THE MEDICAL& WOUNDCARE COMPANY

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User Manual

EXSUDEX® *XS*

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 XS 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 XS, the manufacturer must be notified.
- The Exsudex XS 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 XS is allowed for a maximum period of 30 consecutive days use.
- During operation keep the Exsudex XS upright.
- The Exsudex XS should only be attached to the patient by qualified medical personnel.
- The Exsudex XS should be used with special wound dressings and accessories.
- The Exsudex XS 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 XS.
- The Exsudex XS should not be placed in water or other liquids.
- **Sleeping:**
  - Make sure the Exsudex XS is placed so that the tube cannot bent or clamped of.
  - Make sure the Exsudex XS cannot be pulled of your bedside table or fall to the floor in your sleep.
  - We recommend you to connect the Exsudex XS 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.
- Please contact you doctor or healthcare provider immediately if you cannot resolve a warning condition.
- 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 XS 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 XS 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 XS Wound Drainage Device is connected to the external canister by means of a disposable canister:

A) Mounting the Exsudex XS Disposable canister (contents 300 ml) with integrated bacteria filter on the device;
Placing the canister on the Exsudex XS

Press the Exsudex XS over the canister until you hear a click.
(Figure 1)

The canister is now precisely mounted on the Exsudex XS and ready for use.
(Figure 2)

Figure 1

Mounting canister

Figure 2

Exsudex XS with mounted canister.

B) Removing the Exsudex XS Disposable canister (contents 300 ml) with integrated bacteria filter on the device;

Press the lock button on the back of the unit and pull the canister down.

For inserting a new canister see as described above [A)]

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 XS pump is a means for building negative pressure. The canister, when connected to the pump, functions as wound fluid storage.

The Exsudex XS 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 al 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) Foam is placed in the wound. Then the Pad is placed. The pad is connected by tubing to the Exsudex XS wound drainage pump.
B) A drain is placed into the wound. A gauze dressing is placed over the drain and secured by a seal over the wound bed. Then the Pad is placed. The pad is connected by tubing to the Exsudex XS wound drainage pump.
C) A drain is placed in the wound. A gauze dressing is placed over the drain and secured by a seal over the wound bed.
The drain is connected by tubing to the Exsudex XS wound drainage pump.

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 warning
- Battery- low warning
- 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 XS (see section 3 - Operation) is activated by pressing the start button.

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

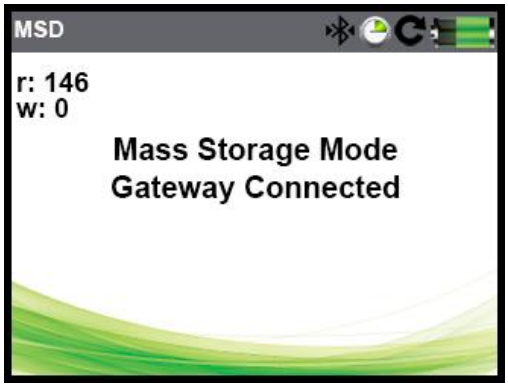
It is recommended that the Exsudex XS is serviced on an annual basis by an approved technician.

1.4 Bluetooth connection

The Exsudex XS 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 XS can only be connected via bluetooth with the Exsudex XS 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 XS is indicated for all patients that benefit from negative pressure therapy for wound treatment.

1.5.2 Contraindications

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

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

The Exsudex XS 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 XS 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 XS 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 XS.
⚠	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 XS.
⚠	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 before treatment when using the Exsudex XS is prescribed for the home environment of the patient.

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 XS 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.

Exsudex XS Disposable Canister with integrated bacterial filter
Disposable canister 300 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 XS 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.*

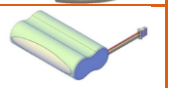
2 Product components

2.1 Scope of delivery

Description	Qty.
Exsudex XS wound drainage system	1
Power adapter 5V – 2A **(The Exsudex XS 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 XS Disposable canister with fixed tube with Christmas tree connector	16690	
Exsudex XS battery 3.7V	3000558	
Exsudex XS power adapter 5V – 2A, length 4 meter. **(EU = European plug, USA = USA plug)**	3000723-EU 3000723-USA	

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

CAUTION:

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

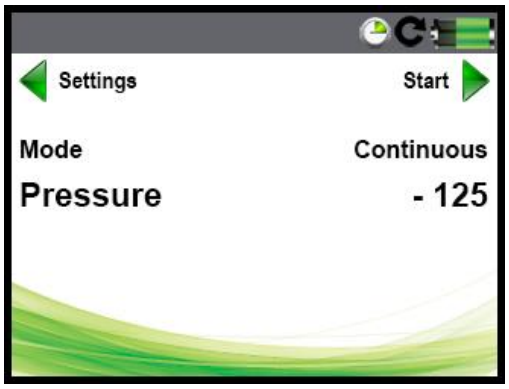
3 Operation

Top view Exsudex XS

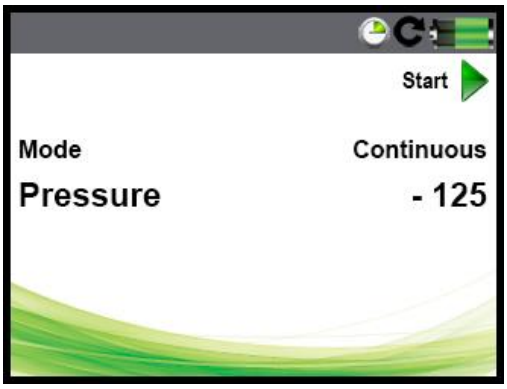
The unit has to be turned on by means of the switch, see picture below, on the top left of the apparatus.

After which the device is operated with the buttons on the top of the apparatus corresponding to the indicated button on the LCD.

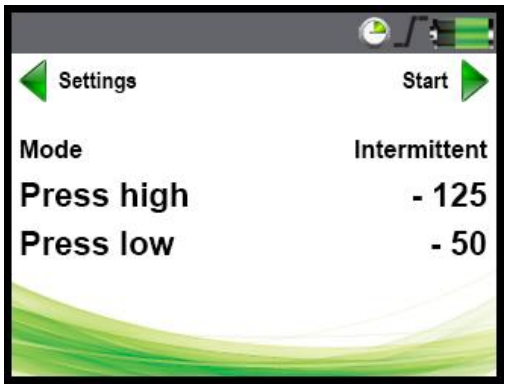
The Exsudex XS features an LCD screen at the top of the unit.
This screen displays information about the current function or setting.



A. Startup window Continuous General setting



B. Startup window Continuous Homecare setting



C. Startup window Intermittent general setting

D. Startup window Intermittent Homecare setting

Switching off the Exsudex XS is only possible if the pump is not running by pressing the On/Off button for approximately 3 seconds.

The Exsudex XS has 4 buttons:

The operation of a corresponding button is indicated on the LCD display.

The master on/off switch has outside the indicated function also the ability to switch off the system when pressing the button for approximately 3 seconds.


Switching of the Exsudex XS by pressing for approximately 3 seconds.


(Start) Starting the treatment with the Exsudex XS


(Settings) Cycle through the menu (see chapter 3.1 - Settings)

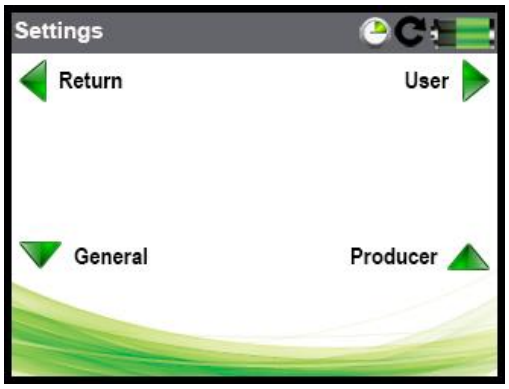
3.1 Settings

To adjust the settings the pump of the Exsudex XS must not be running.

When Settings is not displayed on the LCD display, it means the function is disabled for homecare use.
You can enable the settings by pressing the button for 10 seconds, when you are in the Start menu.
(Please make sure the display is not dimmed!)
Settings will be displayed on the display.

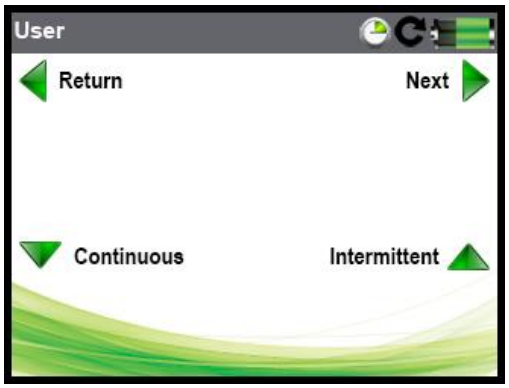
Home Care Suituation
Note: Do not forget to enable/switch off the settings menu after entering the correct settings!
Press the button for 10 seconds in the start menu. The text/function settings is gone now.
This to prevent the ability that the patient can adjust the settings!

Press on *(Settings)*

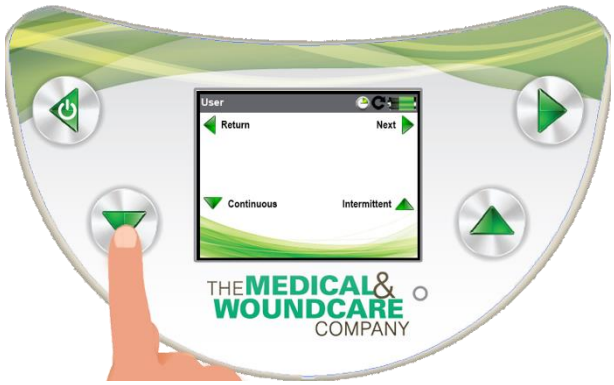


3.1.1 User settings

Press on  *(User*  *)*



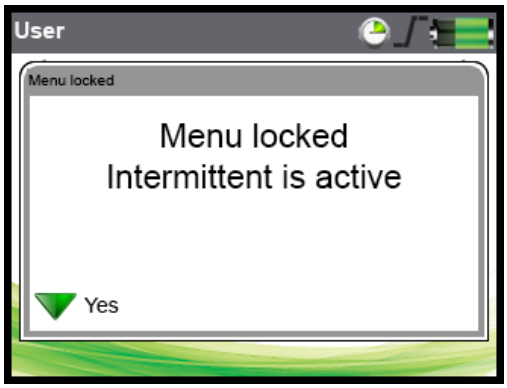
3.1.1.1 Pressure settings Continuous Mode



Press in the User menu on (*Continuous)*

You can now sequentially adjust Pressure, Tolerance, Tube blocking Power mode and Purge mode settings.

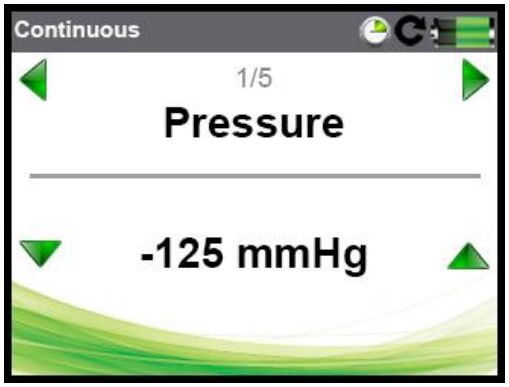
Note:
When intermittent suction is enabled the menu “Continuous” will not be available!
Display will show the next message:



In which:

Back to User menu

3.1.1.1.1 Pressure:



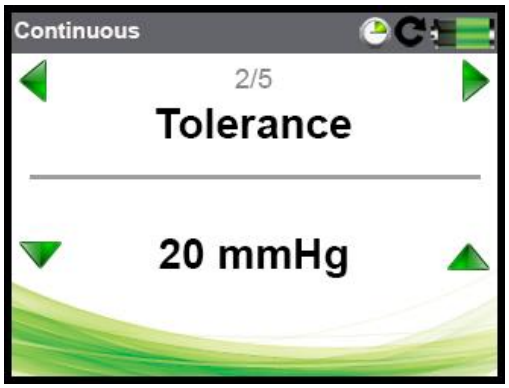
In which:

- Results in → Menu Back
- Step further in menu → Tolerance
- Decreasing the negative pressure value
- Increasing the negative pressure value

The available pressure ranges from -10 to -200 mmHg in 5 mmHg steps.

When done press for the next setting.

3.1.1.1.2 Tolerance:



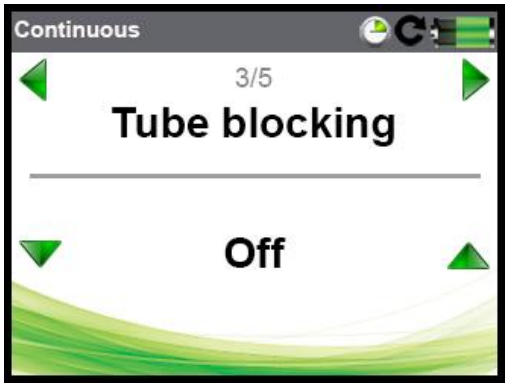
In which:

- Results in → Menu Back
- Step further in menu → Tube blocking
- Decreasing the tolerance
- Increasing the tolerance

The deviation tolerance for the negative pressure can be set between 5 to 80 mmHg in 5 mmHg steps.
The warning “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 -125 mmHg and the tolerance is set on 20 mmHg the warning will sound if the pressure in the system is less than - 105 mmHg.

When done press for the next setting.

3.1.1.1.3 Tube blocking:



In which:

Results in → Menu Back

Step further in menu → Power mode

Toggle between On or Off

Toggle between On or Off

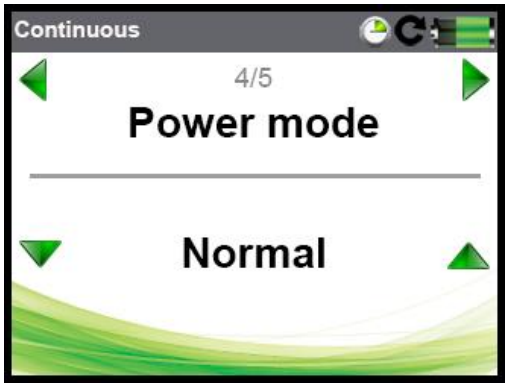
Tube blocking can be set On or Off.
When enabled the next symbol will be displayed on the right side in the grey menu bar:

NOTE:
Tube blocking warning is functional during Purge mode in Interval mode.
If the set time for the tube blocking warning 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 warning is set to 5 minutes.

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

When done press for the next setting.

3.1.1.1.4 Power mode



In which:

 Results in → Menu Back

 Step further in menu → Purge mode

 Toggle between On or Off

 Toggle between On or Off

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.

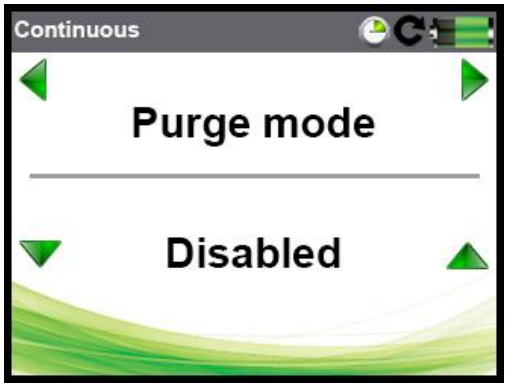
Slow mode:
When patients severe a lot of pain because of the treatment you can set the Power mode to Slow.
The slow mode function has a longer interval in controlling the motor which will result in a longer time before the pump reaches the set value.
When set to Slow the time within the set pressure 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 er 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 done press  for the next setting.

3.1.1.1.5 Purge mode



In which:

Results in → Menu Back

Step further in menu → Pressure

Toggle between Disabled, Interval or Automatic

Toggle between Disabled, Interval or Automatic

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 XS 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.

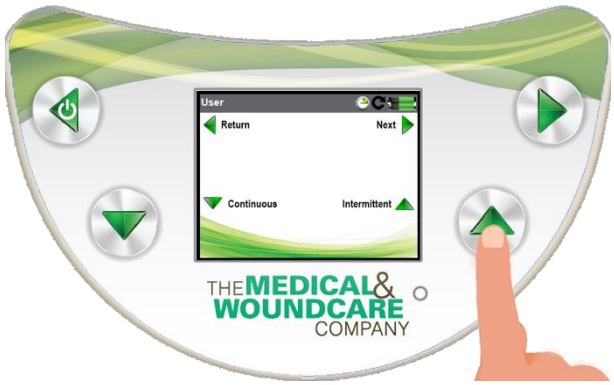
Interval:
Every set time (factory setting is 5 minutes) the Exsudex XS will release pressure for a set period (factory setting is 1 second) and restart treatment again.
If the pump is running at the set time, releasing the pressure will be postponed until the pump stops running.

Automatic:
When the pump has not been running during a set time (factory setting is 5 minutes) the Exsudex XS 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:

When all settings are done press to go back one menu

3.1.1.2 Intermittent settings



Press in the User menu on ▲ *(Intermittent* ▲*)*

You can now sequentially adjust Intermittent, Pressure high, Time high, Pressure low, Time low and Tolerance settings.

3.1.1.2.1 Intermittent

In which:

- ⏻ Results in → Menu Back
- ▶ Step further in menu → Pressure High
- ▼ Toggle between On or Off
- ▲ Toggle between On or Off

Intermittent can be set On or Off.
When Intermittent is set On the next symbol will be displayed on the right side in the grey menu bar: ⎍

When done press ▶ for the next setting.

3.1.1.2.2 Pressure high setting

In which:

- Results in → Menu Back
- Step further in menu → Time High
- Decreasing the negative pressure value
- Increasing the negative pressure value

The available pressure ranges from -15 to -200 mmHg in 5 mmHg steps.

When done press for the next setting.

NOTE:
The minimum pressure to be set is the set Pressure low - 5 mmHg

3.1.1.2.3 Time high setting

In which:

- Results in → Menu Back
- Step further in menu → Pressure Low
- Decreasing the time
- increasing the time

Time can be set in steps of 30 seconds (0.5 min) between 1 and 10 minutes.

When done press for the next setting.

3.1.1.2.4 Pressure low setting

In which:

- Results in → Menu Back
- Step further in menu → Time Low
- Decreasing the negative pressure value
- Increasing the negative pressure value

The available pressure ranges from -10 to -195 mmHg in 5 mmHg steps.

When done press for the next setting.

NOTE:
The maximum pressure to be set is the set Pressure high + 5 mmHg

3.1.1.2.5 Time low setting

In which:

- Results in → Menu Back
- Step further in menu → Tolerance
- Decreasing the time
- Increasing the time

Time can be set in steps of 30 seconds (0.5 min) between 1 and 10 minutes.

When done press for the next setting.

3.1.1.2.6 Tolerance:

In which:

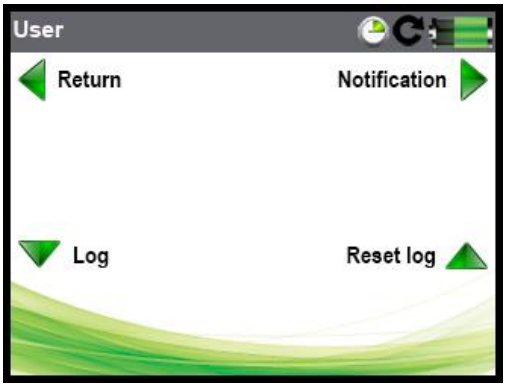
- Results in → Menu Back
- Step further in menu → Intermittent
- Decreasing the tolerance
- Increasing the tolerance

The deviation tolerance for the negative pressure can be set between 5 to 80 mmHg in 5 mmHg steps.
The warning “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 -125 mmHg and the tolerance is set on 20 mmHg the warning will sound if the pressure in the system is less than - 105 mmHg.

When all settings are done press to go back one menu

3.1.2 Warning (Notification) settings

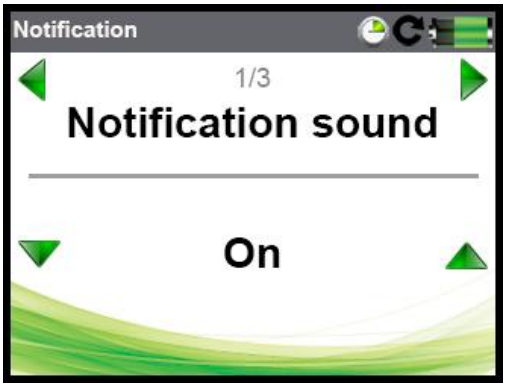
Press in the 1st User menu on  *(Next*  *)*



Press on  *(Notification*  *)*

You can now sequentially adjust Acoustic warning and Delayed warning settings.

3.1.2.1 Notification Sound



In which:

Results in → Menu Back

Step further in menu → Warning delay

Toggle between On or Off

Toggle between On or Off

The sound notification can be set On or Off.

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

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

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

Confirm by pressing or decline by pressing .

When done press for the next setting.

3.1.2.2 Warning Delay

In which:

Results in → Menu Back

Step further in menu → Hold pressure

Decreasing the time

Increasing the time

Following settings are available:

Off ,	(0 min)
30 seconds	(0.5 min),
1 minute	(1 min),
1 minute and 30 seconds	(1.5 min),
2 minutes	(2 min),
2 minutes and 30 seconds	(2.5 min),
3 minutes	(3 min),
3 minutes and 30 seconds	(3.5 min),
4 minutes	(4 min)
4 minutes and 30 seconds	(4.5 min), or
5 minutes	(5 min).

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

When done press for the next setting.

3.1.2.3 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 XS back on line.

In which:

Results in → Menu Back

Step further in menu → Notification sound

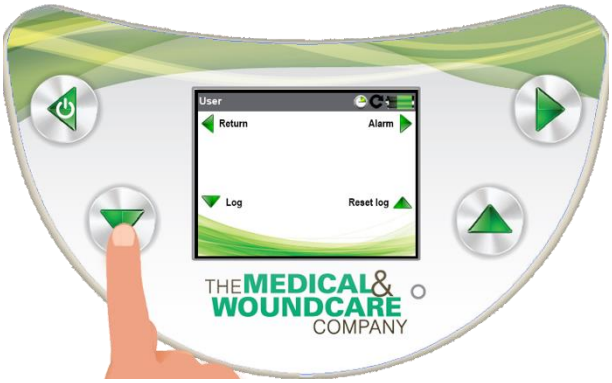
Toggle between On or Off

Toggle between On or Off

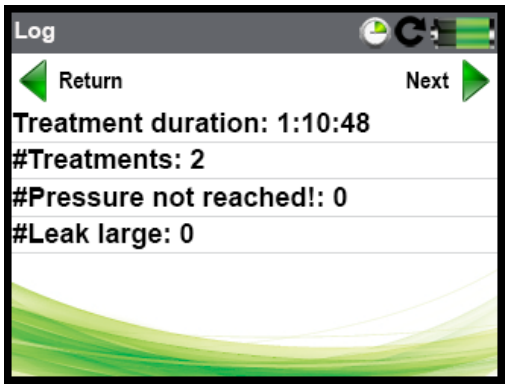
Standard setting is Off.

When all settings are done press to go back one menu

3.1.3 Log



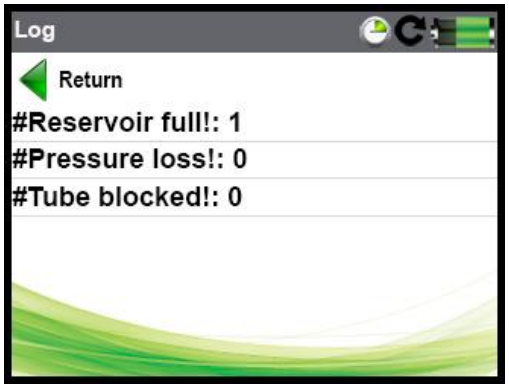
Press in the 2nd User menu on ▼ *(▼ Log)*



You now will see an overview with the recorded:

- Treatment duration in hh:mm:ss
- Treatments in numbers
- Pressure not reached warnings in numbers
- Leak large warnings in numbers

Press on (Next)
to go to the next page which will show you:



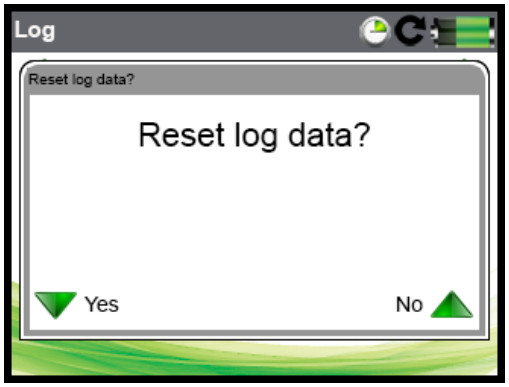
- Reservoir full warnings in numbers
- Pressure loss warnings in numbers
- Tube blocked warnings in numbers

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

3.1.4 Reset Log

Press in the 2nd User menu on ▲ *(Reset log* ▲*)*

After pressing this button the next question will be asked:

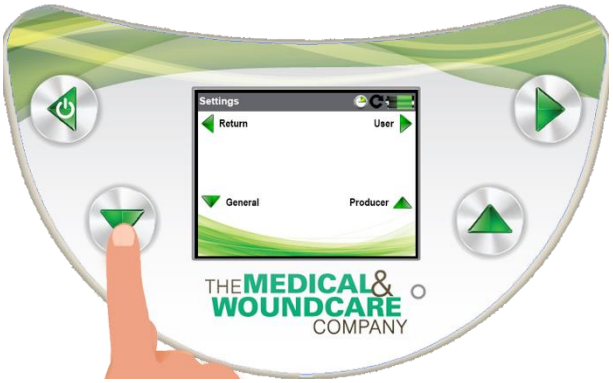


In which:

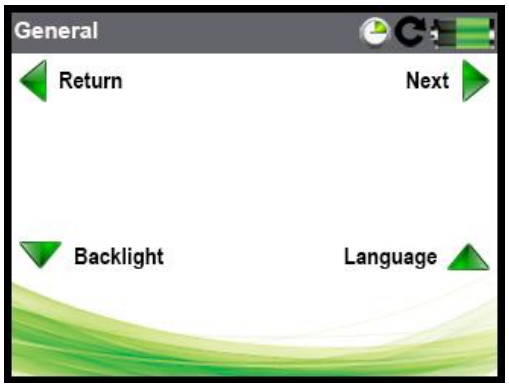
▼ results in setting all numbers back to 0 in the log-file.

▲ results in returning to the menu without adjusting of the values.

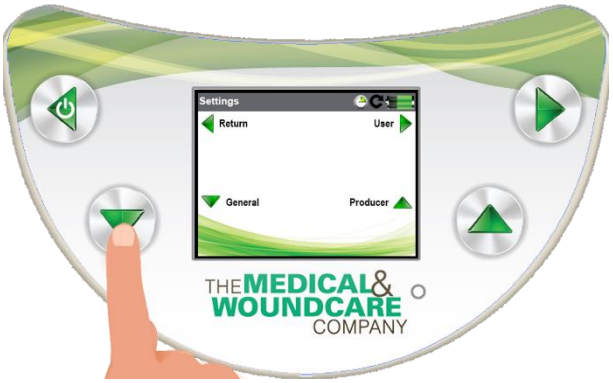
3.1.5 General settings

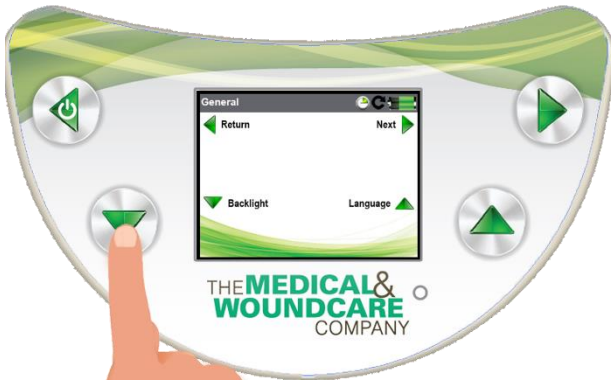


Press in the Settings menu on (▼ *General)*



3.1.5.1 Backlight settings





Press in the General menu on  *(Backlight*  *)*

You can now sequentially adjust Backlight time and Intensity settings.

3.1.5.1.1 Backlight time

In which:

Results in → Menu Back

Step further in menu → Intensity

Decreasing the time

Increasing the time

Following settings are available:

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

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

When done press for the next setting.

3.1.5.1.2 Intensity

In which:

Results in → Menu Back

Step further in menu → Backlight time

Decreasing the intensity

Increasing the intensity

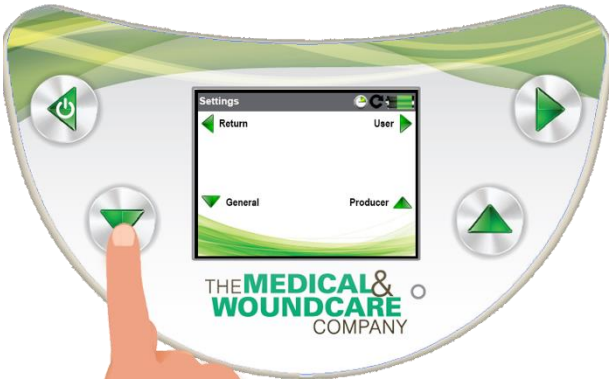
Following settings are available:

0 (Intensity 0%),
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 one of the four buttons results in brightness at 100% brightness.

When all settings are done press to go back one menu

3.1.5.2 Language



Press in the General menu on ▶ *(Language* ▶*)*

You can now select the language.

In which:

- ⏻ Results in → Menu Back
- ▶ Adjusting language
- ▼ Adjusting language

At the present moment following languages are available:

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

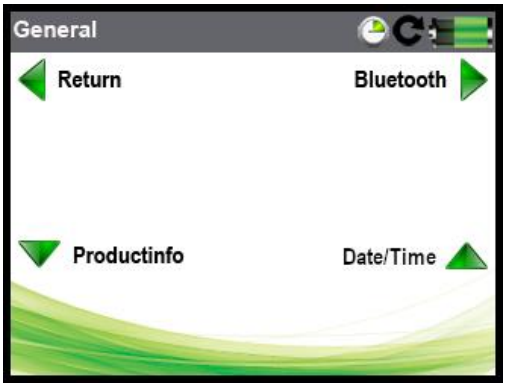
When done press ⏻ to go back one menu

The Medical & Woundcare Company BV
Vlasakker 22
3417 XT Montfoort
The Netherlands

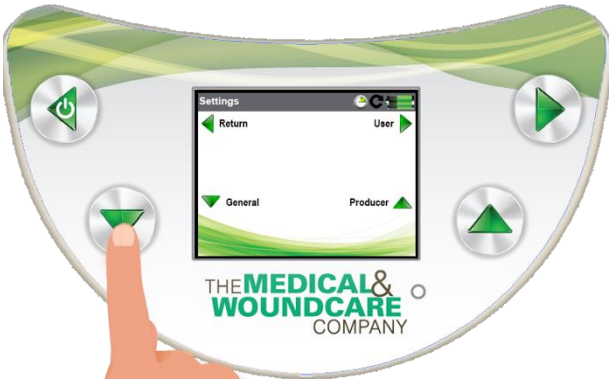
Tel.: +31 (0) 348 475 849
Email: info@tmwc.eu
www.themedcalwoundcare.com

General settings – Continued

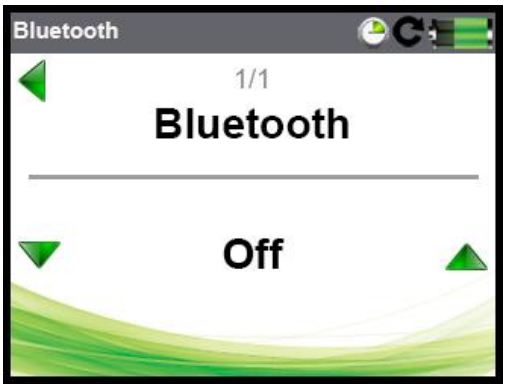
Press in the General Settings on: *(Next)*



3.1.5.3 Bluetooth



Press in the General Settings on:  *(Bluetooth*  *)*



In which:

 Results in → Menu Back

 Toggle between On or Off

 Toggle between On or Off

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

If a Bluetooth connection is established the following symbol is displayed: 

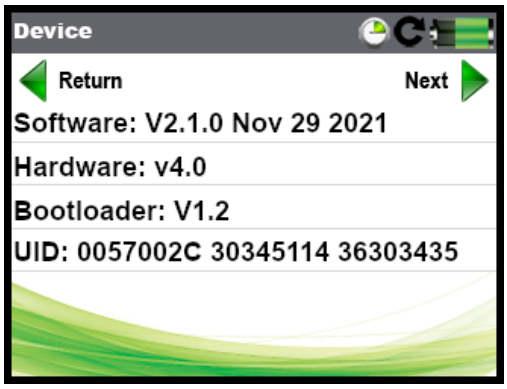
For the time being it is only possible to make a bluetooth connection with the Gateway.

When done press  to go back one menu

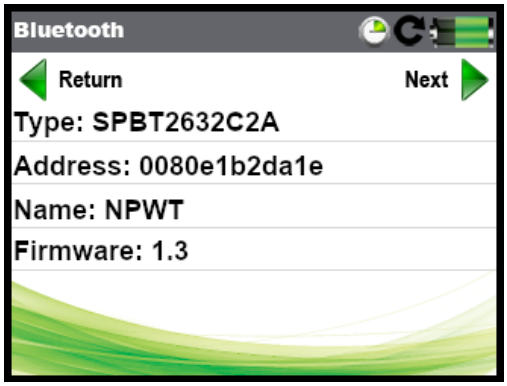
3.1.5.4 Product information

Press in the General menu on ▼ *(▼ Productinfo)*

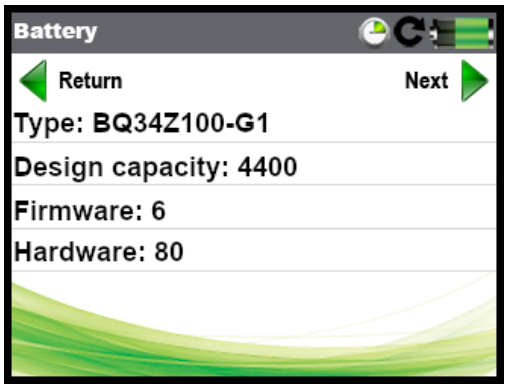
In this screen various information will be displayed about the apparatus, like software version, hardware version and contact details.



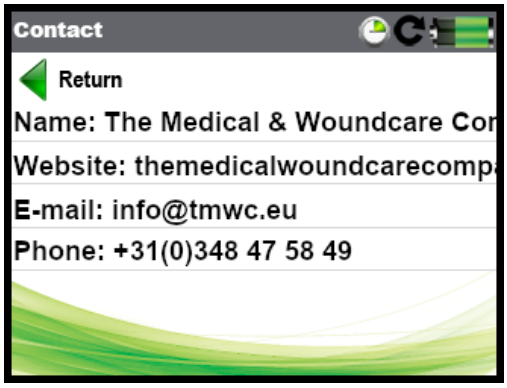
Press on *(Next)*
to go to the next information page (Bluetooth).



Press on *(Next)*
to go to the next information page (Battery).

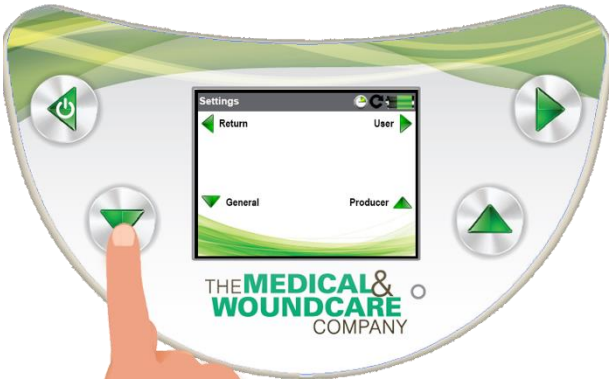


Press on *(Next)*
to go to the next information page (Contact).



Press 4 times on to go back one menu (General).

3.1.5.5 Setting Date and Time



Press in the General menu on (*Date/Time)*

ATTENTION:
The date and time settings will only be saved if a button cell battery is installed on the main board!

3.1.5.5.1 Year

In which:

- Results in → Menu Back
- Step further in menu → Month
- Decreasing the year
- Increasing the year

When done press to go one step further in the menu.

3.1.5.5.2 Month

In which:

- Results in → Menu Back
- Step further in menu → Day
- Decreasing the month
- Increasing the month

When done press to go one step further in the menu

3.1.5.5.3 Day

In which:

- Results in → Menu Back
- Step further in menu → Hour
- Decreasing the day
- Increasing the day

When done press to go one step further in the menu

3.1.5.5.4 Hour

In which:

- Results in → Menu Back
- Step further in menu → Minute
- Decreasing the hour
- Increasing the hour

When done press to go one step further in the menu

3.1.5.5.5 Minute

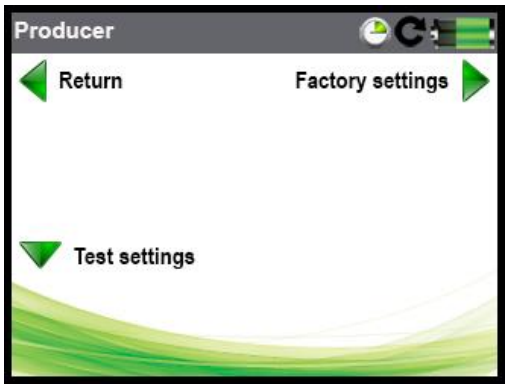
In which:

- Results in → Menu Back
- Step further in menu → Year
- Decreasing the minute
- Increasing the minute

When done press 3 times on to go back one menu (Settings)

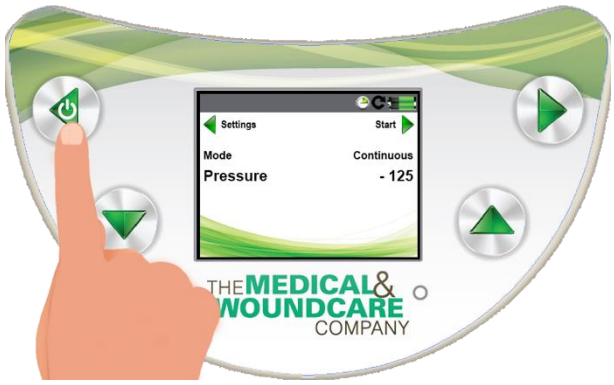
3.1.6 Producer Settings

Press in the Settings menu on (Producer)



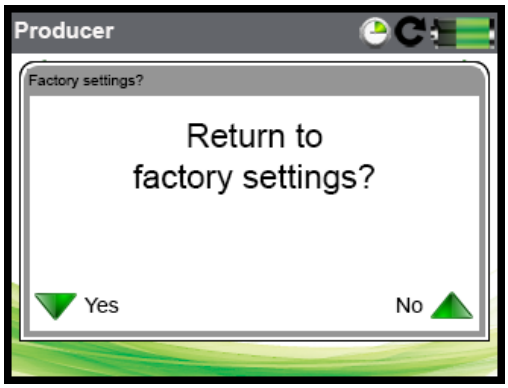
3.1.6.1 Factory Settings

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



Press in the Producer menu on  *(Factory settings*  *)*

After pressing this button the next question will be displayed:



In which:

 results in restoring the Exsudex XS 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 XS 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 displayed.

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

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

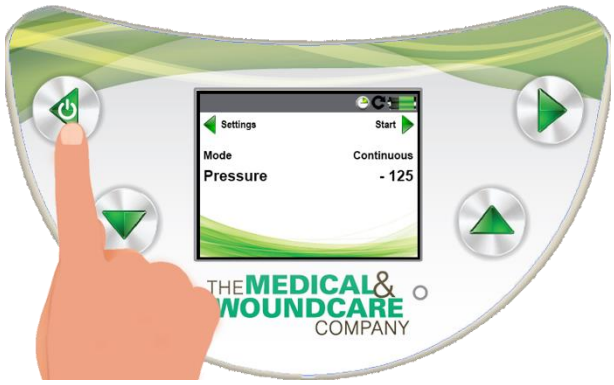
 results in returning to the Settings menu.
The following settings will be restored to the factory settings:

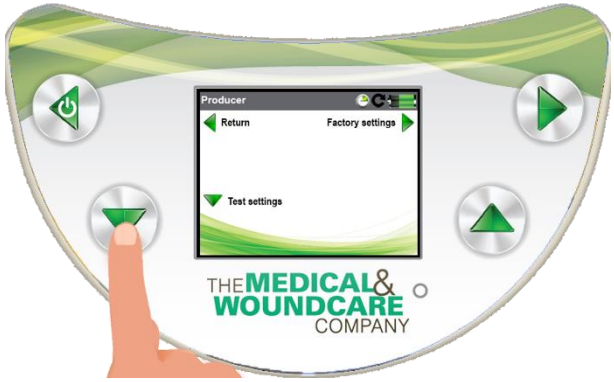
• Continuous mode	Set to:	On
• Intermittent mode	Set to	Off
• Pressure	Set to:	- 125 mmHg
• Tolerance	Set to:	20 mmHg
• Acoustic Warning	Set to:	On
• Warning delay	Set to:	0.5 min
• Tube blocking	Set to:	Off
• Backlight time	Set to:	5 min
• Backlight intensity	Set to:	5
• Power mode	Set to:	Normal
• Purge mode	Set to:	Disabled
• Hold pressure	Set to:	Off
• Bluetooth	Set to:	Off
• Log file	All numbers set to	0

The battery will also be calibrated after restart of the Exsudex XS.

3.1.6.2 Test settings

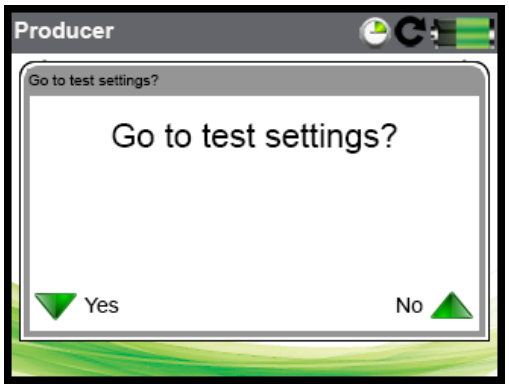
This feature has been built in for the producer to be able to perform a fully automatic operation test.





Press in the Producer menu on  *(Test settings* *)*

After pressing this button the next question will be displayed:



 results in restoring the Exsudex XS to the test settings

 results in returning to the Settings menu.

3.2 Explanation of symbols shown in display

	Battery full
	Battery 60% full
	Battery 30% full
	Battery almost empty
	Battery charging
	Continuous mode enabled
	Intermittent enabled
	Tube blocking enabled
	Acoustic signal warnings disabled
	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.
	Delayed warning enabled
	Slow mode activated
	Fast mode activated
	Purge mode activated
	SD card not available.
	Countdown indicator Stop Button
1/4 (or other numbers)	Field 1 of 4 in the relevant menu
	Bluetooth enabled
	Bluetooth connection active
0080e1b2da1e	Bluetooth ID

Home Care Situation:

Note: Do not forget to enable/switch off the settings menu after entering the correct settings!

Press the  button for 10 seconds in the start menu. The text/function settings is gone now.
This to prevent the ability that the patient can adjust the settings!

3.3 Start

By pressing the “Start”button  the treatment with the Exsudex XS will be started.

4 Use

4.1 Use in continuous mode

When the setup is complete the Exsudex XS 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 XS can be turned off by pressing the “Stop” button for 3 seconds.
The green bar on the left side of the grey bar 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:

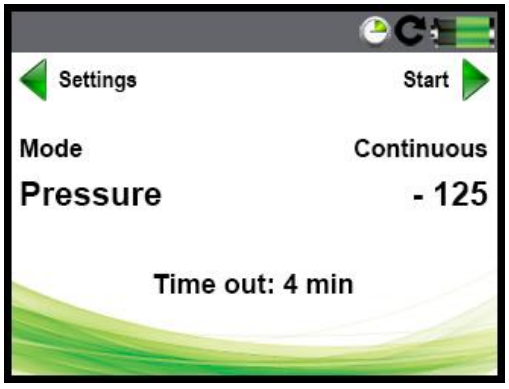

During treatment


Stop button pressed for 1 second


Stop button pressed for 2 seconds


Stop button pressed for 3 seconds

The machine will beep and go back to the start menu.
At the bottom of the screen the remaining time, in minutes, is displayed before the Standby Warning will be activated.



4.2 Use in intermittent mode (tube blocking and slow mode disabled)

When the setup is complete the Exsudex XS 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 XS can be turned off by pressing the “Stop” button for 3 seconds.
The green bar on the left side of the grey bar 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:

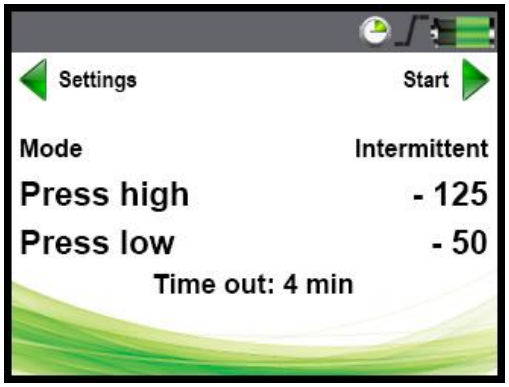

During treatment


Stop button pressed for 1 second


Stop button pressed for 2 seconds


Stop button pressed for 3 seconds

The machine will beep and go back to the start menu.
At the bottom of the screen the remaining time, in minutes, is displayed before the Standby Warning will be activated



4.3 Daily use

The Exsudex XS 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.

4.3.1 Sleeping

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

4.3.2 Bathing and Showering

- Do not use the Exsudex XS during bathing or showering or in a place where it can fall in a bathtub, shower or sink.
- When the Exsudex XS 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 XS of the dressing and contact your home care provider.
- When drying off be careful not to damage the wound dressing.

4.3.3 Travelling with the Exsudex XS

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 XS 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 XS cannot be continued
- Fully charged Exsudex XS wound drainage system including charger.
- Check before leaving if the adapter of the charger is suitable for the destination of the patient.
- Exsudex XS user manual

5 Warnings

The pump has five types of warnings:

- Pressure tolerance warning
- Reservoir full warning
- Tube blocking warning
- Stand by warning
- Battery low warning

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

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

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

During an warning the Exsudex XS will turn off and go into standby mode.

The warning will continue sound until either or is pressed.

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

The following warnings are built in:

- Warning during the building up of negative pressure
- Warning negative pressure loss
- Reservoir full warning
- Stand by warning
- Tube blocking warning
- Battery low warning

5.1 Warning during the building up of negative pressure

If the Exsudex XS 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 warning will be activated. The pump will stop, the warning will sound and the display shows:

In which:

Restarts the treatment

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

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

5.2 Warning negative pressure loss / failure to reach maximum 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 XS 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 warning is activated and the warning will sound.

This warning will only be triggered if the set pressure has been reached already. Otherwise, the warning "no pressure" as described in 5.1 will be in force.
When delayed warning is turned off the warning will sound immediately!

In which:

Restarts the treatment

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

When delayed warning is On the warning 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 warning will sound.

1. By Pressure loss

In which:

Restarts the treatment

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

2. By leakage (failure to maintain set pressure)

In which:

Restarts the treatment

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

5.3 Canister full warning

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

In which:

Restarts the treatment

Results in returning to the Start 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 XS by the main on/off switch.

In which:

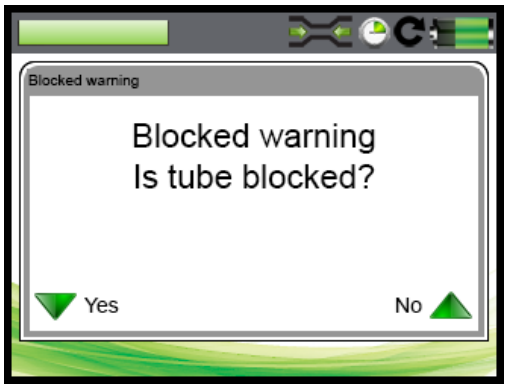
Restarts the treatment

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

5.5 "Tube blocking" warning. (Blocked warning)

A warning will sound if the pump has not run within a set period.
The warning will sound to indicate that the suction tubing is blocked, but be aware that the warning will also sound if the wound is completely airtight sealed!

When turned on the next symbol will be displayed 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 warning

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 deactivated tube blocking warning. When treatment is stopped tube blocking will be active again.

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: When intermittent suction or Purge Automatic mode is activated this warning will not be available!

5.6 "Battery low" warning.

The display has five symbols for the battery power:


Battery full

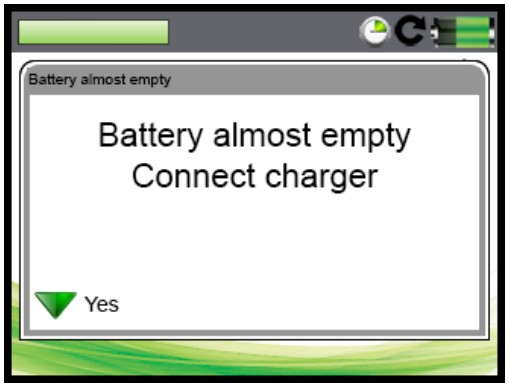

Battery 60% full


Battery 30% full


Battery almost empty


Battery charging

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

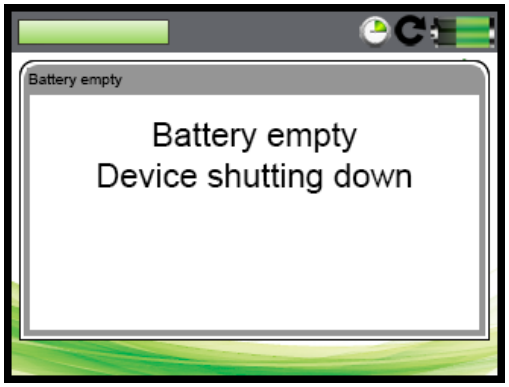


In which:


Returns to the treatment

When connected to the charger the warning will stop.

NOTE:
When not connected to the charger will shut down the Exsudex XS 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.



5.7 "Motor on Time" warning.

The Exsudex XS is provided with a warning 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 Start menu.
Note that the Standby warning will sound after 5 minutes if the pump is not activated again.

5.8 "LED Indicator"

The LED shows the status of both battery and treatment.

Continuous LED	→	No treatment started (pump is not running)
Blinking LED	→	Treatment in progress (pump is running)

The LED has five colors:

Blue	→	Battery is being charged
Green	→	Battery full and not on charger
Orange	→	Battery half full
Purple	→	Battery empty, needs to be charged.
Blue / Green	→	Battery full and still on charger
Red	→	Warning in progress

The LED will also burn when connected to a charger with the Exsudex XS turned off. So you can see if the battery is completely charged. (blue means still charging and green completely charged)

5.9 "Notification Sound disabled" warning

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

In which:

Starts the treatment

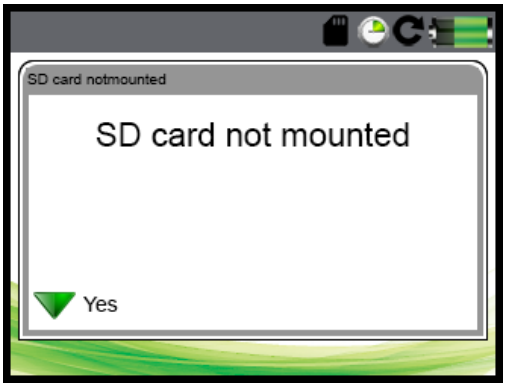
Results in opening the Notification sound setting.
You now can change the setting.

WARNING:
If you do not respond to this message the warning 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

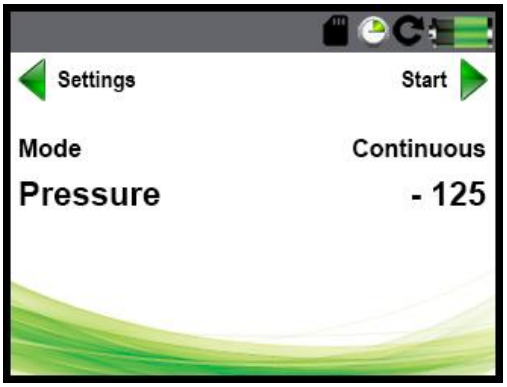
5.10 SD card not present or malfunctioning

When the SD card is not present or not working properly you will see an icon of an SD card on the upper grey button.
Also the language will be set to English. This is also the only available language.

When starting up the Exsudex XS will show a message that the SD card is not mounted.
After confirming with "Yes" the Exsudex XS will start up with only English language available.



Message after startup with SD card not present or malfunctioning



Start menu with SD card not present or malfunctioning

The Exsudex XS has been designed in such a way that the patient during use will not notice anything.
It is only to be noticed by the SD card icon on screen and in the Language setting menu (only English language is available)
Log files will not be updated when the SD-card is not available!

6 Battery

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

6.1 Charging

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

WARNING:
The Exsudex XS 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 5.6 - “Battery low” warning.
With a full battery the Exsudex XS 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 XS functions properly the warning will sound.
The battery icon will be red. This warning can be switched off by connecting the Exsudex XS adapter.
If the mains voltage is lost, the Exsudex XS 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 XS and removal of residues should be done in line with current environmental regulations.
The Exsudex XS 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 XS can be cleaned with normal domestic non-scouring cleaning agents.
The Exsudex XS 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 XS units are checked and that the battery is replaced once a year 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 XS

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 XS. Normally the filter will block the fluid.
Please contact your dealer immediately for a replacement pump.
Do not continue to use the Exsudex XS.

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 Filter

The filter in the Exsudex XS 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 XS canister should be replaced for each new patient and if the canister is in use for 7 days.

8.1 Inspection

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 Exsudex XS canister should be replaced for each new patient and if the canister is in use for 7 days or earlier when full.
This to avoid micro bacterial contamination.

9 Warranty

9.1 Total warranty

The warranty for the Exsudex XS 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

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

9.3 Consumables

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

10 Technical specifications

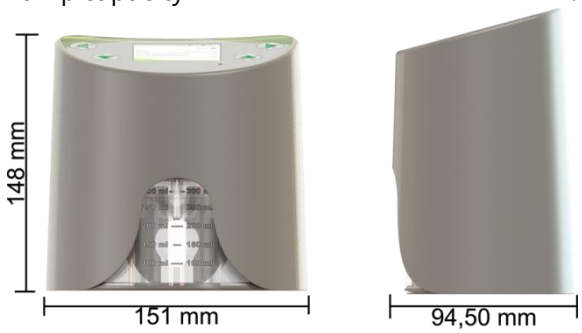
10.1 Safety standards

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
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]	:	151 x 148 x 94.5
Weight with empty canister	:	825 gram
Maximum weight with full canister	:	1125 gram

Pump capacity : Max. 5.5 liters/minute

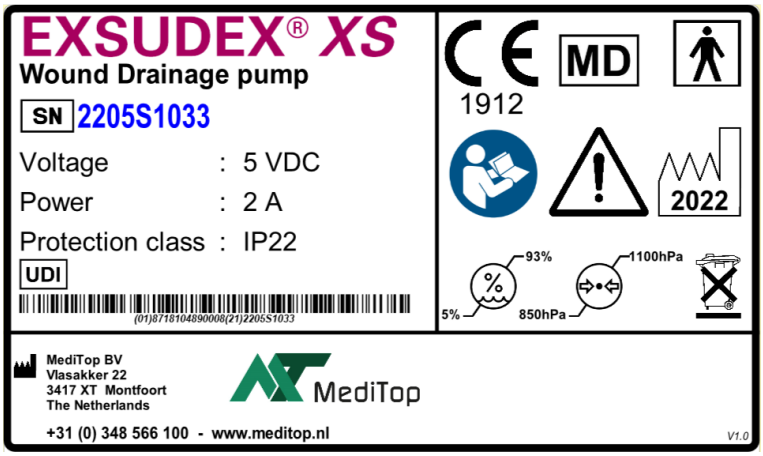


10.3 Environment

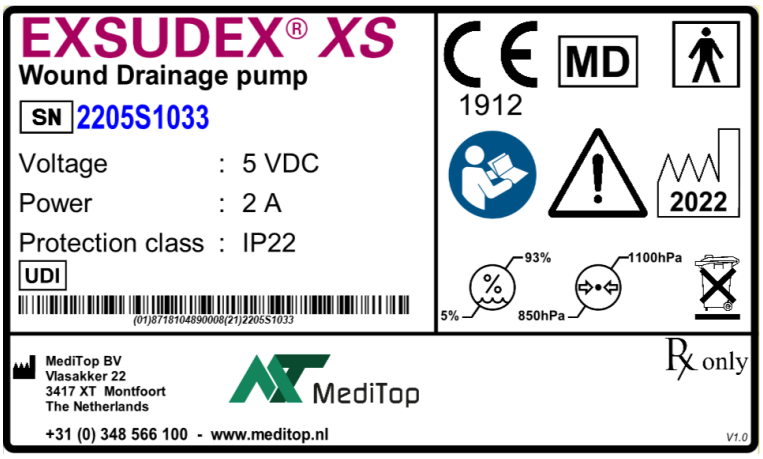
Protection class	:	IP22[2]
Operating temperature	:	+5° C to +40° C
Storage temperature	:	-20° C to +70° C
Humidity	:	5 to 93%, non condensing
Atmospheric pressure	:	850 to 1100 hPa

[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 XS, 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



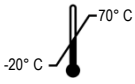
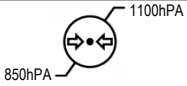
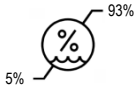
Exsudex XS Label (except for US)



Exsudex XS Label (US)

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

10.5 Explanation of symbols

CE 1912	This symbol indicates that the Exsudex XS 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 XS is type BF according to IEC601-1.
Rx 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 XS 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 XS.

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

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ZIP code: 3417 XT
City: Montfoort
Country: The Netherlands

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

10.8 Disposal

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

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

10.10 Life

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

11 Troubleshooting

11.1 No picture or text appears on the Exsudex XS 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

Is the canister placed on the right way on the Exsudex XS?

- 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”