THE MEDICAL & WOUNDCARE COMPANY

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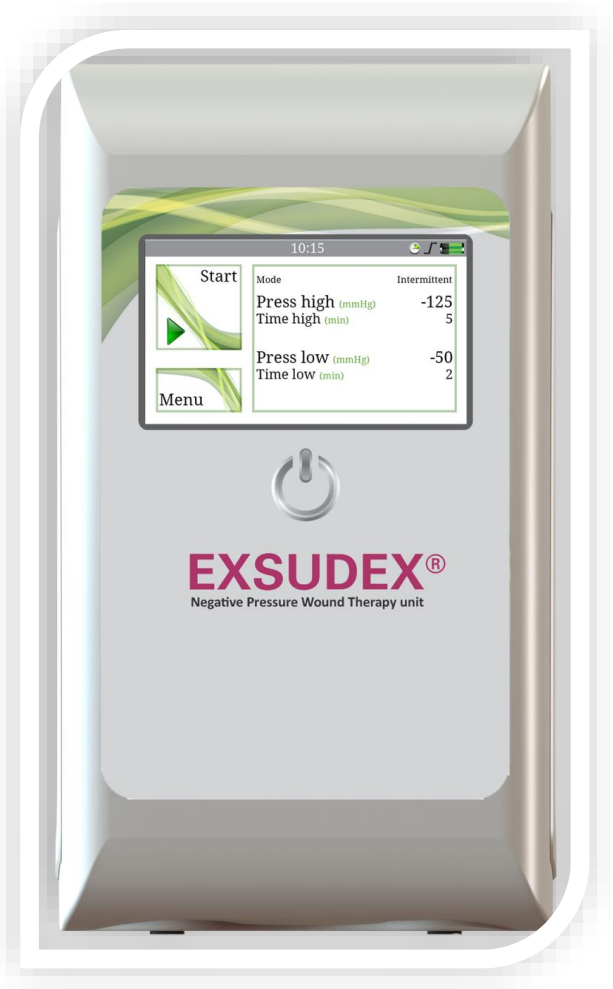

User Manual

EXSUDEX® XL

CONTENT

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CE
1912

Warning for US only

Patient Care Guidelines accompanies this device.
All caregivers should carefully read and follow this guideline.

If there are questions or if the sheet is missing immediately contact your local Exsudex XL representative.

The sheet can be found on the internet at:

https://www.meditop.nl/uploads/file/exsudex-patientcare-guidelines-version-1-0.pdf

Warnings and Safety issues

- In case of incidences with the Exsudex XL, the manufacturer must be notified.
- The Exsudex XL should only be charged with the supplied charger;
- Before connecting the charger please check if the on the charger specified voltage is the same as that in the building.
- The Exsudex XL is allowed for a maximum period of 30 consecutive days use.
- During operation keep the Exsudex XL upright.
- The Exsudex XL should only be attached to the patient by qualified medical personnel.
- The Exsudex XL should be used with special wound dressings and accessories.
- The Exsudex XL can only be connected via bluetooth if treatment is not active.
  Treatment can only be restarted again after closing of the bluetooth connection.
- In the following cases, the apparatus must not be put into operation:
  - Damage to cord and plug;
  - When the device is not functioning flawless;
  - When visible damage to the device appears;
  - When visible security flaws appears.
  - In this case we advise you to contact your dealer or technically qualified person within your company for a replacement device
    Do not keep using the Exsudex XL.
- The Exsudex XL should not be placed in water or other liquids.
- **Sleeping:**
  - Make sure the Exsudex XL is placed so that the tube cannot bent or clamped of.
  - Make sure the Exsudex XL cannot be pulled of your bedside table or fall to the floor in your sleep.
  - We recommend you to connect the Exsudex XL to the charger while you sleep.
- Be careful that no one can stumble over the power cord and tubing. Make sure there is no power cord and hose lying down or posted where people walk.

- All disposables and dressing kits are not designed for cleaning or re-use and must be properly discarded after patient use in accordance with local regulations for medical waste by the public health nurse.
- Take standard precautions with regard to dealing with body fluids or waste. Discharge all components in accordance with the procedure (s) of the institution and local and national regulations.
- In case of emergency, immediately contact your local emergency department.
- Repairs and maintenance may only be performed by qualified personnel that is authorized by The Medical & Woundcare Company or the manufacturer.
- Occupational safety and usability of medical devices are determined not only by your ability, but also the maintenance of the device (see chapter 7 - Maintenance)
- Qualified service and use of original spare parts guarantee the operational safety, usability and value of your medical device retained.
- The device is MRI unsafe and must be disconnected from the patient prior to MRI.
- The device may not be used in the event that defibrillation is needed. In such case the device must be disconnected. Be sure to remove the dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit transmission of electrical energy and/or patient resuscitation.

1 Device description

1.1 Indication for use

The Exsudex XL Wound Drainage Device is a compact, portable device that delivers a controlled negative pressure to a wound bed used for wound therapy.

CAUTION (US ONLY):
Federal law restricts this device to sale by or on the order of a physician, or with the descriptive designation of any other practitioners licensed by the law of the State in which that person practices to use or order the use of the device.

1.2 Function & application

Exsudex XL is an apparatus which produces a pre-set negative pressure between -10 to -200 mmHg by means of a wound drainage pump. The negative pressure is built up in an external canister.
The Exsudex XL Wound Drainage Device is connected to the external canister by means of a disposable canister:

Mounting the disposable canister to the device.

Ensure the back of the Exsudex XL is fitted with the special knob for the canister. (see picture).

Make sure this knob is in a horizontal position.

Put the canister over the knob and turn the knob a quarter turn.

The canister is now precisely mounted on the Exsudex XL and ready for use.


Exsudex XL back plate


Exsudex XL with attached canister

Continuous, automatic checking of the level of negative pressure is achieved by controls which check for the existence of the following:

- An inability to achieve the required level of negative pressure
- Any loss of negative pressure
- Deviation from a level of negative pressure exceeding the set tolerance

The Exsudex XL pump is a means for building negative pressure. The canister, when connected to the pump, functions as wound fluid storage.
The Exsudex XL consists of a medium sized housing that contains a vacuum pump and control system with a location for a fluid canister system. There is also a bacterial filter which is plugged directly into housing in the pump and replaced as necessary. Accessories include a bed clamp, infusion pole clamp and carry bag. For the expanded indication of use for wound healing the unit is used in conjunction with accessory kits conforming to the guidelines for dressings developed by Chariker et al1 already available in the U.S. market. This kit consists of individually reviewed medical components that have added instructions for use. The kits are considered “Convenience Kits,” falling under the General Surgical classification (see 21 CFR 878.4800.)

A drain is placed in the wound. The drain is connected by tubing to the Exsudex XL wound drainage pump. A gauze dressing is placed over the drain and secured by a seal over the wound bed. A seal has to be achieved and maintained over the wound to allow negative pressure to build. The pump will continue to generate negative pressure over a period of time dictated solely by the decision of the clinician. The pump will use dressing kits developed in accordance with the research of Chariker et al. and currently available in the U.S. market.

The pump is designed with several functions and warnings.
All these are controlled by a micro-processor.

- Pump speed
- LCD display
- Function keys
- Pressure measurements
- Canister full monitoring
- Warnings

The device has been designed with the following safety precautions:

- Overflow valve – which is a manual safety feature positioned into the cap of the suction canister. If fluid reaches a maximum level in the canister, floats in the overflow valve will block the inlet port, causing suctioning to automatically stop. This overflow protection prevents back-up of fluid to either the pump or the patient.
- Warning control, check at every pressure setting -10 up to -200mmHg:
- Inability to exceed a pressure higher than –10mmHg
- Warning when pump is out of tolerance
- Reservoir full notification
- Battery- low notification
- Standby warning

1.3 Use

To use the pump, the suction tube must be connected to the canister and to the pad or drain.
After checking the set up and confirming connection between the canister and the drain, the Exsudex XL (see section 3 - Operation) is activated by pressing the start button.

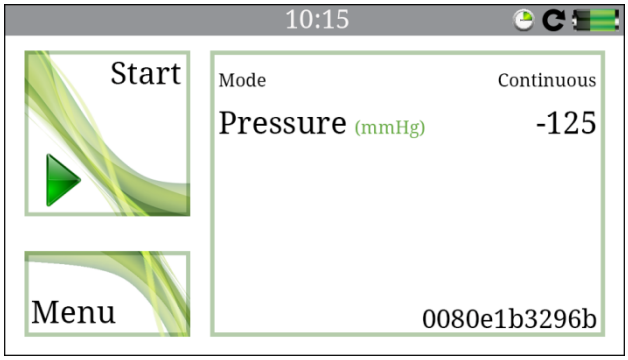
The machine may only be used with the Exsudex XL Disposable Canister.

It is recommended that the Exsudex XL is serviced on an annual basis by an approved technician.

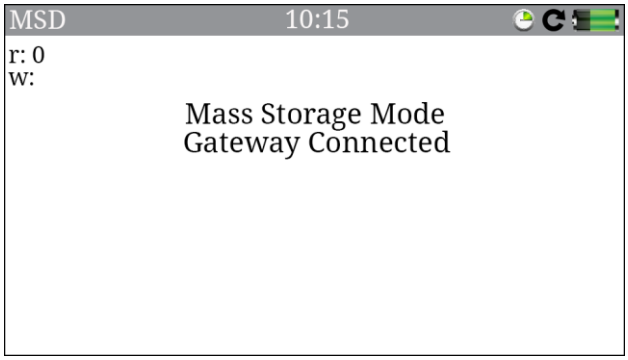
1.4 Bluetooth connection

The Exsudex XL is provided with a Bluetooth module to be connected to a PC or Laptop.
This connection can be used to read data to read or to adjust ID-data.

The Exsudex XL can only be connected via bluetooth with the Exsudex XL Gateway if treatment is not active!
Treatment can only be restarted again after closing of the bluetooth connection.



Display when bluetooth is On



Display when connected to the Gateway

For safety reasons it is not possible to adjust settings via the Bluetooth connection.

1.5 Intended use

1.5.1 Indications for use

The Exsudex XL is indicated for all patients that benefit from negative pressure therapy for wound treatment.

1.5.2 Contraindications

The Exsudex XL is contraindicated for the following reasons for Wound Treatment:

- Neonates
- Patients with clotting problems
- Patients suffering from epidermiolysis bullosa indication

The Exsudex XL is contra-indicated for the following parts of the body/tissue used in/on/for or to interact with:

- Close to exposed viscera and blood vessels,
- Exposed organs,
- Necrotic wound bed,
- Untreated osteomyelitis,
- Neoplastic tissue in the wound area,
- Malignant wounds

1.5.3 Precautions and Cautions

Side-effect(s) from the devices operating principle and use

- May result in angiogenesis and the formation of granulation tissue in open (acute) wound edges

Precautions:

- Patients on anticoagulants or with difficult homeostasis should be treated with caution and have to be controlled regularly for bleeding.
- Patients with infections in the wound and or other parts of the body.
- Non-compliant patients
- The Exsudex XL has not been studied on pediatric patients.

General Precautions for all indications for use:

- Health care provider must evaluate patient to ensure that use of the Exsudex XL is an appropriate use for the patient.

Cautions:

⚠	Physicians should consider patient's size and weight when prescribing device.
⚠	The device is MRI unsafe and must be disconnected from the patient prior to MRI.
⚠	The device may not be used in the event that defibrillation is needed. In such case the device must be disconnected. Be sure to remove the dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit transmission of electrical energy and/or patient resuscitation.
⚠	The device may not be used in a hyperbaric oxygen chamber.
⚠	To prevent unintentional gauze retention, all dressings are removed from the wound and wound bed. Upon removal of dressing(s), the wound bed should be cleaned in accordance with standard wound care practices, prior to the application of new sterile dressing.
⚠	If necessary all wounds should be debrided prior to application of the therapy and/or dressings.
⚠	Ensure there are no pockets left in the wound bed after application of the dressing.
⚠	Infected wounds may need more frequent dressing changes, up to twice a day, and the patient and the wound must be inspected regularly for signs of increased infection or sepsis.
⚠	Patients who do not have adequate homeostasis, who use anticoagulation or platelet aggregation inhibitors have an increased risk of bleeding with or without the Exsudex XL.
⚠	The device has not been studied in pediatric patients. All arteries, veins, tendons, ligaments, nerves and other organs have to be covered completely prior to application of the Exsudex XL.
⚠	Infected tissue such as blood vessels may have a weakened structure and have to be treated with care. Infected blood vessels may bleed more readily than normal blood vessels
⚠	The device is intended for acute, institutional, and long-term care use and only when prescribed by a physician. Product may be indicated for patient home-care, when carefully monitored by licensed home health-care providers, and only when prescribed by a physician.

1.5.4 Considerations for treatment in a Home setting

Caution:

For patients with an increased risk of bleeding complications, treatment must take place in an environment suitable for their situation and must be monitored by the treating physician.

We recommend you to take the following points, in addition to the contraindications, warnings and precautions, in consideration.

Situation of the patient:

- Clinical condition (adequate hemostasis and a low risk of active and / or severe bleeding in the wound area)
- Home Environment (Are patient or family member/caregiver able to solve, respond to warnings and to read and understand the safety instructions on the label)

Wound of the patient:

- All exposed, on surface vessels and organs in and around the wound must be completely covered and protected before the Exsudex XL can be applied.
- At the start of the treatment the negative pressure setting and therapy mode which will be used should be considered. (Continuous suction or intermittent suction)

1.6 Single use disposables (US only)

For the indication of use for wound healing, the device is used in conjunction with accessory kits conforming to the guidelines developed by Katherine Jeter and Dr. Mark Chariker.[1] Similar kits are already available in the U.S. market. The kits consist of individually reviewed medical components from existing manufacturers that have met the regulatory requirements of the FDA (see 21 CFR 878.4800) and include separate, additional instructions for use.

The Kits include:
1. Silicone or Wound drain
2. Connecting tubing
3. Impregnated gauze
4. Gauze fill material
5. Polyurethane Cover dressing
6. Skin prep

Exsudex XL Disposable Canister with integrated bacterial filter
Disposable canister 900 cc
Filter/Positive Shut-Off Valve - Proven filter effectively traps aerosolized microorganisms and particulate matter. Validated shut-off valve prevents fluid overflow.
Easy to Read -Etched and printed graduations ensure total volume accuracy and easily read measurements. The smudge-free surface provides adequate space for marking patient information.
This canister is non-sterile and is designed to be discarded when full or partially full.
Solidifier available

- Effectively gels potentially serious infectious waste within the suction canister quickly.
- Quickly penetrates throughout canister to solidify blood and body fluids
- Gels in seconds, ten times faster than other solidifiers
- No shaking required
- Retains solidity to prevent spills and leaks for safe and easy bagging and easy transport to disposal
- Chlorine-free for non-toxic incineration

The Exsudex XL can also be used in combination with foam kits which met the regulatory requirements of the FDA.

[1] *Effective Management of Incisional and Cutaneous Fistulae With Closed Suction Wound Drainage, Mark E. Chariker MD, Katherine F. Jeter, Ed.D., et al, Contemporary Surgery, Vol. 34 June 1989, pp. 59-63.*

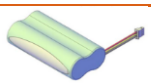
2 Product components

2.1 Scope of delivery

Description	Qty.
Exsudex XL wound drainage system	1
Bed clamp (integrated in back plate)	1
Power adapter 5V – 2A **(The Exsudex XL may only be charged with this original supplied power adapter!)**	1

2.2 Product components and accessories

The following items can only be ordered through The Medical & Woundcare Company or one of its dealers:

Part description	Product code	Picture
Exsudex XL Disposable canister with fixed tube with luer-lock connector	16670	
Exsudex XL battery 3.7V	3000558	
Exsudex XL power adapter 5V – 2A, length 4 meter. (EU = European plug, USA = USA plug)	3000723-EU 3000723-USA	

Note 1:
A tubing set which is compatible with the use in negative pressure (-200 mmHg) must be chosen.

Note 2:
A reusable collecting system, whether or not in combination with a disposable collection bag can be used provided that:

- It has a maximum capacity of 1.3 liter;
- It is equipped with an overflow protection;
- It is equipped with a sachet solidifying agent 25G.
- The connection is compatible with the Exsudex connector.

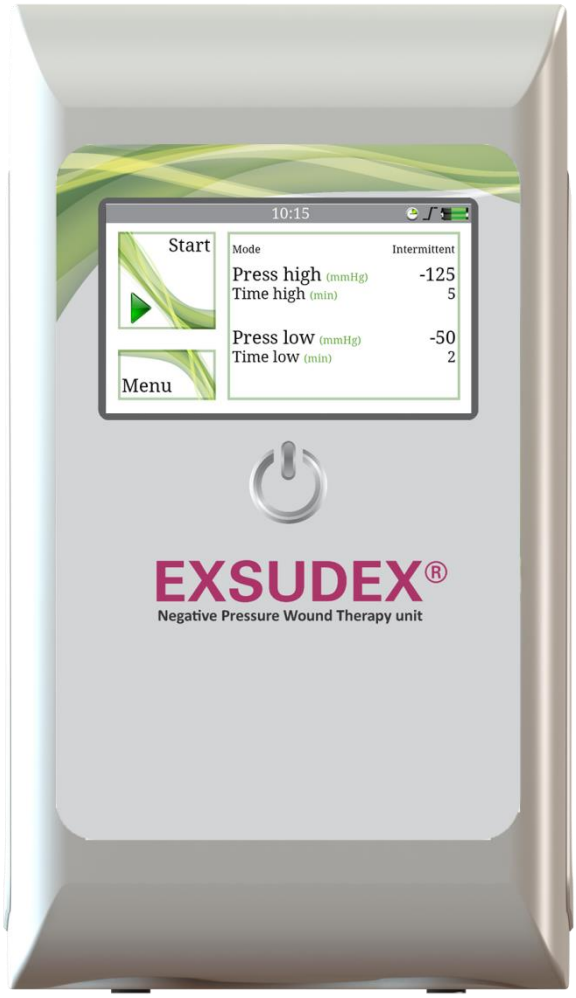
CAUTION:

If another collection system is used as the Exsudex XL disposable canister with solidifying agent the manufacturer cannot guarantee a proper operation of the "reservoir full" warning.

3 Operation

The unit has to be turned on by means of the switch, see picture below, on the front of the apparatus.

After which the apparatus is controlled by means of the buttons (Start and Menu) on the touch screen.
The Exsudex XL is equipped with a touch screen display on the front of the device.
This screen displays information about the current function or setting. It is also to be used for the operation of the device and modifying the settings.
You need to operate the touch screen only with your fingers.
The use of pens or pointing devices can damage the screen, which can affect the operation of the device.



Switching off the device can only if the pump is not running by pressing the main switch for 3 seconds

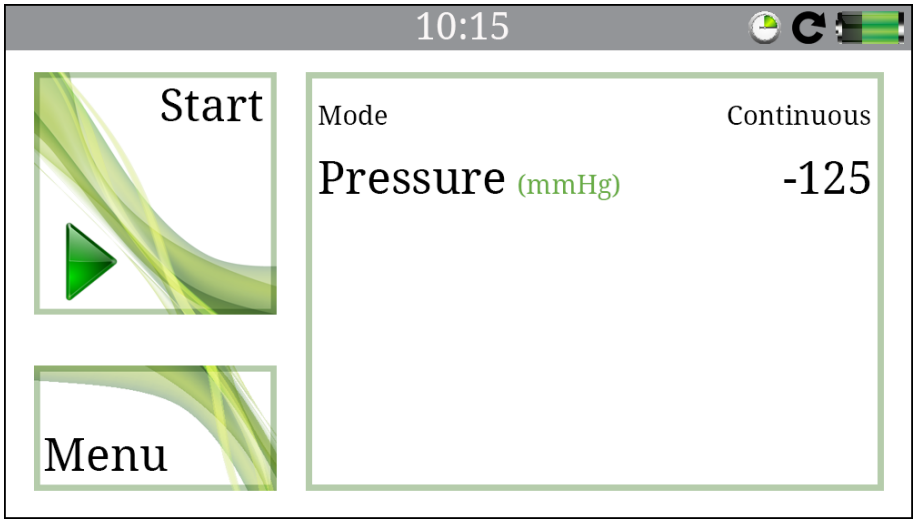
The Exsudex XL has 2 buttons in the Main menu:

Start Starting the treatment with the Exsudex XL.

Menu Cycle through the menu
The menu can be switched on or off in order to prevent the ability that the patient can adjust the settings.
To enable and disable the menu, we refer to
Chapter 3.1.5 - Disabling and Enabling Settings Menu

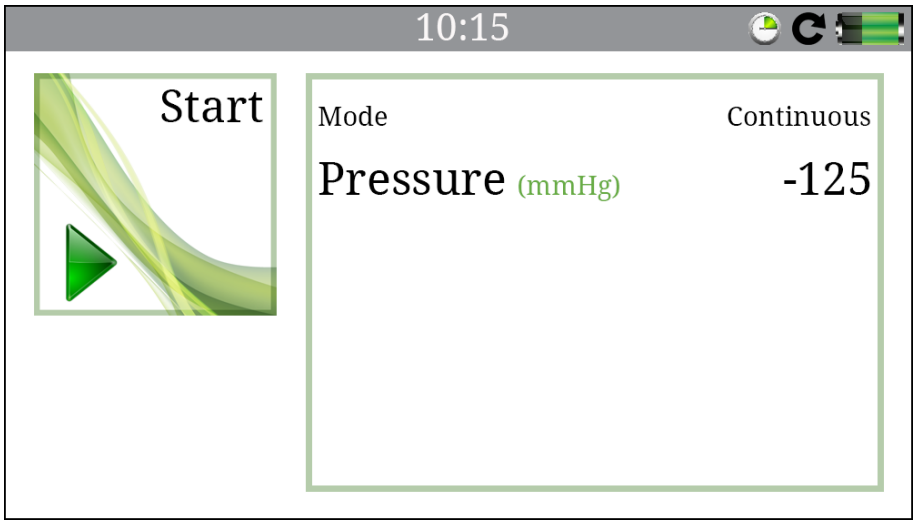
Main menu in Continuous Mode with menu settings enabled (0n)

The shown values on the screen are the current settings.
Pressing on this field will open the Users Menu (see chapter 3.1.1 - User settings)



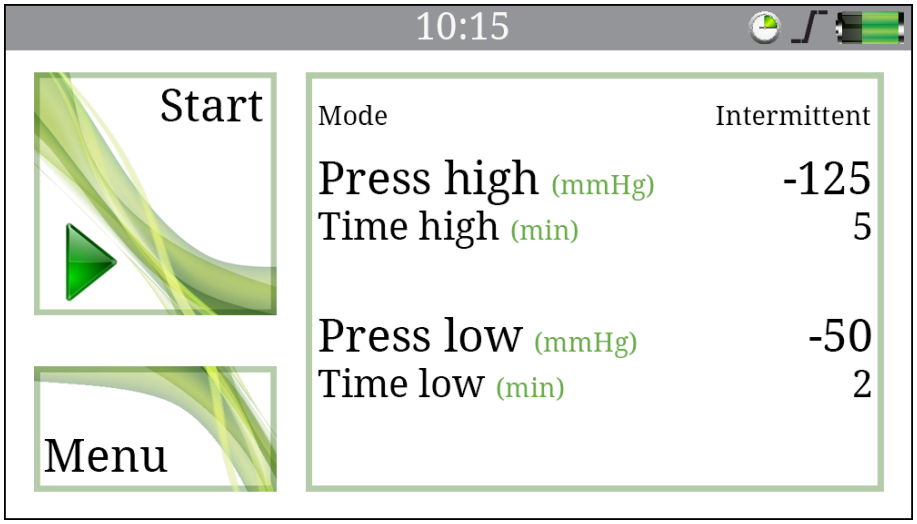
Main menu in Continuous Mode with menu settings disabled (0ff)

The shown values on the screen are the current settings.
Pressing on this field will ***not*** open the Users Menu.



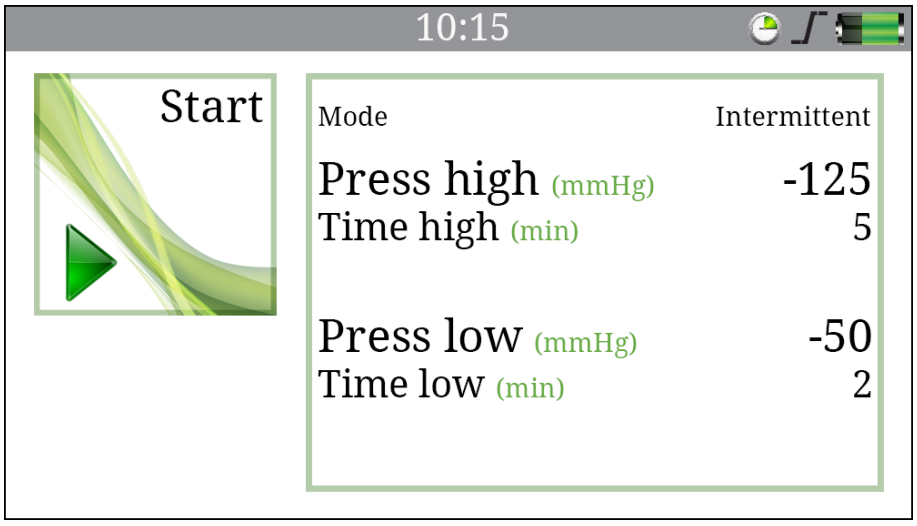
Main menu in Intermittent Mode with menu settings enabled (0n)

The shown values on the screen are the current settings.
Pressing on this field will open the Users Menu (see chapter 3.1.1 - User settings)



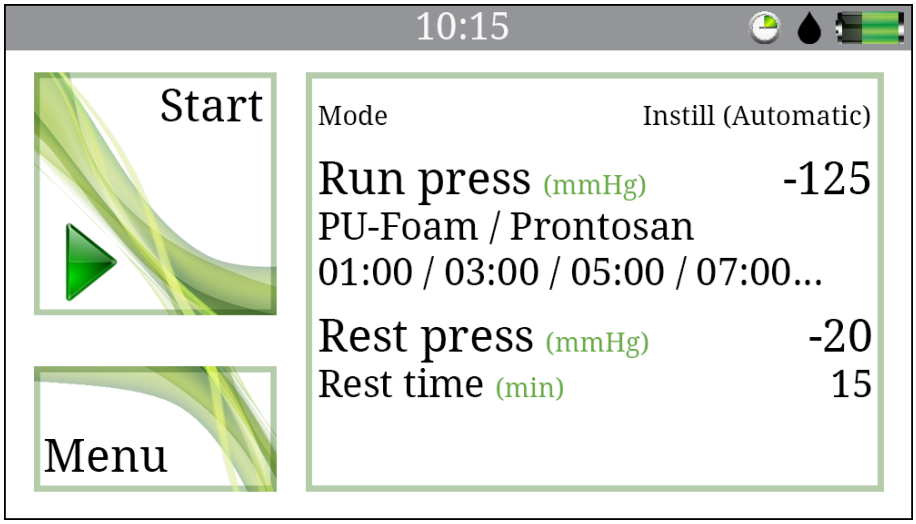
Main menu in Intermittent Mode with menu settings disabled (0ff)

The shown values on the screen are the current settings.
Pressing on this field will ***not*** open the Users Menu.



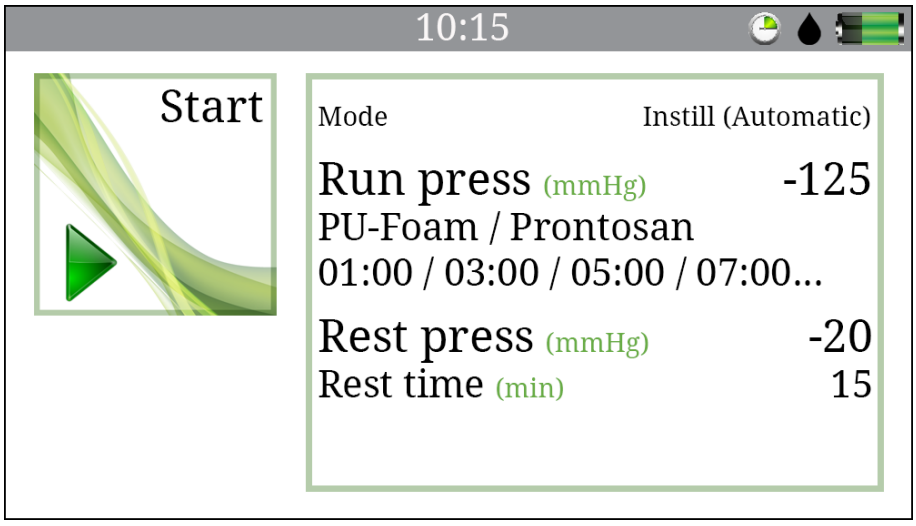
Main menu in Instill mode (Automatic) with menu settings enabled (0n)

The shown values on the screen are the current settings.
Pressing on this field will open the Users Menu (see chapter 3.1.1 - User settings)



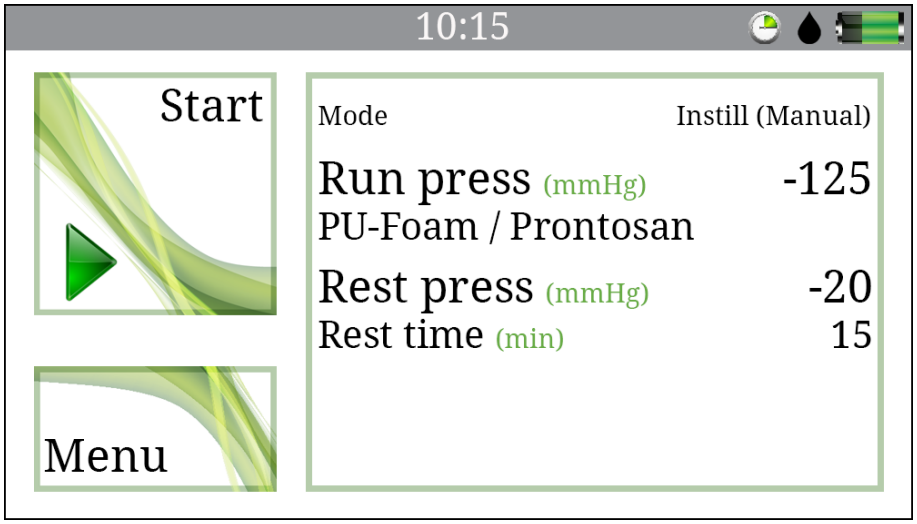
Main menu in Instill mode (Automatic) with menu settings disabled (0ff)

The shown values on the screen are the current settings.
Pressing on this field will *not* open the Users Menu.



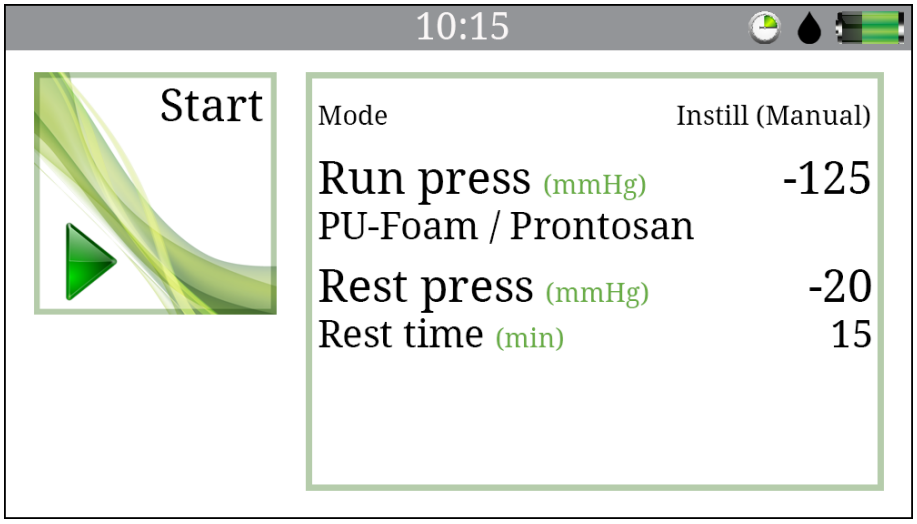
Main menu in Instill mode (Manual) with menu settings enabled (0n)

The shown values on the screen are the current settings.
Pressing on this field will open the Users Menu (see chapter 3.1.1 - User settings)



Main menu in Instill mode (Manual) with menu settings disabled (0ff)

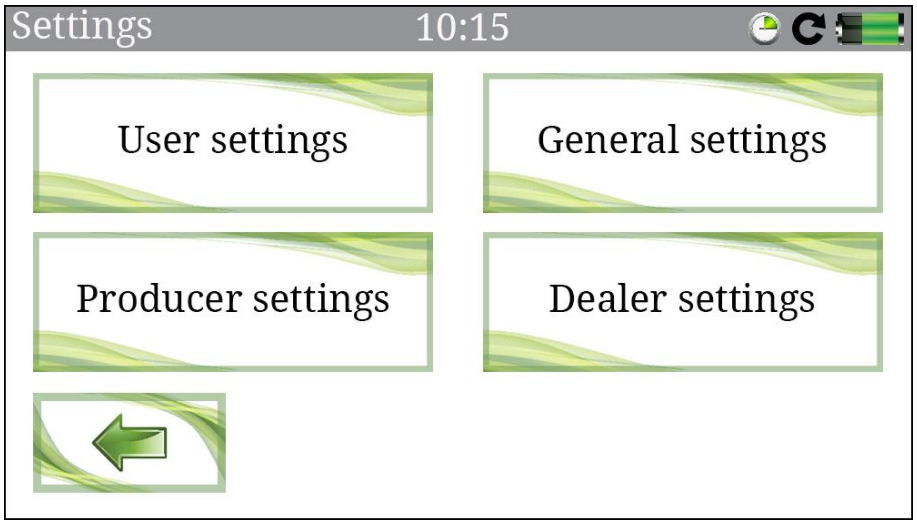
The shown values on the screen are the current settings.
Pressing on this field will ***not*** open the Users Menu.



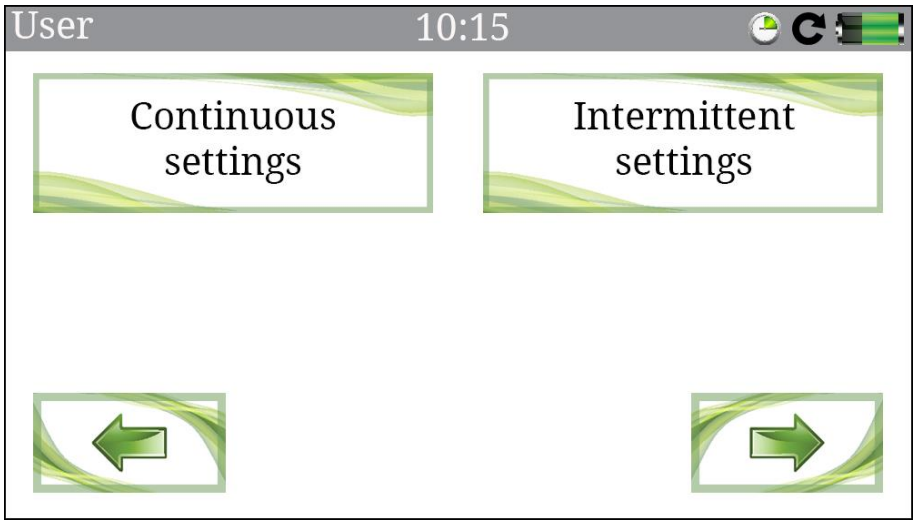
3.1 Settings

To adjust the settings the pump of the Exsudex XL must not be running.
In a home care situation, the nurse must disable the menu after the settings have been done.
See chapter Chapter 3.1.5 - Disabling and Enabling Settings Menu

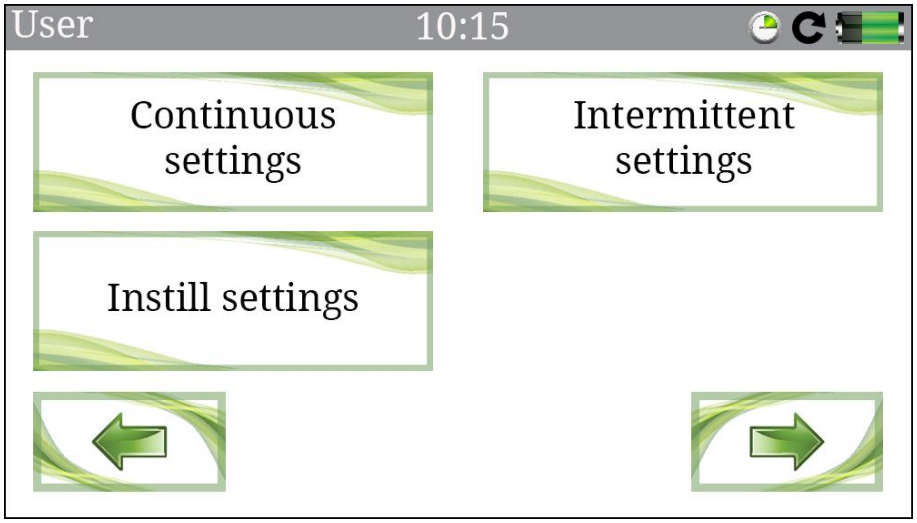
Press on “Menu” 



3.1.1 User settings



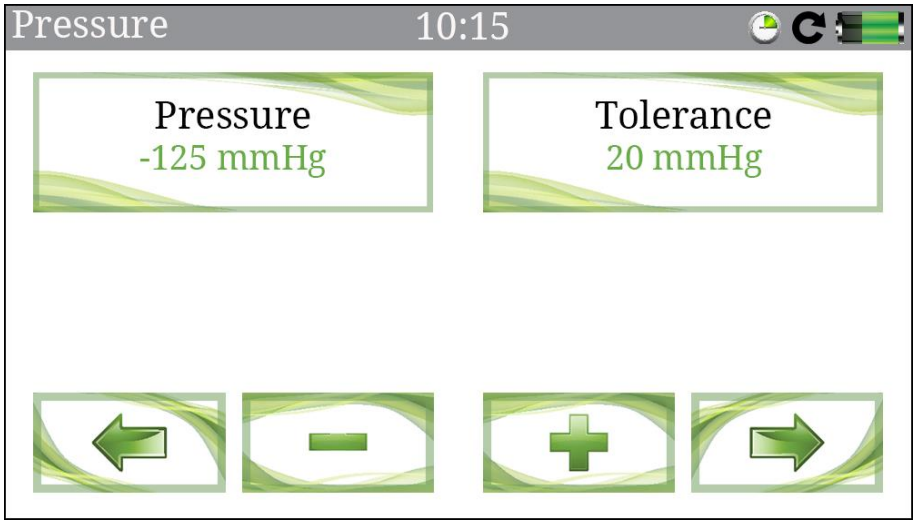
Display when Instill mode is disabled



Display when Instill mode is enabled

3.1.1.1 Continuous settings

Press in the User menu on “Continuous settings”.



Press on the setting you want to adjust.
It will now be dark outlined.
With the and button you can adjust the setting.

The available pressure ranges from -10 to -200 mmHg in 5 mmHg steps.
The deviation tolerance for the negative pressure can be set between 5 to 80 mmHg in 5 mmHg steps.
The notification “Leakage Check Dressing” will sound if the pressure in the system deviates from the set pressure by more than the pre-set tolerance. For example, if the pressure is set on -120 mmHg and the tolerance is set on 20 mmHg the notification will sound if the pressure in the system is less than - 100 mmHg.

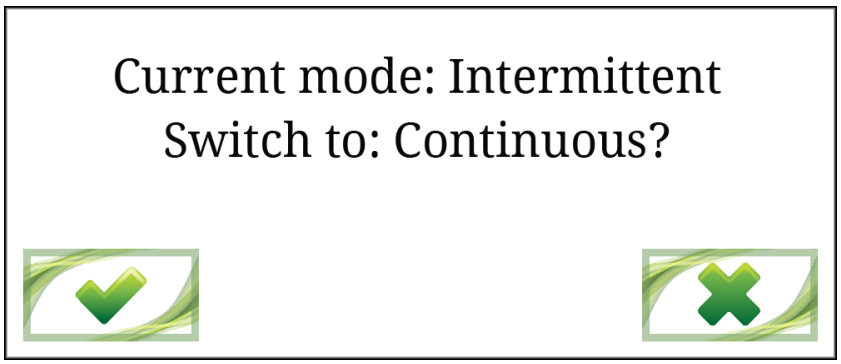
When done:
Press to go back to the Users menu or

Press to start with the treatment.

When Continuous is enabled the next symbol will be shown on the right side in the grey menu bar:

Note:

If continuous mode is not enabled the next message will be shown on the display when for example intermittent mode is enabled:



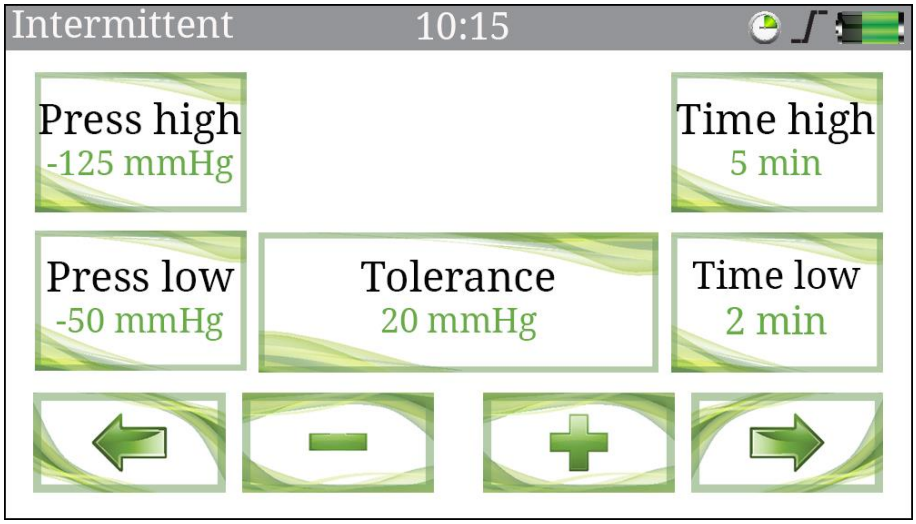
In which:

 : results in continuing to the menu.

 : results in returning to the user menu.

3.1.1.2 Intermittent settings

Press in the User menu on “Intermittent settings”.



Press on the setting you want to adjust.
It will now be dark outlined.
With the and button you can adjust the setting.

Pressure High:	Setting between -10 and – 200 mmHg in steps of 5 mmHg
Time High:	Setting between 30 seconds (0.5 min) and 10 minutes in steps of 30 seconds
Pressure Low:	Setting between -10 and – 200 mmHg in steps of 5 mmHg
Tolerance:	Setting between 5 and 80 mmHg in steps of 5 mmHg
Time Low:	Setting between 1 minute and 10 minutes in steps of 30 seconds

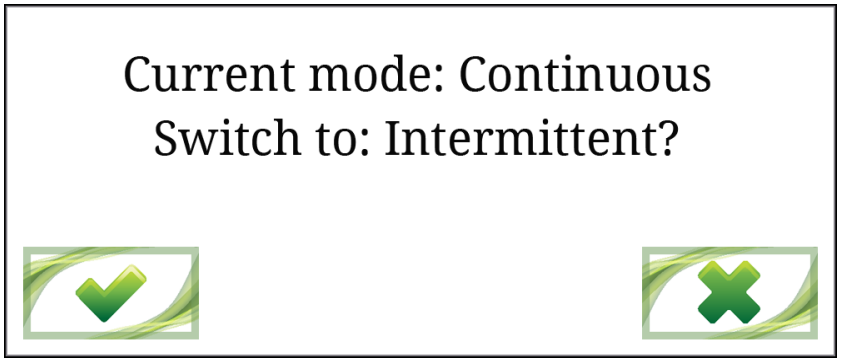
When done:
Press to go back to the Users menu or

Press to start with the treatment.

When Intermittent is enabled the next symbol will be shown on the right side in the grey menu bar:

Note:

If Intermittent mode is not enabled the next message will be shown on the display when for example continuous mode is enabled:



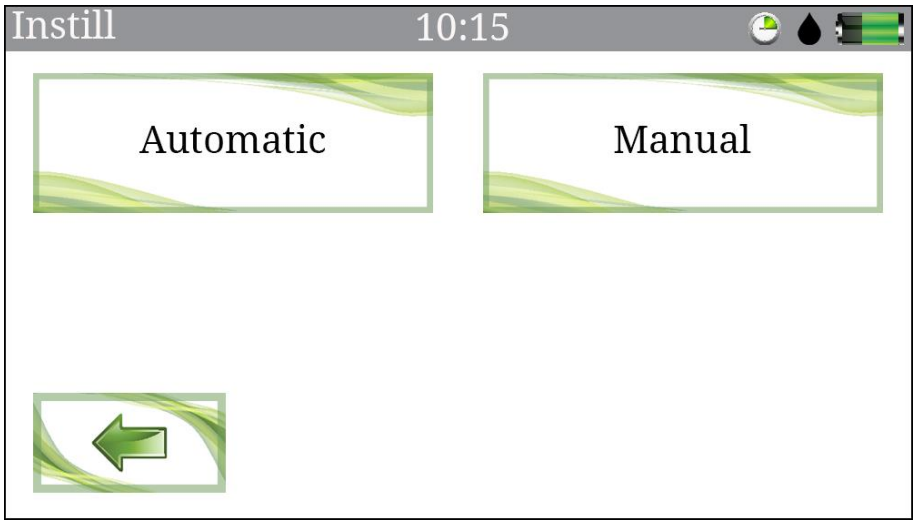
In which:

 : results in continuing to the menu.

 : results in returning to the user menu.

3.1.1.3 Instill settings (only when available)

Press in the User menu on “Instill settings”.



Automatic: This mode includes a notification which alerts the nursing staff when fluid (medication) is to be administered.
You can adjust how many times (up to 12 per day) and the number of days (up to 5) fluid should be administered to the patient.

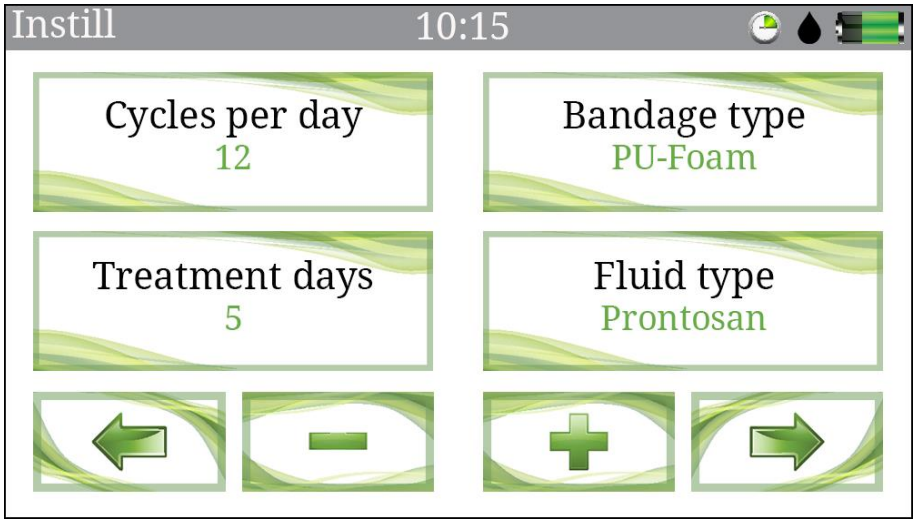
Manual: You must manual start the fluid administration.

3.1.1.3.1 Instill in automatic mode (only when available)

This mode includes a notification which alerts the nursing staff when fluid (medication) is to be administered. You can adjust how many times (up to 12 per day) and the number of days (up to 5) fluid should be administered to the patient.
Also the type of bandage and fluid is adjustable

The displayed rest time per fluid type is based on the minimum time as specified by the manufacturer of the fluid. It remains at all times the responsibility of the attending physician and nursing staff to set the correct values!

Press in the Instill settings menu on 

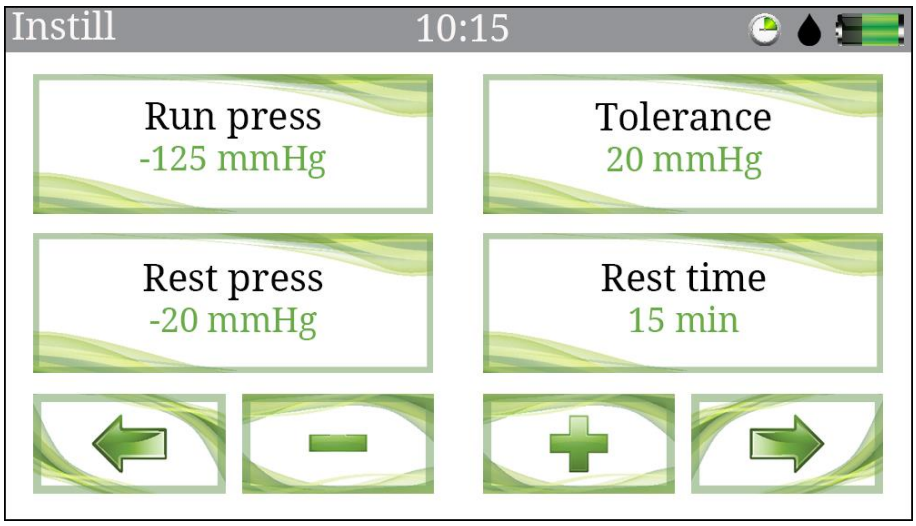


Press on the setting you want to adjust.
It will now be dark outlined.
With the  and  button you can adjust the setting.

Cycles per day: Number of fluid applications per day, setting between 1 and 12 in steps of 1.

Bandage type	Choice of: PU-Foam of Gauze If PU Foam is selected pressure default is set to -125 mmHg and If Gauze is selected pressure default is set to -080 mmHg. It remains at all times the responsibility of the attending physician and nursing staff to set the correct values!
Treatment days:	Number of days, setting between 1 and 5 days in steps of 1 day
Fluid type:	Choice of: Prontosan, Sanoskin or Various. In which Prontosan refers to the product Prontosan of B. Braun Medical and Sanoskin refers to the product Sanoskin Cleanser of Sanomed Manufacturing BV.

When done press  to go one menu further.



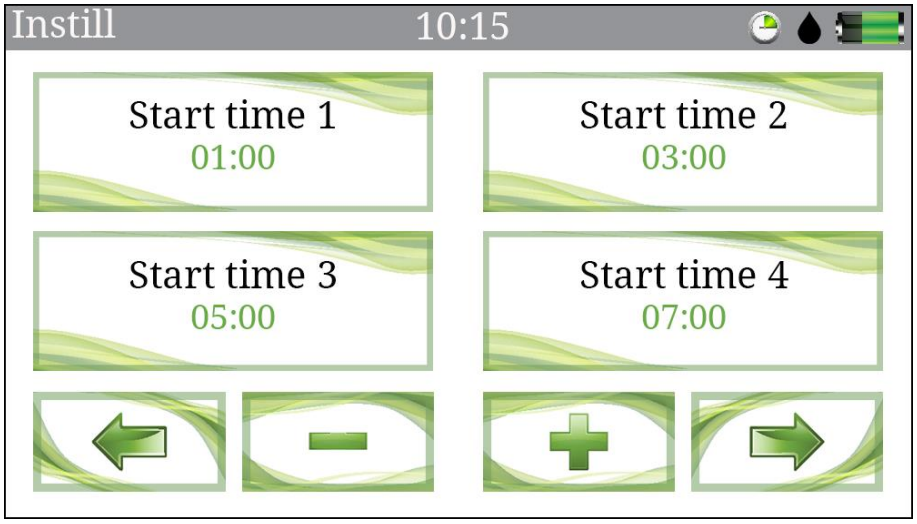
Press on the setting you want to adjust.
It will now be dark outlined.
With the and button you can adjust the setting.

Run press:	Continuous pressure, Setting between -15 and - 200 mmHg in steps of 5 mmHg Upon selection of PU-Foam default will be set to -125 mmHg and when gauze is selected default will be - 80 mmHg
Tolerance:	Setting between 5 and 80 mmHg in steps of 5 mmHg Note: This can never be lower than the lowest set pressure!
Rest press:	Pressure after fluid is administered, Setting between -10 and - 195 mmHg in steps of 5 mmHg
Rest time:	Time that Rest pressure is active after administration of fluid, Setting between 5 and 60 minutes in steps of 5 minutes. Upon selection of Various default will be set to 5 minutes (lowest setting) Upon selection of Prontosan or Sanaskin default will be set to 15 minutes (the minimum rest time prescribed by the manufacturer!)

The displayed rest time per fluid type is based on the minimum time as specified by the manufacturer of the fluid. It remains at all times the responsibility of the attending physician and nursing staff to set the correct values!

When done press to go one menu further.

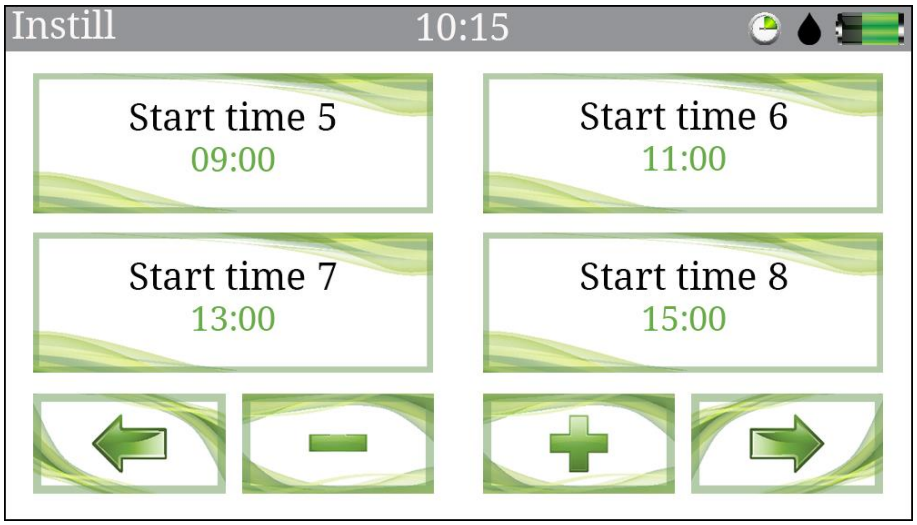
In this guide, we have assumed 12 cycles per day. Because of this there are three menu pages to follow, each with 4 start times. Depending on the set number the following pages may differ in number!



Press on the setting you want to adjust.
It will now be dark outlined.
With the and button you can adjust the setting.

Times can be set in steps of 15 minutes

When done press to go one menu further.



Press on the setting you want to adjust.
It will now be dark outlined.
With the and button you can adjust the setting.

Times can be set in steps of 15 minutes

When done press to go one menu further.

Press on the setting you want to adjust.
It will now be dark outlined.
With the  and  button you can adjust the setting.

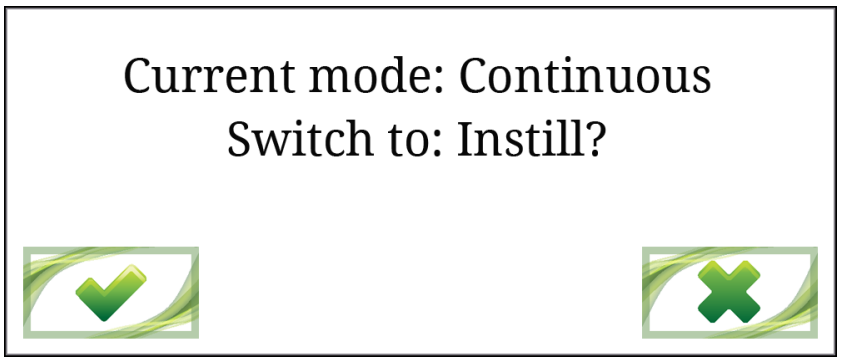
Times can be set in steps of 15 minutes

When done:
Press  6 times to go back to the Users menu or

Press  to start with the treatment.

When Instill is enabled the next symbol will be shown on the right side in the grey menu bar: ●

Note:
If Instill mode is not enabled the next message will be shown on the display when for example continuous mode is enabled:



In which:

 : results in continuing to the menu.

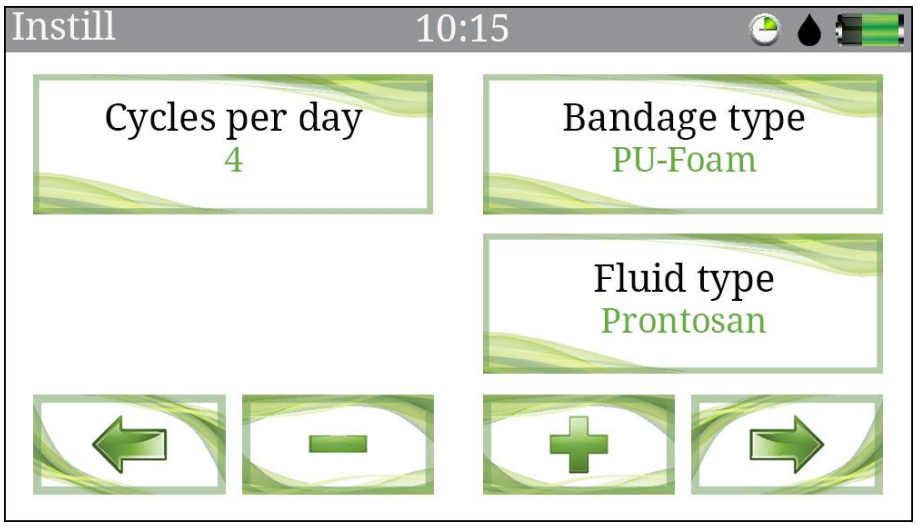
 : results in returning to the user menu.

3.1.1.3.2 Instill in manual mode (only when available)

This mode is included when fluid administration is done manually.
There will be no notification.

You can only press a button for the fluid administration resulting in going to the rest pressure.

Press in the Instill settings menu on 

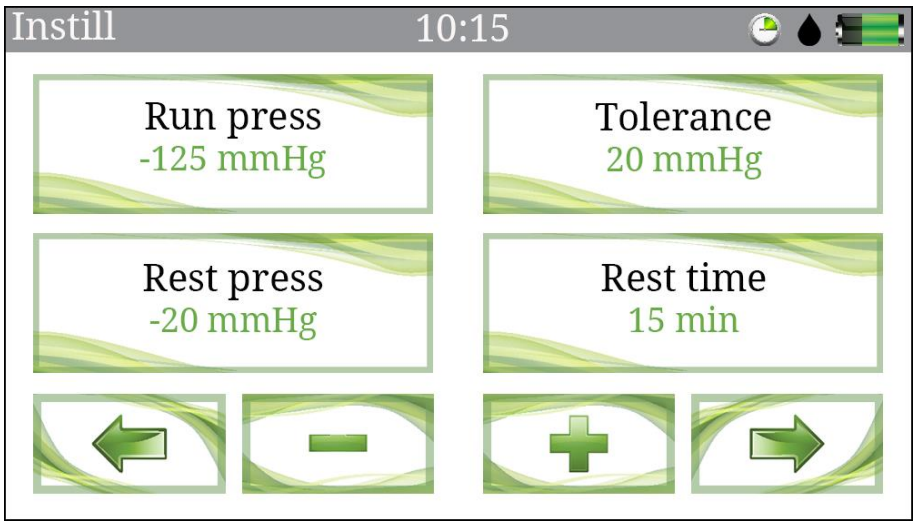


Press on the setting you want to adjust.
It will now be dark outlined.
With the  and  button you can adjust the setting.

Cycles per day: Number of fluid applications per day, setting between 1 and 12 in steps of 1.

Bandage type	Choice of: PU-Foam of Gauze If PU Foam is selected pressure default is set to -125 mmHg and If Gauze is selected pressure default is set to -080 mmHg. It remains at all times the responsibility of the attending physician and nursing staff to set the correct values!
Fluid type:	Choice of: Prontosan, Sanoskin or Various. In which Prontosan refers to the product Prontosan of B. Braun Medical and Sanoskin refers to the product Sanoskin Cleanser of Sanomed Manufacturing BV.

When done press  to go one menu further.



Press on the setting you want to adjust.
It will now be dark outlined.
With the and button you can adjust the setting.

Run press: Continuous pressure, Setting between -15 and - 200 mmHg in steps of 5 mmHg
Upon selection of PU-Foam default will be set to -125 mmHg and
when gauze is selected default will be - 80 mmHg

Tolerance: Setting between 5 and 80 mmHg in steps of 5 mmHg
Note: This can never be lower than the lowest set pressure!

Rest press: Pressure after fluid is administered, Setting between -10 and - 195 mmHg in steps of 5 mmHg

Rest time: Time that Rest pressure is active after administration of fluid,
Setting between 5 and 60 minutes in steps of 5 minutes.
Upon selection of Various default will be set to 5 minutes (lowest setting)
Upon selection of Prontosan or Sanoskin default will be set to 15 minutes (the minimum rest time prescribed by the manufacturer!)

The displayed rest time per fluid type is based on the minimum time as specified by the manufacturer of the fluid. It remains at all times the responsibility of the attending physician and nursing staff to set the correct values!

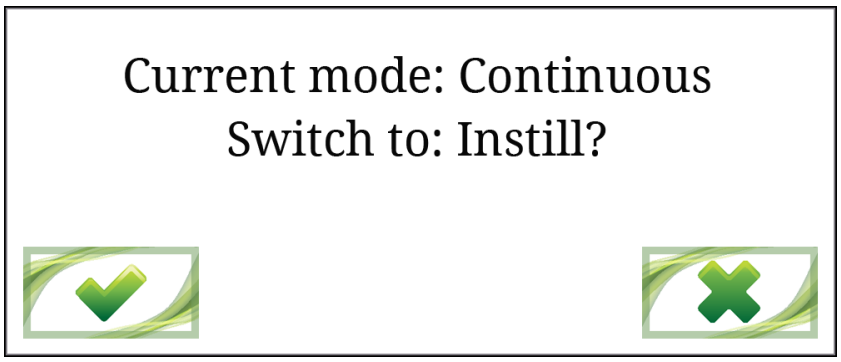
When done:
Press 3 times to go back to the Users menu or

Press to start with the treatment.

When Instill is enabled the next symbol will be shown on the right side in the grey menu bar:

Note:

If Instill mode is not enabled the next message will be shown on the display when for example continuous mode is enabled:



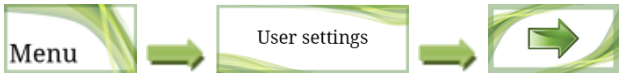
In which:

 : results in continuing to the menu.

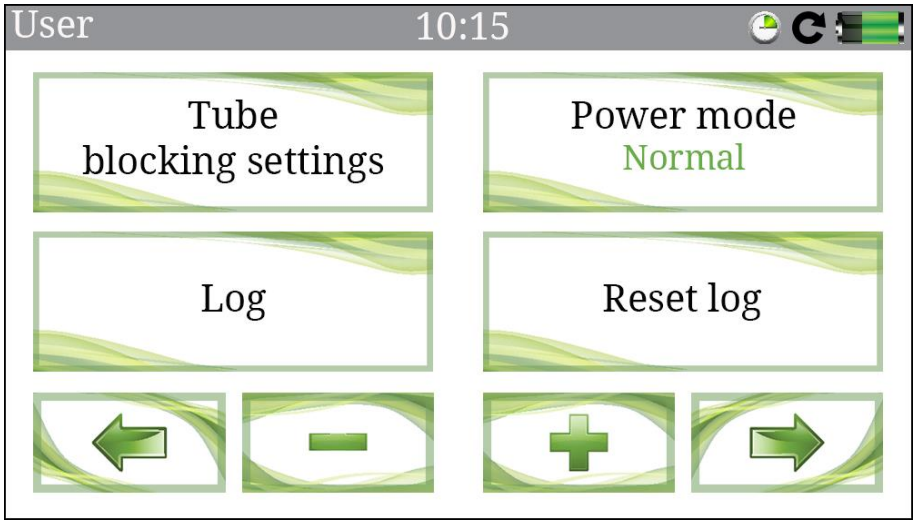
 : results in returning to the user menu.

User menu 2:

Press in the user menu on 



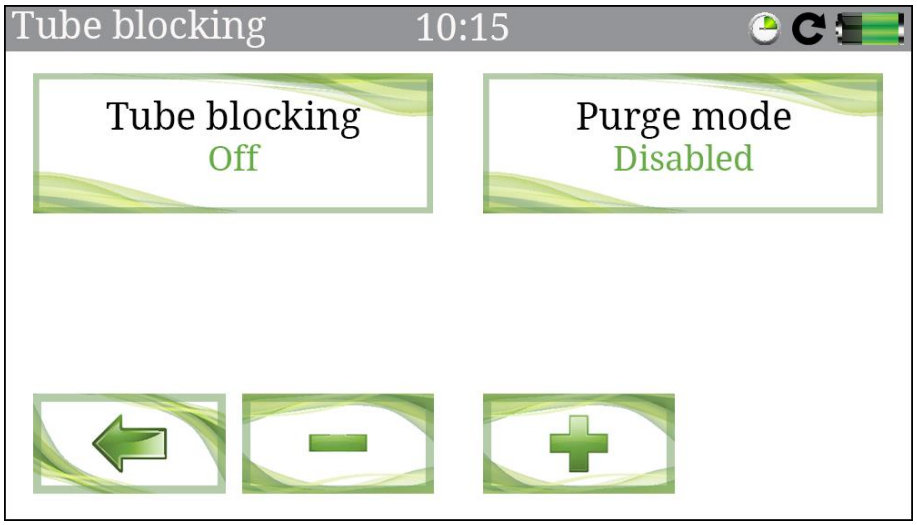
The 2nd user menu will be displayed



3.1.1.4 Tube blocking settings

Press in the 2nd User menu on “Tube blocking settings”

In this menu you can set Tube blocking and Purge mode



3.1.1.4.1 Tube blocking

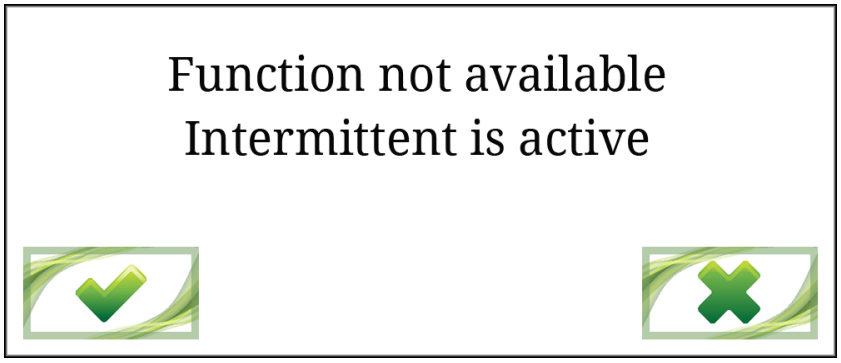
Press in the Tube blocking menu on “Tube blocking”.
It will now be dark outlined.
With the  and  button you can adjust the setting.

When enabled the next symbol will be shown on the right side in the grey menu bar: 

Note 1:
Tube blocking notification is functional during Purge mode in Interval mode.
If the set time for the tube blocking notification is equal to or longer as the interval time, the time will be automatically reduced for 1 minute as the set interval time!
Factory setting for tube blocking notification is set to 5 minutes.

Tube blocking notification is functional during Purge mode in Automatic mode.
At the third purge within a set time (4 times tube blocking notification time) the device will sound the tube blocking notification!

Note 2:
When intermittent is enabled tube blocking will not be available!
Display will show the next message:



In which:
 and  results in returning to the user menu.

When all settings are done press  to go back to the Settings menu.

3.1.1.4.2 Purge mode

Press in the Tube blocking menu on “Purge mode”.

It will now be dark outlined.
With the  and  button you can adjust the setting.

In some occasions it may occur that there is an “air lock” in the tubing.
In order to solve or prevent this you can enable the Purge mode.
At set times the Exsudex XL will release the pressure for a set time and restart treatment again.
(Values can only be adjusted by your local dealer)

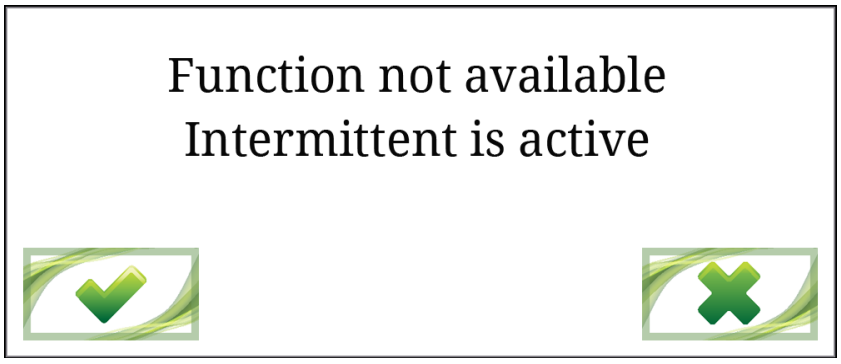
Disabled:
Purge mode is disabled.

Interval:
Every set time (factory setting is 5 minutes) the Exsudex XL will release pressure for a set period (factory setting is 1 second) and restart treatment again.
If the pump is running at the set time, releasing the pressure will be postponed until the pump stops running.

Automatic:
When the pump has not been running during a set time (factory setting is 5 minutes) the Exsudex XL will release pressure for a set period (factory setting is 1 second) and restart treatment again.

When set to Interval or Automatic the next symbol will be displayed on the right side in the grey menu bar: 

Note:
When intermittent is enabled Purge mode will not be available!
Display will show the next message:



In which:

 and  results in returning to the user menu.

When all settings are done press  to go back to the Settings menu.

3.1.1.5 Power mode

Press in the 2nd user menu on “Power mode”.

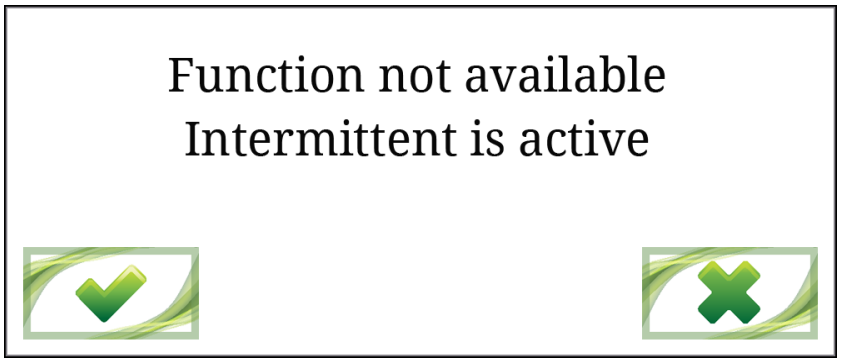
Power mode will now be dark outlined.
With the and button you can adjust the setting.
The Power mode can be set to Normal, Slow or Fast.

Normal mode:
Normal mode is the most common setting.
When set to Normal the time within the set pressure must be reached during first start is set to 40 seconds.

Slow mode:
When patients severe a lot of pain because of the treatment you can set the Power mode to Slow.
The slow mode function has a longer interval in controlling the motor which will result in a longer time before the pump reaches the set value.
When set to Slow the time within the set pressure must be reached during first start is set to 120 seconds.
When enabled the next symbol will be displayed on the right side in the grey menu bar:

Fast mode:
When you have a large wound and the pressure cannot be reached during the first start you can set the Power mode to fast.
The slow mode function has a faster interval in controlling the motor which will result in a shorter time before the pump reaches the set value.
When set to Fast the time within the set pressure must be reached during first start is set to 40 seconds.
When enabled the next symbol will be displayed on the right side in the grey menu bar:
When settings are done press to go back one menu.

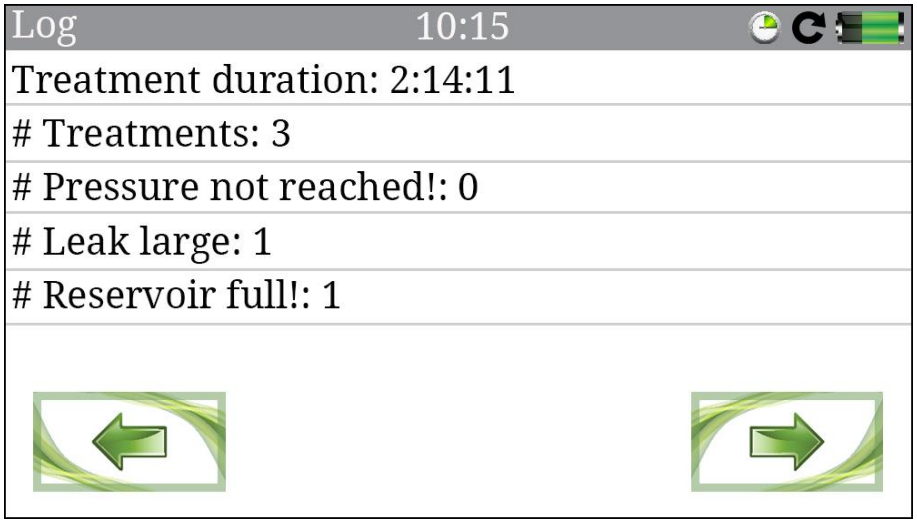
Note:
When intermittent is enabled Power Mode will not be available!
Display will show the next message:



In which:
and results in returning to the user menu.

3.1.1.6 Log

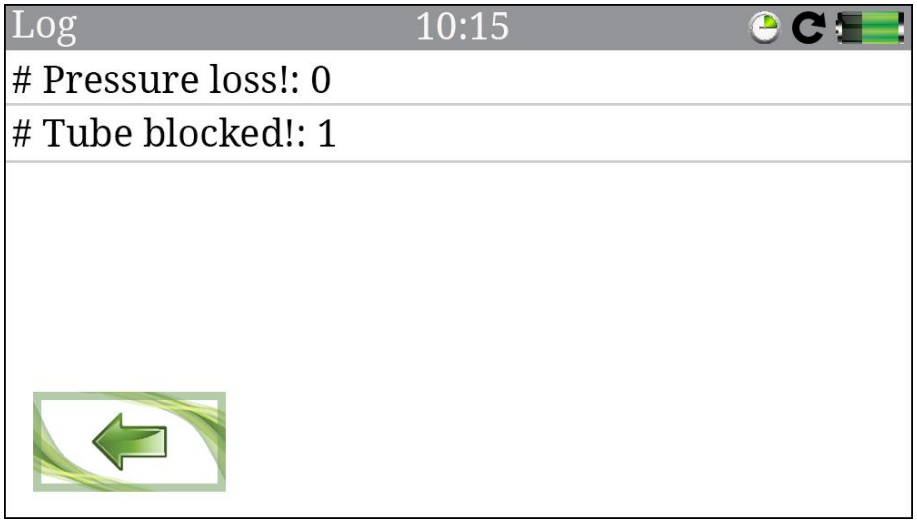
Press in the 2nd user menu on “Log”.



You will now see a list of stored data of the treatment:

- Treatment duration: in days : hours : minutes
- Treatments: in quantities
- Pressure not reached notification: in quantities
- Leak Large notification: in quantities
- Reservoir full notification: in quantities

Press to go to the next page



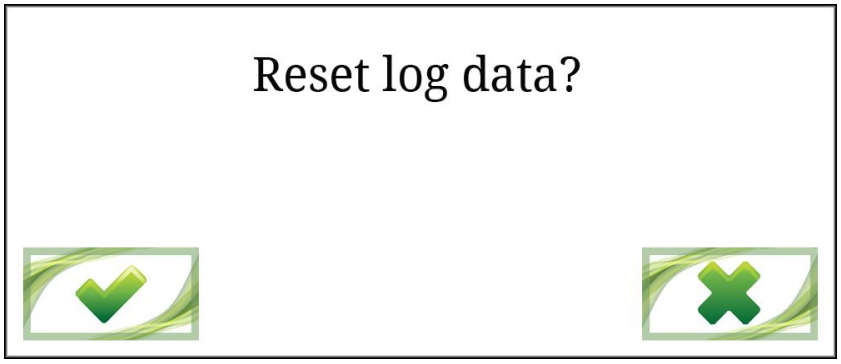
where appears following:

- Pressure loss notification: in quantities
- Tube blocked notification: in quantities

Press twice on to go back to the 2nd user menu.

3.1.1.7 Reset Log

Press in the 2nd user menu on “Reset Log”.



In which:

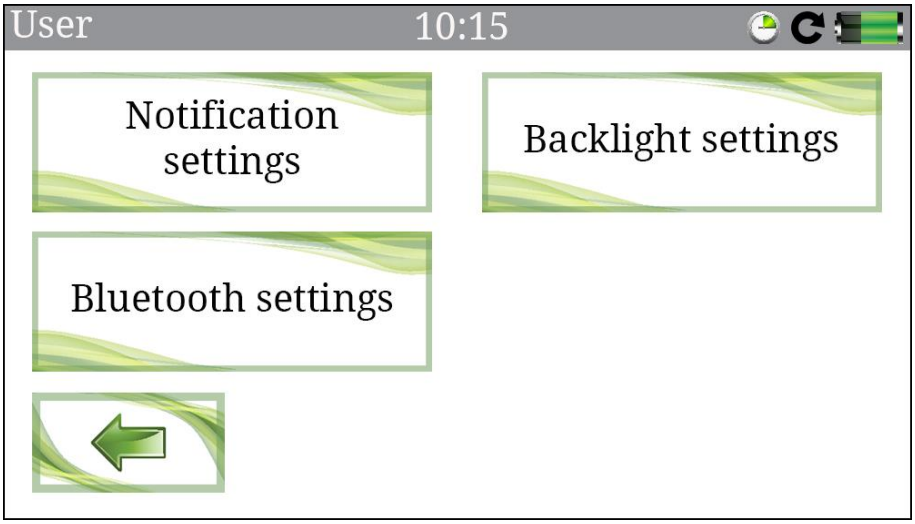
 : results in resetting to 0 for all the values in the log file.

 : results in returning to the menu without resetting the values.

User menu 3:

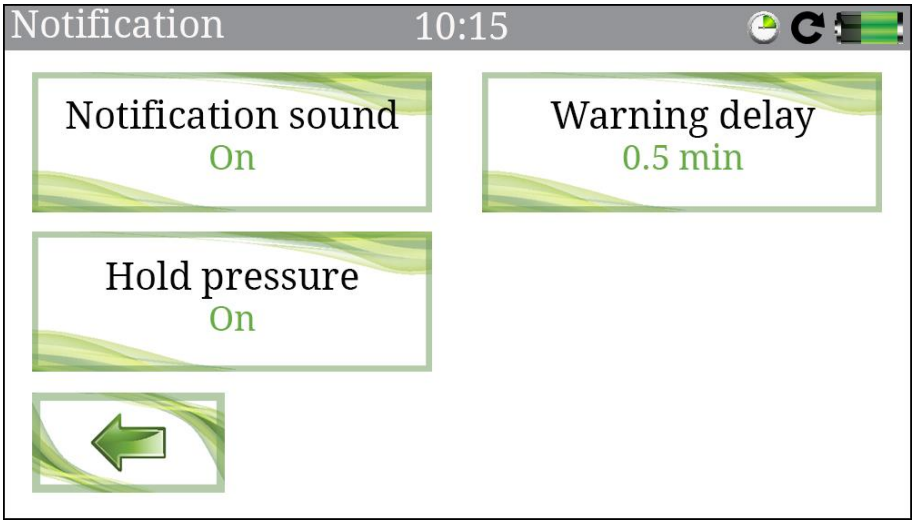
Press in the 2nd user menu on 

The 3th user menu will be displayed



3.1.1.8 Notification settings

Select in the Users menu “Notification settings”.



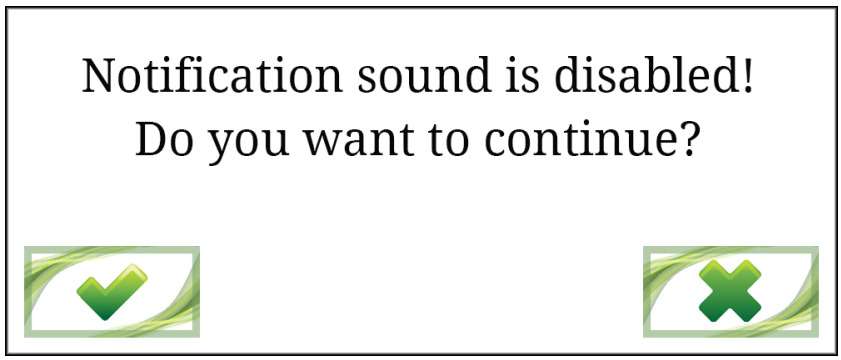
3.1.1.8.1 Acoustic warning (Notification sound)

Press in the Notification menu on “Notification sound”.
It will now be dark outlined.
With the  and  button you can adjust the setting.
The sound notification can be set On or Off.

However, the sound notification for battery low, standby warning and Instill will not be turned off, for all other warnings, the acoustic signal will be set off.
The warnings themselves remain active and will be visually displayed on the screen.

When disabled the next symbol will be shown on the right side in the grey menu bar: 

NOTE:
When set to Off the Exsudex XL will display a message to remind you that the sound notification is disabled.



In which:

 : Starts the treatment

 : Results in opening the Notification setting.
You now can change the acoustic warning setting
Note that the Standby warning will sound after 5 minutes if the pump is not activated again

3.1.1.8.2 Warning delay

Press in the Notification menu on “Warning delay”.
It will now be dark outlined.
With the  and  button you can adjust the setting.
Following settings are available:

Off	(0 min),
15 seconds	(0.25 min)
30 seconds	(0.5 min),
1 minute	(1 min),
2 minutes	(2 min),
3 minutes	(3 min),
4 minutes	(4 min) or
5 minutes	(5 min).

When enabled the next symbol will be shown on the right side in the grey menu bar: 

When done press  to go one menu further.

3.1.1.8.3 Hold pressure

Hold pressure is a feature which in all, non-pressure-related notifications, holds the build-up negative pressure until a nurse can get the Exsudex XL back on line.

Press in the Notification menu on “Hold pressure”.
It will now be dark outlined.
With the  and  button you can adjust the setting between On and Off.

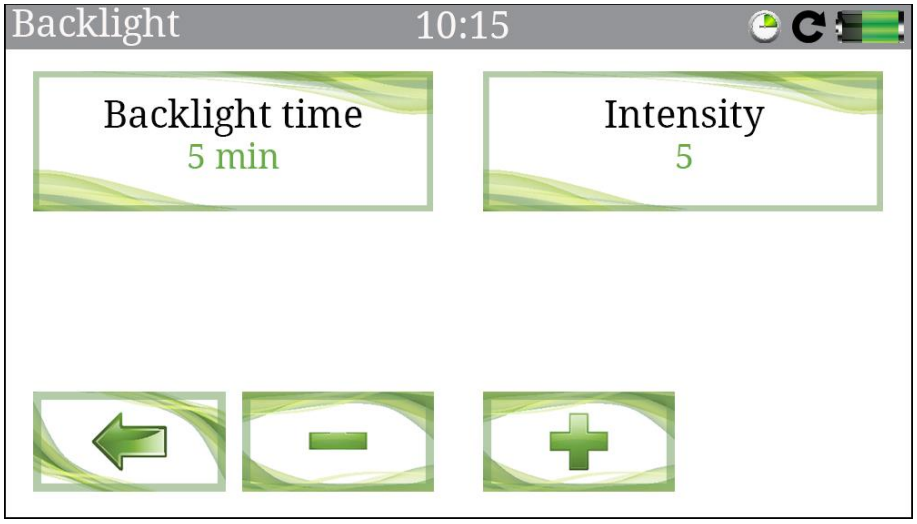
When settings are done press  to go back one menu.

3.1.1.9 Backlight settings

Select in the Users menu “Backlight settings”.

In “Backlight Settings” you can adjust Time and Intensity of the backlight.

The next menu will be shown on screen:



Press in the Backlight menu on “Backlight time”.
It will now be dark outlined.
With the and button you can adjust the setting.
Following settings are available:

30 seconds	(0.5 min)
1 minute	(1 min)
1 ½ minutes	(1.5 min)
2 minutes	(2 min)
2 ½ minutes	(2.5 min)
3 minutes	(3 min)
3 ½ minutes	(3.5 min)
4 minutes	(4 min)
4 ½ minutes	(4.5 min)
5 minutes	(5 min)

The set time is the time after which the backlight is set back to the set intensity.

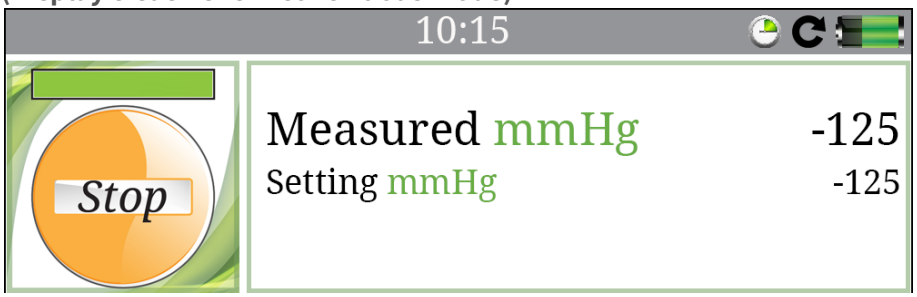
Press in the Backlight menu on “Intensity”.
It will now be dark outlined.
With the and button you can adjust the setting.
Following settings are available:

5	(Intensity 5%),
10	(Intensity 10%),
15	(Intensity 15%),
20	(Intensity 20%),
25	(Intensity 25%),
30	(Intensity 30%),

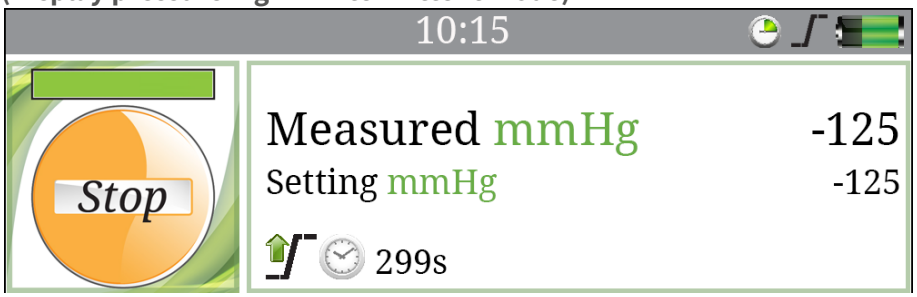
The set values are active for all menus and during treatment.
Touching the touch screen results in brightness at 100% brightness.

During treatment, as shown in pictures below, the activation and deactivation of the intensity is extended as follows:

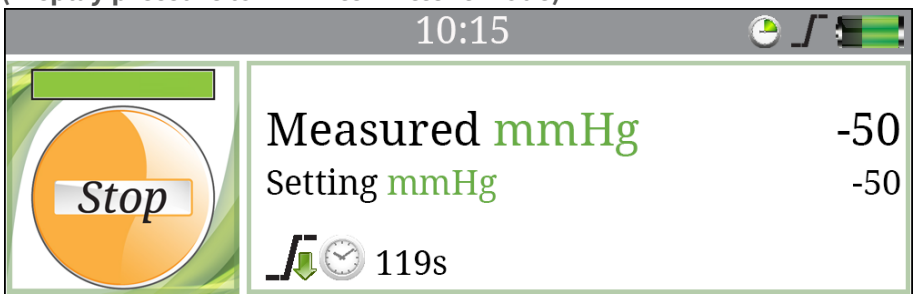
(Display treatment in continuous mode)



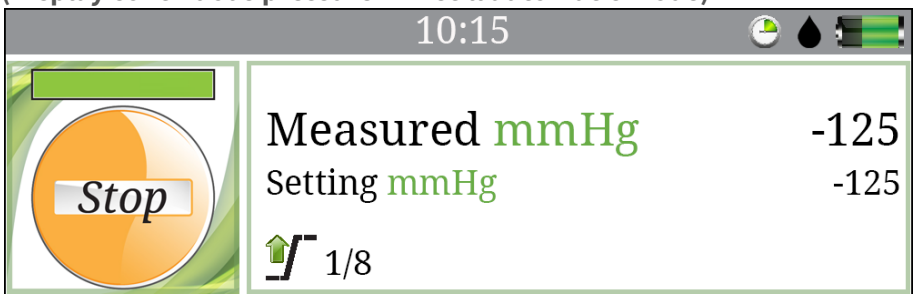
(Display pressure high in intermittent mode)



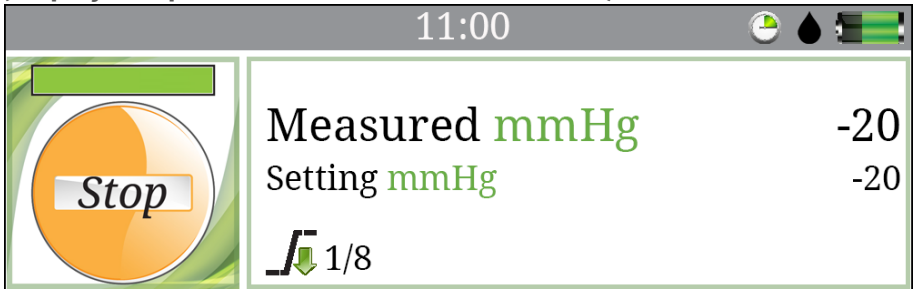
(Display pressure low in intermittent mode)



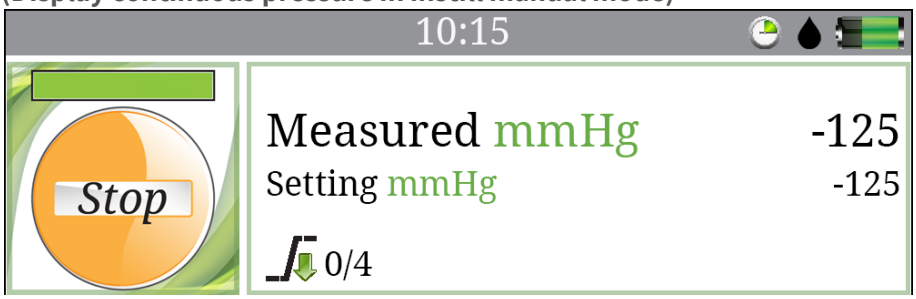
(Display continuous pressure in instill automatic mode)



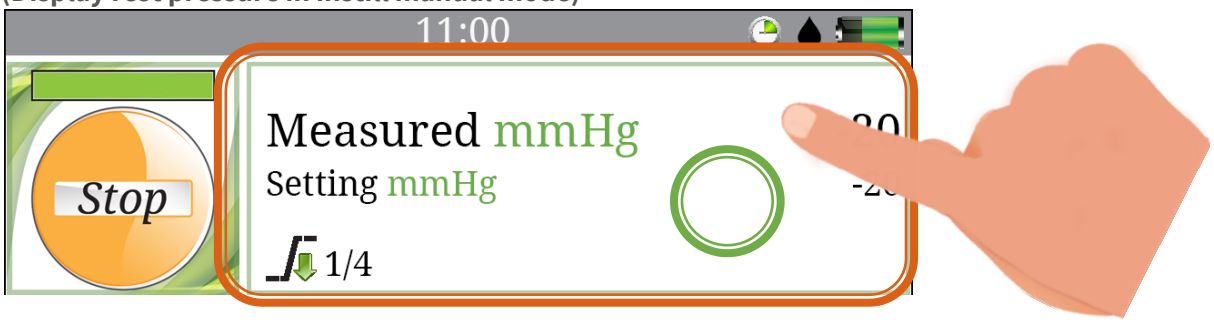
(Display rest pressure in instill automatic mode)



(Display continuous pressure in instill manual mode)



(Display rest pressure in instill manual mode)

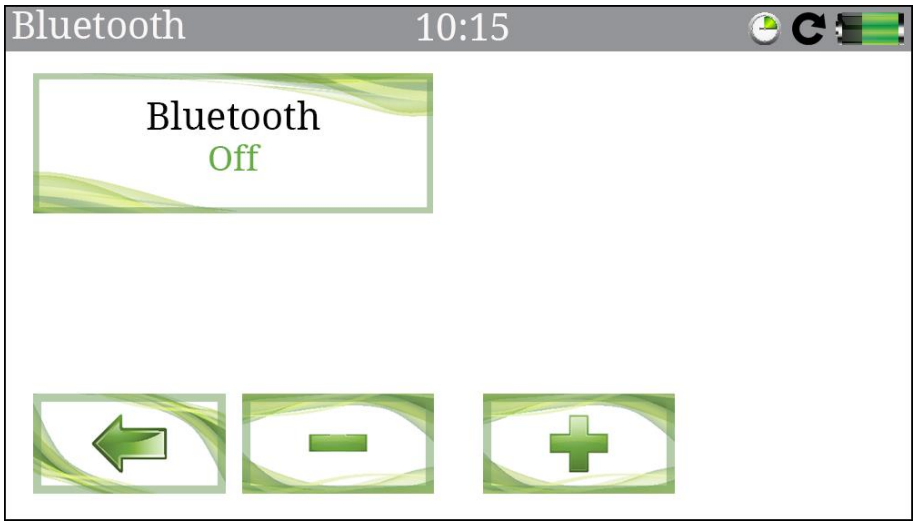


If you touch the touch screen in the area where the pressure is listed
when intensity is dimmed during treatment intensity will go to 100%.
After the set time, the intensity goes back to the set value.
It is also possible to dim to the set brightness by touching the touch screen display for about 1 second.

3.1.1.10 Bluetooth settings

Select in the Users menu “Bluetooth settings”.

In this menu you can enable and disable Bluetooth.



Press in the Backlight menu on “Backlight time”.
It will now be dark outlined.
With the and button you can adjust the setting.
Following settings are available: On
Off

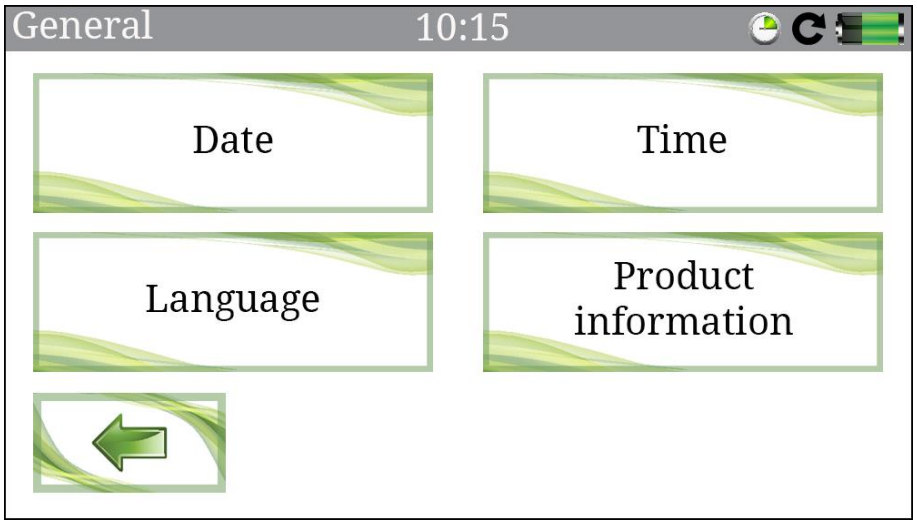
When bluetooth is enabled the next symbol will be shown on the right side in the grey menu bar:
ᛒ
(In the start screen on the bottom right the Bluetooth address of the device will also be displayed)

When bluetooth connection is active the next symbol will be shown on the right side in the grey menu bar: ᛒ

It is only possible to make a connection via bluetooth with the Exsudex XL Gateway.

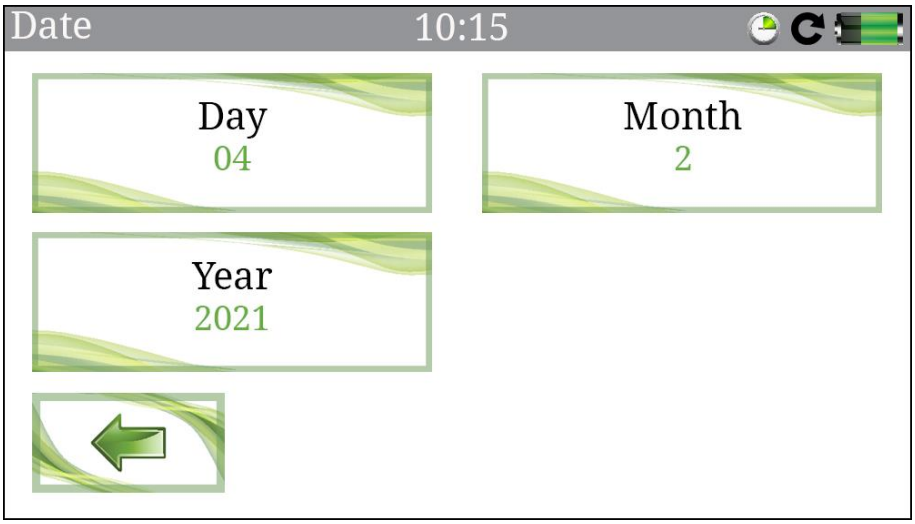
3.1.2 General settings

In the General Settings menu Date, Time and Language can be set.



3.1.2.1 Date

Press in the General menu on “Date”.



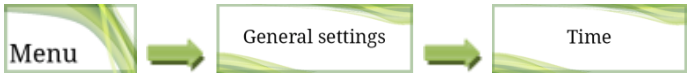
You can now set Date, Month and Year.

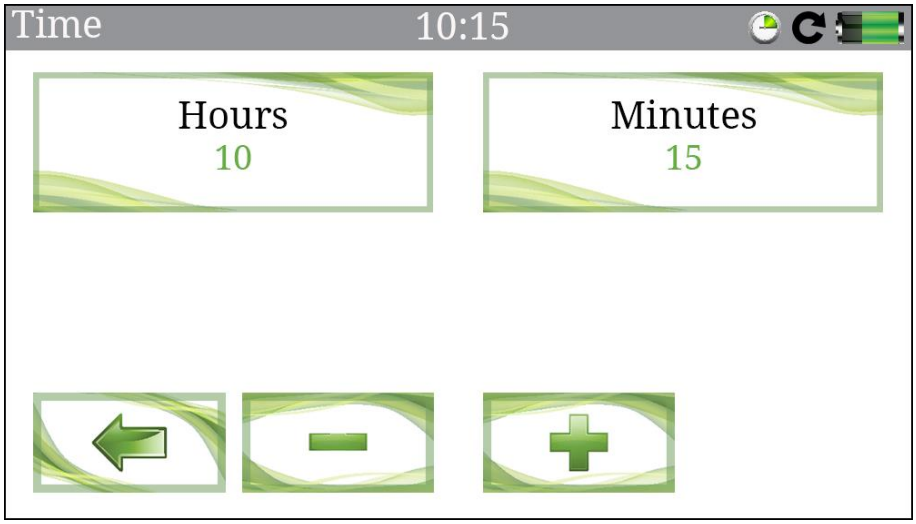
Press on the setting you want to adjust.
It will now be dark outlined.
With the and button you can adjust the setting.

When done press to go back to the General settings.

3.1.2.2 Time

Press in the General menu on “Time”.





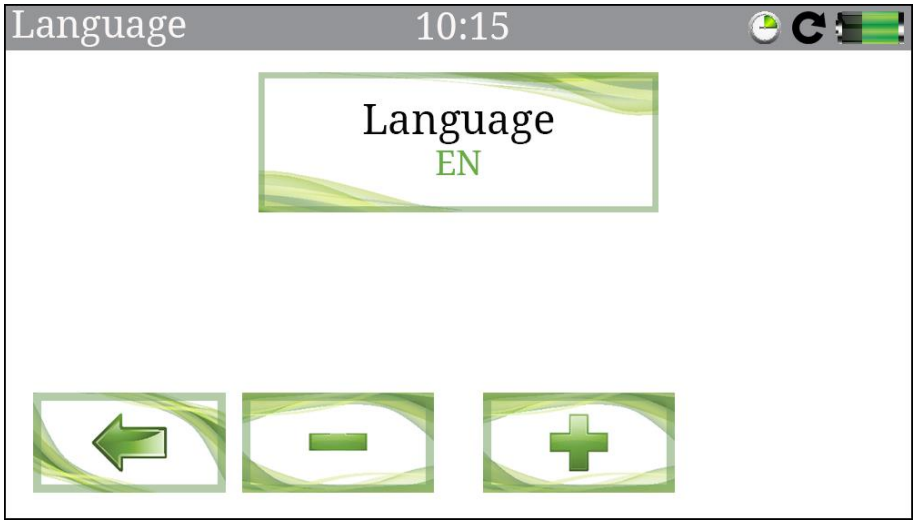
You can now set Hours and Minutes

Press on the setting you want to adjust.
It will now be dark outlined.
With the and button you can adjust the setting.

When done press to go back to the General settings.

3.1.2.3 Language

Press in the General menu on “Language”.



You can now adjust the language.
Press on the “Language-button”.
It will now be dark outlined.
With the and button you can adjust the setting.

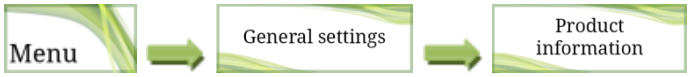
Following languages are available:

English	:	EN
Dutch	:	NL
German	:	DE
Danish	:	DA
French	:	FR
Italian	:	IT
Portuguese	:	PO
Spanish	:	ES
Turkish	:	TR

When done press to go back to the General settings.

3.1.2.4 Product information

Press in the General menu on “Product information”.

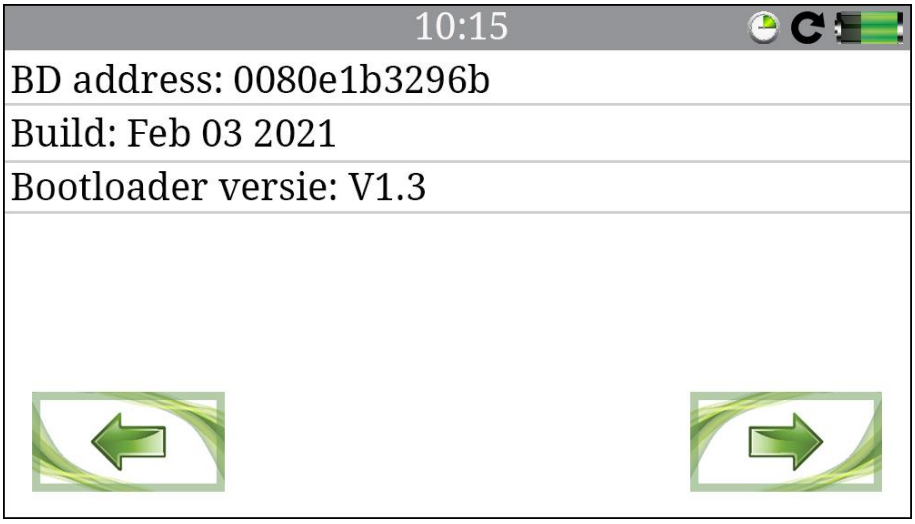


In this screen various information will be shown about the apparatus, like software version, hardware version and contact details.

Productinfo with Instill mode enabled.

Productinfo with Instill mode not available.

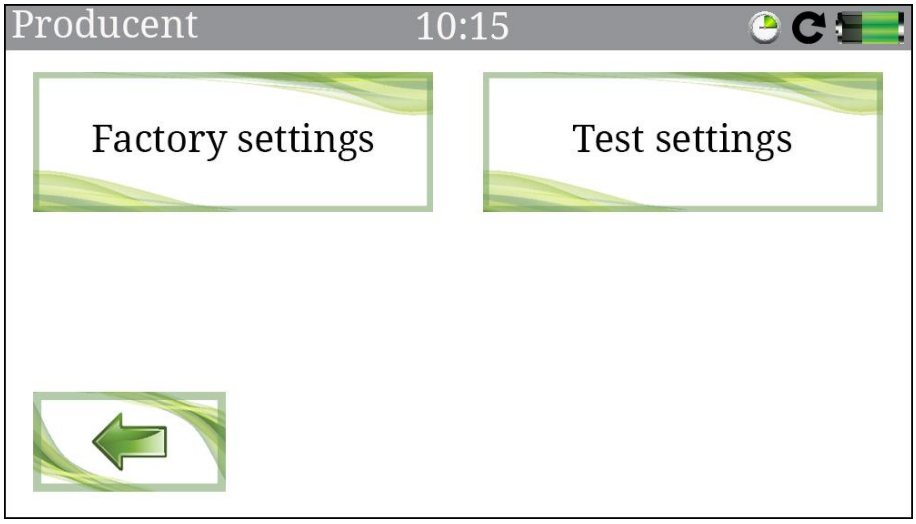
Press  to go to the next page



When all settings are done press 3 times  to go back to the Settings menu.

3.1.3 Producer Settings

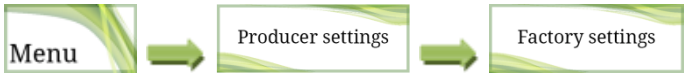
Press in the Settings Menu on “Producer settings”.



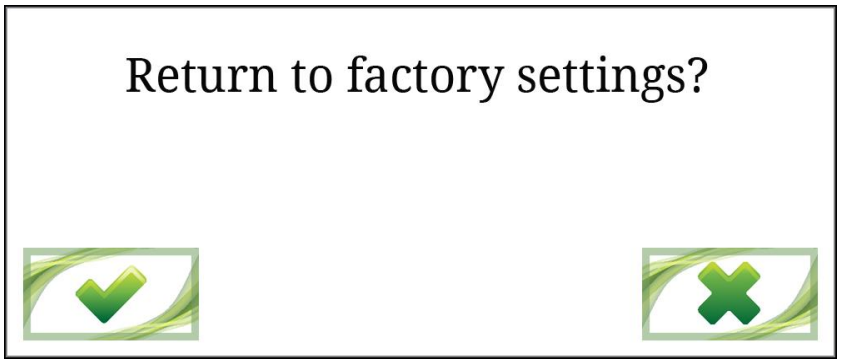
This feature has been put in to return to the factory settings.

3.1.3.1 Factory settings

Press in the “Producer” settings menu on “Factory settings”.



The next window will be displayed.



In which:

 results in restoring the Exsudex XL to the factory settings

This function works in 2 ways

1. Connected to the charger
   After confirming the restoring to the factory settings the Exsudex XL will automatically be turned off and turned on again.
   At startup you will see a message “Battery calibration in progress”. When done the Start Menu will be shown.

2. Not connected to the charger
   After confirming the restoring to the factory settings the Exsudex XL will automatically be turned off.

   You will have to turn on the Exsudex XL again by pressing ⏻
   At startup you will see a message “Battery calibration in progress”.
   When done the Start Menu will be shown.

 : results in returning to the Settings menu.

The following settings will be restored to the factory settings:

- Continuous mode Set to: On
- Intermittent mode Set to: Off
- Instill mode Set to: Off
- Pressure Set to: - 125 mmHg
- Tolerance Set to: 20 mmHg
- Acoustic notification Set to: On
- Warning delay Set to: 0.5 min
- Tube blocking Set to: Off
- Backlight time Set to: 5 min
- Backlight intensity Set to: 5%
- Purge mode Set to: Off
- Power mode Set to: Normal
- Bluetooth Set to: Off
- Hold pressure Set to: Off

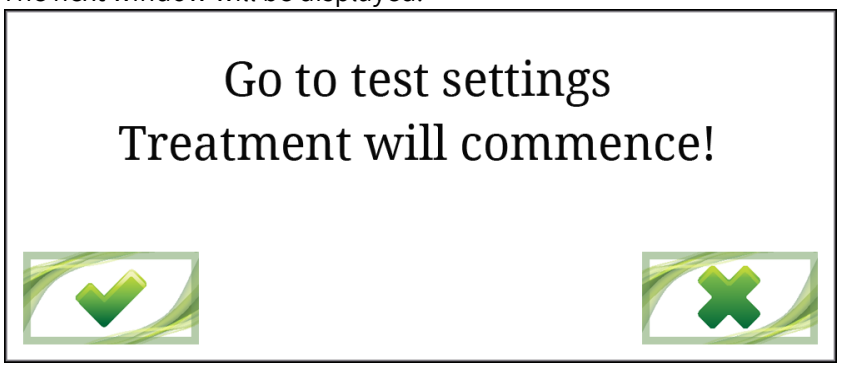
After restart of the Exsudex XL the battery will also be calibrated.

3.1.3.2 Test settings

These settings are built in to be able to perform a fully automatic test on operation by the manufacturer!

Press in the “Producer” settings menu on “Test settings”.

The next window will be displayed.



In which:

 : results in adjusting of several values and automatically start the treatment in test mode.

 : results in returning to the Producer settings menu.

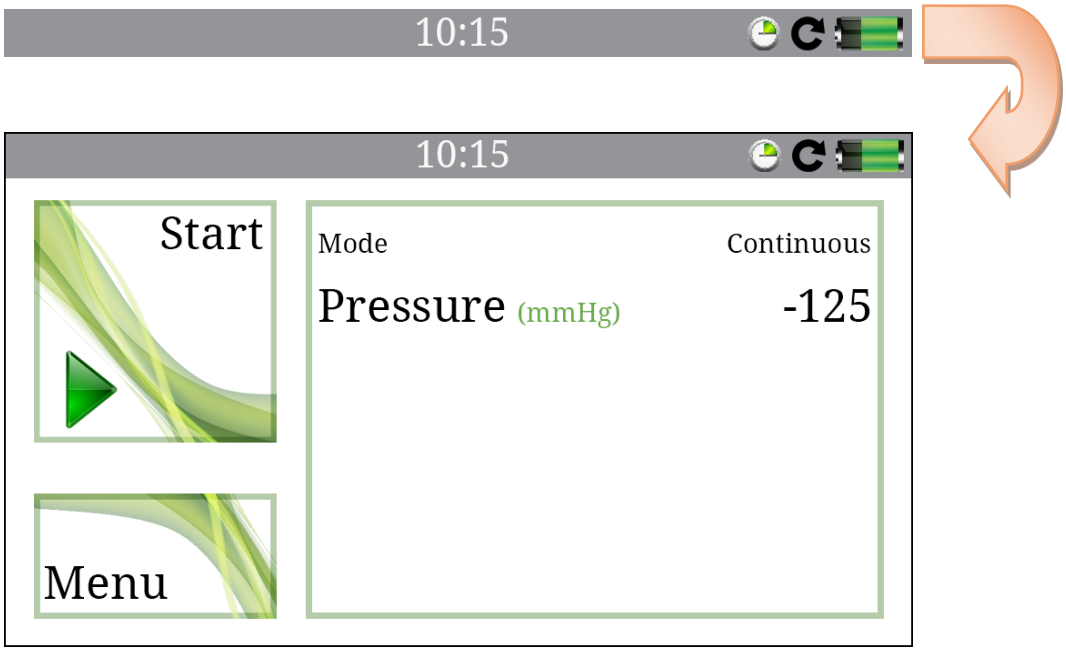
3.1.4 Dealer Settings

This feature is currently unavailable.
When all settings are done press  to go back to the main menu.

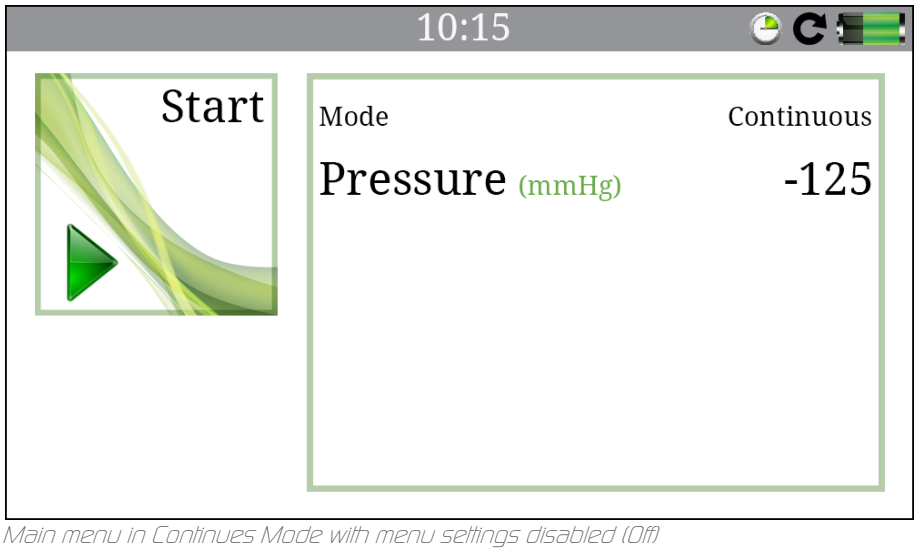
3.1.5 Disabling and Enabling Settings Menu

The ability to turn off the setup menu has been specially built in to prevent the ability that the patient can adjust the settings!

To turn off the menu press for 10 seconds on the gray menu bar at the top of the screen:



Main menu in Continues Mode with menu settings enabled (On)



Main menu in Continues Mode with menu settings disabled (Off)

3.1.6 Explanation symbols shown in display

	Start treatment
	Open Settings Menu
	Battery full
	Battery 60% full
	Battery 30% full
	Battery almost empty
	Battery charging
	Continuous mode enabled
	Intermittent enabled
	Instill mode enabled
	Tube blocking enabled
	Acoustic signal notification disabled
10:15	Time
	Exclamation mark to show you that the pressure is or has been out of setting when delayed warning is enabled.
Time out: 4 min	Remaining time until Standby Warning.
	Intermittent high pressure active or continuous pressure in instill mode active
	Intermittent low pressure active or rest pressure in instill mode active
 299s	Remaining time intermittent active pressure setting.
PU-Foam / Prontosan	Selected type of bandage and fluid in Instill mode
1/8	Cycle 1 of 56 active in Instill mode
01:00 / 03:00 / 05:00 / 07:00...	Set times for fluid administration in Instill mode
	Delayed warning enabled

	Slow mode activated
	Fast mode activated
	Purge mode activated
	Bluetooth enabled
	Bluetooth connection active
0080e1b3296b	Bluetooth ID
	SD card not available.

3.2 Start

By pressing "Start" 

the treatment with the Exsudex XL will be started.

Home Care Situation:

Note: Do not forget to enable/switch off the settings menu after entering the correct settings!
See chapter 3.1.5 - Disabling and Enabling Settings Menu
This to prevent the ability that the patient can adjust the settings!

4 Use

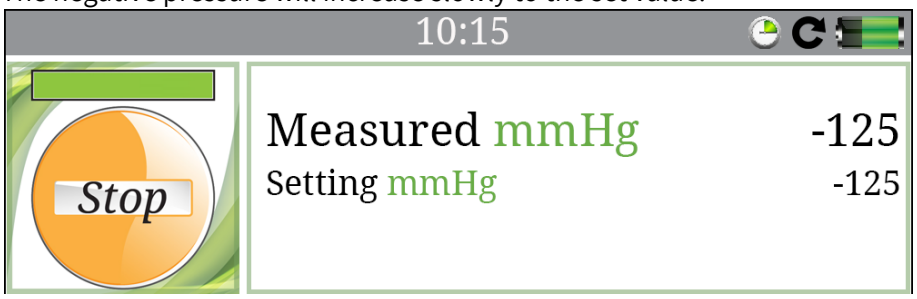
4.1 Use in continuous mode

When the setup is complete the Exsudex XL unit can be started.
Check if the canister and tubing are connected properly.

Press the “Start” button. . 

The machine will beep.

The negative pressure will increase slowly to the set value.



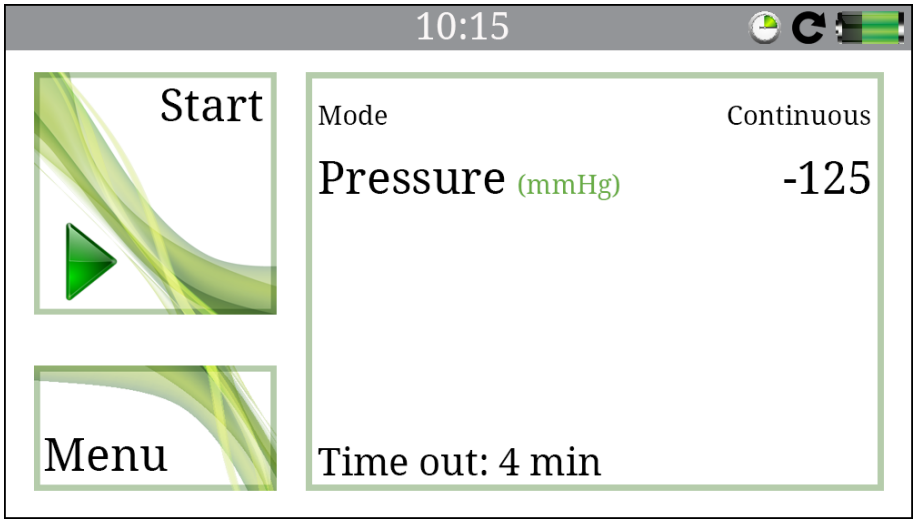
The Exsudex XL can be turned off by pressing the “Stop” button 

for at least 3 seconds.
The green bar above the round Stop button is a countdown indicator.
When you press the “Stop” button the green bar will slowly go to white (visual countdown)
When the bar is completely white, the 3 seconds are over, a beep will sound and the treatment will be stopped.
The machine will go back to the main menu.
When you release the “Stop” button before the 3 seconds are over treatment will go on and the bar will be completely green again.

Overview:

			
Button during treatment	Button when pressed for 1 second	Button when pressed for 2 seconds	Button when pressed for 3 seconds

At the bottom of the screen the remaining time, in seconds, is displayed before the Standby Warning will be activated.



4.2 Use in intermittent mode

When the setup is complete the Exsudex XL unit can be started.
Check if the canister and tubing are connected properly.

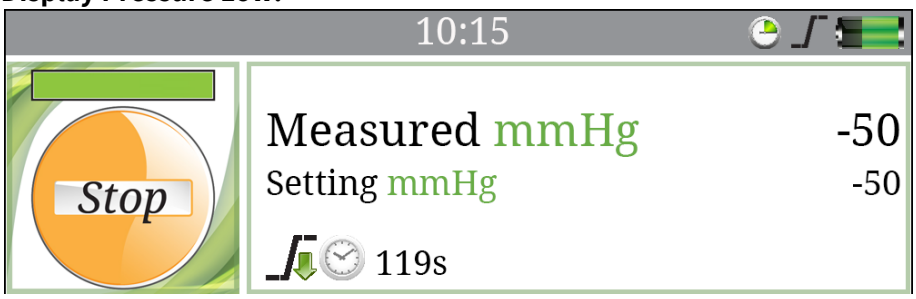
Press the “Start” button. 

The machine will beep.

The negative pressure will increase slowly to the set value.

Display Pressure High:

Display Pressure Low:



The Exsudex XL can be turned off by pressing the “Stop” button 

for at least 3 seconds.
The green bar above the round Stop button is a countdown indicator.
When you press the “Stop” button the green bar will slowly go to white (visual countdown)
When the bar is completely white, the 3 seconds are over, a beep will sound and the treatment will be stopped.
The machine will go back to the main menu.
When you release the “Stop” button before the 3 seconds are over treatment will go on and the bar will be completely green again.

Overview:

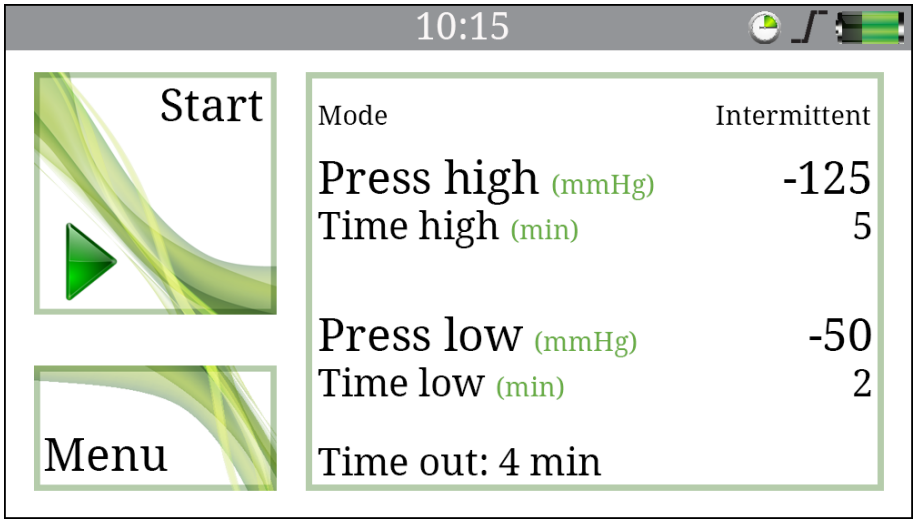
Button during treatment

Button when pressed for 1 second

Button when pressed for 2 seconds

Button when pressed for 3 seconds

At the bottom of the screen the remaining time, in seconds, is displayed before the Standby Warning will be activated

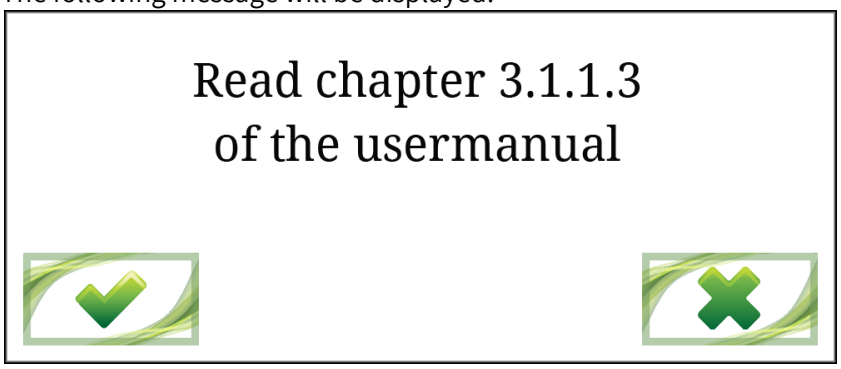


4.3 Use in Instill mode (only when available)

When the setup is complete the Exsudex XL unit can be started.
Check if the canister and tubing are connected properly.

Press the “Start” button. 

The following message will be displayed:



In which:

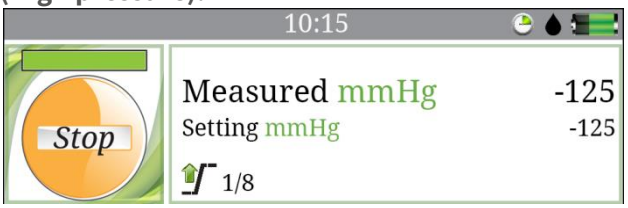
 : Will start the treatment in Instill mode.

 : Results in returning to the Main menu.

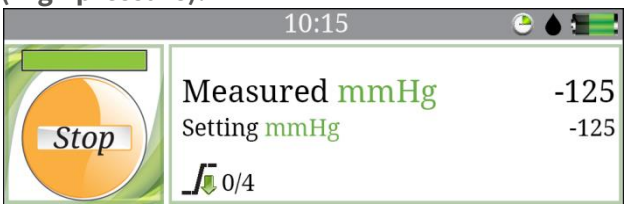
The machine will beep.

The negative pressure will increase slowly to the set value.

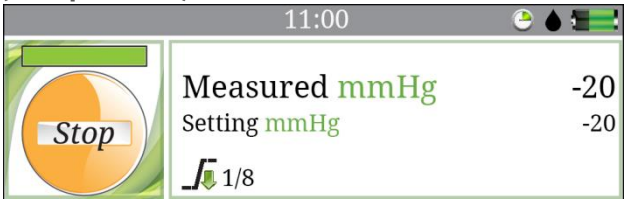
Display Continuous Pressure in Automatic mode (High pressure):



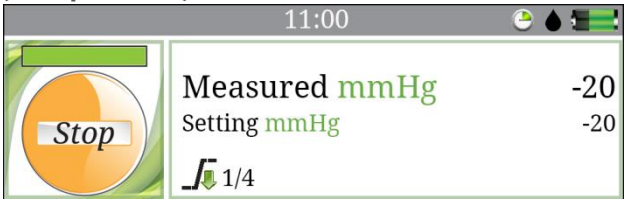
Display Continuous Pressure in Manual mode (High pressure):



Display Rest Pressure in Automatic mode (Low pressure):



Display Rest Pressure in Manual mode (Low pressure):



The Exsudex XL can be turned off by pressing the “Stop” button 

for at least 3 seconds.
The green bar above the round Stop button is a countdown indicator.
When you press the “Stop” button the green bar will slowly go to white (visual countdown)
When the bar is completely white, the 3 seconds are over, a beep will sound and the treatment will be stopped.

The machine will go back to the main menu.
When you release the “Stop” button before the 3 seconds are over treatment will go on and the bar will be completely green again.

Overview:

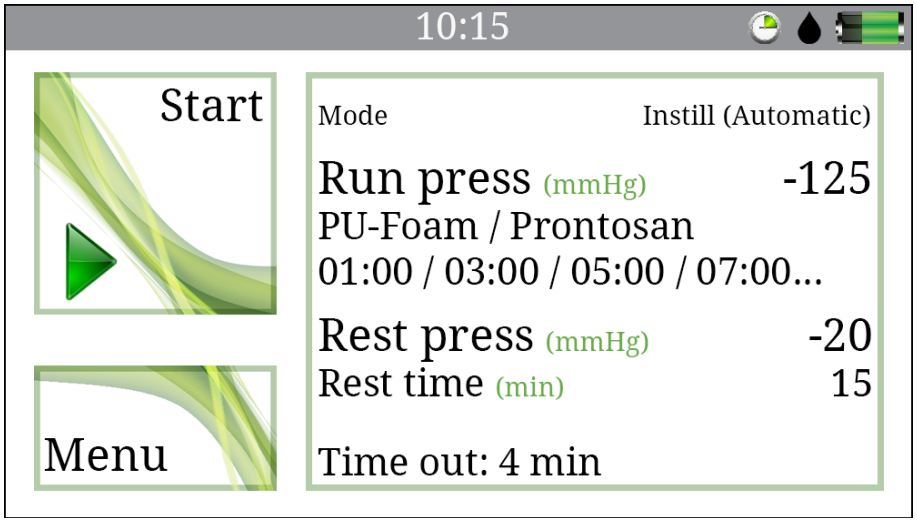
Button during treatment

Button when pressed for 1 second

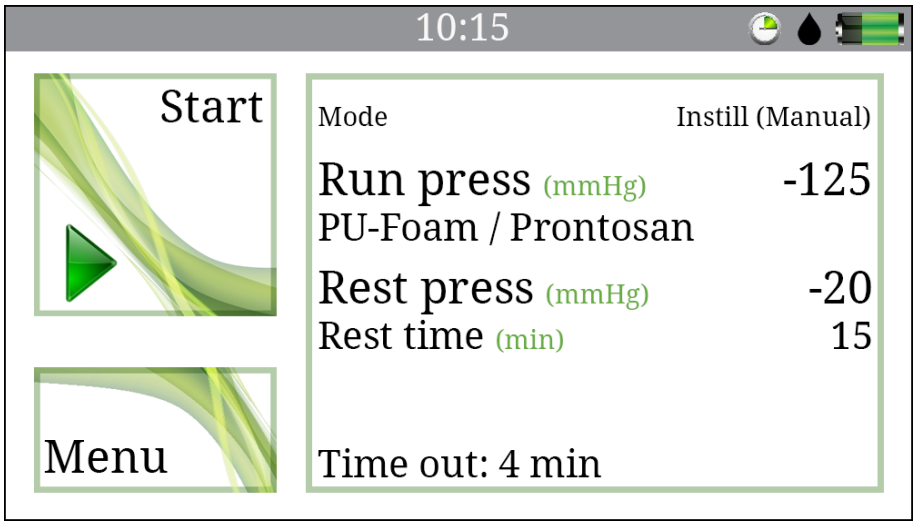
Button when pressed for 2 seconds

Button when pressed for 3 seconds

At the bottom of the screen the remaining time, in seconds, is displayed before the Standby Warning will be activated



Display Instill in Automatic mode:



Display Instill in Manual mode

4.4 Daily use

The Exsudex XL is portable and wearable during normal activities, approved by the treating physician, by the patient.

Be careful that no one can stumble over the power cord and tubing.
Make sure there is no power cord and hose lying down or posted where people walk.

4.4.1 Sleeping

- Make sure the Exsudex XL is placed so that the tube cannot bent or clamped of.
- Make sure the Exsudex XL cannot be pulled of your bedside table or fall to the floor in your sleep.
- We recommend you to connect the Exsudex XL to the charger while you sleep.

4.4.2 Bathing and Showering

- Do not use the Exsudex XL during bathing or showering or in a place where it can fall in a bathtub, shower or sink.
- When the Exsudex XL should fall into the water, do not try to take it out of the water. If the device is plugged in, unplug it immediately. Disconnect the Exsudex XL of the dressing and contact your home care provider.
- When drying off be careful not to damage the wound dressing.

4.4.3 Travelling with the Exsudex XL

Before you go on a trip, contact your healthcare provider if it is safe for you to travel.
Only travel if you have the permission of your doctor and if you know what risks are related your condition and the use of the Exsudex XL Wound drainage system.
Please consider the risk of bleeding, which can have serious consequences.

We recommend the patient to take the next items along:

- Instructions of the patient's doctor, including the therapy settings and the dressing to use.
- Sufficient stock of dressing kits so that the wound can be as prescribed or if so desired be dressed again.
  - The canister or collecting bag should be replaced when full, or at least once a week.
  - Changing of dressing should be done as prescribed by the patient's doctor.
- Alternative dressing, as recommended by your healthcare provider, which can be used in case the therapy with the Exsudex XL cannot be continued
- Fully charged Exsudex XL wound drainage system including charger.
- Check before leaving if the adapter of the charger is suitable for the destination of the patient.
- Exsudex XL user manual

5 Notifications

The pump has five types of notifications:

- Pressure tolerance notification
- Reservoir full notification
- Tube blocking notification
- Stand by warning
- Battery low notification
- Instill notification (fluid administration)

The notification will sound if the negative pressure in the system exceeds the boundaries set in the tolerance.

During the building up of negative pressure the notification has a built-in delay. The notification function will be activated about 40 seconds after starting the pump. If the pressure has not reached set levels within this 40 seconds the notification will sound.

When the canister/reservoir is full the notification will sound.

During an notification the Exsudex XL will turn off and go into standby mode.
The notification will continue sound until either  or  is pressed.

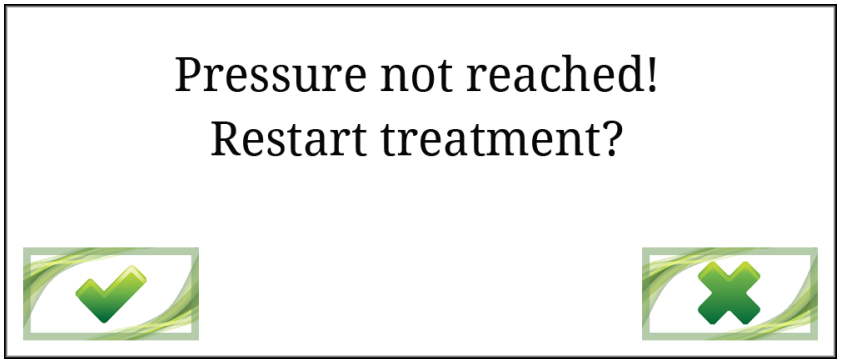
A notification will sound if the pump has not been started again within 5 minutes after you have stopped the pump.

The following notification s are built in:

- Notification during the building up of negative pressure
- Notification negative pressure loss
- Reservoir full notification
- Stand by warning
- Tube blocked notification
- Instill notification for fluid administration
- Battery low notification

5.1 Notification during the building up of negative pressure

If the Exsudex XL is turned on it will attempt to achieve the pre-set negative pressure.
If no tube is connected or there is a significant leak in the system the set negative pressure cannot be reached and the notification will be activated. The pump will stop, the notification will sound and the display shows:



In which:

 : Restarts the treatment

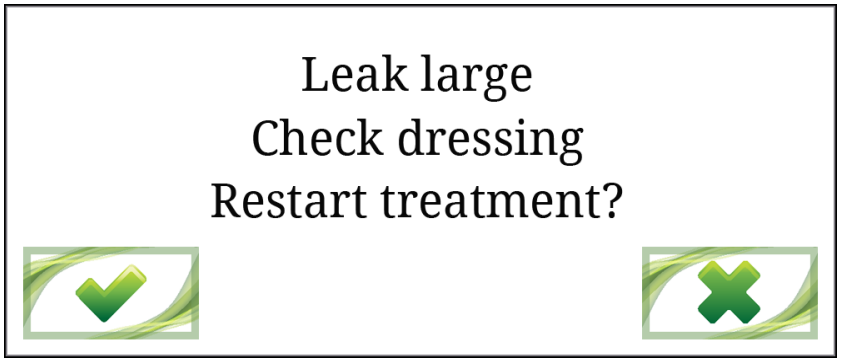
 : Results in returning to the Main menu.
Note that the Standby warning will sound after 5 minutes if the pump is not activated again.

NOTE:
This notification will sound only during initiating of the treatment (after pressing Start).

5.2 Notification negative pressure loss / failure to reach maximal negative pressure

If the set negative pressure is reached and a leak develops (the system is not airtight) or the tubing is disconnected the Exsudex XL will try to reach the set negative pressure. If the pump operates on maximum speed, but still does not reach the set negative pressure within the set delayed warning time, the notification is activated and the notification will sound.

This notification will only be triggered if the set pressure has been reached already.
Otherwise, the notification "no pressure" as described in 0 will be in force.
When delayed warning is turned off the notification will sound immediately!

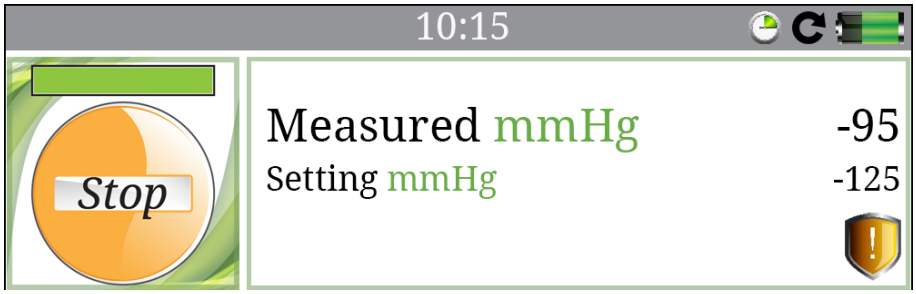


In which:

 : Restarts the treatment

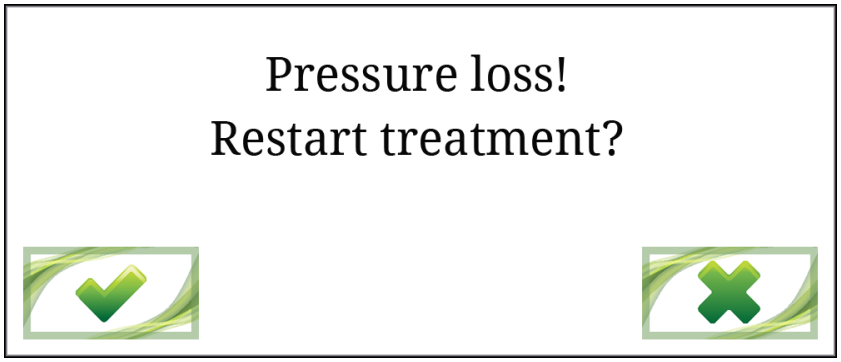
 : Results in returning to the Main menu.
Note that the Standby warning will sound after 5 minutes if the pump is not activated again.

When delayed warning is On the notification will work as follows:
There will be an exclamation mark in the display, indicating that the pressure was outside its setting. The pump has now the time set in the delayed warning to return within the preset settings. If the pressure is inside the settings again , the pump will continue to operate and exclamation mark remains on the screen to indicate that the pressure has been outside its setting.



If the pressure is not within its setting within the set delayed warning time the notification will sound.

1. By Pressure loss



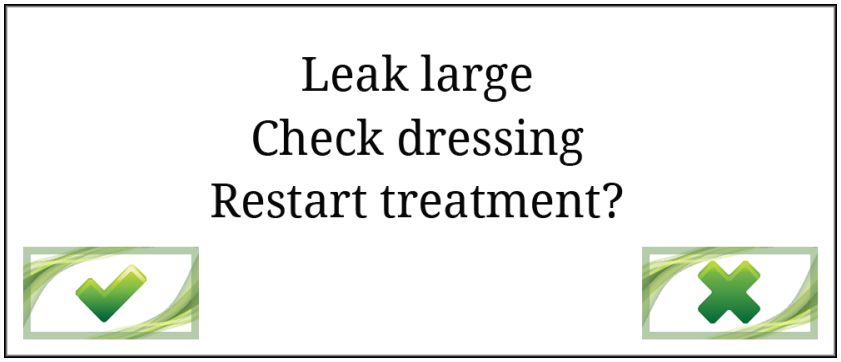
In which:

 : Restarts the treatment

 : Results in returning to the Main menu.
Note that the Standby warning will sound after 5 minutes if the pump is not activated again.

If the pressure is not within its setting within the set delayed warning time the notification will sound.

2. By leakage (failure to maintain set pressure)



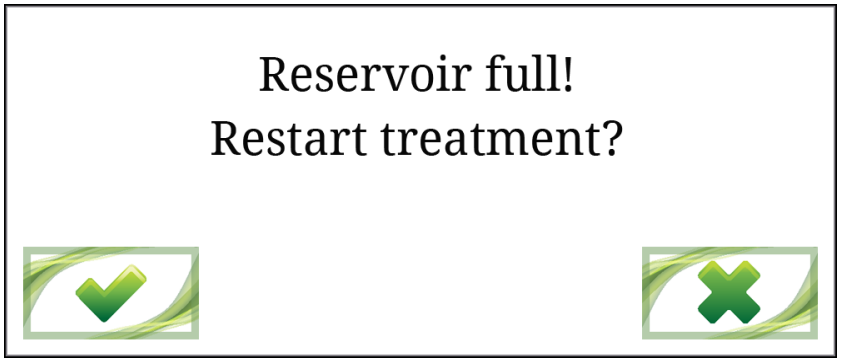
In which:

 : Restarts the treatment

 : Results in returning to the Main menu.
Note that the Standby warning will sound after 5 minutes if the pump is not activated again.

5.3 Reservoir full notification

If the canister/reservoir is full, the reservoir full notification is activated and the notification will sound.
The reservoir full notification is always enabled and cannot be disabled!



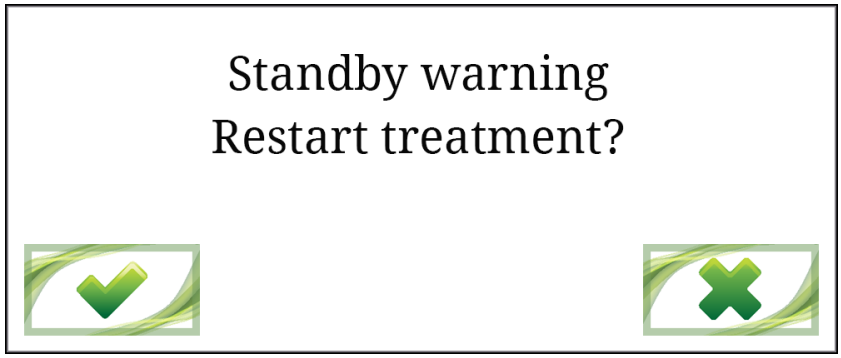
In which:

 : Restarts the treatment

 : Results in returning to the Main menu.
Note that the Standby warning will sound after 5 minutes if the pump is not activated again.

5.4 Standby warning

A warning will sound if the pump has not started again within 5 minutes after you have stopped the pump, e.g. for exchanging dressing.
This warning only works when the pump has been started one time.
The warning will not sound if you have only turned on the Exsudex XL by the main on/off switch.



In which:

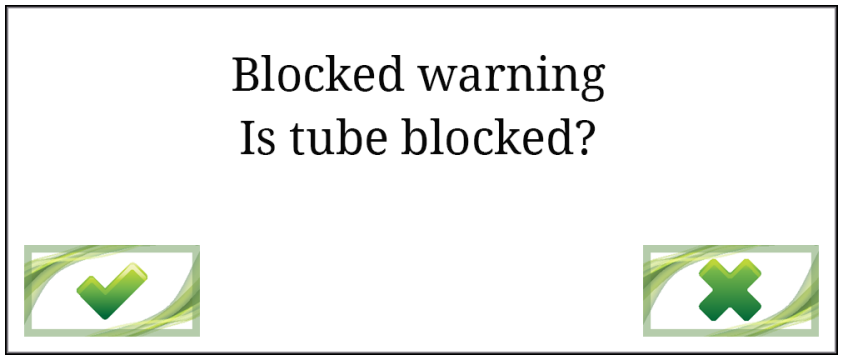
 : Restarts the treatment

 : Results in returning to the Main menu.
Note that the Standby warning will sound after 5 minutes if the pump is not activated again.

If the Exsudex XL has been turned on but no treatment has started within 5 minutes after the last touch on a button the Exsudex XL will automatically be switched off, in order to save power.
When connected to the charger only the LCD screen will be turned off. When disconnected from the charger the Exsudex XL will be completely off.

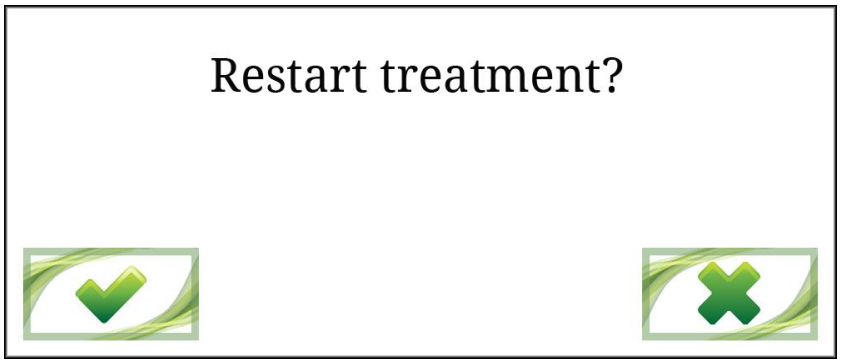
5.5 "Tube blocking" notification.

A notification will sound if the pump has not run within a set period.
The notification will sound to indicate that the suction tubing is blocked, but be aware that the notification will also sound if the wound is completely airtight sealed!
When turned on the next symbol will be shown on the right side in the grey menu bar: 



In which:

 : Confirms a blocked tube resulting in the next question:

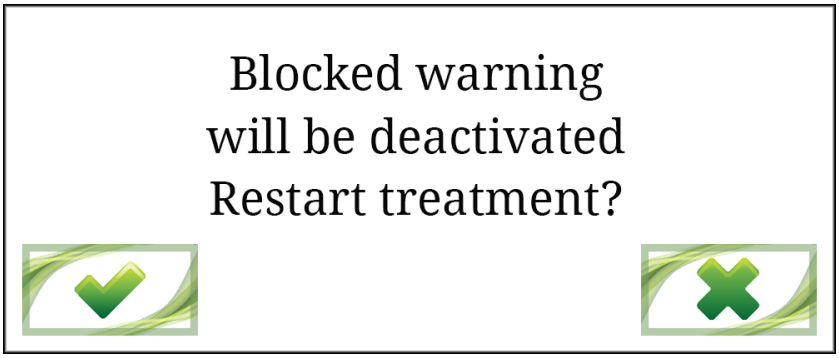


In which:

 : Restarts the treatment with activated tube blocking notification.

 : Results in returning to the Main menu.
Note that the Standby warning will sound after 5 minutes if the pump is not activated again.

 : Indicates that the tube was not blocked and results in the next question:



In which:

 : Restarts the treatment with de-activated tube blocking notification.
Tube blocking will be available again after turning off and on the Exsudex XL.

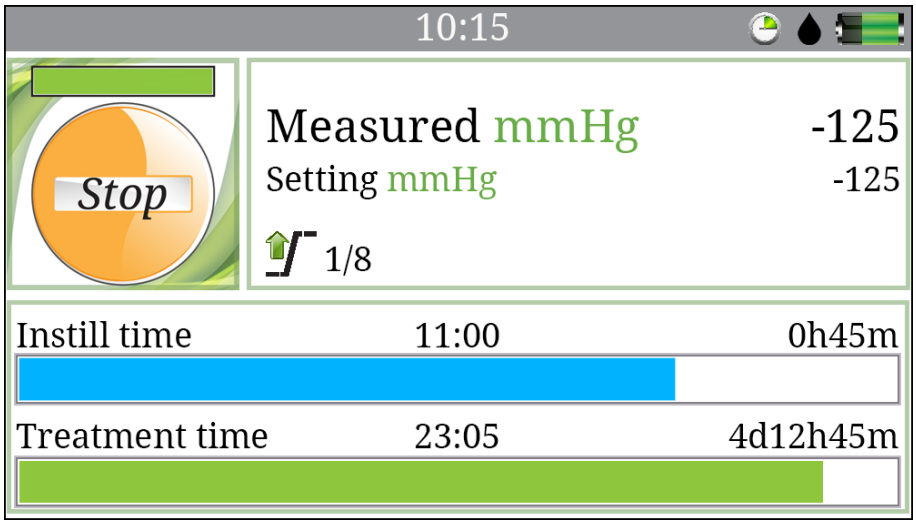
 : Results in returning to the Main menu.
Note that the Standby warning will sound after 5 minutes if the pump is not activated again.

NOTE: Tube blocking is not available when intermittent or purge automatic mode is enabled!

5.6 "Instillation" (only when available)

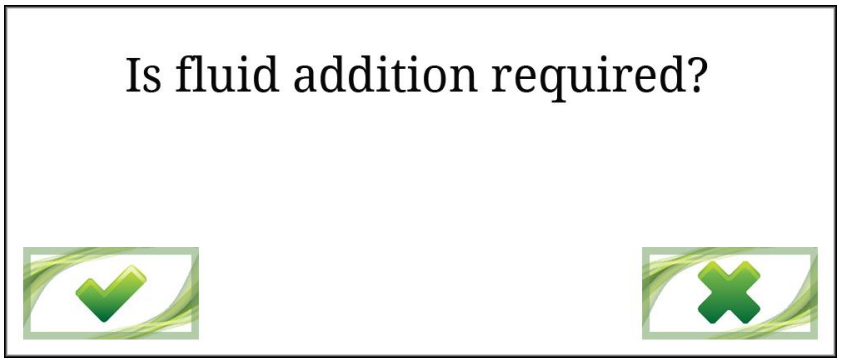
5.6.1 "Instillation" notification when Automatic mode is selected

This notification is as alert for the nursing staff to administer regularly fluid to the patient.
A maximum of 12 daily notification can be set for 5 days.
The Exsudex XL itself does not administer fluid to the patient, but only gives an notification to alert the nursing staff that liquid must be administered



Instill modus (Automatic) in continuous pressure (high pressure)

At set times and days (depending on the settings made) a notification will sound to alert the nursing staff:

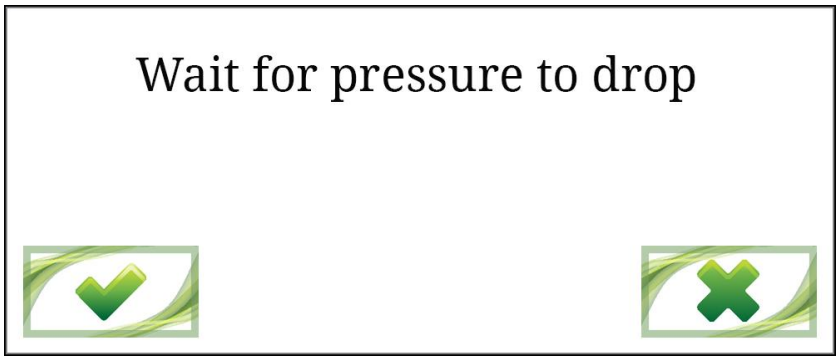


When not pressed within 5 minutes a notification will sound!

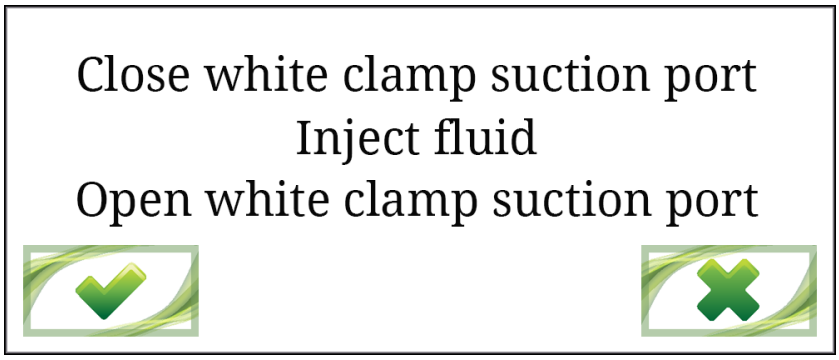
In which:

 : Restarts the treatment without fluid administration.
However, there will be switched to the next cycle time!

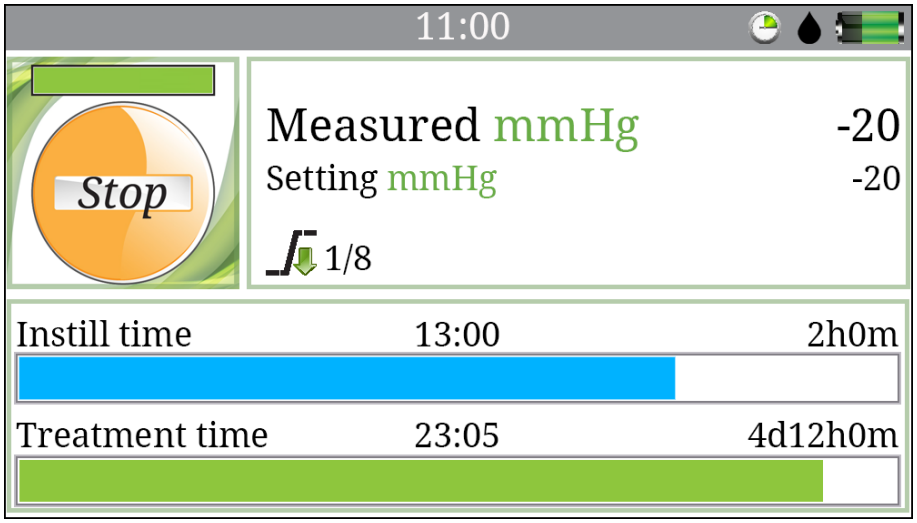
: Resulting in switching to the rest pressure and the following message appears:



If the pressure has dropped to the set value for the rest pressure, the next question will arise.



In which both  and  results in returning to the treatment in rest pressure.
When not pressed within 5 minutes a notification will sound!

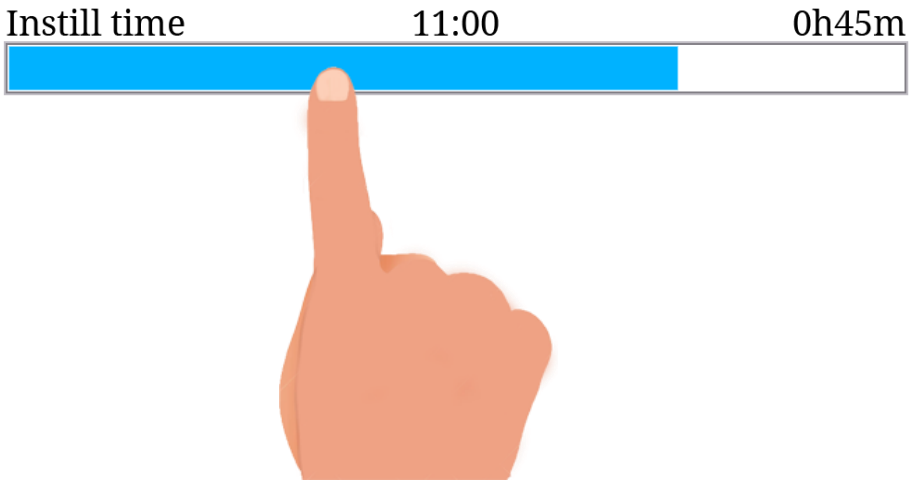


Instill mode (automatic) in rest pressure (after fluid administration)

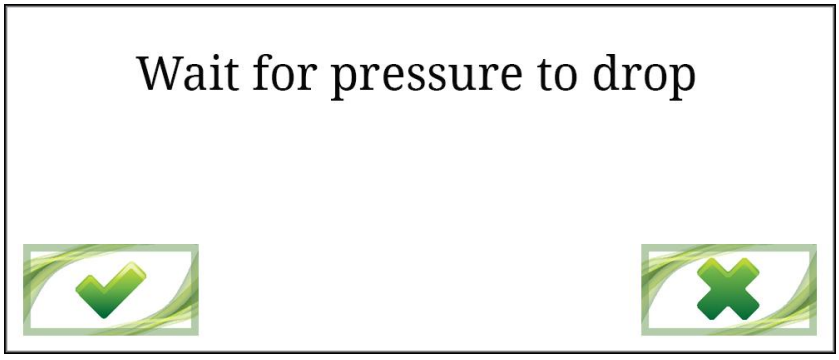
5.6.1.1 Interim fluid administration

If you want to administer liquid prior to the set time you can proceed as follows:

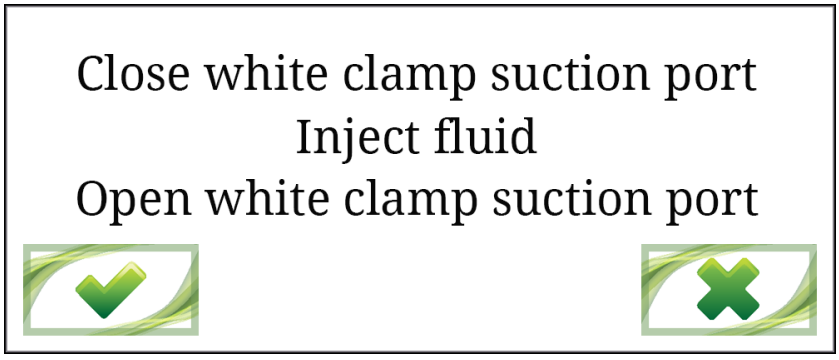
Press for about 1 second on the top blue bar “Instill time”.



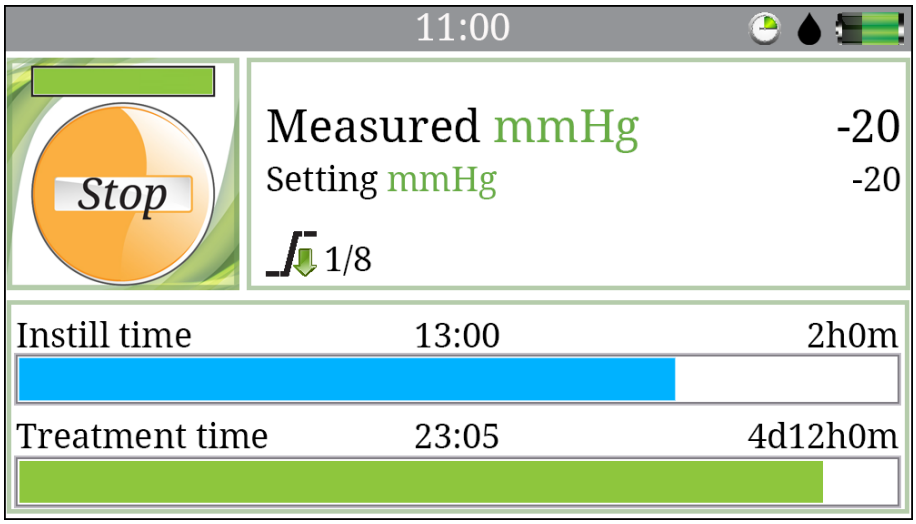
Resulting in switching to the rest pressure and the following message appears:



If the pressure has dropped to the set value for the rest pressure, the next question will arise.



In which both  and  results in returning to the treatment in rest pressure.
When not pressed within 5 minutes a notification will sound!

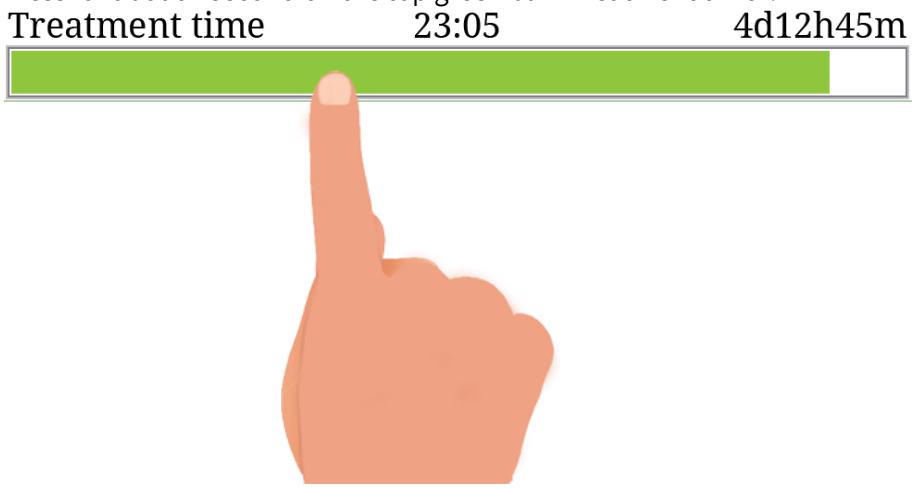


Instill mode (Automatic) in rest pressure (after fluid administration)

5.6.1.2 Stopping Instill notification during treatment

If the administration of liquid has to be stopped for any reason, it is possible to turn off the notification and continue in continuous mode.

Press for about 1 second on the top green bar “Treatment time”.



The notifications are now turned off without having to stop the treatment.

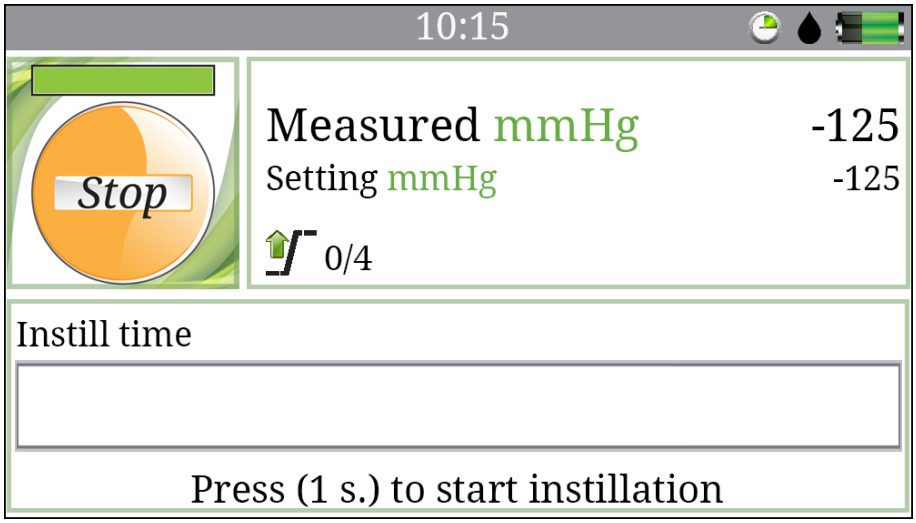
Instill mode (automatic) after stopping the warnings.

Instill mode remains active. After pressing Stop and Starting the treatment again the notifications for fluid administration will be active again.

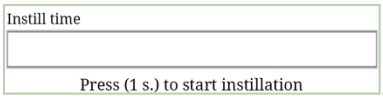
When all notifications have expired the above screen will also be active, indicating that no notifications are set

5.6.2 "Instillation" when Manual mode is selected

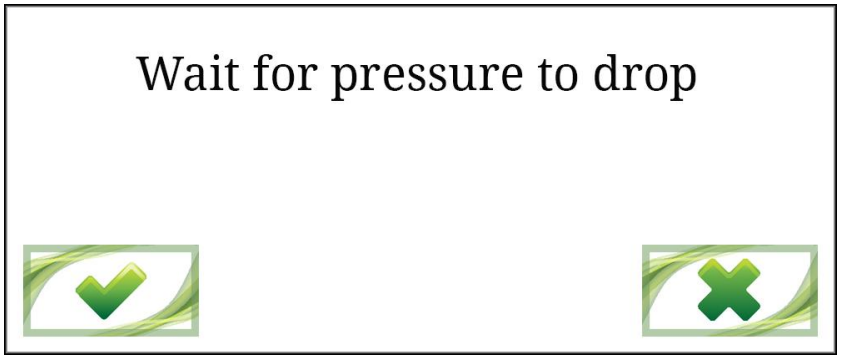
When manual mode is selected there will be no notification/reminder!



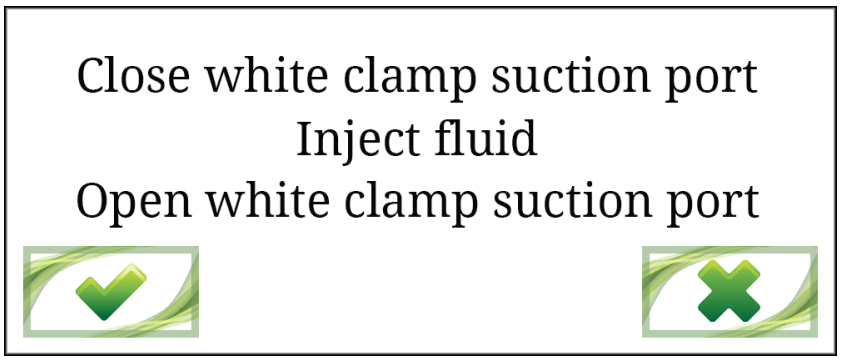
Instill modus (manual) in continuous pressure (high pressure)

When you want to administer fluid press for 1 second on 

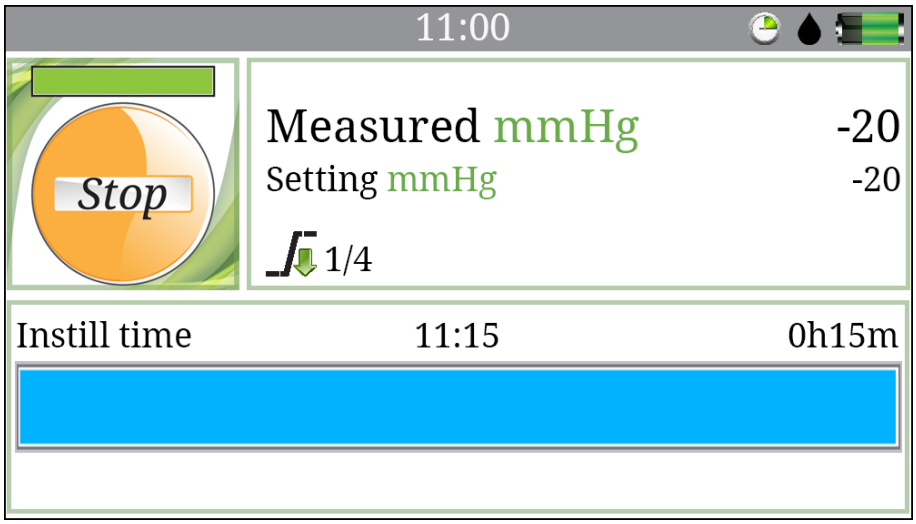
.
Resulting in switching to the rest pressure and the following message appears:



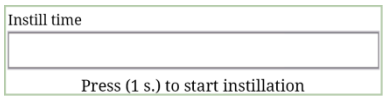
If the pressure has dropped to the set value for the rest pressure, the next question will arise.



In which both  and  results in returning to the treatment in rest pressure.
When not pressed within 5 minutes a notification will sound!



Instill mode (manual) in rest pressure (after fluid administration)

During rest pressure the button 

will be enabled!

5.7 "Battery low" notification.

The display has five symbols for the battery power:

 Battery full

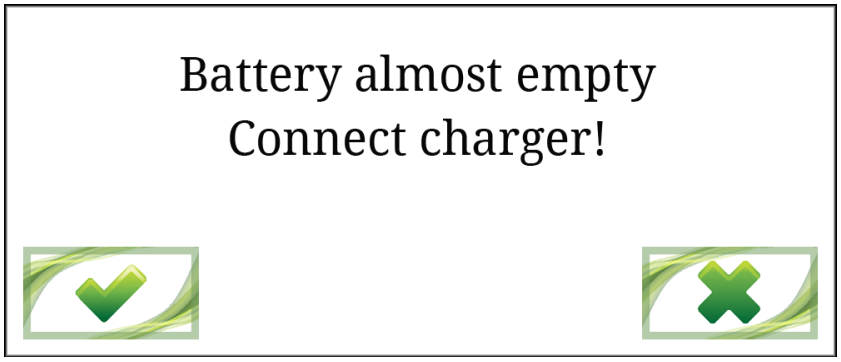
 Battery 60% full

 Battery 30% full

 Battery almost empty

 Battery charging

With an empty battery, the notification will sound and the battery on the display will be red.

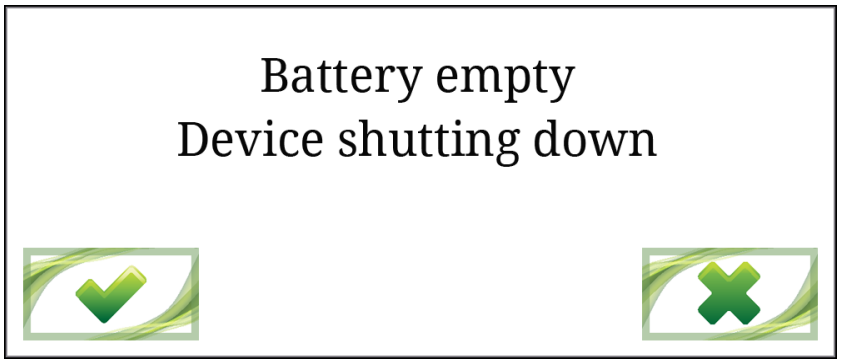


In which:

In which both  and  results in returning to the treatment.

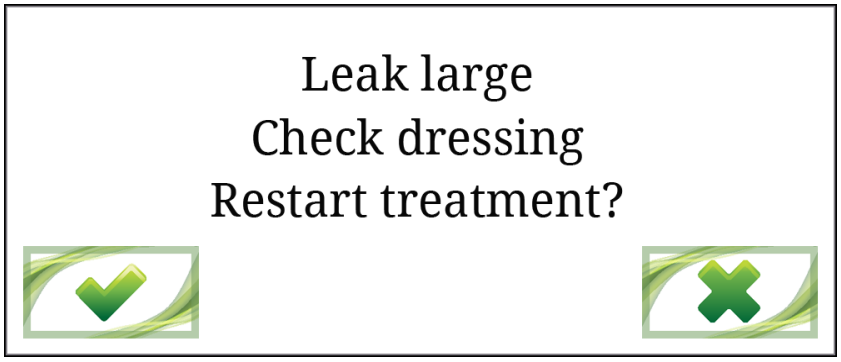
When connected to the charger the notification will stop and the treatment will be restarted.

NOTE:
When not connected to the charger will shut down the Exsudex XL in time to prevent the battery to become completely empty.
Before the device is shut down a beep will sound and the following message appears for a few seconds.



5.8 "Motor on Time" notification.

The Exsudex XL is provided with a notification which controls continuously running from the pump, caused by a leak within the set deviation.
If the pump is running continuously for 5 minutes the warning will sound.



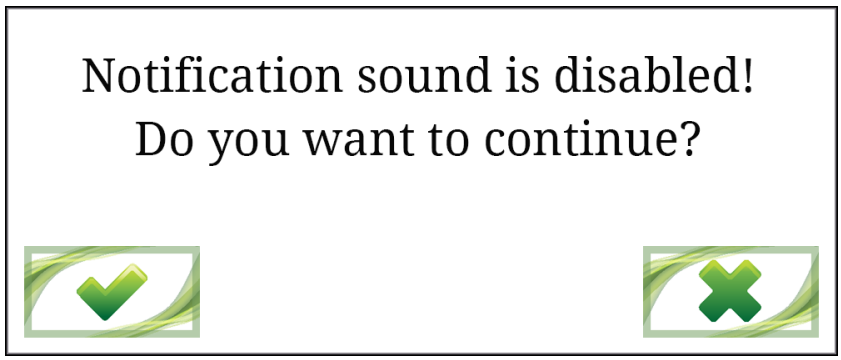
In which:

 : Restarts the treatment.

 : Results in returning to the Main menu.
Note that the Standby warning will sound after 5 minutes if the pump is not activated again.

5.9 "Acoustic Signal disabled" notification (Notification sound)

When you press on Start if the sound notification is disabled the display will show a notification.



In which:

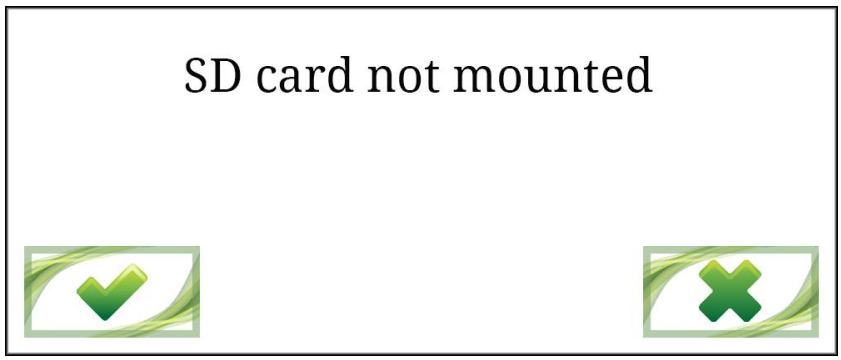
 : Starts the treatment with disabled acoustic warning.

 : Results in opening the Notification setting.
You now can change the notification sound setting
Note that the Standby warning will sound after 5 minutes if the pump is not activated again.

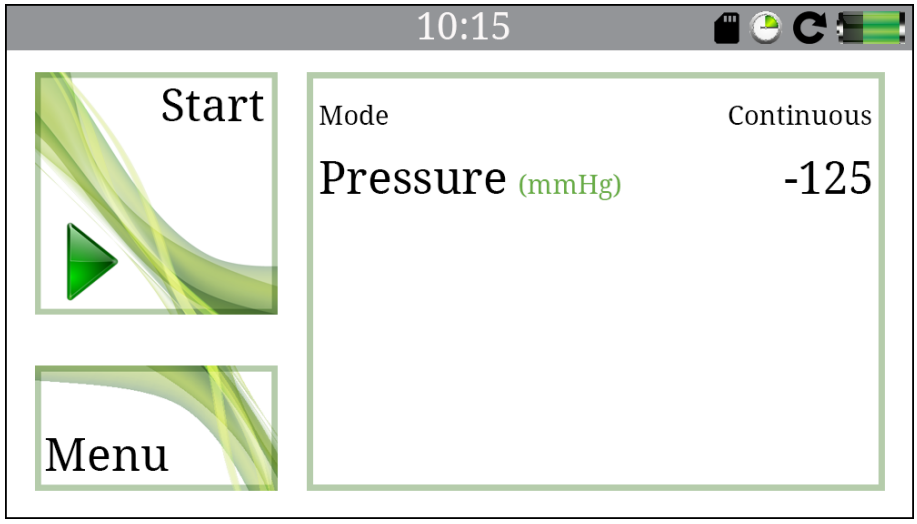
WARNING:
If you do not respond to this message the notification will close after 3 minutes.
If no treatment has been started earlier the system will shut down after 5 minutes
If treatment has been started earlier the "Standby Warning" will sound after 5 minutes.

5.10 SD card not present or malfunctioning

When the SD card is not present or not working properly you will see a notification during start-up and an icon of an SD card on the Start menu.



Notification at start-up



Start menu with no SD card present

The Exsudex XL has been designed in such a way that the patient during use will not notice anything.
After restarting the Exsudex XL the language will be standard English and cannot be adjusted.
Log files will not be updated when the SD card is not available.

6 Battery

The Exsudex XL has a rechargeable battery.
We advice you to check battery each year, and when necessary replaced by a certified technician!

6.1 Charging

By connecting the adapter which is supplied with the Exsudex XL to a power source the battery will be charged

WARNING:
The Exsudex XL should only be charged with the supplied charger;

6.2 Usage

On the right side of the LCD the battery status is indicated.
Display of symbols as shown in chapter 5.7 - “Battery low” notification.
With a full battery the Exsudex XL can maintain its negative pressure for at least 12 hours.

The maximum duration depends upon:

- air tightness of the system from wound to pump
- the level of negative pressure that is used
- the age of the battery

If the battery is at a level at which the Exsudex XL functions properly the warning will sound.
The battery icon will be red. This warning can be switched off by connecting the Exsudex XL adapter.
If the mains voltage is lost, the Exsudex XL will automatically switch to battery power.

7 Maintenance

We recommend that you use personal protective equipment, such as medical gloves, when cleaning the device to reduce the risk of infection and contact with blood and body fluids.

7.1 Daily

The pump is isolated from contact with the patient and his/her bodily fluids, therefore daily cleaning of the pump is not mandated. In the event of accidental contamination, please refer to chapter 7.2 - Weekly, New patient or in case of accidental contamination.
Other maintenance - cleaning the Exsudex XL and removal of residues should be done in line with current environmental regulations.
The Exsudex XL has no components which need to be sterilized after an event of accidental contamination or known environmental contaminant hazard.

7.2 Weekly, New patient or in case of accidental contamination

The Exsudex XL can be cleaned with normal domestic non-scouring cleaning agents.
The Exsudex XL has no components which need to be sterilized
In case of accidental contamination cleaning is essential before any disinfection is carried out.
Any visible soiling on the outside of the unit should be cleaned using a damp single use cloth and neutral detergent.
Dry before disinfection.
Disinfect using a single use anti bacterial wipe suitable for medical equipment e.g. IzoPro (70% isopropyl alcohol)
Cleaning agents and disinfectants should NOT be used in an undiluted form and should be compatible with plastics.
The unit is sealed so that no liquids should enter the device. If cleaning or disinfecting liquid does penetrate the device contact your dealer for assistance.

7.3 Periodical inspection

It is recommended that Exsudex XL units are checked and that the battery is replaced – when necessary - by a certified technician.
It is recommended to replace the battery on the print circuit board every 2 year.

7.4 What to do if fluid enters the Exsudex XL

If fluid is seen in the compartment in the canister where the bacterial filter is situated, this could be an indication that fluid has entered the Exsudex XL. Normally the filter will block the fluid.
Please contact your dealer immediately for a replacement pump.
Do not continue to use the Exsudex XL.

If fluid is seen in the tubing between the canister and the filter on the pump, or if fluid is seen in the filter compartment in the Exsudex XL disposable canister this could be an indication that fluid has entered the Exsudex XL.
Normally the filter will block the fluid.
Please contact your dealer immediately for a replacement pump.
Do not continue to use the Exsudex XL.

7.5 Proper use of accessory kits and canisters.

All products, including the canister and disposable kits of individual components, are not designed for cleaning or reuse and should be properly discarded after patient use.

8 Bacterial filter / Disposable Canister

The bacterial filter is a 2 micron bacterial filter with a 2 inch diameter to prevent microbial contamination whilst allowing enough flow for function.
The bacterial filter should be replaced for each new patient and if the pump is in use for 30 days.
The filter in the Exsudex XL canister is a 3 micron bacterial filter with a 32 mm diameter in order to keep fluid away from the pump whilst allowing enough flow for function.
The Exsudex XL canister should be replaced for each new patient and if the canister is in use for 7 days.

8.1 Inspection

The filter can be checked visually for contamination; if the tube connected to the filter is contaminated the filter should also be considered to be contaminated and both items should be replaced.
The canister can be checked visually for contamination; if the compartment where the filter is situated is contaminated the canister should be replaced.

8.2 New Patient

The bacterial filter should be replaced for each new patient and if the pump is in use for 30 days.
The Exsudex XL canister should be replaced for each new patient and if the canister is in use for 7 days.
This to avoid micro bacterial contamination.

9 Warranty

9.1 Total warranty

The warranty for the Exsudex XL treatment system is 12 months from the date of invoice, unless otherwise in writing agreed.

This warranty includes all parts that fail during the 12-month period and on-site labour.

9.2 Exclusions

NOT covered by the above warranty:

- Faults in or at parts, apparatus and instruments related to misuse or abuse by untrained personnel.;
- Defects related to normal wastage in or at parts, apparatus and instruments.
- Unauthorized alteration or repair.
- Misuse, abuse and incorrect maintenance.
- Damage caused by wrong handling or transportation.
- Damage caused by peaks in supply voltage or wrong voltage characteristics, damaged cause by incorrect ambient conditions or other non-adherence to the applicable ambient requirements.
- Alteration, defacement or removal of the serial number.

The warranty of a component, device, or instrument is void if misuse, abuse or unauthorized use within the warranty period, results to a claim for the above warranty "from any shortage" to the delivered parts, equipment or tools.
"Any shortage" means material or manufacturing error that causes the component, device or mechanism not working properly

The following products are not covered under warranty after the first year of use (in writing agreed warranty period longer than 12 months)

- Replaceable pumping mechanism or motor.
- Items with normal wear and tear.

In case of a malfunction, never attempt to repair the Exsudex XL yourself.
Notify your local distributor. Only qualified technical personnel authorized by the manufacturer or The Medical & Woundcare Company may perform repairs to the Exsudex XL.

9.3 Consumables

Warranty on consumables, such as tubing, filters, canisters and accessory kits will explicit not be granted.

10 Technical specifications

10.1 Safety standards

Reference	Standards	Revision date
QMS		
EN ISO 13485:2016	Medical Devices -Quality Management systems – Requirements for regulatory purposes.	2016
EN ISO 14971	Medical devices - Application of risk management to medical devices	2019
EN IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	C11:2016
Product		
EN-IEC 60601-1:2006 + AC:2010 + A1:2013 + A12:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2006/A12:2014
EN-IEC 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	2015
EN-IEC 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	2010
EN-IEC 60601-1-11:2010	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	2010
EN-IEC 62304:2006 + C11:2006 + A1:2015	Medical device software - Software life-cycle processes	2006/A1:2015
EN-IEC 61000-3-2:2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	2014
EN-IEC 61000-3-3:2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection	2013
EN-ISO 10079-1	Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements	2009
Information supplied		
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices	2008/A1:2013
EN-ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016
Sterility		
N.A.		
Sterile barrier system		
N.A.		

10.2 Specifications

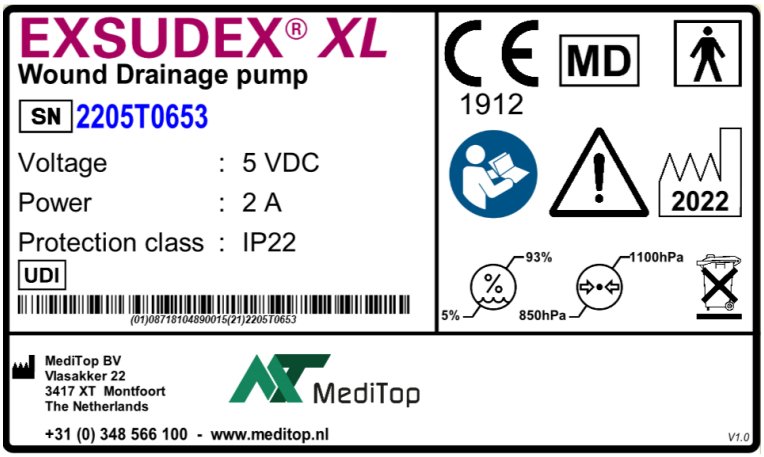
Type (according IEC 60601-1)	:	BF
Classification (according IEC 60601-1)	:	II
Classification (according 93/42/EEG)	:	IIa
Internal voltage	:	5 Volt DC ⎓ 2A
External voltage (Power Adapter)	:	100-240 Volt AC / 50-60 Hz 0.4-0.2A
Maximal use	:	10 Watt
Dimensions H x W x D [mm]	:	255 x 145 x 125 (when used in combination with Exsudex XL canister)
Weight	:	1.1 kg
Pump capacity	:	Max. 5.5 liters/minute

10.3 Environment

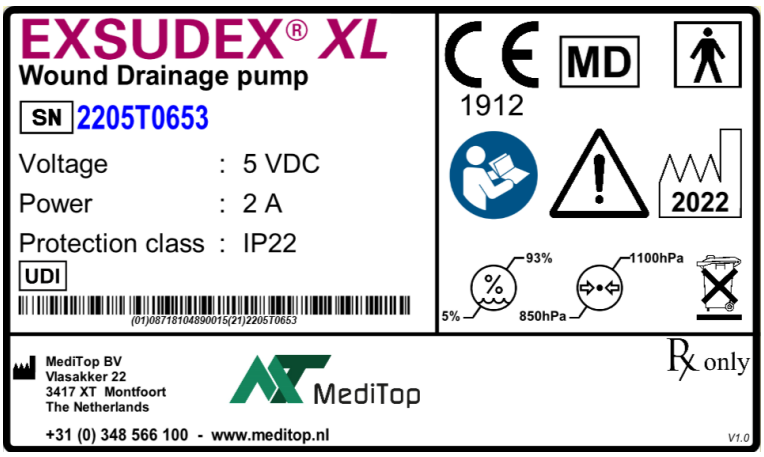
Protection class	:	IP22[2]
Operating temperature	:	+5° C to +40° C
Storage temperature	:	-20° C to +70° C
Humidity	:	5 to 93%, non condensing
Atmospheric pressure	:	850 to 1100 hPa

[2] *The IP Code, International Protection Rating, classifies and rates the degree of protection provided against the intrusion of solid objects (including body parts such as hands and fingers), dust, accidental contact, and water in mechanical casings and with electrical enclosures. It is published by the International Electrotechnical Commission (IEC).*
The standard aims to provide users more detailed information than vague marketing terms such as waterproof.
The Exsudex XL, rated IP22 is protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water.

10.4 Identification Label

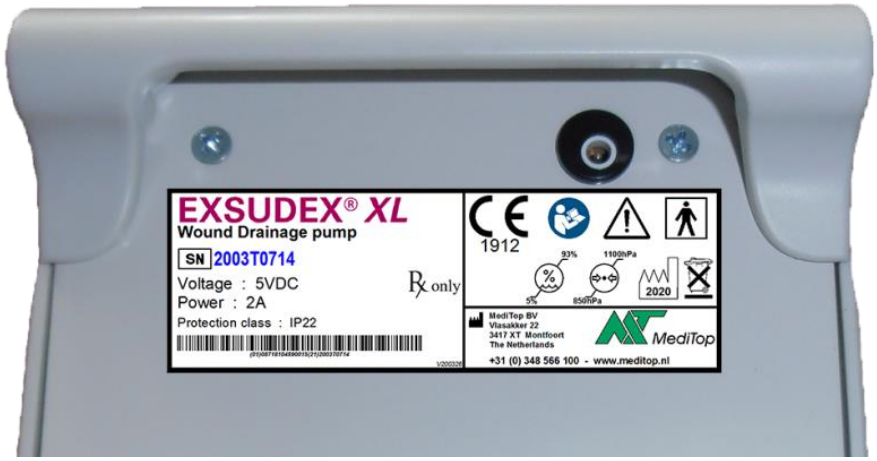


Exsudex XL Label (except for US)

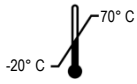
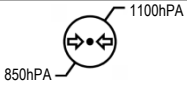
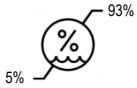


Exsudex XL Label (US only)

You can find the label on the back side of the apparatus under the handle.



10.5 Explanation of symbols

CE 1912	This symbol indicates that the Exsudex XL is a class IIa product which is in accordance with the medical directive 93/42/EEC, Annex II.
	The exclamation mark within an equilateral triangle is intended to alert the user to the presence of important operating and maintenance (servicing) instructions in the literature accompanying the appliance.
	This symbol is to signify that the instruction manual must be read.
	This symbol indicates that the Exsudex XL is type BF according to IEC601-1.
℞ only	Federal law restricts this device to sale by or on the order of a physician, or with the descriptive designation of any other practitioners licensed by the law of the State in which that person practices to use or order the use of the device. (only for US)
	Year of manufacture
	Manufacturer Information.
SN	Serial number.
	Temperature limit for storage.
	Atmospheric pressure limitation.
	Humidity limitation.
	Fragile, handle with care.
	Keep dry.
	Separate waste collection for electrical and electronic devices.

10.6 Guidance and manufacturer's declaration – electromagnetic immunity

The Exsudex XL needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the user manual.

Wireless communication devices, such as wireless devices in the home network, mobile phones, cordless phones and their base stations, walkie-talkies can affect the Exsudex XL.

We advise you not to place the Exsudex XL very close to other electronic equipment.
Should this be the case, the operation of the Exsudex XL should be regularly monitored.

Although this device complies with the standard of IEC 60601-1-2 concerning electromagnetic compatibility, all electrical appliances may cause interference.

If you suspect that interference occurs, you must separate the equipment and contact your local dealer or MediTop

10.6.1 Applied standards

Test	Standard	Class / Level
Emission	NEN-EN-IEC 60601-1-2:2015	-
Immunity	NEN-EN-IEC 60601-1-2:2015	Professional healthcare facility environment
Emission	NEN-EN-IEC 61000-3-2:2014	A
Emission	NEN-EN-IEC 61000-3-3:2013	--

10.6.2 Table 4 - Enclosure port

Phenomenon	Basic EMC standard or test method	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM fields [a)]	IEC 61000-4-3	3 V/m f) 80 MHz – 2,7 GHz [b)] 80 % AM at 1 kHz [c)]	10 V/m f) 80 MHz – 2,7 GHz [b)] 80 % AM at 1 kHz [c)]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See 8.10 of NEN EN ISO 60601-1-2:2015	
Rated power frequency magnetic fields [d) e)]	IEC 61000-4-8	30 A/m [g)] 50 Hz or 60Hz	

a) The interface between the patient physiological signal simulation, if used, and the ME Equipment or ME System shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME Equipment or ME System.
b) ME Equipment and ME Systems that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the Risk Management Process. This test assesses the Basic Safety and Essential Performance of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during test.
c) Testing may be performed at other modulation frequencies identified by the Risk Management Process.
d) Applies only to ME Equipment and ME Systems with magnetically sensitive components or circuitry.
e) During the test, the ME Equipment or ME System may be powered at any nominal input voltage, but with the same frequency as the test signal (see Table 1).
f) Before modulation is applied.
g) This test level assumes a minimum distance between the ME Equipment or ME System and sources of power frequency magnetic field of at least 15 cm. If the Risk Analysis shows that the ME Equipment or ME System will be used closer than 15 cm to sources of power frequency magnetic field, the immunity test level shall be adjusted as appropriate for the minimum expected distance.

10.6.3 Table 5 - Input a.c. power port

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrical fast transients / bursts [a) l) o)]	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges [a) b) j) o)] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges [a) b) j) k) o)] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields [c) d) o)]	IEC 61000-4-6	3 V m) 0,15 MHz – 80 MHz 6 V [m)] in ISM bands between 0,15 MHz and 80MHz n) 80% AM at 1 kHz [e)]	3 V m) 0,15 MHz – 80 MHz 6 V [m)] in ISM and amateur radio bands between 0,15 MHz and 80MHz n) 80% AM at 1 kHz [e)]
Voltage dips [f) p) r)]	IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [q)]	
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles [h)] Single phase: at 0°	
Voltage interruptions [f) i) o) r)]	IEC 61000-4-11	0 % UT; 250/300 cycle [h)]	

a) The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.
b) All ME EQUIPMENT and ME SYSTEM cables are attached during the test.
c) Calibration for current injection clamps shall be performed in a 150 Ω system.
d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.
g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.
h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.
i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.
j) ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).
k) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.
l) Direct coupling shall be used.
m) r.m.s., before modulation is applied.
n) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.
p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.
q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip.
If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.
r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltage. ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input voltage within the range. See Table 1 Note c) for examples calculations.

10.6.4 Table 6 - Input d.c. power port

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrical fast transients / bursts [a) g)]	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges [a) b) g)] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges [a) b) g)] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields [a) c) d) i)]	IEC 61000-4-6	3 V h) 0,15 MHz – 80 MHz 6 V [h)] in ISM bands between 0,15 MHz and 80MHz 80% AM at 1 kHz	3 V h) 0,15 MHz – 80 MHz 6 V [h)] in ISM and amateur radio bands between 0,15 MHz and 80MHz [j)] 80% AM at 1 kHz [e)]
Electrical transient conduction along supply lines [f)]	ISO 7637-2	Not applicable	As specified in ISO 7637-2

a) The test is applicable to all d.c. power PORTS intended to be connected permanently to cables longer than 3 m.
b) All ME EQUIPMENT and ME SYSTEM cables shall be attached during the test
c) INTERNALLY POWERED ME EQUIPMENT is exempt from this test if it cannot be used during battery charging, is of less than 0,4 m maximum dimension including the maximum length of all cables specified and has no connection to earth, telecommunications systems, any other equipment or a PATIENT.
d) The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages.
e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
f) For ME EQUIPMENT and ME SYSTEMS intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems
g) Direct coupling shall be used.
h) r.m.s., before modulation is applied.
i) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
j) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

10.6.5 Table 7 - Patient coupling port

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic discharge [c)]	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Conducted disturbances induced by RF fields [a)]	IEC 61000-4-6	3 V b) 0,15 MHz – 80 MHz 6 V [b)] in ISM bands between 0,15 MHz and 80MHz 80% AM at 1 kHz	3 V b) 0,15 MHz – 80 MHz 6 V [b)] in ISM and amateur radio bands between 0,15 MHz and 80MHz 80% AM at 1 kHz

a) The following apply:
All PATIENT-COUPLED cables shall be tested, either individually or bundled
PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b) r.m.s., before modulation is applied

c) Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation.
PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

10.6.6 Table 8 - Signal input/output parts port

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic discharge [e]	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Electrical fast transients / bursts [b] [f]	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency	
Surges Line-to-ground [a]	IEC 61000-4-5	± 2 kV	
Conducted disturbances induced by RF fields [b] [d] [g]	IEC 61000-4-6	3 V h) 0,15 MHz – 80 MHz 6 V [h] in ISM bands between 0,15 MHz and 80MHz [i] 80% AM at 1 kHz [c]	3 V h) 0,15 MHz – 80 MHz 6 V [h] in ISM and amateur radio bands between 0,15 MHz and 80MHz [i] 80% AM at 1 kHz [c]

a) This test applies only to output lines intended to connect directly to outdoor cables.
b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.
c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
d) Calibration for current injection clamps shall be performed in a 150 Ω system.
e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.
f) Capacitive coupling shall be used.
g) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
h) r.m.s., before modulation is applied.
i) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

10.6.7 Table 9 - Test specifications for enclosure port immunity to RF wireless communications

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation [b]	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 [b], RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 [a]	Pulse modulation [b] 217 Hz	0,2	0,3	9
5500						
5785						

NOTE:
If necessary, to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

10.7 Manufacturer

Name: MediTop BV
Address: Vlasakker 22
ZIP code: 3417 XT
City: Montfoort
Country: The Netherlands

Phone: +31 348 566 100
Email: exsudex@meditop.nl

10.8 Disposal

When the Exsudex XL has reached the end of its lifetime and needs to be replaced, the Exsudex XL should be disposed of in accordance with local laws and regulations.

The Exsudex XL can be dismantled and divided in 3 major parts:

- Metal
- Plastics
- Electronic/electrical parts (please follow the local laws and regulations for electrical equipment)

This symbol means that the product must not be disposed of as normal domestic waste.

Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste, it should be disposed in accordance with the DIRECTIVE 2012/19/EC.
The correct disposal of electrical or electronic devices helps to protect the environment and to prevent potential hazards to the environment and/or human health which may occur as a result of improper handling of the devices concerned. For detailed information on the disposal of the product, please contact your local dealer or the device manufacturer or its legal successor. Please also note the manufacturer's current information on the Internet. In the event of resale of the product or its components, the seller is required to inform the buyer that the product must be disposed of in accordance with the applicable national regulations currently in force.

For regions outside the European Union disposal should be in accordance with local regulations, so this product should be disposed of as an electronic device separately.

10.9 Shelf life

The Exsudex XL has a limited shelf life before commissioning of 5 years.

10.10 Life

The life of the Exsudex XL is 10 years, provided that annual maintenance is performed.

11 Troubleshooting

11.1 No picture or text appears on the Exsudex XL display.

Is the main switch turned on?

- No, Turn the main switch on.
  Should the problem not be resolved, please see as described below under “Yes”.

- Yes, The battery could be empty. Please connect the charger
  Should the problem not be resolved, please contact your local dealer.

11.2 The set pressure is not reached.

Please fold the tubing double so that is sealed!
Is the set pressure reached now?

- Yes, The wound is not airtight closed

- No, See below

When using the Exsudex XL disposable canister:
Is the canister placed on the right way on the Exsudex XL?

- Yes, Replace the canister.
  If now still the set pressure is not reached and you have ensured that the wound is airtight closed please contact your local dealer.

- No, Place the canister on the right way.
  Should the problem not be resolved, please see as described above under “Yes”

When using a reusable canister with disposable bags:
Is the lid of the disposable bag firmly pressed on the collecting bottle?

- Yes, Remove the bacterial filter and connecting tube and replace it
  If now still the set pressure is not reached and you have ensured that the wound is airtight closed please contact your local dealer.

- No, Place the lid on the right way.
  Should the problem not be resolved, please see as described above under “Yes”