



## Tourniquet Touch TT20

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# INSTRUCTIONS FOR USE

Read the instructions for use carefully prior to start-up and observe them.

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><br>Indicates an imminent hazard with high risk which, if not avoided, will result in death or serious personal injury.            |
|  | <b>WARNING</b><br>Indicates a potential hazard with moderate risk which, if not avoided, can result in death or serious personal injury.        |
|  | <b>CAUTION</b><br>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.                                                                                                     |
| IVRA                                                                             | Intravenous regional anaesthesia                                                                                                                |
| EMC                                                                              | Electromagnetic compatibility                                                                                                                   |
| ►                                                                                | Instruction: Prompt for the user to do something.                                                                                               |

## 2. INTENDED USE

The Tourniquet Touch TT20 is an electrically operated surgical tourniquet. 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.

The Tourniquet Touch TT20 is suitable for use with a Single Cuff, two Single Cuffs (bilateral surgery) or a Double Cuff (IVRA).

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.

### 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.

## 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 device was designed and tested for use with Tourniquet Cuffs and Coil Connecting Tubing from the manufacturer. If the user uses Tourniquet 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 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 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 TT20                                                                                                         |
|    | Coil Connecting Tubing, blue; stretched length 3.0 m / 118 inch                                                               |
|    | Coil Connecting Tubing, red; stretched length 3.0 m / 118 inch                                                                |
|    | 2 plugs for air-tight test                                                                                                    |
|    | Mains plug, Europe (all countries except for Great Britain and Switzerland)<br>Type CEE 7 / XVII<br>Cable label ID: 6051.2183 |
|    | Mains plug, Great Britain<br>Type BS 1363<br>Cable label ID: 6051.2188                                                        |
|    | Mains plug, Switzerland<br>Type 12 SEV<br>Cable label ID: 6051.2185                                                           |
|   | Mains plug, Australia<br>Type AS 3112<br>Cable label ID: 6051.2190                                                            |
|  | Mains plug, China<br>Type GB 2099<br>Cable label ID: 3-100-527                                                                |
|  | Mains plug, Japan<br>Type JIS 8303<br>Cable label ID: 6051.2191                                                               |
|  | Mains plug, North America<br>Type NEMA 5-15<br>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



**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.<br>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.<br>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 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 *)<br>* 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:                                            | Settable from 80 - 500 mmHg in increments of 5 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 / red Coil Connecting Tubing with 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 channel. The function of the buttons is not changed thereby.

|  |                                                                    |
|--|--------------------------------------------------------------------|
|  | On/Off button                                                      |
|  | Audio paused (Alarm)                                               |
|  | IVRA mode                                                          |
|  | 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<br>Increase / reduce pressure by 50 mmHg |
|  | Perform self test or leak test                       |

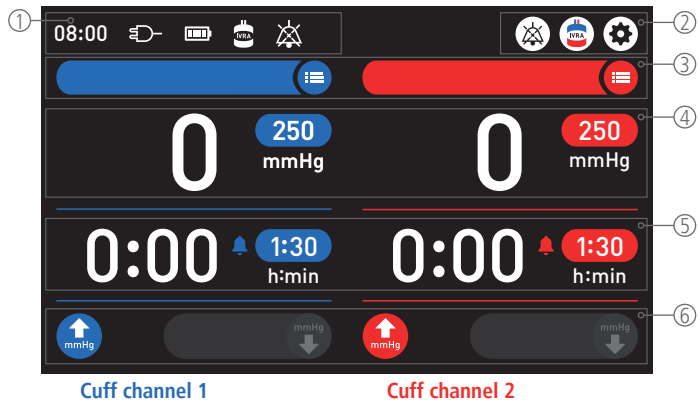
### Status display symbols

|  |                                |
|--|--------------------------------|
|  | 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 |
|  | IVRA mode deactivated          |
|  | IVRA mode activated            |
|  | Audio paused (Alarm) activated |

### Further symbols

|  |                                                |
|--|------------------------------------------------|
|  | Self test                                      |
|  | Manual self test successfully completed        |
|  | Warning                                        |
|  | Notice (IVRA) - deflation of last cuff bladder |
|  | Alarm time                                     |
|  | Log file                                       |
|  | USB                                            |
|  | Saved to USB                                   |
|  | No USB connected                               |
|  | USB error                                      |
|  | USB full                                       |
|  | Tourniquet Touch                               |
|  | Tourniquet Touch power supply interruption     |

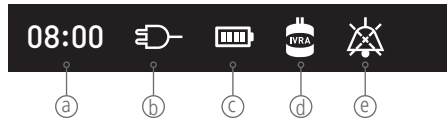
10. MAIN SCREEN



The main screen is divided up into ① status bar, ② control bar, ③ channel bar, ④ pressure display, ⑤ time display and ⑥ inflation / deflation area. The operation of cuff channel 1 and cuff channel 2 is identical. Each cuff channel has its own separate compressed air circuit. Both cuff channels can be operated separately from each other.

① Status bar

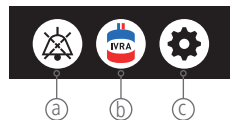
This bar displays information about the device status. No settings are possible.



|                         |                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ① Time:                 | The field displays the current time.                                                                                                                                                                                                                                                                                                                                                                              |
| ② Power supply:         | <div><div></div>Power supply is on</div> <div><div></div>Power supply interrupted</div>                                                                                                                                                                                                                                                                                                                           |
| ③ Battery status:       | <div>The field indicates the status of the battery.</div> <div><div></div>Battery status 80 - 100 %</div> <div><div></div>Battery status 60 - 80 %</div> <div><div></div>Battery status 40 - 60 %</div> <div><div></div>Battery status 20 - 40 %</div> <div><div></div>Battery status 10 - 20 %</div> <div><div></div>Battery status 0 - 10 %</div> <div><div></div>No battery present or battery defective</div> |
| ④ IVRA mode:            | <div>The field indicates the status of the IVRA.</div> <div><div></div>IVRA mode activated</div> <div><div></div>IVRA mode deactivated</div>                                                                                                                                                                                                                                                                      |
| ⑤ Audio paused (Alarm): | <div>The field indicates the status Audio paused (Alarm).</div> <div><div></div>is displayed for 30 seconds if the  button was activated during an alarm. The optical alarm remains active.</div>                                                                                                                                                                                                                 |

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 IVRA:                 | Button activates or deactivates IVRA mode. The button is hidden in the control bar when the Tourniquet Cuff has been inflated.                    |
| ③ Settings:             | Button opens the window for settings. The button is hidden in the control bar when the Tourniquet Cuff has been inflated.                         |

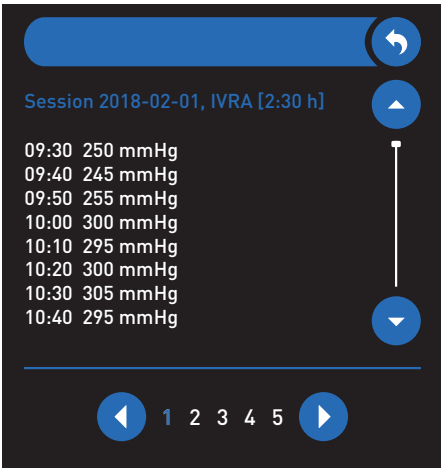
③ Channel bar

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 Tourniquet Cuff has been inflated. |
|------------|--------------------------------------------------------------------------------------------------------------------------|

▶ Select button for the history.

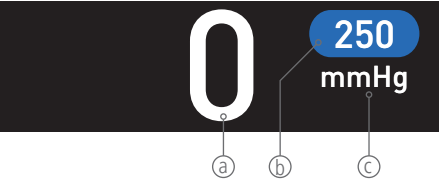


The window is opened. The last 5 sessions for this cuff channel are stored in the history.

- ▶ 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

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.



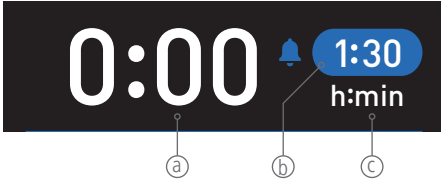
The window is opened.

- 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.

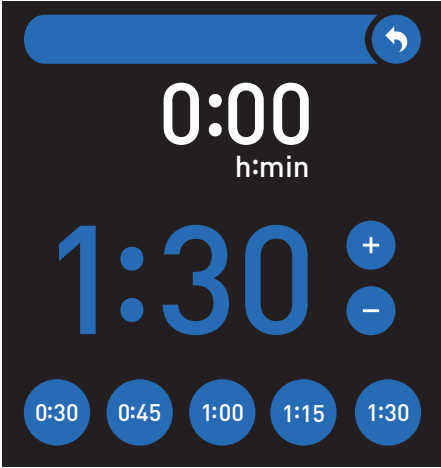
⑤ Time display

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



|               |                        |
|---------------|------------------------|
| ① Timer:      | expired inflation time |
| ② Alarm time: | planned inflation time |
| ③ 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.

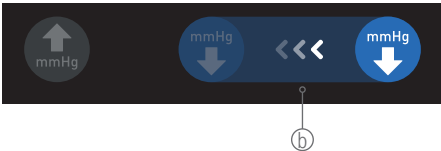
**NOTE**  
If no change is made after opening the operating field, then the window is closed automatically after 5 seconds.

⑥ Inflation / deflation area

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



|                     |                               |
|---------------------|-------------------------------|
| ① Inflation button: | Inflates the Tourniquet Cuff. |
|---------------------|-------------------------------|

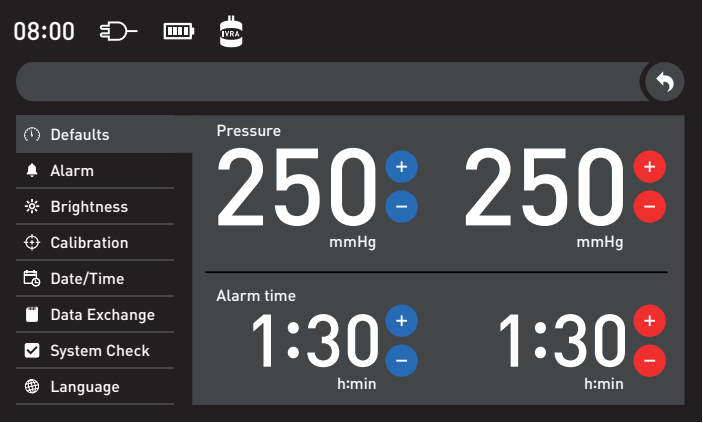


|                         |                                                                                                                     |
|-------------------------|---------------------------------------------------------------------------------------------------------------------|
| ② Slider for deflation: | Deflates the Tourniquet Cuff.<br>► Shift the slider completely over to the left within 2 seconds using the  button. |
|-------------------------|---------------------------------------------------------------------------------------------------------------------|

10.1 SETTINGS

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

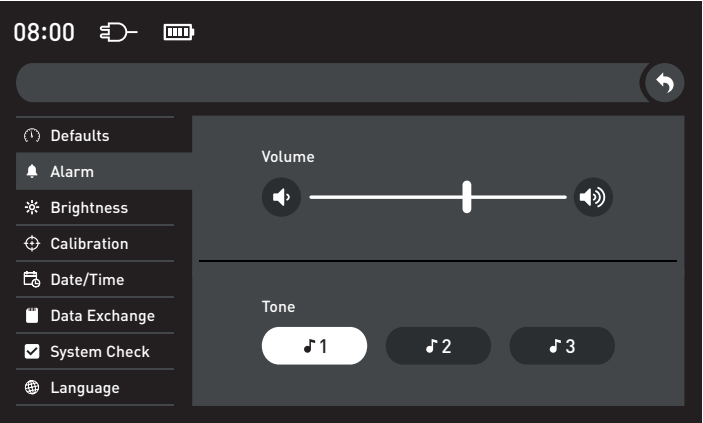
Presetting for pressure and alarm time



- ▶ 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                                 |
|------------|-----------------------------------------------|
| Pressure   | 150 - 400 mmHg in increments of 5 mmHg        |
| Alarm time | 00:15 - 1:30 h:min in increments of 5 minutes |

Volume and tone

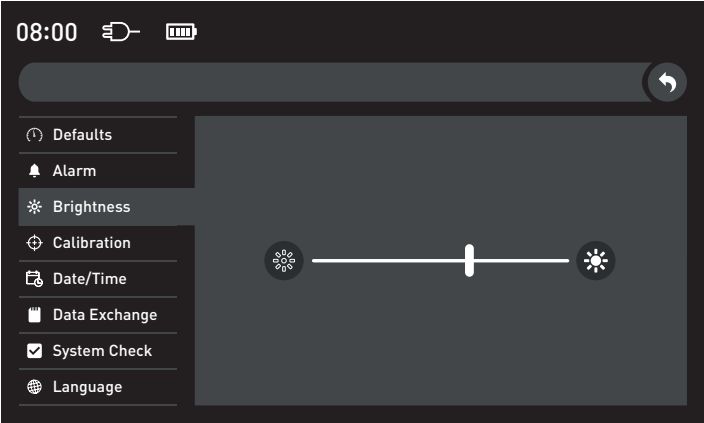


**WARNING**

- 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 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.

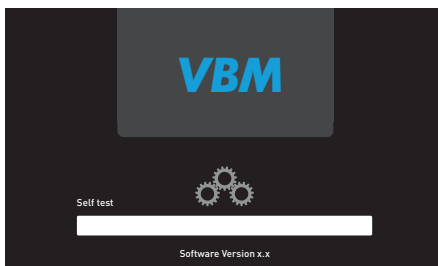


The device then triggers an optical alarm ③ and an alarm sound ④.



### 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.

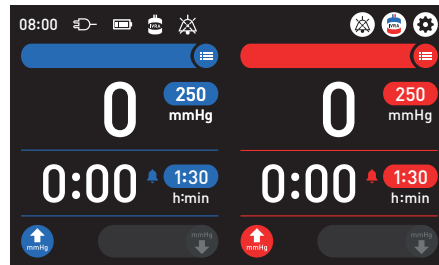
The following functions are checked in the self test:

- Internal safety features
- Voltages and device temperature
- Primary and secondary compressed air supply for cuff channel 1 and cuff channel 2
- 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“).

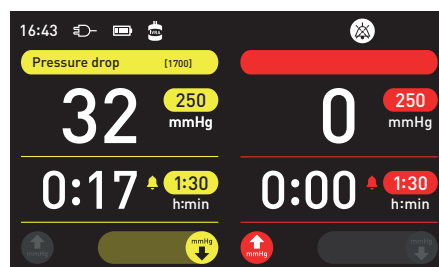
## 12. FUNCTIONAL CHECK



### CAUTION

- Do not use any damaged Tourniquet 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 Coil Connecting Tubing to the cuff channel to be tested, observing the colour coding.
  - ▶ Select the Tourniquet Cuff that is required for the session.
  - ▶ Tightly roll-up the Tourniquet Cuff to enable a counter-pressure to build up when the cuff is inflated.
  - ▶ Connect the cuff tube to the Coil Connecting Tubing in accordance with the colour coding.
  - ▶ For bilateral surgery, connect the second Single Cuff to the Coil Connecting Tubing of the second cuff channel.
  - ▶ Inflate the Tourniquet 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 Tourniquet 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 to be tested 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 Coil Connecting Tubing.
- ▶ Deflate the Tourniquet 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.

## 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.
- In order to ensure a safe bloodless field while avoiding exposure of the patient to unnecessary stress, an appropriate Tourniquet 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 Tourniquet Cuff at regular intervals. If the preset pressure deviates from the current Tourniquet 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 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 or G1046 - Tourniquet Cuffs reusable) must be observed, in particular the chapters Use, Reprocessing and Disposal.

### 13.1 USE WITH SINGLE CUFF

- Observe the 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 Coil Connecting Tubing in accordance with the colour coding.

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 button. 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“).

### 13.2 USE WITH TWO SINGLE CUFFS FOR BILATERAL SURGERY

- Observe the applied parts (see chapter „22. Article numbers“, column “Applied parts for: chapter „13.2 Use with two Single Cuffs for bilateral surgery“”).

The procedure is identical to that described in chapter „13.1 Use with Single Cuff“, except for the following points:

- The second cuff channel is used for the additional extremity.
- When both Single Cuffs are inflated, the current pressure and the elapsed inflation time are displayed for each Single Cuff.



### WARNING

If the procedure on one extremity is to be terminated, then it must be ensured that the corresponding cuff channel is deflated. Should the wrong cuff channel be deflated by accident, then this will result in haemorrhage into the extremity.

### 13.3 USE WITH DOUBLE CUFF (IVRA)

The procedure is identical to that described in chapter „13.1 Use with Single Cuff“, except for the following points:



### CAUTION

- For IVRA, an alternative system and the appropriate accessories must be immediately available in order to restore the bloodless field in the event of malfunction of the device or the accessories.
- Only use Double Cuffs (see chapter „22. Article numbers“, column “Applied parts for: chapter „13.3 Use with Double Cuff (IVRA)“”).
- In order to prevent accidental complete deflation of the Double Cuff, the IVRA mode must be activated.
- If VBM Double Cuffs are used, it is recommended to place the blue cuff bladder proximally and the red cuff bladder distally. Connect the cuff tubes to the Coil Connecting Tubings in accordance with the colour coding. If Double Cuffs from other manufacturers are used, then a possible deviation of the colour coding must be taken into account.

- Activate IVRA mode with the button.

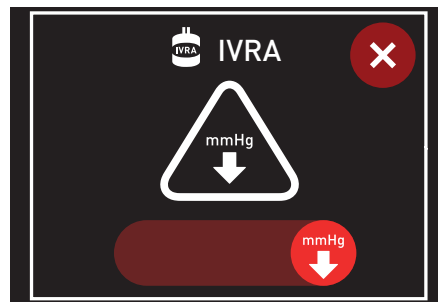
The symbol is displayed in the status bar.

- Inflate the Double Cuff in the sequence specified according to the guideline of the institution.



### WARNING

- After administration of the anaesthetic, the minimum bloodless field time of 20 minutes must be observed in order to prevent a toxic reaction.
- If the inflated cuff bladder loses pressure during the action time of the anaesthetic, the second cuff bladder must be inflated immediately.



When the last remaining inflated cuff bladder is deflated, the pop-up window shown here is displayed. This additional query prevents accidental deflation of the last cuff bladder.

- If the cuff is supposed to be deflated, shift the slider completely over to the left within 2 seconds using the

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.



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.

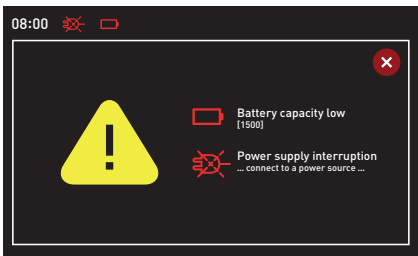
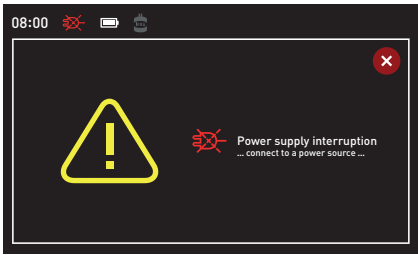
**CAUTION**

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<br>Alarm for one cuff channel or both cuff channels (global alarm) | Pop-up window<br>(example picture) |
| High     | 10 alarm tones every 3 seconds | <br>Red flashing light  |                                                                                | -                                  |
|          |                                |                         | -                                                                              |                                    |
| High     | Alarm tone every second        | <br>Red permanent light | -                                                                              | -                                  |

| Priority                      | Alarm sound                    | Optical alarm                                                                                               | Additional alarm                                                                                                                                       |                                                                                                             |
|-------------------------------|--------------------------------|-------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
|                               |                                |                                                                                                             | Channel bar<br>Alarm for one cuff channel or both cuff channels (global alarm)                                                                         | Pop-up window<br>(example picture)                                                                          |
| Medium                        | 3 alarm tones every 4 seconds  | <br>Yellow flashing light  |                                                                      | -                                                                                                           |
|                               |                                |                                                                                                             | -                                                                                                                                                      |                          |
| Low                           | 2 alarm tones every 16 seconds | <br>Yellow permanent light |                                                                      | -                                                                                                           |
|                               |                                |                                                                                                             | -                                                                                                                                                      |  <p>Timer Alarm</p>      |
| None, the message is a notice | -                              | -                                                                                                           | -                                                                                                                                                      |                        |
| Additional information        | -                              | -                                                                                                           | The channel switches colour every second (from yellow to the respective channel colour).<br>a Error indicator<br>b Error description<br>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                         | The device temperature is too high.                                | Device temperature > 65 °C (+149 °F)                  | <ul style="list-style-type: none"> <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> |
| 0x00000400, 0x00001000, 0x00001400 | The device detects that a Tourniquet Cuff is connected.            | Tourniquet Cuff is connected to the device.           | <ul style="list-style-type: none"> <li>▶ Disconnect the Tourniquet 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>                                                                                                                   |

### 15.2 USE

| Error message (cuff channel 1 / 2) | 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.<br>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.<br>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 / 1601                        | 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 / 1603                        | 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<br>Leakage in the Coil Connecting Tubing, the Tourniquet 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 Cuff.</li> <li>▶ Restart the device.</li> <li>▶ If the error occurs again, contact the manufacturer.</li> </ul> <p><b>Important in the case of IVRA</b></p> <ul style="list-style-type: none"> <li>▶ In the event of a drop in pressure, immediately inflate the second cuff bladder or use the manual tourniquet or an alternative system.</li> </ul> |
| 1702 / 1703                        | High     | High pressure                       | High pressure > 15 mmHg persists since at least 60 seconds.<br>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 / 1705                        | Medium   | High pressure                       | High pressure > 15 mmHg persists since 6 - 60 seconds.<br>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>                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 1706 / 1707                        | High     | Low pressure                        | Low pressure > 15 mmHg persists since at least 60 seconds.<br>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>                                                                                                                                                                                                                                                                                                                                                                           |

| Error message<br>(cuff channel 1 / 2) | Priority | Fault / failure    | Cause                                                                                                                                                                         | Fault remediation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---------------------------------------|----------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1708 / 1709                           | Medium   | Low pressure       | Low pressure > 15 mmHg persists since 6 - 60 seconds.<br>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>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1710 / 1711                           | Low      | Leakage            | Device has a higher activity than expected.<br>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 Cuff and the Coil Connecting Tubing.</li> <li>▶ Then perform a leak test on the device.</li> </ul>                                                                                                                                                                                                                                                                                                                                                            |
| 1712 / 1713                           | 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>                                                                                                                                                                                                                                                                                                                                                |
| 1714 / 1715                           | Low      | Deflate failure    | When the Tourniquet Cuff is deflated, the pressure does not drop as quickly as expected.                                                                                      | <ul style="list-style-type: none"> <li>▶ Disconnect the Tourniquet 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 the Tourniquet Touch 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------------------------------------------------------------------------------------------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <br>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 the Tourniquet Touch 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 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 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 „17.2 Repairs“).                                                                                                                                                                                                                                                                                                                                                                        |
|                                                                                                                          | The device is not connected to the power supply.<br>The battery is deeply discharged.          | ▶ Connect the device to the power supply.<br>The charging process can take several hours.                                                                                                                                                                                                                                                                                                                               |
|  button flashes five times in succession | The device has insufficient battery status.<br>The device is not ready for operation.          | ▶ Connect the device to the power supply.<br>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 „4. 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 „4. 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<br>0,15 MHz - 30 MHz |
| Radiated electromagnetic field                | CISPR-11                          | Group 1 - Class A<br>30 MHz - 1000 MHz |
|                                               | CISPR-32                          | 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:<br>± 2 kV, ± 4 kV, ± 8 kV      |
|                                                           |                                   | Air discharge:<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV |
| Radiated, radio-frequency, electromagnetic field          | IEC 61000-4-3                     | 10 V/m<br>80 MHz - 2,7 GHz<br>AM 80% at 1 kHz     |
| Electrical fast transient (Burst)                         | IEC 61000-4-4                     | ± 1 kV, ± 2 kV<br>Burst frequency 5 / 100 kHz     |
| Surge voltages (line-to-line)                             | IEC 61000-4-5                     | ± 0,5 kV, ± 1 kV                                  |
| Surge voltages (line-to-ground)                           | IEC 61000-4-5                     | ± 0,5 kV, ± 1 kV, ± 2 kV                          |
| Conducted disturbances, inducted by radio frequency field | IEC 61000-4-6                     | 10 V<br>0,15 MHz - 80 MHz<br>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.

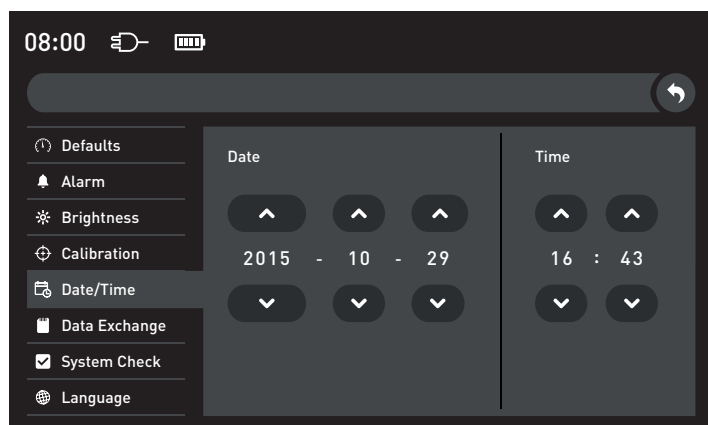
### 17. MAINTENANCE

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.

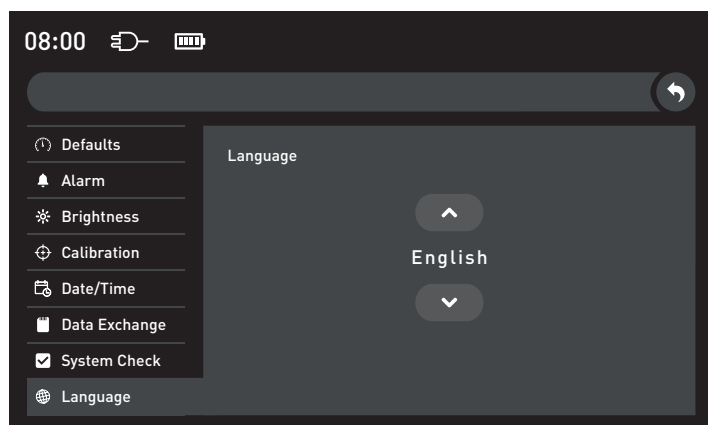
If any other tasks are performed on the medical device, all warranty claims are rendered invalid.

#### Setting date / time



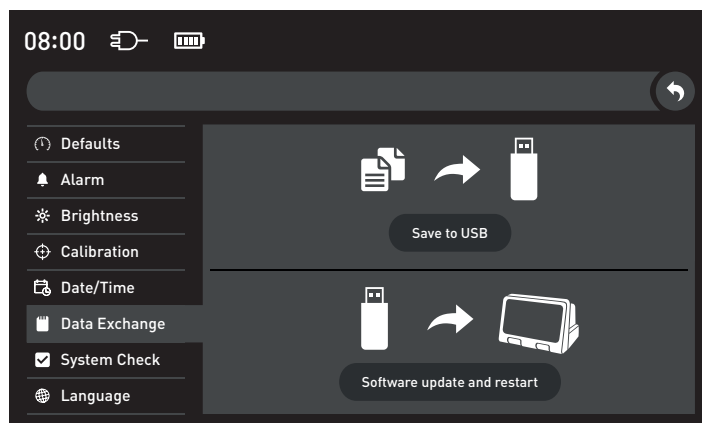
- ▶ Set the date using the / button.
- ▶ Set the time using the / button.

#### 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.

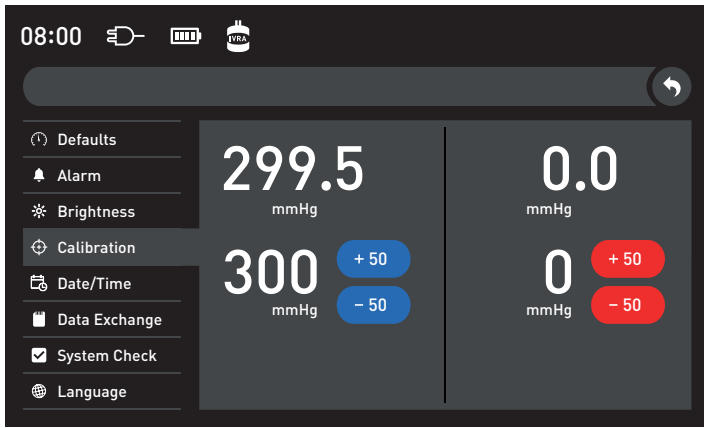
#### NOTE

The device must only be readjusted by the manufacturer.

- ▶ Connect the blue Coil Connecting Tubing to cuff channel 1.
- ▶ 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 **+ 50** / **- 50** button.
- ▶ Read the upper pressure on cuff channel 1.
- ▶ Read the pressure on the reference measuring device.



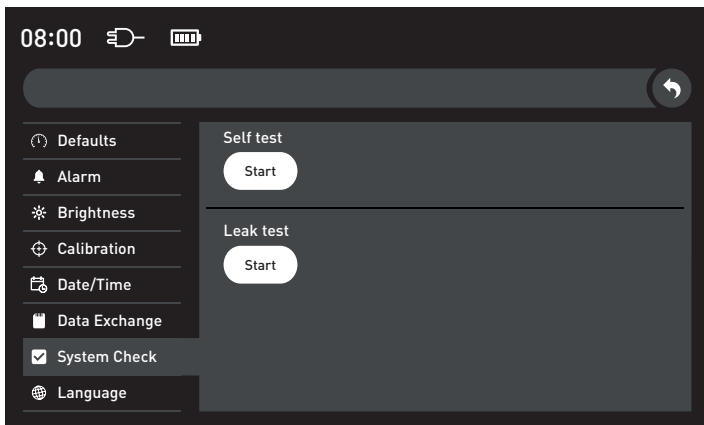
#### CAUTION

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 cuff channel 2 using the reference measuring device.

### 17.1.2 SELF TEST

- ▶ Disconnect the Coil Connecting Tubings and the Tourniquet Cuff from the device.
- ▶ Select the "System Check" operating field.



- ▶ Start the self test by activating the **Start** button.

The following functions are tested in the self test:

- Voltages and device temperature
- Primary and secondary compressed air supply for cuff channel 1 and cuff channel 2
- All data storage devices
- Battery
- Software and hardware versions
- All audible alarm systems

The completed self test is shown on the display.

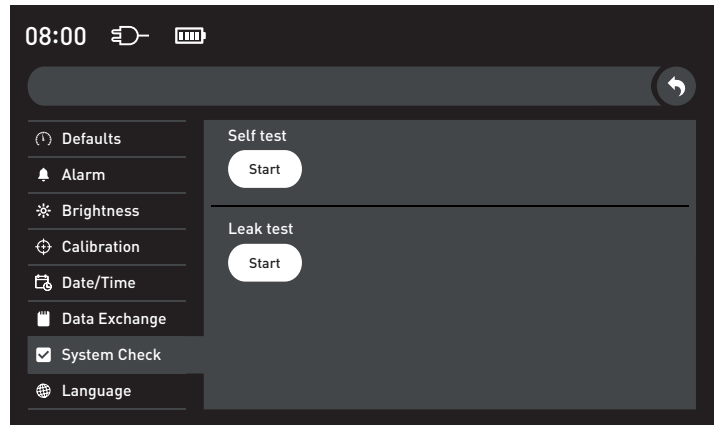
- ▶ Close the message using the **X** button.



#### 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 to cuff channel 1 and cuff channel 2 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 **Start** button.

The leak test takes 180 seconds.

The deviation is indicated on the display.



#### CAUTION

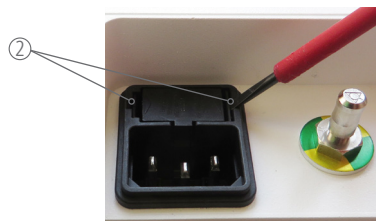
If the deviation is greater than +/- 15 mmHg, immediately label the device as defective and contact the manufacturer.

## 17.2 REPAIRS

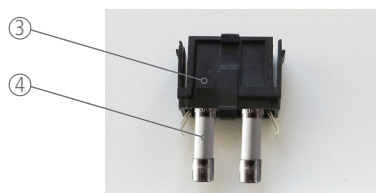
### Replace the fuse



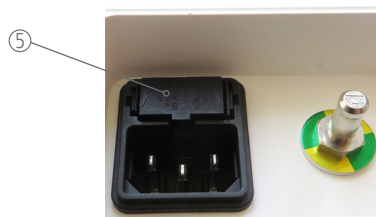
- ▶ Disconnect the device from the power supply.
- ▶ Release the V-Lock inlet connector from the socket. Press the sliding lever ①.



- ▶ 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 TT20

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 Use with Single Cuff“ | Chapter „13.2 Use with two Single Cuffs for bilateral surgery“ | Chapter „13.3 Use with Double Cuff (IVRA)“ |
| 01-20-000      | Tourniquet Touch TT20                                                          |                                     |                                                                |                                            |
|                | <b>Spare Parts</b>                                                             |                                     |                                                                |                                            |
| 20-20-744      | Coil Connecting Tubing, blue; stretched length 3.0 m / 118 inch                | x                                   | x                                                              | x                                          |
| 20-20-742      | Coil Connecting Tubing, red; stretched length 3.0 m / 118 inch                 |                                     | x                                                              | x                                          |
| 20-20-944      | Smooth Connecting Tubing, blue; length 4.5 m / 177 inch                        | x                                   | x                                                              | x                                          |
| 20-20-942      | Smooth Connecting Tubing, red; length 4.5 m                                    |                                     | x                                                              | x                                          |
| 01-00-510      | Coil Connecting Tubing, blue; stretched length 6.0 m / 236 inch                | x                                   | x                                                              | x                                          |
| 01-00-520      | Coil Connecting Tubing, red; stretched length 6.0 m / 236 inch                 |                                     | x                                                              | x                                          |
| 22-50-406      | Plug for air-tight test                                                        |                                     |                                                                |                                            |
| 01-00-410      | Mains cable, EU, V-Lock, 4 m                                                   |                                     |                                                                |                                            |
| 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 | Single Cuff for infant, length 20 cm / 8 inch                                  | x                                   | x                                                              |                                            |
| 20-34-710SLZ-1 | Single Cuff for child, length 30 cm / 12 inch                                  | x                                   | x                                                              |                                            |
| 20-34-711SLZ-1 | Single Cuff for arm, length 35 cm / 14 inch                                    | x                                   | x                                                              |                                            |
| 20-34-712SLZ-1 | Single Cuff for long arm, length 46 cm / 18 inch                               | x                                   | x                                                              |                                            |
| 20-34-715SLZ-1 | Single Cuff for lower leg/arm, contour shape, length 46 cm / 18 inch           | x                                   | x                                                              |                                            |
| 20-34-722SLZ-1 | Single Cuff for leg, contour shape, length 61 cm / 24 inch                     | x                                   | x                                                              |                                            |
| 20-34-727SLZ-1 | Single Cuff for long leg, contour shape, length 76 cm / 30 inch                | x                                   | x                                                              |                                            |
| 20-34-728SLZ-1 | Single Cuff for extra long leg, contour shape, length 86 cm / 34 inch          | x                                   | x                                                              |                                            |
| 20-34-729SLZ-1 | Single Cuff for super long leg, contour shape, length 107 cm / 42 inch         | x                                   | x                                                              |                                            |
| 20-30-710SLZ-1 | Double Cuff for child, length 30 cm / 12 inch                                  |                                     |                                                                | x                                          |
| 20-30-712SLZ-1 | Double Cuff for long arm, length 46 cm / 18 inch                               |                                     |                                                                | x                                          |
| 20-30-722SLZ-1 | Double Cuff for leg, length 61 cm / 24 inch                                    |                                     |                                                                | x                                          |
|                | <b>Tourniquet Cuffs, reusable</b>                                              |                                     |                                                                |                                            |
| 20-54-700      | Single Cuff for infant, length 20 cm / 8 inch                                  | x                                   | x                                                              |                                            |
| 20-54-710      | Single Cuff for child, length 30 cm / 12 inch                                  | x                                   | x                                                              |                                            |
| 20-54-711      | Single Cuff for arm, length 35 cm / 14 inch                                    | x                                   | x                                                              |                                            |
| 20-54-712      | Single Cuff for long arm, length 46 cm / 18 inch                               | x                                   | x                                                              |                                            |
| 20-54-729      | Single Cuff for super long leg, length 107 cm / 42 inch                        | x                                   | x                                                              |                                            |
| 20-54-512      | Single Cuff for lower leg/arm, contour shape, length 46 cm / 18 inch           | x                                   | x                                                              |                                            |
| 20-54-522      | Single Cuff for leg, contour shape, length 61 cm / 24 inch                     | x                                   | x                                                              |                                            |
| 20-54-527      | Single Cuff for long leg, contour shape, length 76 cm / 30 inch                | x                                   | x                                                              |                                            |
| 20-54-528      | Single Cuff for extra long leg, contour shape, length 86 cm / 34 inch          | x                                   | x                                                              |                                            |
| 20-64-700      | Silicone Single Cuff for infant, length 20 cm / 8 inch                         | x                                   | x                                                              |                                            |
| 20-64-710      | Silicone Single Cuff for child, length 30 cm / 12 inch                         | x                                   | x                                                              |                                            |
| 20-64-611      | Silicone Single Cuff for arm, length 35 cm / 14 inch                           | x                                   | x                                                              |                                            |
| 20-64-612      | Silicone Single Cuff for long arm, length 46 cm / 18 inch                      | x                                   | x                                                              |                                            |
| 20-64-512      | Silicone Single Cuff for lower leg/arm, contour shape, length 46 cm            | x                                   | x                                                              |                                            |
| 20-64-522      | Silicone Single Cuff for leg, contour shape, length 61 cm / 24 inch            | x                                   | x                                                              |                                            |
| 20-64-527      | Silicone Single Cuff for long leg, contour shape, length 76 cm / 30 inch       | x                                   | x                                                              |                                            |
| 20-64-528      | Silicone Single Cuff for extra long leg, contour shape, length 86 cm / 34 inch | x                                   | x                                                              |                                            |
| 20-74-700      | Single Slim-Cuff for infant, length 20 cm / 8 inch                             | x                                   | x                                                              |                                            |
| 20-74-710      | Single Slim-Cuff for child, length 30 cm / 12 inch                             | x                                   | x                                                              |                                            |
| 20-74-711      | Single Slim-Cuff for arm, length 35 cm / 14 inch                               | x                                   | x                                                              |                                            |
| 20-74-712      | Single Slim-Cuff for long arm, length 46 cm / 18 inch                          | x                                   | x                                                              |                                            |
| 20-74-715      | Single Slim-Cuff for lower leg/arm, length 46 cm / 18 inch                     | x                                   | x                                                              |                                            |
| 20-74-722      | Single Slim-Cuff for leg, contour shape, length 61 cm / 24 inch                | x                                   | x                                                              |                                            |
| 20-74-727      | Single Slim-Cuff for long leg, contour shape, length 76 cm / 30 inch           | x                                   | x                                                              |                                            |
| 20-74-728      | Single Slim-Cuff for extra long leg, contour shape, length 86 cm / 34 inch     | x                                   | x                                                              |                                            |
| 20-74-729      | Single Slim-Cuff for super long leg, contour shape, length 107 cm / 42 inch    | x                                   | x                                                              |                                            |

| REF       | Description                                               | Applied parts for:                  |                                                                |                                            |
|-----------|-----------------------------------------------------------|-------------------------------------|----------------------------------------------------------------|--------------------------------------------|
|           |                                                           | Chapter „13.1 Use with Single Cuff“ | Chapter „13.2 Use with two Single Cuffs for bilateral surgery“ | Chapter „13.3 Use with Double Cuff (IVRA)“ |
| 20-50-700 | Double Cuff for infant, length 20 cm / 8 inch             |                                     |                                                                | X                                          |
| 20-50-710 | Double Cuff for child, length 30 cm / 12 inch             |                                     |                                                                | X                                          |
| 20-50-711 | Double Cuff for arm, length 5 cm / 14 inch                |                                     |                                                                | X                                          |
| 20-50-712 | Double Cuff for long arm, length 46 cm / 18 inch          |                                     |                                                                | X                                          |
| 20-50-722 | Double Cuff for leg, length 61 cm / 24 inch               |                                     |                                                                | X                                          |
| 20-50-727 | Double Cuff for long leg, length 76 cm / 30 inch          |                                     |                                                                | X                                          |
| 20-50-728 | Double Cuff for extra long leg, length 86 cm / 34 inch    |                                     |                                                                | X                                          |
| 20-50-729 | Double Cuff for super long leg, length 107 cm / 42 inch   |                                     |                                                                | X                                          |
| 20-60-711 | Silicone Double Cuff for arm, length 35 cm / 14 inch      |                                     |                                                                | X                                          |
| 20-60-712 | Silicone Double Cuff for long arm, length 46 cm / 18 inch |                                     |                                                                | X                                          |
| 20-60-722 | Silicone Double Cuff for leg, length 61 cm / 24 inch      |                                     |                                                                | X                                          |

### 23. DESCRIPTION OF SYMBOLS

|                                                                                    |                                                                                                                          |
|------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
|  | Manufacturer                                                                                                             |
|  | Date of manufacture                                                                                                      |
|  | Article number                                                                                                           |
|  | Serial number                                                                                                            |
|  | Type                                                                                                                     |
|  | Observe instructions for use                                                                                             |
|  | Follow instructions for use                                                                                              |
|  | Caution                                                                                                                  |
|  | <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                                                                                                      |
|  | Type B applied part                                                                                                      |

|                                                                                                                                             |                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                          | Potential equalisation                                                                                                                                                                                                                                          |
|                                                          | Do not dispose of electrical or electronic equipment in household waste                                                                                                                                                                                         |
|                                                          | Do not dispose of battery in household waste                                                                                                                                                                                                                    |
|                                                          | CE marking with identification number of the notified body.                                                                                                                                                                                                     |
|                                                          | This product does not contain any hazardous substances exceeding concentration limits. The product is environmentally friendly and can be recycled.                                                                                                             |
|                                                          | 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. |
|  | 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.                                                                        |
|                                                          | <b>CAUTION</b><br>Risk of electric shock<br>Do not open the housing.<br>Refer servicing to qualified service personnel                                                                                                                                          |

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