SEVACO LK3

User Manual

SEVACO LK3 Operating Instructions

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User Manual
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1. Orientation

1.1. About this Manual

This manual provides the basis for the intended purpose, use, and proper care of the active Vacuum-Controller SEVACO LK3. This device is designed and optimized to be intuitive and user-friendly. However, a detailed study of this manual is crucial for an efficient and safe use of the device.

Please read the manual carefully before the first use of the device!

Even experienced users should study this manual. Next to the description of operation processes, the manual contains instructions to avoid malfunctions and situations of danger. Additionally, help is provided to identify and analyze problems as well as instructions to effectively counter their causes.

1.2. Overview of Chapters of this Manual

Chapter		Content
1	Orientation	Symbols in this user manual Terminology and abbreviations
2	Safety	Important safety instructions for operation and inspection of the device
3	System Description	Description of components and device structure Description of interfaces to users, patients and other devices
4	Installation	Important notes before first installation Connection to other devices
5	Operation	Establishing the state of operation Functionality-tests Instructions on how to correctly use all features
6	Errors	Tips on how to avoid and resolve errors Description of all error messages
7	Service and Maintainance	General maintenance instructions for the user (no service instructions) Instructions for correct cleaning and disinfection of all components Instructions for safety and functional tests
8	Approvals and Certifications	Patents Approvals and certifications

9	Attachement	Technical data of all components Article numbers

1.3. Symbols in this user manual

Checklists describing important process steps. This allows a quick check if all necessary steps have been completed.

Important information on correct and safe use of the device.

Safety information to avoid damaging the device or other devices.

Warning information, to avoid dangerous situations for patients and/or operators of the device.

1.4. Terminology and Abbreviations

Description	Explanation
SEVACO LK3	Active Vacuumcontroller of Irasun GmbH
HLM	Heart-Lung-Machine
VAVD	Vacuum-assisted venous drainage
EMC	Electromagnetic Comparability
OR	Operating Room
DMS	Data Management System
STK	Annual Safety Controls

2. Safety

2.1. Legislative Basis

The device SEVACO LK3 was developed according to the following laws and standards:

Description	Explanation
CE	Certificate of Conformity to European standards
DIN EN 60601-1	Safety instructions on medical electrical devices
DIN EN 60601-1-2	Electromagnetic Comparability
MDD	European Directive for Medical Devices 93/42/EWG
DIN EN ISO 13485	Quality-Management-System for Medical Devices

SEVACO LK3 is a class 1 (MDD 93/42) medical device with a signed certificate of conformity.

2.1.1. Intended Use

The SEVACO LK3 device is intended to be used for adjustment, regulation, and monitoring of a vacuum in medical applications. Particularly, it has been designed and developed to be used in vacuum assisted venous drainage during extracorporeal circulation by supporting patient drainage via applying a vacuum to the cardiotomy reservoir of the heart-lung machine. The purpose of the SEVACO LK3 is accurate adjustment of the hospital's vacuum lines (-0.8 bar to -0.6 bar) to a required level (e.g. 0.107 bar).

It is not intended for any other use.

2.1.2. Specifications and Safety Instructions

The company IRASUN GmbH is not accountable for damages or harms resulting from not intended use.

National regulations for the prevention of accidents and all other general or industrial medicine rules and safety regulations apply. IRASUN GmbH is not accountable for damages resulting from negligence of these regulations.

IRASUN GmbH is not accountable for damages or harm resulting from the negligence of safety regulations, this manual, or the infringement of the duty to take care. This is also applicable if the duty for care is not specifically mentioned.

2.1.3. General Safety Notes

SEVACO LK3 was developed according to state-of-the-art and recognized safety requirements. Nonetheless, hazardous situations for patients, operators or material assets can occur during use.

Only use the device SEVACO LK3 in technically faultless state and according to the intended use. Always keep safety regulations in mind and act according to this manual.

Take care that the inflow into the cardiotomy-reservoir (e.g. caused by the OP-sucker), does not exceed the maximal supplied outflow of your vacuum network. **If not abided, maintaining the desired vacuum level cannot be granted!**

Ensure that this manual is permanently available at the field of use of the device SEVACO LK3. If the manual is not in a usable state, it must be exchanged immediately.

To ensure safe use of the device, SEVACO LK3 must undergo annual security inspection performed by authorized service-personnel. **This check must be performed after 1000 hours of use, but at least once within 12 months.**

Additional to the recommendations and instructions of this manual, general regulations as well as legislative regulations apply.

Clinic-specific characteristics (e.g. in regard to standard operating procedures), may be added to this manual.

The study of this manual is obligatory for every operator before using the device SEVACO LK3.

All alterations to the device SEVACO LK3 must be approved beforehand by IRASUN GmbH. All approvals must be given in written form. Otherwise, no guarantees and liabilities can be given.

Always keep the device clean. Especially the interfaces and the fluid-detection-unit must to be kept clean to avoid contamination-related errors.

2.1.4. Safety warnings during Operation of the Device

Only qualified and trained personnel may operate and handle the device Sevaco LK3.

The device SEVACO LK3 is only to be used under constant surveillance. Neglect may lead to the endangerment of operator or patient. The security functions of the device act as supporting aid for the operator but do not substitute the operator's surveillance.

The device SEVACO LK3 measures the pressure inside the device, not the reservoir. These measurements can deviate from the actual pressure inside the reservoir, especially if the reservoir is not sealed. Correct functioning of the device is only granted, if the reservoir is closed and sealed.

Carefully monitor the blood volume in the cardiotomy reservoir at all times.

Always check the displayed data of the device for plausibility.

Check the disposable in regular intervals. Specifically, the moisture-trap and the filters must be inspected for kinks as well as condensation buildup.

2.1.5. Operational Safety

Personnel must be properly trained and qualified. Each operator must read this manual before use. Furthermore, a detailed knowledge of the functionality of SEVACO LK3 as well as all attached and interacting devices is required for safe use of the device.

All cables, tubing, connectors, as well as all further accessories, must be checked prior to use. Any worn or damaged components must be replaced immediately. In case of any doubts, please contact IRASUN GmbH or your individual contact person.

Avoid bending the tubing as much as possible. Kinks and twist must be avoided in any case in order to avoid measurement errors and safety risks.

Always keep the reservoir sealed to avoid measurement errors of the device. The device SEVACO LK3 can only function correctly in a closed setting with an airtight reservoir.

Ensure unhindered air circulation by keeping the air inlet clean and unblocked.

Individual adaptions to the device as well as the use of spare parts not tested and cleared from IRASUN GmbH may impede the functionality or safety of the device. Clearance must always be given in written form. If not abided, IRASUN GmbH cannot assume liability.

Only use accessories which are listed in this manual. The measurement- as well as the control-functions of the device have been calibrated in regard to these accessories. Neglect may falsify measurements and impede the functionality and safety of the device, causing hazards for operator and patient.

2.1.6. Electrical Safety

The electrical installation must fulfill requirements listed in respective ISO standards (e.g. DIN VDE 0107 in Germany). Technical data of the device must be considered.

The device SEVACO LK3 is classified as safety class 1 (DIN EN 60601-1). Thus, it must be connected to a grounded power source.

The functionality of all electrical connections and cables must be checked at regular intervals.

Only use the original power supply. Other power supplies may lead to a loss in functionality or endangerment of operator or patient.

Devices connected to SEVACO LK3 must fulfill all requirements of the harmonized standards for medical electrical device safety (DIN EN 60601-1). Furthermore, connection and data exchange must be approved by IRASUN GmbH.

2.1.7. Safety Instructions for Care and Maintenance

The device SEVACO LK3 may only be maintained by qualified personnel.

The device must be disconnected from power supply prior to care and maintenance measures.

The maintenance intervals given in this manual must be followed and shall not be exceeded. Always consider the instructions for care and maintenance provided by this manual.

Avoid the ingress of water through inlets and all other openings of the device.

Please use the suggested cleaning fluids to avoid premature aging of all components.

Only authorized service personnel may repair the device. To grant safety and functionality of the device, only original replacement parts of IRASUN GmbH may be used.

2.2. Safety Features of the Device

In case of system errors during startup, an optical and acoustical alarm is triggered.

In case of system errors during use, an error message is displayed, and an acoustical alarm is triggered.

The device SEVACO LK3 performs an automated self-assessment at startup.

The functionality of the fluid-detection-unit is checked by the operator during the startup procedure.

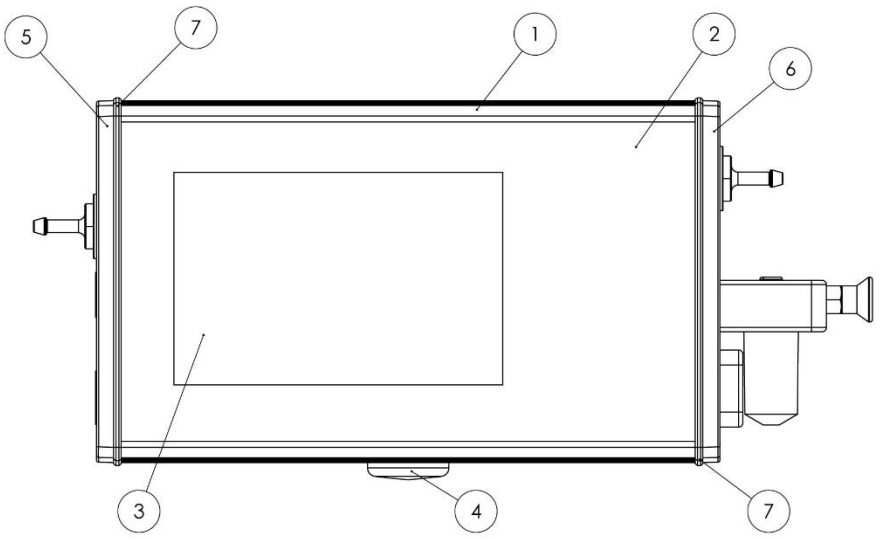
3. Device Description

3.1. General Description

The vacuum controller SEVACO LK3 is a device to safely regulate and control vacuum in medical applications. It was designed especially for the use of vacuum assisted venous drainage. The device allows an automated and active regulation of vacuum in the blood reservoir during extracorporeal circulation. SEVACO LK3 is actively controlling the pressure in the reservoir. This way, a stable pressure is granted even if counteracting measures (such as medical suckers) influence the pressure in the reservoir. Integrated safety measures ensure that the safety margins are not exceeded.

3.2. Design of the Device

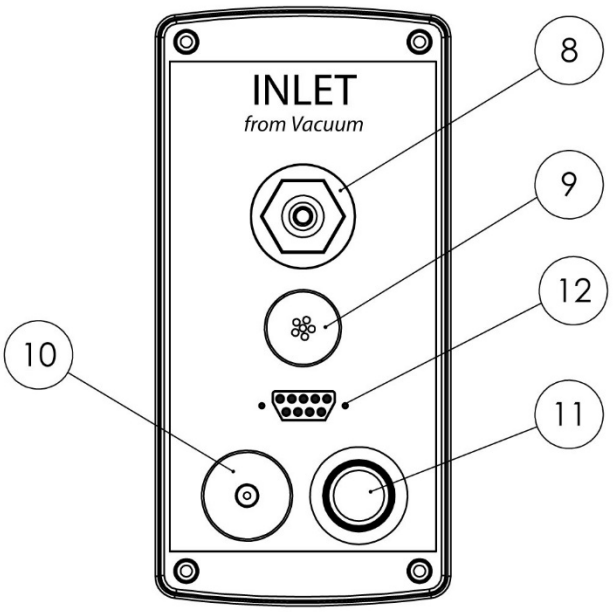
3.2.1. Overview



#	Name	Functionality
1	Aluminum-Housing	Contains and protects electronic components and valves
2	Glass-Cover	Protects the Touch-Display

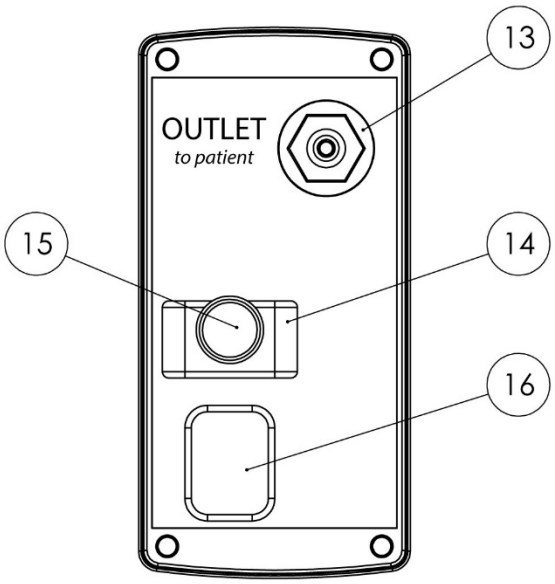
3	Touch-Display	Allows user-interaction and provides information
4	Mounting Clamp	Allows the fixation of the device on standardized surgery theater tracks as well as on the Heart-Lung-Machine
5	Coverplate Inlet	Provides all interfaces to the environment
6	Coverplate Outlet	Provides the interface to the patient as well as the safety sensors
7	Gaskets	Seal the coverplates

3.2.2. Overview of all Components - Inlet



#	Name	Functionality
8	Tubing Connector Inlet	Allows connection to the clinics vacuum network via standardized tubes (see accessories).
9	Airfilter	Provides a sterile ventilation of the housing
10	24V Connector	Connector for the power supply (see accessories)
11	Power Button	Switch for the power supply of the device
12	Serial Port	Interface for data management

3.2.3. Overview of all Components - Outlet



#	Name	Functionality
13	Tubing Connector Outlet	Allows connection of the disposable (see accessories)
14	Reservoir-fixation unit	Positioning of the medium reservoir
15	Locking bolt	Locks the reservoir in place
16	Sensor-Block	Contains and protects the sensors

3.2.4. Overview of required Accessories

	Name	Functionality
	Disposable SEVACO LK3	Disposable with fluid reservoir as well as sterile filter
	Vacuum-Tube	Connector with the vacuum supply of the clinic
	24V Power Supply	Power supply of the device Only uses original power supply provided by IRASUN GmbH!

4. Installation

4.1. Preparation prior to Installation

The vacuum controller SEVACO LK3 is delivered in a protective case. The casing and the device must be inspected for damages due to transport. Perfusionists trained in handling the device may unpack and mount it according to individual requirements.

Please inform your individual contact person immediately in the case of any visible damages to the device and / or the case. Do not use the device!

If the responsible perfusionists are not yet trained in handling the device SEVACO LK3, your contact person will arrange an individual training for you. The perfusionist will be shown how to use and how to take care of the product. Furthermore, the error handling will be explained in detail.

4.1.1. Environmental Requirements

Only use the device at temperatures between +10 °C and +40 °C.

Store the device in a cool and dry location at temperatures between 0 °C and +40 °C.

The electrical installation must fulfil the requirements of DIN VDE 0107 (or corresponding country-specific standards).

The vacuum network must be accessible, stable and at a sufficiently high level. Pressures between -800mbar and -600mbar are recommended.

The device must to be mounted on a sufficiently stable fixation point.

The humidity should not exceed values of 85% during use of the device.

The humidity should not exceed values of 70% during storage.

4.2. Installation of the device SEVACO LK3

Only trained and able personnel may perform the installation of the device. Neglect may lead to damages of the device and loss in functionality and safety.

4.2.1. Scope of Delivery

The vacuum controller SEVACO LK3 is delivered with the following components included:

- SEVACO LK3 (main device)
- Mounting clamp (including four screws and the respective Allen key)
- 24V power supply (including respective power cable)
- Manual

4.2.2. Mounting

The mounting clamp allows to mount the device on horizontal as well as on vertical installations. These may be standardized round mounting columns as well as standardized mounting rails. Place the mounting clamp in the desired orientation on the backside of the main device and fixate it with the included screws. Only use the included screws for fixation. In case of loss, please contact your contact person.

When mounting the device and prior to use check the following checklist:

- Always fixate the device in a stable and slip-free way on the desired mounting rail or column.
- Always take care not to kink, twist, or jam any cables.
- Organize and fixate all cables in an orderly and stable manner. Do not allow loose cables, to avoid damages of cables or undesired unplugging of cables during transport or use.

- Organize and fixate the vacuum tube connecting the device to the vacuum network in a way to avoid kinking and twisting.

- Finally recheck all fixations and connections in regard to firm and stable connection.

5. Operation

5.1. Overview: Use of the vacuum controller SEVACO LK3

The following tables give an overview of all processes needed for the intended use of the device SEVACO LK3. A detailed description of all processes can be found in the subsequent chapters.

5.1.1. Processes performed once or periodically

Process	Interval	Corresponding Chapter
Setting of basic parameters	Once	5.3.6
Annual safety check	12 Months / 1000 hours of operation	5.3.7

5.1.2. Processes performed at every use

Processes prior to surgery

Process	Corresponding Chapter
Mounting of the device	5.3.8
Connection to the vacuum network	5.3.9
Setting of warning limits	5.3.6
Setting of the maximum vacuum limit	5.3.6
Preparation of the disposable	5.3.11

Processes during surgery

Process	Corresponding Chapter
Monitoring of the vacuum level	5.3.12
Warning- and Error-Management	5.3.13
Exchanging the disposable	5.3.14

Processes after surgery

Process	Corresponding Chapter
Correct shutdown of the device	5.3.15
Removal of the disposable	5.3.16
Cleaning of the device	5.3.17
In case of any problems: Contact service	6

5.2. Getting the device ready to use

5.2.1. Prior to power up

Before powering up the device, check if all requirements for safe and intentional use of the vacuum controller SEVACO LK3 are met. The following checklist offers an overview of all necessary steps:

- ☑ Is the power supply connected correctly?
- ☑ Is the original power supply connected?
- ☑ Is the vacuum tube connected correctly?

- Is the device mounted in a stable and safe way?
- Is the air inlet of the device freely accessible?
- Has the disposable been connected correctly?
- Is a second disposable prepared?

If all above requirements are met, the device SEVACO LK3 may be turned on safely.

5.2.2. Powering Up the Device

Press the main power button (11).

Once the device is correctly connected to the power supply, the main power button will illuminate in red. Once the device is turned on, the red light switches to green light.

Once the device is turned on, an automated self-check is performed, including the following aspects:

Electronic components and internal connections
The hours of operation since the last inspection
The state of the internal data logging system

In case of any errors, please follow the instructions in chapter **6.2 Info-Messages presented on the User Interface**. There you will get information regarding the error code, plausible causes, and instructions on what to do.

If the self-check is passed, the fluid-detection-unit is checked in an interactive test by the operator. The operator is guided through all steps by illustrations and explanatory text displayed on the screen. The following parameters are evaluated:

The functionality of the presence-detector of the fluid-detection-unit
The functionality of the fluid-detector of the fluid-detection-unit

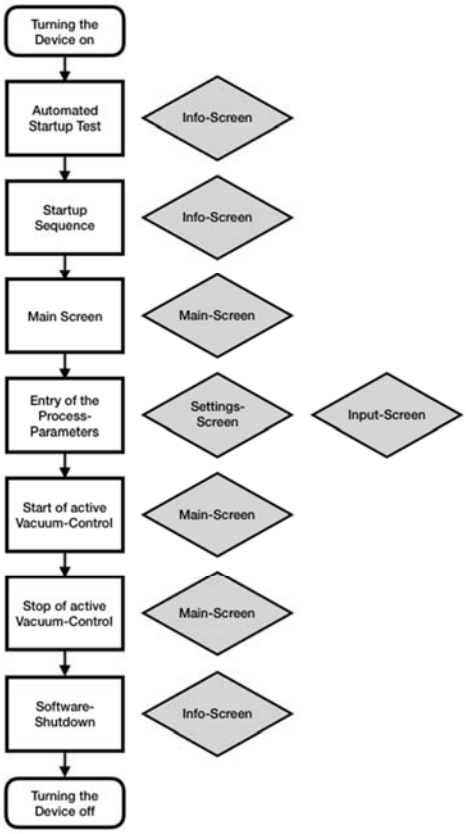
If this test cannot be concluded successfully, please refer to chapter **6 Errors and Error Handling** to identify possible causes. Please inform your contact person at IRASUN GmbH.

If the operator test is passed, the system panel displays the **Main Screen** to control the device.

5.3. General Handling of the System Panel

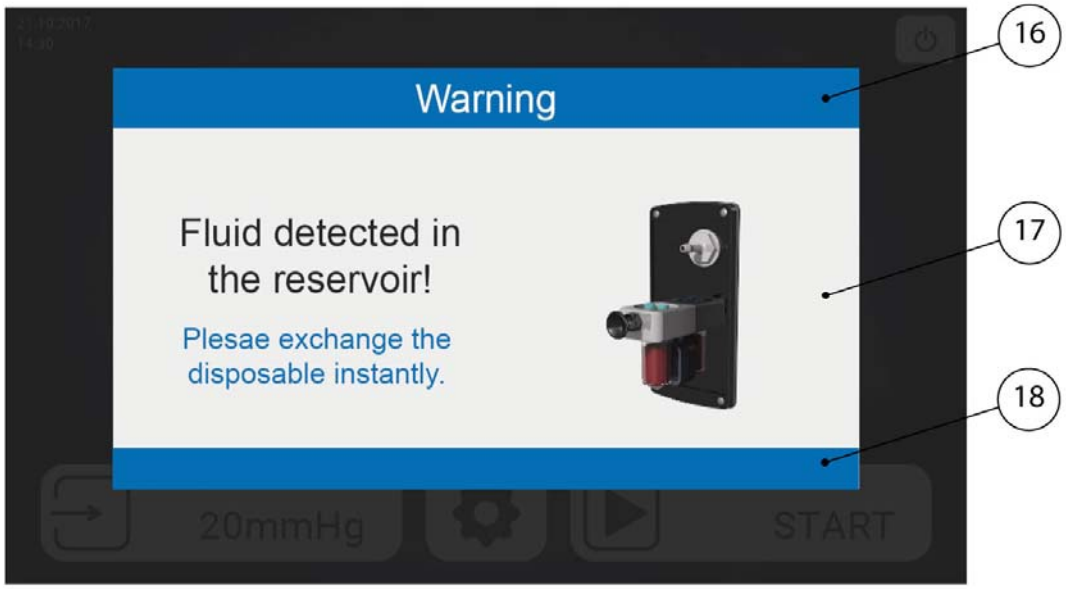
5.3.1. Symbols and Views of the System Panel

The system panel displays the different screens of the user interface such as the Main Screen.



5.3.2. System Panel Overview - Info Screen

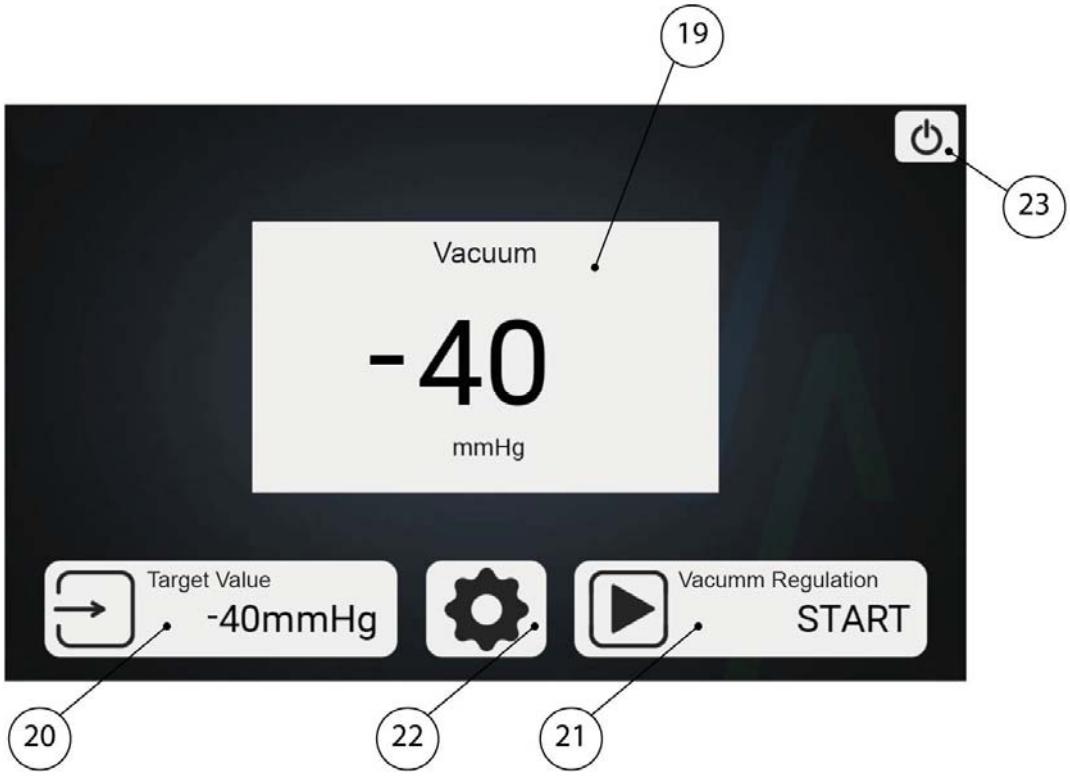
The **Info Screen** provides important information to the operator. This includes error messages as well as descriptions and illustrations of process steps (e.g. Startup-Sequence; Shutdown-Sequence).



#	Name	Functionality
16	Titlebar	Description of the current Information screens (optional)
17	Information Area	Area to describe and illustrate the information to be presented
18	Footer	Area for additional information (optional)

5.3.3. System Panel Overview - Main Screen

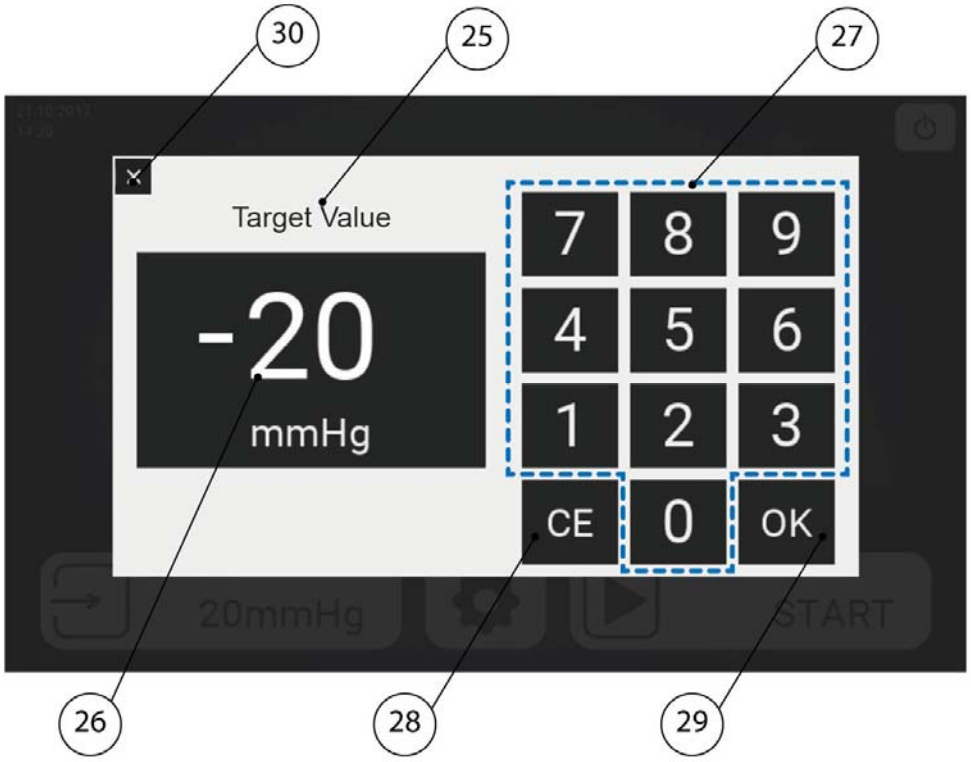
The **Main Screen** represents the standard screen displayed during intended use. It displays the current status of the device in a clear way and allows fast access to all sub-screens.



#	Name	Functionality
19	Vacuum-Display	Displays the measured pressure on the outlet in mmHg
20	Target-Button	Button to open the sub-screen **Input Screen** to set the target-value
21	Start-Button	Button to turn the device on and off
22	Settings-Button	Button to open the sub-screen **Settings Screen**
23	Shutdown-Button	Button to initialize the shutdown-process

5.3.4. System Panel Overview - Input Screen

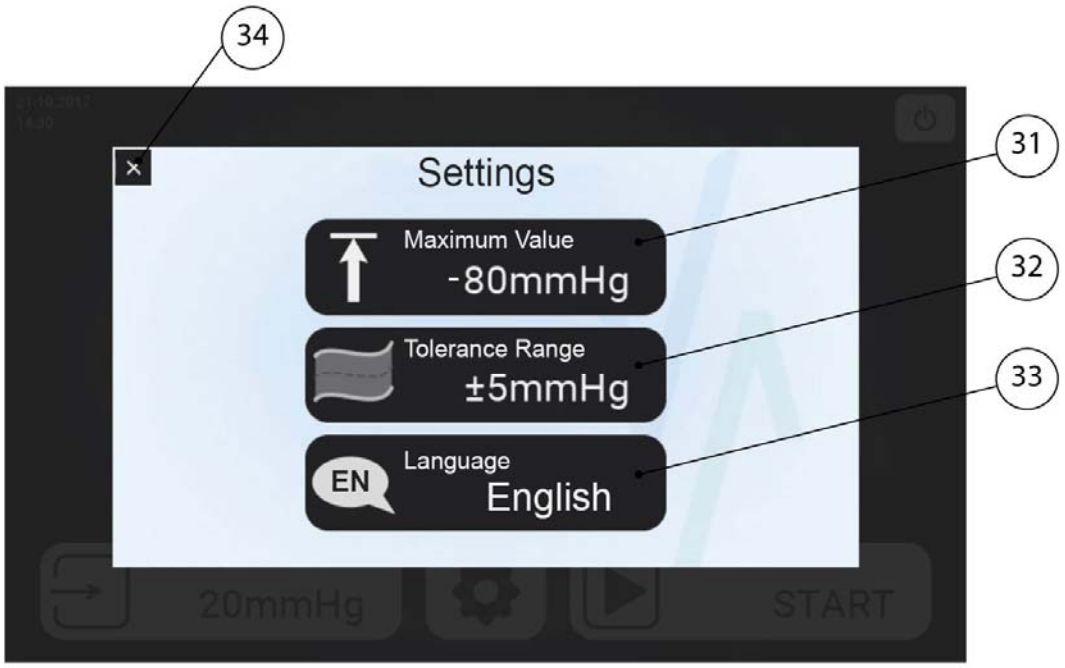
The **Input Screen** allows the precise and fast setting of target values. The entered values will be immediately validated and, if needed, corrected. The user can either directly overwrite the current value or delete the entry by pressing the Clear button (28). To set the entered value as target value, the user has to confirm it by pressing the Confirm button (29).



#	Name	Functionality
25	Titlebar	Description of the value to be set
26	Display of the current value	Displays the value to be set in mmHg
27	Numpad	Interface to enter the value to be set
28	Clear-Button	Button to clear the current value
29	Confirm-Button	Button to confirm the value to be set
30	Close-Button	Button to close this sub-screen without changing the value

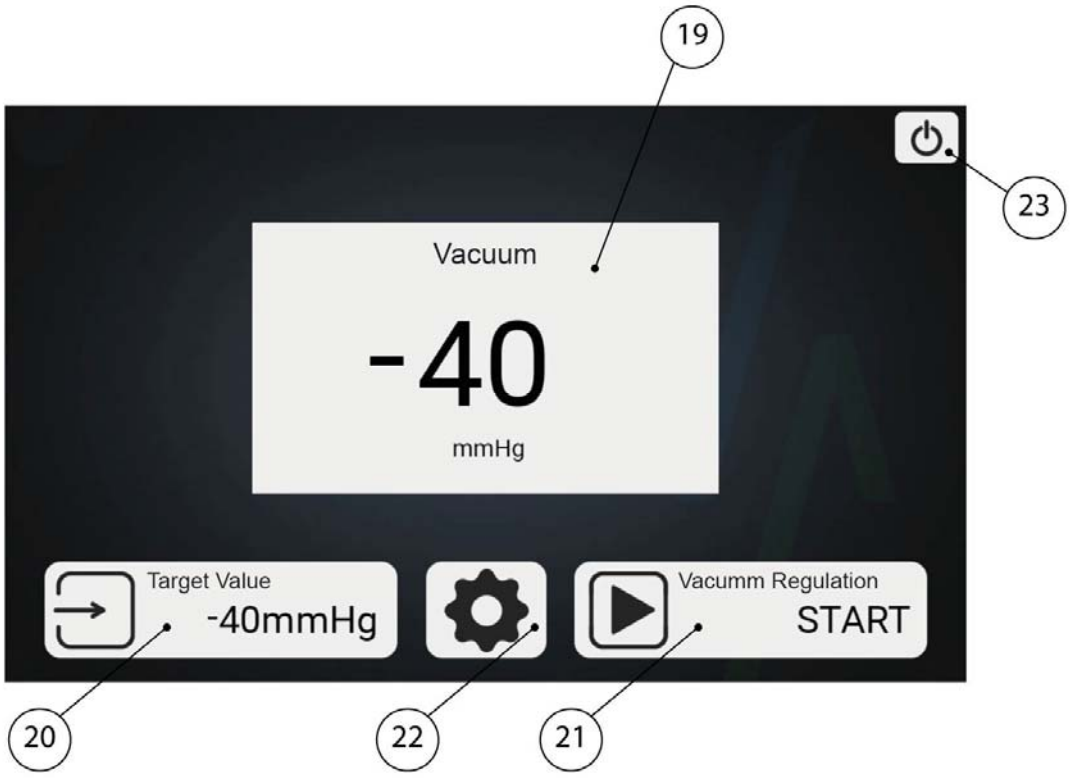
5.3.5. System Panel Overview - Settings Screen

The **Settings Screen** offers an overview of user-definable settings. The operator may set an upper limit, a range of tolerance as well as the system language.



#	Name	Functionality
31	Max-Button	Button to open the **Input Screen** to set the maximum limit
32	Margin-Button	Button to open the **Input Screen** to define the range of tolerance
33	Language-Button	Button to switch between available system languages
34	Close-Button	Button to close the settings-screen

5.3.6. System Panel - Basic Settings



Before the first use of the device, as well as prior to every use, the operator should check the basic settings of the device. Especially the maximum limit as well as the range of tolerance have to be examined. This is done by pressing the Settings-Button (22) of the Main Screen. The opening sub-screen (Settings Screen) allows to set the requested value.

To set the maximum limit as well as the range of tolerance, a sub-screen (**Input Screen**) appears, allowing a simple setting of the values. The referring value is described in the Titlebar (**25**). The user can delete the entry by pressing the Clear-Button (**28**) or he can directly overwrite this value. The value is set after pressing the Confirm-Button (**29**). Erroneous input will be directly corrected. To cancel the input, the screen can be closed by pressing the Close-Button (**30**).

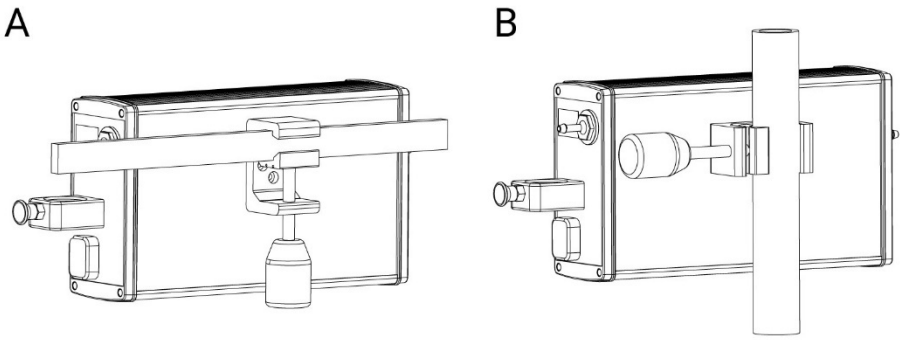
After setting of each value, all other parameters will be evaluated in regard to conformity. If necessary, they will be automatically adapted. This way, it is not possible, that the target value is above the maximum limit for example.

It is further possible to set the system language in the **Settings Screen**. By clicking the Language-Button (**33**), the language iterates between all available values.

5.3.7. Annual Safety Control

Refer to your service-contract or personal service contact for contents and extent of the annual safety control.

5.3.8. Mounting of the Device



The device can be mounted on horizontal (A) as well as on vertical (B) rails. Mounting is possible on standardized round mounting columns as well as standardized mounting rails.

It lies in the responsibility of the user to ensure that the device is always mounted in a sufficiently stable way.

Always ensure, that the device is mounted on a higher level than the cardiotomy-reservoir to which it will be attached. Negligence may cause risks or danger to the patient.

5.3.9. Connecting to the Vacuum Network

The device can be connected to the vacuum network via a standardized (DIN EN ISO 9170, DIN 13260) vacuum tube for medical purposes (see accessories).

Connect the tubing end with the Inlet (8) of the device, before connecting the metal connector to the vacuum port of the clinic.

5.3.10. Setting the Target Value

You can change the target value by pressing the Target-Button (20). This opens the **Input Screen** to set the new value. Values up to a maximum of 80 mmHg are accepted. However, the value cannot exceed the user-defined maximum (see chapter **5.3.6 System Panel - Basic Settings**).

A safety margin of 5 mmHg is applied by the system to avoid unwanted shutdown of the device. If a maximum of 85 mmHg is set, the maximal accepted target value would be 80 mmHg.

Due to safety reasons, setting a target value larger than 80 mmHg is not possible.

The operator must always ensure , that the inflow into the cardiotomy reservoir (e.g. induced by surgical suckers) does not exceed the maximum intake of the vacuum network. **Neglect may result in an unwanted decrease of vacuum**

After confirming the user input by pressing the Confirm-Button the new target value is set and the display returns to the **Main Screen**. If the device is active, it will immediately regulate the vacuum to the new target value.

5.3.11. Preparation and Use of the Disposable

The disposable is delivered in a sterile packaging. Please check the packaging for damages prior to opening.

Do not use the disposable in the case of any visible damage to the packaging or the disposable itself. Sterility and safe use of the disposable can no longer be guaranteed. Neglect may cause risks for the patient.

The device is color coded to increase usability. The connector to the reservoir is covered with a blue cap. Additionally, a badge saying „TO RESERVOIR“ is attached to that end.

Remove the blue cap and connect the tubing to the vacuum connector of the cardiotomy reservoir.

Ensure that the tubing is reachable and clearly visible all the way between the cardiotomy reservoir and the vacuum controller. Small radii, torsion and pressure or tension on the tubing must be avoided. Check the tubing for kink-free attachment multiple times.

Remove the white cap and connect the tubing to the Outlet of the vacuum controller Sevaco LK3.

Do not yet place the reservoir of the disposable in the reservoir fixation unit (14) of the device. Once the device is turned on, a sensor test of the device has to be performed by the operator. The sensor block (16) has to be accessible for that and will otherwise be blocked by the reservoir of the disposable.

Close the clamp on the open end of the disposable and remove the yellow cap. The clamp allows a manual equalization of the cardiotomy-reservoir.

Two caps (length approx. 5 cm) are included in the disposable set. These are used to close and protect the Inlet (8) and Outlet (13) after each use of the device.

5.3.12. Surveillance of the Vacuum Status

The **Main Screen** centrally displays the measured vacuum (19). If the device is not active, the pressure value is written in black. Once the device is active, the value is written in blue, indicating that the difference between target value and measured value lies within the user-defined tolerance (32).

If the difference between target value and measured value is out of tolerance, the device signals this via an acoustical warning sound. Additionally, the measured vacuum (19) is written in red to optically signal the warning (see chapter **6.2.2 Warning-Messages**)

5.3.13. Alarm Management

The vacuum controller SEVACO LK3 uses both an active as well as a passive alarm management functionality. In case of non-critical alarm-situations, the operator is informed via optical and acoustical error messages.

However, if a potential risk to the operator or patient may result from the current alarm-situation, the alarm management function actively controls the device and sets it to a safe state. It also does this in the event of a power loss.

Setting the device into safe state results in a direct cutoff of the primary vacuum (connected to the vacuum network) directly after the Inlet (8). Additionally, the Outlet (12) is equalized to the environment.

The safe state ensures, that a pressure buildup in the cardiotomy reservoir is not possible and that it is always equalized. Moreover, wasting of vacuum is avoided.

The operator will still be informed about critical alarm-situations via optical and acoustical error messages. A detailed overview of possible error messages is listed in chapter **6.2 Info-Messages presented on the User Interface**.

5.3.14. Changing the Disposable

Usually, the use of one disposable is sufficient for a single VAVD. In that case, following the instructions in chapter **5.3.16 Removal of the Disposable** is sufficient.

In some cases, an exchange of disposables may be required during a VAVD. If fluids are gathering in the reservoir of the disposable, it must be exchanged to ensure a safe functioning of the device. This is most likely to happen during extremely long VAVD.

5.3.15. Shutting the Device Down

If the device SEVACO LK3 is no longer needed, you can turn it off via the Shutdown-Button (23).

To avoid unintentional shutdown, the Shutdown-Button has to be pressed for 3 seconds to induce the shutdown procedure.

Once the shutdown procedure is started, information on the shutdown process is displayed (see chapter **6.2 Info-Messages presented on the User Interface**). After shutdown, the device informs the user, that a safe power off via the Power-Button (11) can be done.

Only turn off the device via the Power-Button once the device informs you to do so.

Always turn the device off before disconnecting it from power supply.

5.3.16. Removal of the Disposable

After completion of VAVD, the vacuum controller SEVACO LK3 must be turned off (see chapter 5.3.15). Thereafter it is safe to remove the disposable.

Open the Locking Bolt (15) and remove the reservoir from the fixation unit (14). Carefully remove the tubing from the Outlet (13) of the device. Thereafter you can remove the tubing from the reservoir and dispose of it.

Each disposable comes with two protective caps (length approx. 5 cm). These are intended to close and protect the Inlet and Outlet of the device after the procedure.

5.3.17. Cleaning of the Device

Only use approved cleaning solutions to clean the vacuum controller SEVACO LK3 to avoid damaging the device.

Clean all surfaces and grooves.

Always ensure, that the Sensor-Block (15) is kept clean and free from any residues. Otherwise, the correct functioning of the device may be impeded.

Always ensure, that the complete glass cover (2), especially the Touch-Display (3) is kept clean and free from any residues. Otherwise, the use of the device may be impeded.

Approved cleaning solutions:

Bacillol® AF; Bode Chemie Hamburg (GER);

Fermacidal D2; IC Products SA, Minusio (CH);

6. Errors and Error Handling

6.1. Avoidable Sources of Defect

Many errors and sources of defect can be avoided if proper precautions are taken. It is essential to be aware of possible sources of defect. This allows the user to act accordingly and assures failure-free operation of the vacuum controller SEVACO LK3.

Additionally, to reduce down-times, methods to detect and recover those errors are provided.

Moreover, instructions and information are provided to significantly reduce the probability of defects and errors.

6.1.1. Errors during installation

Always mount the vacuum controller on a higher level than the cardiotomy reservoir. *Otherwise, entry of fluids into the vacuum controller is possible.*

Ensure a safe and slip-free fixation of the device, especially if fixed on vertical mounting rails.

The device must be mounted in a way to be visibly and audibly accessible to the perfusionist. *The perfusionist must always be able to receive visual and acoustical signals .*

Please ensure enough space next to the Inlet- and Outlet-Connectors. Small radii in the attached tubing may lead to kinks and torsion resulting in occlusion of the respective tubing.

6.1.2. Errors during Mounting of the Disposable

Always grant a kink- and torsion-free guiding of the tubing. *Neglect may lead to measurement errors or loss of function of the device.*

Always ensure that the reservoir of the disposable is fixed firmly in the respective fixation unit and that the locking bolt is completely closed. *Neglect may lead to measurement errors or result in falsely triggered error warnings.*

Always ensure that the tubing is firmly attached to the respective connectors and to fix it with cable ties. *Loose or insufficiently fixed tubing may lead to leaks or measurement errors.*

Take care to mount the disposable in the correct direction. *If mounted the wrong way, the disposable should not be used due to sterility issues.*

Always check the packaging of the disposable for damages prior to unpacking. *In case of damages, the sterility of the disposable is no longer ensured.*

Always inspect the disposable prior to use for damages. *Damaged disposables should not be used. They may inflict hazardous situations for the patient.*

6.1.3. Configuration Errors

The vacuum controller SEVACO LK3 allows no configuration of the hardware by the operator. Changes on the hardware must be checked by the manufacturer. Without written consent of the manufacturer, changes to the hardware are strictly forbidden. *Neglect may cause hazardous situations for the patient or operator.*

The operator may set the warning boundaries and absolute maximum of the device to his or her individual needs. The device safes the last set configuration on shutdown.

6.1.4. Errors during Use

If the vacuum controller SEVACO LK3 is correctly mounted and configured and the disposable is correctly connected, most sources of defect are already prevented.

Two main types of sources of defect remain: Device-failure or operator errors. The identification of device failures and their effects are described in the following chapter.

To avoid operator errors, please take care of the following:

Read the manual carefully and completely. Be aware of all functions and risks of the vacuum controller SEVACO LK3.

VAVD is a complex and intricate procedure. It is of utmost importance to have detailed knowledge of all systems and devices influencing or influenced by the device and the patient.

Familiarize with the different warning- and error-messages. Even though they are kept in a clear and short manner, it is of utmost importance to be aware of the different messages. This ensures a fast and correct response of the operator and a minimal down-time.

Ensure that the vacuum controller SEVACO LK3 stays turned off for at least 10 seconds before turning it on again. Otherwise, the automated startup tests may not be performed properly.

Monitor the startup tests and perform the operator tests exactly according the presented instructions (see above). Neglect may cause danger to the operator or the patient.

The vacuum controller SEVACO LK3 uses highly sensitive measurement equipment. Always handle it with care.

Do not expose the device to high acceleration or vibration. Do not use any devices with visible damages.

6.1.5. Errors during Maintenance

Maintenance includes all legally necessary inspections and calibrations as well as procedures performed to maintain the functionality of the vacuum controller SEVACO LK3. Some of these procedures must be performed by the manufacturer or a trained technician and cannot be performed by the operator. Technicians of other companies than the manufacturer must be approved by the manufacturer to perform the inspections. Approval must be given in written form. Please inform your contact person as soon as possible to arrange inspections, to avoid down-times of devices.

The most crucial danger in regard to maintenance is the neglect of regular care and maintenance of the device and not to keep to the inspection intervals. It lies in the sole responsibility of the operator to ensure that the inspection intervals are kept as instructed.

Additional endangerment is posed by the neglect of the maintenance instructions presented in this manual. Insufficient maintenance and care may reduce functionality or permanently harm the device.

6.2. Info-Messages presented on the User Interface

In the case of errors or warnings, an acoustical alarm is given to direct the operator's attention to the device. Next to that, info-messages are presented un the user interface. These may contain information in regard to the error or warning, an individual error code and / or illustrations.

In the following chapters a detailed description of all info-messages is listed.

6.2.1. Status-Messages

The vacuum controller SEVACO LK3 performs an automated startup test after turning on. The startup test evaluates the functionality of the following components:

The internal electronic of the device
The communication of all actors and sensors

If the startup test has been performed without errors, the operator will be instructed to test the following components:

The calibration of the presence-detection sensors

If both tests have been performed without errors, the **Main Screen** will be displayed on the user interface.

If an error is detected during the startup procedure, a safe functioning of the vacuum controller is not guaranteed. In that case, please perform the following steps:

Turn the device off and remove the power supply. Wait for at least 10 seconds.
Reconnect the power supply and turn the device on again.

If the error is still present, the device is not working properly and cannot be used under any circumstances. Please inform your individual contact person for further instructions.

6.2.2. Warning-Messages

Warnings are defined as acceptable deviations of the desired status of the device. Warnings can under no circumstances lead to hazardous situations for the operator or the patient.

Therefore, warning-messages will not be presented on full-screen as it is the case with error-messages. This allows using the device even if warning-messages are displayed. Warnings do not lead to an active reaction of the alarm management.

Possible warning-messages:

The measured value is out of bounds of the user defined tolerance	
Cause:	The measured value was for more than 10 seconds out of bounds of the user defined tolerance margin
Illustration:	The measured value is displayed in red and an acoustical warning sound is given.
Effect:	None

The acoustical warning sound can be deactivated by pressing the displayed warning sign. The warning is still visibly displayed. A permanent deactivation of the warning sound is not possible.

The device is close to the maximum runtime	
Cause:	The remaining runtime until the next necessary inspection is less than 20 hours.
Illustration:	The remaining runtime until the next necessary inspection is displayed above the measured pressure value.
Effect:	None

6.2.3. Error-Messages

Operator errors or device failure may lead to hazardous situations for operator and / or patient. Consequently, error-messages will always be displayed on full-screen to immediately draw the operator's attention. Additionally, the alarm management actively reacts to the error by setting the device into safe-state.

The following list contains all error-messages which can be resolved by the operator:

Fluid is detected in the reservoir	
Cause:	The amount of fluid in the reservoir of the disposable exceeds the allowed maximum.
Illustration:	An **Info Screen** is displayed with a description as well as an additional illustration of the error.
Effect:	The active vacuum control is stopped, the target value will be set to zero and an acoustical alarm is sounded.

No reservoir is detected	
Cause:	No reservoir can be detected in the reservoir fixation unit
Illustration:	An **Info Screen** is displayed with a description as well as an additional illustration of the error.
Effect:	The active vacuum control is stopped, the target value will be set to zero and an acoustical alarm is sounded.

The measured vacuum exceeds the maximum	
Cause:	The measured vacuum exceeds the user-defined maximum.
Illustration:	An **Info Screen** is displayed with a description as well as an additional illustration of the error.
Effect:	The active vacuum control is stopped, the target value will be set to zero and an acoustical alarm is sounded.

Startup-Error	
Cause:	The automated startup tests were not successful.
Illustration:	An **Info Screen** is displayed with a description of the error.
Effect:	The device is stopped and the active vacuum control is disabled.

Operating errors surpassed	
Cause:	The maximal allowed operating hours are exceeded.
Illustration:	An **Info Screen** is displayed with a description of the error.
Effect:	Active vacuum control is disabled.

In the case of hardware-errors or other errors which cannot be handled by the operator, an **Info Screen** is displayed showing an individual error code. Additionally, the device is set into safe state. In the case of the display of an error code, please not the code and contact your individual contact person immediately.

6.3. Other Errors

The internal surveillance electronic of the device detects most of the possible errors. However, if you detect anomalies, visible or regarding functionality, please contact your individual contact person.

Always handle the device carefully. Watch out for signs of wear or fatigue which do not yet cause an error but might lead to errors in the future. In particular, watch out for the following:

Is the device sounding different than usual, especially when the target value is changed?

Is there any noise coming from the power supply?

Are all components firmly connected or is any component getting loose?

Does the device display any visible damage?

A timely inspection or maintenance avoids errors during use as well as hazardous situations for operator or patient.

7. Maintenance

7.1. General Maintenance Instructions

Regular maintenance and proper care of the device are necessary to grant the safety and functionality of the vacuum controller SEVACO LK3.

The maintenance instructions described below are part of the operating conditions of the device. This refers to the regular maintenance and care performed by the operator as well as to the necessary maintenance and inspection performed by the manufacturer or an approved technician.

7.1.1. Safety Instructions in Regard to Maintenance

- Always disconnect the device from its power supply before performing maintenance procedures.
- Keep to the maintenance instructions and procedures given in this manual.
- Solely use approved cleaning solutions.
- All personnel performing maintenance must be proper qualified to do so.
- Repairs must be performed solely by the manufacturer or authorized service technicians.
- Only original parts, replacements or disposables of IRASUN GmbH may be used. The use of not approved parts, replacements or disposables may result in severe hazardous situations for the operator or the patient.

7.1.2. Annual Safety Inspection

The vacuum controller SEVACO LK3 must undergo continuous inspections and calibrations by authorized service personnel (directive 93/42 EEC). This inspection is necessary after 1000 hours of operation or at least every 12 months, whichever case is met first.

7.1.3. Environmentally responsible Disposal

The disposal of the device SEVACO LK3 is to be performed according to EU guideline 2002 96 EEG WEEE.

All used disposables must be disposed of in an environmentally sound and safe manner. Please use the individual way of disposal of your institution.

7.2. Cleaning and Disinfection

The cleanliness of the vacuum controller SEVACO LK3 is an essential requirement for the safety and functioning of the device. Please perform the following cleaning procedures after each use:

- Disconnect the device from its power source
- Only use lint less cleaning cloths moistened with pure water.
- Carefully and thoroughly dry the device.
- Remove all fluids as fast as possible from the device, in particular from the glass cover (2) and the sensor-block (16).
- To avoid biological contamination, the device must be cleaned with gentle disinfection solutions after each use. Therefore, all surfaces of the device must be swiped carefully and thoroughly with an approved disinfectant.
- Do not use aceton-based cleaning solutions. These may cause damages on the surfaces of the vacuum controller.
- Always ensure that no fluids enter the housing of the vacuum controller!

7.3. Safety- and Functionality-Inspections

7.3.1. Optical Inspections

Visually check the composition and functioning of all device components on a regular basis.

Check the following points in particular:

Always disconnect the device before starting any maintenance procedures.

Are all connectors clean and without any visual contamination?

Are all connectors without any visual damage?

Are all cables and wires without any visual damage?

Are all surfaces free from any visual damage?

In the case of optical deficits inform your personal contact person immediately.

7.3.2. Automated Startup Test

Carefully monitor the automated startup test of the device at every startup.

Follow the instructions of the operator test to validate the correct functioning of the device.

Immediately inform your personal contact person, if any errors occur during these procedures.

8. Certifications

8.1. Patents

System zur Vakuum-unterstützten venösen Drainage (VAVD)

File reference 102017124927.3

8.2. Details in Regard to Electromagnetic Tolerance

EMC-Examination Report 17165-1-R00 – TÜV Nord

Applied Standards:

- EN60601-1-2 (2015)
- EN55011 (2009) + A1 (2010)
- EN61000-3-3 (2008)
- EN61000-4-2 (2009)
- EN61000-4-3 (2006) + A1 + A2
- EN61000-4-4 (2012)
- EN61000-4-5 (2006)
- EN61000-4-6 (2014)
- EN61000-4-8 (2010)
- EN61000-4-11 (2004)

9. Appendix

9.1. Technical Device Information

9.1.1. Dimensions and Weight

Height:	170 mm
Width:	394 mm
Depth:	84 mm; 130 mm incl. Mounting Clamp
Weight:	3.450 g

9.1.2. Operating Conditions

Temperature (operation):	+10 °C to +40 °C
Temperature (storage):	0 °C to +40 °C
Relative humidity:	30% to 75%

9.1.3. Operating Data

Minimal primary vacuum:	-400mBar
Maximal secondary vacuum:	-80mmHg
Minimal secondary vacuum	-10mmHg

9.1.4. Elektrische Daten

Device Safety Rating	Protection Class 1
International Protection	IPX1

9.2. Order Numbers

9.2.1. Device

Sevaco LK3	12020083

9.2.2. Disposables and Accessories

Assisted Venous Drainage Kit (1 piece)	12010248
Vacuum tube, black, unsterile	12020088

9.3. Warranty

The warranty options as stated in your individual contract apply.