

SCPC – Important Safety Information

INDICATIONS:

In accordance with the applicable regulations, the SCPC System is used for operating the Stöckert Centrifugal Pump System (SCP System).

CONTRAINDICATIONS:

There are no known contraindications for the SCPC System. The attending physician is solely responsible for the use of the system.

WARNINGS:

1. The SCPC System has been designed according to current state-of-the-art technology and accepted safety standards. Although this is the case, danger may arise for the patient, the user or for other equipment during operation
2. The SCPC System must not be used in the presence of explosive substances.
3. The SCPC System may only be operated when the equipment is in good technical running order and, when used, in accordance with the applicable regulations and the operating instructions. Be sure to take note of cautions and warnings.
4. The operating instructions must be available close to the SCPC System at all times. Incomplete or illegible operating instructions must be replaced immediately.
5. The SCPC System must be subjected at regular intervals to a regular maintenance check by an authorised service technician (in accordance with national regulations). For the SCPC System, this check must be carried out after every 1000 operating hours or at least after every 12 months, whichever comes first.
6. In addition to the operating instructions, the relevant legal, general and binding regulations concerning the prevention of accidents must be observed.
7. In order to take situations into account which are clinic-specific and outside of normal routines, e.g. certain work procedures, the operating instructions must be supplemented with relevant instructions (supervision and registration requirements, etc).
8. Personnel operating the SCPC System must have acquainted themselves thoroughly with the operating instructions prior to working on the system!
9. - If modifications affecting safety or system performance are noticed when the SCPC System is not in use in the O.R., power it down immediately and have it checked by an authorised service technician.
10. Do not perform any modifications or extensions to the SCPC System unless they have been tested and approved by LivaNova Deutschland GmbH, or else LivaNova Deutschland GmbH cannot assume any liability or responsibility.
11. For safety reasons, ensure that a minimum distance of 1.50 m (5 feet) is kept between the patient and electronic equipment.
12. The serial port is only intended to transmit DMS data (e.g. to another computer).
Maintenance and care : See chap. 7
13. Keep the SCPC System clean. This will prevent premature wear and faults due to dirt.

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.