequency, electromagnetic field	IEC 61000-4-3	10 V/m 80 MHz - 2,7 GHz AM 80% at 1 kHz
Electrical fast transient (Burst)	IEC 61000-4-4	$\pm 1$ kV, $\pm 2$ kV Burst frequency 5 / 100 kHz
Surge voltages (line-to-line)	IEC 61000-4-5	$\pm 0,5$ kV, $\pm 1$ kV
Surge voltages (line-to-ground)	IEC 61000-4-5	$\pm 0,5$ kV, $\pm 1$ kV, $\pm 2$ kV
Conducted disturbances, inducted by radio frequency field	IEC 61000-4-6	10 V 0,15 MHz - 80 MHz 80 % AM at 1 kHz

## MAINTENANCE AND DIAGNOSIS

Repairs which are not described in these instructions must only be carried out by the manufacturer or by persons authorized by the manufacturer.

The information required for this is provided to the authorised person in a separate servicing manual.

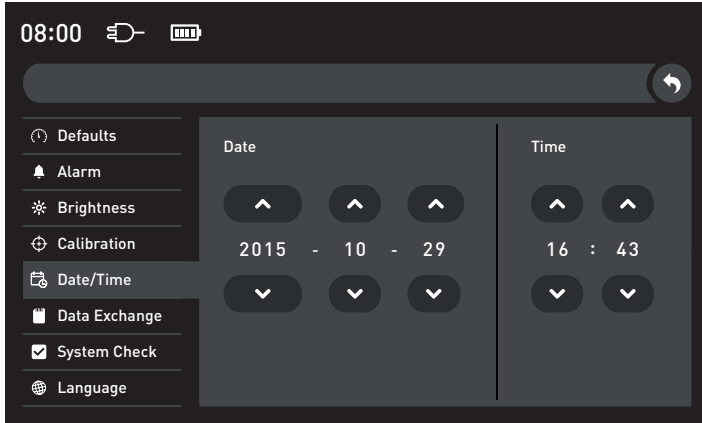
### 17. MAINTENANCE

After servicing the medical device, the structural and functional features essential for safety and functionality must be checked.

Only the tasks specified in these instructions for use may be carried out.

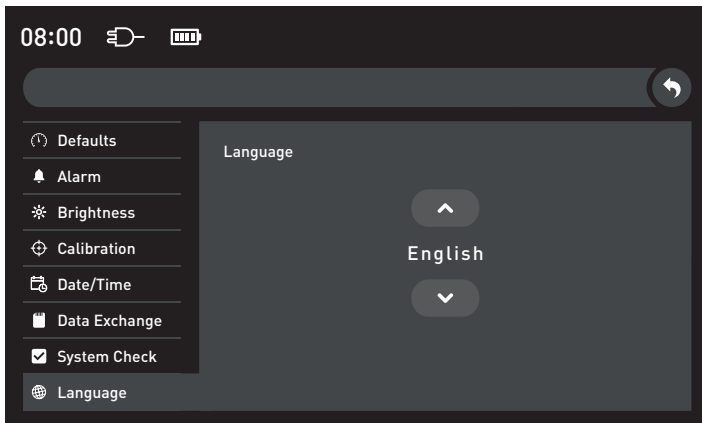
If any other tasks are performed on the medical device, all warranty claims are rendered invalid.

#### Setting date / time



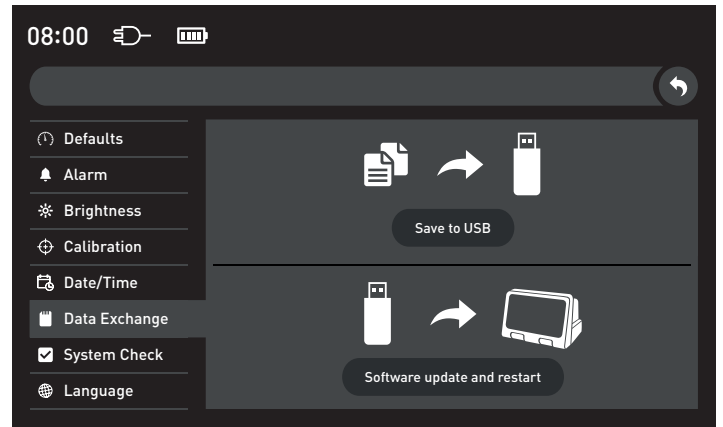
- ▶ Set the date using the / button.
- ▶ Set the time using the / button.

#### Setting the language



- ▶ Select the language using the / button.

#### Data exchange



#### CAUTION

- The manufacturer prohibits a network installation on the USB port.
- The USB port is for service purposes only.
- The USB flash drives tested for compatibility may only be used for service purposes.
- Software updates are only carried out with USB flash drives tested for compatibility.

The device provides the following functions:

- Saving the log file
- Installing a software update

#### Saving the log file

For device analysis, the manufacturer requires a log file upon request. This is loaded to the USB stick as follows:

- ▶ Insert the USB stick into the device.
- ▶ Select the requested option from the illustrated window.
- ▶ Save the log file to the USB stick using the button.

When the log file has been saved to the USB stick, the symbol appears on the display.

#### Installing a software update

The manufacturer must be contacted for potential software updates.

Compatibility has been tested with the following USB flash drives:

- SanDisk ULTRA Fit; USB 3.0; 16 GB
- Intenso Slim Line; USB 3.0; 16 GB
- Kingston DT 50; USB 3.0; 16 GB

### 17.1 INSPECTION



#### WARNING

The inspection of the device must be performed annually.

For a device inspection, chapters „17.1.1 Calibration“, „17.1.2 Self test“ and „17.1.3 Leak test“ must be carried out.

#### 17.1.1 CALIBRATION



#### CAUTION

- All tube connections must snap firmly into place.
- Do not use any damaged connections or Coil Connecting Tubings.
- Do not kink Coil Connecting Tubings or cuff tubes.

The calibration is used to check whether the measurement accuracy of the device is within the tolerance range specified by the manufacturer.

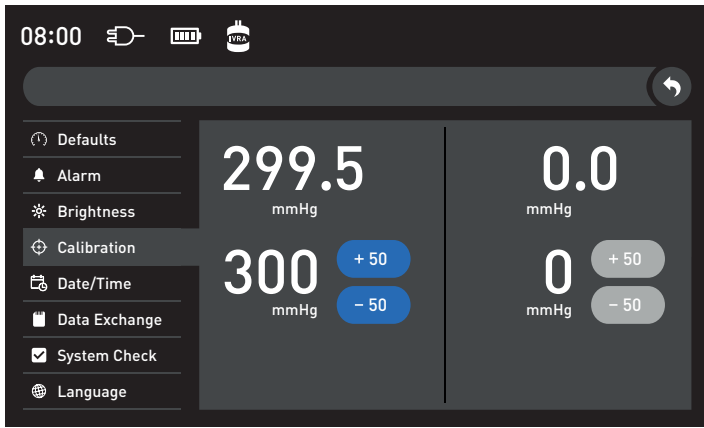
#### NOTE



The device must only be readjusted by the manufacturer.


- ▶ Connect the blue Coil Connecting Tubing to the cuff channel.
- ▶ Connect a reference measuring device to the blue Coil Connecting Tubing with the aid of appropriate connectors.

In order to stabilise the pressure, an additional non-elastic volume (50 cm<sup>3</sup> min. to 500 cm<sup>3</sup> max.) should be installed between the reference measuring device and the device. Several pressures must be selected for the calibration. The entire pressure range of the device must be covered.

- ▶ Open the menu for settings using the button.

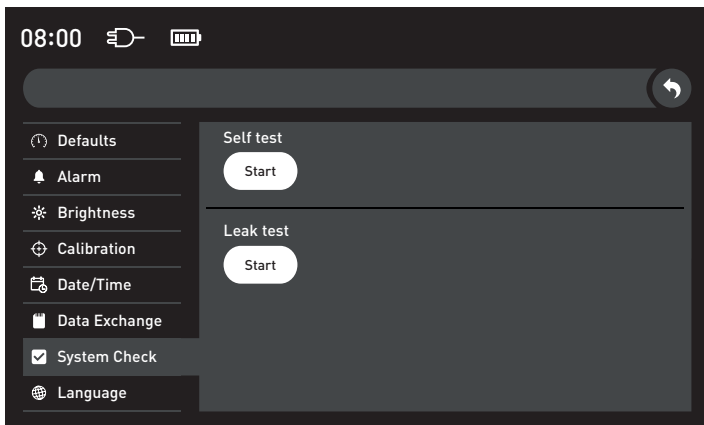



- ▶ Select the "Calibration" operating field.
- ▶ Set the selected pressure using the  /  button.
- ▶ Read the upper pressure on the cuff channel.
- ▶ Read the pressure on the reference measuring device.

**CAUTION**  
 If the discrepancy is greater than +/- 5 mmHg, immediately label the device as defective and contact the manufacturer.

- ▶ Repeat the process until all pressures have been determined with the reference measuring device.
  - ▶ Repeat the process on the irrigation channel using the reference measuring device.
- In order to stabilise the pressure, an additional non-elastic volume (min. 3000 cm<sup>3</sup> to max. 4000 cm<sup>3</sup>) should be installed between the reference measuring device and the device., e.g. VBM Pressure Infusion Cuff ≥ 1500 ml.

### 17.1.2 SELF TEST




- ▶ Disconnect the Coil Connecting Tubings and the Tourniquet / Pressure Infusion Cuff from the device.
- ▶ Select the "System Check" operating field.
- ▶ Start the self test by activating the  button.

The following functions are tested in the self test:

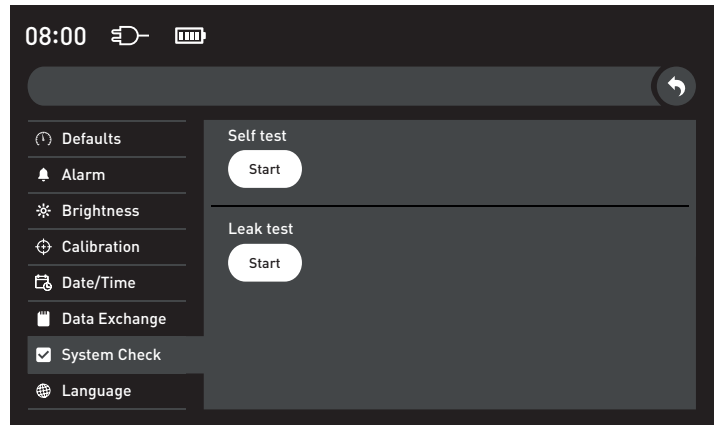
- Voltages and device temperature
- Primary and secondary compressed air supply for cuff channel and irrigation channel
- All data storage devices
- Battery
- Software and hardware versions
- All audible alarm systems


The completed self test is shown on the display.


- ▶ Close the message using the  button.


**CAUTION**  
 If the device fails to pass the self test, restart the device. If the error occurs again, contact the manufacturer.

### 17.1.3 LEAK TEST



**CAUTION**  
 Plugs for air-tight test must snap firmly into place.

- ▶ Connect the Coil Connecting Tubings in accordance with the colour coding. Connect a plug for air-tight test to each Coil Connecting Tubing.
  - ▶ Start the leak test by activating the  button.
- The leak test takes 180 seconds.  
 The deviation is indicated on the display.

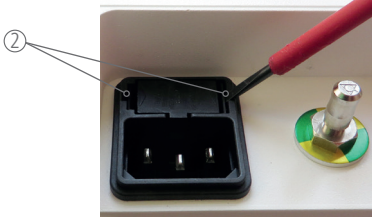
**CAUTION**  
 If the deviation is greater than +/- 15 mmHg, immediately label the device as defective and contact the manufacturer.

## 17.2 REPAIRS

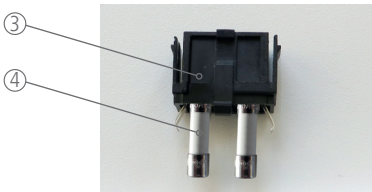
### Replace the fuse



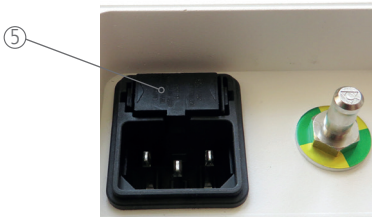
- ▶ Disconnect the device from the power supply.
- ▶ Release the V-Lock inlet connector from the socket. Press the sliding lever ①.



- ▶ Release the fuse holder with a slotted screwdriver ②.



- ▶ Remove the fuse holder ③ and the fuses ④ from the opening.
- ▶ Remove the defective fuse from the fuse holder.
- ▶ Insert a new fuse (2x Littelfuse 215 Series: T2,5 AH, 250 V, 5 x 20 mm (¾ inch)) into the fuse holder.



- ▶ Insert the fuse carrier into the provided opening.

#### NOTE

The fuse holder ⑤ must click into place on both sides.

Further repair procedure is restricted to the manufacturer.

## 18. RETURN

The precondition for a fast repair process is that the medical device is returned with as detailed a fault description as possible.

Before medical devices are returned, the devices must be thoroughly cleaned and disinfected (see chapter „19. Wipe disinfection“) in order to rule out exposure of the manufacturer's staff to a hazard. The manufacturer reserves the right to refuse soiled or contaminated products for reasons of safety.

## 19. WIPE DISINFECTION



#### CAUTION

- The device cannot be automatic or manual cleaned respectively sterilised.
- Do not immerse the device in liquids.

- ▶ Switch off the device with the On/Off button.
- ▶ Unplug the mains plug.
- ▶ Remove connecting tubings from the device.
- ▶ Clean the device and connecting tubing as follows:

Wipe disinfection must be performed with commercially available surface disinfectants based on alcohol or QACs (quaternary ammonium compounds). When choosing a product for disinfection, a disinfectant with appropriate ranges of action must be used: bactericidal, yeasticidal and virucidal. After wipe disinfection, inspect the product for visible contamination. If necessary, repeat wipe disinfection. After completing the wipe disinfection, check the function of the device (see chapter „12. Functional Check“).

## 20. SHELF LIFE

### Tourniquet Touch TT15

The shelf life of the device is 7 years in accordance with the intended use.

Date of manufacture: see rating plate.

### Connecting tubing

The shelf life of the Connecting Tubing is 8 years.

## 21. DISPOSAL

The device and the battery must be disposed of separately.

- ▶ Remove the battery from the device.

### Electrical and electronic equipment



Do not dispose of electrical and electronic equipment in household waste. Disposal within the EU must be carried out in accordance with Directive 2012/19/EU (WEEE Directive). In non-EU countries, the device must be disposed of in accordance with the local statutory regulations.

### Battery

The device contains a rechargeable battery that is required for operation and for certain functions.



Do not dispose of the battery in household waste. The battery must be disposed of in accordance with the applicable national and international statutory regulations.



#### CAUTION

Protect the battery from heat, do not open, short-circuit, immerse in water or throw into fire.

### Accessories























The used or damaged products must be disposed of in accordance with the applicable national and international statutory regulations.

## 22. ARTICLE NUMBERS

REF	Description	Applied parts for:	
		Chapter „13.1 Bloodless field with Single Cuff“	Chapter „13.2 Irrigation with Pressure Infusion Cuff“
01-15-000	Tourniquet Touch TT15		
	<b>Spare Parts</b>		
20-20-744	Coil Connecting Tubing, blue; stretched length 3.0 m / 118 inch	x	
20-20-740	Coil Connecting Tubing, black; stretched length 3.0 m / 118 inch		x
20-20-944	Smooth Connecting Tubing, blue; length 4.5 m / 177 inch	x	
01-00-510	Coil Connecting Tubing, blue; stretched length 6.0 m / 236 inch	x	
01-00-530	Coil Connecting Tubing, black; stretched length 6.0 m / 236 inch		x
22-50-406	Plug for air-tight test, for cuff channel		
22-50-409	Plug for irrigation channel		
01-00-410	Mains cable, EU, V-Lock, 4 m / 157 inch		
01-00-420	Mains cable, Switzerland, V-Lock, 4 m / 157 inch		
01-00-430	Mains cable, GB, V-Lock, 4 m / 157 inch		
01-00-440	Mains cable, US, V-Lock, 4 m / 157 inch		
01-00-450	Mains cable, CN, V-Lock, 5 m / 197 inch		
01-00-460	Mains cable, AU, V-Lock, 4 m / 157 inch		
01-00-470	Mains cable, JP, V-Lock, 4 m / 157 inch		
	<b>Accessories</b>		
01-00-100	Mobile Stand with basket for Tourniquet		
	<b>Tourniquet Cuffs, single use</b>		
20-34-700SLZ-1	Tourniquet Dispo Cuff, Single Cuff for infant, length 20 cm / 8 inch	x	
20-34-710SLZ-1	Tourniquet Dispo Cuff, Single Cuff for child, length 30 cm / 12 inch	x	
20-34-711SLZ-1	Tourniquet Dispo Cuff, Single Cuff for arm, length 35 cm / 14 inch	x	
20-34-712SLZ-1	Tourniquet Dispo Cuff, Single Cuff for long arm, length 46 cm / 18 inch	x	
20-34-715SLZ-1	Tourniquet Dispo Cuff, Single Cuff for lower leg/arm, contour shape, length 46 cm / 18 inch	x	
20-34-722SLZ-1	Tourniquet Dispo Cuff, Single Cuff for leg, contour shape, length 61 cm / 24 inch	x	
20-34-727SLZ-1	Tourniquet Dispo Cuff, Single Cuff for long leg, contour shape, length 76 cm / 30 inch	x	
20-34-728SLZ-1	Tourniquet Dispo Cuff, Single Cuff for extra long leg, contour shape, length 86 cm / 34 inch	x	
20-34-729SLZ-1	Tourniquet Dispo Cuff, Single Cuff for super long leg, contour shape, length 107 cm / 42 inch	x	
	<b>Tourniquet Cuffs, reusable</b>		
20-75-700	Tourniquet Wipe Cuff, Single Cuff, length 20 cm / 8 inch	x	
20-75-710	Tourniquet Wipe Cuff, Single Cuff, length 30 cm / 12 inch	x	
20-75-711	Tourniquet Wipe Cuff, Single Cuff, length 35 cm / 14 inch	x	
20-75-712	Tourniquet Wipe Cuff, Single Cuff, length 46 cm / 18 inch	x	
20-75-715	Tourniquet Wipe Cuff, Single Cuff, contour shape, length 46 cm / 18 inch	x	
20-75-722	Tourniquet Wipe Cuff, Single Cuff, contour shape, length 61 cm / 24 inch	x	
20-75-727	Tourniquet Wipe Cuff, Single Cuff, contour shape, length 76 cm / 30 inch	x	
20-75-728	Tourniquet Wipe Cuff, Single Cuff, contour shape, length 86 cm / 34 inch	x	
20-75-729	Tourniquet Wipe Cuff, Single Cuff, contour shape, length 107 cm / 42 inch	x	
20-54-700	Single Cuff for infant, length 20 cm / 8 inch	x	
20-54-710	Single Cuff for child, length 30 cm / 12 inch	x	
20-54-711	Single Cuff for arm, length 35 cm / 14 inch	x	
20-54-712	Single Cuff for long arm, length 46 cm / 18 inch	x	
20-54-729	Single Cuff for super long leg, length 107 cm / 42 inch	x	
20-54-512	Single Cuff for lower leg/arm, contour shape, length 46 cm / 18 inch	x	
20-54-522	Single Cuff for leg, contour shape, length 61 cm / 24 inch	x	
20-54-527	Single Cuff for long leg, contour shape, length 76 cm / 30 inch	x	
20-54-528	Single Cuff for extra long leg, contour shape, length 86 cm / 34 inch	x	
20-64-700	Silicone Single Cuff for infant, length 20 cm / 8 inch	x	
20-64-710	Silicone Single Cuff for child, length 30 cm / 12 inch	x	
20-64-611	Silicone Single Cuff for arm, length 35 cm / 14 inch	x	
20-64-612	Silicone Single Cuff for long arm, length 46 cm / 18 inch	x	
20-64-512	Silicone Single Cuff for lower leg/arm, contour shape, length 46 cm / 18 inch	x	
20-64-522	Silicone Single Cuff for leg, contour shape, length 61 cm / 24 inch	x	
20-64-527	Silicone Single Cuff for long leg, contour shape, length 76 cm / 30 inch	x	
20-64-528	Silicone Single Cuff for extra long leg, contour shape, length 86 cm / 34 inch	x	

REF	Description	Applied parts for:	
		Chapter „13.1 Bloodless field with Single Cuff“	Chapter „13.2 Irrigation with Pressure Infusion Cuff“
	<b>Pressure Infusion Cuff for single use</b>		
56-01-300	Dispo Infusor 3000 ml with Luer Lock		X
	<b>Pressure Infusion Cuff, reusable</b>		
52-01-300	Pressure Infusion Cuff 3000 / 5000 ml with Luer Lock connection only		X
57-01-300	Infusor 3000 with Luer Lock		X

### 23. DESCRIPTION OF SYMBOLS

	Medical device		Type B applied part
	Manufacturer		Potential equalisation
	Date of manufacture		Do not dispose of electrical or electronic equipment in household waste
	Article number		Do not dispose of battery in household waste
	Serial number		CE marking with identification number of the notified body.
	Type		This product contains certain hazardous substances and can be used safely during its environmental protection use period (as indicated by the number in the center) which should enter into the recycling system after its environmental protection use period.
	Observe instructions for use		The Mobile Stand can tilt over on a ramp > 5°. During transport of the Mobile Stand the instruction for use 004-01-0336 - Mobile Stand, chapter "Transport conditions" must be observed.
	Follow instructions for use		<b>CAUTION</b> Risk of electric shock Do not open the housing. Refer servicing to qualified service personnel
	Caution		
	MRI, not suitable		
	<b>Caution:</b> Sale or prescription of the product by physicians is restricted by federal law. For USA and Canada only.		
	Temperature limit		
	Air humidity, limit		
	Air pressure, limit		

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