VADO® by OPED plex

VASCULAR IMPULSE TECHNOLOGY

Instructions for use

OPED

Safety notes

Do not use the VADOplex system without having received a technical instruction on its use! You will find readable instructions for use on our OPED homepage.

WARNING

⚠ WARNING: Do not use the VADOplex System without having received the instruction for use!

⚠ WARNING: Before switching the device on to using it for therapy, make sure to read and understand the instructions for use. Always be aware of the limits and risks when using the device.

⚠ WARNING: Do not use the VADOplex System for purposes other than those described in the instructions for use.

⚠ WARNING: If you feel sick or if you experience any discomfort when operating the device, consult your doctor immediately.

⚠ WARNING: Side effects concerning device - No side effects have been claimed so far. Side effects concerning pads – Regularly check patient comfort and skin for irritation, particularly for patients with poor circulation, fragile skin, insensitive extremities, Diabetes mellitus and patients under anticoagulation therapy. Feeling of tension should be investigated.

⚠ WARNING: Pads: Single patient-multiple use: The pads are to be used for one patient only and may neither be used for several patients nor refurbished.

⚠ WARNING: If the device is not attached at the hospital bed, make sure that the device is positioned on a solid and flat surface providing the necessary stability when in use.

⚠ WARNING: Do not drop the device, impact, or immerse in water. Don't try to open the device!

⚠ WARNING: Make sure having switched off the device before leaving it unsupervised.

⚠ WARNING: Never pull the cord to unplug the device. Always pull the plug out itself.

⚠ WARNING: the device must not be serviced / maintained while in use.

⚠ WARNING: Always make sure to unplug the power cord before maintenance and cleaning tasks are performed. Not unplugging it could cause electric shock or injuries.

⚠ WARNING: If the power cord or device case is obviously damaged, do not connect it to an AC power source as electrical shock could occur.

⚠ WARNING: Parts of the device could burn or catch fire if exposed to an ignition source.

⚠ WARNING: Do not use the VADOplex System outside or on wet surfaces.

⚠ WARNING: Do not store or operate the VADOplex System in direct sunlight, as overheating could occur.

⚠ WARNING: Opening the housing or exposing the device to humidity/dampness creates a risk of electric shock.

⚠ WARNING: Only use original OPED parts and accessories. In case of non-observance, risks may include: electric shock, fire, bad treatment results.

Safety notes

⚠ WARNING: Do not disassemble and/or modify this equipment without authorization of the manufacturer. This is only allowed by educated medical engineers.

⚠ WARNING: The VADOplex System is designed in a way protecting it from being affected by incontinence. Nonetheless, preventive measures to avoid the device from coming into contact with fluids should be taken.

⚠ WARNING: The VADOplex System can optionally contain NiMH battery packs. Don't try to openthe device! The batteries may only be replaced by authorized specialists.

Note: Not made with natural rubber latex.

Transport

⚠ When carrying, transporting and storing the VADOplex System, take care not to damage the system by dropping it or by transporting or storing it incorrectly.

Children/Pets

⚠ Pay special attention when using the device on or in the presence of children.

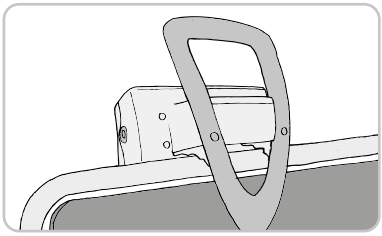
⚠ Do not use the VADOplex System as a toy.

⚠ Risk of suffocation and strangulation. Keep the cables/tubes away from children and pets.

⚠ Keep children and pets away from the power cord. Otherwise, cables could be damaged, causing a defect in the device power supply.

⚠ The VADOplex System must not be used on animals.

Attaching the VADOplex at the hospital bed



Note: If located on the floor take care not to crush the controller when altering the bed height.

Usage environment

For ward-based use in the medical environment. Operation and adjustment of the program are carried out by medical personnel.

Product Details

Device for improving venous return and arterial flow by periodic air pulse compression of the upper and lower extremities. The device is connected to pads by means of hoses. The pads are inflated with a pre-defined, fast compression pulse for 1 or 3 seconds, depending on the program. The pad presses on the venous plexus of the foot or on the venous vessles of the hand. This process is repeated every 20 or 50 seconds, depending on the program.

Contraindications

The use of this device requires the recommendation of the attending physician regarding the indication and the recommended duration of use.

Absolute contraindications:

- In patients where increased backflow to the heart could have a negative effect, e.g patients with decompensated heart failure or severe, non-adjustable hypertension
- Acute thrombophlebitis
- Acute deep leg vein thrombosis
- Full-blown compartment syndrome (with necrosis of the musculature)

Relative contraindications for the following cases - after weighing-up of the benefits and risks by the treating physician:

- Pulmonary embolism
- Severe infection of the treated extremity

Indications

The use of this device requires the recommendation of the attending physician regarding the indication and the recommended duration of use. The following are examples of indications and their recommended duration of use.

Indication	***Recommended duration of use***
Rapid decongestion in acute oedema of the upper and lower extremities (e.g. post-traumatic and after surgery)	Post-traumatic: continuous After surgery: 6 to 8 hours daily (with interruptions if necessary)
Prevention of compartment syndrome following extensive extensive soft tissue damage	Continuous, without breaks
Prevention of deep vein thrombosis	6-18 hours daily* Depending on the degree of mobilisation and the use of further prophylactic measures
Rapid decongestion in chronic vascular oedema of the arms and legs (e.g. CVI, therapeutic support in chronic lymphoedema) Ulcers of various aetiologies (venous, arterial, mixed) Diabetic foot syndrome (including with ulcer formation) Peripheral arterial occlusive disease (PAOD) and arterial circulatory disorders of the extremities (including in non-revascularisable situations)	At least 4 hours daily for several weeks with interruptions if necessary

Population

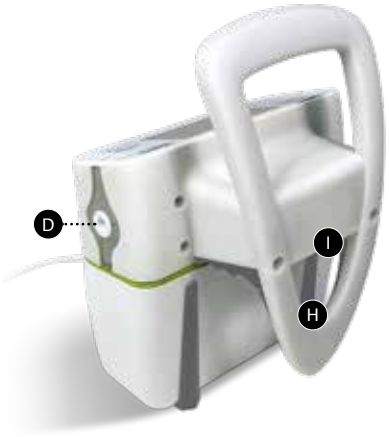
Recommended patient age: Youth starting at age 14 It is critical to ensure that the pad is seated correctly. The attending physician decides at what age the VADOplex is used.

* Recommended duration of use in combination with further measures

References:

1) Eisele R, Kinzl L, Koelsch T. Rapid-inflation intermittent pneumatic compression for prevention of deep venous thrombosis. J Bone Joint Surg Am. May; 89(5):1050-6.

2) Arabi YM, Al-Hameed F, Burns KEA, Mehta S, Alsolamy SJ, Alshahrani MS, Mandourah Y, Almekhlafi GA, Almaani M, Al Bshabshe A, Finfer S, Arshad Z, Khalid I, Mehta Y, Gaur A, Hawa H, Buscher H, Lababidi H, Al Aithan A, Abdukahil SAI, Jose J, Afesh LY, Al-Dawood A; Saudi Critical Care Trials Group. Adjunctive Intermittent Pneumatic Compression for Venous Thromboprophylaxis. N Engl J Med. 2019 Apr 4;380(14):1305-1315.



Device description

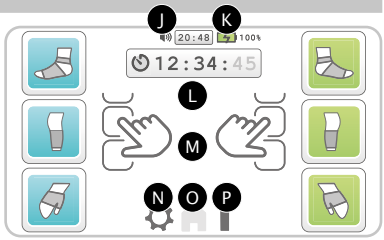
A Touch display
B On/Off button
C Start/Stop button

D Right connection for connecting hose
E Left connection for connecting hose
F LED status display: unlit - inactive, green - active, red - error

G Communication interface – check chapter „Treatment history“
H Carrying handle/bed hanger
I Power cable

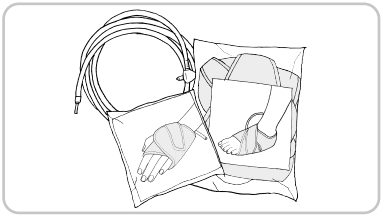
Description of control panel

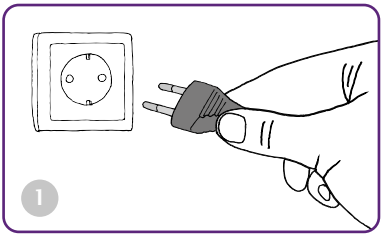
J Volume
K Battery state of charge
(available depending on delivery)
L Runtime/Timer
M Preset program
N Settings (gear symbol)
O Home-button - return from submenus
P i - Information

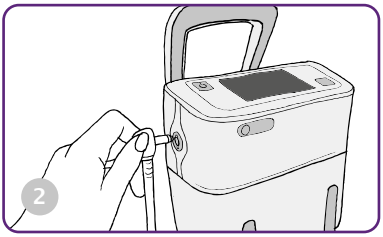


Accessories

Q Two connecting hoses
R Pad - depending on the application




1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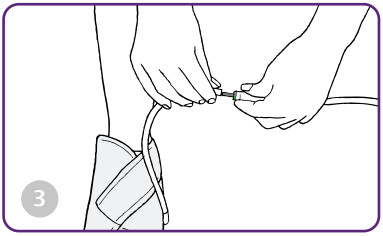
3


100%
34:45
4
5


VASCULAR IMPULSE TECHNOLOGY
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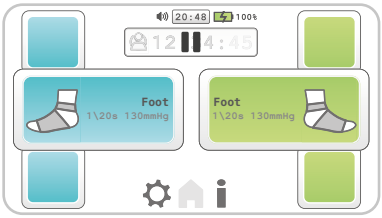
Instructions for use for ward-based use in the medical environment

The following programs are pre-set as factory defaults.

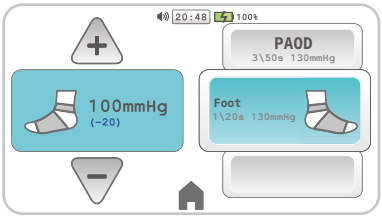
Note: The pre-set programs may differ depending on the country of delivery.

Program summary

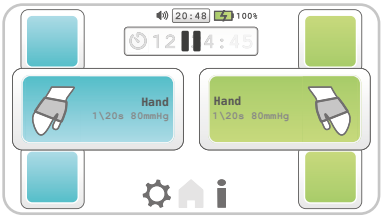
Foot
130 mmHg
Pressure pulse duration 1 second
Cycle time 20 seconds



Calf
130 mmHg
Pressure pulse duration 3 seconds
Cycle time 50 seconds

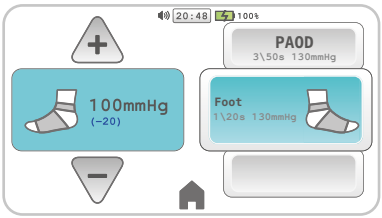


Hand
80 mmHg
Pressure pulse duration 1 second
Cycle time 20 seconds

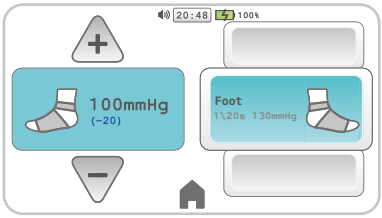


Submenu foot/PAOD

To enter the submenu press the icon foot.
Choose POAD. Press Home-button

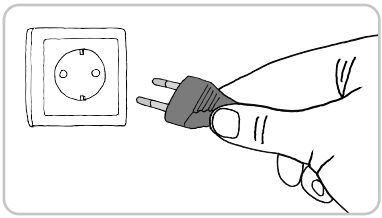


Individual setting



The pressure in mmHg can be adjusted by pressing the +/- button on the display.
The value and the deviation from the factory setting is shown in the display.

Commissioning the device



Connect the power cable to a socket.

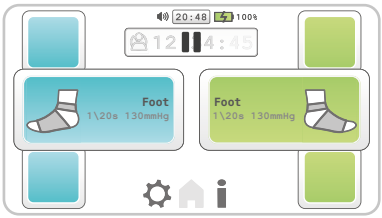
Caution

Make sure that the power cable plug is easily accessible and that it can be unplugged at any time.

Initialisation/activation/preparation of the device

Press the On/Off button to switch the device on. After switching on, the On/Off button lights up green.

A welcome screen appears on the touch display/control panel.
The device carries out a self-test.

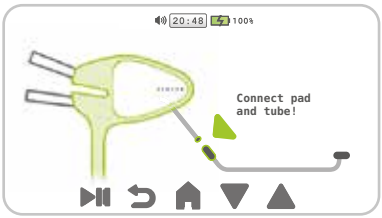


After the self-test has been completed, the device is ready for operation. The desired program can now be selected.

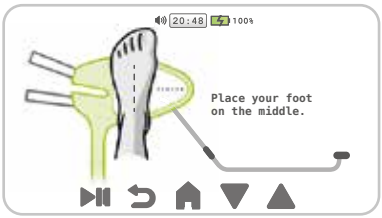
Use

To make the device ready for use, please first read the safety instructions on pages 2 and 3 before following the installation steps below.

Connect the connecting hose to the pad hose. To do so, insert the metal connector on the connecting hose into the pad hose.

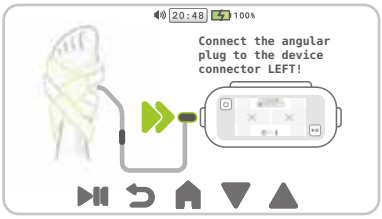


Put on the VADOplex pads and make sure that they fit correctly (operating instructions are included with the pads).



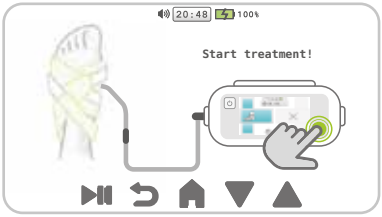
Single patient - multiple use.
The pads may only be used for one patient, but several times for that patient. The device may only be used with the pads provided for this purpose. The pads must not be reprocessed.

Insert the connecting hoses into the right and left side connections. For use on one side, simply insert a connecting hose into a side connection.



Positions for use
The functionality of VADOplex can be supported by a good positioning of the device. (see Page 18, Device setting)

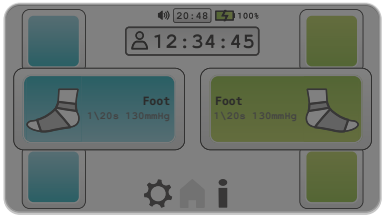
Once the self-test has been completed, the device is ready for operation. The desired program can now be selected. The Start/Stop button flashes green.



Use

Operation is started by pressing the Start/ Stop button. The button changes to green and the program starts. Pressing it again switches the device from operating mode to pause mode.

Programs



During problem-free operation, the display switches to sleep mode: The brightness of the backlight is reduced.

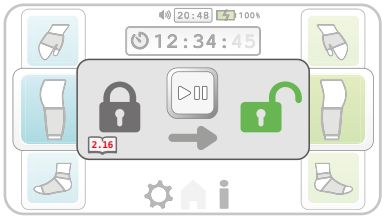
Switching off the device

Exit operation by pressing the Start/Stop button.

Remove the pad(s) and turn off the device with the On/Off button.

Then remove the power cable from the socket.

Lock touch display

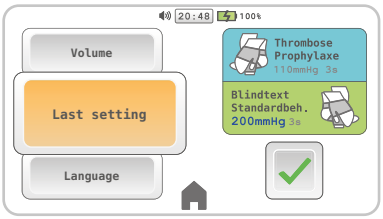


It is possible to lock the touch display for the duration of the therapy. Press and hold the Start/Stop button for at least three seconds to start the therapy. The therapy starts and a pulsating window indicates the lock on the screen. To unlock, press the Start/Stop button again (therapy is paused).

Last setting

Pressing the Setting icon displays the "Last setting" sub-menu.

The device starts automatically with the last program setting.



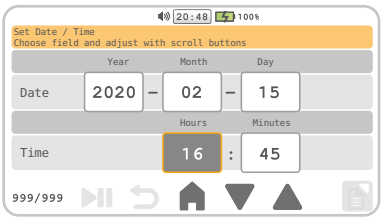
Protected area (for medical personnel only)

Access to the protected area can be reached by pressing the icon during the running self-test in the switch-on phase. Enter the PIN. This is provided by the manufacturer when the device is delivered.

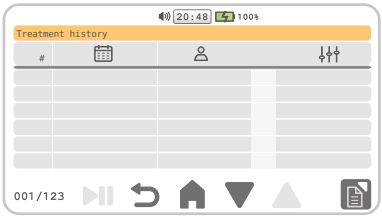
Time/date

Setting the time/date display

By pressing the desired field, the setting can be made using the arrow keys. The correct date must be set for correct documentation.

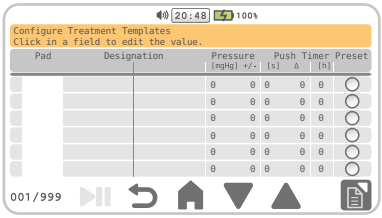


Export the entire treatment history



Each use of the device is stored and filed internally.If necessary, the device's entire treatment history can be exported . To do this, an external data medium with a USB-On-The-Go cable can be connected to the communication interface.

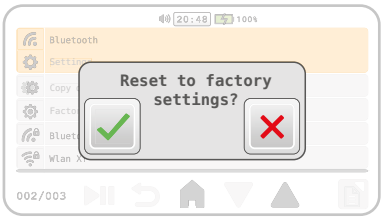
Configure treatment templates



For each treatment template the following parameters must be completed: Pad type, name of the program, pressure in mmHg, permissible adjustment range of the pressure in mmHg, pressure pulse duration, cycle time, timer/runtime of the therapy. Except for the timer, all values must be adjusted. Otherwise an error message appears. If no timer is set, the program runs until it is manually terminated using the Start/Stop button.

Change PIN, factory settings

Change PIN
Assigning an individual PIN



Factory setting
Individual settings are reset to factory settings.

Service area (for educated medical engineers only)

System test
Operational test
Reset maintenance hours
Service partner

For further information, see the "Service Manual" provided by the manufacturer.

Device setting

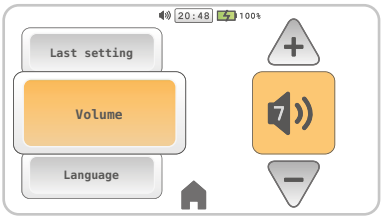
Press the Setting icon to display the sub-menu.

Languages

Choice of languages German, English, French, Italian.

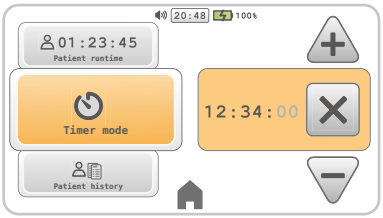
Volume control

Adjust the volume of the signal tones between 1 = quiet and 9 = loud.



Patient runtime/timer mode

Display of the patient runtime and activation of timer mode. The field shows the length of use per patient. After pressing the field 12:34:45 , the timer can be set with +/- and deleted with ✕ After the previously set application time (timer) has expired, the device enters standby mode.

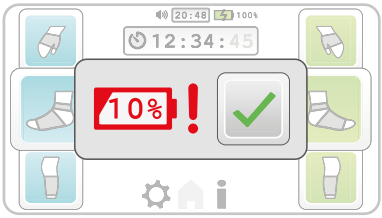


The use of the device for each patient is documented internally. If necessary, this list can be exported. To do this, an external data medium with a USB On-the-go cable can be connected to the communication interface.

It is then possible to delete the patient history by resetting the patient runtime.

Tip: The patient runtime must be set to 0 for each new patient.

Battery operation

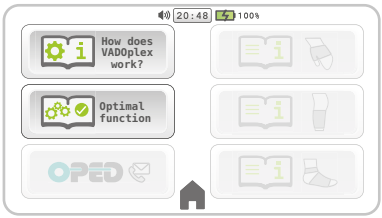


For temporary mains-independent use, the device is equipped by the manufacturer with a rechargeable battery. As the battery charge diminishes, an alert will be issued at 10% and 5% remaining charge. It is charged by connecting the power cable to a power socket. The device may heat up slightly when charging. This is normal and is not a malfunction.

Patient information

The patient information sub-programs are displayed by pressing the “i -information”.

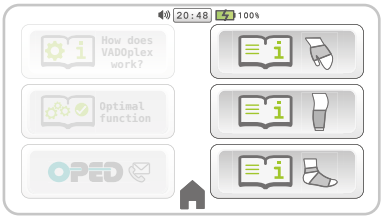
Operating principle/Optimal function



How does VADOplex work?

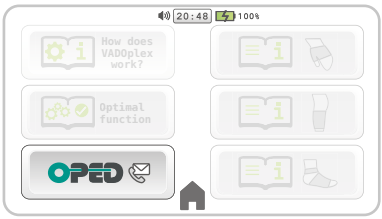
Information on the ideal sitting/lying position.

Pad fitting procedures



Information about fitting the pads.

Hotline



Hotline to the manufacturer/distributor.

Error diagnosis/troubleshooting – Device continues to run

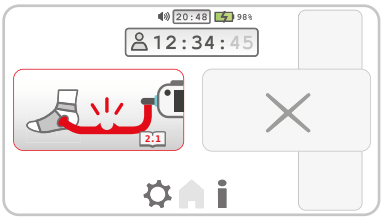
In the event of an error, a signal tone sounds with each pressure pulse. After the error has been rectified, the signal tone does not sound.

The following errors can occur:

Error code 2.1

Possible error
Pad not plugged in or pad or hose leaking

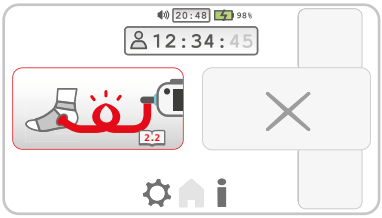
Remedy
Check hose connections and the pad for leaks and replace if necessary.



Error code 2.2

Possible error
Hose kinked or blocked

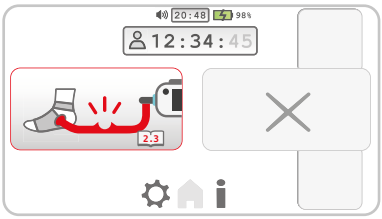
Remedy
Check hose for kinks or blockages, replace if necessary.



Error code 2.3

Possible error
Pad not plugged in or pad or hose leaking

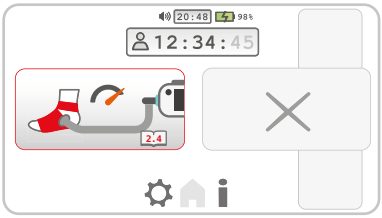
Remedy
Check hose connections and the pad for leaks and replace if necessary.

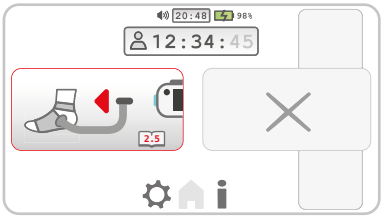


Error code 2.4

Possible error
Pad squeezed (stand on it) or fitted extremely tight

Remedy
Was the correct pad fitted?
Check pad for correct fit.

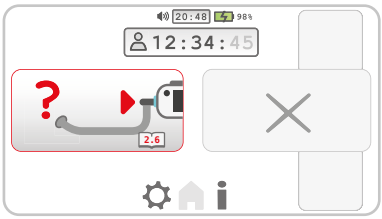




Error code 2.5

Possible error
Hose disconnected

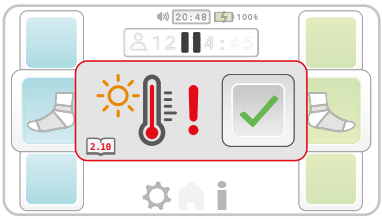
Remedy
Check the hose connection on the device side.
Restart treatment.



Error code 2.6

Possible error
Hose connected during operation

Remedy
Check the hose connection on the device side.
Restart treatment.



Error code 2.10

Possible error
High ambient temperature and/or installation site with direct sunlight

Remedy
Protect the device from direct sunlight/move it into a cooler environment.

Note

In the event that the above measures do not solve the problem or an error code not listed here appears on the control panel: To ensure that therapy is carried out properly, the device must be checked by qualified personnel or the manufacturer must be contacted.

Error diagnosis/troubleshooting - Device stops

In the event of an error the device stops.
The Start/Stop button lights up red.

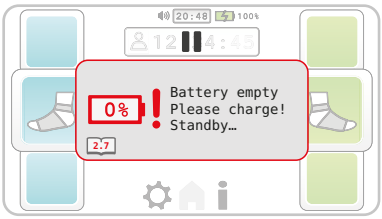
Clicking the error symbol displays the relevant measures directly from the device.

The following errors can occur:

Error code 2.7. to 2.9

Possible error
Device disconnected from the mains for too long

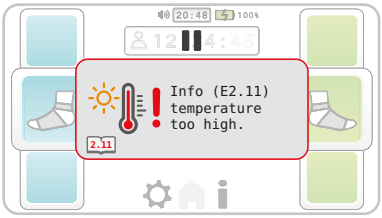
Remedy
Connect the device to the mains.



Error code 2.11

Possible error
Ambient temperature too high and/or installation site with direct sunlight.

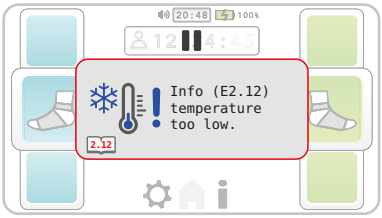
Remedy
Protect the device from direct sunlight/ move it into a cooler environment.



Error code 2.12

Possible error
Outdoor temperature too low

Remedy
Place the device in a room with an ambient temperature compliant with the technical data and let it warm up.



Accessories

Depending on the indication

Footpads	Article number
1 foot pad, size medium (37-41), left	VXFP-01-1-M-LI
1 foot pad, size medium (37-41), right	VXFP-01-1-M-RE
1 foot pad, size large (42-47), left	VXFP-01-1-L-LI
1 foot pad, size large (42-47), right	VXFP-01-1-L-RE
1 pair of foot pads, size medium (37-41)	VXFP-02-1-M
1 pair of foot pads, size large (42-47)	VXFP-02-1-L
1 box with 5 pairs of VADOplex foot pads, size medium (37-41)	VXFP-05-1-M
1 box with 5 pairs of VADOplex foot pads, size large (42-47)	VXFP-05-1-L

Calf pads	Article number
1 pair of calf pads	VXCD-06-1

Hand pads	Article number
1 hand pad, left	VXHP-04-1-LI
1 hand pad, right	VXHP-04-1-RE

Under-cast pads	Article number
1 foot pad for VACOped/ VACOped Diabetic	VXCP-03-1

Packing list

- VADOplex device incl. power cable
- Two connecting hoses (3 m)
- Instructions for use
- Outer packaging for storage/shipping of device and accessories
- Incl. safety packaging

Service and technical maintenance

While the VADOplex system remains the property of its manufacturer, all servicing and maintenance work, as well as safety-related checks (SRCs) must be carried out by the manufacturer. However the operator is expressly responsible for complying with the maintenance intervals (if necessary consult the operator regulations).

When used in the home, the patient is not permitted to carry out any servicing / maintenance work, or to carry out the safety and function tests (SFT). In home and hospital ward settings, these must be carried out only by educated medical engineers.

The service intervals specified by OPED must be complied with: The VADOplex system must be serviced after every 5,000 hours of operation. The device indicates this (wrench symbol). From 150h before the service is due, the wrench icon in the start screen changes to yellow to indicate the upcoming service. If the service interval is exceeded, the icon color changes to red (see illustration).

Only OPED spare parts must be used.

Upon request, the manufacturer will gladly provide circuit diagrams, spare parts lists and other documents for qualified personnel.

Once under the ownership of the customer, servicing and maintenance work, as well as safety-related checks (SRCs), can be carried out by the manufacturer upon request for a charge.

Cleaning and maintenance

Users/patients
The device is delivered in hygienically perfect condition. A lint-free, soft cloth may be used to wipe the device and the connecting hoses. All conventional mild detergents can be used as cleaning agents. To do this, wring the cloth out well so that no liquid can run into the device.

Operators
Before each use on another patient, the device must be cleaned, disinfected and subjected to a functional check as prescribed by law. Care should be taken to ensure that these agents do not attack and damage the surface. Since the device has a display, the disinfectant must be suitable for displays. Disinfectants to be used for surfaces must also be identified. The disinfectants must be designed for your specific pathogen spectrum and comply with the DIN-EN or national standards. Observe the concentrations and exposure times of the manufacturers (see hygiene plan). You can obtain detailed instructions on how to prepare the device from the manufacturer. The device and its accessories are not suitable for sterilisation.

Return

In the context of outpatient care, the device is the property of the manufacturer and must be returned to the manufacturer. This is done using both connecting hoses. Dispose of used pads in household waste. Under no circumstances enclose these with the device when returning it to the manufacturer.

Technical data

MDD class	IIa (93/42/EEC, Annex IX, Rule 9)
Protection class	II, Type BF
CE marking	CE 0123

Classification

Input	100-240V~,0.8-0.5A, 50/60Hz
Power supply unit	Manufactured by Magic Power Technology GmbH
Power supply unit model	MPM-S055
	Battery (optional) 2x 12V NiMH 2000mAh
	Battery lifetime >500 cycles
DIMDI No.	10-969 in accordance with UMDNS
Classification	UMDNS compression device, intermittent
Code of the competent authority	DE CA 57 (Upper Bavaria administrative district)
Article No.	VXSY-10-1

This device is suitable for continuous operation. Tested according to IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11. The service and maintenance intervals specified by OPED in the service manual must be observed:

Currently every 5000 operating hours. If the recommended maintenance intervals are observed and the device is handled properly, the lifetime will extend far beyond this.

Information on possible electromagnetic interference and instructions for avoiding or minimising such interference can be found in the annex to these operating instructions for use.

Environmental conditions for transport/storage

- Temperature range: -25º C to 70º C
- Relative humidity: up to 90 % non-condensing
- Ambient pressure: 700 hPa to 1,060 hPa

Environmental conditions during operation

- Temperature range: 5º C to 40º C
- Relative humidity: up to 90 % non-condensing
- Ambient pressure: 700 hPa to 1,060 hPa

Warranty

The warranty is provided in line with statutory regulations. The terms and conditions of business of OPED GmbH also apply, where permissible.

Device dimensions

Height with carrying handle	28.5 cm, total
Height without carrying handle	20.0 cm, total
Depth	16.0 cm
Width	21.0 cm
Weight	3.3 kg

Conversion table mmHg/KPa

mmHg	KPa	mmHg	KPa	mmHg	KPa
60	8.0	110	14.7	160	21.3
70	9.3	120	16.0	170	22.7
80	10.7	130	17.3	180	24.0
90	12.0	140	18.7	190	25.3
100	13.3	150	20.0	200	26.7

Hand
80mmHg = 10.7 kPa, pressure pulse duration 1 second, cycle time 20 seconds

Foot/PAOD/calf
130 mmHg = 17.3 kPa, pressure pulse duration 3 seconds, cycle time 50 seconds

Foot
130 mmHg = 17.3 kPa, pressure pulse duration 1 second, cycle time 20 seconds

Data protection

Germany Information about the processing of your personal data can be found at:
https://oped.de/support/ihre-daten/.

Switzerland Information about the processing of your personal data can be found at:
http://oped.ch/kontakt/ihre-daten/.

Disposal

Caution: If the device is still the property of the manufacturer, please consult them before disposal.

Germany/Rest of Europe Dispose of used pads in household waste. The device, including its packaging, must not be disposed of in household waste and should be delivered to an appropriate collection facility for recycling.

Other countries Disposal is carried out according to country-specific requirements and local environmental protection regulations.

Information on potential electromagnetic interference and advice on how to avoid or minimize such interference

Guidance and manufacturer's declaration – electromagnetic emission

The model VADOplex is intended for use in the electromagnetic environment specified below. The customer or the user of the model VADOplex should assure that it is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The model VADOplex uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The model VADOplex is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distances between portable and mobile RF communications equipment and the model VADOplex

The model VADOplex is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model VADOplex can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model VADOplex as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz d = 1,2	**80 MHz to 800 MHz** d = 1,2	**800 MHz to 2,5 GHz** d = 2,3
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Information on potential electromagnetic interference and advice on how to avoid or minimize such interference

Guidance and manufacturer's declaration – electromagnetic immunity

The model VADOplex is intended for use in the electromagnetic environment specified below. The customer or the user of the model VADOplex should assure that it is used in such an environment. The device complies with the requirements (electromagnetic immunity) listed in Section 8.9 of IEC 60601-1-2:2014.

Immunity test	IEC60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location of a professional healthcare facility environment and Home healthcare environment.
Radiated RF EM fields: Proximity fields from RF wireless communications equipment IEC 61000-4-3	IEC 60601-1-2:2014 table 9	IEC 60601-1-2:2014 table 9	
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz Repetition Frequency	±2 kV 100 kHz Repetition Frequency	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment.

Immunity test	IEC60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles single phase: at 0 degrees 0 % U_T; 250/300 cycles	0 % U_T; 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles single phase: at 0 degrees 0 % U_T; 250/300 cycles	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source. If the device is optionally equipped with a rechargeable battery, these voltage drops are intercepted by this battery.
Conducted RF IEC 61000-4-6 Radiated RF EM fields IEC 61000-4-3	$3V_{RMS}$ (0.15 – 80 MHz) $6V_{RMS}$ (ISM) 10 V/m 80 MHz – 2,7 GHz	$3V_{RMS}$ (0.15 – 80 MHz) $6V_{RMS}$ (ISM) 10 V/m 80 MHz – 2,7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz – 800 MHz $d = 2,3\sqrt{P}$ 800 MHz – 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a)] should be less than the compliance level in each frequency range.[b)] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters such as base stations for radio (cellular/cordless) telephones, land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters an electromagnetic site survey should be considered. If the measured field strength in the location in which the model VADOplex is used, exceeds the applicable RF compliance level above, the model VADOplex should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 10 V/m.

Declaration of Conformity

KONFORMITÄTSERKLÄRUNG

gemäß RL 93/42/EWG, Anhang V

DECLARATION of CONFORMITY

in accordance to MDD 93/42/EEC, Annex V

Der Hersteller von Medizinprodukten/The Manufacturer of medical Devices:

OPED GmbH
Medizinpark 1
D-83626 Valley/Oberlaindern

erklärt hiermit in alleiniger Verantwortung, dass die folgenden Medizinprodukte:
declares under its sole responsibility that the following Medical devices:

Produktname/Name of product:	Artikelnummer/Kinds of Product: *
VADOplex	**VXSY-10-1**

(*Diese Konformitätserklärung gilt für alle Geräte, welche unter der genannten Artikelnummer gebaut werden /This declaration of conformity is valid for all devices which are built under the named article number)

den Grundlegenden Anforderungen nach Anhang I der Richtlinie 93/42/EWG erfüllen und der Medizinprodukteklasse IIa nach der Richtlinie 93/42/EWG, Anhang IX, Regel 9 sowie
- der Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHs) entsprechen.

comply the essential requirements to Annex I of the directive 93/42/EEC the medical device class IIa according to the directive 93/42/EEC, Annex IX, Rule 9 and to
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHs)

Produktkategorie gemäß/Category of Product according to UMDNS: 10-969
Produktkategorie gemäß/Category of Product according to GMDN: 44784
Nomenklaturbezeichnung/identification of nomenclature:
Pumpe für System zur Intermittierenden Venenkompression/ Intermittent venous compression system pump

Certified body of Medical Devices: TÜV Süd, Munich/Germany (no. 0123)
EC - Certificate of Production Quality AssuranceG
Certificate No: G2 16 08 45664 0008 Rev. 01
Issued by: TÜV SÜD Product Service GmbH (0123), Ridlerstr.65, D-80339 Munich
Valid from: 2020-02-14
Valid until: 2024-05-26

Unterschrift/Signature:

Verantwortliche Person des Herstellers gemäß Artikel 15 der MDR 2017/745
Person responsible from the manufacturer for regulatory compliance according to Article 15, MDR 2017/745
Thekla Kresse

Ausstellungsort/Place of issue: 83626 Valley/Oberlaindern, Germany
Datum/Date: **2021-11-02**

	EN
MD	Medical device
	Manufacturer
	Date of manufacture
	Product name
SN	Serial number
LOT	Batch
REF	Article number
CE	CE mark
	Note the instructions for use
	Caution
	Risk of falling
	Risk of explosion
	Before opening the device, unplug the power supply.
CE 0123	The device meets all essential requirements of the applicable EU guidelines.

	EN
	Type BF applied part
	Observe accompanying documents!
	Temperature range
	Data-Matrix
	The product, including its packaging, must not be disposed of in household waste. Disposal is carried out according to country-specific requirements and local environmental protection regulations. See also „Disposal / Return“ in these instructions for use.
	Single Patient – multiple use
	Appliance Class II
IP 22	IP Code IP 22
	Protect the device from direct sunlight

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