iLA active® CONSOLE

INSTRUCTIONS FOR USE

iLA ACTIVVE® CONSOLE

novalung®

Solutions for Lung Failure

Copyright notice

This copyright holder of this user guide is Novalung GmbH, Heilbronn. All rights reserved, including translation rights.
This document may not be reproduced, in whole or in part, in any form by printing, photocopying, microfilming or any other means, nor may it be processed, replicated, translated or distributed with the aid of an electronic system, in whole or in part, without the written permission of Novalung GmbH. Violation of this prohibition is subject to prosecution under criminal law.

Manufacturer

Medos Medizintechnik AG
Obere Steinfurt 8-10
52222 Stolberg
Germany

info@medos-ag.com
www.medos-ag.com
Tel: +49 2402 9664 - 0
Fax: +49 2402 9664 - 60

Date of issue

September 2014
Software version 3.0

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF FIGURES

1 INTRODUCTION

1 INTRODUCTION

The purpose of this user guide is to familiarise users with the equipment. It describes the construction, operation and use of the equipment. Please observe the instructions in this user guide in order to use the equipment safely and efficiently.

1.1 Explanation of symbols

DANGER 	This symbol designates an imminent hazard. The patient's life and health are at risk if this warning is ignored.
CAUTION 	This symbol designates a potential hazard. Personal injury or damage to equipment may occur if this warning is ignored. The patient's life and health may also be endangered.
ATTENTION 	This symbol designates a potentially harmful situation. The equipment will be damaged or destroyed if this situation is not avoided.

 This symbol marks additional information or practical tips.

The following symbols are used in the text to clarify the operating instructions:

- • Bullet list marker
- ⇨ Designates a task to be performed
- ↳ Designates a consequence of a task
- ❑ Designates a supervisory task
- ☑ Designates a completed task
- ■ Designates an important result

LABELLING AND SYMBOLS ACCORDING TO EN 15223-1

 Item number

 Batch code

 Attention

 Manufacturer

 Date of manufacture (YYYY-MM)

 Use before date (YYYY-MM)

 Sterilisation with ethylene oxide

 Do not reuse

 Allowable temperature range (5 - 40 °C)

 Store protected from sunlight

 Store in a dry place

 Do not use if package damaged

 Observe use instructions

LABELLING AND SYMBOLS ACCORDING TO DIN EN 50419

Separate collection of electrical and electronic devices

LABELLING AND SYMBOLS ACCORDING TO EN 60601-1:2007

Follow use instructions

Equipotential (same electrical potential)

Non-ionising electromagnetic radiation

Fuse / circuit breaker

Type CF application component [applies to the device and sensors]

1.2 Dimensions

All dimensions are stated in millimetres (mm). Any other dimensional units are individually marked.

1.3 Page numbering

The pages of this user guide are numbered sequentially by section.

Page 1 – 2 means page 2 of Section 1.

2 SAFETY INSTRUCTIONS

2 SAFETY INSTRUCTIONS

Knowledge of the basic safety instructions and safety regulations is a basic prerequisite for the safe use and trouble-free operation of this device. This user guide contains all relevant instructions for the safe use of the device.

Everyone who uses or operates the device must follow this user guide, and in particular the safety instructions.

In addition, users must observe the rules and regulations regarding occupational safety, accident prevention and environmental protection applicable to the site of use.

NOTE

Read the safety instructions in this section carefully and completely before using the device for the first time. By signing the documents for this device, every operator or users of this device confirms that he or she has read and understood the safety instructions in this section.

2.1 Hazard instructions

DANGER 	Connection to the wrong supply voltage is dangerous. Before connecting the device to a power source, ensure that it matches the nameplate specifications on the rear of the device and is approved for the device. An incorrect supply voltage can destroy the device and endanger the patient's life. Do not use multiple outlet adapters or extension cables to supply power to the device. Use only the cable and plug included with the device.
DANGER 	Ensure that the power source is adequate for the device. Ensure that fully charged battery packs are installed before using the console. Recharge empty battery packs immediately. If possible, always connect the device to an external power source whenever an AC mains or external DC power source conforming to supply voltage range in the 'Specifications' section is available. Sudden stoppage of the device due to an empty battery pack endangers the patient's life!
DANGER 	Damaged or defective components pose a risk of fatal injury to the patient. The following points must be checked regularly while the iLA activve® blood pump system is operating: • Secure connection of the tubing system to the blood pump. • No formation of thrombotic deposits. • No formation of air bubbles. • No leaks.
DANGER 	Defective components pose a risk of fatal injury to the patient. Use only components in perfect working condition. Check the tubing for kinks and holes before use. Replace flawed or defective components immediately.
DANGER 	Defective components pose a risk of fatal injury to the patient. Use only components in perfect working condition. Check the tubing for kinks and holes before use. Replace flawed or defective components immediately.
DANGER 	To avoid the risk of transmitting air embolisms to the patient, the manufacturer recommends fitting a suitable air elimination component, such as a bubble trap or an arterial filter acting as a bubble trap, in the arterial line.

DANGER

The iLA activve® console system is equipped with a bubble detection function that signals air penetration. Due to the operating principle of the pump, forward flow of the blood is not possible if a relatively large volume of air enters the pump module. The bearing can also be damaged in this situation due to dry running, leading to pump failure. An alarm for the lower limit of blood flow must be activated to avoid undersupply to the patient.

DANGER

The 0-flow mode is a safety feature. Avoid long-term operation in 0-flow mode, since it can lead to increased blood damage.

DANGER

Always keep ventilation openings unobstructed. Excess heat can damage the equipment. Ensure adequate ventilation of the system. Functionally impaired equipment may endanger the patient's life. Clean soiled ventilation openings immediately.

DANGER

Risk of pinching or crushing. Use both hands to fit the iLA activve® Console control panel in the mount on the power supply unit.

DANGER

Extended exposure to direct sunlight can cause overheating of the equipment. Excess heat can damage the equipment. Functionally impaired equipment may endanger the patient's life.

DANGER

All maintenance activities must be performed exclusively by qualified maintenance staff certified by the manufacturer. Improperly performed maintenance can endanger the patient's life.

CAUTION

The iLA activve® console control panel weights approximately 2 kg. It will be damaged if it falls or is dropped. Always use both hands and proceed carefully when detaching the control panel from the iLA activve® power supply. The weight of the equipment can lead to injuries during transport. With the exception of the iLA activve® power supply unit, always use both hands to carry the equipment. Always place the equipment on a solid, stable and level surface or secure it using the brackets intended for this purpose.

CAUTION

The following precautions must be observed when the s.pump® drive unit is used with the iLA activve® console: The operating ambient temperature range is limited to 18 – 32 °C. If the ambient temperature exceeds the upper limit of 32 °C, there is a risk that the surface temperature of the s.pump® drive unit will rise above 56 °C . Keep a spare pump drive unit available at all times, for use as a back-up drive (replacement drive) in the event of an emergency.

2 SAFETY INSTRUCTIONS

2.2 Instructions for use

- Only authorised specialist staff may perform work on the electrical supply system. Check the electrical supply lines of the equipment each time before it is used. Damaged cables must be replaced.
- The manufacturer guarantees the proper operation and safety of the iLA activve® console blood pump system only under the following conditions:
  - the system is used for the intended purpose;
  - no unallowable changes are made to the equipment (including reconditioning or resterilisation of items intended to be disposable);
  - specified maintenance activities are carried out according to the specified schedule;
  - the equipment is handled in accordance with the technical specifications and storage instructions (see section „3.14 Specifications“ on page 3-15).
- sterile disposable products are not used if their expiry date has passed and/or their packaging is damaged to such extent that their sterility and/or functionality is in doubt.
- Only accessories and/or accompanying material approved by Medos may be used to operate the iLA activve® console system.
- The battery packs are subject to specifically tested requirements and may only be used under the allowable ambient conditions!
- To ensure a continuous supply of power to the equipment, always check the battery pack charge level before using the equipment. To ensure adequate capacity, the iLA activve® console system must be connected to an external power source for at least 6 hours before being put into service. We recommend keeping at least two additional, fully charged battery packs on hand.
- The iLA activve® console drive unit contains strong magnets. Keep sensitive devices and/or objects, such as memory cards, pacemakers, AICD, etc. well away from the drive unit!

⇨ Fit the device on the equipment trolley whenever possible.

- Leave the device on the equipment trolley while in storage.
- For optimal retention of battery capacity, remove the battery packs from the equipment while in storage.
- Never pull on the connecting cables at the rear of the unit to move the overall system (including the equipment trolley) with the unit fitted on the trolley. Always use the handle on the equipment trolley to move the system.
- Ensure that the equipment is securely fastened when transporting the iLA activve® console system. The weight of the equipment can cause injuries to users and/or patients with improper use or handling. Do not attempt to transport the iLA activve® console blood pump system over cobblestone pavement or similar rough surfaces on the equipment trolley.
- Always park the equipment trolley on a secure, flat surface and lock the wheel brakes. On sloping surfaces, there is a risk that the trolley may roll away or tip over.
- When moving the equipment card with the iLA activve® console blood pump system, ensure that the tubing cannot be damaged by sharp edges or by get ting caught on corners.
- Protect all components against dirt and contamination.

⇨ In case of contamination, clean the unit with a cleaning or disinfectant approved by Novalung (see section „8.2 Cleaning“ on page 8-1). Do not allow liquids to come in contact with (live) electrical components.

⇨ Prevent foreign objects from entering connector sockets.

❑ Ensure that the ventilation openings of the iLA activve® console power supply unit are not covered.by other objects, as otherwise the interior of the unit may become overheated.

⇨ Clean the fan filter regularly. Dirty filters can lead to inadequate cooling of the drive unit.

❑ Do not bring chemicals other than those designated for disinfection in contact with the unit and its components.

- Never open the enclosure of the iLA activve® console blood pump system without the permission of a Novalung service technician.
- Never set liquids on the system components.
- Never use flammable narcotics or cleaning agents in the immediate vicinity of the unit.
- This device may be affected by portable or mobile wireless communication devices.
- Zero adjustment relative to the atmosphere or system must be performed before and during use of the iLA activve® console system. For more information, see section „Flow sensor zero adjustment“ on page 5-13 and section „Zero adjustment for pressure sensors P1 to P4“ on page 5-14.

2.3 Conditions of use

☑ The person responsible for the operation of the equipment must have received instruction on the functions and use of the iLA activve® blood pump system based on the user guide (pursuant to Sect. 31 of the German Medical Products Act).

☑ Keep a second, standby drive unit on hand in the hospital at all times.

⇨ Always read this user guide carefully before putting the iLA activve® console blood pump system into service for the first time.

⇨ When using the iLA activve® console system without mains power, such as for patient transport lasting longer than 60 minutes, keep sufficient fully charged battery packs within reach. In transport situations, ensure that the battery packs can be exchanged even in cramped quarters. Beware of insufficient space.

⇨ Before using the unit with a patient, verify that the battery packs of the iLA activve® console blood pump system are fully charged. If both battery packs are fully discharged, the charging time with the system switched off is approximately 6 hours.

■ Do not use the unit unless at least one battery pack is installed.

■ To eliminate possible sources of problems before actual use, check the equipment before putting it into service.

❑ Visually inspect the level sensor and the flow sensor before use. For each of these, inspect the cable, connector and sensor for integrity.

⇨ Sensors that pass visual inspection must be checked after installation in the system by performing a functional test with a primed circuit.

■ The iLA activve® console blood pump system performs an internal self-test after it is switched on. The drive may not be used for its intended purpose until this self-test has been completed with no faults.

■ The user is responsible for checking the visual and acoustic indicators during the self-test.

❑ Only iLA activve® pump modules and approved accessories may be used to operate the iLA activve® console blood pump system.

■ The tubing and pump module may be used only once.

■ When operated from mains power, the medos® deltastream® MDC blood pump system can additionally be connected to the existing earthing system using the terminal for a potential equalisation conductor. This is not recommended in Class 2 rooms (operating theatres, intensive care stations, etc.) with a mains network corresponding to an IT or TN-S network as described in VDE 0100 Part 710. Improper connection can have a detrimental effect on the medos® deltastream® MDC blood pump system, which can affect electromagnetic emissions and noise immunity. If the operator nevertheless requires connection of a potential equalisation conductor, care must be taken to avoid earth loops (for example, by routing the potential equalisation conductor along the mains power cable and securing it to the cable). The operator must also check whether connecting the potential equalisation conductor can cause the leakage current to exceed the allowable limit. The requirements of the IEC 60601-1 and IEC 60601-1-1 standards should also be observed in this regard.

■ The unit may be operated only by suitably instructed and trained staff. When the iLA activve® console system issues an alarm or operator instructions, always check and assess the corresponding display or indicator and observe the patient.

■ The unit may be operated only by suitably instructed and trained staff. A backup drive unit (replacement drive) must be used in the event of critical or internal faults that cannot be corrected by the operator.

■ If the P1 limiter is used, flow monitoring (lower alarm limit) must be enabled.

■ The allowable ambient conditions, in particular those necessary for the trouble-free operation of the iLA activve® console blood pump system, are described in section „3.14 Specifications“ on page 3-15 of the user guide for the iLA activve® console blood pump system.

❑ Every iLA activve® console blood pump system must be serviced annually in accordance with a precisely defined maintenance programme specified by Novalung GmbH. The obligation of Novalung GmbH to honour warranty claims and the liability obligations of Novalung GmbH are nullified if the equipment is not serviced and maintained properly at regular intervals.

■ No additional protective equipment is necessary for operating the iLA activve® console blood pump system.

■ Additional devices connected to the analogue and digital interfaces of the unit must be certified to comply with the

relevant EN specifications, such as EN 60950 for data processing equipment and EN 60601 for medical electrical equipment. In addition, all configurations must comply with the applicable version of the EN 60601-1-1 standard. Anyone who connects additional devices to the signal input or signal output portion is deemed to be the system configurer and is therefore responsible for maintaining compliance with the applicable version of the EN 60601-1-1 standard. In case of questions, please contact your local dealer or the technical service department.

- If desired, the manufacturer will dispose of the iLA activve® console blood pump system free of charge. The provisions of the German Electrical Equipment Act (ElektroG) with regard to the marketing, taking back and environmentally compatible disposal of electrical and electronic equipment must be observed in the decommissioning and disposal of the equipment.
- When entering parameter settings, always check the pump for proper operation and observe the patient.
- This device is classified as medical electrical equipment and is therefore subject to special precautionary measures with regard to electromagnetic compatibility (EMC). It may be installed and operated only in accordance with the EMC instructions in this user guide. It may not be used in the vicinity of magnetic fields (MRT, CT, etc.). See also section „Guidelines and manufacturer‘s declaration regarding electromagnetic immunity“ on page 2-11.
- Using accessories or cables other than those described in this user guide may impair the proper operation of the system and lead to higher interference emission or reduce the immunity of the equipment to electromagnetic interference.
- The device should not be used directly adjacent to or stacked together with other equipment. If operation directly adjacent to or stacked together with other equipment is necessary, the device should be observed to check whether it can be used as intended in this arrangement.
- Life support systems in hospitals must always be operated with power drawn from secure emergency power systems.
- A sufficient number of fully charged battery packs must be kept within reach when the iLA activve® console blood pump system is used for purposes such as patient transport.
- Operating the iLA activve® console blood pump system without mains power in the absence of replacement battery packs is not permissible and endangers the patient.
- The alarm transfer to an external alarm system is not failsafe (referred to IEC 60601-1-8). Don´t rely solely on the alerting of the external alarm system. There is a danger of alerts being ignored.

❑ During the therapy with an extracorporeal circulatory system, the vital parameters of the patient have to be monitored. Check the overall system for completeness before use.

- The operating position is in front of the console. The console must be installed so that the operator has always access to all controls and all indicators are visible. Make sure that the optical alarm indicators are visible at any time.

2.4 Instructions on the use of blood pumps

- Observe expiry dates. Do not use if the expiry date has been exceeded.
- The product may not be modified, altered either technically or structurally, or subjected to any rework.
- Use only if the sterile packaging is fully intact.
- It is recommended to check the product carefully before use. The structure, operation or packaging of products may be impaired by transport. Consequently, Medos cannot guarantee the faultless operation of products after transport.
- Keep away from sources of heat.
- Users are fully responsible for the consequences of improper use and use deviating from the instructions.
- Spare products (backup or comparable alternative products) should always be available during perfusion.
- Use the product immediately after removing the protective caps.
- The DP3 and s.pump® blood pumps may only be used by qualified staff. Users must be familiar with the use and handling of extracorporeal circuits (e.g. perfusionists, cardiovascular technicians, specialist nurses or intensive care staff).

❑ Check the overall system for completeness before use.

- Do not allow cleaning agents to come in contact with the surface of the blood pump.
- Do not allow solvents (e.g. alcohol, ether, acetone, etc.) or inhalation anaesthetics (e.g. Halothan, Enfluran, etc.) to come in contact with the surface of the pump.

❑ Check the circuit, including the pump, for bubbles before putting the equipment into service.

❑ Check the circuit, including the pump, for leaks before putting the equipment into service.

- Do not operate the blood pump under conditions with high negative input pressure, due to the risk of cavitation.
- During use, ensure adequate blood anticoagulation by administering suitable medications and regularly monitoring the relevant blood parameters.

❑ The condition of the pump and the extracorporeal circuit must be monitored constantly.

- Reverse flow may occur when the pump is stopped.
- Ultrasonic gel must be used between the flow sensor and the tube surface to ensure accurate flow measurement by the iLA activve® drive console.

⇨ All tubing connections must be secured by suitable cable ties.

- Store the blood pump only in accordance with the information provided in section “8.6 Storage” on page 2-6.

❑ When removing the protective caps from the pump, take care that no residues from the caps enter the circuit.

❑ Observe the indicated flow direction (arrow on the pump housing).

- If an open heart tray reservoir is used ahead of the pump, suitable external fill level monitoring or the internal fill level monitoring function must be used for the prompt detection of emptying of the reservoir. Blood flow must be stopped if this occurs.

❑ Even if fill level monitoring is used, the fill level must constantly be checked manually by the user.

- Observe the instructions in the user guides for the various pump modules.

2 SAFETY INSTRUCTIONS

2.5 Actions related to defibrillator use

DANGER

When using a defibrillator, ensure that no electrical circuits can be formed from the patient being defibrillated, the treating person or persons in the immediate vicinity to the earth or to metallic parts of the bed or the operating table.

DANGER

The unit does not have any protection against hazards arising from defibrillation of the patient. The relevant safety instructions must be observed in order to avoid electric shock. All persons in the immediate vicinity must maintain a safe distance from the equipment and the extracorporeal circuit during defibrillation.

2.6 Anticoagulation management

DANGER

The iLA activve® console blood pump system may be used only if suitable anticoagulation management is in place, as with customary HLM or ECMO applications, by constant monitoring of the activated clotting time (ACT) or other suitable parameters.

2.7 Safety devices

Technical system faults are indicated by an illuminated red warning triangle at the bottom of the monitor screen. The unit may not be used in this state and must be replaced immediately by another unit. For more information, see „Figure 3–8: Warning triangle on iLA activve® console control panel“ on page 3-7.

Operator errors, such as improper connections, are indicated by warning messages on the monitor. For more information, see section “7 ALARMS” on page 7-1 and following. A warning tone also sounds.

The warning message continues to be displayed on the monitor, and the warning tone continues to sound, until the cause of the alarm has been corrected.

2.8 Working safely with electrical equipment

Only qualified electricians are allowed to carry out work on the electrical supply system.

Check the electrical equipment of the device regularly. Correct or replace loose connections and charred cables immediately.

2.9 Intended use

The unit may only be used:

- for the intended purpose;
- with all safety devices and features in perfect condition.

DANGER

Malfunctions that impair the safety or proper operation of the equipment must be corrected immediately.

Intended use

The iLA activve® console blood pump system is intended to pump blood as part of an extracorporeal circuit. The typical application areas are temporary cardiovascular support during and after surgical operations and provision of temporary cardiopulmonary support for patient stabilisation or therapy:

The overall system consists of the following components:

- pump,
- tubing,
- drive console,
- replaceable battery packs

The iLA activve® drive console may only be used with the associated components and the specified iLA activve® blood pumps in compliance with the corresponding use instructions.

The iLA activve® console blood pump system may only be operated by medically qualified specialists with product-specific training. Operators must always obtain a comprehensive overall picture of the patient, in particular with regard to configuring the operational parameters, and monitor the operation of the pump. Observation of the patient and the pump minimises the risk of an undetected operator error, which means that the unit must never be operated blind. The system is intended to be used in a hospital environment. The scope of use of the drive console extends from the initial use of the iLA activve® console blood pump system in the operating theatre to patient care in the intensive care ward and patient transport in an ambulance. The compact construction of the equipment and installation of the drive console in an equipment trolley provide a high degree of mobility. Replaceable battery packs in the drive console enable temporary use independent of mains power. Any other use or any use exceeding what is described here constitutes improper use.

Proper use also includes:

- observing all instructions in the user guide;
- performing inspection, service and maintenance activities on schedule.

Liability in case of improper use

Warranty and liability claims in case of personal injury or property damage are excluded if they can be attributed to one or more of the following causes:

Improper use of the equipment

- Improper putting service, operation, servicing or maintenance of the equipment.
- Operating the equipment with defective safety devices.
- Failure to observe the instructions in the user guide with regard to transport, storage, installation, putting into service, operation, servicing or maintenance of the equipment.
- Unauthorised structural changes to the equipment.
- Inadequate monitoring of equipment components subject to wear.
- Improperly performed repairs or maintenance.
- Disaster situations resulting from the action of foreign bodies or force majeur.

Contingent misuse

Operation of the equipment by persons other than those authorised to operate it or operation with pumps other than the approved pumps may be regarded as improper use.

2.10 Organisational measures

Structural changes during ongoing operation

Immediately shut down the equipment if even the smallest change occurs in the operational behaviour of the equipment or the characteristics of components relevant to safety.

- ⇨ Keep a second unit on hand in the hospital at all times.
- ■ Report malfunctions immediately to the responsible person.

Troubleshooting and maintenance

- ■ Maintenance activities must be performed properly and regularly. The operator must document all maintenance activities.
- ⇨ Perform the specified configuration, maintenance and inspection activities on schedule.
- ❑ Check safety devices for proper operation after completion of maintenance activities.

2.11 Requirements on staff

Staff training

The product may only be used on order of a physician and under medical supervision and may only be used by medically trained specialists(e.g. perfusionists, cardiovascular technicians, specialist nurses or intensive care staff). In the interest of patient safety, the product must be monitored constantly by the above-mentioned staff while in operation.

Responsibilities

Staff responsibilities for putting the equipment into service, operation, maintenance and servicing must be clearly defined.

Instructions related to safety

Enable staff members using the equipment to refuse to follow instructions from other parties if they are contrary to safety.

2.12 Structural changes to the equipment

Any form of structural change to the equipment is strictly prohibited.

2.13 Equipment cleaning and disposal

Use cleaning agents and materials properly and dispose of them in an environmentally compatible manner. In this regard, observe

- the instructions given in section „8 OTHER HANDLING“ on page 8-1;
- the operating instructions of the relevant manufacturer;
- statutory provisions regarding environmental protection and disposal.

Novalung GmbH will take back defective equipment for disposal.

2.14 Information regarding electromagnetic compatibility

The key performance feature of the medos® deltastream® MDC is pumping blood in an extracorporeal circuit using a diagonal-flow pump.

Guidelines and manufacturer‘s declaration regarding electromagnetic emissions

The iLA activve® console iequipment is intended to be used in the environment specified below. The customer or user of the iLA activve® console system should ensure that it is used in such an environment.

Emitted interference measurements	Compliance	Electromagnetic environment guidelines
HF emissions in accordance with CISPR 11	Group 1	The iLA activve® device uses HF energy solely for its internal operation. It therefore has a very low HF emission level, and it is unlikely that it will cause interference to nearby electronic devices.
HF emissions in accordance with CISPR 11	Class A	The iLA activve® device device is suitable for use in facilities other than those in a residential area and those connected directly to a public power grid that also supplies power to buildings used for residential purposes.
Harmonic emissions in accordance with IEC 61000-3-2	Class A	
Voltage fluctuation emissions (flicker) in accordance with IEC 61000-3-3	Compliant	

2 SAFETY INSTRUCTIONS

Guidelines and manufacturer's declaration regarding electromagnetic immunity

The iLA activve® console equipment is intended to be used in the electromagnetic environment specified below. The customer or user of iLA activve® console system should ensure that it is used in such an environment.

Immunity test	IEC 60601 test rule	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) in accordance with IEC 6100-4-2	±6 kV contact discharge ±8 kV air discharge	± 6 kV ± 8 kV	The floor should be made of timber or concrete or covered with ceramic tiles. If the floor is covered with a synthetic material, the relative humidity must be 30%.
Fast electrical transients (bursts) in accordance with IEC 61000-4-4	± 2 kV for mains power lines ± 1 kV for input and output lines	± 2 kV ± 1 kV	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges in accordance with IEC 61000-4-5	± 1 kV between external conductors ± 2 kV between external conductor and earth	± 1 kV ± 2 kV	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Dips, short interruptions and variations in the supply voltage in accordance with IEC 61000-4-11	< 5% U_T [> 95% dip in U_T] for a half cycle < 40% U_T [> 60% dip in U_T] for 5 cycles < 70% U_T [> 30 % dip in U_T] for 25 cycles < 5% U_T [> 95% dip in U_T] for 5 s	< 5% U_T [> 95% dip in U_T] for a half cycle < 40% U_T [> 60% dip in U_T] for 5 cycles < 70 % U_T [> 30 % dip in U_T] for 25 cycles < 5% U_T [> 95% dip in U_T] for 5 s	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the iLA activve® device requires continued operation of the equipment even in the event of power supply interruptions, it is recommended to power the iLA activve® device from an uninterruptible power supply or a battery.
Magnetic field at the supply frequency [50 – 60 Hz] in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to the levels typical in a business or hospital environment.

Remark: U_T is the AC mains voltage to be used for application of the test rule.

Recommended safety distance between portable and mobile HF telecommunication equipment and the iLA activve® console device

The iLA activve® console device is intended to be used in an electromagnetic environment with controlled HF interference levels. The customer of user of the iLA activve® device can help avoid electromagnetic interference by ensuring that portable and mobile HF telecommunication equipment (transmitters) and the iLA activve® device are always separated by at least a certain minimum distance depending on the output power of the telecommunication equipment as stated below.

	Safety distance [m] depending on transmit frequency			
Rated transmitter output power W	150 kHz to 80 MHz outside the ISM bands $d = 0{,}35\sqrt{P}$	150 kHz to 80 MHz within the ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 2.3\sqrt{P}$
0.01	0.0035	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.11	3.8	3.8	7.23
100	3.5	12.0	12.0	23.0

For transmitters whose maximum rated power is not shown in the above table, the distance can be determined using the formula in the relevant column, where P is the maximum rated output of the transmitter in watts (W) according to the manufacturer's data and d is the recommended safety distance in metres (m).

Remark 1: The higher frequency band is applicable if both 80 MHz and 800 MHz are relevant.

Remark 2: The industrial, scientific and medical (ISM) frequency bands in the range of 150 kHz to 80 MHz are 6.765–6.795 MHz, 13.553 MHz, 13.567 MHz, 26.957–27.2837 MHz and 40.66–40.70 MHz.

Remark 3: The compliance levels in the ISM bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2.5 GHz are intended to reduce the likelihood that mobile or portable communication devices can cause interference when they are unintentionally brought into the vicinity of patients. For this reason, an additional factor of 10/3 is used to calculate the recommended safety distance in these frequency ranges.

Remark 4: These guidelines may not be usable in all cases. The propagation of electromagnetic fields is affected by absorption and reflection by buildings, objects and people.

2 SAFETY INSTRUCTIONS

Guidelines and manufacturer's declaration regarding electromagnetic emissions

The iLA activve® console iequipment is intended to be used in the electromagnetic environment specified below. The customer or user of the iLA activve® console system should ensure that it is used in such an environment.

Immunity test	IEC 60601 test	Compliance level	Electromagnetic environment – guidelines
			Portable and mobile radio equipment should not be used closer to the iLA activve® device or its cables than the safety distance calculated using the formula applicable to the transmit frequency. Recommended safety distance:
Conducted HF interference in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz outside the ISM bands [a)]	10 V	$d = 1.17 \sqrt{P}$
	10 V_{eff} 150 kHz to 80 MHz outside the ISM bands [a)]	10 V	$d = 1.2 \sqrt{P}$
Radiated HF interference in accordance with IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2 \sqrt{P}$ for 80 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum rated output of the transmitter in watts (W) and d is the recommended safety distance in metres (m)[b)] The field strength of stationary transmitters as measured at the site[c)] should be lower than the compliance level.[d)] Interference is possible in the vicinity of equipment bearing the following symbol: 

Remark 1: The higher frequency band is applicable if both 80 MHz and 800 MHz are relevant.

Remark 2: These guidelines may not be usable in all cases. The propagation of electromagnetic fields is affected by absorption and reflection by buildings, objects and people.

a) The industrial, scientific and medical (ISM) frequency bands in the range of 150 kHz to 80 MHz are 6.765–6.795 MHz, 13.553 MHz, 13.567 MHz, 26.957–27.2837 MHz and 40.66–40.70 MHz.

b) The compliance levels in the ISM bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2.5 GHz are intended to reduce the likelihood that mobile or portable communication devices can cause interference when they are unintentionally brought into the vicinity of patients. For this reason, an additional factor of 10/3 is used to calculate the recommended safety distance in these frequency ranges.

c) The field strength of stationary transmitters, such as base stations for mobile phones and mobile terrestrial telecommunication equipment, amateur radio stations, AM and FM broadcast stations, and television transmitters, cannot be calculated precisely in advance based on theoretical considerations. A site survey should be considered in order to determine the electromagnetic environment with regard to stationary transmitters. If the measured field strength at the site where the iLA activve® device is used exceeds the compliance level stated above, the iLA activve® device should be monitored to verify proper operation. If unusual behaviour is observed, additional measures may be necessary, such as changing the orientation of the iLA activve® device or moving it to a different location.

d) The field strength should be less than 10 V/m over the frequency range of 150 kHz to 80 MHz.

3 PRODUCT DESCRIPTION

The iLA activve® console blood pump system is a Class IIb medical technology product in accordance with the German Medical Products Act (MPG). This section provides an overview of the operation of the system components and their specifications.

3.1 Indications and contraindications for clinical use

Indications for use

The iLA activve® console blood pump system is designed to pump blood as part of an extracorporeal circuit.

The iLA activve® DP3 and s.pump® blood pumps are intended for short-term use in extracorporeal circuits. They are typically used for temporary cardiovascular support during and after surgical operations and to provide temporary cardiopulmonary support for patient stabilisation or therapy. In this regard, it is recommended to use the pumps in combination with the system components of cardiopulmonary bypass systems commonly used in clinical practice and complying with hospital standards.

The iLA activve® console blood pump system is approved for the following application periods, depending on the type of pump used:

Blood pump	Duration of use
s.pump® pump module	Up to 6 hours
iLA activve® DP3 pump module	Up to 7 days
iLA activve® drive console	Up to 30 days

Contraindications for use

The following complications may occur in connection with the use of the equipment:

- mechanical failure, haemolysis or thromboembolisms. These potential complications can occur with all types of extracorporeal blood pump systems.
- Operation of the system outside the scope of the stated specifications is not allowed.
- The iLA activve® console blood pump system may not be used if anticoagulation corresponding to that used for extracorporeal circulation cannot be assured.
- Use of the system as a suction pump is contraindicated.

3.2 System overview

The iLA activve® drive console is the core system unit for operating, powering, controlling, regulating and monitoring the operation of a type DP3 pump. It consists of the following components:

- iLA activve® drive (drive motor for the pump module, with a control panel for emergency operation)
- iLA activve® sensor box (central control unit with connectors for various sensors)
- iLA activve® power supply unit
- iLA activve® control panel (user interface with touchscreen display)

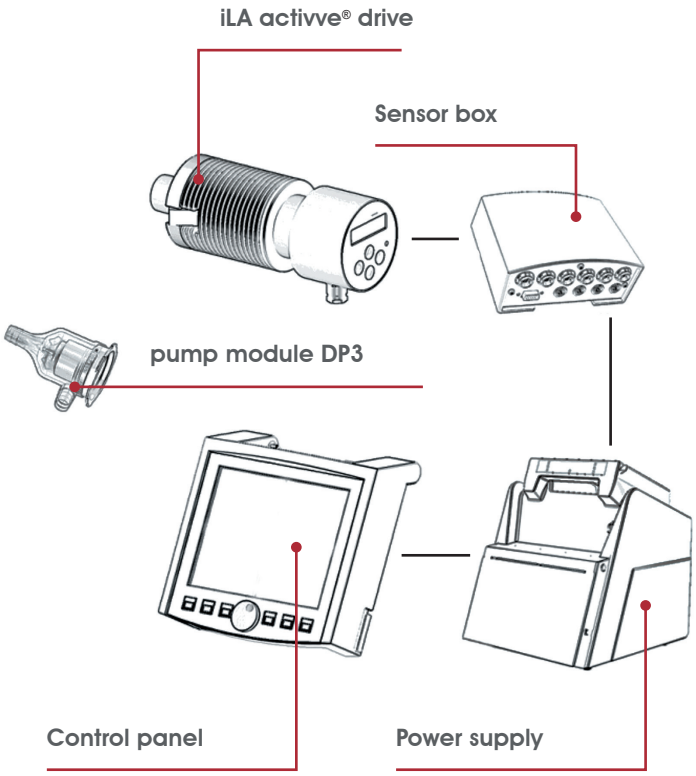


Figure 3–1: Overview iLA activve® console blood pump system

The iLA activve® drive console can be used with the optionally available s.pump® drive unit as a central system unit for an s.pump® unit (operation, power supply, control, regulation and monitoring of pump operation).

3 PRODUCT DESCRIPTION

3.3 Scope of delivery

The scope of delivery of the iLA activve® drive console comprises the following components:

2 x iLA activve® console DP3 pump drive	1 x 3/8"x3/32" (or1/4"x1/16") flow sensor
1 x iLA activve® console sensor box	2 x Pressure sensor connecting cable
1 x iLA activve® console power supply	1 x iLA activve® console temperature sensor
1 x iLA activve® console control panel	1 x Bracket for pump drive
2 x iLA activve® console battery pack	1 x iLA activve® console dual adapter hook
1 x AC power cord	1 x User guide
1 x Potential equalisation cable	

3.4 iLA activve® power supply unit

The iLA activve® power supply unit supplies power to the entire system and is housed in a convenient enclosure. The iLA activve® power supply unit contains all components necessary for supplying power to the system. A continuous supply of power is ensured by the following measures:

- Connector for mains power supply on the rear of the unit.
- Connector for external DC power supply (e.g vehicle power system in an ambulance) on the rear of the unit.
- Emergency operation by exchangeable battery packs when mains power or external DC power is not available (compartment for two battery packs on front of unit).

Power connectors on rear of unit

The power connectors are located on the right at the rear of the unit. The battery packs in the battery compartment are charged whenever the power is switched on.

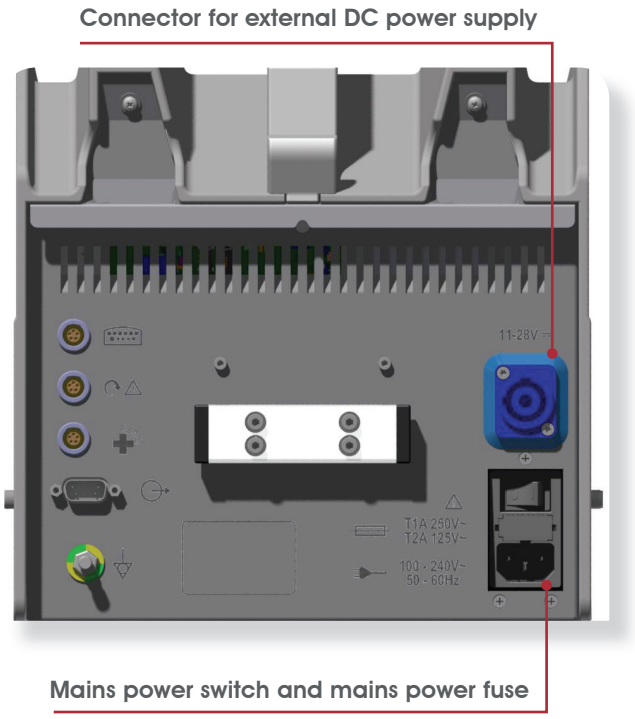


Figure 3–2: Power connectors on rear of unit

Battery pack compartments on front of unit

The battery packs for emergency operation plug into two compartments on the front of the MDC power supply unit. The battery pack compartments are protected by a moveable cover. A charge level indicator for each battery pack is located in the carrying handle. In the event of a power failure, the battery packs supply power to the MDC console in emergency mode.

- For detailed information on emergency operation, see section .3.12, “Emergency operation”.
- Both battery packs should be installed and kept fully charged at all times.

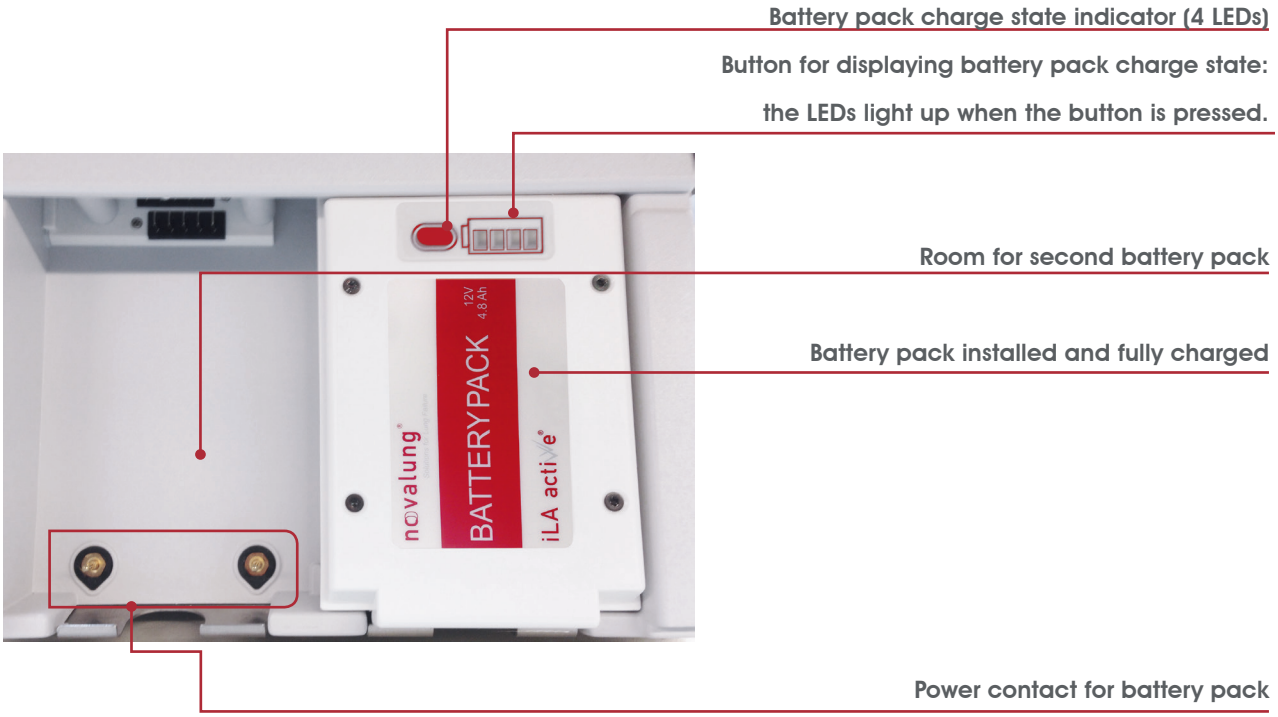


Figure 3–3: Battery pack compartments on front of power supply unit

Charge level indicator on battery pack

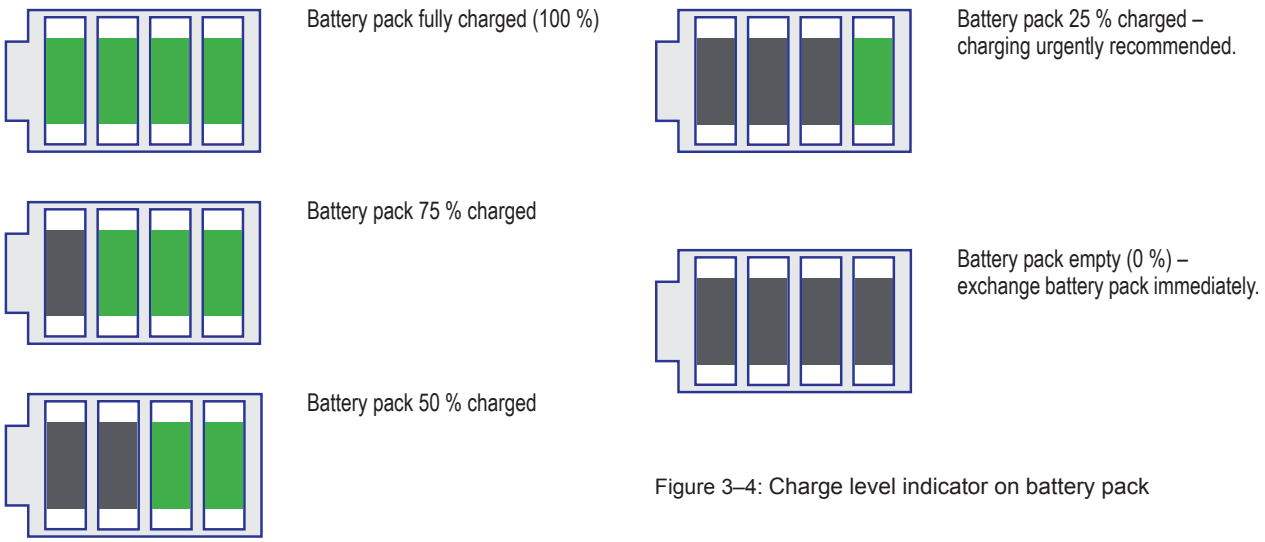


Figure 3–4: Charge level indicator on battery pack

3 PRODUCT DESCRIPTION

Battery pack charge level indicator in carrying handle

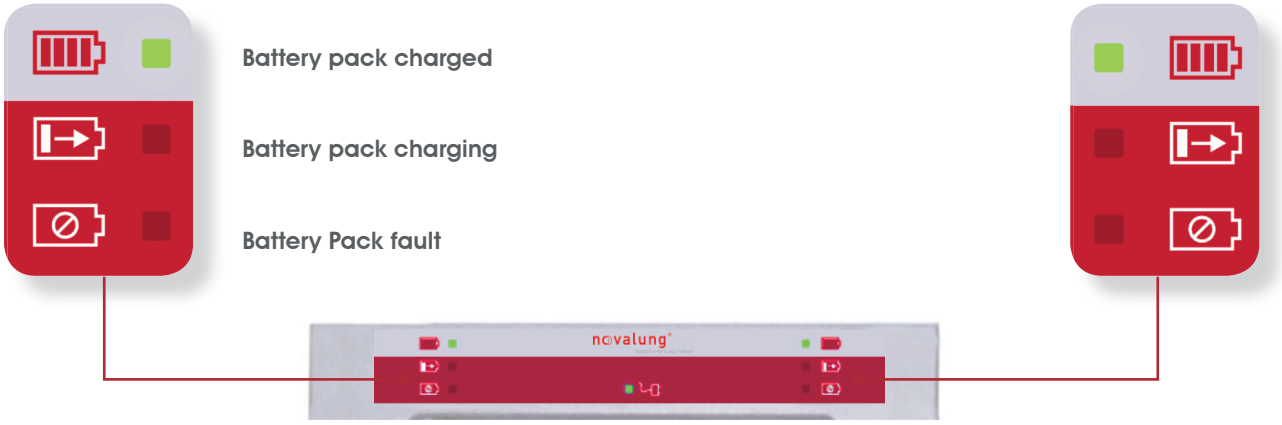


Figure 3–5: Battery pack charge level indicator in carrying handle

Peripheral device connectors on rear of unit

The connectors for peripheral devices are located on the left at the rear of the unit. All connectors are designed to prevent accidental misconnections.

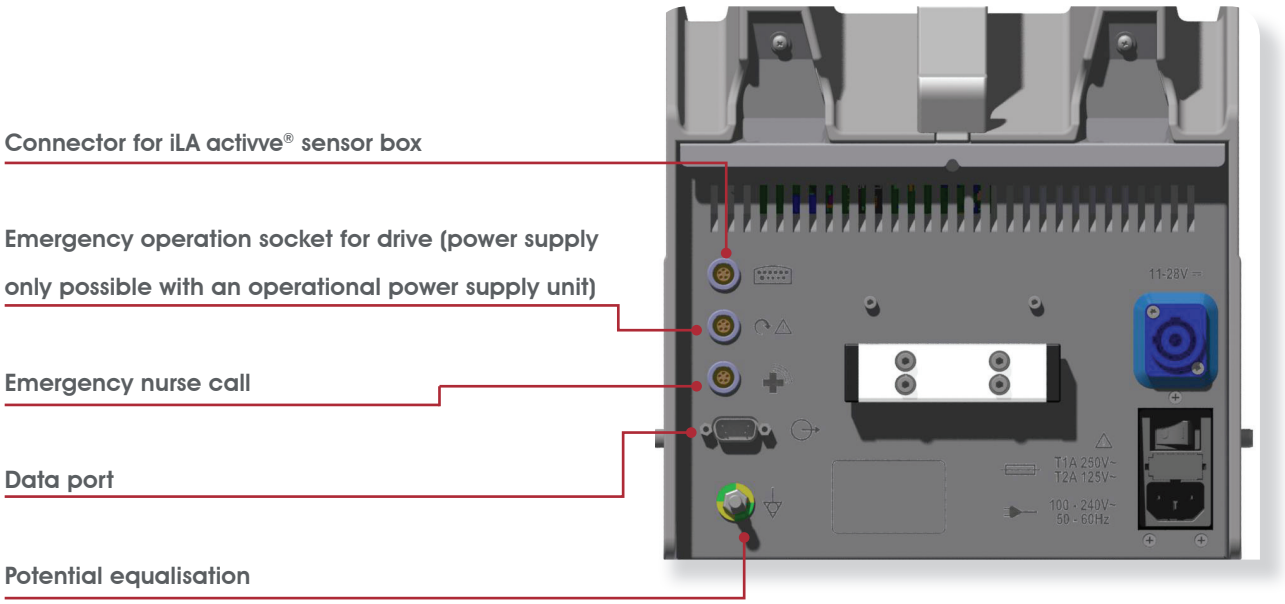


Figure 3–6: Peripheral device connectors on rear of unit

3.5 iLA activve® console control panel

The iLA activve® console control panel has a touchscreen display. It provides convenient visualisation of system parameters and allows users to save operational and patient data. This gives medical staff access to all relevant parameters at a glance.

The iLA activve® console control panel can be detached from the power supply unit and positioned as desired.

The controls and indicators of the iLA activve® console control panel are described in a separate section. For details please refer to chapter „4 CONTROLS AND INDICATORS“.

DANGER

A red warning triangle lights up on the front of the iLA activve® console control panel in the event of a system fault. Defective components pose a risk of fatal injury to the patient. Immediately replace the entire iLA activve® console blood pump system by a system in good working order.

Figure 3–8: Warning triangle on iLA activve® console control panel

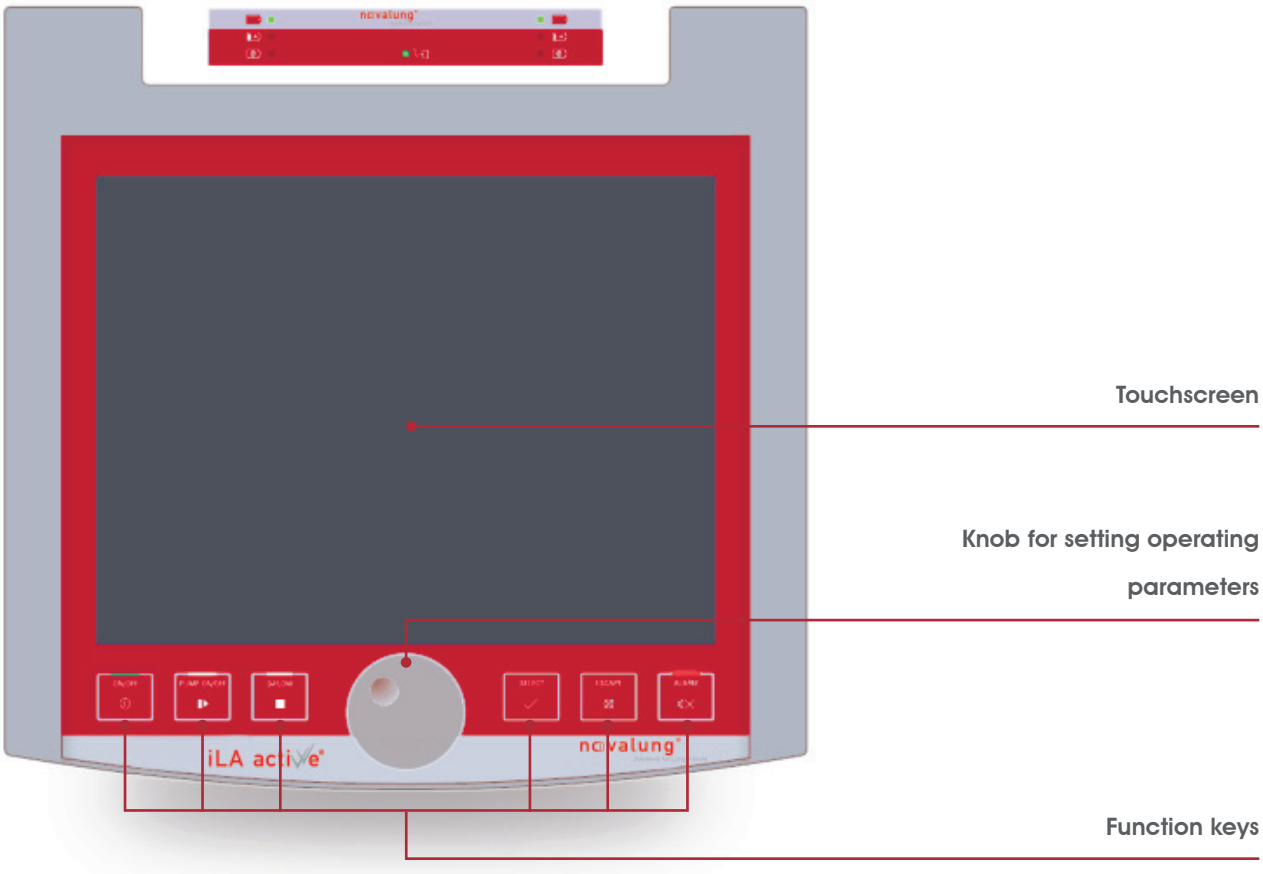


Figure 3–7: iLA activve® console control panel

3.6 USB port

The USB port is located on the rear of the control panel at the top right. The following system requirements must be observed in the interest of electrical safety:

- ☑ Compatible with USB 1.1 and USB 2.0.
- ☑ Only formatted USB storage devices may be connected to the USB port.
- ⇨ Use only empty storage devices for data storage. Data previously stored in the storage device may be lost.

3.7 iLA activve® sensor box

Several sensors are connected to the iLA activve® sensor box. The drive system is able to measure various parameters in the circulatory system. The iLA activve® sensor box can be positioned to avoid long cable paths from the sensors to the sensor box. This prevents tripping over the cables and accidental disconnection of the cables.

The iLA activve® sensor box is connected to the iLA activve® power supply unit by a connecting cable.

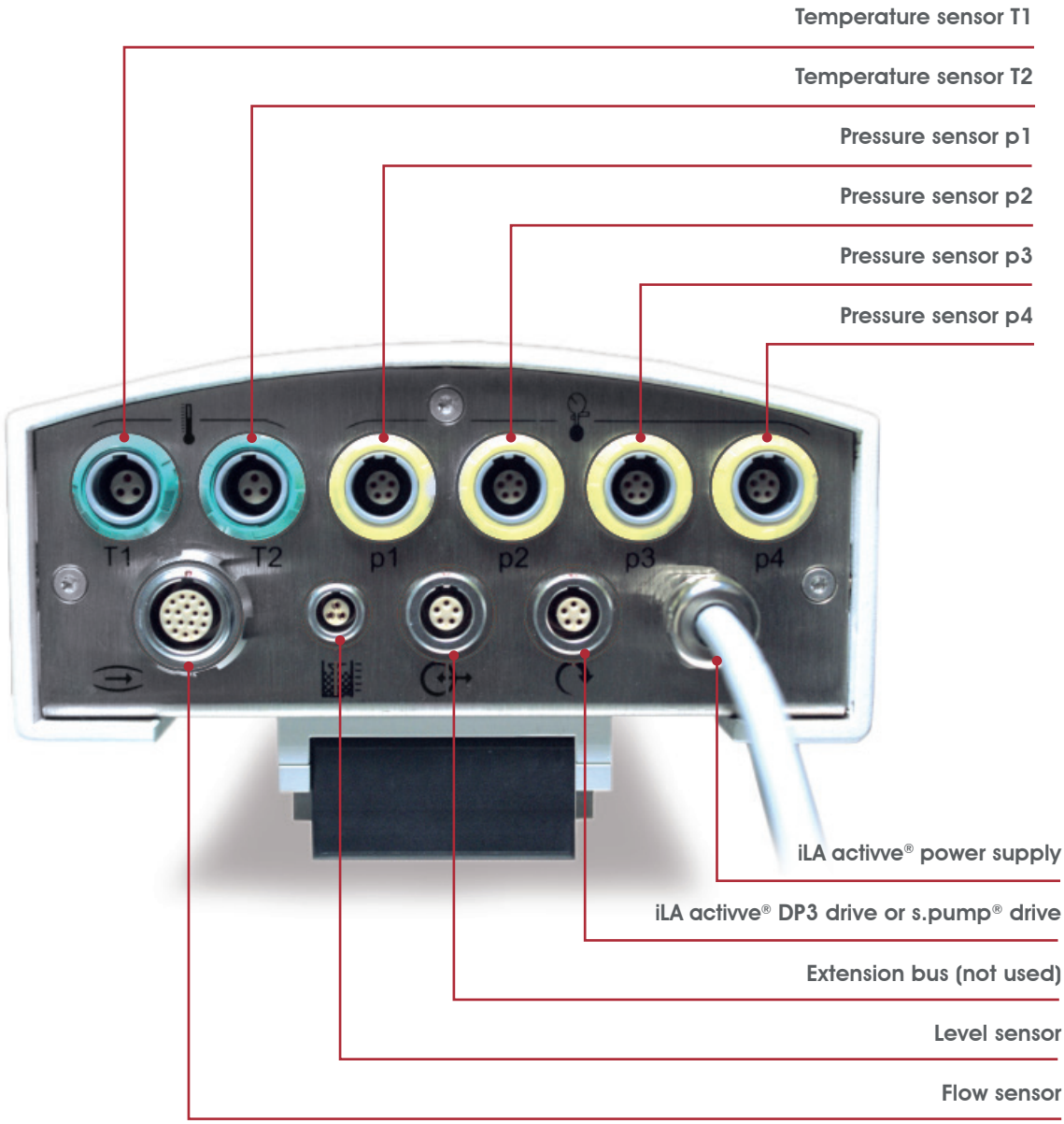


Figure 3–9: iLA activve® sensor box connectors for sensors

3 PRODUCT DESCRIPTION

3.8 iLA activve® DP3 drive unit

The DP3 pump module is attached to the iLA activve® DP3 drive unit. It is properly attached when the pump module audibly clicks into place.

A control panel for emergency operation of the pump module is located on the rear of the iLA activve® drive unit.

The controls and indicators of the iLA activve® DP3 drive unit are described in section “4.3 Controls and indicators on the iLA activve® drive unit” on page 4-14.

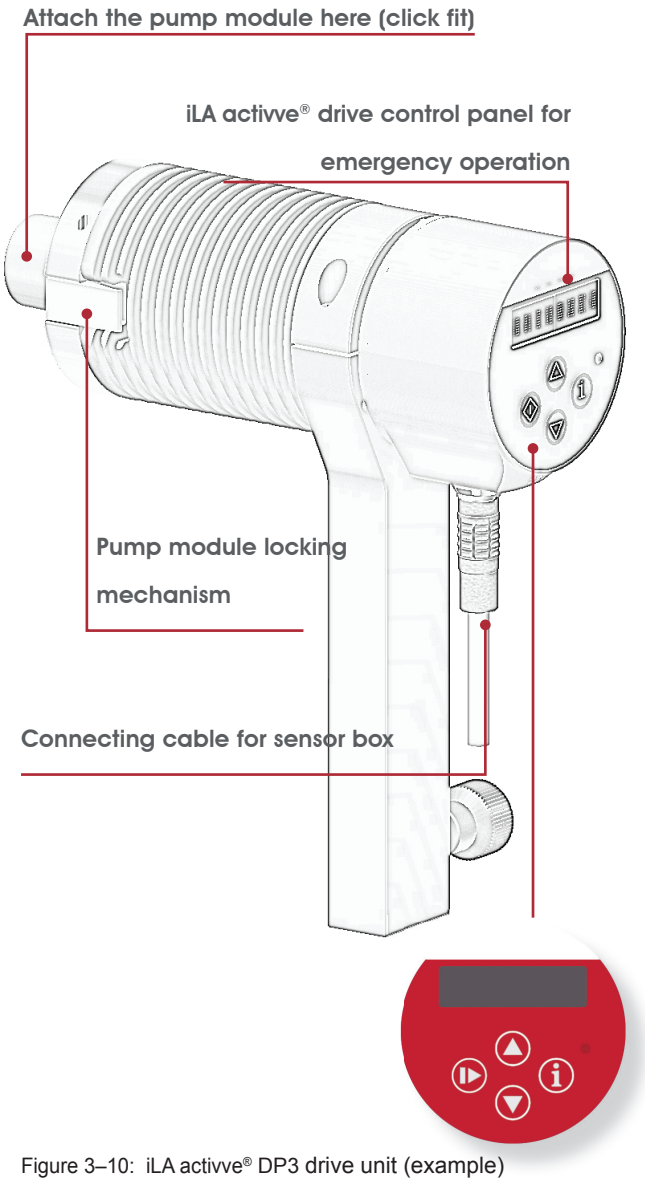


Figure 3–10: iLA activve® DP3 drive unit (example)

3.9 s.pump® drive unit

The s.pump®pump module is attached to the s.pump® drive unit. It is properly attached when the pump module audibly clicks into place.

A control panel for emergency operation of the pump module is located on the rear of the pump drive unit.

The controls and indicators for the s.pump® drive unit are the same as for the iLA activve® drive unit. They are described in section “4.3 Controls and indicators on the iLA activve® drive unit” on page 4-14.

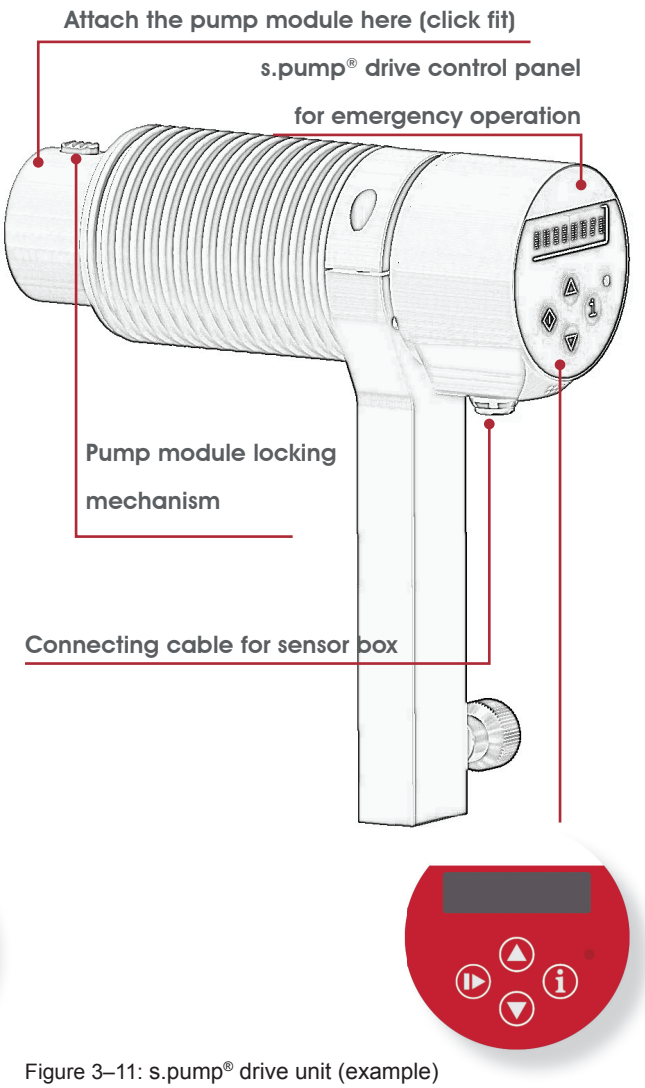


Figure 3–11: s.pump® drive unit (example)

3.10 DP3 drive module

The DP3 pump module is a sterile extracorporeal blood pump for disposable use. It has couplings suitable for use with 3/8" tubing. The impeller is driven by the drive unit via a magnetic coupling.

See the applicable user guide for the DP3 pump module for additional information and instructions.

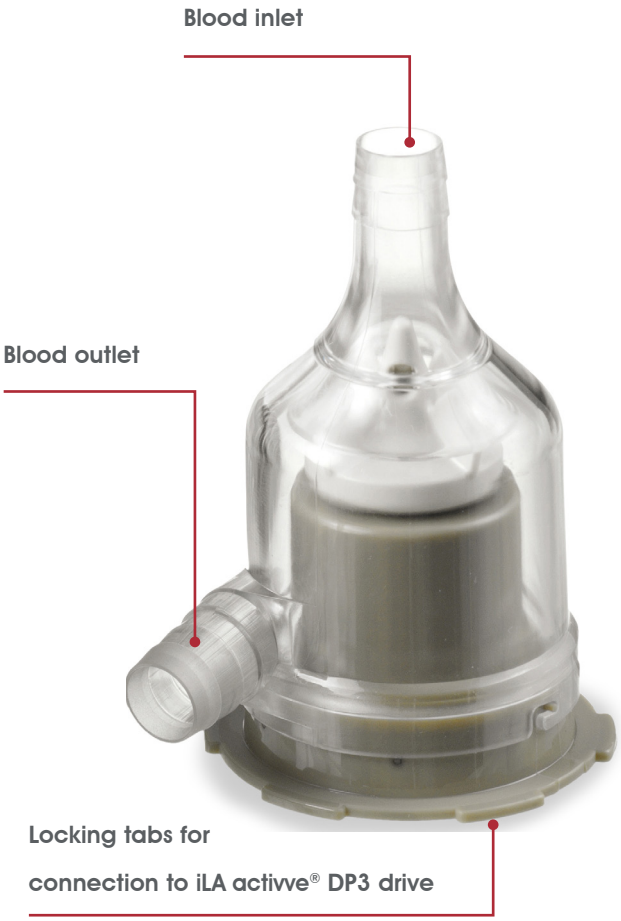


Figure 3–12: DP3 pump module

3.11 s.pump® pump module

The s.pump® pump module is a sterile extracorporeal blood pump for disposable use. It has couplings suitable for use with 3/8" tubing. The impeller is driven by the drive unit via a magnetic coupling.

See the applicable user guide for the s.pump® pump module for additional information and instructions.

Figure 3–13: s.pump® pump module

3.12 Emergency operation

IIf there is a malfunction in one or more modules, the drive unit can be operated in emergency mode to maintain pump operation until the user can correct the problem or provide another pump system. The following message appears on the control panel in this situation:

Figure 3–14: Fault message: “Technical fault in control panel”

Depending on the nature of the fault, the drive unit can be powered directly from the iLA activve® power supply unit or from a battery pack if necessary.

The interface between the s.pump® drive unit and the iLA activve® is the same as for the iLA activve® DP3 drive unit. The description of emergency mode operation in this section also applies to the s.pump® drive unit without restriction. This is also true for section “4.3 Controls and indicators on the iLA activve® drive unit” on page 4-14 and section “6.13 Emergency operation” on page 6-28.

The iLA activve® drive unit control panel only enables simple speed control (see the figure below: iLA activve® drive unit).

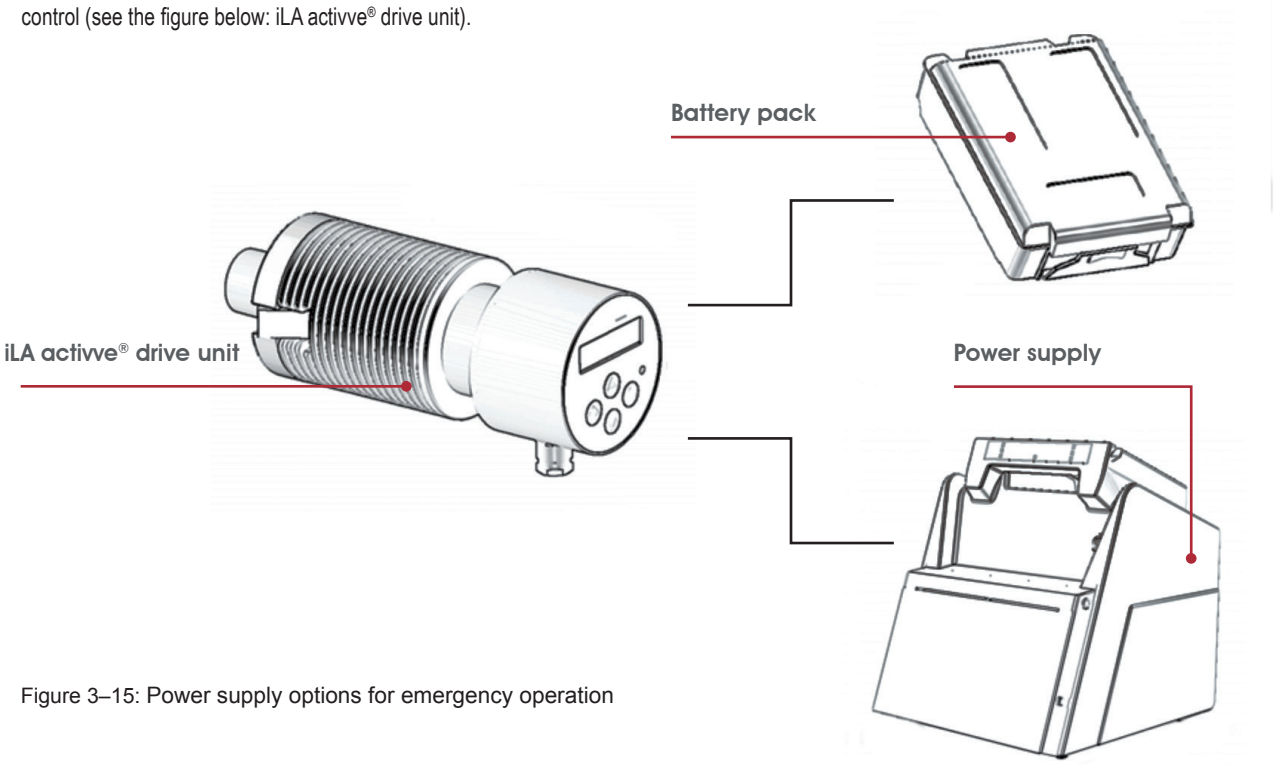


Figure 3–15: Power supply options for emergency operation

Figure 3–16: Connection option for iLA activve® drive unit in emergency operation

Figure 3–17: Emergency operation with iLA activve® drive unit connected to battery pack (example)

If there is a malfunction in one or more modules, the system can be operated in emergency mode to maintain pump operation until the user can correct the problem or provide another pump system. For example, in the event of failure of the internal monitoring computer the system generates technical fault message number 401.

- In this case it is no longer possible to display any parameter values. Emergency operation must be ensured.

3.13 Accessories and sensors

Flow sensor

The flow sensor is used to measure and monitor the resulting blood flow in the circulatory system. The connecting cable is permanently attached to the flow sensor. The flow sensor included with the console is suitable for measuring blood flow in 3/8" PVC tubing with a wall thickness of 3/32". A flow sensor for 1/4" tubing with a wall thickness of 1/16" is available as an optional accessory. Consult Novalung to determine whether your tubing is suitable for use with this flow sensor.

Figure 3–18: Flow sensor

Pressure sensor

The PvB pressure sensors are used to measure and monitor the pressures before and after the pump (P1 and P2). Additionally, two other sensors (P3 and P4) can be positioned at any desired location on the extracorporeal circuit for pressure monitoring.

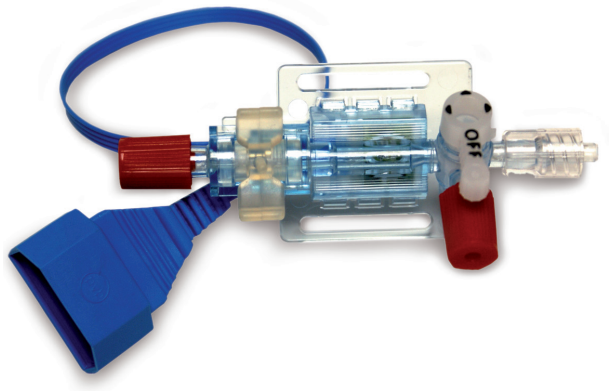


Figure 3–19: Pressure sensor

Level sensor

The level sensor is used to monitor the fluid level when a reservoir is used. The level sensor is attached to a level sensor pad fitted to the outside of the reservoir.

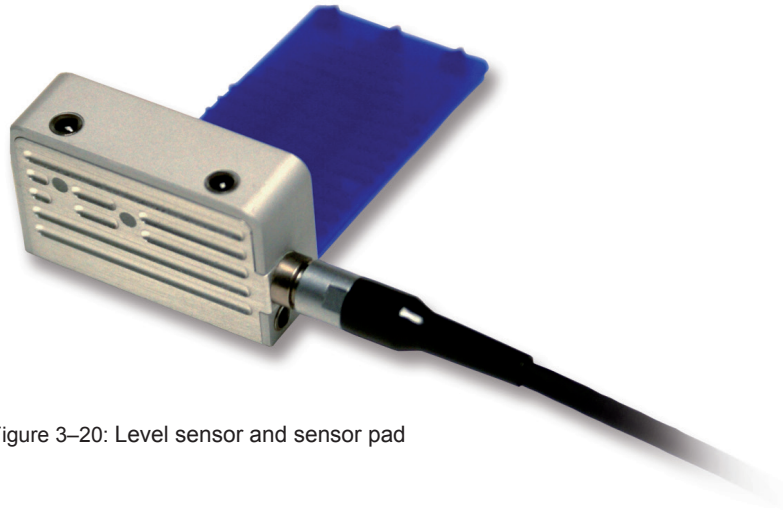


Figure 3–20: Level sensor and sensor pad

Temperature sensor

The temperature sensor is used to monitor the temperature of the blood in the extracorporeal circuit. Two temperature sensors may optionally be connected.

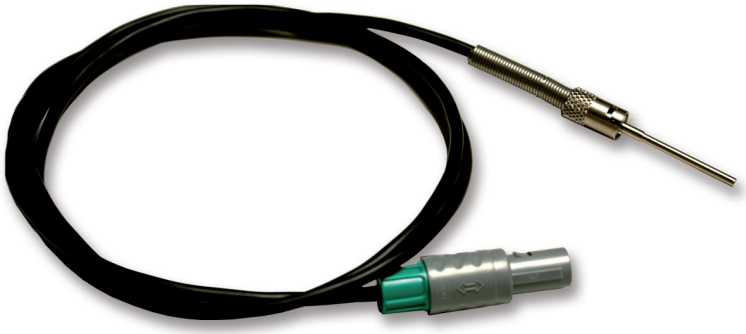


Figure 3–21: Temperature sensor

3.14 Specifications

iLA activve® DP3 pump module

Flow rate	0 – 8 * l/min
Speed	0 – 10,000 rpm
Pressure drop	0 – 600 mmHg
Fill volume	approx. 16 ml
Geometric dimensions (length x diameter)	75 x 50 mm
Weight	approx. 30 g
Operating temperature range	18 °C to 40 °C
Temperature range for storage and transport	5 °C to 40 °C
Ambient pressure range, operating storage and transport	700 – 1060 hPa

s.pump® pump module

Flow rate	0 – 8 * l/min
Speed	0 – 10,000 rpm
Pressure drop	0 – 600 mmHg
Fill volume	approx. 17 ml
Geometric dimensions (length x diameter)	75 x 40 mm
Weight	approx. 82 g
Operating temperature range	18 °C to 32 °C (in connection with s.pump® drive)
Temperature range for storage and transport	5 °C to 40 °C
Ambient pressure range, operating storage and transport	700 – 1060 hPa

iLA activve® drive console

Dimensions (W x H x D)	290 x 300 x 369 mm
Weight	approx. 10 kg
Power supply AC mains operation	100 – 240 V AC, 50 – 60 Hz
Ext. power supply	11 – 28 VDC
Power consumption	175 W max.
Power supply battery pack	10.8 VDC, 8.64 Ah, 93.3 Wh
Operating time without ext. power supply (two battery packs.)	120 – 420 min 260 min at 5.5 l/min, 6500 rpm
Mains inlet fuses	2x T 2A H (250 V)
Protection class	Class I with internal power supply
Device type	CF
IP protection rating (protection against penetration of objects and fluids)	IP21
Display	TFT touchscreen
Measurement functions	1x Flow [-2 to +8 l/min] 4x pressure -400 to +400 mmHg 2x Temperature [+10 to +45°C] 1x Liquid level (reservoir) 1x Bubbles
Operating temperature range	18 °C to 40 °C
Temperature range for storage and transport	5 °C to 40 °C
Ambient pressure range, operating storage and transport	700 – 1060 hPa
Operating humidity range storage and transport	20% to 90% RH, non-condensing

Pump module operating modes

	DP3	s.pump®
Motor speed control	Yes	Yes
Pulsatility	Yes	No
Flow control	Yes	Yes
Pressure control	Yes	Yes

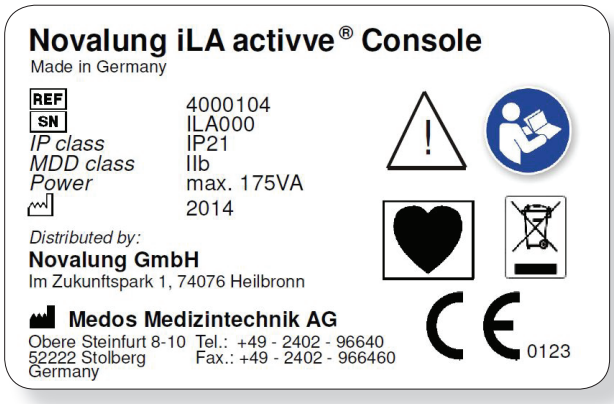
Physical accuray

Quantity	Value
Motor speed	±2% of full scale
Flow rate	0.0 – 1.0 l/min: ±0.1 l/min 1.01 – 8.0 l/min: ±8% if indicated value
Pressure	±10 mm Hg
Temperature	±1 °C (at T_{env}=23°C ±0.2°C)

- The required volumetric blood flow from the pump depends on the patient and the chosen therapy. The selected blood flow rate usually does not exceed 6 l/min.
- Utilisation of the spare capacity up to 8 l/min is only allowed briefly with patients and is not suitable for continuous operation.

3.15 Nameplate

Nameplates as illustrated below are used for product identification.

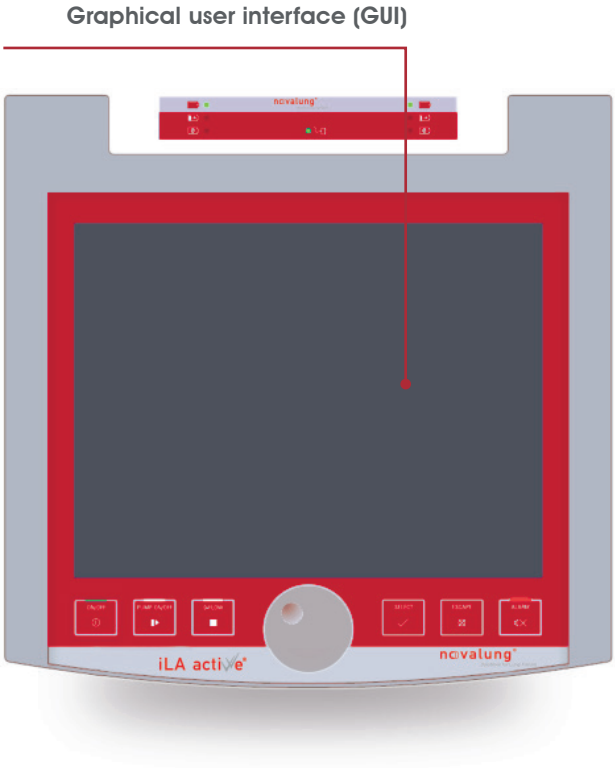


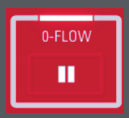
4 CONTROLS AND INDICATORS

This section provides an overview of the operation of the controls and indicators on the front and rear of the units and their functions.

4.1 Controls and indicators on the iLA activve® control panel

The removable iLA activve® console control panel is located at the front of the iLA activve® power supply unit. The iLA activve® control panel consists of a touchscreen display for the graphical user interface and various controls. The iLA activve® control panel is detachable and includes all the controls and indicators necessary for clinical use. The controls (function keys and knob) are located below the touchscreen.



	[ON/OFF] button This button switches the console on and off. The LED indicates that the console is switched on (green = mains operation, orange = battery operation). The console performs a self-test after it is switched on.
	[PUMP ON/OFF] button This button enables pump operation. The white LED is lit when pump operation is enabled.
	[0-FLOW] button This button activates zero-flow mode. The white blinking LED indicates that zero-flow mode is activated. Reverse blood flow can occur when the pump is stopped. In zero-flow mode, the pump impeller speed is adjusted to prevent reverse blood flow (press and hold for 1 second).
	This knob adjusts and sets the speed of the pump impeller. The values in the input field are set using the knob.
	[SELECT] button This button is reserved for Medos service staff.
	[ESCAPE] button Unlock/ lock the console (press and hold for 1 second).
	[ALARM] button The red LED indicates an active alarm condition. When an alarm s present, pressing this button mutes the acoustic tone. The alarm message reappears after a specified time as long as the cause of the alarm or warning has not been corrected.

Graphical user interface (GUI)

Attention

Always use a fingertip to touch the buttons on the touchscreen in order to bring up individual functions. Touching the buttons on the screen with a sharp object, such as scissors or tweezers, will damage the touchscreen.

The graphical user interface is implemented using a touchscreen. All console functions can be configured and used via the graphical user interface. It also displays all relevant patient data.

The graphical user interface is divided into four areas:

Figure 4–1: Schematic overview of graphical user interface

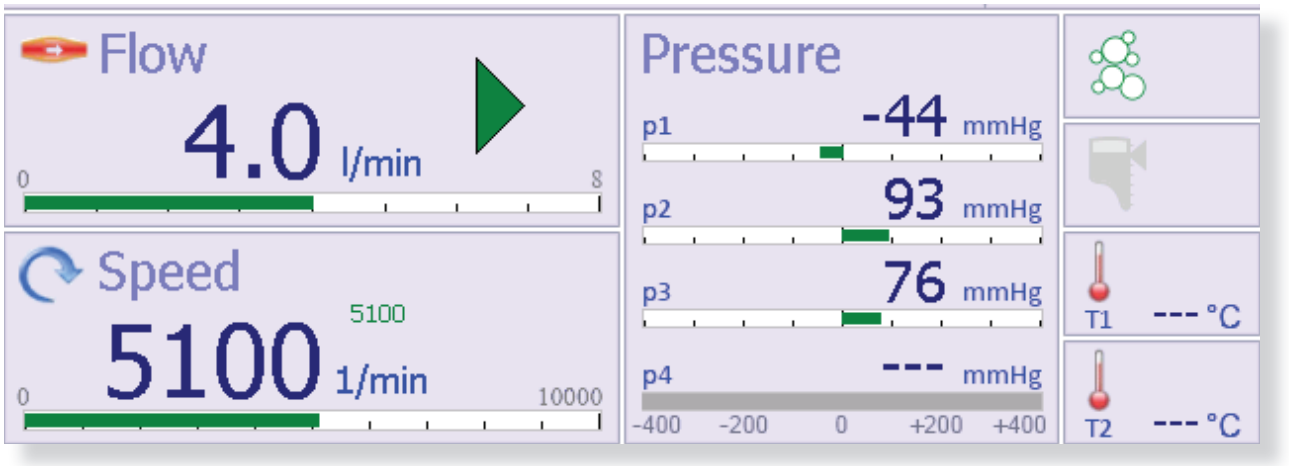
Header bar

The following information is shown in the header bar:

- Alarm messages
- Date and time
- Console locked/unlocked (padlock symbol)

4 CONTROLS AND INDICATORS

Display window for patient data and operating parameters



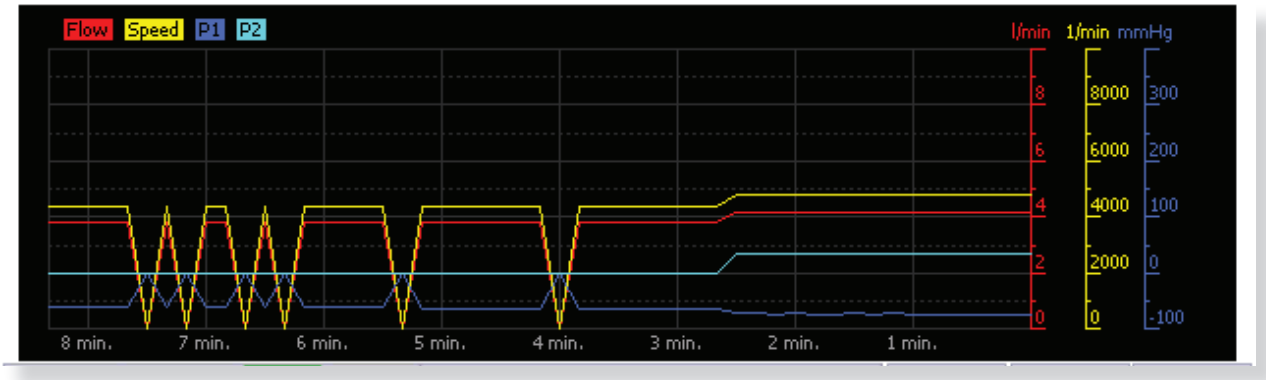
The following parameters are displayed:

- Flow (litres per minute or millilitres per minute)
- Pump impeller speed (rpm)
- Pressures P1 to P4 (mmHg)
- Temperatures T1 and T2 (°C)

Functions not currently available are greyed out (for example: P3, P4 and T2 in the above figure). A parameter configuration dialog is opened below this window if you touch one of the displayed parameters.

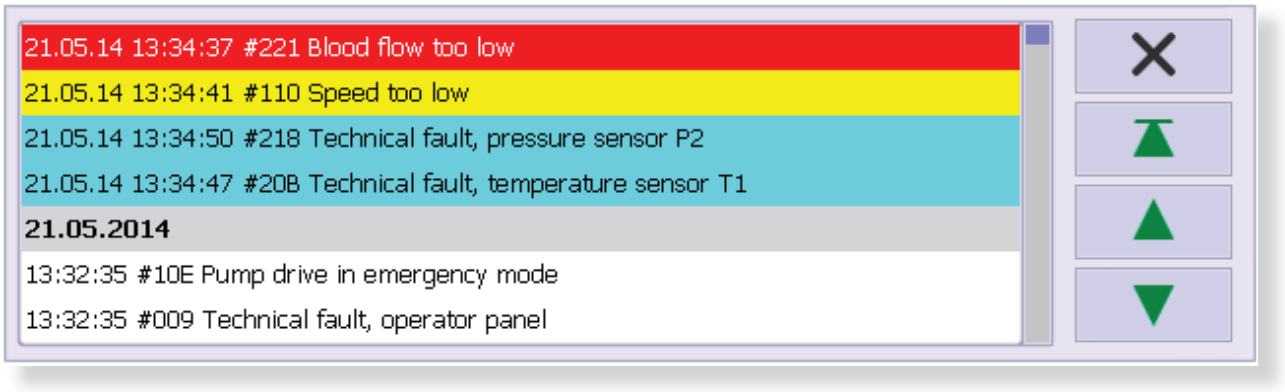
Trend chart, alarm and information window, entry window

Trend chart



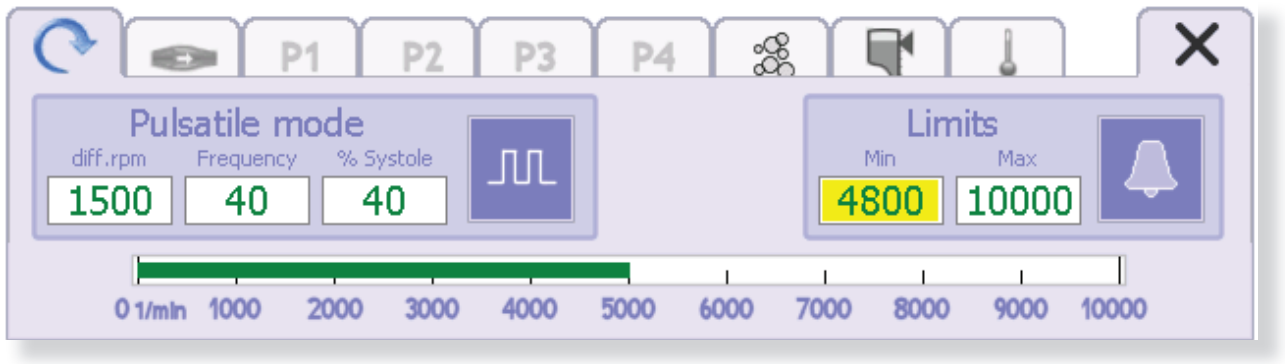
In normal operating mode, data from the patient data display window is shown here in the form of a trend chart. For detailed information, see section 6 „USING THE iLA ACTIVVE® CONSOLE“ on page 6-1 and following.

Alarm window



Active and historical alarm messages are displayed in this window. For detailed information, see section 7 „ALARMS“ on page 7-1 and following.

Entry window for operating parameters



The operating parameter settings dialogs are displayed in this window while the operating parameters are being configured.Touch the tabs at the top of the dialog pane to navigate to the individual dialogs.

4 CONTROLS AND INDICATORS

Status bar

The power source is indicated in the left-hand part of the status bar. The currently active power source is highlighted in green. The following power sources can be displayed:

- Battery pack [2x] 
- Mains power 
- 11–28 VDC 

To the right there are four buttons that provide access to the following submenus:

- Timer 
- Show/hide trend chart 
- Settings 
- System settings 

When you touch an icon, the corresponding display window or menu opens..

Alarm messages

The alarm system classifies alarm messages into three different priorities: high, medium and low!

Alarm messages are displayed on the iLA activve® control panel below the operating parameters window. The red LED above the [ALARM] button remains lit as long as an alarm condition is present or an alarm has not been acknowledged by pressing the [ALARM].button.

High priority alarm messages

- The cause of the alarm must be corrected immediately. Failure to act may endanger the patient's life.
- High priority alarm messages are displayed in red. The alarm message in the header bar blinks alternately red and black, and the upper display area of the message window is alternately red and black (blink rate 1.67 Hz). An alarm tone also sounds (sound pressure level 65.2 dBA). The alarm tone and displayed message can be muted or blanked by pressing the [ALARM] button. However, the alarm tone and message will recur at regular intervals until the cause(s) of the alarm is/are corrected.

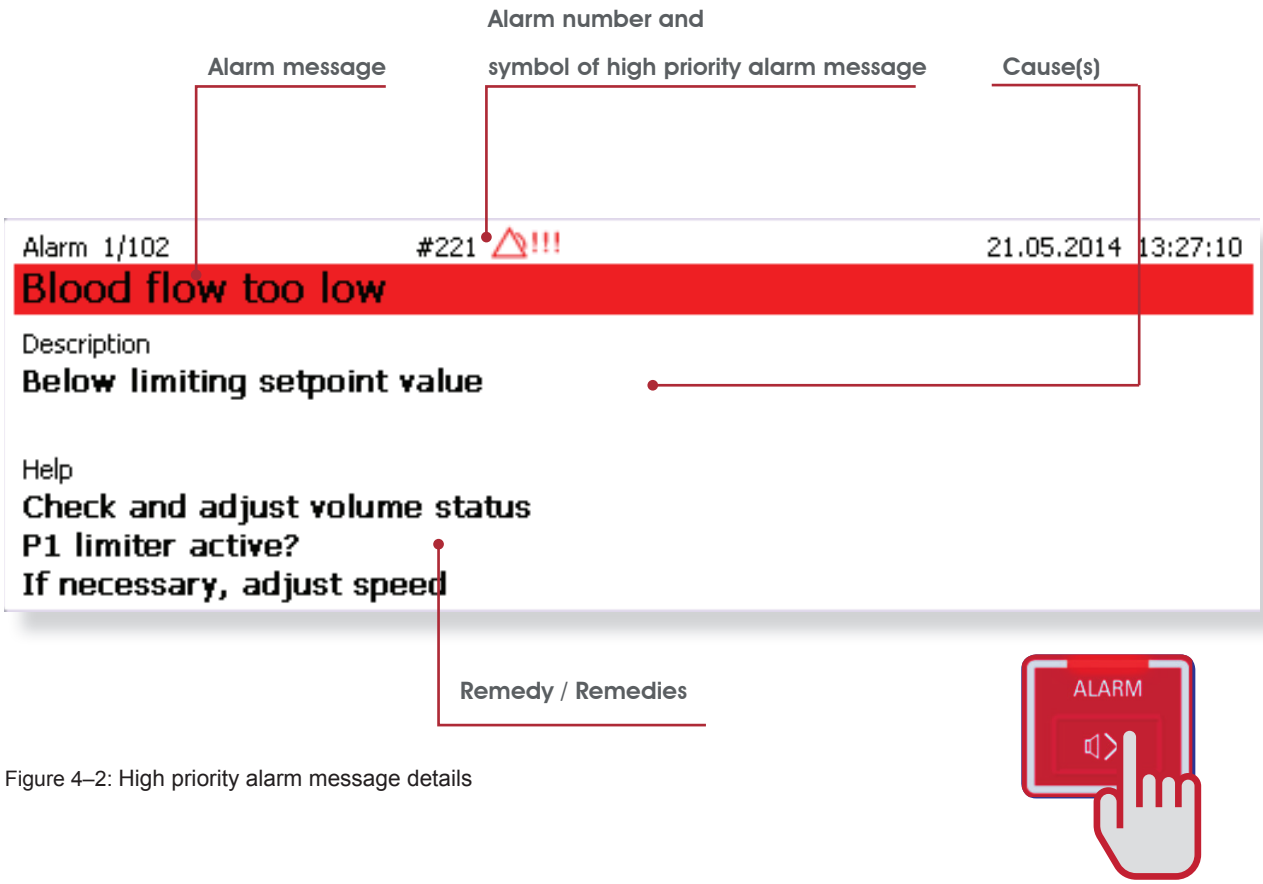


Figure 4–2: High priority alarm message details

Medium priority alarm message

- Medium priority alarm messages are displayed in yellow. The alarm message in the header bar blinks alternately yellow and black, and the upper display area of the message window is alternately yellow and black (blink rate 0.63 Hz). A warning tone also sounds (sound pressure level 59.8 dBA). The warning tone and message can be muted or blanked by pressing the [ALARM] button. However, the warning tone and message will recur at regular intervals until the cause(s) of the fault is/are eliminated.

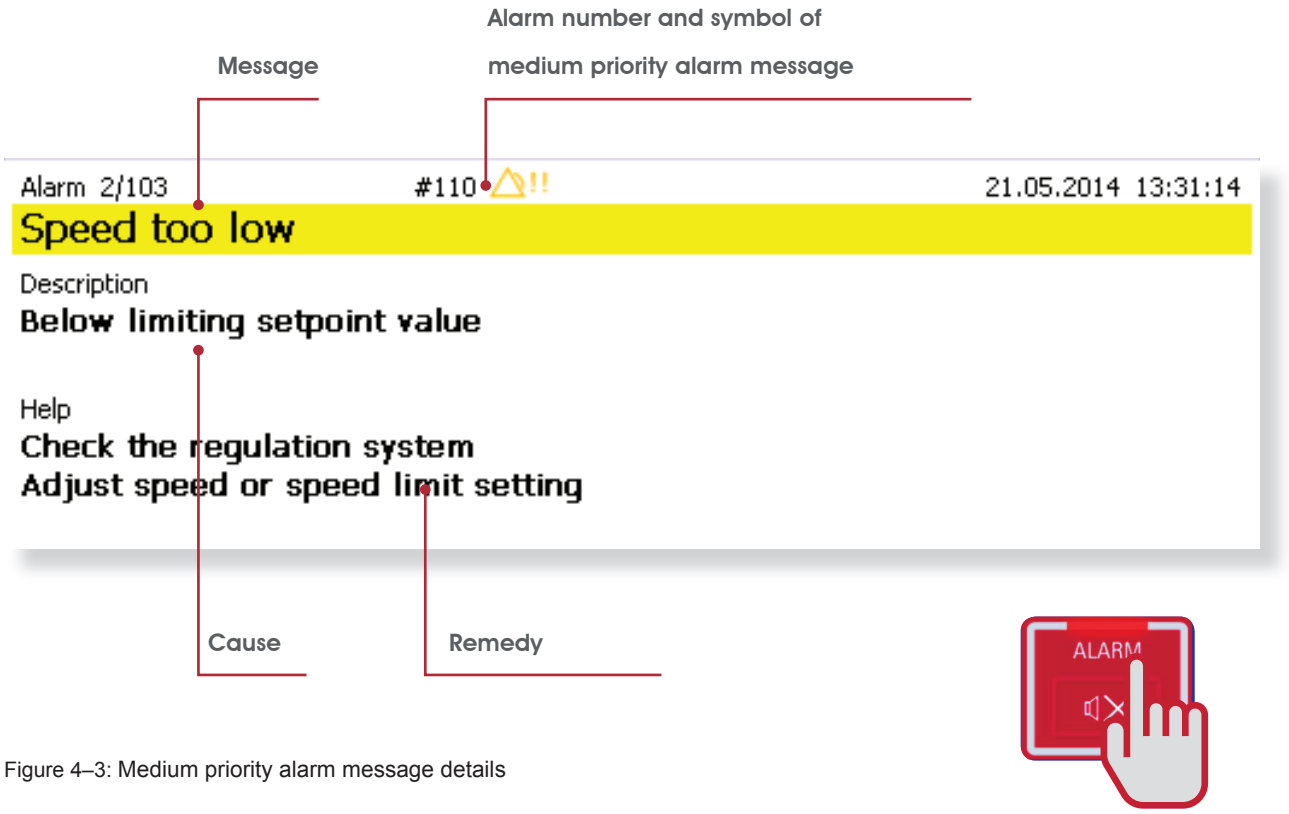


Figure 4–3: Medium priority alarm message details

Low priority alarm message

- Low priority alarm messages are displayed in turquoise. The upper part of the message window is also displayed in turquoise. A notification tone (sound pressure level 52.2 dBA) sounds at the same time. Specific operator instructions are shown below. The notification tone and message can be muted or blanked by pressing the [ALARM] button. However, the notification tone and message will recur at regular intervals until the cause(s) of the fault is/are eliminated.

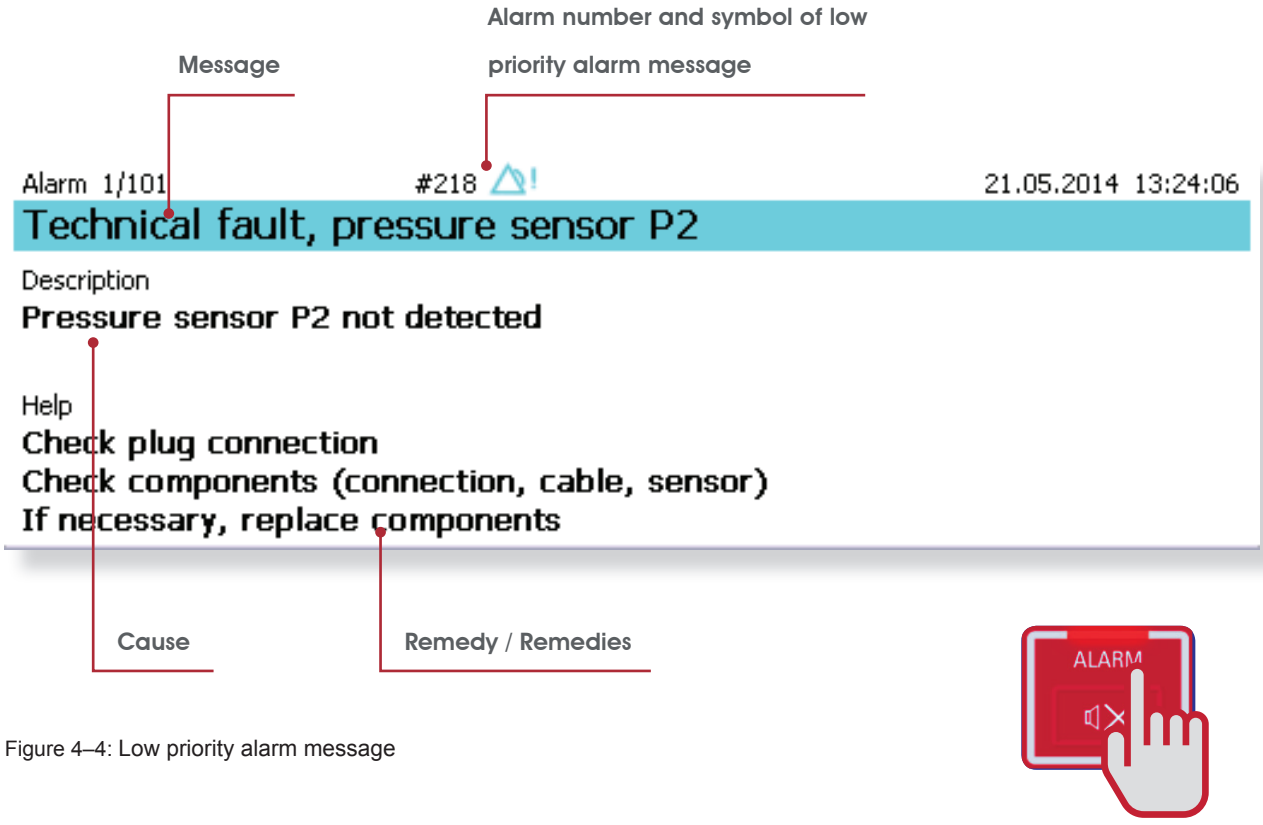


Figure 4–4: Low priority alarm message

4 CONTROLS AND INDICATORS

Status bar indications

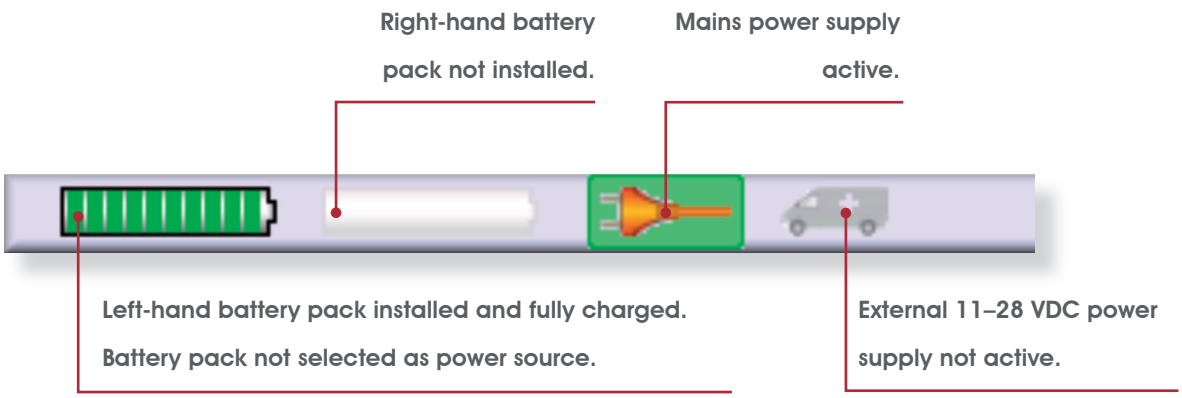
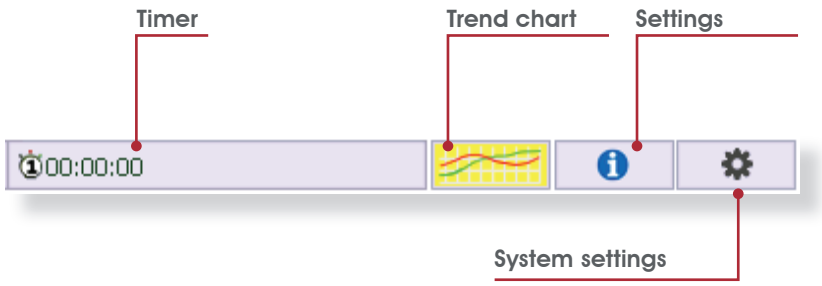


Figure 4–5: Status bar indicator details

Available power sources are shown in colour. The currently active power source is highlighted in green. Unavailable power sources are greyed out.

Buttons on the status bar

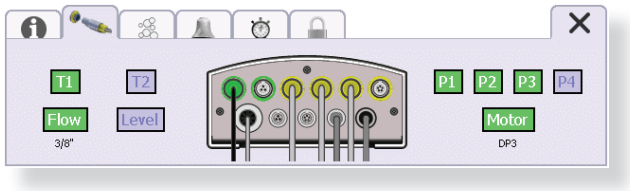


Timer button 

Enable/disable timer setting.

Trend chart 

Show/hide trend chart

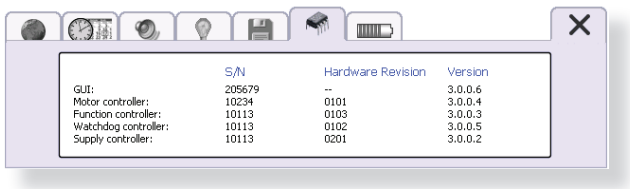


Settings button 

This button provides access to the device functions and overview pages. Touch one of the tabs at the top to open the corresponding page.

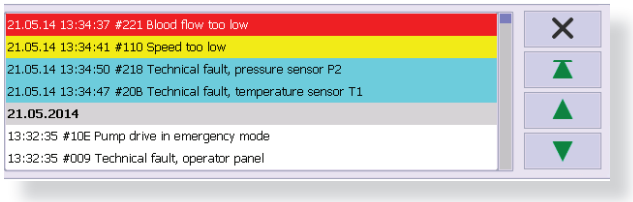
System Settings button 

This button provides access to the system settings.



Alarm bell tab in settings window

The alarm history is shown on this tab.



[Alarm muted] icon

This icon appears at the right end of the header bar when the [Alarm] button is pressed and held for 3 seconds (see section „4.1 Controls and indicators on the iLA activve® control panel“ on page 4-1).

4.2 iLA activve® console power supply indicators and controls

Indicators in carrying handle

Status indicators for the power source and the battery pack charge levels are integrated into the carrying handle of the iLA activve® console power supply unit.

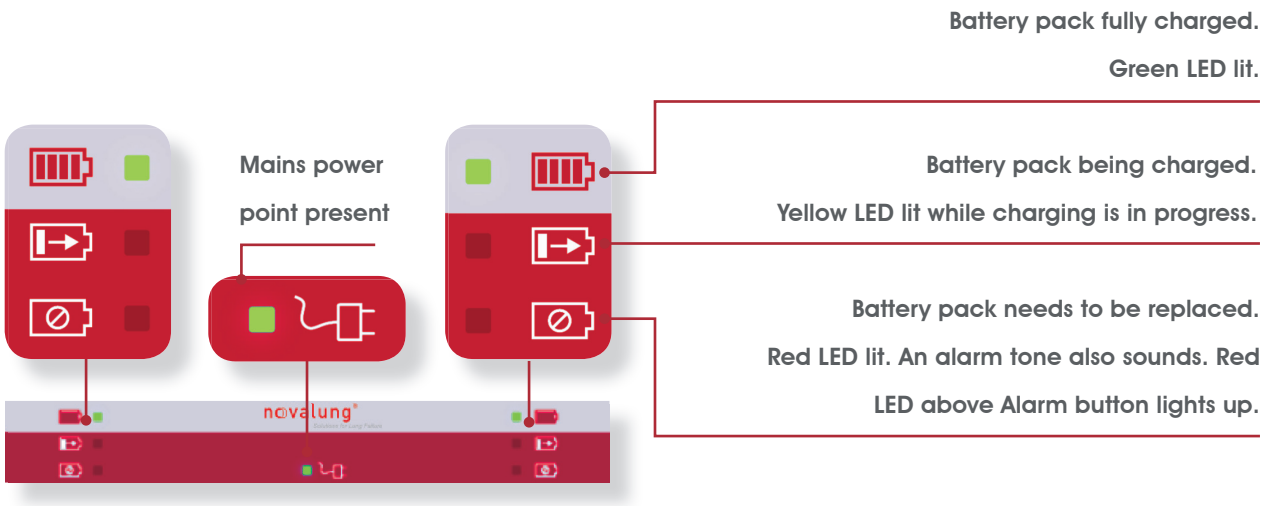
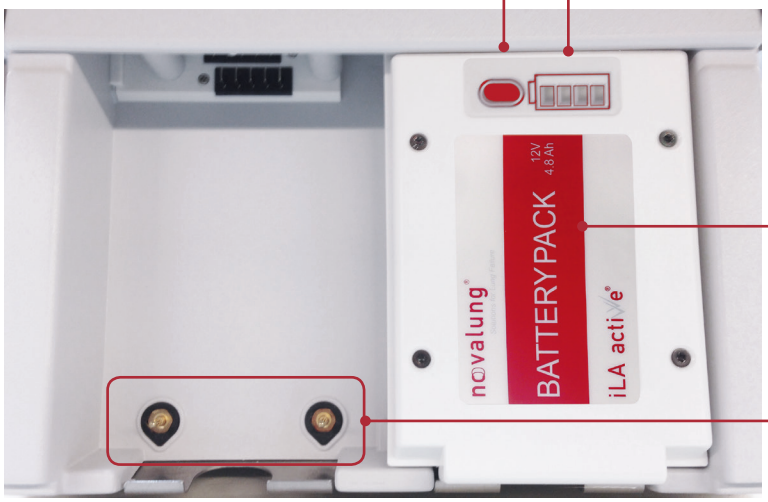


Figure 4–6: Power supply indicators on the front of the device

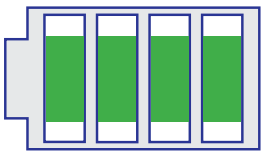
4 CONTROLS AND INDICATORS

Charge level indicator on front of battery pack

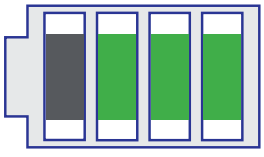
Each battery pack has a button on the front that can be used to show its charge level on an LED indicator. The following figure shows the unit with the MDC control panel and battery cover removed.



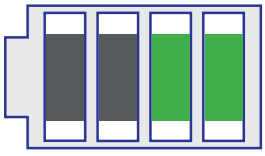
Charge level indicator on battery pack



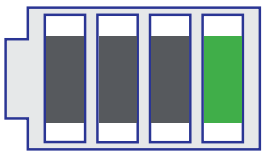
Battery pack fully charged (100%)



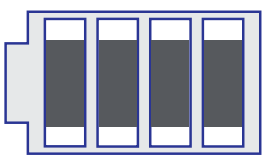
Battery pack 75% charged



Battery pack 50% charged



Battery pack 25% charged – charging urgently recommended.



Battery pack empty (0%) – exchange battery pack immediately.

Figure 4–7: Charge level indicator on battery pack

Battery packs replacement

DANGER

When operating the unit without mains power, take care to remove only one battery pack at a time. The battery pack with the lower remaining capacity should be replaced first. Check this first with the indicator.

The two battery packs are discharged in parallel. When mains power is connected, both battery packs are charged in parallel if not already fully charged.

- A sufficient number of fully charged battery packs must be kept within reach when the iLA activve® console blood pump system is used for purposes such as patient transport.

The control panel and battery cover must be moved out of the way in order to exchange the battery packs. The battery cover can be clipped below the control panel to hold the panel in place. Now the battery pack can be removed by pressing the lock with your index finger and pulling the battery pack toward you.

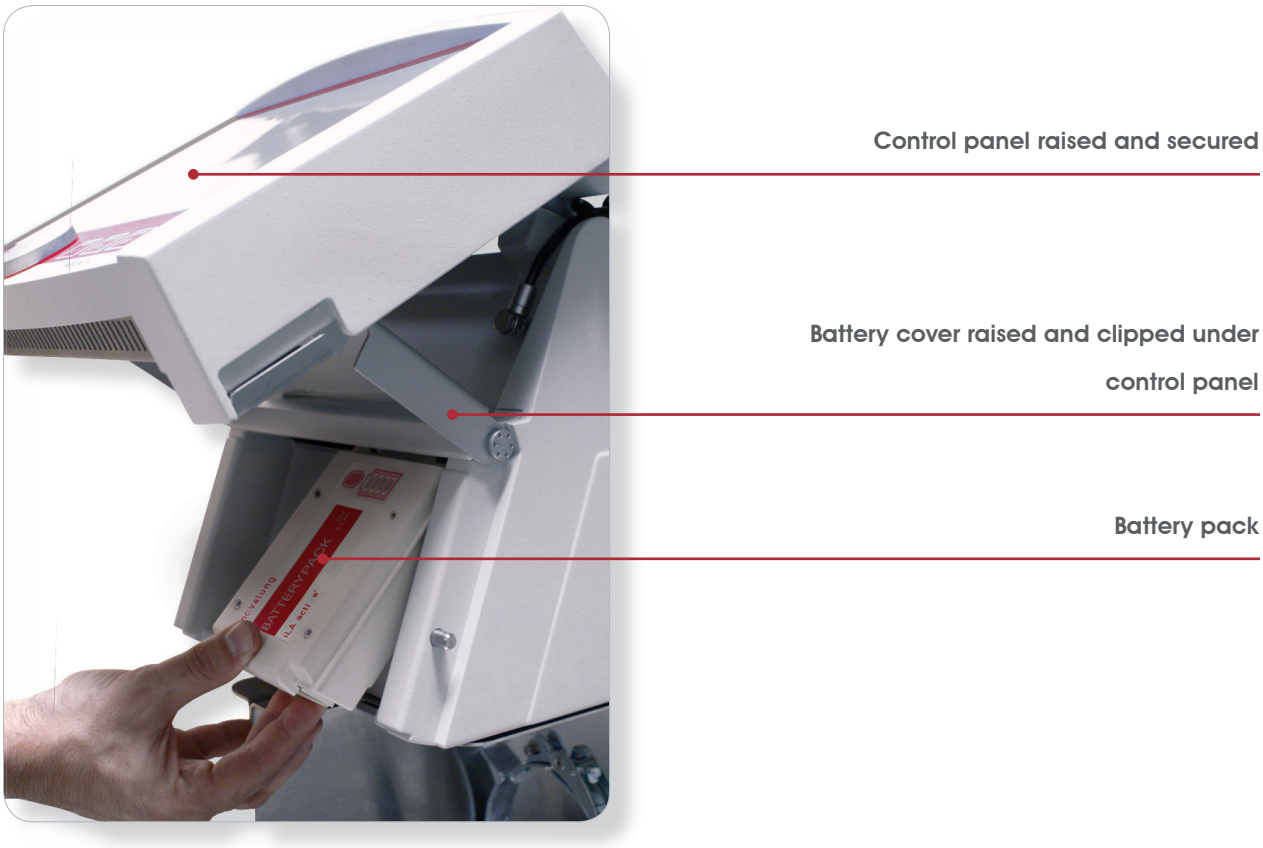


Figure 4–8: Battery replacement

4 CONTROLS AND INDICATORS

Mains power switch

The power switch is located at the right on the rear of the unit.

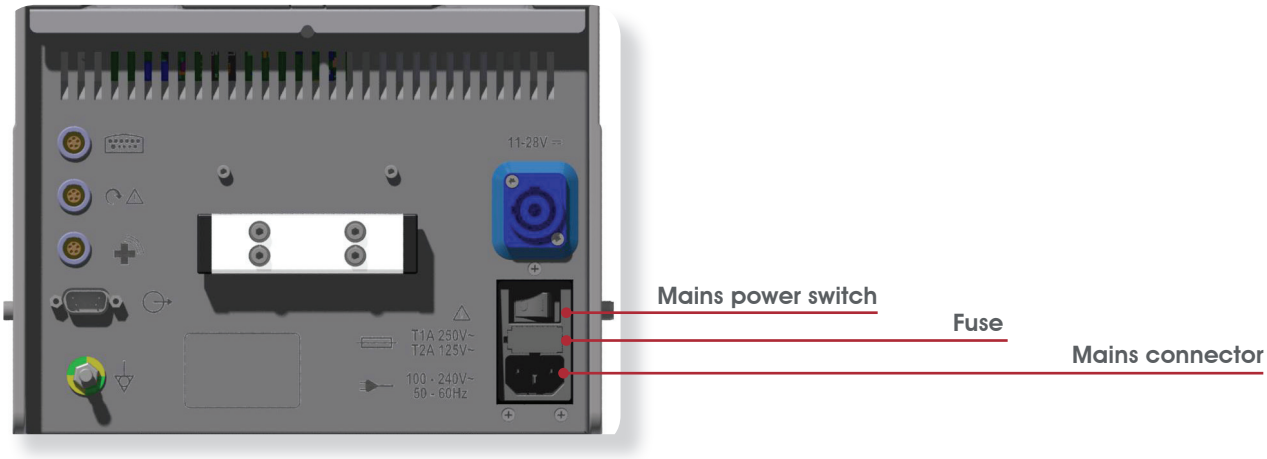
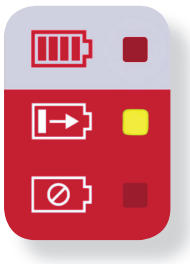


Figure 4–9: Power switch on rear of unit

The battery packs in the battery compartment are charged automatically when the power switch is in the On position.

The power source indicator in the status bar is highlighted in green. Mains power has been selected in this case.



Both battery pack charge level indicators in the carrying handle light up yellow.

If the iLA activve® control panel is switched on, the battery pack charge level indicator in the status bar shows the progress of battery charging for each installed battery pack.

When operating from battery power, a controlled shutdown of the MDC console occurs when the batteries are fully discharged. Alarm #31E is indicated 5 minutes before the shutdown.

DANGER 	Use only fuses designated for the mains voltage used. Verify that the AC mains voltage matches the specified supply voltage.

DANGER 	Risk of electric shock. Disconnect the equipment from the AC mains before replacing the fuses.

- Observe the safety instructions in section „2 SAFETY INSTRUCTIONS“ on page 2-1 and following.

The mains inlet is protected by two fuses [2x T 2A H (250V)]. They are located in the integrated fuse holder below the AC power connector (see figure at right).

⇨ Unplug the power cord before replacing the fuses.

⇨ Then pull out the fuse holder and replace the blown fuse.

❑ If the either of the fuses blows again after being replaced, have the equipment inspected by Novalung service staff.

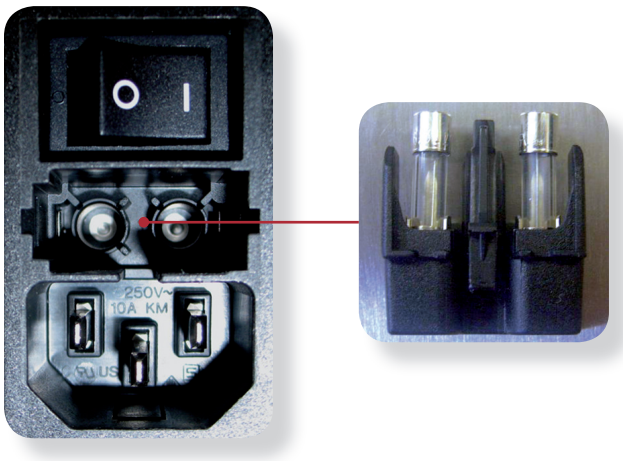


Figure 4–10: IEC appliance inlet (left) and fuse holder (right)

4.3 Controls and indicators on the iLA activve® drive unit

There is a control panel on the rear of the pump drive that can be used for emergency pump operation in the event of failure of the iLA activve® control panel.

	[PUMP ON/OFF] button This button enables pump operation. The pump starts running immediately at 500 rpm.
	[Raise pump speed] button The pump speed increases by 100 rpm each time this button is pressed. If the button is pressed and held, the speed gradually increases by 2000 rpm. After this, the button must be pressed again to further increase the speed.
	[Lower pump speed] button The pump speed decreases by 100 rpm each time this button is pressed. If the button is pressed and held, the speed gradually decreases by 2000 rpm. After this, the button must be pressed again to further decrease the speed.
	[Info] button Pressing this button causes information to be shown on the display.
	The red LED is lit when emergency mode is enabled.
	Display The character string ****** is shown on the display during normal operation with the MDC control panel. The pump speed setting is shown on the display in emergency mode. Information can be displayed by pressing the [Info] button.

5 PUTTING INTO SERVICE

The actions and procedures that must be performed each time before the equipment is used with a patient are described in this section.

- ❑ Before putting the equipment into service, check all components for damage during transport or storage.

5.1 Safety instructions

DANGER 	Connection to the wrong supply voltage is dangerous. Always connect the equipment to an earthed socket-outlet with a voltage matching the supply voltage on the nameplate. An incorrect supply voltage can damage the device and endanger the patient's life. Do not use multiple-outlet adapters or extension cables to supply power to the device. Use only the cable and plug included with the device.

DANGER 	Ensure that the power source is adequate for the device. Ensure that fully charged battery packs are installed before using the console. Recharge empty battery packs immediately. If possible, always connect the device to an external power source whenever an AC mains or external DC power source conforming to the specified supply voltage range is available. Sudden stoppage of the device due to an empty battery pack endangers the patient's life!

DANGER 	Always keep ventilation openings unobstructed. Excess heat can damage the device.

DANGER 	To avoid the risk of transmitting air embolisms to the patient, the manufacturer recommends fitting a suitable air elimination component, such as a bubble trap or an arterial filter acting as a bubble trap, in the arterial line.

DANGER 	Visually inspect the level sensor and the flow sensor before use. For each of these, inspect the cable, connector and sensor for integrity. Sensors that pass visual inspection must be checked after installation in the system by performing a functional test with a primed circuit.

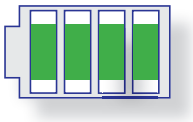
- ■ All safety instructions, advice and measures described in section „2 SAFETY INSTRUCTIONS“ on page 2-1 must also be followed and strictly observed.

5.2 Charging battery packs

DANGER

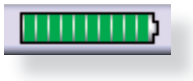
Before using the system with a patient, verify that both battery packs in the drive console are fully charged. The charge level indicators of the battery packs should show full charge. When both battery packs are fully discharged, the charging time with the console connected to the AC mains is approximately 6 hours. The unit may not be used with patients before the batteries are again fully charged!

Indications of a fully charged battery pack



The charge level indicator on front of battery pack shows full charge.

The battery pack charge level indicator in the carrying handle lights up green.



All segments of the battery pack charge level indicator on the status bar of the graphical user interface are green.

Battery pack charging procedure

Attention

Use only the power cable supplied with the equipment to connect it to the AC mains. Ensure that the mains voltage matches the supply voltage stated on the equipment nameplate. The mains voltage range and appropriate fuse values for the voltage concerned are printed on the rear panel of the power supply unit next to the power switch. [Note: The standard fuses are type T 2A H 250 V.

⇨ Plug the power cable into the AC power connector of the iLA activve® console, and then plug the other end into a properly installed earthed socket-outlet compliant with VDE 0107.

⇨ When operated from mains power, the medos® deltastream® MDC blood pump system can additionally be connected to the existing earthing system using the terminal for a potential equalisation conductor. This is not recommended in Class 2 rooms (operating theatres, intensive care stations, etc.) with a mains network corresponding to an IT or TN-S network as described in VDE 0100 Part 710. Improper connection can have a detrimental effect on the medos® deltastream® MDC blood pump system, which can affect

⇨ Put the power switch on the rear of the unit in the [I] position.

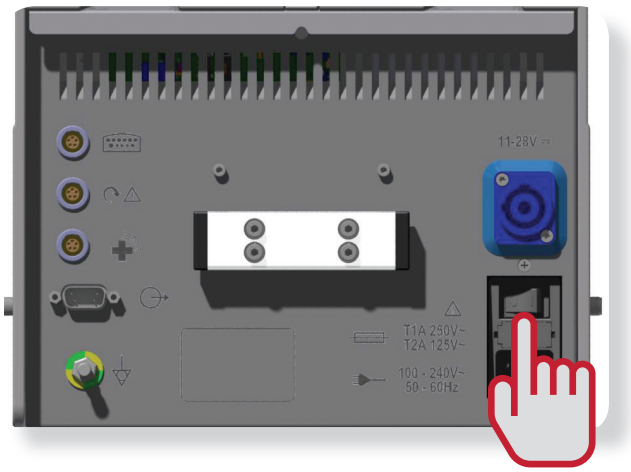


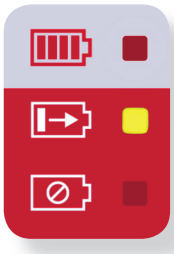
Figure 5–1: Power switch on rear of unit

⇨ The green LED next to the plug symbol on the carrying handle lights up.

Mains voltage or external DC voltage switched on.

⇨ Partially discharged battery packs start charging automatically when mains power or power from an external DC source is applied to the drive console.

⇨ The yellow LED next to the corresponding battery pack symbol on the carrying handle lights up while the battery pack is charging.

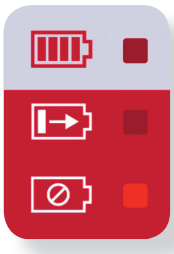


Battery pack being charged.

■ If the red LED for a battery pack symbol is lit, there is a fault in the battery pack.

❑ First check that the battery pack is installed correctly and the battery retainer is latched in place.

■ If the fault condition is not cleared by removing and reinstalling the battery, the battery pack must be replaced.



Battery pack defective.

↳ The installed battery packs are charged parallel.

⇨ Recharge discharged battery packs immediately.

5.3 Connecting device components

Connecting the iLA activve® control panel

⇨ Connect the control panel to the power supply unit [plug the connector on the spiral cable into the front of the power supply unit].

Connecting cable for control panel

Figure 5–2: Control panel connection to the power supply unit

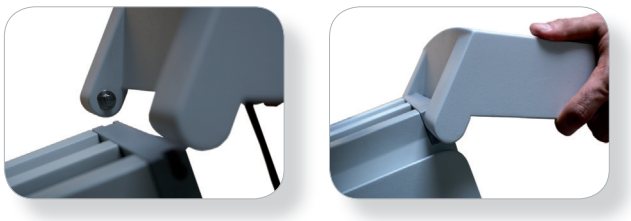


Figure 5–3: Fitting the control panel on the power supply unit

- ⇨ With the control panel held horizontal, slide the metal bushes into the bracket on the power supply unit. Ensure that the bushes are inserted all the way down before allowing the control panel to tilt downward. To remove the control panel, first tilt it up to the horizontal position and then pull it free from the power supply unit.
- ⇨ The control panel can optionally be attached to a standard profile rail. For this purpose, a double claw adapter must be attached to the profile rail and the back of the control panel. Take care that the adapter is oriented correctly so the tongue and groove mate.

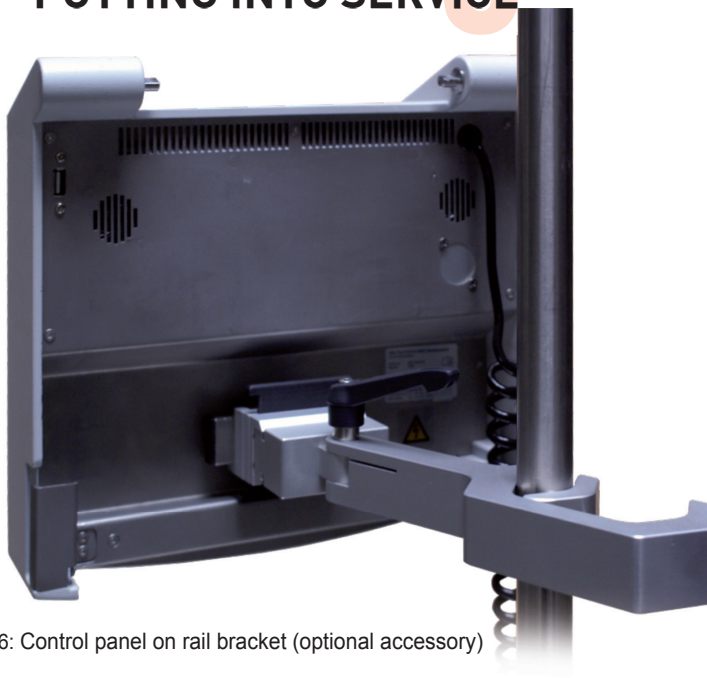


Figure 5–6: Control panel on rail bracket (optional accessory)

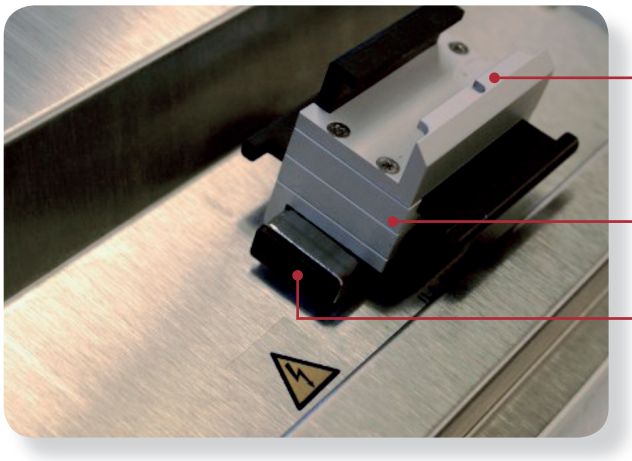


Figure 5–4: Dual claw adapter attached to control panel rail

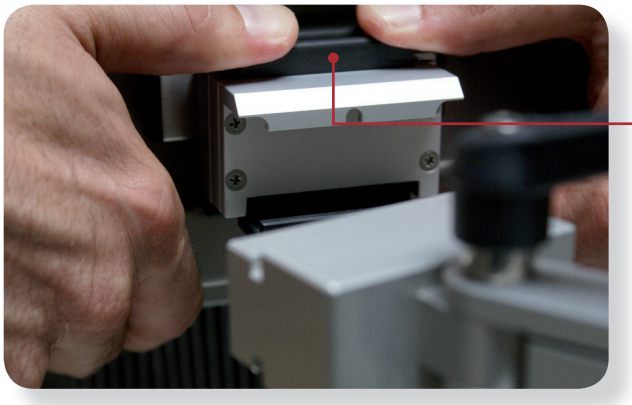


Figure 5–5: Attaching the control panel to the profile rail

5 PUTTING INTO SERVICE

Connecting the sensor box and the iLA activve® drive

- ⇨ Connect the iLA activve® sensor box to the power supply unit (plug the cable into the back of the power supply unit at the upper left).
- ⇨ Connect the iLA activve® drive to the sensor box.

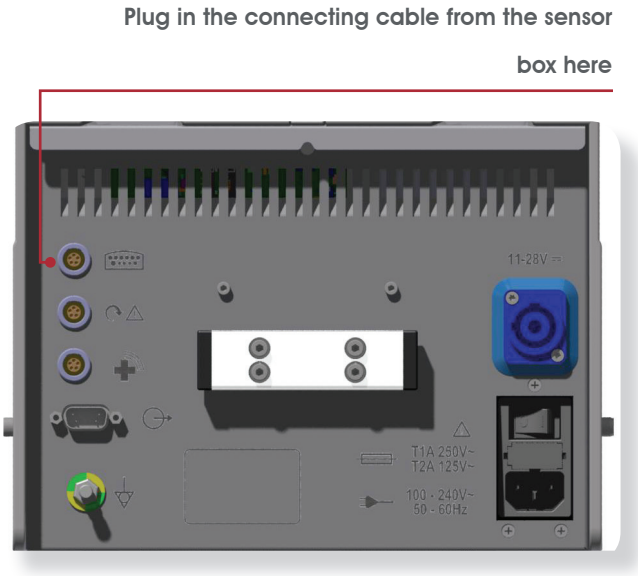


Figure 5–7: Connector for sensor box

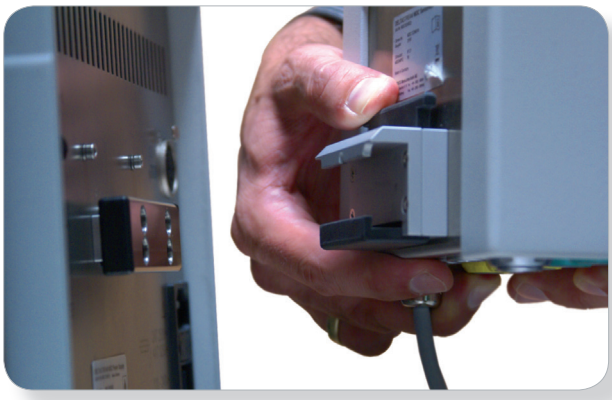


Figure 5–8: Mounting the sensor box on the power supply rail

The sensor box may be mounted on the profile rail at the rear of the power supply or on any other standard profile rail.

The iLA activve® drive may be attached to the mounting bracket for deltastream® drive units (optional accessory).

The connector assignments of the sensor box are also shown in the [Settings] menu on the iLA activve® control panel.

- ⇨ Touch the Info symbol on the toolbar at the bottom of the touchscreen.
- ⇨ Then select the [Connections] tab .
- ↳ The [Connections] tab is shown on the iLA activve®control panel.

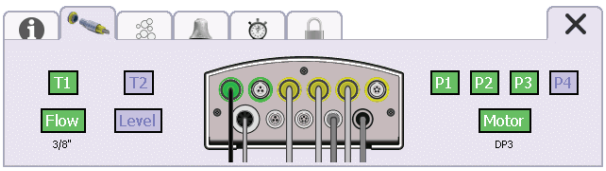


Figure 5–9: Connections tab

- This gives you a detailed overview of which peripheral devices and sensors are currently connected to the sensor box and available.
- For a detailed description of this tab, see section „6 USING THE iLA ACTIVVE® CONSOLE“ on page 6-1.

5.4 Connecting the DP3 pump module

- Always observe the information and instructions on the current package insert included with the DP3 pump module.

ATTENTION Always fill the DP3 pump module with blood or synthetic blood plasma before starting the pump.

DANGER Ensure that the sterile packaging is intact. An expiry date is shown on the packaging. If this date has been exceeded or the packaging is damaged, do not use the DP3 pump module for clinical purposes.

⇨ First remove the protective caps from the inlet and outlet of the DP3 pump module.

DANGER Take care that no particles are present on the pump module ports after the protective caps have been removed. Such particles could enter the blood stream and thereby endanger the life of the patient.

⇨ Now connect the pump module to the extracorporeal circuit in a suitable location by sliding 3/8“ x 3/32“ tubing over the inlet and outlet ports.

- The pumping direction is marked on the DP3 pump module next to the ports.

⇨ Secure the tubing connections with cable ties at the ports.

DANGER Ensure that the cable ties are tight.

- When connecting the pump module, bear in mind that in some cases it may be necessary to fit Luer Lock connectors before and after the pump module to allow the pressure sensors to be connected.

⇨ Place the pump module on the magnetic coupling of the pump drive such that the lock tabs of the pump module engage with the recesses of the pump drive.

⇨ Press the pump module onto the drive unit until you hear the lock tabs click into place.

↳ The pump module is now protected against accidental rotation and separation from the pump drive.

Figure 5–10: DP3 pump module on iLA activve® drive

PUTTING INTO SERVICE

5.5 Connecting the s.pump® pump module

Observe the applicable use instructions for the s.pump®.pump module.

ATTENTION

Always fill the s.pump® pump module with blood or synthetic blood plasma before starting the pump.

DANGER

Ensure that the sterile packaging is intact. An expiry date is shown on the packaging. If this date has been exceeded or the packaging is damaged, do not use the s.pump® pump module for clinical purposes.

⇨ First remove the protective caps from the inlet and outlet of the s.pump®.

DANGER

Take care that no particles are present on the pump module ports after the protective caps have been removed.
Such particles could enter the blood stream and thereby endanger the life of the patient.

⇨ Now connect the pump module to the extracorporeal circuit in a suitable location by sliding 3/8“ x 3/32“ tubing over the inlet and outlet ports.

■ The pumping direction is marked on the s.pump® module next to the ports.

⇨ Secure the tubing connections with cable ties at the ports.

DANGER

Ensure that the cable ties are tight.

⇨ When connecting the pump module, bear in mind that in some cases it may be necessary to fit Luer Lock connectors before and after the pump module to allow the pressure sensors to be connected.

⇨ Place the pump module on the magnetic coupling of the pump drive such that the teeth of the pump module engage with the bayonet pins of the s.pump®drive.

⇨ Turn the pump module until you hear the locking mechanism click into place.

⇨ The pump module is now protected against accidental rotation and separation from the pump drive.

Figure 5–11: s.pump® module on s.pump® drive

ATTENTION

The bottom of the pump module must rest flat on the magnetic coupling. The pump module must be audibly latched in place and checked for secure seating on the pump drive.

To remove the pump module, press back the lock mechanism and turn the pump module until the bayonet lock mechanism releases the pump module. Due to the magnetic force of the coupling, it takes a slight pull to detach the pump module from the drive.

5.6 Connecting the sensors

Flow sensor

DANGER

The arrow marked on the flow sensor must point in the direction of blood flow in the extracorporeal circuit.

Fit the flow sensor on the tubing and lock the sensor clamp.

Pressure sensors

DANGER

Ensure that the sterile packaging is intact. An expiry date is shown on the packaging. If this date has been exceeded or the packaging is damaged, the pressure sensors may not be used for clinical purposes.

- Always observe the information and instructions on the current package insert included with the PvB pressure sensors.

The pressure sensors are connected to the circuit using Luer Lock connectors. This allows the three-way valve to be used to connect the sensor directly to the open port in the circuit or through a connecting line acting as a pressure monitoring line.

⇨ Position the pressure sensor at the connector location in the circuit in order to obtain correct pressure readings at this location.

⇨ Connect an irrigation line to the back end of the sensor to allow a constant stream of a suitable isotonic irrigation solution to flow through the pressure line with the aid of a pressure sleeve.

- All air must be bled from the pressure line before the sensor is connected to the circuit.

⇨ To do this, press the silicone wings together at the sensor to quickly flood the pressure line with irrigation solution.

- Ensure that all air bubbles have been expelled from the entire pressure line before connecting it to the pressure measurement point on the circuit.

⇨ Then plug the signal connector of the pressure sensor (blue connector) into the sensor end of the connecting cable.

DANGER

To avoid misorientation when plugging in the connector, ensure that the plug and socket are properly mated (note the shape of the connector).
Do not try to force the plug into the socket.

⇨ Then connect the other end of the pressure sensor connecting cable to the appropriate connector on the sensor box (one of the connectors labelled P1 to P4).

- The connector should latch into place with a click.

❑ To avoid misorientation, align the nib of the cable plug with the matching recess in the panel connector.

- Always connect pressure sensor P1 as close as possible to the inlet port of the pump (i.e. before the pump). This is important for the proper operation of the P1 limiter.
- Always connect pressure sensor P2 as close as possible to the outlet port of the pump (i.e. after the pump).
- Pressure sensors P3 and P4 are only used to observe the pressure and can be fitted at any desired locations in the extracorporeal circuit. Use of these sensors is optional.

Level sensor

ATTENTION Use only original Medos level sensors.

⇨ For monitoring the liquid level in a hard-shell reservoir, the sensor pad can be stuck onto the outside of the reservoir.

⇨ To do this, remove the protective film from the pad and attach it horizontally at the level where pumping should start (middle arrow at the edge of the pad).

❑ To ensure reliable level measurement, make sure that the pad adheres properly to the reservoir and that the entire surface of the pad is in contact with the reservoir.

■ Then plug the connector of the level sensor onto the pad.

■ Discard the level sensor pad after use. Reliable operation cannot be ensured with reuse.

■ Use the level sensor only with reservoirs made from polycarbonate (Makrolon) or equivalent materials.

⇨ Ensure that the wall thickness of the reservoir at the location where the sensor pad is attached is between 2 and 5 mm.

❑ Avoid locations with irregularities in wall thickness.

■ With reservoirs equipped with a heat exchanger, ensure that the distance between the reservoir wall and the heating coil is at least 40 mm.

⇨ Do not stick the sensor pad on top of a metallised label.

⇨ Avoid touching the contact surface of the level sensor pad.

⇨ Do not use sensor pads with wavy, cracked, torn, or detached contact surfaces.

❑ Make sure that the location where the sensor pad is attached is free of grease and dust.

⇨ Attach the pad at the desired location on the reservoir so the arrow is aligned with the threshold level.

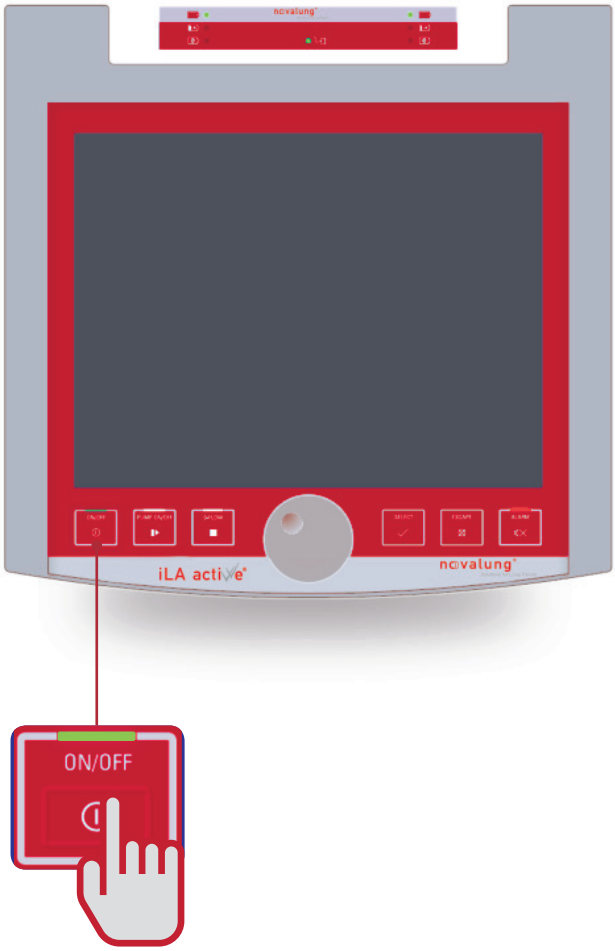
⇨ Ensure that the sensor pad is fitted horizontally with the arrow pointing to the right.

⇨ Take care that the entire surface of the sensor pad is stuck to the reservoir.

PUTTING INTO SERVICE

5.7 iLA activve® console start-up

- ☑ Ensure that the iLA activve® console blood pump system (including accessories) is complete.
- ☑ Visual inspection: No external damage with exposure of electrical components.
- ☑ Mains power connection present.
- ☑ Pump module connected (check direction).
- ☑ Flow sensor connected (check direction).
- ☑ Pressure sensors connected as necessary (with P1 before pump).
- ☑ Level sensor connected if necessary.
- ☑ Circuit checked for secure connections.
- ☑ Circuit checked for absence of leaks and air bubbles.
- ☑ Both battery packs fully charged and installed in their compartment.
- ☑ Drive console connected to AC mains or an external DC power source, depending on what is available.
- ☑ Power switch on the back of the unit in the [I] position.
- ■ If the iLA activve® console blood pump system has been assembled correctly, the iLA activve® console may be switched on.
- ↳ The green LED next to the plug symbol on the handle lights up.
- ⇨ Press and hold the [ON/OFF] button on the control panel for at least 2 seconds, until an acoustic signal sounds.
- ↳ The unit performs a self-test of all of its functions.
- ❑ The user is responsible for checking the visual and acoustic indicators during the self-test.
- ❑ Check that all LED indicators on the front of the unit light up briefly during the self-test phase (lamp test).
- ↳ Verify that no alarm or fault messages appear on the monitor.
- ☑ Check the status of the LED indicators.



LED	Status	Colour
Battery pack 1 installed and fully charged	On	Green
Battery pack 1 charging	On	Yellow
Battery pack 1 fault	Off	Red
Mains power or external DC power	On	Green
Battery pack 2 installed and fully charged	On	Green
Battery pack 2 charging	On	Yellow
Battery pack 2 fault	Off	Red
[ON/OFF] button for operation from AC mains	On	Green
[ON/OFF] button for operation from internal battery packs	On	Orange
[ALARM] button	Off	Red

↳ The following screen is shown on the iLA activve® control panel while the console is starting up.

Figure 5–12: Start-up screen

- The unit is ready for use after it passes the self-test with no faults.
- Next all system functions and parameters of the iLA activve® console must be initialised using a compulsory menu-guided procedure.
- The Connections tab appears first. All of the connected peripherals are shown on this tab.

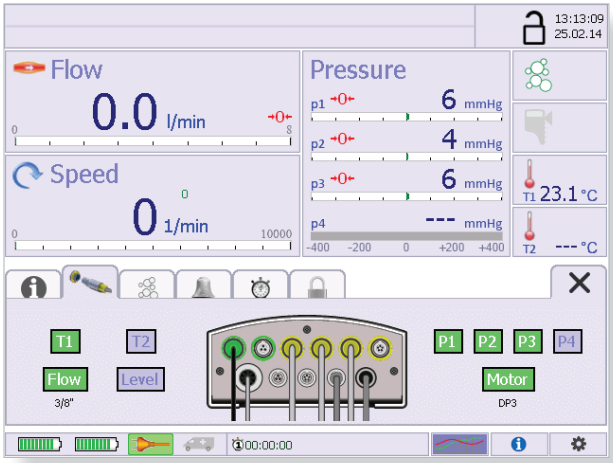


Figure 5–13: Connections tab

Settings for key operating parameters must be configured before the console can be used. These are specifically:

- Priming mode
- Flow sensor zero adjustment
- Pressure sensors zero adjustment

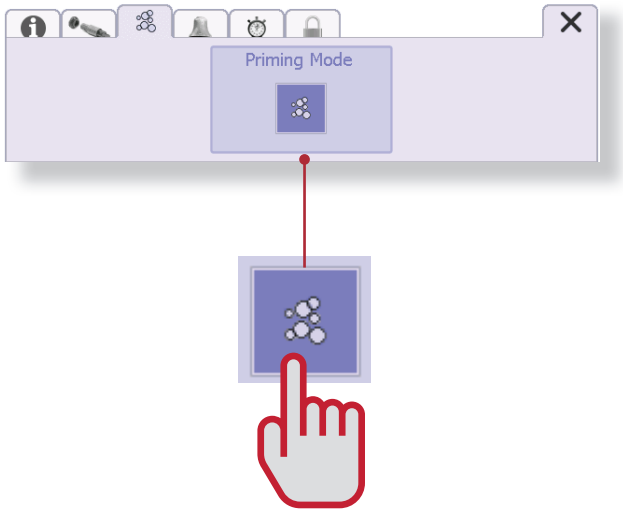
This is done by means of a compulsory menu-guided procedure.

5 PUTTING INTO SERVICE

Priming mode

Debubbling mode can be used to assist in the filling and debubbling of the tube set. Physiological alarms are suppresses when priming mode is active. See also section “Table of Physiological Alarms” on page 7-6.

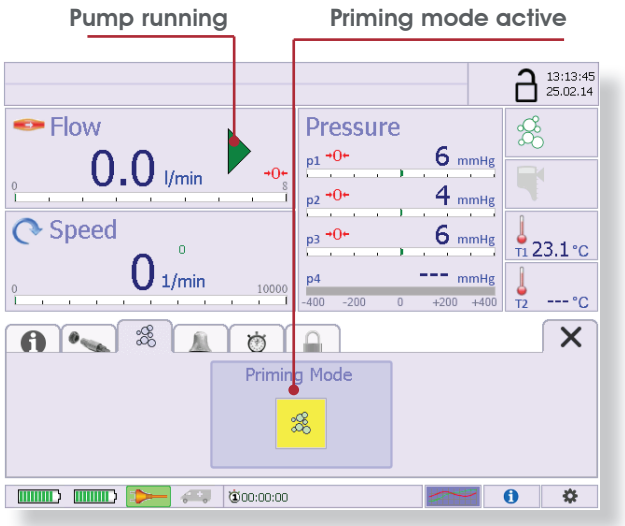
↳ After the „Connections“ tab is closed with ✕, the „Priming mode“ tab opens.

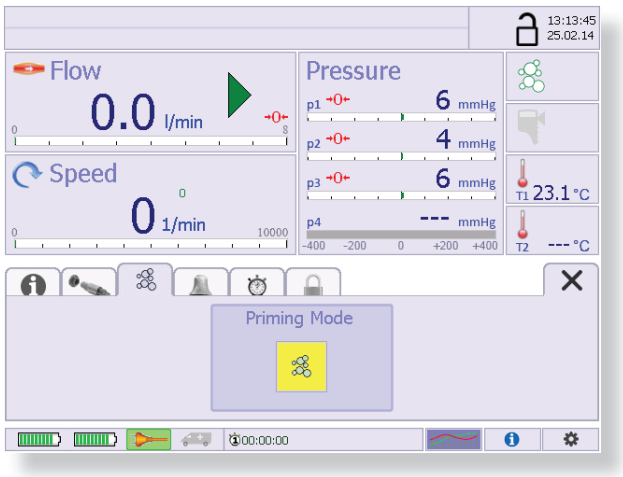


⇨ Touch the [Priming mode] button.

↳ This activates debubbling mode.

↳ The pump function is activated automatically. The speed can be set with the knob.



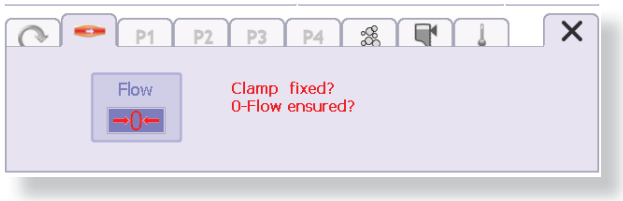


⇨ Touch the yellow button to exit priming mode.

⇨ After the „Priming mode“ tab is closed with ✕, the „Flow sensor zero adjustment“ tab opens automatically.

Flow sensor zero adjustment

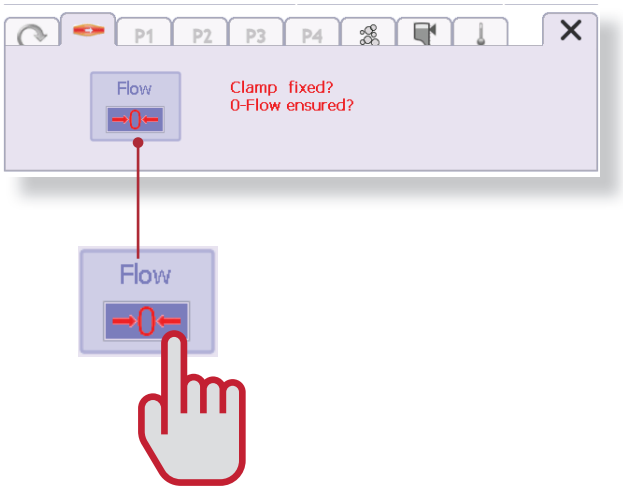
■ A zero adjustment must always be performed before the pump is started. This means that no flow is allowed in the circuit at this time.



■ The button remains highlighted in red until the zero adjustment has been performed.

⇨ Be sure to set the clamp.

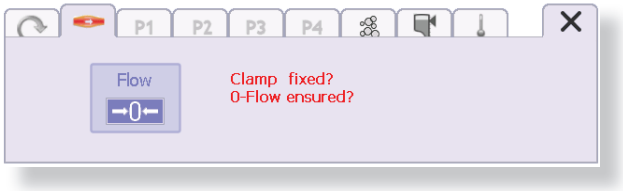
⇨ Touch the [Flow] button.



↳ After you press the [Flow] button, a suitable message appears.

↳ The button colour changes to white.

↳ The console performs the zero adjustment.



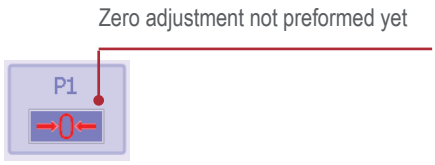
Zero adjustment is not possible if the offset is 0.5 l/min or more.

⇨ After the „Flow sensor zero adjustment“ tab is closed with ✕, the „Pressure sensors zero adjustment“ tab opens automatically.

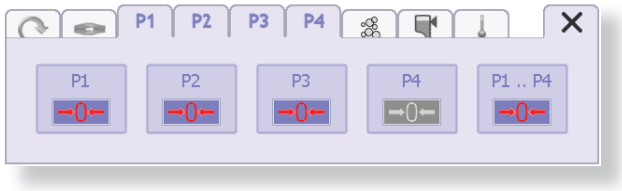
Zero adjustment for pressure sensors P1 to P4

Zero adjustment must be performed for the connected pressure sensors before the pump is started. Zero adjustment of the sensors can be performed with reference to external (ambient) air pressure or with reference to system pressure. However, with the latter option the difference due to the hydrostatic pressure in the system must be taken into account when the values are interpreted later.

■ If the status indicators for pressure sensors P1 to P4 are red, this means that zero adjustment has not been performed for these sensors.

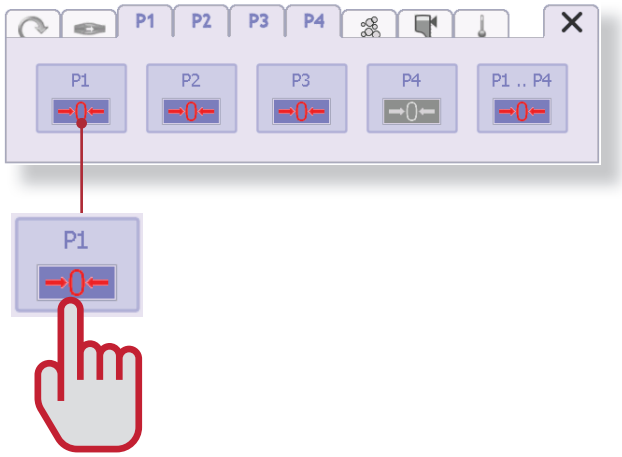


↳ The „Pressure zero adjustment“ tab has been opened.

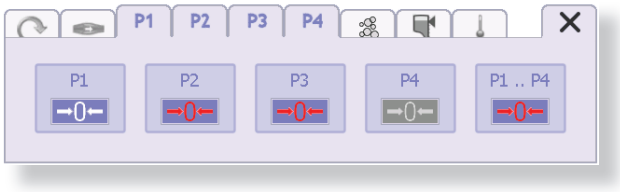


Zero adjustment for pressure sensor P1 is described below. The same procedure applies to all pressure sensors (P1 to P4).

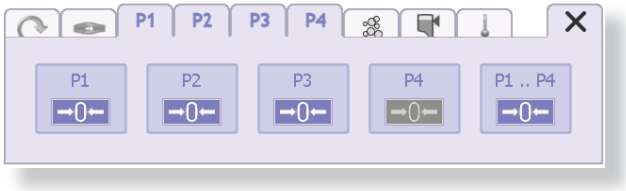
⇨ Touch the [P1] button.



PUTTING INTO SERVICE



- The console performs zero adjustment for the corresponding pressure sensor.
- The button colour changes to white.
- ⇨ If you touch the [P1 ... P4], button, zero adjustment will be performed simultaneously for all connected pressure sensors.



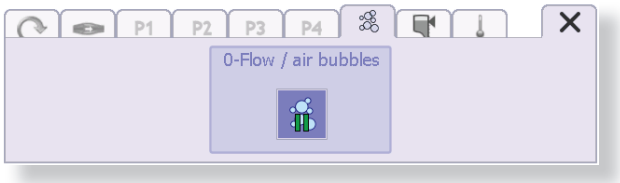
Zero adjustment is only possible within the pressure range of -100 mmHg to +100 mmHg.

- ⇨ After the „Pressure sensors zero adjustment“ tab is closed with ✕, the „Zero flow if bubbles present“ tab opens automatically.

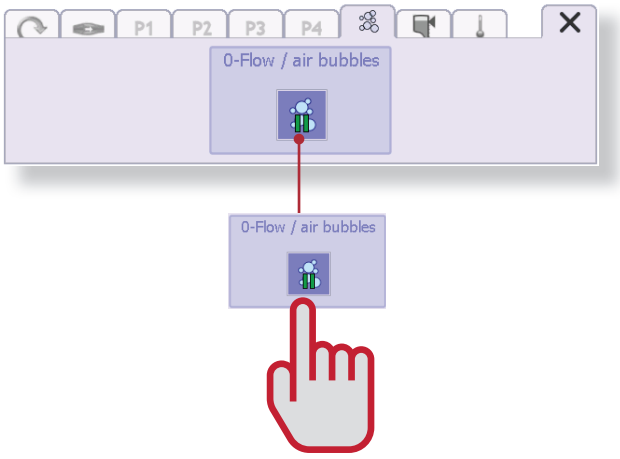
0-Flow / air bubbles

The “0-Flow / air bubbles” function can be activated on this tab. This function is described in section “0-Flow / air bubbles” on page 6-19.

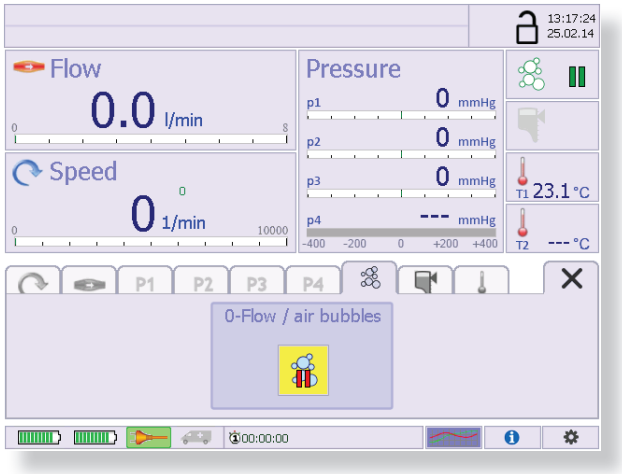
To activate this function:



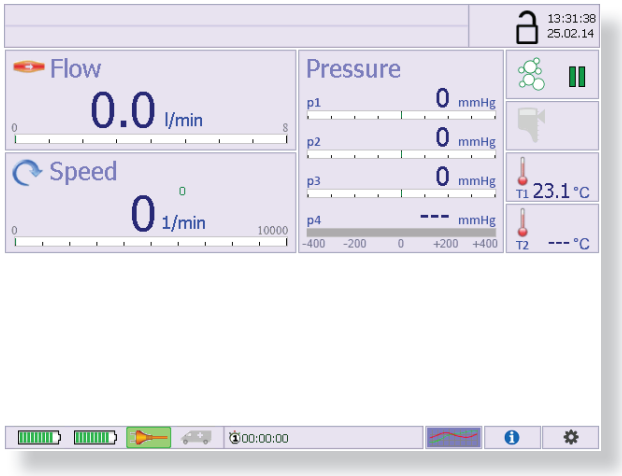
- ⇨ Touch the [0-Flow / air bubbles] button.



- The following indication appears on the monitor while the „0-Flow / air bubbles“ function is active:



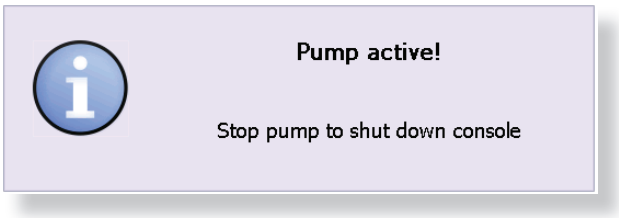
- Closing this tab with ✕ ends the compulsory menu-guided procedure.



- The console is now ready for use.

5.8 iLA activve® console shut down

- The unit may not be shut down as long as the pump is running.
- If you press the [ON/OFF] button while the pump is still active, the following message is shown on the display for 5 seconds.

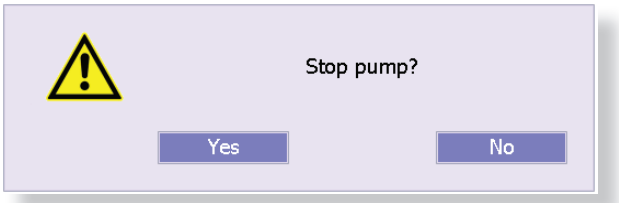


You can dismiss this message by touching the message window.

Stop the pump

⇨ To stop the pump, press the [PUMP ON/OFF] button.

↳ A query dialog with a choice of Yes or No is displayed for 5 seconds.



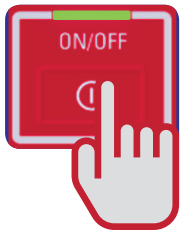
⇨ Press the [Yes] button.

↳ The pump drive is stopped.

You can dismiss the query by touching the dialog window.

Shut down the console

⇨ Press and hold the [ON/OFF] button for at least 2 seconds, until an acoustic signal sounds.



↳ The following message appears on the iLA activve® control panel during shutdown.

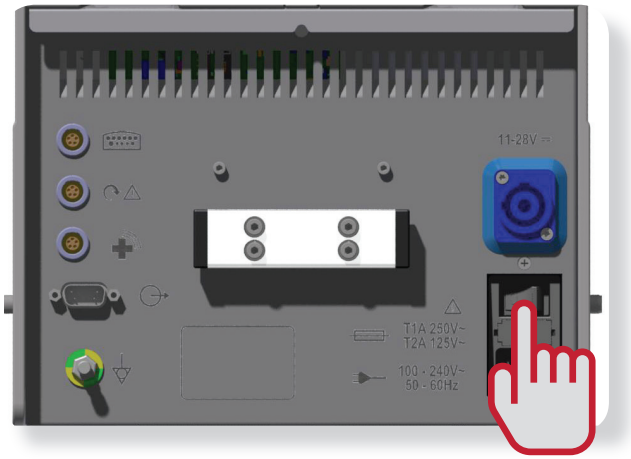
⇨ Wait until the console has finished shutting down.

↳ The end of the shutdown process is signalled by an acoustic tone.

Switching off mains power

- As long as the unit is connected to the AC mains and the power switch is on, power is supplied to the internal charger and the battery packs are charged automatically.

⇨ To completely switch off the unit, put the power switch in the [0] position.



6 USING THE iLA ACTIVVE® CONSOLE

This section provides a detailed description of how to use the iLA activve® control panel and configure the parameter settings.

- ❑ Verify that your patient has an adequate volume balance.
- ❑ When entering parameter settings, always check the pump for proper operation and observe the patient.
- ■ In order to use the drive console properly, you must first carefully read and understand the safety instructions, use instructions and conditions of use in section „2 SAFETY INSTRUCTIONS“ on page 2-1.

The actions to be performed before using the equipment with a patient are not described in this section. See section “5 PUTTING INTO SERVICE” on page 5-1 for information on these actions.

6.1 Safety instructions

DANGER

Incorrect parameter settings may endanger the patient's life. Always observe the patient and the operation of the pump while making parameter settings. The equipment may only be operated by specifically trained medical specialists. Ensure that parameter settings cannot be made by unauthorised persons while the equipment is being used with a patient. Always lock the console to prevent unauthorised use.

DANGER

Connection to the wrong supply voltage is dangerous. Before connecting the device to a power source, ensure that it matches the nameplate specifications on the rear of the device and is approved for the device. An incorrect supply voltage can seriously damage the device and endanger the patient's life. Do not use multiple-outlet adapters or extension cables to supply power to the device. Use only the cable and plug included with the device.

DANGER

Ensure that the power source is adequate for the device. Ensure that fully charged battery packs are installed before using the console. Recharge empty battery packs immediately. If possible, always connect the device to an external power source whenever an AC mains or external DC power source conforming to the specified supply voltage range is available. Sudden stoppage of the device due to an empty battery pack endangers the patient's life.

DANGER

Always keep ventilation openings unobstructed. Excess heat can damage the device. Ensure adequate ventilation of the system. Functionally impaired equipment may endanger the patient's life. Clean soiled ventilation openings immediately.

DANGER

To avoid the risk of transmitting air emboli sms to the patient, the manufacturer recommends fitting a suitable air elimination component, such as a bubble trap or an arterial filter acting as a bubble trap, in the arterial line. If an open heart tray reservoir is used ahead of the pump, suitable external fill level monitoring or the internal fill level monitoring function must be used for the prompt detection of emptying of the reservoir. Blood flow must be stopped if this occurs. Even if fill level monitoring is used, the fill level must constantly be checked by the user.

DANGER

Visually inspect the level sensor and the flow sensor before use. For each of these, inspect the cable, connector and sensor for integrity. Sensors that pass visual inspection must be checked after installation in the system by performing a functional test with a primed circuit.

6 USING THE ILA ACTIVVE® CONSOLE

6.2 Checking the flow

After setting the operating point on the iLA activve® control panel, the user should check the plausibility of the measured flow value by comparing it to the characteristic curves for the DP3 pump. The expected flow for a measured pressure differential Δp (between the pump inlet and the pump outlet) and motor speed n (in rpm) can be read from the characteristic curves. A large difference between the flow value determined in this manner and the measured flow value indicates a sensor fault. Relatively small differences are not significant.

The following figure shows the characteristic curves of a DP3 pump with a fluid temperature T of 37 °C and a viscosity η of 3.6 cP. The curves may vary with different temperature and viscosity values.

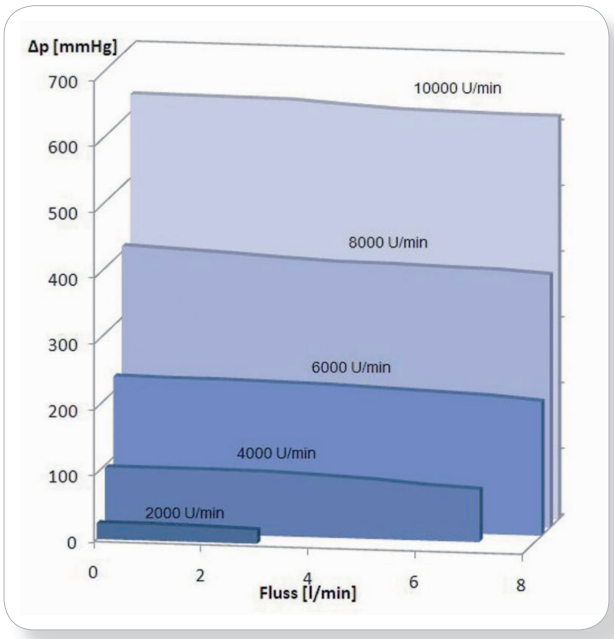


Figure 6–1: DP3 characteristic curves for T = 37 °C, η = 3.6 cP

6.3 iLA activve® control panel start-up

⇨ Press the [ON/OFF] button on the front of the iLA activve® control panel to switch it on.

↳ The unit will perform a self-test procedure.

↳ The unit is ready for use after completion of the self-test.

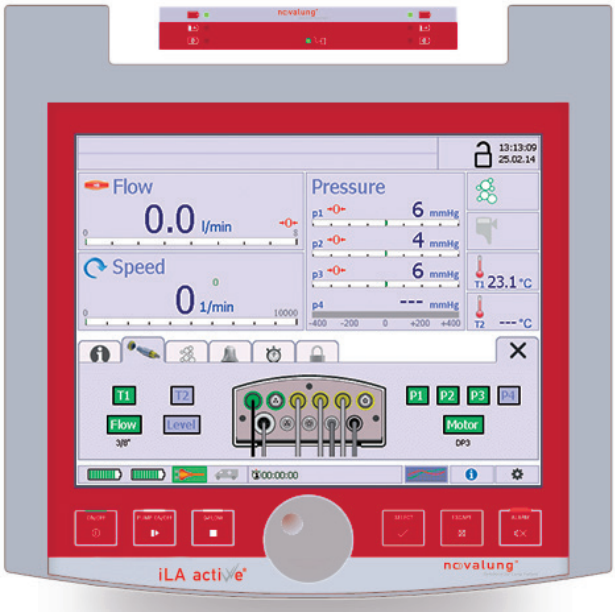


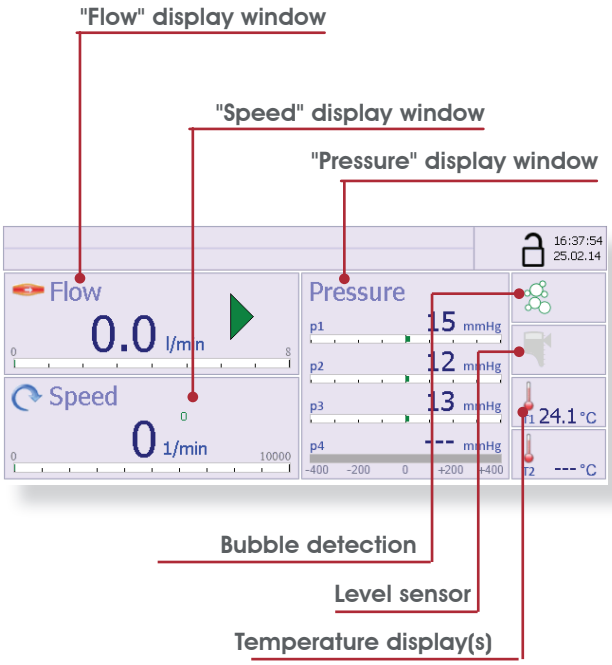
Figure 6–2: iLA activve® monitor

See section “5 PUTTING INTO SERVICE” on page 5-1 for the actions to be performed before using the device with a patient.

6.4 Instructions for use

Display window

The key operating parameters are shown in display windows.

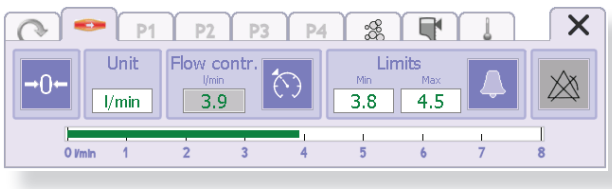


"Flow" display window

The current blood flow in litres per minute is shown in this window.

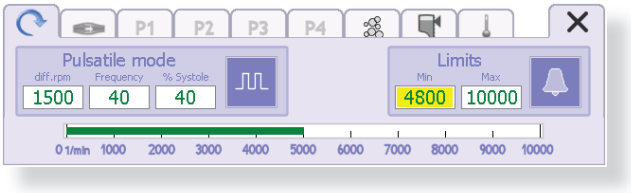
To set the flow level, touch this window to open the flow settings dialog.

Touch the [Unit] button to switch the display between litres (l) and millilitres (ml).



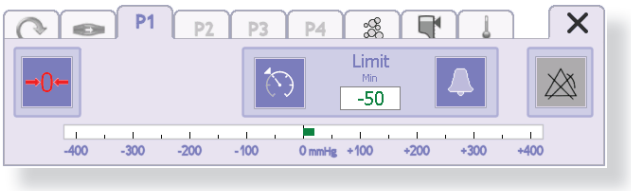
"Speed" display window

This window shows the current pump speed in rpm. To set the pump speed limits and pulsation mode parameters, touch this window to open the pump settings dialog.



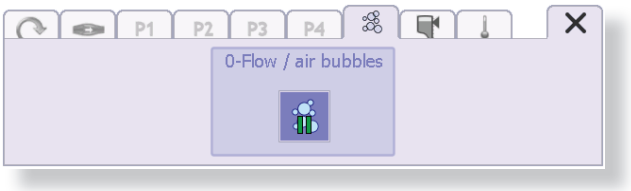
Pressure" display window

The current pressure readings (in mmHg) of the connected pressure sensors are shown in this window. To set the pressure levels, touch this window to open the pressure settings dialog.



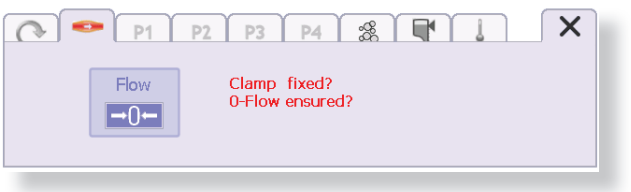
0-Flow / air bubbles (bubble detection)" function status display

This window shows the status of the "0-Flow / air bubbles" function. Touching this window opens the dialog "0-Flow / air bubbles" on page 6-19.



"0-Flow / low level (level sensor)" function status display

This window shows the status of the "Zero flow with low fill level" function. Touching this window opens the dialog "0-Flow / low level" on page 6-20.

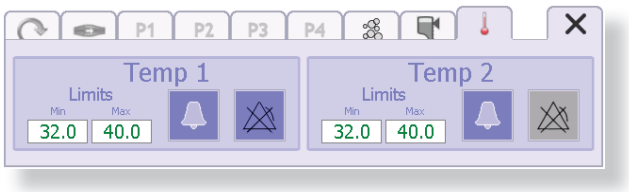


6 USING THE ILA ACTIVVE® CONSOLE

“Temperature display” window

The current temperatures are shown in this window.

This is a display-only window. The temperature values cannot be modified by the user. Touching this window opens the Temperature dialog, where the temperature alarm limits can be set.



Symbols used in display windows

	**In the [Flow] display window** Flow control is active. The pump speed is regulated to maintain the configured flow (in litres or millilitres per minute) through the circuit.
	**In the [Pressure] display window** The P1 Limiter is enabled. (This limiter can only be configured for pressure P1.)
	This symbol may appear in the [Flow], [Speed] or [Pressures] display windows. It means that alarm limits have been set for the corresponding parameters.
	This symbol may appear in the [Flow], [Speed] or [Pressures] display windows. It means that zero adjustment has not yet been performed for the corresponding parameters.

Buttons

Buttons showing the current status of selected parameters or functions are present in the dialogs for setting operating parameters.

The various function states are explained here using the colours of the [Alarm] button as examples.

	**Yellow** Function enabled.
	**Blue** Function disabled.
	**Grey** Function not available.
	These button colours apply to all function buttons in all dialogs.

Entry fields

Entry fields for parameter settings are present in the dialogs for configuring operating parameter settings. Use the knob on the front of the iLA activve® control panel to enter these settings.

	**Yellow** Entry field selected. Use the knob to adjust and enter the setting.
	**White** Entry field not selected.
	**Grey** Entry field not selectable. The peripheral device may not be available.

Opening and closing dialogs

- ⇨ To enter data or parameter settings, touch the corresponding display in the [patient data and operating parameters] display window.
- The corresponding submenu with dialogs for entering parameter settings opens in the lower part of the monitor.
- The symbols on the tabs are the same as in the display windows.
- The tab of the selected dialog is highlighted  .
- All other tabs are greyed out.

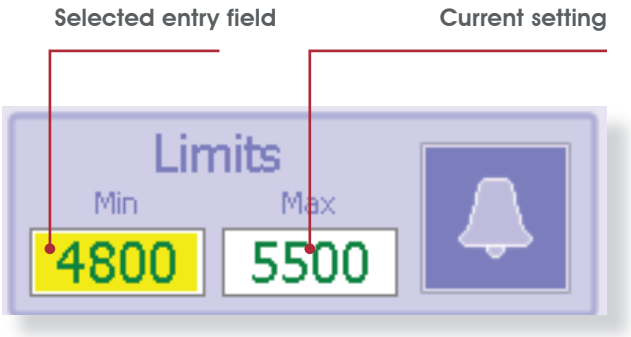
⇨ Touch ✕ to close a dialog.

6 USING THE ILA ACTIVVE® CONSOLE

Setting values

Settings for all numerical values are entered with the knob on the front of the iLA activve® control panel.

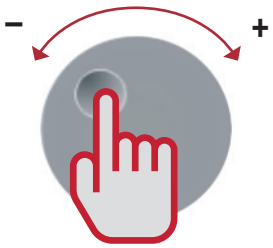
⇨ To set a value, touch the corresponding entry field in the dialog.



↳ The entry field appears highlighted in yellow.

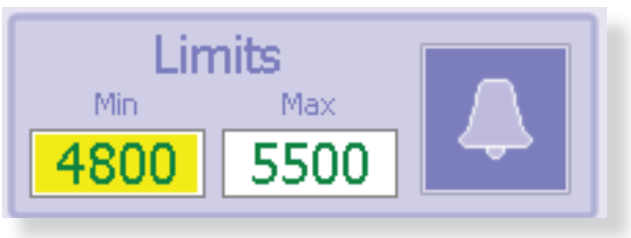
↳ Current settings are shown in green on a white background.

⇨ Use the knob on the front of the control panel to set the value.



⇨ Turning the knob to the left [-] reduces the value.

⇨ Turning the knob to the right [+] increases the value.



↳ The new value is highlighted in yellow.

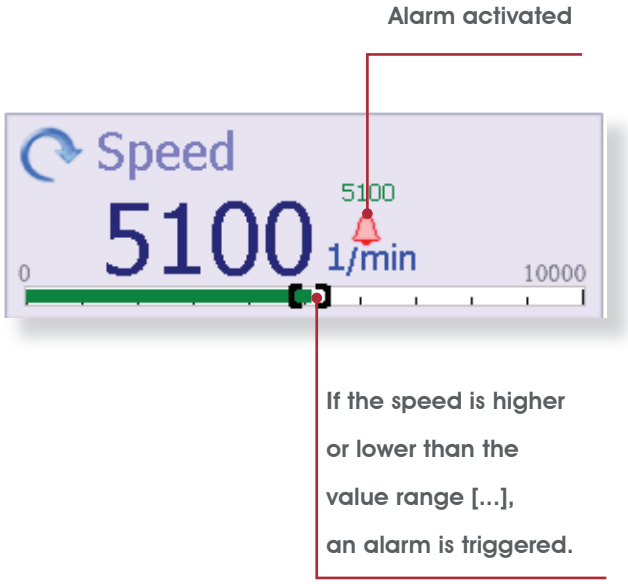
↳ The new value becomes effective immediately.

Displaying alarm limits

Alarm limits can be set for the [Flow], [Speed], [Pressure] (P1 pressure limiter) and [Temperature] parameters.

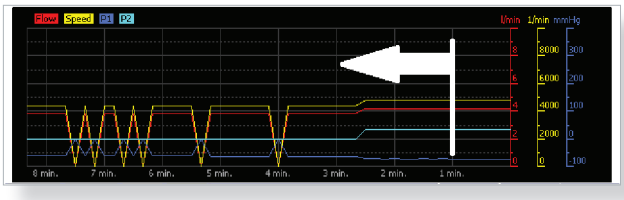
The activated alarm is indicated by the bell symbol in the corresponding display window.

The configured alarm limits are clearly marked and highlighted by a pair of square brackets on the graphic bar scale. Example: alarm limit set in the [Speed] menu.



Trend chart

The trend chart can be shown below the [patient data and operating parameters] display window.



The curves move from right to left along the time scale.

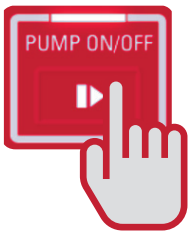
See section “6.10 Trend chart” on page 6-21 for a detailed description of the [trend chart].

6.5 Speed control mode

The main control function of the iLA activve® drive is maintaining the motor speed at the value set with the knob on the front of the control panel.

☑ The unit has successfully completed the self-test.

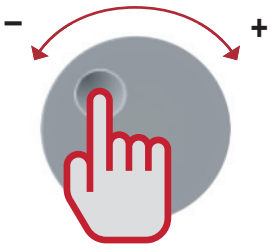
⇨ Press the [PUMP ON] button.



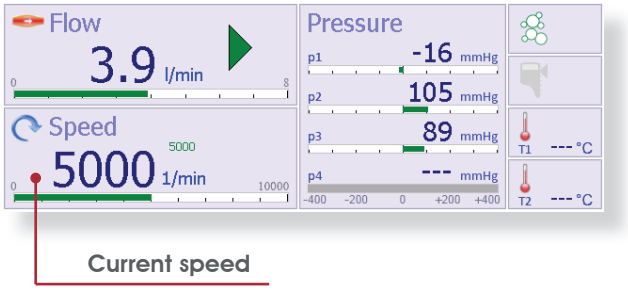
↳ The LED lights up and the pump is switched on.

↳ The unit enters speed control mode after the speed is set with the knob.

⇨ Turn the knob to raise or lower the speed of the iLA activve® drive.

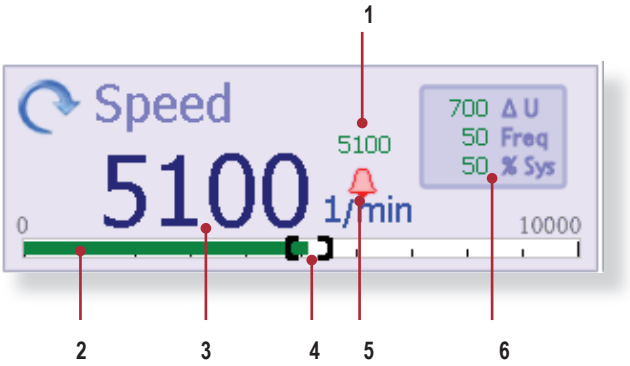


↳ The currently measured speed of the drive is shown on the monitor of the iLA activve® control panel.



Speed display window details

The Speed display window shows the following overview data:



1	Setpoint speed
2	Green speed bar.
3	Numerical speed value in rpm.
4	Limit values are marked by square brackets. An alarm is triggered if the speed rises above the upper limit or drops below the lower limit.
5	Limit alarm symbol. Upper and lower limits may be set by the user. An alarm is triggered if either of these limits is exceeded.
6	The unit is operating in pulsation mode. The motor speed is controlled by the displayed values.

6 USING THE ILA ACTIVVE® CONSOLE

Enabling pulsatile mode

Note that pulsation mode cannot be activated when an s.pump® drive is used with the iLA activve® console!

To enable pulsation mode:

- ⇨ Touch the [Speed] display.
- ↳ The following [Pulsation mode] dialog appears.

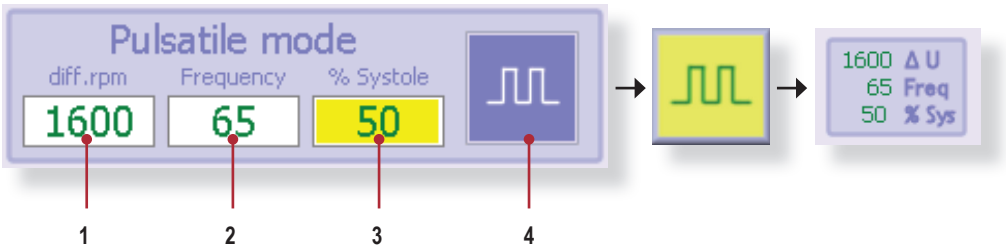
Setting the pulsation mode parameters

Parameter values for pulsation mode can be set in the left-hand part of the dialog. The pump operates at varying speed in this mode. The amplitude of the pulsations, which means the maximum speed variation relative to the average value, can be set in the range of 100 to 2500 rpm.

dU/min: 100 rpm to 2500 rpm in steps of 100

Pulse rate: 40 to 90

% Systolic: 30 to 70

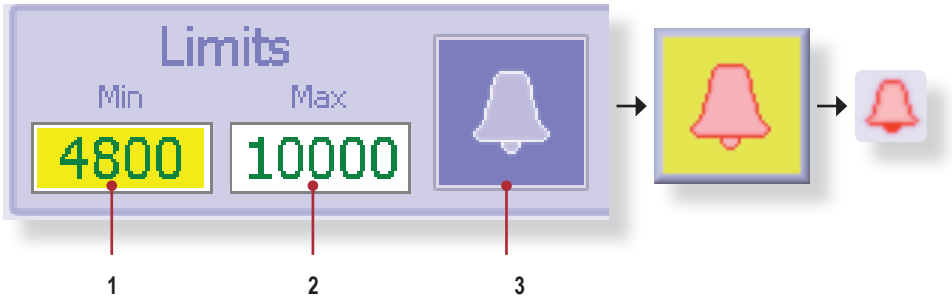


1	Using the knob, set the desired speed amplitude for pulsation mode here. The entry field turns yellow when you touch it, and then you can set the value. The amplitude can be set as high as 2500 rpm.
2	Using the knob, set the rate here. The entry field turns yellow when you touch it, and then you can set the value.
3	Using the knob, set the ratio of the systolic interval to the diastolic interval here (percentage value). The diastolic value is set automatically. The entry field turns yellow when you touch it, and then you can set the value.
4	Press this button to activate pulsation mode. When you touch this button, the function is enabled and becomes active immediately. The button is highlighted yellow, and the settings for pulsation mode are shown in the display window.

6 USING THE ILA ACTIVVE® CONSOLE

Setting alarm limits for a speed range

Upper and lower alarm limits for the pump speed can be set in the right-hand part of the dialog.

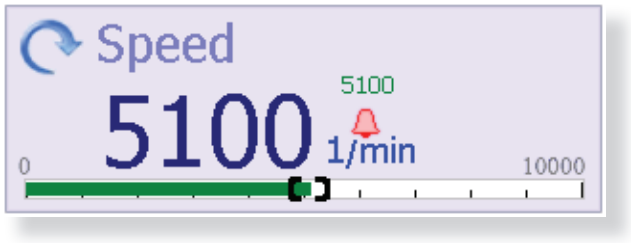


1	Using the knob, set the lower limit here. The entry field turns yellow when you touch it, and then you can set the value. An alarm is triggered if the pump speed is below this value.
2	Using the knob, set the upper limit here. The entry field turns yellow when you touch it, and then you can set the value. An alarm is triggered if the pump speed is above this value.
3	Press this button to activate the alarm function. When you touch this button, the function is enabled and becomes active immediately. The button is highlighted yellow, and the [Alarm bell] symbol appears in the display window.

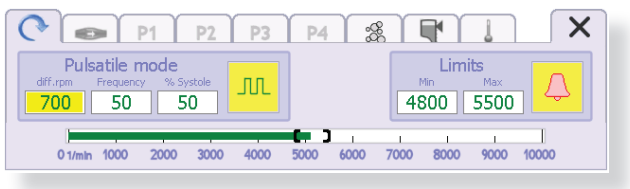
⇨ Touch [X] to close the entire dialog.

↳ The alarm limits are marked by square brackets on the speed bar scale.

1. In the [Speed] display window:



2. In the [Speed parameter settings] dialog:

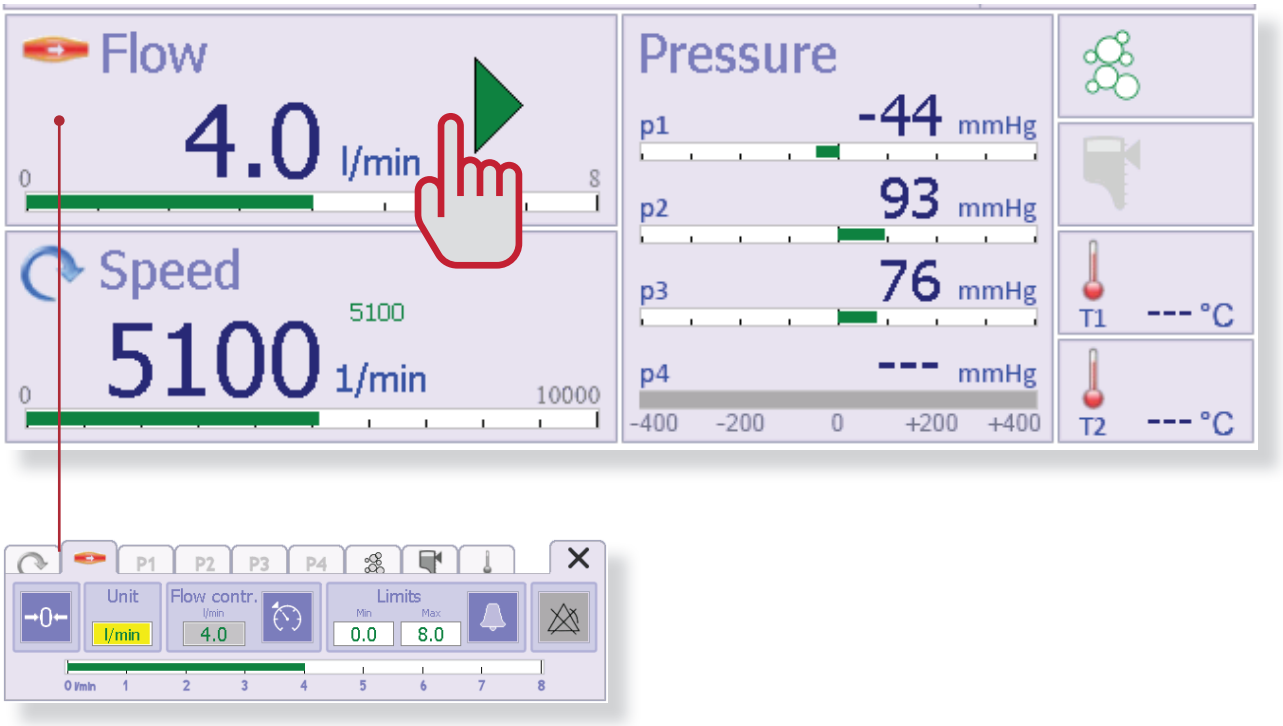


6.6 Flow control mode

In flow control mode the configured flow setting is taken as the setpoint value. The console regulates the pump speed to maintain the desired flow.

The pump speed is varied within a defined range.

Use the following procedure to configure and enable flow control mode.



⇨ First adjust the flow in the circuit to the desired value by changing the pump speed.

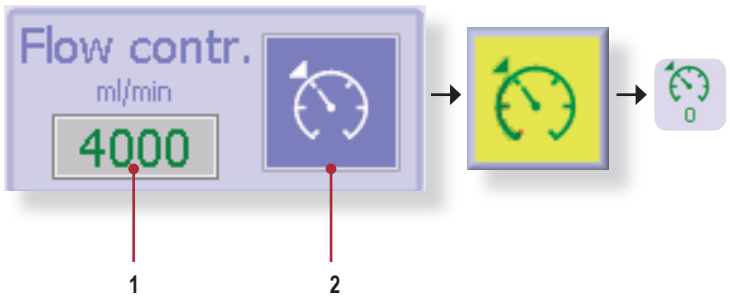
⇨ For more information, see section „6.5 Speed control mode“ on page 6-8 and following.

⇨ Touch the [Flow] display.

6 USING THE ILA ACTIVVE® CONSOLE

Setting the flow control parameters

The currently measured flow is shown in the middle of the dialog. After flow control is activated, the pump speed is adjusted to constantly maintain this flow volume per minute in the circuit.



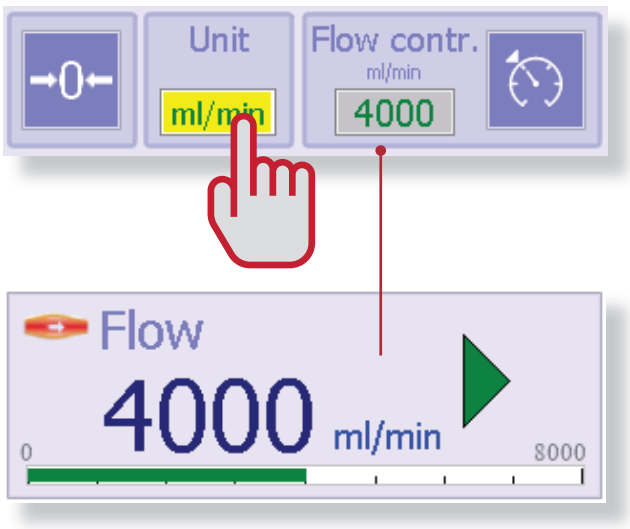
1	The current flow value is shown here. This value is used as the setpoint value for control when flow control is activated.
2	Press this button to activate flow control. When you touch this button, the function is enabled and becomes active immediately. The button is highlighted yellow, and the "Flow control" symbol appears in the [Flow] display window.

When flow control is active, the system automatically responds to any deviation of the flow from the desired setpoint value. The system can change the speed within a range of ±1500 rpm relative to the nominal speed. If the flow setpoint cannot be achieved within this range, the system reports an alarm.

Switching the flow measurement unit

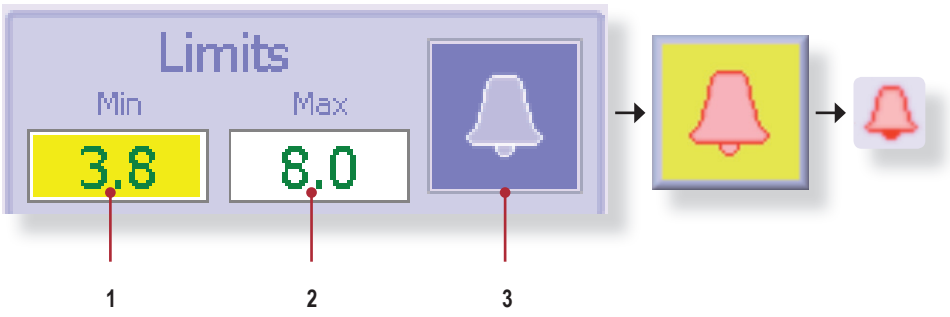
When low flows are used, the flow measurement unit can be changed from litres (l) to millilitres (ml) on the [Flow] display for easier reading.

- ⇨ To do this, touch the [Unit] button in the [Flow control] dialog.
- ⇨ When the field is active (highlighted yellow), use the knob to change the Unit setting.
- ↳ Displayed unit l/mm: turn the knob to the left to display ml/min
- ↳ Displayed unit ml/mm: turn the knob to the right to display l/min
- ↳ The measurement unit shown in the [Flow] display window will be "ml".



Setting the flow alarm limits

Upper and lower alarm limits for the flow can be set in the right-hand part of the dialog.

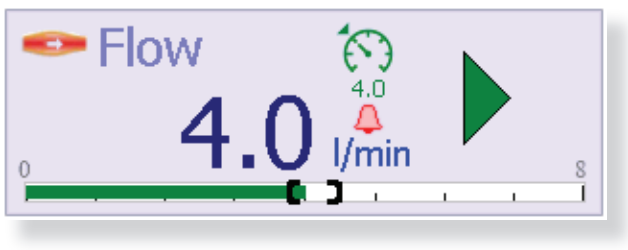


1	Using the knob, set the lower limit here. The entry field turns yellow when you touch it, and then you can set the value. An alarm is triggered if the pump speed is below this value. If the selected measurement unit is "ml", that is what will be shown here.
2	Using the knob, set the upper limit here. The entry field turns yellow when you touch it, and then you can set the value. An alarm is triggered if the pump speed is above this value. If the selected measurement unit is "ml", that is what will be shown here.
3	Press this button to activate the alarm function. When you touch this button, the function is enabled and becomes active immediately. The button is highlighted yellow, and the [Alarm bell] symbol appears in the display window.

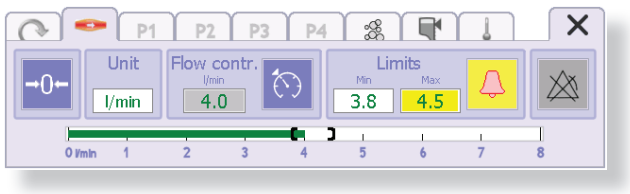
⇨ Touch [✕] to close the entire dialog.

↳ The alarm limits are marked by square brackets on the flow control bar scale.

1. In the [Speed] display window:



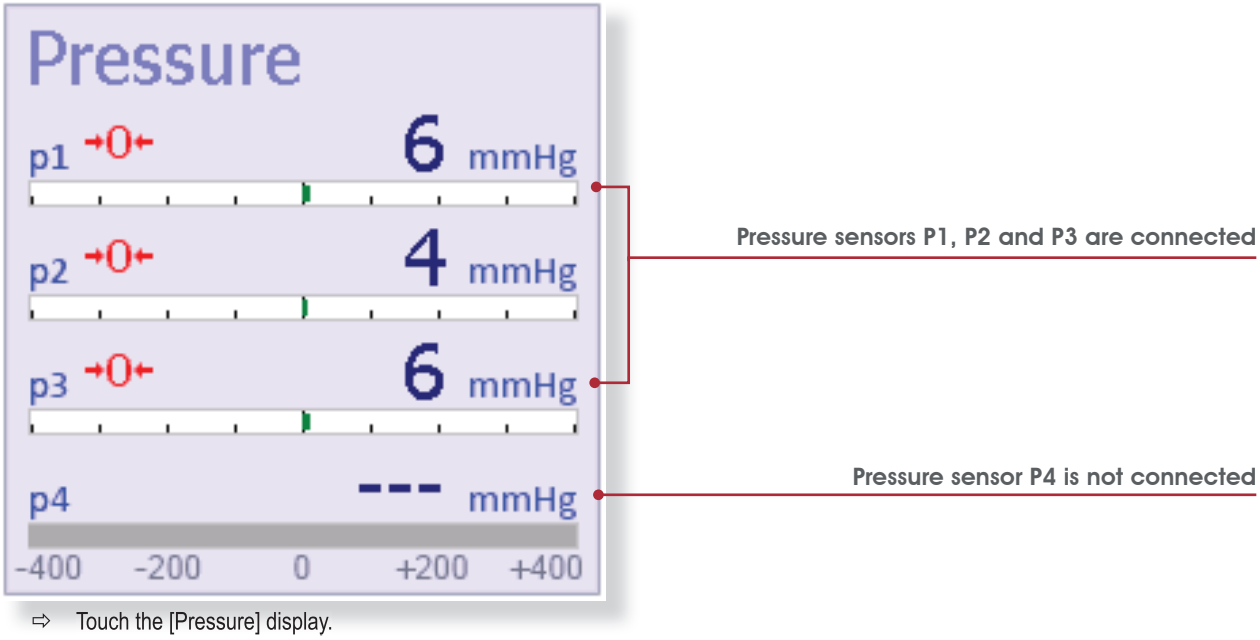
2. In the [Flow parameter settings] dialog:



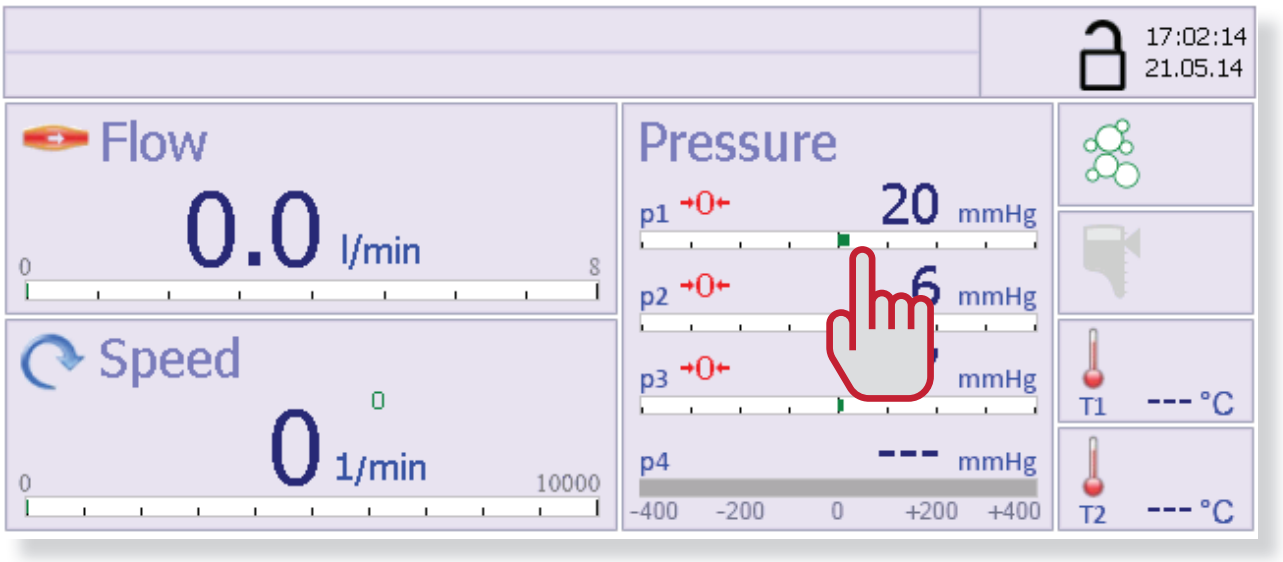
6.7 Setting limits for pressures

Limits for a total of four pressures can be set in the [Pressures] menu. Which limits can be set depends on how many pressure sensors are connected to the iLA activve® sensor box.

- Unconnected pressure sensor ports are greyed out.

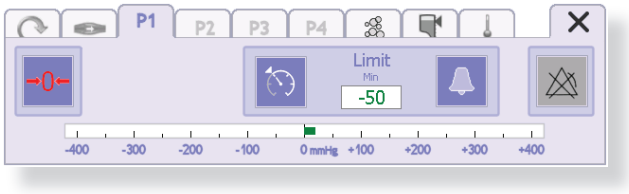


⇨ Touch the [Pressure] display.



⇨ P1 Limiter function. Touch the P1 area of the [Pressure] display.

↳ The [Pressure sensor P1] dialog opens in the bottom part of the touchscreen.

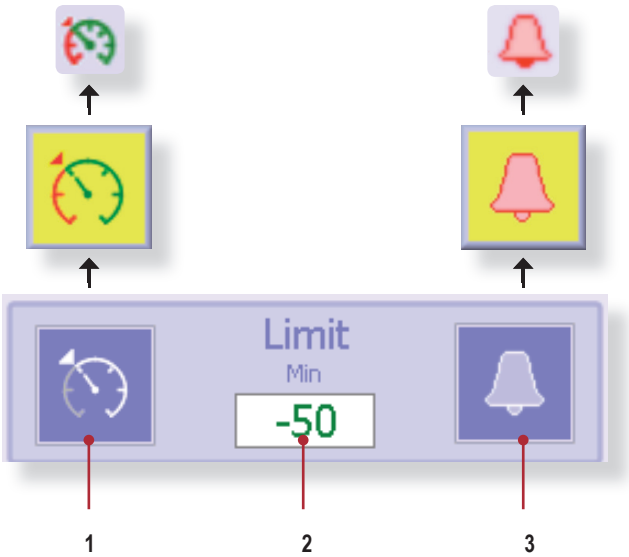


Setting the lower limit for P1 (P1 Limiter function)

CAUTION

The P1 Limiter function is a protection function intended to avoid blood damage due to high negative pressures. When this function is activated, the system automatically reduces the pump speed when the pressure in the system reaches the limit value set by the user, in order to avoid further violation of the limit.

Enter the lower limit for P1 in the right-hand part of the dialog.



1 "P1 Limiter" button: Press this button to activate the pressure limiter function for P1. When you touch this button, the function is enabled and becomes active immediately. The button is highlighted in yellow. The "P1 Limiter activated" symbol appears in the display window.

2 Using the knob, set the limit for P1 here. The entry field turns yellow when you touch it, and then you can set the value. The following occurs if the measured value drops below this value:

1. If the P1 Limiter function is activated: The P1 Limiter becomes active and automatically reduces the speed to avoid further violation of the limit.

2. If the Alarm function is activated: An alarm is triggered.

3. If both functions are activated: Both actions occur.

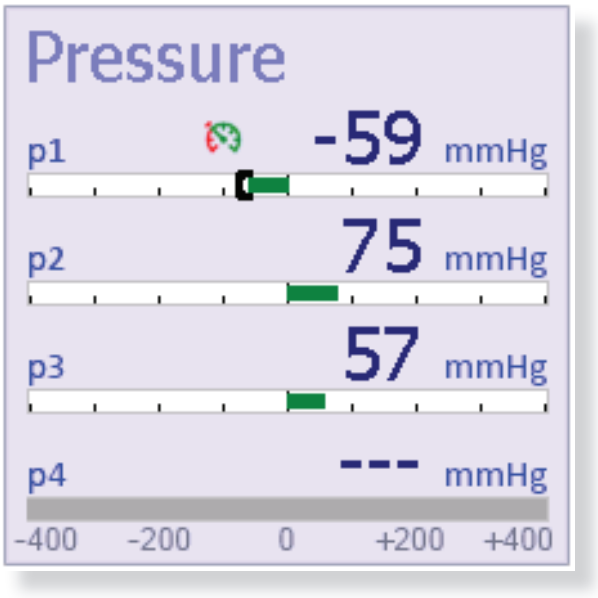
3 Press this button to activate the alarm function. When you touch this button, the function is enabled and becomes active immediately. The button is highlighted yellow, and the [Alarm Bell] symbol appears next to P1 in the display window.

↳ The lower limit is marked by a square bracket on the P1 bar scale.

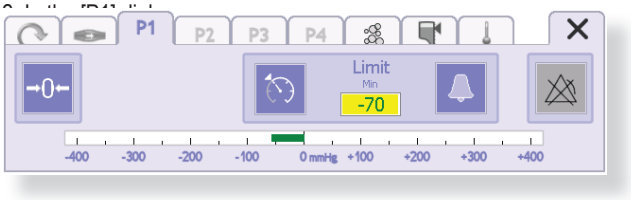
⇨ Touch the [P1 Limiter] button.

↳ The function is activated.

1. In the [Pressure] display window

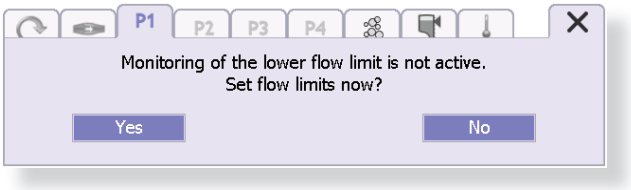


USING THE ILA ACTIVVE® CONSOLE



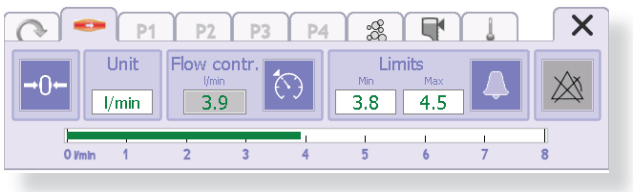
If the P1 Limiter is active, the system automatically reduces the speed. As reducing the speed causes the flow to decrease, users are strongly advised to configure a limit alarm for the flow (lower flow limit).

↳ If monitoring of the lower flow limit has not been configured, the following message appears automatically after the P1 Limiter is activated:



⇨ Touch the „Yes“ button.

↳ This automatically takes you to the „Flow“ dialog.



⇨ Activate monitoring of the lower flow limit.

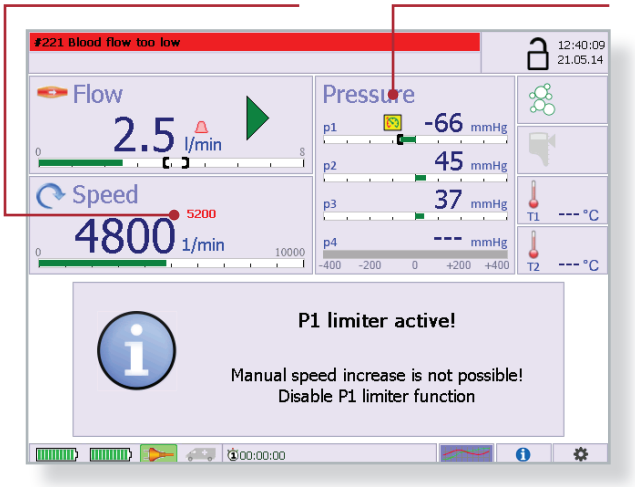
⇨ For more information, see section „6.6 Flow control mode“ on page 6-12 and section „Setting the flow alarm limits“ on page 6-14.

P1 Limiter active

When the P1 Limiter is active, which means that the system reduces the speed as necessary to avoid further violation of the limit, it is not possible to manually increase the speed. A corresponding message is shown on the monitor (see figure below).

Setpoint speed shown in red: actual speed is below setpoint speed

Symbol for "P1 Limiter active"

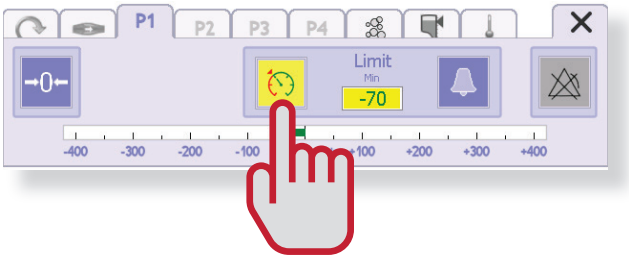


The message window is displayed for 5 seconds. You can dismiss this message by touching the message window.

Deactivating the P1 Limiter

⇨ Touch the [Pressure] display.

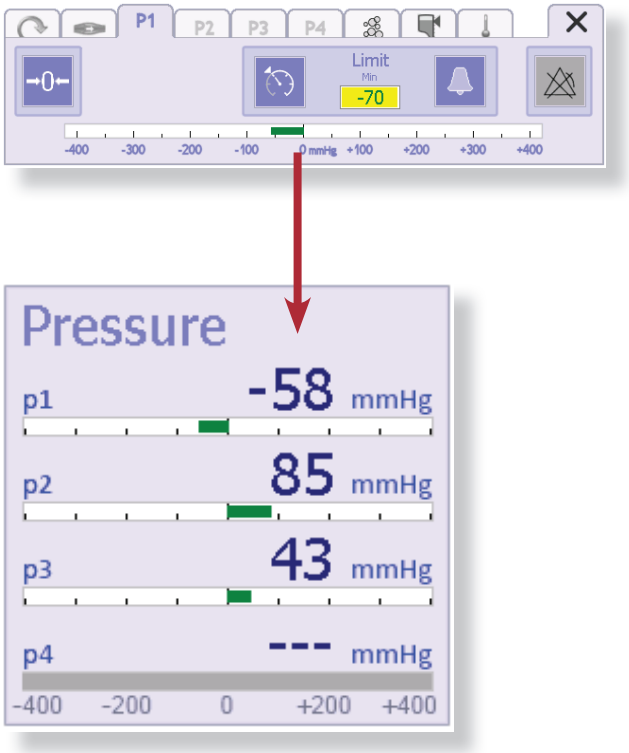
↳ The [Pressure sensor P1] dialog opens in the bottom part of the touchscreen.



⇨ Touch the [P1 Limiter] button.

↳ The function is deactivated. The button highlighting changes back to blue.

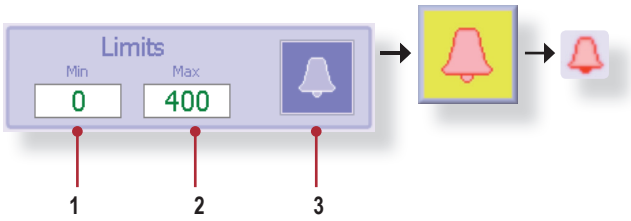
↳ The „P1 Limiter“ symbol is hidden.



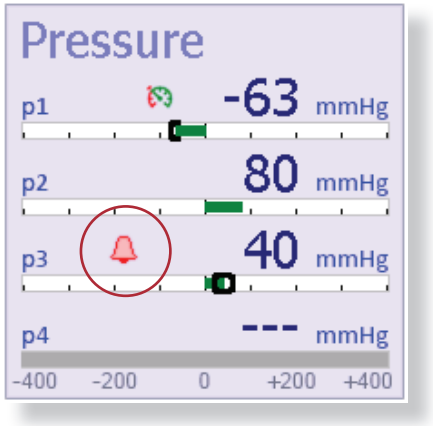
Setting alarm values for P2 to P4

The same procedure is used to configure the settings for sensors P2 to P4. It is described below for P3 as an example. A lower limit can also be set for P3 and P4.

Enter the upper limit for the corresponding pressure sensor in the right-hand part of the dialog.



1	Using the knob, set the lower limit for the pressure sensor here. The entry field turns yellow when you touch it, and then you can set the value. An alarm is triggered if the measured pressure drops below this value.
2	Using the knob, set the upper limit for the pressure sensor here. The entry field turns yellow when you touch it, and then you can set the value. An alarm is triggered if the measured pressure drops below this value.
3	Press this button to activate the alarm function. When you touch this button, the function is enabled and becomes active immediately. The button is highlighted yellow, and the "Alarm Bell" symbol appears next to P3 in the display window.



6.8 Configuring alarm behaviour

DANGER

Air bubbles in the circuit or a low liquid level in the reservoir can lead to life-threatening situations for the patient. The [0-Flow / air bubbles] and [0-Flow / low level] functions must be enabled during operation with a patient. Do not use the console if there are any problems with these functions.

Both situations can be prevented and corrected immediately by using the alarm function. Configure the alarm behaviour of the console for the [0-Flow / air bubbles] or [0-Flow / low level] functions on the corresponding tabs.

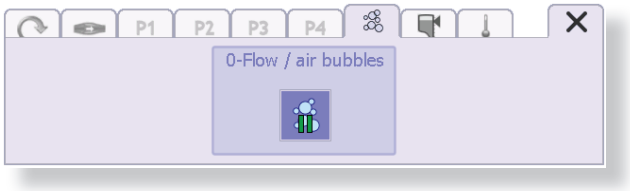


Figure 6–3: [0-Flow / air bubbles] tab

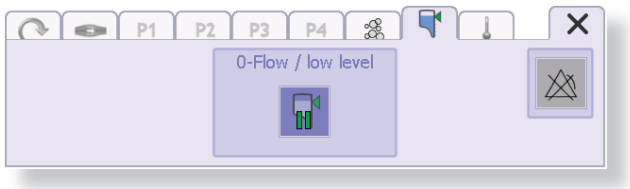


Figure 6–4: [0-Flow / low level] tab

0-Flow / air bubbles

Air bubbles in the system are detected by the flow sensor. If the [0-Flow / air bubbles] function is enabled, the system automatically activates the 0-flow function when bubbles are detected. The pump speed is then adjusted automatically to generate sufficient back pressure, and circulation in the system stops. The bubbles are thus kept where they are and can be removed. An acoustic alarm is also triggered when bubbles are detected.

Indication on main monitor				
Indication	**Sensor**	**Event**	**Function**	**0-Flow active**
	Yes	–	Enabled	No
	Yes	–	Disabled	–
	Yes	Bubbles detected	Enabled	No
	Yes	Bubbles detected	Enabled	Yes
	Yes	Bubbles detected	Disabled	–
	No	–	Enabled	–
	No	–	Disabled	–

0-Flow / low level

A level sensor is attached to the reservoir, where it constantly monitors the fill level. If the level falls below the minimum mark, an acoustic alarm is triggered. When this happens, the pump speed is automatically adjusted to prevent any further flow in the system. Circulation through the system stops.

Indication on main monitor				
Indication	Sensor	Event	Function	0-Flow active
	Yes	Fill level OK	Enabled	No
	Yes	Fill level OK	Disabled	–
	Yes	Fill level too low	Enabled	No
	Yes	Fill level too low	Enabled	Yes
	Yes	Fill level too low	Disabled	–
	No	–	Enabled	–
	No	–	Disabled	–

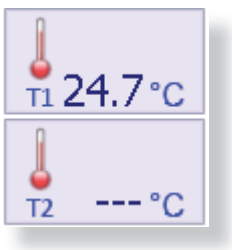
For detailed information about alarm behaviour, see section 7 „ALARMS“ on page Seite 7-1 and following.

6.9 Temperature display

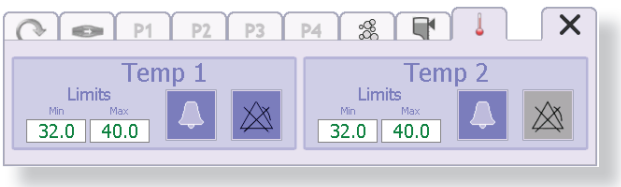
The temperature display is a display-only function. It is not possible to set any limits here. This display provides information on the temperatures measured in the circuit.

- No values are shown for ports with no temperature sensor connected.

The currently measured temperature is shown numerically.



The limits are set in the same way as other limits.



6.10 Trend chart

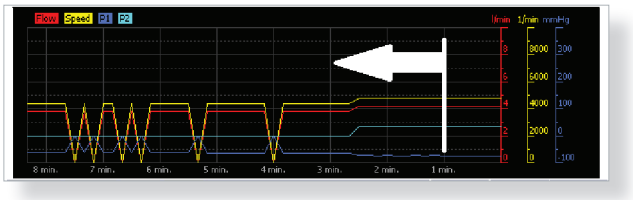
Use the button on the status bar to show or hide the trend chart.

Up two four parameters can be plotted in different colours on a trend chart in a window below the display windows for [Flow], [Speed], [Pressure] and [Temperature].

This gives you a convenient overview of the key parameters and patient data over an extended period.

The plots show the values of each of the parameters for the last eight minutes.

The names of the four plotted parameters are shown at the top of the chart. These parameters can be chosen from a selection window.



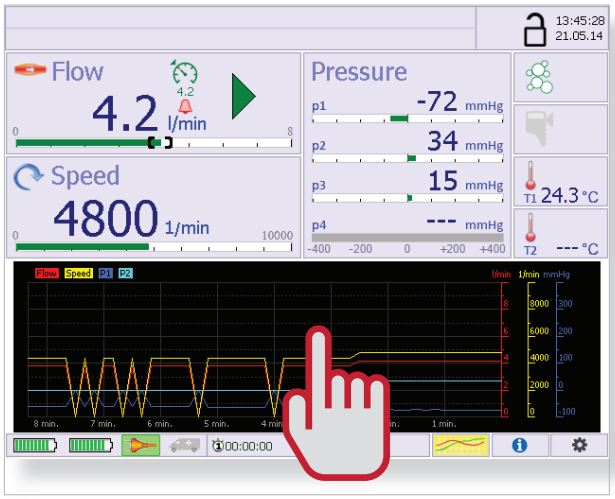
The curves move from right to left along the time scale.

The trend chart is initially hidden when the console starts up. It can be shown or hidden at any time by pressing the "Trend chart" button.

Selecting parameters for the trend chart

Use the following procedure to select the parameters to be displayed:

⇨ Touch the trend chart area.

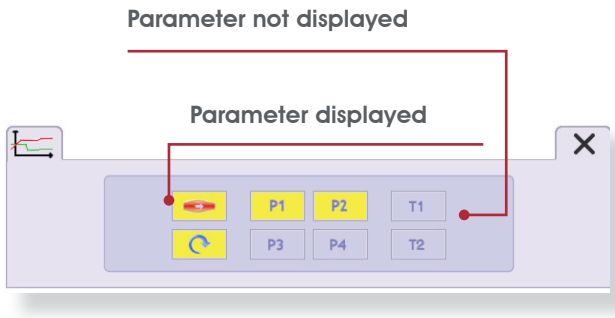


↳ The parameter selection window is displayed.

⇨ Then touch the buttons for the parameters to be shown as curves.

■ You can select up to four parameters for display.

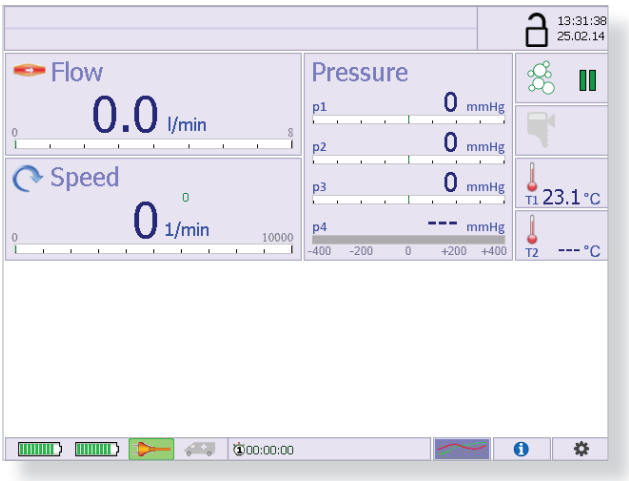
↳ The selected button(s) is/are is highlighted in yellow.



⇨ Touch ✕ to close the selection window.

6.11 [Info] menu

The [Info] menu provides access to all device settings and important device information.



⇨ Touch [i] on the status bar at the bottom of the touchscreen.

↳ This opens the window with the settings tabs.

⇨ Use the tabs to select the desired settings.

⇨ Touch [X] to exit the individual tabs.

Info tab

Status information for the following functions is provided on the [Info] tab:

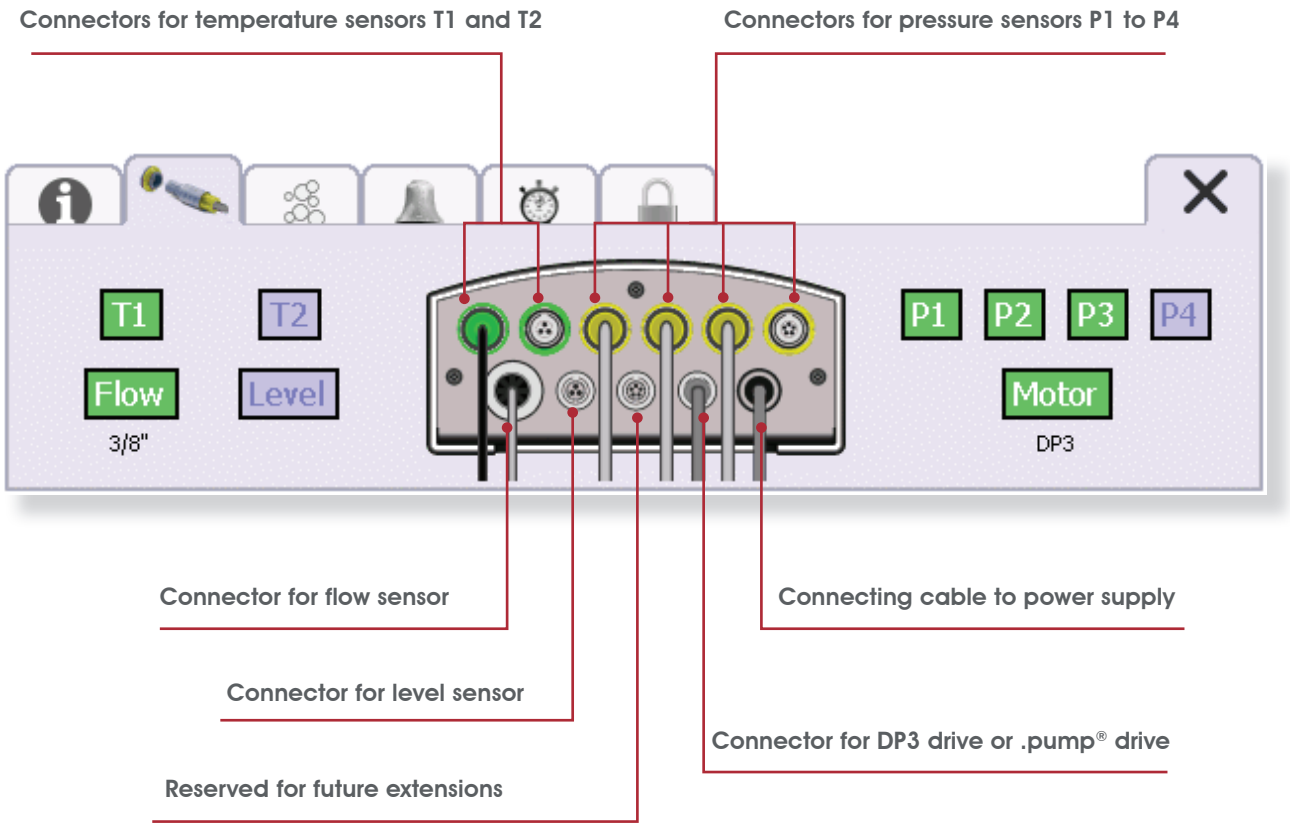
- P1 Limiter
- 0-Flow / air bubbles
- 0-Flow / low level

6 USING THE ILA ACTIVVE® CONSOLE

Connections

⇨ Touch  .

↳ The iLA activve® sensor box overview tab [Connection status] opens.



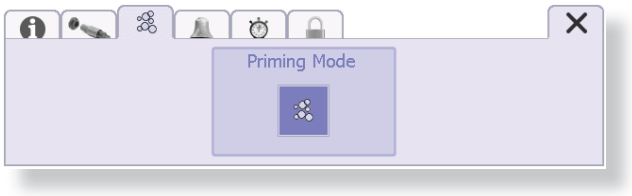
This gives you a detailed overview of which peripheral devices and sensors are currently connected to the iLA activve® sensor box and available. The two connectors for the temperature sensors are shown in green. The four connectors for the pressure sensors are shown in yellow. When all necessary peripheral devices are connected, the icons of the peripheral devices and sensors are highlighted in yellow.

Priming mode

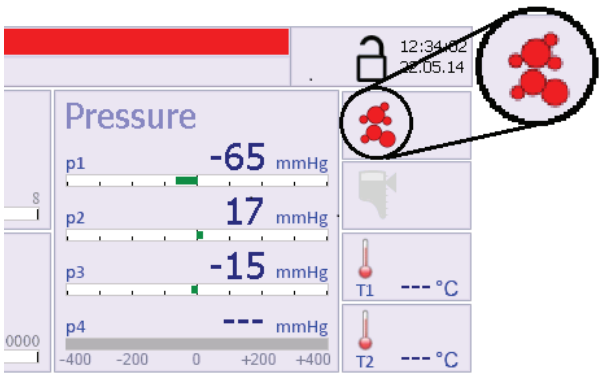
Priming mode can be used to assist in the filling and debubbling of the tube set. This function can only be selected when the pump function is disabled.

⇨ Touch .

↳ The [Priming mode] tab opens.



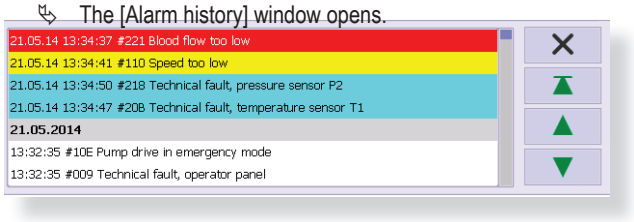
All physiological alarms (see section “7.1 Physiological alarms” on page 7-2) are suppressed when [Priming mode] is active. The [Priming mode] button is highlighted in yellow in this state. If bubbles are detected, the symbol in the [0-Flow / air bubbles] field is shown in red.



Viewing the alarm history

⇨ Touch .

↳ The [Alarm history] window opens.



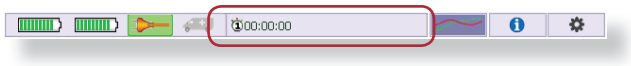
↳ All active messages are shown in this window, colour coded by category (see section „7.7 Alarm lists“ on page 7-5). The historical and/or cancelled alarms are shown below the active messages. The list can hold up to 100 entries.

	Press this button to jump to the first entry in the alarm list.
	Press this button to jump to the previous entry in the alarm list.
	Press this button to jump to the next entry in the alarm list.
	Close the alarm list.

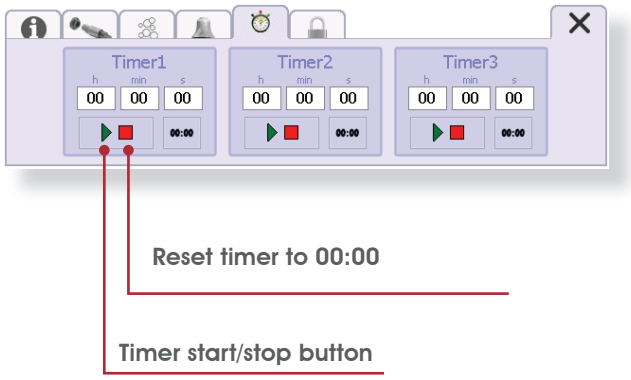
Setting the timers

⇨ Touch .

⇨ You can also navigate to the [Timer settings] tab by touching one of the timer symbols on the status bar.



↳ The [Timer settings] tab opens.



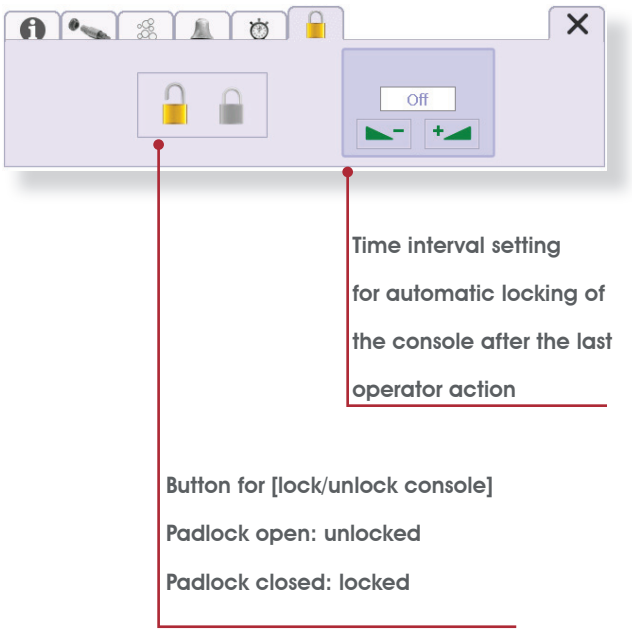
■ The timers are pure „stopwatch“ functions.

6 USING THE ILA ACTIVVE® CONSOLE

Locking the console

⇨ Touch the tab or the padlock symbol on the header bar.

↳ The [Lock console] tab opens.



Automatic activation of the lock function

⇨ Enter a time interval for automatically locking of the console to prevent unintentional operator actions. The time interval can be set up to 60 minutes in steps of 30 seconds. The entry field turns yellow when you touch it. Then you can set the time interval with the knob.

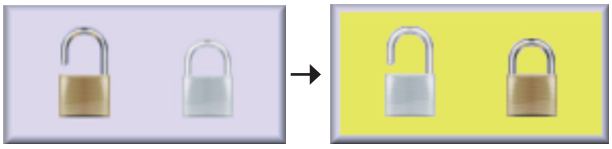
■ Automatic locking is inactive when no time interval has been entered ("Off" indication).

↳ The console is locked automatically after the configured time interval expires. The padlock symbol is shown on the header bar.

The configured time interval for automatic locking is copied as a default setting when the console is restarted.

Manual activation of the lock function

⇨ Touch the [Lock] button.

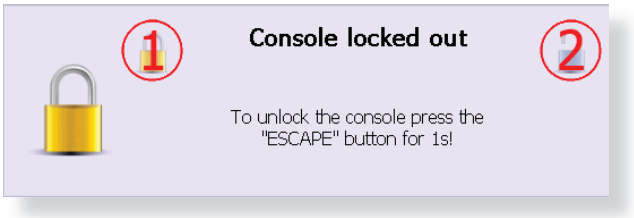


↳ The [Padlock] symbol is highlighted in yellow .

↳ The console is locked. The padlock symbol is shown on the header bar.

Unlocking the console

When the console is locked, the following messages is displayed when there is a change in a control function:



↳ This message is automatically removed after 5 seconds.

⇨ To unlock the console, press and hold the [Escape] button on the front of the control panel for 1 second or press the unlocking points [1] and [2] in succession.

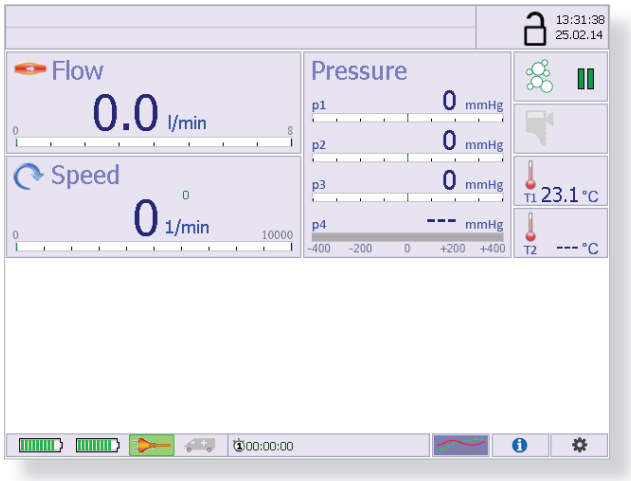
↳ The console is now unlocked and can be used. An acoustic signal sounds to confirm unlocking.

If a fault message occurs during the message display interval (5 seconds), it is indicated visually by a red alarm bell on the status bar. The fault message is signalled visually and audibly immediately after the message display time expires (see section “7 ALARMS” on page 7-1).

The message window is displayed for 5 seconds. You can dismiss this message by touching the message window.

6.12 [Systems settings] menu

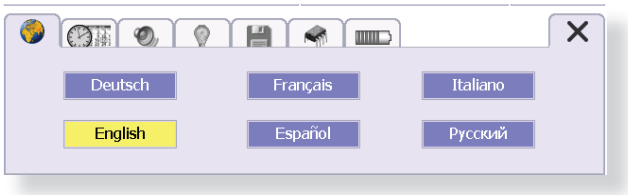
The [System Settings] menu provides access to the device settings.



⇨ Touch ⚙ on the status bar at the bottom of the touchscreen.

↳ This opens the window with the settings tabs.

⇨ Touch ✕ to exit the individual tabs,.



⇨ Use the tabs to select the desired settings.

Selecting the menu language

⇨ Touch 🌐.

↳ The [Select menu language] tab opens.

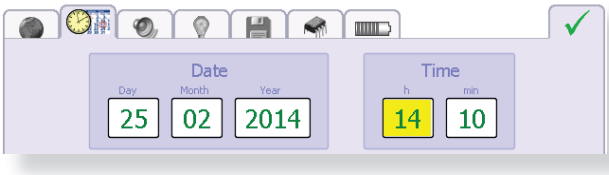
⇨ Select the desired language by touching the corresponding button.

↳ The language is activated immediately.

Setting the date and time

⇨ Touch 🕒.

↳ The [Date & time] tab opens.



⇨ Touch the appropriate entry field.

⇨ Then use the knob on the front of the unit to set the [date] and [time].

⇨ Touch ✓ to close the tab.

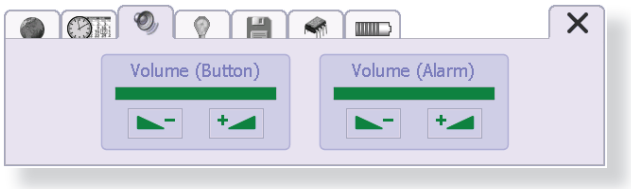
↳ The data and time settings become effective immediately.

6 USING THE ILA ACTIVVE® CONSOLE

Setting the key click and alarm loudness

⇨ Touch .

↳ The [Key click and alarm loudness] tab opens.



⇨ Set the key click loudness with the (softer) and (louder) buttons.

↳ The loudness is indicated by a green bar.

⇨ Set the key alarm loudness with the (softer) and (louder) buttons.

↳ The loudness is indicated by a green bar.

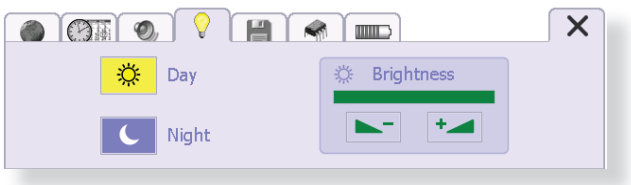
⇨ Touch to close the tab.

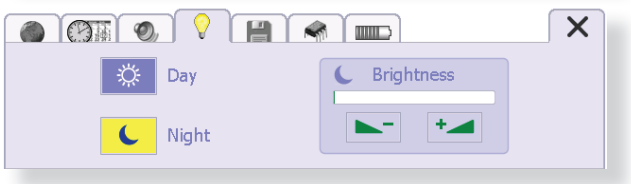
Setting the display brightness

For operation from battery packs, the display brightness should be set to a level that minimises power consumption for display backlighting. The brightness setting for night mode is automatically used for battery operation.

⇨ Touch .

↳ The [Display brightness] tab opens.





■ The display brightness for day and night mode can be set separately on this tab. Press „Day“ or „Night“ to select the desired mode. Now you can set the brightness for the selected mode. The setting procedure is described here using Day mode as an example.

⇨ Activate Day mode by pressing the „Day“ button.

↳ The button turns yellow.

⇨ Set the brightness with the (darker) and (lighter) buttons.

❑ You can see the display brightness while adjusting the setting.

↳ The display brightness is indicated by a green bar.

The settings for Day and Night mode are saved when the console is switched off and are restored when it is restarted. When the console is started up with AC mains power , the brightness setting for Day mode is used. The brightness setting for night mode is automatically used for battery operation. If the console is started up with battery power and then switched to AC mains power, the display brightness remains at the Night mode setting. It must be manually changed to Day mode.

Saving the log file

All relevant system data is recorded in the log file. This file can be copied to a USB stick.

⇨ Touch .

↳ The [Save data] tab opens.

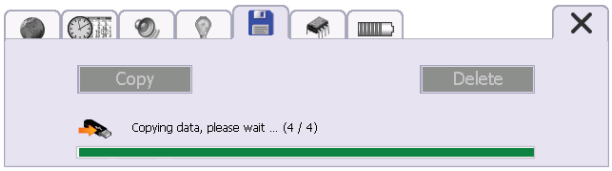
↳ The following message appears if no USB stick is plugged in:

⇨ Plug a USB stick into the USB port on the back of the control panel.

↳ It may take a while for the unit to recognise the USB stick, depending on its storage capacity.

⇨ Now you can copy the log file to the USB stick. This log file contains all relevant system data for the Service staff, such as fault messages and diagnostics.

⇨ Touch the Copy button.



↳ The log file is copied.

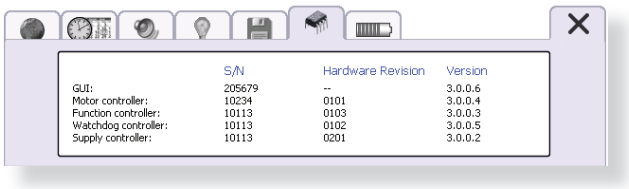
⇨ Touch Delete to clear the log file.

⇨ Remove the USB stick after the copying and/or clearing process is finished.

System data

⇨ Touch .

↳ The [System data] tab opens.

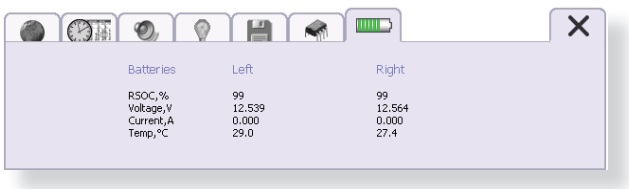


Viewing the battery pack charge state

⇨ Touch .

↳ The (Battery packs charge state] tab shows the following:

- Battery pack charge states.
- Battery pack serial numbers.
- Battery pack capacities.



DANGER

Always use this function to check the states and capacities of the installed battery packs before using the system in a mobile situation. The capacity of the fully charged battery packs should always be in the 'good' range. Battery packs in the poor range can endanger the patient's life.

6.13 Emergency operation

- Emergency operation is an exceptional situation.
- The system switches to emergency mode automatically if communication with the monitoring computer in the console is interrupted or the control panel fails.

↳ The iLA activve® control panel can no longer be used in this situation!

↳ The following alarm message appears on the iLA activve® control panel if the monitoring computer fails.

↳ An alarm tone also sounds.

↳ The red warning triangle next to the knob lights up red.

↳ Operation is only possible with the iLA activve® drive unit.

↳ When an automatic change to emergency mode occurs, the most recent speed setting is copied automatically.

⇨ Replace the iLA activve® drive console immediately with another unit in good working order.

6 USING THE ILA ACTIVVE® CONSOLE

There is a control panel on the rear of the pump drive that can be used for emergency pump operation in the event of failure of the iLA activve® control panel.

See also section 4.3 „Controls and indicators on the iLA activve® drive unit“ on page 4-14.

7 ALARMS

The actions and procedures to be followed in case of alarms are described in this section.

■ The cause of the alarm must be corrected immediately. Failure to act may endanger the patient's life.

Alarms are divided into two groups: physiological and technical. Both physiological and technical alarms can affect patient safety. The alarm messages in both groups are divided into three priority categories: high, medium and low.

- All active alarms are shown in the header of the iLA activve® control panel.
- If more than two alarms are active at the same time, they are displayed sequentially (i.e. alternately).

Figure 7–1: Alarm messages in the header line

An active alarm state is also indicated by the red LED above the [Alarm] button.

An acoustic alarm sounds at the same time. The acoustic alarm can be muted for a defined interval by pressing the [Alarm] button (see the "Audio Pause" column in the alarm list). The acoustic alarm sounds again after this interval expires, until the cause of the alarm is corrected.

⇨ To open the alarm list, touch the alarm message display area.

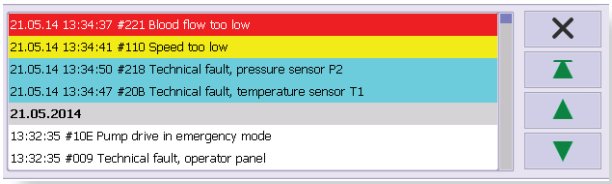


Figure 7–2: Alarm list

↳ All active alarm messages are shown in this window, colour coded by category. Historical and/or corrected alarms are shown below the active messages. The list can hold up to 100 entries.

⇨ You can use the navigation arrows to scroll through the list.

	Press this button to jump to the first entry in the alarm list.
	Press this button to jump to the previous entry in the alarm list.
	Press this button to jump to the next entry in the alarm list.
	Close the alarm list.

⇨ Touch an entry in the alarm list to view the alarm details.

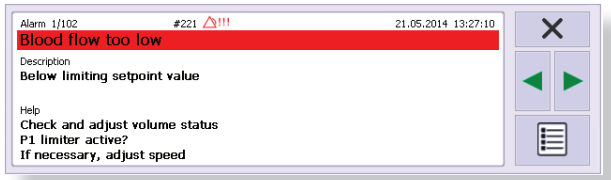


Figure 7–3: Alarm details

	Press this button to jump to the previous alarm message.
	Press this button to jump to the next alarm message.
	Press this button to open the alarm list.
	Closes the alarm message.

7 ALARMS

7.1 Physiological alarms

Physiological alarms provide information about the condition of the patient and are derived from measured values, such as pressures that exceed defined limits, or in part from the inability to determine specific measured values. The response of the medical staff relates to the condition of the patient. For more information, see “Table of Physiological Alarms” on page 7-6.

7.2 Technical alarms

Technical alarms are signs of malfunctions or impaired device operation. The malfunction or defect may require corrective action, or the device may be totally defective. These alarms require the user to makes changes to the device (including connected sensors and actuators) or exchange the device or components. For more information, see “Table of Technical Alarms” on page 7-9.

DANGER

A red warning triangle lights up on the front of the iLA activve® control panel in the event of a technical alarm. Defective components pose a risk of fatal injury to the patient. Immediately replace the entire iLA activve® blood pump system by a system in good working order.

7.3 High priority alarm messages

High priority alarm messages are displayed in the header, blinking red. The alarm message is shown in alternating red and black at a blink rate of 1.67 Hz. An acoustic alarm also sounds (sound pressure level 65.2 dBA). The acoustic alarm can be muted for a defined interval by pressing the [Alarm] button (see the "Audio Pause" column in the alarm list). The acoustic alarm sounds again after this interval expires, until the cause of the alarm is corrected.

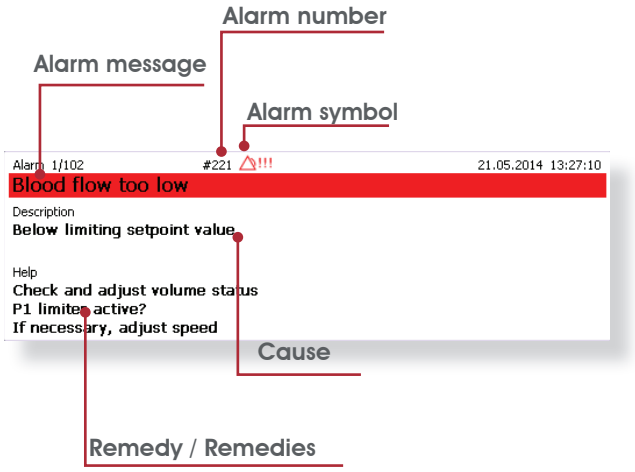


Figure 7–4: High priority alarm message details

7.4 Medium priority alarm messages

Medium priority alarm messages are displayed in the header, blinking yellow. The alarm message is shown in alternating yellow and black at a blink rate of 0.63 Hz. An acoustic alarm also sounds (sound pressure level 59.8 dBA). The acoustic alarm can be muted for a defined interval by pressing the [Alarm] button (see the "Audio Pause" column in the alarm list). The acoustic alarm sounds again after this interval expires, until the cause of the alarm is corrected.

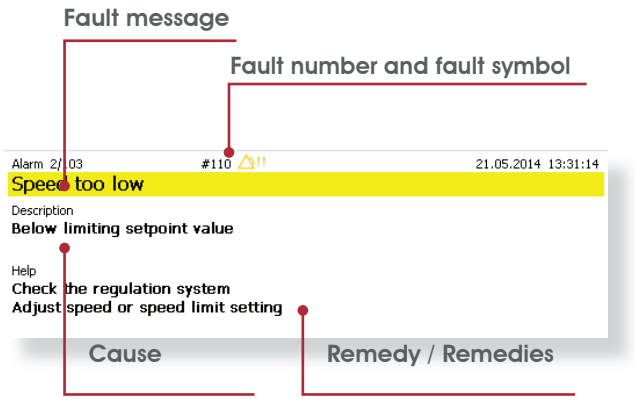


Figure 7–5: Medium priority alarm message details

7.5 Low priority alarm messages

Low priority alarm messages are displayed in the header in cyan. An acoustic alarm also sounds (sound pressure level 52.2 dBA). The acoustic alarm can be muted for a defined interval by pressing the [Alarm] button (see the "Audio Off" column in the alarm list). The acoustic alarm sounds again after this interval expires, until the cause of the alarm is corrected.

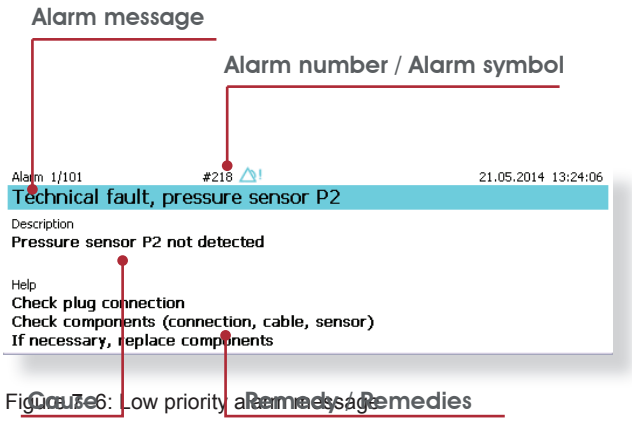


Figure 7-6: Low priority alarm message

7.6 Muting alarms

DANGER	Muting an alarm does not correct the cause of the alarm. Always respond immediately to every alarm and correct the cause of the alarm if possible.

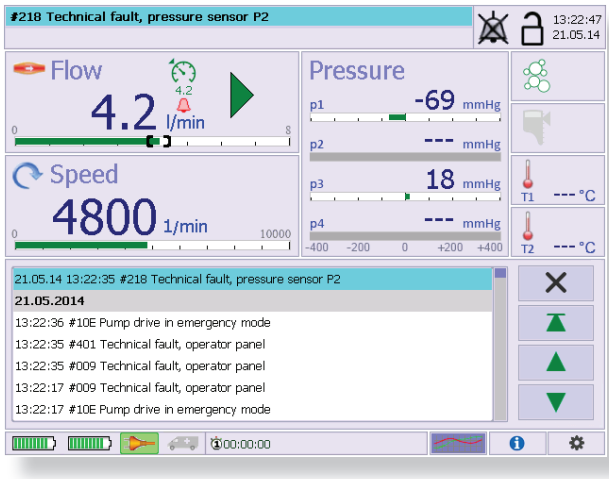
Audio pause

The acoustic alarm can be muted for a defined interval by pressing the [Alarm] button (see the "Audio Pause" column in the alarm list). The acoustic alarm sounds again after this interval expires, until the cause of the alarm is corrected.

Global Audio Off

To activate the Global Audio Off function, press and hold the [Alarm] button for 3 seconds. Acoustic alarms are suppressed while this function is active.

- However, alarms marked "Yes" in the "Exception Global Audio Off" column of the alarm list below form an exception and remain audible.
- The [Alarm history] menu is displayed automatically.



- Activation of this function is indicated in the header by a crossed-out bell symbol .
- A reminder signal sounds every 60 seconds as long as the Global Audio Pause function is active.
- New alarms occurring during the mute interval are labelled as active alarms and are shown in the [Alarm history] menu and in the header.

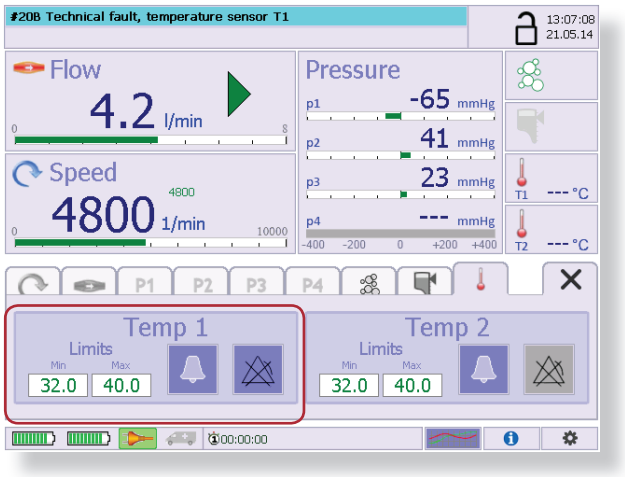
Alarm Off

Specific alarms from connected sensors can be manually deactivated with this function. This relates exclusively to technical alarms when connected sensors cannot be detected, for example when a sensor has been intentionally disconnected by the user. These alarms are identified by "Off" in the "Alarm Off" column.

7 ALARMS

Alarm Off

Specific alarms from connected sensors can be manually deactivated with this function. This relates exclusively to technical alarms when connected sensors cannot be detected, for example when a sensor has been intentionally disconnected by the user. These alarms are identified by “Off” in the “Alarm Off” column.



Remarks on the above screenshot:

The system cannot detect temperature sensor T1 (the user has disconnected the sensor or the sensor is defective).

The “Alarm Off” button is active (blue background). Alarms assigned to temperature sensor T1 can be disabled by pressing this button.

If the sensor is reconnected, the “Alarm Off” state will be exited automatically.

7.7 Alarm lists

Alarm messages are classified into three different priorities in the alarm system: high, medium and low. The priorities are listed in the "Priority" column of the alarm list. The messages are also categorised in the "Group" column as physiological alarms or as technical alarms in connection with the application.

Priority indication

Priority	Symbol	Colour	Blink rate
High priority	!!!	Red	1.67 Hz
Medium priority	!!	Yellow	0.63 Hz
Low priority	!	Cyan	Continuously on
Information	No symbol or	None	No blinking

With blinking display, the symbol and the alarm message are first shown in black, with the background colour corresponding to the priority.

Then the alarm is shown with the colours reversed (black background with the symbol and message in the colour corresponding to the priority).

7 ALARMS

Explanation of terms in the alarm list

Term	Explanation
Number	This is the alarm ID number displayed on the console . It is shown in the message in the form #nnn, which for example means that ID 0x0217 in the table appears in the message as #217.
Group	Alarms are grouped into physiological alarms and technical alarms.
Priority	Alarm priority category: high, medium or low.
Alarm Off	Alarms marked "Off" in this column can be manually deactivated. This applies exclusively to technical alarms when connected cannot be detected. These alarms can be disabled with the "Alarm Off" button in the corresponding display area when this button is active.
Audio Pause Duration	Duration of alarm muting after the mute button ("Alarm" button on the control panel) has been pressed. The acoustic alarm sounds again after this pause if the alarm condition is still present. • The pause is 120 seconds for all physiological alarms. • There are various pause times for technical alarms (120 s, 600 s, 3,600 s, infinite).
Exception Global Audio Off	Alarms that remain audible even when the "Global Audio Off" function is activated are marked here.
Head, Description, Remedy	Message text, description, possible actions.

Table of Physiological Alarms

Alarm Number	Priority	Alarm Off	Audio Pause Duration	Exception Global Audio Off	Message, Description, Remedy
0x0110	Medium priority	No	120	No	Speed too low. Below set limit. Check control system. Adjust speed or speed limit.
0x0111	Medium priority	No	120	No	Speed too high. Above set limit. Check control system. Adjust speed or speed limit.
0x0112	High priority	No	120	No	Air bubbles detected. Zero flow active. Check hose set for air bubbles. Remove any air bubbles. Manually raise motor speed.
0x0113	High priority	No	120	No	Below set level. Zero flow active. Check volume status and adjust. Manually raise motor speed.
0x0114	High priority	No	120	No	Return flow detected. Zero flow active. Flow direction / arrow mismatch? Patient pressure > pump pressure
0x0115	Low priority	No	120	No	P1 limiter active. Flow and pressure reduced. Check volume status and adjust. Reduce speed if necessary. Adjust limit value if necessary.

Alarm Number	Priority	Alarm Off	Audio Pause Duration	Exception Global Audio Off	Message, Description, Remedy
0x0116	Medium priority	No	120	No	Blood flow setpoint not reached. Check volume status and adjust. Check tube set. Manually adjust motor speed.
0x0117	High priority	No	120	No	0-flow manual activatet.
0x0210	High priority	Off	120	No	Air bubbles detected. Check hose set for air bubbles. Remove any air bubbles.
0x0213	High priority	No	120	No	Below set level. Check volume status and adjust.
0x0214	Low priority	No	120	No	P1 pressure too low. Below set limit. Check volume status and adjust. Reduce speed if necessary. Adjust limit value if necessary.
0x0215	Low priority	No	120	No	Technical fault, pressure sensor P1 Pressure sensor P1 not detected Check plug connection Check components (connection, cable, sensor) If necessary, replace components
0x0217	Low priority	No	120	No	P2 pressure too high. Above set limit. Check tube set. Check pressure system. Adjust limit value if necessary.
0x0218	Low priority	No	120	No	Technical fault, pressure sensor P2 Pressure sensor P2 not detected Check plug connection Check components (connection, cable, sensor) If necessary, replace components
0x021A	Low priority	No	120	No	P3 pressure too low. Below set limit. Check tube set. Adjust limit value if necessary.
0x021B	Low priority	No	120	No	Technical fault, pressure sensor P3 Pressure sensor P3 not detected Check plug connection Check components (connection, cable, sensor) If necessary, replace components
0x021D	Low priority	No	120	No	P4 pressure too low. Below set limit. Adjust limit value if necessary.
0x021E	Low priority	No	120	No	Technical fault, pressure sensor P4 Pressure sensor P4 not detected Check plug connection Check components (connection, cable, sensor) If necessary, replace components
0x0221	High priority	No	120	No	Blood flow too low. Below set limit. Check volume status and adjust if necessary. P1 Limiter active? Adjust speed if necessary.

Alarm Number	Priority	Alarm Off	Audio Pause Duration	Exception Global Audio Off	Message, Description, Remedy
0x0222	High priority	No	120	No	Blood flow too high. Above set limit. Reduce speed if necessary. Adjust limit value if necessary.
0x0225	High priority	No	120	No	Speed deviation. Actual speed < setpoint speed. Check pump module and replace if necessary.
0x0229	Low priority	No	120	No	T1 temperature too low. Below set limit. Check patient temperature. Adjust limit value if necessary.
0x0231	Low priority	No	120	No	P3 pressure too high. Above set limit. Check tube set. Check pressure system. Adjust limit value if necessary.
0x0232	Low priority	No	120	No	P4 pressure too high. Above set limit. Check pressure system. Adjust limit value if necessary.
0x0233	Low priority	No	120	No	T1 temperature too high. Above set limit. Check patient temperature. Adjust limit value if necessary.
0x022A	Low priority	No	120	No	T2 temperature too low. Below set limit. Check patient temperature. Adjust limit value if necessary.
0x0234	Low priority	No	120	No	T2 temperature too high. Above set limit. Check patient temperature. Adjust limit value if necessary.

Table of Technical Alarms

Alarm Number	Priority	Alarm Off	Audio Pause Duration	Exception Global Audio Off	Message, Description, Remedy
0x0005	Low priority	No	Infinite	No	Technical malfunction with control panel. Error during self-test. Restart drive console. Further operation possible.
0x0007	High priority	No	120	No	Technical malfunction with power supply. Initiate emergency operation. Exchange drive console.
0x0008	High priority	No	120	No	Technical malfunction with sensor box. Initiate emergency operation. Exchange drive console.
0x0009	High priority	No	120	No	Technical malfunction with control panel. Initiate emergency operation. Exchange drive console.
0x000A	High priority	No	120	No	Technical malfunction with pump drive. Use spare pump drive.
0x000B	Medium priority	No	120	No	Technical malfunction with control panel. Acoustic alarm malfunction. Further operation possible. Use emergency speaker for acoustic alarm.
0x000C	Medium priority	No	120	No	Technical malfunction with control panel. Faulty display on control panel. Initiate emergency operation. Exchange drive console.
0x000D	Low priority	No	Infinite	No	Technical malfunction with control panel. "Start" button defective; pump drive activated automatically. Further operation possible. Inspection by maintenance department.
0x000E	Low priority	No	Infinite	No	Technical malfunction with control panel. "0 Flow" button defective; manual activation of zero flow not possible. Further operation possible.
0x0010	Low priority	No	Infinite	No	Technical malfunction with control panel. "Escape" button defective; screen lock automatically deactivated. Further operation possible.
0x0011	Low priority	No	Infinite	No	Technical malfunction with control panel. "Alarm" button defective. Muting not possible. Further operation possible.
0x0012	Low priority	No	Infinite	No	Technical malfunction with control panel. "Power" button defective. Further operation possible.
0x0014	Medium priority	No	120	No	Technical malfunction with control panel. Initiate emergency operation. Exchange drive console.
0x0015	Low priority	No	600	No	Control panel temperature too high. Temperature limit reached. Ensure adequate ventilation. Check ambient conditions.

7 ALARMS

Alarm Number	Priority	Alarm Off	Audio Pause Duration	Exception Global Audio Off	Message, Description, Remedy
0x0016	Low priority	No	600	No	Technical malfunction with control panel. Buttons not working (intermittent). Further operation possible.
0x0101	Low priority	No	600	No	Pump drive temperature too high. Temperature limit reached. Check drive. Ensure adequate cooling. Reduce power.
0x0102	Medium priority	No	120	No	Malfunction in pump drive. Input power limit reached. Check pump module. Check pump drive. Reduce speed if necessary.
0x0103	High priority	No	120	No	Speed deviation. Motor speed does not match setting. Check drive; exchange if necessary.
0x0109	High priority	No	120	No	Technical malfunction with pump drive. Use spare pump drive.
0x010B	High priority	No	120	No	Technical malfunction with pump drive. Use spare pump drive.
0x010E	High priority	No	120	No	Pump drive operating in emergency mode. Emergency mode activated manually or automatically. Exchange drive console. Use spare pump drive.
0x0202	Medium priority	No	120	No	Technical malfunction with sensor box. Possible sensor fault. Exchange drive console if necessary.
0x0204	Low priority	No	120	No	Sensor box temperature high. Temperature limit exceeded. Ensure adequate ventilation. Check ambient conditions.
0x0205	High priority	No	120	No	Technical malfunction with flow measurement. Flow measurement/control and bubble detection not possible. Operation without flow monitoring possible. Strict monitoring of vital parameters. Exchange drive console.
0x0206	Medium priority	Off	120	No	Technical malfunction with flow measurement. Flow sensor not detected. Check cable connection. Exchange flow sensor if necessary.
0x0207	High priority	No	120	No	Technical malfunction with flow measurement. Flow sensor defective. Exchange flow sensor.
0x0208	High priority	No	120	No	Technical malfunction with flow measurement. Flow measurement/control and bubble detection not possible. Operation without flow monitoring possible. Strict monitoring of vital parameters. Exchange drive console.
0x0209	Low priority	Off	120	No	Technical malfunction with level sensor. Level sensor not detected. Check cable connection. Exchange level sensor if necessary.

Alarm Number	Priority	Alarm Off	Audio Pause Duration	Exception Global Audio Off	Message, Description, Remedy
0x020B	Low priority	Off	120	No	Technical malfunction with T2 temperature sensor. T1 temperature sensor not detected. Check cable connection.
0x020C	Low priority	No	120	No	Technical malfunction with T2 temperature sensor. T1 temperature sensor defective. ExchangeT1 temperature sensor.
0x020D	Low priority	Off	120	No	Technical malfunction with T2 temperature sensor. T2 temperature sensor not detected. Check cable connection.
0x020E	Low priority	No	120	No	Technical malfunction with T2 temperature sensor. T2 temperature sensor defective. ExchangeT2 temperature sensor.
0x020F	Low priority	No	120	No	Technical malfunction with sensor box. Pressure measurement potentially faulty. Operation without pressure monitoring possible. Exchange drive console.
0x0211	Medium priority	Off	120	No	Technical fault, flow measurement. Signal too weak. Check locking Re-position flow sensor If necessary, clean the flow sensor.
0x0227	Medium priority	No	120	No	Technical fault, level sensor. Level monitoring not possible. Check plug connection Check components (connection, cable, sensor) If necessary, replace components.
0x0235	Low priority	Off	120	No	Technical malfunction with sensor box. Pressure measurement and level sensing may be impaired. Further operation possible. Exchange drive console.
0x0301	Medium priority	No	Infinite	No	Technical malfunction with charging controller. Battery charging no longer assured. Ensure that AC mains power is available. Manually check charge states of batteries.
0x0302	Medium priority	No	Infinite	No	Technical malfunction with charging controller. Battery charging no longer assured. Ensure that AC mains power is available. Manually check charge states of batteries.
0x0303	High priority	No	600	No	No battery detected. Batteries defective or not installed. Ensure that AC mains power is available. Batteries installed correctly? Check batteries and replace if necessary.
0x0304	Low priority	No	3600	No	Left battery not detected. Left battery defective or not installed. Battery installed correctly? Check battery and replace if necessary.

7 ALARMS

Alarm Number	Priority	Alarm Off	Audio Pause Duration	Exception Global Audio Off	Message, Description, Remedy
0x0305	Low priority	No	3600	No	Technical malfunction with left battery. Left battery defective. Exchange battery.
0x0306	Low priority	No	600	No	Left battery capacity reduced. Capacity < 85% at start. Ensure that AC mains power is available.
0x0307	Low priority	No	600	No	Left battery capacity ≤ 50%. Ensure that AC mains power is available.
0x0308	Medium priority	No	600	No	Left battery charge level ≤ 20%. Ensure that AC mains power is available.
0x0309	Medium priority	No	600	No	Left battery empty. Ensure that AC mains power is available.
0x030A	Low priority	No	3600	No	Right battery not detected. Right battery not detected or not installed. Battery installed correctly? Check battery and replace if necessary.
0x0308	Low priority	No	3600	No	Technical malfunction with right battery. Check battery and replace if necessary.
0x030C	Low priority	No	600	No	Right battery capacity reduced. Capacity < 85% at start. Ensure that AC mains power is available.
0x030D	Low priority	No	600	No	Right battery capacity ≤ 50%. Ensure that AC mains power is available.
0x030E	Medium priority	No	600	No	Right battery capacity ≤ 20%. Ensure that AC mains power is available.
0x030F	Medium priority	No	600	No	Right battery empty. Ensure that AC mains power is available.
0x0315	Low priority	No	3600	No	Technical malfunction with fan. Ensure adequate ventilation. Check ambient conditions. Further operation possible.
0x0316	Low priority	No	600	No	Power supply temperature high. Temperature limit reached. Ensure adequate ventilation. Check ambient conditions.
0x031B	Low priority	No	600	No	Technical malfunction with left battery. Battery voltage too high. Exchange left battery.
0x031C	Low priority	No	600	No	Technical malfunction with right battery. Battery voltage too high. Exchange right battery.
0x031D	Low priority	No	3600	No	Technical malfunction with power supply. No connection for emergency operation.
0x031E	Low priority	No	Infinite	No	Battery capacity depleted. The console will be shut down in a few minutes. Check power supply.
0x031F	Low priority	No	Infinite	No	Data export not possible. Data export cable disconnected. Please check the connection and reestablish the connection if necessary
0x0312	Low priority	No	Infinite	No	Change to battery operation. Ensure that AC mains power is available.

Alarm Number	Priority	Alarm Off	Audio Pause Duration	Exception Global Audio Off	Message, Description, Remedy
0x0401	High priority	No	120	No	Technical malfunction with control panel. Parameter display not possible; automatic emergency mode activated. Exchange drive console.

7.8 Default settings

The default settings configured when the console is restarted are listed in the following table.

Parameter/Function	Factory default setting	Value set after console restart	Setting range	Remark
Flow, lower limit	0 ml/min	0 l/min	0 – 7,900 ml/min	i (see notes below table for explanation)
Flow, upper limit	8.0 l/min	8.0 l/min	0.1 – 8.0 l/min	ii
Speed, lower limit	500 rpm	500 rpm	500 – 9,900 rpm	i
Speed, upper limit	10,000 rpm	10,000 rpm	600 – 10,000 rpm	ii
P1, lower limit	-50 mmHg	-50 mmHg	-400 – 0 mmHg	
P2, upper limit	400 mmHg	400 mm Hg	-400 – +400 mmHg	
P3, lower limit	0 mmHg	0 mmHg	-400 – +395 mmHg	i
P3, upper limit	400 mmHg	400 mmHg	-395 – +400 mmHg	ii
P4, lower limit	0 mmHg	0 mmHg	-400 – +395 mmHg	i
P4, upper limit	400 mmHg	400 mmHg	-395 – +400 mmHg	ii
T1, lower limit	32 °C	32 °C	10 – 44.9 °C	i
T1, upper limit	40 °C	40 °C	10.1 – 45 °C	ii
T2, lower limit	32 °C	32 °C	10 – 44.9 °C	i
T2, upper limit	40 °C	40 °C	10.1 – 45 °C	ii
Flow, limit alarm	0 (off)			Alarm not active after restart. The user can manually activate the alarm.
P1, limit alarm	0 (off)	0 (off)	0 (off) 1 (on)	Alarm not active after restart. The user can manually activate the alarm.
P2, limit alarm	0 (off)	0 (off)	0 (off) 1 (on)	Alarm not active after restart. The user can manually activate the alarm.
P3, limit alarm	0 (off)	0 (off)	0 (off) 1 (on)	Alarm not active after restart. The user can manually activate the alarm.
P4, limit alarm	0 (off)	0 (off)	0 (off) 1 (on)	Alarm not active after restart. The user can manually activate the alarm.
T1, limit alarm	0 (off)	0 (off)	0 (off) 1 (on)	Alarm not active after restart. The user can manually activate the alarm.
T2, limit alarm	0 (off)	0 (off)	0 (off) 1 (on)	Alarm not active after restart. The user can manually activate the alarm.
Level alarm	1 (on)	0 (off)	0 (off) 1 (on)	Alarm active after restart. The level sensor must also be connected.
Return flow detected, intervention necessary.	Activated	Activated	Activated	Return flow detection: automatic detection of zero-flow mode after return flow detected.
Air bubbles detected, intervention necessary	Deactivated	Deactivated	Activated or deactivated	Air bubble detection: automatic detection of zero-flow mode after air bubbles detected.

7 ALARMS

Parameter/Function	Factory default setting	Value set after console restart	Setting range	Remark
Level, intervention necessary	Deactivated	Deactivated	Activated or deactivated	automatic detection of zero-flow mode after lower level limit exceeded.
P1 Intervention necessary	Deactivated	Deactivated	Activated or deactivated	P1 Limiter: automatic speed reduction to maintain set P1 limit.
Pulsation mode: amplitude	500 rpm	500 rpm	100 – 2,500 rpm	Speed tab
Pulsation mode: rate	40 bpm	40 bpm	40 – 90 bpm	Speed tab
Pulsation mode: % Systolic	50	50	30 – 70	Speed tab
Screen lock (automatic activation)	Off	Last state [iii]	Off until 1:00:00 hr	
Brightness, day	Maximum value (10)	Last state [iii]	0 – 10	"0" corresponds to minimum brightness, not dark.
Brightness, night	Medium value (5)	Last state [iii]	0 – 10	"0" corresponds to minimum brightness, not dark.
Loudness (keyclick)	Maximum value (4)	Maximum value (4)	0 – 4	"0" corresponds to minimum loudness, not mute.
Loudness (alarm)	Maximum value (4)	Maximum value (4)	0 – 4	"0" corresponds to minimum loudness, not mute.
Language	English	Last state [iii]	German English French Spanish Italian Russian	
Flow display unit	l/min	Last state [iii]	ml/min or l/min	

Notes:

i	The setting range for the lower limit only applies when the associated upper limit is set to the maximum value.
ii	The setting range for the upper limit only applies when the associated lower limit is set to the minimum value.
iii	Last state: the most recently parameter value or state set by the user.

8 OTHER HANDLING

This section provides important information on servicing and storing the iLA activve® console.

8.1 Safety instructions

DANGER

All maintenance activities must be performed by qualified maintenance staff. Improperly performed maintenance can endanger the patient's life.

DANGER

If a system fault occurs (red warning triangle on front panel illuminated), immediately replace the iLA activve® console by another device in good working order. Only qualified Novalung staff are allowed to open equipment enclosures. The warranty is rendered null and void if the user opens any enclosure.

8.2 Cleaning

If the exterior of the equipment or the accessories (e.g. sensors or brackets) is soiled, the surface may be cleaned with a mild detergent solution or standard, non-flammable and non-explosive disinfectants.

- In case of contamination, clean the unit with a cleaning or disinfectant approved by Novalung GmbH (e.g. Kamasept Spray from Dr. Nüsken Chemie).
- Clean with a lint-free cloth.
- Do not allow liquids to come in contact with (live) electrical components.
- Also avoid allowing liquid spray to enter the interior of the equipment through the ventilation openings.
- Never immerse enclosure components in water. Instead, wipe them clean with a moist cloth.

Also observe the following stipulations of the DGHM Disinfectants List:

- Working solutions should normally be prepared fresh for use. This applies in particular to disinfectants based on peroxide compounds or compounds that release free chlorine.
- There is a risk of explosion when alcohol-based disinfectants are used on large areas.
- As the 1-hour value is primarily intended for use in risk areas such as ORs and intensive care stations, concentrations below 0.5% should be avoided.
- Flammable disinfectants and cleaning agents may not be used while the equipment is operating.

DANGER

Always unplug the power cable before cleaning the equipment.

8 OTHER HANDLING

8.3 Protection against damage

Proper use and maintenance are essential for protecting the iLA activve® console against damage. Secure set-up and placement of the system is also important. This also includes protection against moisture, contamination and contact with flammable or explosive substances.

8.4 Maintenance and inspection

In particular, the allowable ambient conditions [see section „8.6 Storage“ on page 8-3] must be observed in this regard. To ensure adequate dissipation of heat generated during use, do not obstruct air circulation in the vicinity of the ventilation openings of the drive console.

Unit / Component	Interval	Action
Complete unit maintenance	Annually	Maintenance by Novalung service technician.
Clean air filter	Weekly	The air filter is located on the bottom of the iLA activve® power supply enclosure. Check the filter and remove accumulated dust and lint as necessary. For intensive filter cleaning, pull off the filter cover and remove the filter.
Replace air filter	Every 3 months	The air filter is located on the bottom of the iLA activve® power supply enclosure. Remove accumulated dust and lint as necessary. To replace the filter, pull off the filter cover and remove the filter.
iLA activve® control panel	Each time before use	Check the touchscreen for damage (scratches or cracks). Replace the entire unit if it is defective.

8.5 Sterilisation instructions

Do not use an autoclave, UV sterilisation devices or similar means to sterilise the iLA activve® console blood pump system.

8.6 Storage

The storage conditions stated below must be observed in order to ensure proper storage and transport of the iLA activve® console blood pump system and its accessories:

Remove the battery packs from the iLA activve® power supply unit while it is in storage.

Always store battery packs fully charged.

Do not store battery packs longer than six months without recharging.

Cover the peripheral device connectors on the rear of the iLA activve® power supply unit and the connectors on the rear of the iLA activve® controller to protect them against the entry of dust and dirt.

Pack the iLA activve® drive in dust-proof packaging for storage.

Ambient conditions for storage

Entire system	
Storage/transport temperature range	5 °C to +40 °C
Storage/transport ambient pressure range	700 hPa to1060 hPa
Storage/transport humidity range	20% to 90% RH, non-condensing

8.7 Packaging

Special packaging is used for delivery and return transport to avoid potential damage during transport. If a product must be transported or returned under warranty, the owner bears the associated cost and risk.

- Always use the original packaging material for transport.

8.8 Disposal

To ensure proper disposal, the iLA activve® drive console must always be returned to Novaling GmbH. Never dispose of used battery packs as household waste.

Components that come in contact with the circulatory system of the patient are designed as disposable products. Novalung recommends adhering to the standards listed below or sending the components concerned to the hospital's usual waste disposal service for consumable material contaminated with blood.

Standards:

- Act for Promoting Closed Substance Cycle Waste Management and Ensuring Environmentally Compatible Waste Disposal] (Kreislaufwirtschafts- und Abfallgesetz, KrW-/AbfG), 27 September 1994
- EU Directive 75/442/EEC of 15 July 1975 on waste (for products)
- EU Directive 94/62/EEC of December 1994 on packing and packaging waste (for production)
- EU Directive 91/157/EEC of 18 March 1991 on batteries and accumulators containing dangerous substances (for products)
- EU Directive 91/689/EEC of 15 July 1991 on hazardous waste (for products and contaminated disposables)

8 OTHER HANDLING

8.9 Warranty

General warranty conditions

The iLA activve® console system is designed for a service life of eight years. Novalung GmbH guarantees the availability of functionally equivalent spare parts at the module or assembly level for the iLA activve® console system, including the accessories supplied by Novalung, for a period of five years.

All sterile products are subject to the provisions stated on the accompanying package insert.

Scope of warranty

The costs of repairs and spare parts involved in repairs performed under warranty will be borne by Novalung GmbH. Spare parts installed during the term of warranty are guaranteed for six months.

Term of warranty

The term of warranty for the iLA activve® console system is six months following the date of delivery.

Warranty exclusions and restrictions

Unauthorised opening of any part of the iLA activve® console system renders the warranty null and void. The warranty does not cover:

- faults due to incorrect clinical use;
- damage due to improper transport, handling or storage;
- use of unapproved accessory components;
- technical modifications by the user.

Due to numerous factors outside the control of the manufacturer, such as shipping, storage and handling by the user, Novaling GmbH cannot guarantee that the product is unconditionally free of defects. Consequently, Novalung GmbH cannot be held liable for any loss, damage, injury or alteration resulting either directly or indirectly from the use of the product or resulting from a defect or any other cause.

The cost of maintenance and repairs attributable to improper operation, force majeur or damage due to external causes (failure to observe the user guide, damage resulting from falling or dropping, water damage, etc.) and not instigated by Novalung GmbH will be charged separately.

9 COMMUNICATION WITH PHILIPS PATIENT MONITOR

This section provides basic information about connecting Philips IntelliVue patient monitors.

For detailed information, consult the user guide for the connected Philips IntelliVue monitor.

9.1 Terminology

IVOI	IntelliBridge and VueLink Open Interface
EC5	IntelliBridge EC5 module
EC10	IntelliBridge EC10 module

9.2 Compatible Philips patient monitors

The iLA activve® drive console communicates with Philips IntelliVue patient monitor systems over the VueLink interface module (M1031A #A05) or over the IntelliBridge EC10 interface.

Monitor	Model	Software Revision
Philips IntelliVue	MP40/50/60/ 70/ 80/90	Rev. H.0 or later
	MX400/450/ 500/550/600/ 700/800	All
Philips CMS monitor family		Release C or later

9.3 Interfaces

VueLink

Interface	VueLink Type B	M1032A #A05 (Philips spare part number)
Cable	Philips M1032A/ M1182A #K6C (9-pin RS232 socket)	M1032-61699 (Philips spare part number)

IntelliBridge EC10

Interface	EC5 module 865144 #104, L0x
	EC10 module 865115 #A01, 101
Cable	Philips M8081-61002 (Ethernet) (included with EC5 module)

9.4 Displayed parameters

The displayed parameters are sent to the patient monitor from the console.

Parameter	Range	Unit
Flow	-2.00 to10.00	l/min
Speed	0 to 9999	rpm
P1	-99 to 400	mmHg
P2	-99 to 400	mmHg
P3	-99 to 400	mmHg
P4	-99 to 400	mmHg
T1	0.0 to 50.0	°C
T2	0.0 to 50.0	°C

9 COMMUNICATION WITH PHILIPS PATIENT MONITOR

9.5 IVOI alarm list

The IVOI alarm list comprises the alarms that can be sent to the patient monitor from the console.

For more information, see “Table of Physiological Alarms” on page 7-6 and “Table of Technical Alarms” on page 7-9.

No.	Message	Type	Priority	Measured value	Validity	Associated alarms*
1	BUBBLE for iLA	ALARM	Red	Flow	--	112, 210
2	Backflow for iLA	ALARM	Red	Flow	--	114
3	Flow Limit for iLA	ALARM	Red	Flow	--	116, 221, 222
4	Heart Rate for iLA	ALARM	Red	-	--	503, 504, 505
5	Level Low for iLA	ALARM	Red	-	--	213, 113
6	Speed Lim for iLA	ALARM	Yellow	Speed	--	110, 111
7	p1 Limit for iLA	ALARM	Yellow	P1	--	214, 215
8	p2 Limit for iLA	ALARM	Yellow	P2	--	217
9	p3 Limit for iLA	ALARM	Yellow	P3	--	21A, 231
10	p4 Limit for iLA	ALARM	Yellow	P4	--	21D, 232
11	T1 Limit for iLA	ALARM	Yellow	T1	--	229, 233
12	T2 Limit for iLA	ALARM	Yellow	T2	--	22A, 234
13	Device Error for iLA	INOP**	Hard	GENERAL	Invalid	007, 008, 009, 00B, 00C, 017
14	Flow Fault for iLA	INOP	Hard	Flow	Invalid	205, 206, 207, 208, 211
15	Drive Error for iLA	INOP	Hard	Speed	Invalid	10B, 00A
16	p1 Fault for iLA	INOP	Hard	P1	Invalid	215
17	p2 Fault for iLA	INOP	Hard	P2	Invalid	218
18	p3 Fault for iLA	INOP	Hard	P3	Invalid	21B
19	p4 Fault for iLA	INOP	Hard	P4	Invalid	21E
20	Level Fault for iLA	INOP	Hard	-	Invalid	209, 227
21	T1 Fault for iLA	INOP	Soft	T1	Invalid	20B, 20C
22	T2 Fault for iLA	INOP	Soft	T2	Invalid	20D, 20E
23	Device Fault for iLA	INOP	Soft	-	Valid	005, 00D, 00E, 010, 011, 012, 014, 015, 016, 202, 204, 20F, 235 301, 302, 315, 316, 31D, 501, 502
24	Battery for iLA	INOP	Soft	-	Valid	303, 304, 305, 306, 307, 308, 309, 30A, 30B, 30C, 30D, 30E, 30F, 312, 31B, 31C
25	Drive Fault for iLA	INOP	Soft	Speed	Valid	101, 102, 103, 109, 10E, 225

*** Explanation of "associated alarms"**

Alarm numbers are listed in this column. They refer to the corresponding alarm numbers in the Physiological Alarms and Technical Alarms tables. For more information, see “Table of Physiological Alarms” on page 7-6 and “Table of Technical Alarms” on page 7-9.

**** Explanation of the term INOP (inoperative)**

Information for the operator regarding the state of the device. INOPs are divided into two sorts, which are shown in the "Priority" column:

- **Hard:** Hard INOPs indicate that valid measurement data transfer and alarm detection are not possible, for example because a sensor has been unplugged.
- **Soft:** Soft INOPs indicate a potential technical problem of low importance.

Each INOP has supplementary information about the validity of the corresponding measurement data.

This information is shown in the "Validity" column:

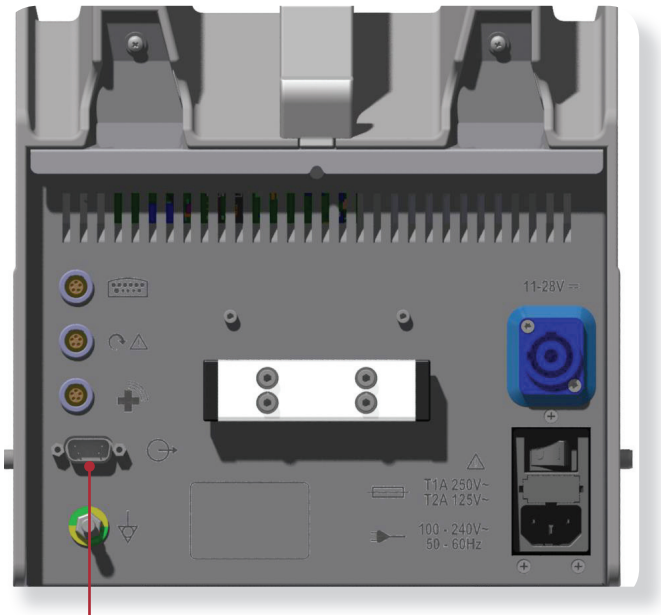
- **Valid:** The corresponding measurement data remains valid.
- **Invalid:** The corresponding measurement data is incorrect. A question mark (?) is shown on the monitor instead of the measured value.

9.6 Connecting Philips IntelliVue monitors

A prerequisite for connecting a Philips IntelliVue patient monitor is that the RS232 data port show in the adjoining figure is present on the rear of the iLA activve® console.

The data port on the iLA activve® console can be used directly without any additional system settings. Communication starts automatically after a connection is established to a compatible monitor.

Using a suitable cable (for more information, see section „VueLink“ on page 9-1 and the section „IntelliBridge EC10“ on page 9-1), connect the Philips IntelliVue patient monitor to the data port on the rear of the power supply unit.



RS232 data port for connection of Philips IntelliVue patient monitors

9 COMMUNICATION WITH PHILIPS PATIENT MONITOR

10 NOTES

10 NOTES

NOTES

NOTES

www.novalung.com – Your source for extrapulmonary lung support

Manufactured by:

Medos Medizintechnik AG

Obere Steinfurt 8-10
52222 Stolberg
Germany

info@medos-ag.com
www.medos-ag.com
Phone +49 2402 9664-0
Fax +49 2402 9664-60

Distributed by:

Novalung GmbH

Im Zukunftspark 1
74076 Heilbronn
Germany

info@novalung.com
www.novalung.com
Phone +49 7131 2706-0
Fax +49 7131 2706-299

A Xenios company

novalung®

Solutions for Lung Failure

Art.-#:400151, Version: EN_007_2014_09
All rights reserved © 2014