HARTMANN

Vivano® Tec

Pro

Negative pressure unit

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CAUTION!

1. Important safety instructions

The VivanoTec Pro negative pressure unit is designed in accordance with IEC 60601-1 / EN 60601-1. The negative pressure unit and the supplied power supply constitute a medical electrical system with Class II protection.

Please note the environmental conditions as stated in the technical data (see chapter **Technical data**).

Transportation
The packaging material must be stored in case the unit needs to be transported again. Please observe the applicable national regulations.

Before usage
Before use, check that the exudate canister and the connection tubing are not damaged.

Before using the unit, the user (physician or a qualified person) must check that the displays and acoustic signals function correctly.

The user (physician or a qualified person) must have an unimpeded view of, and easy access to the touchscreen.

Positioning of the device
The negative pressure unit must always remain in an upright position during operation.

The negative pressure unit must not be placed on a patient's bed.

Monitoring
IMPORTANT: The monitoring frequency must be adapted according to the overall health status of the patient and the treated wound condition, evaluated by the supervising physician.

Regularly monitor the patient, the unit and the wound dressing. Watch out for wound exudate, maceration, infection and loss of vacuum. In order to ensure a safe therapy, it is necessary to check the wound dressing frequently. In doing so, be sure to check the wound dressing for imperviousness, and also for negative pressure, check the wound edges for maceration and check the wound edges and the exudate for signs of infection. In the event of signs of an infection, the attending physician must be informed immediately.

The user (physician or a qualified person) must check the functionality of the negative pressure unit regularly. In the unlikely event of failure of the negative pressure unit, the user (physician or a qualified person) must make provisions to continue the patient's therapy by other suitable methods.

Avoid the risk of the tube becoming blocked by regularly checking the tubing system and its connections for leaks and kinks.

IMPORTANT: No liquid must be allowed to enter the negative pressure unit. If liquid has nevertheless entered the negative pressure unit, the unit must be checked by customer service.

IMPORTANT: If there are any signs of infection, the attending physician must be notified immediately.

Exudate canister/ Dressing Change
The exudate canister may only be changed by the user (physician or a qualified person) during the therapy.

When changing the dressing, please observe the corresponding instructions for the materials that you use.

Disclaimer
The manufacturer assumes no liability for personal injury or material damage if

- the manufacturer's original parts have not been used,
- the information contained in these operating instructions has not been observed,
- assembly, resetting, modifications, expansions or repairs have not been carried out by manufacturer-authorised persons

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IMPORTANT: The VivanoTec Pro negative pressure unit may only be used together with components of Vivano System by PAUL HARTMANN AG.

1.1 Contraindications

Contraindications for the use of the Vivano System:

- Malignant tumour wounds
- Non-enteric/unexplored fistulas
- Untreated osteomyelitis
- Necrotic tissue

NOTE: For more information on a particular contraindication, please refer to the Warnings and Precautions sections of this document.

1.2 Warnings

Please pay attention to the following warnings related to the use of the VivanoTec Pro unit:

Bleeding
NOTE: The Vivano System was not developed for the prevention or stopping of bleeding.

IMPORTANT: In the case of blood occurring suddenly or more frequently on the dressing, in the tubes or in the exudate container switch the negative pressure wound therapy unit off immediately, undertake haemostatic measures and inform the attending physician.

NOTE: Regardless of using the negative pressure wound therapy, certain medical conditions favor occurrence of bleeding complications.

The following circumstances increase the risk of possibly fatal bleeding, if not controlled with appropriate care:

- Surgical sutures and/or anastomoses
- Non-sutured haemostatic agents, e.g. spray wound sealant or bone wax
- Trauma
- Irradiation
- Inadequate haemostasis
- Wound infection
- Treatment with anticoagulants or coagulation inhibitors
- Protruding bone fragments or sharp edges

Patients with increased risk of bleeding complications should be monitored with additional level of care, under the responsibility of the supervising physician.

IMPORTANT: In patients with diagnosed acute bleeding, coagulation disorders or being treated with anticoagulants, the 800 ml canister should not be used for the exudate collection. Instead, a 300 ml canister should be utilized. Such practice enables more frequent monitoring of the patient by the health professionals, thereby reducing the potential risk of excessive blood loss.

IMPORTANT: When using non-sutured haemostatic agents, additional protective measures should be implemented, to prevent them from accidental displacement. Suitability for negative pressure wound therapy should be assessed by a supervising physician on an individual basis.

Malignant tumour wounds
Negative pressure wound therapy for malignant tumour wounds is contraindicated, as it is linked to the risk of enhanced tumour formation by proliferation support effect. However, it is considered as legitimate in a palliative context. For patients in the end-of-life stage in whom a complete cure is no longer the aim, the improvement of their quality of life by controlling the three most disabling elements: the odour, exudate, and pain associated with changing the dressings, outweighs the risk of accelerating the spread of tumours.

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Non-enteric/unexplored fistulas
Application of the wound dressing on non-enteric or unexplored fistulas is contraindicated, as it may damage the intestinal structures and/or organs.

Untreated osteomyelitis
Application of the wound dressing in wounds with untreated osteomyelitis is contraindicated, as it may result in the spreading of the infection.

Necrotic tissue
Application of the wound dressing on necrotic tissue is contraindicated, as it may lead to local spreading of the infection.

Application of VivanoMed Foam on nerves, anastomosis points, blood vessels or organs

VivanoMed Foam must not be applied directly over exposed nerves, anastomosis points, blood vessels or abdominal organs as it may result in deterioration of the underlying structures.

1.3 Special precautions

Please pay attention to the following precautions:

Infected wounds
Wound dressings should be changed at regular intervals, according to the corresponding instructions for the materials that you use. Infected wounds should be monitored more frequently, and may require wound dressings to be changed more often.

NOTE: For more information on wound monitoring in the context of negative pressure wound therapy, please refer to the Monitoring section of the corresponding instructions for the materials that you use.

Typical signs of wound infection are redness, swelling, itching, increased warmth of the wound itself or in the neighbouring area, foul odour etc.

Infected wounds may trigger systemic infection, manifesting by high fever, headache, dizziness, nausea, vomiting, diarrhea, disorientation, erythroderma etc. The consequences of systemic infection can be fatal.

IMPORTANT: If there is any suspicion of either local or systemic infection, contact the supervising physician and consult if negative pressure wound therapy should be stopped, or an alternative therapy should be considered.

Blood vessels and organs
Blood vessels and organs should be adequately protected by means of fascias, tissues or other types of protective layers placed above them.

IMPORTANT: Special precautions need to be taken, when dealing with infected, weakened, irradiated or sutured blood vessels or body organs.

Bone fragments or sharp edges
Protruding bone fragments and sharp edges should be removed, or covered accordingly, before using VivanoMed Foam, as they may damage blood vessels or body organs and cause bleeding.

NOTE: For more information related to bleeding in the context of negative pressure wound therapy, please refer to the Bleeding section of this document.

Surgical incisions
Application of VivanoMed Foam on surgical incisions may be performed only with a suitable wound contact layer e.g. Atrauman Silicone.

Enteric fistulas
In case of treatment of wounds containing explored enteric fistulas, additional level of precautions needs to be implemented, if negative pressure wound therapy is to be applied. Presence of enteric fistula in close proximity to the wound increases the risk of wound contamination and/or infection. In order to mitigate the risk associated with the

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potential contact of intestinal content with the wound, enteric fistula needs to be surgically separated, following local guidelines or established surgical practices.

Spinal cord injuries with the development of autonomic hyperreflexia
Discontinue the negative pressure wound therapy if the patient has spinal cord injuries with the development of autonomic hyperreflexia.

Magnetic Resonance Imaging
This device is not considered as MRI safe and must not be used in close proximity to an MRI unit.

Defibrillation
The VivanoTec Pro unit must be disconnected if resuscitation of the patient using a defibrillator is necessary.

Hyperbaric oxygen therapy (HBO)
The VivanoTec Pro unit must be disconnected for patients undergoing hyperbaric oxygen therapy, as its use is considered a potential fire hazard.

External heat sources
Keep the negative pressure unit away from sources of heat and flames.

Electrical safety
Before connecting the device, check that the mains voltage and mains frequency indicated on the device correspond to the values for the supply network. The connecting cable and the accessories must be checked for damage before use of the negative pressure unit.

IMPORTANT: Damaged cables must be replaced immediately.

NOTE: Only medical and undamaged mains connections must be used. Multiple socket outlets or extension cables may not be used.

IMPORTANT: The patient must not take a bath or shower while the VivanoTec Pro negative pressure unit is in place. The therapy should be interrupted for this purpose only after consultation with the attending physician.

IMPORTANT: Never touch the mains plug or the power supply with wet hands and never touch the power supply cable or the DC input and the patient at the same time.

IMPORTANT: No alterations may be made to the unit or the supplied power supply.

Flammable or explosive gases and/or liquids
The negative pressure unit must not be used in the presence of readily flammable or explosive gases and/or liquids.

IMPORTANT: The negative pressure unit is not designed for use within areas at risk of explosion and oxygen-enriched areas. Areas at risk of explosion can occur through the use of flammable anaesthetic agents, (or mixtures with air, oxygen or nitrous oxide), skin cleansers and skin disinfectants.

1.4 General precautions

Please pay attention to the following precautions:

Damaged, expired or contaminated product
Do not use any component of the Vivano System in case of damage, expiration or any suspicion of contamination. It may cause overall decline in the therapeutic efficiency, wound contamination and/or infection.

Single use only
All disposable components of the Vivano System are meant for single use only. Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

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Resterilization
Components of the Vivano System that are provided sterile are meant for single use. Do not resterilize any of these components as it may cause overall decline in the therapeutic efficiency of the kit and potentially lead to wound contamination and/or infection.

Safety measures for infection prevention
Implement and apply adequate personal protection and institutional infection control measures when handling the components of the Vivano System (e.g. the use of sterile gloves, masks, gowns etc.).

IMPORTANT: Before and after using the stopper on the VivanoTec Port connector, it must be cleaned and disinfected.

Patient population
No general restrictions for the usage of the Vivano System in different patient populations (e.g. adults and/or children) are given. However, the Vivano System has not been evaluated for use in paediatrics.

IMPORTANT: Before prescribing its use on a child, weight and height along with the overall health condition must be medically evaluated first.

Patient health status
Weight and general condition of the patient should be taken into consideration during any application of negative pressure wound therapy.

Dressing size
The size of the dressing must be adapted to the size of the wound being treated with the negative pressure wound therapy.

Improper wound dressing size may either cause maceration and disintegration of the peri-wound tissue, or wound margins drying out and inefficient transfer of exudate.

NOTE: For more information on complications related to excessive coverage of the intact skin, please refer to the Dressing of the intact skin section of this document.

IMPORTANT: In order to provide optimal conditions for negative pressure wound therapy, the film dressing should cover about 5 cm of intact skin around the wound.

Dressing placement
Use only dressings coming directly from sterile packages.

Do not force the placement of the foam, as it may lead to direct tissue damage or subsequent wound healing delay or even local necrosis, due to an elevated level of compression.

IMPORTANT: Always record the number of foams used for each wound. The number of layers of film in the dressing can be adapted to each medical condition. Placement of multiple layers of film increases the risk of tissue maceration and consequently tissue irritation.

IMPORTANT: In case of tissue irritation, due to the use of multiple layers of the film, discontinue the Vivano negative pressure wound therapy.

Dressing removal
IMPORTANT: Always record the number of foams removed from the wound in order to guarantee the removal of all foams introduced.

Foam left in the wound for a longer period of time than indicated in the Dressing change section may cause growth of granulation tissue into the foam. This may increase the difficulty of dressing change and may promote wound infection, among other medical complications.

Dressing changes may possibly lead to disruption of the new granulation tissue, which may result in bleeding.

IMPORTANT: Implement additional protective measures, when changing the dressing of patients with identified increased risk of bleeding.

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NOTE: For more information related to bleeding in the context of negative pressure wound therapy, please refer to the Bleeding section of this document.

Disconnection from the VivanoTec Pro unit
The decision on how long the patient can be disconnected from the VivanoTec Pro unit is a clinical assessment that has to be made by the attending physician.

The time interval for safe interruption of the therapy is strongly depended on the overall patient and wound status, as well as the exudate composition and amount of exudate extracted per time unit.

Long interruption might lead to exudate retention and local maceration effects, as well as to a blocked wound dressing due to coagulation effects within the foam matrix. Lack of the effective barrier between the wound and the non-sterile environment increases the risk of infection.

IMPORTANT: Do not leave the dressing with the VivanoTec Pro unit being switched off for prolonged time periods. In case of leaving the dressing for a longer time period, it is recommended for a physician to perform an evaluation of the wound condition along with the overall health status of the patient. According to the physician's evaluation, either rinsing of the wound along with a dressing change or switching to an alternative therapy is recommended.

Intermittent pressure mode
Intermittent pressure, as compared to continuous pressure, may be used for enhancing local perfusion and granulation formation, if tolerable for the patient, the patients' health and wound condition. However, the continuous therapy is generally recommended for the treatment of patients with an increased risk of bleeding, acute enteric fistulas, highly exudating wounds, or when wound bed stabilization is required.

Pressure settings
PRECAUTION: Pressure settings below 50 mmHg may potentially lead to exudate retention and decreased therapeutic efficiency.

PRECAUTION: High pressure settings may increase the risk for micro-trauma, hematoma and bleeding, local hyperfusion, tissue damage or fistula formation.

Correct pressure setting for the Vivano negative pressure wound therapy must be decided by the supervising physician and should be based upon the exudate output, overall patient status as well as recommendations from therapeutic guidelines.

Dressing of the intact skin
Dressing of the intact skin should cover about 5 cm around the wound. Prolonged or repeated dressing of bigger areas might result in tissue irritation.

IMPORTANT: In case of tissue irritation, discontinue the Vivano negative pressure wound therapy. Application of the wound dressing on intact skin may create wrinkles on the dressing surface. Formation of wrinkles significantly increases the risk of dressing leakage, and as a consequence occurrence of infection.

IMPORTANT: Special care should be taken when applying the wound dressing to the peri-wound area's fragile skin.

Dressing of wounds susceptible to irritation
For wounds susceptible to constant irritation (close proximity to limbs), continuous (rather than intermittent) therapy is indicated.

Circumferential dressings
Circumferential dressings should be used under medical supervision. Lack of adequate protective measures might cause local hypoperfusion.

Dressings in the vicinity of the vagus nerve
Dressings in the vicinity of the vagus nerve should be used under medical supervision as its stimulation might cause bradycardia.

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Allergies
Application of the Vivano negative pressure wound therapy is not recommended if the patient is allergic to any component of the Vivano System.

Thermal risks
To reduce the risk of overheating, the power supply should not be covered and should be used in a location where air is free to circulate.

Electromagnetic fields
The VivanoTec Pro negative pressure unit must not be used in the presence of strong magnetic fields (such as an induction stove) and must not be used near the application of HF surgical equipment.

Electromagnetic fields might essentially alter performance, pressure may be different to that set or the unit may behave erratically or stop operating.

IMPORTANT: In case of unexpected operation or events, please contact the manufacturer.

Small parts
Do not inhale or swallow small parts.

Outer casing composition
VivanoTec Pro casing parts contain PFBS salt (Potassium 1,1,2,2,3,3,4,4,4-nonafluorobutane-1-sulphonate).

Auxiliary battery composition
The VivanoTec Pro auxiliary battery contains EGDME (1,2-dimethoxyethane, ethylene glycol dimethyl ether).

Special notes
Keep out of the reach of children.

1.5 Incident reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation (EU) 2017/745 on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

2. Manufacturer/Sales

Further information, accessories, consumables and spare parts are available from:

PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 Heidenheim, Germany
www.vivanosystem.info

3. Introduction

3.1 Notes on the operating instructions

These operating instructions contain important information on safe, correct and effective operation of the VivanoTec Pro negative pressure unit. The operating instructions must be completely read and followed. The instructions for use serve the purpose of teaching the user about the operation and as a reference book. Reprinting, even of excerpts, is permitted only with the written consent of PAUL HARTMANN AG.

The operating instructions must always be kept in the vicinity of the device. Cleaning, care and inspection as well as correct operation ensure the operational safety and capability of the VivanoTec Pro negative pressure unit and are indispensable. Repairs, recurrent tests and replacement of the rechargeable battery may only be carried out by specialist personnel authorised by PAUL HARTMANN AG.

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3.2 Intended use

The negative pressure unit is used to create and control a sub-atmospheric (negative) pressure at the site of an acute or chronic wound in a human patient during negative pressure wound therapy (NPWT).

Specification of the main function
The controlled negative pressure established by the system drains wound exudate and skin fragments away from the surroundings of the wound and into a wound dressing and an associated tube system for collection in a designated exudate canister[1]. In addition, the negative pressure stimulates cell growth[2] and blood circulation in the wound[3, 4].

VivanoTec Pro is only intended for use in conjunction with the Vivano System by PAUL HARTMANN AG.

NOTE: To establish a functional negative pressure wound therapy dressing, at least the following further components are required:

- VivanoMed Foam
- Hydrofilm transparent film dressing
- VivanoTec Port
- VivanoTec Exudate Canister

IMPORTANT: The negative pressure unit must not be used for non-medical applications.

The Vivano System is meant only for use in humans. No general restrictions for the usage of the Vivano System in different patient populations (e.g. adults and/or children) are given. However, the Vivano System has not been evaluated for use in paediatrics.

VivanoTec Pro may be used in hospital, residential care and home-care settings.

IMPORTANT: Please observe the environmental conditions as stated in the technical data (see chapter **Technical data**).

The system has not been evaluated for use for emergency medicine in rescue operations (rescue vehicles, sites of accidents).

IMPORTANT: VivanoTec Pro is not suitable for use in certain special environments (e.g., presence of strong electromagnetic fields, high frequency surgical equipment or flammable liquids or gases, hyperbaric oxygen chambers, military areas,...). (See chapter **Special precautions**).

IMPORTANT: The Vivano System may only be used by a physician or a qualified person, as per law of your country, in accordance with physician's instructions.

Some activities can be transferred to the patient at the discretion of the attending physician by training. Activities which may only be carried out by a physician or a qualified person are specifically marked in these operating instructions. All other activities can be safely performed by the patient if trained by the attending physician.

NOTE: For patients, there is some important information regarding events that can occur during the therapy and which should be observed (see chapter **Additional information for patients**).

[1] Lalezari S, Lee CJ, Borovikova AA, Banyard DA, Paydar KZ, Wirth GA, Widgerow AD. (2016) Deconstructing negative pressure wound therapy. Int Wound J. doi:10.1111/iwj.12658
[2] McNulty AK, Schmidt M, Feeley T, Kieswetter K. (2007) Effects of negative pressure wound therapy on fibroblast viability, chemotactic signaling, and proliferation in a provisional wound (fibrin) matrix. Wound Repair Regen. 15:838-46.
[3] Chen SZ, Li J, Li XY, Xu LS. (2005) Effects of vacuum-assisted closure on wound microcirculation: an experimental study. Asian J Surg. 28:211-7.
[4] Wackenfors A, Sjögren J, Gustafsson R, Algotsson L, Ingemansson R, Malmsjö M. (2004) Effects of vacuum-assisted closure therapy on inguinal wound edge microvascular blood flow. Wound Repair Regen. 12:600-6.

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3.3 Indications

The Vivano System is used in wounds with injured tissue to support healing by secondary intention. VivanoMed Foam may be used on intact skin and wounds healing by primary intention when direct contact with the underlying structure is prevented by a suitable wound contact layer.

VivanoTec Pro is used to establish controlled negative pressure at the site of an acute or chronic wound.

3.4 Scope of delivery

The VivanoTec Pro negative pressure unit has been thoroughly tested and carefully packaged before shipping. Please check the contents of the package for completeness immediately after receipt. (See delivery note)


Negative pressure unit


Power supply cable (country specific)


Operating instructions


Power supply


Shoulder strap


Hanger bar


Carry case with inserts


Send in airtight packaging

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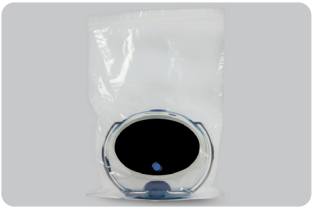
3.5 Transport and storage

The negative pressure unit must only be transported and stored in the VivanoTec Pro carry case. Transport damage must be immediately documented and reported.



> Before shipping the negative pressure unit, package it in the supplied plastic bag with transparent closure.
> Close the bag at the top. Ensure that only a minimum amount of air remains in the bag when closing.
> Package the negative pressure unit in the VivanoTec carry case.
> Package the VivanoTec carry case in the transport packaging.

3.6 Explanation of signs and symbols

Abbreviations/symbols used in these operating instructions

	Please read this important information
	Do not re-use
•	Enumeration
>	Process step

Signs used in these operating instructions

	Warning, observe carefully

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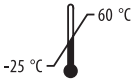
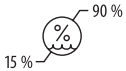
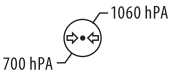
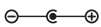
Symbols on the VivanoTec Pro negative pressure unit and power supply

	Follow instructions for use		Temperature limit
MD	Medical device		Humidity limitation
	Manufacturer		Atmospheric pressure limitation
	Date of manufacture		Type BF applied part
REF	Catalogue number	IP22	Protected against solid objects with a diameter of 12,5 mm and against vertically falling drops of water when enclosure titled up to 15º
SN	Serial number		Polarity
	Consult instructions for use		Direct current
	Caution		Ensure appropriate disposal
UDI	Unique Device Identifier		For indoor use only
	Keep dry		Corrugated fiberboard
	Keep away from sunlight		Protection class II equipment

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4. Set-up and initial operation

4.1 Overview of the device

Front side

1. Touchscreen (touch-sensitive display)
2. On/Off switch
3. Exudate canister (not part of scope of delivery)
4. Exudate canister unlock key
5. Connector

Side view

6. Hanger bar
7. Charging socket
8. USB port

Rear side

9. Exudate canister unlock key
10. Exudate canister connections
11. Type plate
12. Canister guidance
13. Exhaust air opening (device dependant)

Applied parts of the device: VivanoMed Abdominal Kit, VivanoMed Foam Kit, VivanoMed Round Dressing Kit, VivanoMed Thin Dressing Kit, VivanoMed Foam, VivanoMed White Foam, VivanoMed Gel Strip, Hydrofilm transparent film dressing, VivanoTec Port
Accessible parts of the device: Power supply, front cover, back cover, exudate canister unlock key, On/Off switch, USB cover, base plate and hanger bar, DC connector, VivanoTec Exudate Canister, VivanoTec Y-Connector

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4.2 Keys and symbols

The VivanoTec Pro negative pressure unit is equipped with a touchscreen. The device is operated by tapping and touching the keys on the touchscreen.

Keys

Key	Designation	Function
	On/Off switch	Press the switch for 2 seconds. Switches the negative pressure unit on or off.
	Start key	Starts the therapy.
	Stop key	Stops the therapy.
	Menu key	Calls up the settings menu.
	Plus key	Increases the current value.
	Minus key	Decreases the current value.
	Cont key	Switches the continuous mode on. After activation, the surrounding key border turns white.
	Int key	Switches intermittent mode on. After activation, the surrounding key border turns white.
	Save/Return	Saves the new settings and returns to the main menu. **IMPORTANT!** If the new settings are not to be saved, wait until the system returns automatically to the previous menu. This takes about 30 seconds.
	Up	Moves up in the menu.
	Down	Moves down in the menu.
	Close	Switches off the warning message and suppresses the warning message till device is restarted again.
	Close	Switches off the warning message and suppresses the warning message for a limited duration.
	Information	Calls up information about the negative pressure unit, such as serial number, software version and operating data.
	Filter	Filters the event history messages.

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Symbols

Symbol	Definition
	Displays the battery charge level.
	Battery charging
	Key lock enabled
	Key lock disabled
	Leakage indicator. This symbol is only visible when the pump is running.
	Slowly pulsating green symbol -> no leaks in system Quickly pulsating green symbol -> a tolerable leak in the system
	Pulsating red symbol -> in the case of an intolerable leak in the system After two minutes in this condition, the leakage warning message is issued.
	Indicates that a warning message has been suppressed. The symbol extinguishes once the cause of the leakage warning has been rectified.
	USB stick inserted

4.3 Display illumination

Day/night mode

The negative pressure unit reacts automatically to the ambient light conditions in the room and readjusts the display brightness.

Display switch-off during battery operation

The display illumination switches off after 5 minutes of battery operation.

4.4 Preparing the negative pressure unit for use

CAUTION! Tripping hazard. Strangulation hazard.
Loosely laid power supply cables, straps and tubing can lead to a tripping or strangulation hazard.
> Always lay out the power supply cable, the straps and the tubing safely.

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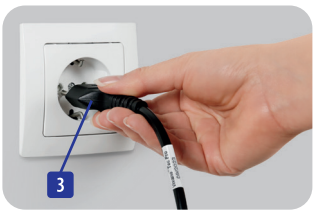
IMPORTANT!
- Unpack the negative pressure unit carefully.
- Hold the negative pressure unit securely and do not allow it to fall.
- Only operate the negative pressure unit using the original power supply supplied.
- Time required from minimum or maximum storage temperature to usage temperature is at least 2 hours.

Installation site and position of the negative pressure unit

The negative pressure unit can be carried by the patient or installed close to the patient. If the device is installed, ensure that it is stable and cannot fall down. Please always position the tubing loosely without tension.

The negative pressure unit must not be installed immediately next to, or stacked on top of other devices.

- Place the device as vertically as possible, or hang it up
- at a maximum of 1 m above the wound dressing
- height of normal use 1 m
- Separable plugged connectors must be made accessible
- Operator's position (physician or a qualified person) must be in front of the device, facing the display



Charging the battery

IMPORTANT!
Before operating the unit for the first time, the battery must be fully charged. Only the original power supply and power supply cable (marked with VivanoTec Pro) may be used for charging. The negative pressure unit should be charged in a location as cool as possible, away from direct sunlight. Incorrect procedures can cause severe damage to the negative pressure unit. Damage caused by incorrect handling is not covered by the warranty.

> Push the plug of the power supply into the socket 1 on the negative pressure unit.
> Connect the power supply to the supplied country-specific power supply cable 2.
> Plug the mains plug (means for mains isolation) into the mains socket 3.

The charging symbol is displayed on the negative pressure unit .

> When the battery is completely charged , unplug the device from the mains socket. For this, remove the plug from the mains socket and remove the power supply plug from the socket on the negative pressure unit.
> The device can also be operated while still connected to the mains supply (mains operation).

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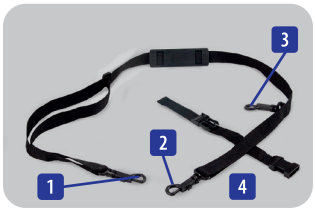
INFORMATION
The negative pressure unit signals when the battery charge is low. A warning message appears on the touchscreen (see chapter **Warning messages**).
If the battery is too low, the negative pressure unit switches off automatically.

Hanger bar

Attaching the negative pressure unit using the hanger bar
VivanoTec Pro can be easily attached using the hanger bar. For example, to bed rods or tables.

Attaching the hanger bar
> First insert the hanger bar into the hollow on one side, then insert the second end (while applying a little tension) into the second hollow.



Shoulder strap

1 Strap clip for attachment to the hanger bar (long)

2 Strap clip for attachment to the hanger bar (long)

3 Strap clip for attachment to the hanger bar (short)

4 Loop for attachment to the bed

Shoulder strap
> Attach the strap clip 1 to the side of the hanger bar.
> Attach the strap clip 2 to the other side of the hanger bar.

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Attaching the negative pressure unit to the patient's bed

> Unhook the strap clip 2 and hook in the clip 3.
> Place the loop 4 around the bed rail and close it.

Carry bag

> Insert the negative pressure unit with the installed 300 ml exudate canister into the carry bag.
> Close the carry bag at the top using the zip fastener.
> Lead the canister tubes out of the top through the opening in the zip fastener.

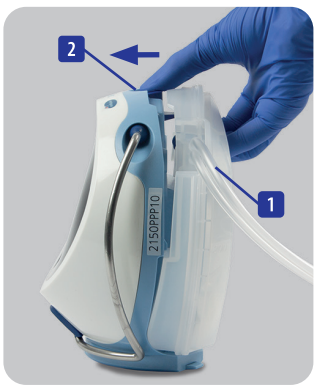
IMPORTANT!
Do not catch the tube in the zip fastener.

The display of the negative pressure unit can always be seen through the viewing window.

4.5 Exudate canister

The activities in this chapter may be carried out only by a physician or a qualified person.

IMPORTANT!
The exudate canisters of the negative pressure unit are sterile components and can therefore be used in a sterile surgical environment.



Inserting the exudate canister

> Carefully remove the exudate canister from the sterile peel pack.

Caution.
The attached tubing piece must not be allowed to fall onto a non-sterile surface.

> Insert the exudate canister at a slight angle into the guidance on the negative pressure unit 1.
> Tilt the exudate canister in the direction of the negative pressure unit until it fully engages with the blue unlock key 2.
> Pull gently on the exudate canister to make sure that it is securely attached to the negative pressure unit.

Please make sure that the exhaust opening is not covered while the therapy is running.

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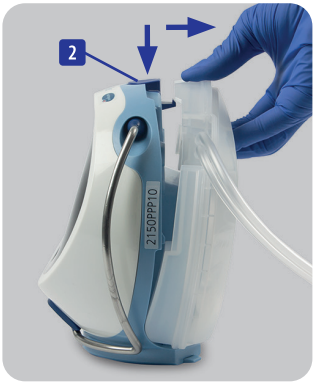


Removing the exudate canister

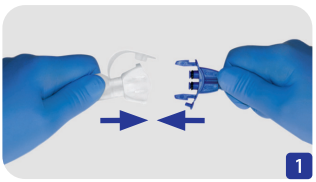
> Removing the exudate canister (see chapter **Connecting/removing the negative pressure unit to/from the wound dressing**).
> Press the blue unlock key 2 on the negative pressure unit.
> Slightly tilt the exudate canister and remove it.
> Properly dispose of the exudate canister.

Observe local regulations.

Connecting and removing the negative pressure unit to and from the wound dressing

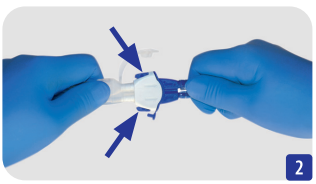
CAUTION!

- Make sure that the tube connectors are always correctly connected to each other in order to prevent malfunction.
- For application of the wound dressing set, follow the instructions for use of the wound dressing set.



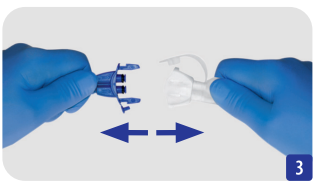
Connecting

> Attach the connectors (tube ends) of the exudate canister to the connectors of the wound dressing set 1.



Removing

> Press the unlocking device at the side of the connector and keep it pressed 2.
> Pull the two ends apart 3.



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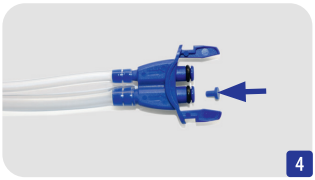


Disposal

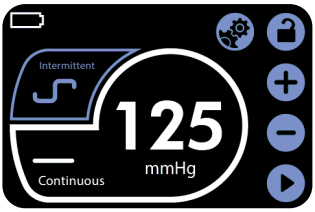
> Before disposal, break off the stopper from the connector and plug it onto the exudate lumen 4.

This ensures that no exudate can escape from the canister.

5. Basic functions

The activities in this chapter may be carried out only by a physician or a qualified person.

5.1 Switching the negative pressure unit on and off



Main menu

Switching the negative pressure unit on

> Press the On/Off switch for 2 seconds.

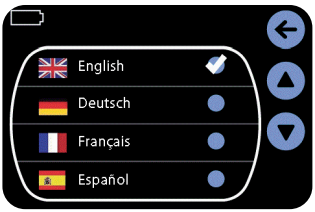
The main menu is displayed.

Switching the negative pressure unit off

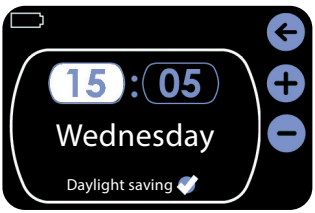
> Press the On/Off switch for 2 seconds.

The negative pressure unit switches itself off.
The key lock must be disabled.

5.2 Initial operation



Language selection menu



Setting the time

Switching the negative pressure unit on

> Press the On/Off switch for 2 seconds.

After the first start-up, the language selection menu is displayed.

> Tap on the required language.

A checkmark appears next to the selected language.

> Confirm the entry by pressing.

The time setting menu appears.

> Enter the time of day by pressing the and keys.
> Enter the day of the week by pressing the and keys.
> Tap on the blue field behind „Daylight saving“ if the clock is to be automatically changed for summer time.
> Confirm the entry by pressing.

The main menu is displayed again.

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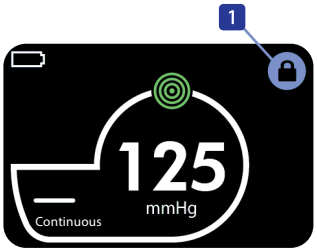
5.3 Checking for correct function of the display

> Start the therapy without an exudate canister.
> Manually cover the left opening on the rear side of the device.
The warning message "Exudate canister full" appears after a few seconds.

5.4 Key lock



Key lock enabled

Automatic key lock

The VivanoTec Pro negative pressure unit has an automatic key lock.

If the touchscreen is not touched for longer than 1 minute, the automatic key lock 1 is enabled.
This prevents any unintentional entry.

During battery operation, the display illumination switches off after 5 minutes.

Switching the key lock on

> Tap on the open lock symbol.
The key lock is enabled. This is indicated by the symbol .

Disabling the key lock

Disabling the key lock

> Tap briefly on the touchscreen or press the On/Off switch.
This activates the touchscreen and the closed lock symbol appears.
> Tap on the 1 closed lock symbol.
This activates the second flashing 2 closed lock symbol.
> Tap on the 2 closed lock symbol.
This disables the key lock.
This is indicated by the flashing open lock symbol.

6. Settings

Settings menu

The activities in this chapter may be carried out only by a physician or a qualified person.
> In the main menu, tap on the key.
The settings menu appears.

Return to main menu

Tap on the key.

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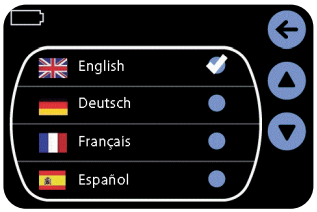
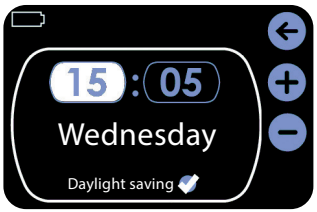
6.1 Language



Language selection menu

> Tap on Language in the settings menu
Language selection menu appears.
> Tap on the required language.
The language is marked with a checkmark.
> Using the ▲ and ▼ keys, scroll to the next page with more languages.
> Confirm the entry by pressing ←.
The main menu is displayed again.

6.2 Setting local time



Setting local time

> Tap on Local Time in the settings menu
The time setting menu appears.
> Enter the time of day by pressing the ⊕ and ⊖ keys.
> Tap on the blue field behind "Daylight saving" if the clock is to be automatically changed for summer time.
> Confirm the entry by pressing ←.
The main menu is displayed again.

6.3 Event history

Event history

Events (settings and error messages) are displayed in the event history. The device has sufficient memory to store the event history over its entire service life. The memory is not lost even after switching the device off or in the event of a power loss.

Retrieving the event history

> Tap on Event History.
The event history is called up. Here, the most important events are recorded together with the time of day.

Browsing through the days

> Browse through the daily records using the ◀ and ▶ keys.

Scrolling through the event history

> Scroll through the event history using the ▲ and ▼ keys.

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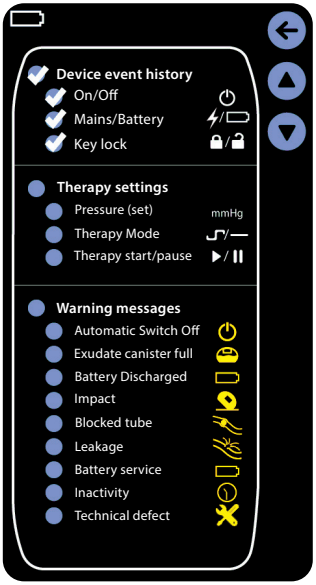


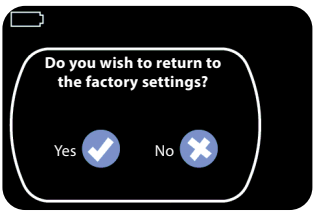
Filtering the event history

> Tap on the key.
A selection of all recordable events appears.
In the factory settings, all events are displayed.

> Tap on the events that should no longer be displayed.
The checkmark next to the item is deleted. The event is no longer displayed in the event history.
> Confirm the entry by pressing .
The filtered event history is displayed.

INFORMATION
The events can also be shown and hidden in groups.

6.4 Factory settings



> Tap on Factory Settings in the settings menu.
You will be asked again:
"Do you wish to return to the factory settings?"
> Tap on "Yes"
The factory settings are restored.
> Tap on "No"
The factory settings are not restored. The main menu is displayed again.

6.5 USB port

The USB port may be used only by the staff of PAUL HARTMANN AG for data transfer. No other USB device may be connected to the VivanoTec Pro negative pressure unit.

The connection to IT networks could result in previously unidentified risks to patients, operators or third parties.

These risks should be identified, analysed, evaluated and controlled by the responsible organisation.

Changes in IT network could introduce new risks that require additional analyses.

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7. Negative pressure therapy

The activities in this chapter may be carried out only by a physician or a qualified person.
Two therapy modes are available:

> Continuous mode
> Intermittent mode

Continuous mode
The factory setting is 125 mmHg in continuous mode.
Generally the most recent settings are always stored.

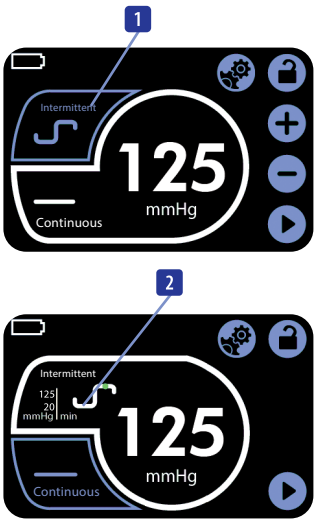
7.1 Setting the negative pressure

7.1.1 Continuous mode

Main menu

> Tapping on the ⊕ key increases the negative pressure in 5 mmHg steps.
> Tapping on the ⊖ key decreases the negative pressure in 5 mmHg steps.

7.1.2 Intermittent mode



Change-over range for settings

Intermittent mode
In contrast to continuous mode, which operates with a constant negative pressure, intermittent mode allows therapy with changing pressure intervals.

Switching intermittent mode on
> Tap on the 1 key.
Intermittent mode is activated.
The surrounding key border turns white.
The factory setting for intermittent mode is 125 mmHg for 5 minutes and 20 mmHg for 2 minutes.
The most recent setting is always stored.

> Tap on the 2 area.
The settings menu for intermittent mode is displayed.
> Tap on the value that is to be changed.
The affected field turns white.
> Tap on the ⊕ or the ⊖ key to set the desired value.
> Confirm the entry by pressing ↩.
The activated intermittent mode is displayed.

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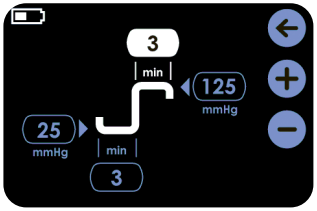


Setting the values

IMPORTANT!
Tapping on the ← key closes the intermittent menu and saves the values. If the new values are not to be saved, wait without touching the touchscreen until the display switches to the main menu.

7.2 Starting the therapy

CAUTION!
To achieve the correct negative pressure in the system as set, before starting the therapy ensure that all connections are correctly made and that all therapy parameters have been set.

Select the required therapy mode.
> Tap on the ▶ key.
The negative pressure unit starts and generates the set negative pressure.

7.3 Interrupting/terminating the therapy

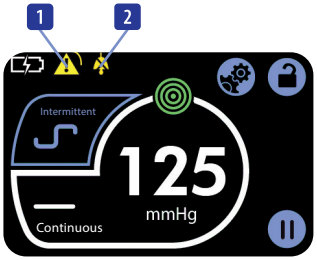
> Tap on the ⏸ key.
The therapy is interrupted or terminated.

IMPORTANT!
If no therapy has been commenced within the previous 30 minutes, the inactivity warning message appears (see chapter **Device Inactive**).

8. Warning messages

The activities in this chapter may be carried out only by a physician or a qualified person.

If no other information is provided with the individual warning message description, the delay time for detection of a warning message condition or for generating a warning message signal is less than 1 second in each case. In the case of discrepant information regarding the time span, the actual duration depends on the point in time of the pressure measurement.



1 Warning message present

2 The warning message was suppressed

By tapping on the warning message symbol (1 or 2), the warning message is displayed again.

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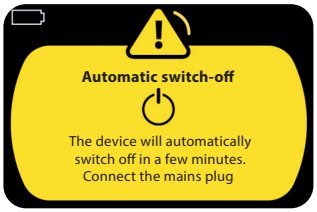
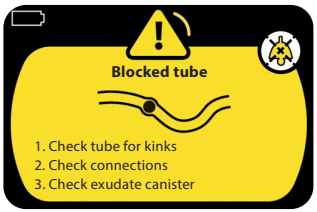
Prioritisation of the warning messages is in accordance with the following table, in decreasing priority.



Automatic switch-off

If no power supply was connected despite repeated "Battery discharged!" warning messages, the negative pressure unit switches itself off automatically 1 minute after the warning message.

IMPORTANT!
The negative pressure unit can be switched on again after the power supply cable has been reconnected and therefore the rechargeable battery is recharged.



Blocked tube

The warning message "Blocked tube" appears when the negative pressure unit identifies a blockage in the exudate canister or in the tubing system.

The delay until this warning message condition is determined is 3.5 - 8.5 minutes (+/-5 seconds).

WARNING!
The device is not able to identify a blockage for negative pressure settings below 50 mmHg. For this reason, the wound dressing must be checked frequently for correct compression of the foam.

This warning message can have the following causes:

- A kink in the tubing system

> Position the tube such that no kink can arise.

- Blockage at the connection points

Check all connection points for possible blockages or incorrect connections.

- Check the exudate canister

> Tap on the key.

The warning message is suppressed for 5 minutes.

IMPORTANT!
If the fault cannot be rectified by way of the above-mentioned measures, the exudate canister should be changed.

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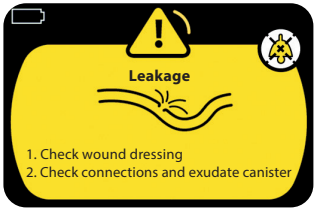


Leakage

This error message appears in the case of a leakage in the system which cannot be compensated for by the negative pressure unit.
The delay until this warning message condition is determined is 2 minutes (+/-5 seconds).

> Check the wound dressing for possible leakage.
> Check all connections for leakage.
> Check if the exudate canister is firmly connected to the negative pressure unit.

If it is not possible to rectify the leakage through these measures, it might be advisable to replace the wound dressing and the tubing system.

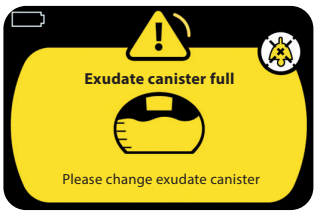
> Tap on the key.

The warning message is suppressed for 5 minutes.

Technical defect

The negative pressure unit is no longer functioning correctly and is possibly damaged.

> The negative pressure unit is no longer in an operational condition. Return it to your specialist dealer or to PAUL HARTMANN AG for checking and repair.



Exudate canister full

The delay until this warning message condition is determined is 2 - 47 seconds (+/-1 second).
This error message can be triggered by the following causes:

- The exudate canister is full.

> Change the exudate canister.

- Blocked bacteria filter in the exudate canister. If the bacteria filter is wetted by the exudate, it will block.

> Change the exudate canister.
> Tap on the key.

The warning message is suppressed for 5 minutes.

IMPORTANT!
To avoid a blockage in the filter, the negative pressure unit must always remain in an upright position and must not tilt.
The therapy must be restarted after the exudate canister has been changed (see chapter **Starting the therapy**).

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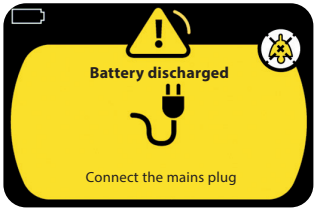
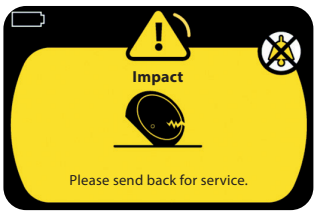


Battery discharged

The warning message "Battery discharged" appears when the remaining operating time is less than one hour.
Connect the power supply as soon as possible.
> Tap on the key.
The warning message is suppressed for 15 minutes.
The therapy can meanwhile be continued unimpeded.

IMPORTANT!
If this warning message is ignored, the negative pressure unit switches itself off automatically to protect the battery (see chapter **Automatic switch-off**).



Impact

The negative pressure unit is no longer functioning correctly and is possibly damaged.
> The negative pressure unit is no longer in an operational condition. Return it to your specialist dealer or to PAUL HARTMANN AG for checking and repair.
> Tap on the key.
The warning message will not appear again until the negative pressure unit is switched on again.

Device Inactive

The therapy was not started during the past 30 minutes.
> Tap on the key.
> Disable the key lock.
The main menu is displayed again.
> Start the therapy or switch the negative pressure unit off.
The warning message will be repeated after 30 minutes if it was suppressed.

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Battery service life exceeded

When the useful life of the rechargeable battery has been reached, a warning message appears each time the negative pressure unit is switched on.

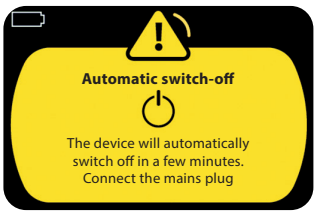
Have the battery replaced by the manufacturer as soon as possible to avoid a loss of function.

CAUTION!
Battery exchanged by inadequate trained personnel could result in a hazard.

> Tap on the key.
The warning message will not appear again until the negative pressure unit is switched on again.

9. Additional information for patients

9.1 Warning messages

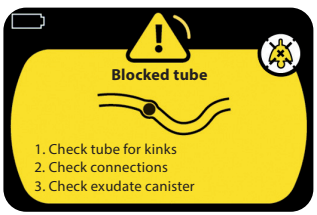


Automatic switch-off

If no power supply was connected despite a repeated "Battery discharged" warning message, the device switches itself off automatically.

> Please plug in the power supply without delay.
(See **Battery discharged**.)
> If the negative pressure unit has already switched itself off, inform the attending physician or nursing staff immediately.
> Push the plug of the power supply into the socket on the negative pressure unit.
> Connect the power supply to the supplied country-specific power supply cable.
> Plug the mains plug into the mains socket.

On the display of the negative pressure unit, the animated symbol shows the charge status, the battery is being charged.



Blocked tube

This message is displayed if the device detects a blockage in the canister or tube system (e.g. kinks).

> Please check the tube for kinks and rectify these if found.
> If the message is displayed repeatedly, notify your attending physician or nursing staff immediately.
> Tap on the key.

The warning message is suppressed for 5 minutes.

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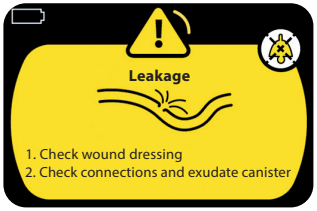


Leakage

This warning message is displayed if the system detects a leak which cannot be compensated for by the negative pressure unit.

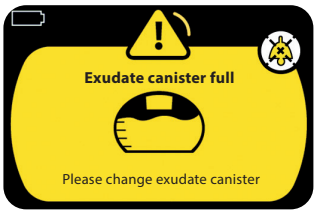
> Notify your attending physician or nursing staff immediately.
> Tap on the key.

The warning message is suppressed for 5 minutes

Technical defect

The negative pressure unit is no longer functioning correctly and is possibly damaged.
Warning cannot be removed – Continues display.

> Notify your attending physician or nursing staff immediately.

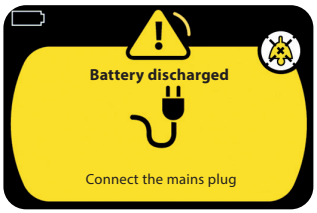


Exudate canister full

This warning message is displayed when the canister is full.

> Notify your attending physician or nursing staff immediately. The exudate canister must be changed without delay so that the therapy is not interrupted.
> Tap on the key.

The warning message is suppressed for 5 minutes.

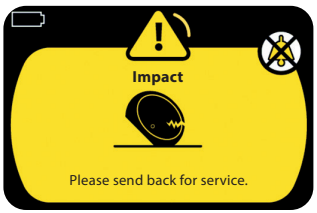


Battery discharged

This message is displayed when the remaining operating time is less than one hour (see chapter "**Preparing the negative pressure unit for use**".

> Push the plug of the power supply into the socket on the negative pressure unit.
> Connect the power supply to the supplied country-specific power supply cable.
> Plug the mains plug into the mains socket.
> Tap on the key.

The warning message is suppressed for 15 minutes.
The therapy can meanwhile be continued unimpeded.



Impact

The negative pressure unit is no longer functioning correctly and is possibly damaged.

> Notify your attending physician or nursing staff immediately.
> Tap on the key.

The warning message will not appear again until the negative pressure unit is switched on again.

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Device Inactive

This warning message appears if the therapy has not been started within the previous 30 minutes.

> Notify your attending physician or nursing staff immediately.

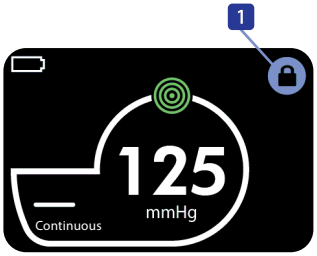
Battery service life exceeded

This warning message will be displayed if the average lifetime of the storage battery is reached.
This occurrence has no direct effect on the course of therapy.

> Please notify your attending physician or nursing staff during their next visit.
> Tap on the key.

The warning message will not appear again until the negative pressure unit is switched on again.

9.2 Key lock



Key lock enabled

Automatic key lock

The VivanoTec Pro negative pressure unit has an automatic key lock.
If the touchscreen is not touched for longer than 1 minute, the automatic key lock 1 is enabled.
This prevents any unintentional entry.

During battery operation, the display illumination switches off after 5 minutes.

Switching the key lock on

> Tap on the key.

The key lock is enabled. This is indicated by the symbol .

9.3 When should I contact my physician or nursing staff?

- In the case of warning messages (see chapter **Warning messages**).
- If there is a considerable change in the wound fluid, e.g. if a lot of wound exudate is discharged within a very short time or if blood is clearly visible in the canister.

9.4 What must only be carried out by a physician or a qualified person?

- Changing the exudate canister
- Cleaning the negative pressure unit
- Changing the dressing
- Making settings on the device, particularly therapy settings

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10. Cleaning and care instructions

10.1 Basic information

IMPORTANT!

- Some disinfection solutions can cause discolouration of the plastic surfaces. Avoid the ingress of fluids.
- Please use disposable gloves at all times when carrying out all work.
- All surface disinfectants listed in Chapter 10.3 "Recommended disinfectants", are suitable for disinfection.
- Remove and dispose of all disposable articles, such as the exudate canister, wound dressings and tubes, before a complete cleaning.
- The cleaning and disinfection measures described herein do not replace the respective local hygiene regulations applicable for operation!
- When changing the unit from one patient to another, all parts coming into contact with aspiration material (exudate canisters, tubes and wound dressings) must be discarded.
- We recommend, as a matter of principle, the documentation of all maintenance and replacement procedures in writing.

Do not use any

- Disinfectants containing organic or inorganic acids or bases as these can cause corrosion damage.
- Disinfectants containing chloramides or phenol derivatives, as these can cause stress cracking in the plastic materials used.

CAUTION!

- To avoid electric shocks, separate the power supply cable and the power supply from the negative pressure unit and remove the mains plug before cleaning the device.
- The handling of the negative pressure unit has a decisive influence on reliability and safety. The hygiene measures below are necessary measures for protecting the patient and user from contamination and for maintaining the functional reliability of the negative pressure unit.
- The cleaning and disinfection measures described here do not replace the respective regulations applicable for operation!
- Please comply with the instructions for use given by the manufacturers of the disinfectants, above all with regard to the concentration details, information relating to material compatibility and contact times.
- Cleaning and disinfection of the negative pressure unit must be carried out according to the respective applicable procedures for cleaning and disinfection of surfaces of other electronic, non-submersible medical devices.

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10.2 Cleaning and disinfecting

IMPORTANT!
- Fluids in the internal parts of the device can damage the negative pressure unit and the power supply.

> The device and the power supply must never be autoclaved, rinsed under running water or immersed in liquids.

If changing patients

> Clean the entire surface of the device using a moist (never wet) cloth.
> Following this, disinfect the device using one of the following surface disinfectants.

Please note the exposure time of the used disinfectant. After the exposure time, the unit should be dried with a suitable cloth.

> Clean and disinfect the case, including the inserts.
> Replace and dispose of the shoulder strap and the transport bag.

If not changing patients

> Clean the entire surface of the device weekly using a moist (never wet) cloth.
> Following this, disinfect the device using one of the following surface disinfectants.

10.3 Recommended disinfectants

(Manufacturer: Bode Chemie, Hamburg, Germany)

Disinfectant	Ingredients	(per 100 g)
Dismozon plus (application solution)	Magnesium monoperoxyphthalate hexahydrate	95.8 g
Kohrsolin FF (application solution)	Glutaral	5 g
	Benzyl-C12-18-alkyldimethylammonium chloride	3 g
	Didecyldimethylammonium chloride	3 g
Mikrobac Tissues	Benzyl-C12-18-alkyldimethylammonium chloride	0.4 g
	Didecyldimethylammonium chloride	0.4 g
Bacillol 30 Sensitive Tissues / Bacillol 30 Sensitive Foam	Ethanol	14.0 g
	Propan-2-ol	10.0 g
	Propan-1-ol	6.0 g
	Amines, N-C10-C16-alkyltrimethylenedi-, reaction products with chloroacetic acid	0.2 g
Bacillol zero	(+)-tartaric acid	0.5 g
	Sodium benzoate	0.5 g

For cleaning the negative pressure unit, all cleaning and disinfecting agents with the stated ingredients are also suitable.

The use of disinfectants containing aldehydes and amines on the same object can result in discolouration.

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10.4 Hygiene plan

What	Type	When				
		After each dressing change	Daily	Weekly	Monthly	After each patient
VivanoTec Pro	Manual cleaning by wiping			X		X
	Manual disinfection by wiping			X		X
VivanoTec Exudate Canister	Single-use product, not suitable for reprocessing. Replace after use			X		X
VivanoTec Shoulder Strap	Single-use product, not suitable for reprocessing. Replace after use					X
VivanoTec Bag	Single-use product, not suitable for reprocessing. Replace after use					X
VivanoMed Foam Kit	Single-use product, not suitable for reprocessing. Replace after use	X				X
VivanoTec Pro carry case including inserts	Manual cleaning by wiping and disinfection by wiping					X

11. Maintenance and service

11.1 Basic information

The negative pressure unit and its application components must be regularly and thoroughly cleaned. The negative pressure unit must be operated only in accordance with the operating instructions. Comply with all national and international regulations applicable to your institution.

11.2 Recurrent Tests and Repairs

The complete unit including power supply shall be sent to the manufacturer or authorised service partner for recurrent tests every three years. Should repairs become necessary, please contact the manufacturer or an approved service partner. Please contact the manufacturer or authorised service partner by telephone before sending the unit.

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CAUTION!
Service is not intended during therapy.

Operational and functional faults which cannot be rectified by the measures set out in the chapter "Rectifying malfunctions".

Measures to be taken when sending in the negative pressure unit

If the negative pressure unit needs to be sent in after consultation with the manufacturer or an authorised service partner, the following points must be observed:

> Send in the complete unit (see delivery note)
> Remove all disposable materials and consumables
> Send only after thorough cleaning and disinfection
> Send in airtight packaging
> Attach a detailed description of the malfunction (see chapter **Transport and storage**).

11.3 Handling of rechargeable batteries

> Always store the device with rechargeable batteries 100 % charged.
> The device should never be covered, exposed to direct sunlight or charged, operated or stored in the immediate vicinity of heaters.
> Recharge the batteries after 4 weeks at the latest.
> Always recharge the batteries using the associated charging accessories.
> If rechargeable batteries are charged at a high or a low ambient temperature, their capacity cannot be fully utilised.
> If the negative pressure unit is operated at a low ambient temperature, the capacity of the rechargeable batteries cannot be fully utilised.

CAUTION!
There is a risk of explosion if a different charger is used.

12. Accessories

Name	REF
Accessories	
VivanoTec Shoulder Strap	409 572
VivanoTec Bag	409 506
VivanoTec Hanger Bar	030 239
VivanoTec Pro Power Supply	030 232
Power Supply Cable – Europe	030 285
Power Supply Cable – Brazil	030 286
Power Supply Cable – UK/HK	030 284

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13. Rectifying malfunctions

The activities in this chapter may be carried out only by a physician or a qualified person.

Description	Possible causes	Measures
Device cannot be switched on	The rechargeable battery is completely empty.	Connect the power supply cable in order to charge the battery. Charge status display shown on the left of the touchscreen.
The battery does not charge. The power supply symbol is not displayed although the power supply cable is connected.	The power supply cable is defective or not properly connected.	Carefully insert the power supply cable again and check for correct function. If the error remains: Please send back for service.
	The power supply or the battery is defective.	
Error message:	Possible causes	Measures
Battery discharged	The rechargeable battery is almost empty.	Connect the power supply cable in order to charge the battery. Charge status display shown on the left of the touchscreen.
Tube blocked	Kink in the tube system	Remove the kinks
	There is a blockage at the connection points.	Check the connections. Change the exudate canister if necessary.
Automatic switch-off	The rechargeable battery is empty.	Connect the power supply cable in order to charge the battery. Charge status display shown on the left of the touchscreen.
Exudate canister full	The exudate canister is full.	Change the exudate canister.
Leakage	The wound dressing has a leak.	Check the wound dressing for leaks and replace if necessary.
	There is a leak in the connection between the negative pressure unit and the exudate canister.	Check the connection between the negative pressure unit and the exudate canister. Change the exudate canister if necessary.
Battery service life exceeded	The battery must be replaced.	Please contact HARTMANN Customer Service.

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14. Technical data

VivanoTec Pro Essential performance	The essential performance characteristic of the negative pressure unit is the generation and maintenance of the set negative pressure (+ 7 %) or the generation of a warning message conforming with EN 60601-1-8 (for further information refer to Technical Data Sheet).
VivanoTec Pro power supply	Model: AFM45US24C2-XE1047 Input: 100-240 V ac, 1.1 A, 50-60Hz Output: 24 V dc 2.01 A Manufacturer: XP Power Limited Model: AKM45US24C2-XZ1579 Input: 100-240 V ac, 1.1 A, 50-60Hz Output: 24 V dc 2.0 A 48W Manufacturer: XP Power Limited
VivanoTec Pro power supply cable	Length: 5 m
VivanoTec Pro	The device is either powered by external power supply or internally powered (input: 14,40 - 14,52 V dc, 2 A)
Operation time	Charging time approx. 2 h, operation up to 16 h, (80 mmHg and 0.4 l/min), leakage and capacity display on the touchscreen, uninterrupted operation on mains power supply
Negative pressure regulation	max. 200 mmHg, min. 20 mmHg in steps of 5 mmHg, requires a connected exudate canister for a stable negative pressure control
Display	Touchscreen
Operating modes	Continuous and intermittent
Data memory	Internal memory for therapy data: 1Gb
Intermittent mode	Time interval: 2-10 minutes in each case Upper pressure value: 40-200 mmHg Lower pressure value: 20-80 mmHg The preset minimum pressure difference between upper pressure and lower pressure value is 20 mmHg. Standard values for the upper pressure range: 5 min. 125 mmHg Standard values for the lower pressure range: 2 min. 20 mmHg
Continuous mode	Standard value 125 mmHg; pressure range: 20-200 mmHg

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Warning message signal	3 pulses of 200 ms and 150 ms pause, with 2.5 seconds separation sound pressure level: min. 47 dB (A) (measured in a hemisphere with a radius of 1 m)
Transport and storage conditions	Temperature: -25 to +60 °C Relative Humidity: 15 to 90 %, non-condensing Pressure: 700 hPa to 1060 hPa
Ambient conditions in operation	Temperature: +5 to +40 °C Relative Humidity: 15 to 90 %, non-condensing Pressure: 700 hPa to 1060 hPa
Dimensions	H x W x D 172x214x105 mm without exudate canister Depth with 300 ml exudate canister: max. 117 mm Depth with 800 ml exudate canister: max. 148 mm
Weight	Negative pressure unit (without canister) 1.2 kg Exudate canister 300 ml 0.25 kg Exudate canister 800 ml 0.29 kg Power supply and power supply cable 0.50 kg
Recurrent test	A recurrent test must be performed every three years.
Protection class	II
Degree of protection	Applied parts type BF
Type of protection	IP 22 (Protected from touch by fingers, objects greater than 12 millimetres and water spray less than 15 degrees from vertical.)
Classification	IIa (according to Annex IX EC Directive 93/42/EEC)
CE mark	CE 0123
UMDNS code	Suction Unit Wound 10-223
Battery	Battery: Rechargeable Li-ion Battery 14,40 - 14,52 V, 2 A, 2600 - 2900 mAh, 38,00 - 42,48 Wh

For further technical information (e.g. circuit diagrams, component part lists, description, fuses...), please contact the manufacturer.

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15. Disposal

Used in compliance with the operating instructions, the expected service life of the device is 5 years. It is assumed that regular thorough cleaning and disinfection of the negative pressure unit and its application components or the operation of the device are carried out in accordance with the operating instructions.

> Possible contamination of the negative pressure unit through incorrect operation or non-compliance with the operating instructions cannot be ruled out.
> The negative pressure unit and its accessories must be cleaned and disinfected before disposal (see chapter **Cleaning and care instructions**).
> Comply with the applicable national regulations for the disposal of disposable materials and consumables.
> Comply with country-specific disposal regulations (e.g. waste incineration).

15.1 Disposal in the EU

The device described above is a high-quality medical device with a long service life. At the end of its life cycle, the device must be disposed of correctly. According to the EU Directives (WEEE and RoHS), the device must not be disposed of as part of general household waste. Please comply with the legislation and regulations applicable in the relevant country for the disposal of used devices.
Contact the manufacturer for more information on disposal.

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16. Information relating to EMC (electromagnetic compatibility)

- Medical electrical devices are subject to special precautionary measures with regard to EMC and must be installed in accordance with the EMC information described in the following.
- Portable and mobile HF communication systems can influence medical electrical devices.
- Accessories, current converters and connecting cables other than those specified can lead to an increase in electromagnetic emission or to reduced interference immunity of the device or the system.

The VivanoTec Pro negative pressure unit is intended for operation in an environment as set out below. The customer or user of the VivanoTec Pro negative pressure unit must ensure that it is operated in a corresponding environment.

16.1 Guidelines and manufacturer's declaration – electromagnetic emissions

Emissions Tests	Compliance	Electromagnetic Environment - Guidelines
HF emissions in accordance with CISPR 11	Group 1	The VivanoTec Pro negative pressure unit uses HF energy exclusively for its internal functions. Therefore its HF emissions are very low and it is unlikely that there is any interference with nearby electronic devices.
HF emissions in accordance with CISPR 11	Class B	The VivanoTec Pro negative pressure unit is suitable for use in all facilities including in living areas and those directly connected to a public supply network which also supplies buildings used for residential purposes.
Emission of harmonics in accordance with IEC 61000-3-2	Class A	
Emission of voltage fluctuations/ Flicker in accordance with IEC 61000-3-3	Compliant	

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16.2 Guidelines and manufacturer's declaration – electromagnetic interference immunity

Electromagnetic interference immunity tests	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidelines
Electrostatic discharge (ESD) in accordance with IEC 61000-4-2	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	as test level	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor has a synthetic material covering, the relative humidity must be at least 30 %.
Rapid transient electrical interference / bursts in accordance with IEC 61000-4-4	± 2 kV for power supply cables ± 1 kV for input and output cables	± 2 kV for power supply cables (power supply) not applicable	The quality of the supply voltage should be that of a typical business or hospital environment, e.g. according to EN 50160.
Surge voltages (surges) in accordance with IEC 61000-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	± 1 kV normal mode voltage ± 2 kV common mode voltage, not applicable	The quality of the supply voltage should be that of a typical business or hospital environment, e.g. according to EN 50160.
Magnetic field at supply frequency (50 / 60 Hz) in accordance with IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 and 60 Hz	Magnetic fields at mains frequency should correspond to the typical values found in a business or hospital environment.
Voltage drops, brief interruptions and fluctuations in the supply voltage in accordance with IEC 61000-4-11	0 % U_T (100 % drop in U_T) for 0.5 cycles; 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°. 0 % U_T (100 % drop in U_T) for 1 cycle. 70 % U_T (30 % drop in U_T) for 25/30 cycles 0 % U_T (100 % drop in U_T) for 5 s	as test value	The quality of the supply voltage should be that of a typical business or hospital environment. If the user of the VivanoTec Pro negative pressure unit requires continuous functioning even in the event of interruptions to the power supply, it is recommended to supply the VivanoTec Pro negative pressure unit through an uninterruptible power supply or a battery.

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Electromagnetic interference immunity tests	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidelines
Conducted interference in accordance with IEC 61000-4-6	$V_1 = 3\ V_{eff}$ 150 kHz to 80 MHz $V_1 = 6\ V_{eff}$ ISM and amateur radio bands frequencies	3 V 6 V	Portable and mobile radio devices should not be used closer to the VivanoTec Pro negative pressure unit, including the cables, than the recommended safety distance, which is calculated according to the equation applicable to the transmission frequency. Recommended safety distance: 30 cm
Radiated HF interference in accordance with IEC 61000-4-3	$E_1 = 10$ V/m 80 MHz to 2.7 GHz	10 V/m	
Proximity fields from wireless communication IEC 61000-4-3	Spot Tests: 710, 745, 780, 5240, 5500, 5785 MHz. 385 MHz. at 27 V/m 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz. at 28 V/m	at 9 V/m 27 V/m 28 V/m	RF wireless communication equipment should not be used closer to the VivanoTec Pro negative pressure unit (including the cables) than the recommended safety distance of 30 cm.
Radiated fields in close proximity IEC 61000-4-39	30 kHz with 8 A/m 134.2 kHz with 65 A/m 13.56 MHz with 7.5 A/m	As test level	If interference occurs, it may be necessary to place the VivanoTec Pro negative pressure unit further away from the sources of radiated magnetic fields in the close proximity or to install magnetic shielding.
Note: U_T is the mains alternating voltage before applying the test levels.			

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Recommended protective distances
Between portable and mobile RF telecommunications devices and the VivanoTec Pro negative pressure unit

The VivanoTec Pro negative pressure unit is designed for operation in an electromagnetic environment in which the RF interference parameters are controlled. The user of the VivanoTec Pro negative pressure unit can help to avoid electromagnetic interference by adhering to the minimum prescribed distance between portable and mobile RF telecommunications devices (transmitters) and the VivanoTec Pro negative pressure unit – dependent on the output power of the communications device.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than the distances as shown in the table below or at least 30 cm (12 inches) to any part of VivanoTec Pro, including cables specified by manufacturer. Otherwise, degradation of the performance of this equipment could result.

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17. Warranty certificate

HARTMANN

Warranty certificate
2-year warranty

Vivano® Tec
Pro

Serial no.:
Purchase date:

Dealer's stamp / Signature

Name:
Address:

Phone / Fax:

Service

HARTMANN

If you need technical support, please contact:

Distributor:
Address:

Phone / Fax:
URL /E-Mail:

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PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 HEIDENHEIM, GERMANY
www.hartmann.info

www.vivanosystem.info

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