

## S5 – Important Safety Information

### WARNINGS:

- Before operating the S5 System, read the instructions with great care
- In accordance with the applicable regulations, the Stockert S5 System is used to perform, control and monitor extracorporeal blood circulation during an operation.
- The S5 System must not be used in the presence of explosive substances
- When in operation, the S5 System must be monitored at all times. Non-compliance with this duty may result in danger to the patient's health! The safety features of the S5 System (alarm signals etc.) are intended to assist the user and do not free him from his responsibility to monitor the equipment continuously and conscientiously.
- A cardiopulmonary bypass requires comprehensive monitoring of both the patient and the perfusion status. For this reason, all relevant values which are not recorded directly on the S5 System must be monitored externally.
- Medical conclusions must not be drawn from and interventions in the perfusion must not be carried out on the basis of the displays which have been obtained from serial data.
- Carefully monitor the blood volume in the blood reservoir.
- All values from the entire system which have been determined or displayed must be checked for plausibility. Pay attention to the pump parameters which are being used and the material and diameter of the tubing.
- Before using the machine, check all cables, tubes, connectors and other accessories to make sure that they are connected correctly, are not leaking and are in perfect working order. Replace all damaged components immediately.
- Do not use any more connectors or tubing than is necessary for operating the machine in accordance with the regulations. Additional connectors etc. increase the risk of faults.
- Accessories and supplementary devices which have not been tested and approved by LivaNova Deutschland GmbH must have evidence to show that their use does not represent a safety hazard.
- Before carrying out maintenance and cleaning work on the machine, disconnect it completely from the power supply. Make sure that the system is switched off (as the UPS permits operation even without the mains power supply).

### Installation

- The Stockert S5 System must only be unpacked, installed and tested by authorized service technicians. After the installation has been performed, the service technician from LivaNova will train the perfusionist(s) who are responsible for operating, maintaining and carrying out the emergency procedures on the system. The S5 System must only be operated by personnel who are trained and instructed to do so. Before having the system installed, please make sure that at least one responsible perfusionist on your team can take part in this training. The participation is mandatory and must be countersigned by the participant.
- Only authorized service technicians are permitted to carry out the initial installation of the S5 System. However, the following description may also serve as a guideline for the experienced operator as far as routine assembly and setting up the S5 system are concerned
- Only use the level sensor on oxygenators/reservoirs made from rigid polycarbonate or similar plastics. The wall thickness at the intended sensor position should not exceed the following values:
  - 2-3 mm for the white sensor holder (23-27-41)
  - 2-4 mm for the green sensor holder (23-27-60)

- Non-compliance with these requirements may result in the level sensor not operating properly
- When connecting external devices, accumulated leakage currents may result in safety hazards.
- Before connecting the S5 System, check again to make sure that all previous installations and connections have been carried out correctly
- Warning: If the pump is set to turn in the wrong direction during an operation (e.g. when operating the pump with the hand crank), the resulting negative pressure poses a serious threat to the life of the patient. If the pump head is manually rotated in the wrong direction when the system is switched off, the pump will sound an alarm signal.
- Each time immediately before using the machine: switch off the S5 System and switch it on again. Monitoring the self-test when switching on.

## **Operation**

- To make sure that the machine is kept running when there is a power failure: the batteries must be charged and in working order for the machine to operate. In the S5 System, there is an integrated control system which allows you to monitor the status of the batteries and UPS at any time. The entire control system consists of several components:
  - ▶ UPS controller for continually monitoring the discharging process of the batteries during a power failure
  - ▶ Mains power supply monitor for activating and deactivating the UPS automatically
  - ▶ Charging device for controlling the charging of the batteries when there is a mains power supply
  - ▶ UPS menu with status display on the system panel
  - ▶ Integrated test routines for regular testing of the physical operation and capacity of the batteries (every 120 days)
- The physical characteristics of the batteries have to be checked regularly to ensure that the entire UPS continues to operate reliably. Apart from measuring the battery's efficiency, this check also detects faults arising from damage to the batteries due to deep discharge etc In this case, the S5 System is not ready for use without an operational UPS and, in the interest of your patients' safety, must not be used Then pass the S5 System immediately to the authorised service technician
- The pumps are the "heart" of the S5 System. You must follow all the safety and operating instructions. The lives of your patients depend on you operating the S5 System safely!
- Each time before using the machine, check:
  - ▶ That the pumps and the corresponding control and display modules are operating perfectly.
  - ▶ That all the sensors and devices connected to the pumps are working perfectly.
  - ▶ The basic settings and assignments of the pumps. These settings may have been changed during previous operations.
  - ▶ Pump occlusion
  - ▶ Actual flow rate
- Pay particular attention to the following:
  - ▶ The control and monitoring functions of the S5 System make your work easier but they are not a substitute for your complete and undivided attention!

- ▶ Make yourself familiar with all possible alarm situations (bubbles etc.) by simulating the alarms and clearing them. In an emergency situation, there will not be enough time available to look anything up in this manual.
  - ▶ Make absolutely sure that there is no electromagnetic interference caused by third party devices. Only use devices which comply with the applicable EMC regulations.
  - ▶ Whenever you notice any such interference, disconnect all pumps from the assigned control and monitoring devices (sensors). In this case, you must observe all events and conditions (blood level in the oxygenator etc.) with even more attention.
  - ▶ Ensure that maintenance and calibration is carried out regularly by the authorised customer service technicians.
  - ▶ Regularly carry out all the basic adjustments required (occlusion etc.).
  - ▶ If an arterial pump stop occurs, the venous line must be clamped.
  - ▶ If an arterial pump stop occurs while intentionally set for underocclusion, the arterial line must be clamped.
  - ▶ Practise emergency operation using the hand crank.
  - ▶ Practise installing the tubing in order to be able to install the tubing in another pump in case of pump failure.
  - ▶ Secure the tubing system tightly to stop vibration occurring during pulse mode.
  - ▶ When silicon tubing is used and the flow exceeds 5 l/min, the tubing should always have a wall thickness of 1/2" x 1/8
- When using the master/follower link, make sure that the direction of rotation of the two selected pumps is correct.
  - If the pump is operated with the cover open, there will be a risk of injury from crushing or by getting caught on rotating parts of the pump!
  - The user is solely responsible for deciding whether to continue using a pump in spite of the existence of an alarm situation. Pay particular attention and treat this case with the utmost care!
  - If a monitoring device does not function correctly, the pump is disconnected from the device by means of the override and is then subject again to manual control
  - Check very carefully to determine whether the pump can actually continue to run without endangering the patient's life.
  - Monitoring the perfusion by means of a bubble detector is part of the protection system against air delivery. However, the greatest degree of protection can only be guaranteed if the following conditions have been fulfilled:
    - ▶ The level sensor on the oxygenator/reservoir must be mounted at a point which is high enough to prevent air from being included because of the level being too low.
    - ▶ The arterial line must be monitored with a bubble sensor.
    - ▶ Before using the machine, always carry out a simulation on the bubble detector to make sure that it is working properly.
    - ▶ Always use an arterial filter.
    - ▶ Only use PVC tubes with appropriate diameters for the bubble.
    - ▶ The minimum distance between the bubble sensor and the patient is
      - 1.00 m where tubing diameter is constant over the entire perfusion length;
      - 2.50 m where there is a reduction in the tubing diameter to the next smallest size and the pump speed is greater than 100 rpm.
    - ▶ Never leave the machine during an operation. Pay close and constant attention to the whole system during the entire period of the perfusion.
  - The level sensor on the oxygenator/reservoir must be mounted at a point which is high enough to prevent air from being included because of the level being too low.

- Always use an arterial filter.
- Use the bubble sensor.
- The ventilation line must be provided with a safety check valve ("one-way" safety valve). When installing the safety check valve, note the correct direction of flow. !
- Make sure that the level sensor is positioned correctly. The level in the oxygenator/reservoir must not drop below the minimum value.
- Before using the machine, always carry out a simulation on the level control to make sure that it is working properly.
- If the level control is activated, pulse mode may not be started on the corresponding pump.
- Never leave the machine during an operation. Pay close and constant attention to the whole system during the entire period of the perfusion
- To ensure safe and reliable operation of the pressure monitor:
  - ▶ Only use pressure transducers which comply with the required specifications.
  - ▶ The arterial line must be monitored using a pressure transducer.
  - ▶ In any case, follow the separate operating instructions of the pressure transducer being used (pressure limits, temperature and storage etc.).
  - ▶ Handle the pressure transducer with the utmost care. The pressure membrane is highly susceptible to damage. For information on suitable protective measures, refer to the separate operating instructions of the transducers being used.
  - ▶ Before each operation, calibrate the pressure monitor (both channels) to the transducers being used.
  - ▶ If the pressure control is activated, pulse mode may not be started on the corresponding pump.
  - ▶ Never leave the machine during an operation. Pay close and constant attention to the whole system during the entire period of the perfusion
- Only set the pump speed as high as is necessary for perfectly regulated operation. Otherwise, the pump speed will be too high in the event of an override or faulty measurement and the patient's life will be put at risk.
- Note that the dosage accuracy has to comply with the requirements for cardioplegic solutions. The cardioplegia control and the pumps are not suitable for dosing or delivering very potent drugs.
- To ensure safe and reliable operation of the cardioplegia control:
  - ▶ Before use, check whether the dosage accuracy is sufficient for the present application.
  - ▶ Ensure that the pump occlusion and the flow rate have been adjusted correctly. This is essential for achieving the highest possible dosage accuracy.
  - ▶ The blood cardioplegia must only be delivered via the cardioplegia control.
  - ▶ Do not operate cardioplegic control with bubble or pressure sensors disconnected.
  - ▶ Before using the machine, always carry out a simulation of all monitoring functions to make sure that they are working properly.
  - ▶ Operate the cardioplegia pump only in combination with the arterial pump linked using the "stoplink".
  - ▶ Only use pressure transducers which comply with the required specifications. In any case, follow the separate operating instructions of the pressure transducer being used (pressure limits, temperature, storage and calibration etc.).
  - ▶ Before each use, calibrate the pressure monitor to the transducer being used.
  - ▶ The temperature probe for measuring the cardioplegia temperature must be connected to the third channel of the sensor module of the 4-channel temperature monitor.
  - ▶ Never leave the machine during an operation. Pay attention to the level in the cardioplegia bottle.

- ▶ Pay close and constant attention to the whole system during the entire period of the perfusion.
- Before activating cardioplegia recirculation mode, the cardioplegic line must be connected in a closed circuit
- To guarantee that the temperature monitor operated safely and reliably:
  - ▶ Only use 400series-compatible temperature probes with BF grade insulation.
  - ▶ The entire temperature monitor system, i.e. the sensor module and the temperature probes have to be calibrated or certified every two years (according to the Medical Product Operating Directives or equivalent local regulations). The date of the next calibration must be clearly marked on the device.
- To guarantee safe and reliable operation of the Air Purge Control (APC):
  - ▶ The APC suction line must be fitted with a safety check valve ("one-way" safety valve). When installing the safety check valve, be sure to observe the direction of flow.
  - ▶ Test for leaks at occlusion settings up to -100 mmHg.
  - ▶ Test the APC suction line for leaks at settings up to -100 mmHg.
  - ▶ Before using the machine, always carry out a simulation on the bubble alarm and the suction pump to make sure that it is working properly.
- The APC can only be operated in automatic mode with a preset purge time if the following conditions have been fulfilled:
  - ▶ The centrifugal pump system must be switched on.
  - ▶ The centrifugal pump system must be operated with a flow sensor that continuously monitors the arterial blood flow.
  - ▶ The centrifugal pump system must not be in a "negative flow" alarm situation.
- If there is air in the venous bubble trap at the end of the purge time, it must be removed:
  - ▶ Switch to manual mode and remove the remaining air.
  - ▶ Then switch back to automatic mode

## Sensors

### *Bubble Sensor*

- The level sensor on the oxygenator/reservoir has to be attached high enough to prevent the inclusion of air.
- Always use an arterial filter.
- The bubble sensor has to be mounted behind the oxygenator. (Either in front of or behind the arterial filter.)
- The bubble sensor must not be mounted in front of the arterial pump.
- The minimum distance between the bubble sensor and the patient is
  - 1.00 m where tubing diameter is constant over the entire perfusion length;
  - 2.50 m with a transition to the next smallest tubing diameter and a pump speed of more than 100 rpm.
- Never leave the machine during an operation. Pay close and constant attention to the whole system during the entire period of the perfusion.
- Only use sensors which fit the tubing.
- Only use tubing inserts which fit the tubing and the sensor.
- The bubble detector can only fulfil its safety function by following the guidelines below when inserting the tubing:
  - Only use PVC tubes with the appropriate diameters for the bubble sensors.
  - Choose the right sensor for the tubing. The following sensors are available

- a sensor for 1/2" tubing
- a sensor for 3/8" tubing
- a sensor for 1/4" tubing
- a sensor for 3/16" tubing

## *Level Sensor*

- Only use the level sensor on oxygenators/reservoirs made from rigid polycarbonate or similar plastics! The wall thickness at the intended sensor position should not exceed the following values:
  - 2-3 mm for the white sensor holder (23-27-41)
  - 2-4 mm for the green sensor holder (23-27-60)
- Non-compliance with these requirements may result in the level sensor not operating properly

## *Pressure Sensor*

- When working with pressure sensors, bear in mind the following points:
  - ! ▶ Only use pressure transducers which comply with the required specifications.
  - ▶ In any case, follow the separate operating instructions of the pressure transducer being used (pressure limits, temperature, storage and calibration etc.).
  - ▶ Handle the pressure transducer with the utmost care. The pressure membrane is highly susceptible to damage. For information on suitable protective measures, refer to the separate operating instructions of the transducers being used.
  - ▶ Only store the transducer in the containers provided for the purpose

## *Pumps*

- To guarantee safe (for the operator and the patient) and reliable operation of the pumps:
- ▶ If the pumps are operated with the cover open or with the tubing clamp block a removed, there will be a risk of injury from crushing or by getting caught on rotating parts).
  - Therefore, only operate the pumps with the cover closed.
  - Only operate the pump when the tubing clamp block a has been installed.
- Never change the direction of rotation of the pumps without labelling it accordingly (arrow c) for everyone to see. If the pump is set to turn in the wrong direction during an operation (e.g. when operating the pump with the hand crank), the resulting negative pressure poses a serious threat to the life of the patient. If the pump head is manually rotated in the wrong direction, the pump will sound an alarm signal (even when the system is switched off).
- Always use the correct tubing clamp inserts for the tubing.
- Adjust the pump occlusion and measure the flow rate each time before using the machine.
- Secure all the cables with cable ties.
- When using a double roller pump 85 with a 1/4" x 3/32" tubing, please note that 1/4" x 3/32" PVC tubes must not be used.
- When using a double roller pump 85 with a 5/16" x 3/32" tubing clamp block, please note that PVC tubes must not be used.
- Select the appropriate tubing clamp for the double roller pump. Incorrect tubing clamps can result in serious disruptions during perfusion because the tubing is pinched or not seated securely in the pump.

- Choose compatible tubing clamp inserts. Incorrect tubing clamp inserts can result in serious disruptions during perfusion because the tubing is pinched or not fixed properly in the pump.
- Always check whether the tubing sets (or other accessories) are suitable for the intended current application according to their specifications (in terms of type of operation and size of the patient etc.). Compatibility with the S5 System must be guaranteed by the manufacturer in question; a CE label is obligatory.
- Overocclusion can cause hemolysis and can overload the pump and damage the tubing.
- Underocclusion causes a backflow of the blood and can result in false indications of the flow rate.
- The following basic settings are necessary for the safe operation of the S5 System. These settings must be readjusted at the following time intervals:
  - ▶ Adjusting and checking the pump occlusion: each time before using the S5 System.
  - ▶ Measuring the flow rate: each time when changing the occlusion adjustment.
  - ▶ Calibrating the pressure monitor: each time before using the S5 System.

### *Pressure Monitor calibration*

- Make sure that the junction to the extracorporeal circuit is sterile when connecting the pressure dome

### *Preoperative check*

- Always carry out the following system checks each time before using the S5 System. By doing so, you will achieve the maximum safety for performing the operation with a system which functions with the optimum configuration.
- Checks before switching on the system.
- Have the power cable and the potential equalisation cable been connected in compliance with the applicable regulations?
- Have all the sensors which are intended to be used been connected to the E/P pack?
- Have all the plugs of the System panel and any other devices been connected according to the applicable regulations?
- Has a suitable and reliable tubing set been installed?
- Is an extra oxygenator available?
- Have all the cables and tubes been fixed (cable ties) so that they will not get caught under the castors or on other objects when moving the machine? Also bear in mind that the patient might have to be transported while the machine is working.
- Have all the castor brakes of the S5 System been locked?
- Is another heart-lung machine available for emergencies.

### *Function Check*

- Switch off the S5 System each time before using it and switch it on again after at least ten seconds.
- The system runs a complete component test (which is only performed after switching on the machine).

- Note: Switching the machine off and on does not have any effect on the settings. All the basic settings and configurations of the sensors and control modules are saved.
- Faults which occur when switching on the S5 System or the pumps are displayed in the System menu
- The correct operation of the level control mode not only depends on the operation of the S5 level monitor but also the physical characteristics of the oxygenator/reservoir being used, the flow rate of the blood and the possible occurrence of vibrations. It is therefore essential that the level control is checked to make sure that it is operating correctly by carrying out a simulation each time before using the machine

## *Emergency*

- The term "emergency" covers the following malfunctions:
  - ▶ A power failure of the mains power supply.
  - ▶ A fault in the UPS module.
  - ▶ Total failure of the mains power supply and the UPS.
- Solutions are available for all of these malfunctions which will make it possible to start, continue or conclude an operation.

## *UPS*

- Deep discharge allows the UPS to operate beyond the normal capacity limits (i.e. beyond the time remaining 00:00). However, the batteries are likely to be damaged by doing so. A "Deep discharge" should therefore only be selected in emergency
- Carefully monitor the time remaining display ("Battery time") during the remainder of the operation and take steps to conclude the operation in time
- In case of power fail and manual control of the pumps
  - ▶ Lock the brakes on the front castors of the console of the S5 System.
  - ▶ Ensure that the direction of rotation of the pump is correct (arrow). Turning in the wrong direction is indicated by an alarm signal.
  - ▶ Turn the pump as smoothly and evenly as possible and not too quickly
- Do not use the S5 System when a UPS fault occurs but pass it immediately to your service technician. In principle, it is possible to continue using the machine in the event of an emergency but both the safety of the machine and its operation will be limited
- If the fault occurs while it is operating, you can continue to use the S5 System while paying more attention to its operation and any further fault messages. Hand the machine over to your service technician immediately afterwards.

## *Operating the H/C*

- To comply with the regulations, the Heater-Cooler System 3T (abbreviation: Heater-Cooler) can only be used on or with a Stöckert HLM (in this case S5) for monitoring the temperature control of 3 water circuits during an extracorporeal perfusion. The water circuits are used for controlling the temperature of the blood (in the oxygenator), cooling/heating pads or cardioplegia solutions etc. Any use outside this specification is not in accordance with the regulations.

## *Operating the Gas Blender*

- To comply with the regulations, the gas blender can only be used for monitored mixing, regulation and display of gas flow rates (air/O<sub>2</sub>/CO<sub>2</sub>). The gas mixture is used for enriching the blood with oxygen in an oxygenator. Any use outside this specification is not in accordance with the regulations.



## *Operating the SCP*

- In accordance with the applicable regulations, the SCP System is used together with the Revolution® and the Stöckert HLM (in this case S5) as a centrifugal pump during cardiopulmonary bypass procedures. Any use outside this specification is not in accordance with the regulations.

## *Operating the electrical remote-controlled tubing clamp*

- To comply with the regulations, the electrical remote-controlled tubing clamp (tubing clamp for short) is used to clamp the arterial line. In the event of an alarm (air bubbles, level or “negative flow”), the tubing clamp automatically clamps the arterial line. The tubing clamp may only be used with the SCP System during an extracorporeal perfusion. Any use outside this specification is not in accordance with the regulations.

## *Fault Situations*

- If a fault appears before use: Replace the defective pump and send it in for servicing as quickly as possible.
- Problems and faults can be prevented from occurring during operation by checking and correcting any apparent symptoms and deviations from normal operation before they become more serious

## *Routine maintenance*

- Regular care and maintenance is important for the function and operation of the S5 System because this
  - ▶ Increases operational safety and reliability,
  - ▶ Reduces susceptibility to failure and
  - ▶ Increases the service life of all the components (value maintenance)
- Before carrying out routine maintenance, disconnect the S5 System fully from the mains power supply. Make certain that the system is switched off (as the UPS permits operation even without mains power supply).
- Do not fail to follow the regulations concerning routine maintenance, as well as the prescribed maintenance intervals stated in the operating instructions.
- Follow the separate operating instructions for all accessories.
- Use recommended cleaning agents.
- Wear protective gloves when disconnecting used tubing sets and disposables.
- Routine maintenance work must only be carried out by qualified personnel.
- Repair work on the machine must only be carried out by authorised service technicians. To guarantee safe and reliable operation of the S5 System, only genuine spare parts from LivaNova Deutschland GmbH may be used.
- Apart from the hygienic aspect, it is essential for the operational safety and reliability of the S5 System that it is kept clean. Perform the following cleaning routine every time the system has been used.
  - ▶ Before cleaning the S5 System, disconnect it from the mains power supply and ensure that the system is switched off. This is important because the UPS will enable the system to operate even if it is not connected to the mains power supply.
  - ▶ Close the flap on the E/P pack.
- Never use cleaning agents containing oil or grease.

- Never use cleaning agents containing acetone, because these can damage the plastics or lacquered surfaces.

## *Accessories*

- In addition to the information below, please follow the separate operating instructions for all accessories.

## *EMC*

- Note: Medical electrical equipment needs precautions regarding electromagnetic compatibility and has to be installed and put into service according to the EMC information provided in the following guidance and the manufacturer's declaration.
- Portable and mobile RF-communications equipment can affect medical electrical equipment.
- The use of cables other than those specified in the Instruction for Use may result in increased emissions or decreased immunity of the heater-cooler and/or the heart-lung machine.

## **CAUTIONS:**

### *Mast and Swivel arms*

- Mounting the vertical mast and stabilizing the mast system extension. The horizontal masts can be positioned as required. The greater the distance between the two horizontal masts, the greater the stability of the mast system extension. A minimum distance of 500 mm must be observed. Do not attach any loads to the horizontal masts
- Mounting the mast system extension on the mast system of the S5 System. The lower swivel arm can also be secured below the console plate. The greater the distance between the two swivel arms, the greater the stability of the mast system extension. A minimum distance of 600 mm must be observed. Do not attach any loads to the swivel arms.

### *Installation*

- Position the S5 System on a horizontal level surface.
- While doing so, ensure that no cables are pinched or kinked.
- Lay and secure all the cables so that the power cable is prevented from being rolled over by the machine or disconnected.
- Are the height-adjustable telescope masts and the push bars optimally positioned and fixed (Allen key in console cover)?
- Is the shelf (optional) installed on the horizontal mast, level to the floor and secured with the bolts along the sides (allen key supplied with the shelf)?
- Make sure again that all mountings and screws are tight.
- When opening fast clamp connectors: Always hold on to the attached component firmly before opening the fast clamp connector.

- Fastening the cables and tubing enables the S5 System to be transported and used safely. Using a cable holder prevents the machine from rolling over and/or accidentally disconnecting a cable or tube.
- Make sure that none of the cables are pinched when installing the pump housing.
- Do not lift the pump housing by the pump head
- When attaching equipment and accessories, the weight allowed on the S5 System is 5 kg max. (per infusion rack) or 20 kg max. (per telescope mast) with a cantilever of  $\leq 20$  cm. At the rear of the console, equipment and accessories must not be attached at a height greater than  $\leq 120$  cm. The entire mast system must not carry more than 45 kg in total. Do not attach any loads to the horizontal mast.
- The S5 System and mast system extension should always be installed on a level surface. All foot brakes should be engaged
- The S5 System should only be moved after the mast system extension has been folded and secured. The clamping levers of the mast system extension can be released to compensate for uneven floor surfaces.
- The cables of the sensors or temperature probes which have been connected must be equipped with blocking ferrites in order to meet the EMC guidelines
- The surface a of the reservoir must be smooth and free of dust and grease. Do not touch the adhesive surface when attaching the sensor holder. The sensor holder must be attached level (i.e. with the left and right level indicator arrows at the same height).
- The Heater-Cooler System 3T can only be connected to the S5 System using the connection cable 45-12-16.
- The gas blender (25-28-50) can only be connected to the S5 System using the connection cable 45-12-02
- The additional devices (in this case: gas blender) may only be connected to System slots 62 or 63. The cable path depends on the choice of installation on the mast system: Feed the cable a or b through the hole c or d in the side of the console. Insert the plug into the corresponding socket. Fix the cables with the cable holder system and cable ties at suitable positions (e.g. on the mast).
- Additional devices may only be connected to the S5 System using the cables specified here.

Additional device (part number)	Connection Cable
SCP System (60-00-00)	45-12-00
Electrical remote-controlled tubing clamp (60-05-00 and 60-05-40)	45-12-00
SCP System (only for S5 System) (60-00-50)	Connection cable with S5 system
Electrical remote-controlled tubing clamp (60-05-60 and 60-05-65)	Connection cable with S5 system slot 62 or 63
SCP System (60-00-00)	slot 62 or 63
Electrical remote-controlled tubing clamp (60-05-00 and 60-05-40)	slot 62 or 63
SCP System (only for S5 System) (60-00-50)	slot 62 or 63
Electrical remote-controlled tubing clamp (only for S5 System)(60-05-60 and 60-05-65)	slot 62 or 63

## Operation

- Because the S5 System is used with a variety of accessories (tubing and sensors etc.), there is no standard configuration or calibration for the machine prior to delivery. Some

basic settings will therefore have to be carried out before using the system during an operation in the OT:

- ▶ General settings of the S5 System on the system panel
- ▶ Pump occlusion (dependent on the diameter and material of the tubing)
- ▶ Measurement and calibration of the flow rate (dependent on the occlusion and the tubing tolerances)
- ▶ Calibration of the pressure monitor (according to the local operating conditions and sensor tolerances)

However, in order to perform these basic settings, you must be familiar with how the machine is generally handled. Therefore, before carrying out these basic settings, please read the following information carefully on how to operate the S5 System.

- When the self-test has been carried out successfully, the main page will appear on the system panel. The S5 System is now switched on and ready to use.
- Always switch off the S5 System using the main switch. Otherwise, the batteries may totally discharge.
- The S5 System retains the last parameters set.
- The S5 System has its own "Uninterruptible Power Supply" (UPS) which is automatically activated when the following situations occur:
  - ▶ if there is a mains power failure or the mains power supply is generally unstable, or
  - ▶ if the internal power supply unit fails.
- The UPS can also be manually activated by:
  - ▶ starting the S5 System without mains power (switching on the machine when it is disconnected from the mains power supply), or
  - ▶ whenever the machine is (intentionally) disconnected from the mains power supply while it is switched on.
- If a fault has been detected during the test, a test message appears on the System menu.
- In this case, the S5 System is not ready for use without an operational UPS and, in the interest of your patients' safety, must not be used!
- All parameters which are adjusted in the pump menu are saved even when the S5 System is switched off. This means that the status of the pump configuration is always the same as it was when the machine was last used. Check to ensure that the configuration meets the current requirements each time before using the machine.
- For safety reasons, it is only possible to change the direction of rotation of the pump with the pumps at standstill. A change in the direction of rotation of the pump during the last time it is used is saved.
- If the System direction of rotation is not the same as that of the pump after switching on the entire system, this is indicated in the System menu.
- If silicon tubing is used, the actual flow is up to 20% less than the displayed flow. This results from the tubing's greater malleability on the suction side of the pump where the pressure is lower.
- If the level or pressure is being monitored during pulse mode, it is also important to observe the following:
  - If the level monitor is switched on, the Start/Stop mode must be selected ("Level control: Off").
  - If the pressure monitor is switched on, the set value must be equal to or exceed the set stop limit.
- The level control is indicated by the warning tone (if activated). If the warning tone is deactivated, you must pay particular attention to the assigned pump

- A sustained pump stop during pressure monitoring is indicated by an alarm tone
- The pressure control is indicated by the warning tone (if activated). If the warning tone is deactivated, you must pay particular attention to the assigned pump.
- If the APC automatic function is deactivated and the suction pump's set speed is greater than "0", the pump starts at the set speed.

## Sensors

### Level Sensor

- The surface of the reservoir must be smooth and free of dust and grease.
- Do not touch the adhesive surface when attaching the sensor holder
- The sensor holder must be attached level (i.e. with the left and right level indicator arrows at the same height).
- The pump stop is triggered (response of the level sensor) with a tolerance of  $\pm 10$  mm.

### Pumps

- Correct adjustment of the pump occlusion is an essential requirement for operating the S5 System. Therefore, the adjustment has to be checked or readjusted each time before using the machine
- Check the position of the tubing in the pump head housing once again. The tubing
  - must lie evenly along the pump raceway,
  - must not be twisted, kinked or pinched,
  - must be fixed securely in the tubing clamp and
  - must not have any play inside the pump.
- Correct adjustment of the pump occlusion is an essential requirement for operating the S5 System. Therefore, the adjustment has to be checked or readjusted each time before using the machine
- Check the position of the tubing in the pump head housing once again. The tubing
  - must lie evenly along the pump raceway,
  - must not be twisted or kinked,
  - must be tightly secured in the tubing clamp inserts and
  - must not have any play inside the pump
- Check the position of the tubing in the pump head housing once again. ! Both tubes
  - must lie evenly along the outer edge,
  - must not be twisted or kinked,
  - must not overlap each other,
  - must be firmly fixed in the tubing clamp inserts and
  - must not have any play inside the pump

### UPS

- After a deep discharge, a battery test must always be carried out in order to rule out any damage to the battery. You will be requested to carry out the battery test regardless of when the test was carried out last.

### Circuit breakers, pumps and devices:

- If one of the circuit breakers 53, 54 or 55 trips, it can be switched on again by pressing it in. If the circuit breaker trips again, the corresponding pump that is connected (or the device) is defective and must not be used

## *Routine maintenance*

- The instructions for routine maintenance which are given in the following sections form part of the operating conditions for the S5 System. This applies both to the routine maintenance which is carried out by the user of the S5 System and to the service inspections (some of which are required by law) which are performed by authorised service technicians and other testing entities
- Regardless of whether there is a service contract or not, the S5 System must be subjected to a regular maintenance check by the authorised service technician (in accordance with the European Directive 93/42 EEC and the national standards which are based on this directive). The maintenance check must be carried out on the S5 System every 1000 operating hours or every 12 months (whichever comes first). The operating hours of the system are displayed in the System menu.

## *Temperature sensor*

- The temperature probes and the sensor module must be checked or calibrated and labelled accordingly every 2 years by authorised personnel (in accordance with the German MDD).
  - ▶ Disinfect the probes by using hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) or isopropyl/ethyl alcohol (70%).
  - ▶ If necessary, remove the distal parts d from the probes for sterilisation purposes. Only the distal ends may be steam-autoclaved. The proximal parts of the probes could be destroyed if sterilised in a steam-autoclave. Gas sterilisation can be used as an alternative method.
  - ▶ Make sure that the contacts on the plug e are in perfect condition (clean surfaces, no damage)
  - ▶ Never boil the temperature sensor

## *Tubing clamp*

- Clean the tubing clamp with a cleaning agent which is commonly used for such purposes in your hospital.
- Disinfect using a commonly used, alcohol-based hand disinfectant.
- When disinfecting, again make sure that no liquids enter the Housing
- Warning: The tubing clamp must not be disassembled any further.

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.