

Bcare5 EQUIPMENT – Important Safety Information

SAFETY INSTRUCTIONS:

General Safety Instructions

- B-Care5 has been designed using state-of-the-art technology while adhering to accepted safety standards. Nevertheless, the patient, the user or other equipment may be put at risk during operation.
- B-Care5 may only be used if in perfect working order and according to regulations and operating instructions. Be sure to take note of any cautions or warnings.
- The operating instructions for B-Care5 should be kept close to the device at all times. Incomplete or illegible operating instructions must be replaced immediately.
- Also applicable to B-Care5 in combination with the S5/C5 System (overall system): According to the European Directive 93/42 EEC and the national standards based on this directive, B-Care5 must be subjected to a regular maintenance check by an authorized service technician. B-Care5 must be subjected to this maintenance check every 1000 operating hours or every 12 months, depending on which comes first.
- In addition to the operating instructions, the relevant legal, general and binding regulations concerning the prevention of accidents must be observed.
- In order to take situations into account which are clinic-specific and outside of normal routine, e.g. certain working procedures, the operating instructions must be supplemented with relevant instructions (supervision and registration requirements, etc.).
- An S5/C5 System is required to operate B-Care5. You will find the firmware information inside the front cover and in the separate operating instructions for the S5/C5 System. Only authorized service technicians may upgrade the relevant firmware.
- If modifications affecting safety or performance come to notice when the overall system is not in use, do not use the machine and have it checked by an authorized service technician immediately.
- Do not modify or extend the system unless the changes have been tested and approved by LivaNova DEUTSCHLAND GmbH. LivaNova DEUTSCHLAND GmbH cannot assume liability or responsibility for unauthorized modifications or changes.

Safety instructions during use

- B-Care5 should only be operated and maintained by trained and qualified personnel.
- B-Care5 must be monitored at all times during operation. Non-compliance with the responsibility of monitoring the equipment can put the patient at risk! The safety features of the overall system (alarm signals etc.) are intended to support the operator and do not free him from his responsibility to monitor the equipment continuously and conscientiously.
- Medical conclusions must not be drawn from and interventions in the perfusion must not be carried out on the basis of B-Care5 displays. Medical intervention and therapeutical procedure must not be based solely on the displays.
- B-Care5 does not offer absolute accuracy. Values determined by and displayed on B-Care5 are trends and must be checked for plausibility.

- Position the measuring head correctly on the tube or on the reference element. Incorrect positioning can result in incorrect values.

Operational safety

- The safety guidelines for the overall system in which B-Care5 is operated also apply to B-Care5.
- The operator must read these operating instructions carefully and be familiar with the functionality before operating B-Care5 for the first time!
- B-Care5 may only be used with a S5/C5 System. Only one B-Care5 may be used.
- The sensor module of B-Care5 and the venous sensor constitute a unit and they should only be operated together.
- The operator should read the separate operating instructions for the S5/C5 System and be familiar with the functionality of the overall system before using B-Care5 for the first time!
- Only authorised service technicians may upgrade B-Care5. The sensor module and the measuring head constitute a unit and may not be operated separately. The measuring head values are stored in the sensor module.
- Alterations to the module or the use of spare parts and accessories which have not been tested and approved by LivaNova DEUTSCHLAND GmbH could have a detrimental effect on the safety and operation of the overall system. In such cases, LivaNova DEUTSCHLAND GmbH cannot accept any liability or responsibility.
- You should only use LivaNova venous measuring connectors with a 1/2" or 3/8" diameter.
- The different measuring locations should be taken into account when the measured values of B-Care5 and other measuring systems are compared.
- Values (e.g. blood flow, temperature, etc.) can fluctuate at the beginning and towards the end of a cardiopulmonary bypass procedure. This can lead to considerable deviation between the parameters displayed and the reference values of the laboratory device.

Safety instructions for routine maintenance

- Routine maintenance work should only be carried out by qualified personnel.
- The regulations concerning routine maintenance for the S5/C5 System in which B-Care5 is used also apply to B-Care5.
- Disconnect the overall system from the mains power supply before carrying out routine maintenance.
- You must always follow the regulations concerning routine maintenance outlined in these operating instructions.
- Always use recommended cleaning agents.
- Repairs should only be carried out by authorised service technicians. To guarantee safe and reliable operation of the module, only original spare parts from LivaNova DEUTSCHLAND GmbH should be used.
- Alterations to the module or the use of spare parts and accessories which have not been tested and approved by LivaNova Deutschland GmbH could have a detrimental effect on the safety and operation of the overall system. In such cases, LivaNova Deutschland GmbH cannot accept any liability or responsibility.

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.

DISPOSABLE (applicable for Bcare5 and Datamaster) – Important Safety Information

CONTRAINDICATIONS:

- No contraindications are known if the device is used for the purpose described and in accordance with the stated operating conditions.
- Do not use the device for any purpose other than indicated.

SAFETY INFORMATION

WARNINGS:

- The operator must check the device closely during assembly and filling in order to identify any leaks. Do not use the device if any leaks are found.
- Only use the device if it is STERILE.
- The arterial connector must be used following these instructions for use and the DATA MASTER user's manual. The Venous connector must be
- used following these instructions for use, the DATA MASTER user's manual and the B-Care5 user manual.
- The device is intended for professional use.
- SORIN GROUP ITALIA is not responsible for problems arising from inexperience or improper use.
- FRAGILE, handle with care.
- For single use and for single-patient use only. During use the device is in contact with human blood, body fluids, liquids or gases for the purpose of eventual infusion, administration or introduction into the body, and due to its specific design it cannot be fully cleaned and disinfected after use.
- Therefore, reuse on other patients might cause cross-contamination, infection and sepsis. In addition, the reuse increases the probability of
- product failure (integrity, functionality and clinical effectiveness).
- Sterile Contents/Non-Pyrogenic Fluid Pathway unless package is opened or damaged.
- The device must not undergo any further processing.
- Do not resterilize.
- Always give and maintain a correct dose and accurate monitoring of the anticoagulant before, during and after the bypass.
- Keep away from moisture. Store at ambient temperature.
- After use, dispose of the device in accordance with applicable regulations in force in the country of use.



Health innovation that matters

- For further information and/or in case of complaint contact SORIN GROUP ITALIA or the authorized local representative.

CAUTIONS:

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

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