

## CONNECT – Important Safety Information

### CONTRAINDICATIONS:

- There are no known contraindications for Sorin CONNECT.

### SAFETY INSTRUCTIONS:

#### General safety Instructions

- The safety guidelines for the overall system within which Sorin CONNECT is operated also apply to Sorin CONNECT.
- Sorin CONNECT may only be used by trained and qualified perfusionists and may only be maintained by trained and qualified personnel.
- The operator must read these operating instructions carefully and be familiar with the functionality before operating Sorin CONNECT for the first time.
- Also applicable to Sorin CONNECT in combination with the overall system: Sorin CONNECT must undergo a regular maintenance inspection by an authorised service technician. Sorin CONNECT must be subjected to this maintenance inspection every 1000 operating hours or every 12 months, depending on which comes first. ► The regulations concerning routine maintenance and care of the overall system in which Sorin CONNECT is used also apply to Sorin CONNECT.
- Medical conclusions must not be drawn from and interventions in the perfusion must not be carried out on the basis of the software displays. These displays include data recorded in CONNECT from external devices as well as results displayed from formula calculations and measure conversions. Medical intervention and therapeutic procedures must not be based solely on the displays. Values determined by the software must be checked for plausibility.
- All disposables used in connection with the overall system must be disposed of in accordance with the applicable environmental laws and regulations. Comply with your hospital's regulations when disposing of these items.
- Ensure that the manually entered values and data are consistent with the corresponding data source. Manually entered values and data must be checked for plausibility.
- Connecting additional devices may lead to the creation of a medical electrical system (ME system). ME systems can have a negative effect on safety. Ensure that the connected medical devices comply with the valid standard IEC 60601-1 and observe the IEC 60601-1 requirements for ME systems.
- Always ensure that all external devices providing relevant data to calculate GDP parameters are fully calibrated according to their individual calibration procedure, otherwise the calculated GDP parameters may be incorrect.

#### Safety instructions during use

- Sorin CONNECT and the overall system must be monitored by trained and qualified perfusionists at all times during operation. Non-compliance with the responsibility of monitoring the device may put the patient at risk! The safety features are intended to

assist users but do not release them from their responsibility to monitor the system at all times.

- The patient condition and the perfusion status must be continuously monitored.
- Set up the overall system in such a way that unobstructed view of all screens and displays is ensured at your workplace.
- Make sure that you have unobstructed access to touch screens, keys, and setting controls at any time.
- The user is responsible for taking due care when entering values manually. Calculated values must be checked additionally for plausibility.
- It is possible to display the gain and loss of fluids as a fluid balance on the perfusion screen of the CONNECT Recorder software. Medical intervention and therapeutic procedure must not be based solely on this display.
- Compare the calculated haematocrit value with the measured haematocrit value. Medical intervention and therapeutic procedure must not be based solely on calculated values. ► Values displayed on the GDP Monitor must be checked additionally for plausibility.
- Check the patient ID. Ensure that the lab values (e.g., laboratory adjustment of oxygen saturation and haematocrit) are assigned to the appropriate patient.
- Check the blood products used. The blood type information in the software must not be used as the basis for selecting blood products. Observe your hospital's specified procedure for the selection of blood products.
- Medical intervention and therapeutic procedure must not be based solely on the perfusion records (reports).
- Do not make therapeutic decisions based on a possible trend in the displayed data.

## Data security instructions

These instructions refer to the general handling of your computers and data:

- Use antivirus software to protect the PC on which the CONNECT software is installed. Ensure that the hospital network is protected by a firewall or similar security system.
- Protect your PC using antivirus software and firewalls. Check and update your antivirus software and firewalls at regular intervals to ensure operational reliability.
- Ensure that all Datapad devices in your hospital are protected by antivirus software. LivaNova Deutschland GmbH does not install additional antivirus software. To ensure optimum monitoring and easier updating, all hospital PCs should be protected by the same antivirus software. The users are responsible for the security of the system.
- Set a password on the PC on which the CONNECT software is installed to protect it against unauthorised access. Never leave the PC unattended during operation. The user is responsible for the security of all data.
- Perform regular backups of all the data on your PC, preferably every day! Use appropriate backup media.
- The user is responsible for the security of all data. Patient data must be protected against unauthorised access by third parties (e.g., by means of a password). Printed perfusion records must be stored in a safe location.
- Any information that is relevant to data privacy protection is encrypted during data transfer on the USB stick. This prevents unauthorised access by third parties.

- Ensure that the USB stick used for data transfer is virus-free. Use the current antivirus software on your PC to check USB sticks for viruses before using them to transfer data.
- Use the USB stick exclusively for data transfers between the two software components CONNECT Manager and CONNECT Recorder (and vice versa). Do not use the USB stick for other applications to protect the system against viruses and/or malware.
- Label or mark your USB memory sticks (removable media). This prevents mix-ups and data loss.
- Check the patient data after every data transfer. Before the start of the surgery, ensure that all required data have been transferred correctly and completely.
- If you wish to use WLAN (or LAN) transfer, note the current encryption method when establishing the connection. Contact your Service department, if necessary.
- If transfer via WLAN is not required, the function must be disabled on the Datapad. If WLAN transfer is used, a protected wireless network must be configured to prevent unauthorised WLAN access to the Datapad.
- The hospital's IT department is required to manage and maintain the central CONNECT database in the hospital network and to protect the database against unauthorised access. The user privileges of the CONNECT users must be limited to operating the software and must not include administrator rights.

For professional use. Please [click here](#) to find instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Consult your labeling.