
		Technical Data Sheet							
VivanoTec NPWT			<table><tr><td>Spec.-No.:</td><td>D 4.0050</td></tr><tr><td>Department:</td><td>CMO-DNP</td></tr><tr><td>Date:</td><td>2015-09-01</td></tr></table>	Spec.-No.:	D 4.0050	Department:	CMO-DNP	Date:	2015-09-01
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1. General Product Description

VivanoTec NPWT is a mobile suction device for use in negative pressure wound therapy. It is designed for long-term use on humans. It is portable, mains-independent and features electronic monitoring functions with optical and acoustic status displays. VivanoTec NPWT must only be used with VivanoMed wound dressing sets and VivanoTec Secretion Canisters.

VivanoTec NPWT is a particularly practical suction device for negative pressure therapy. The negative pressure unit is operated with a maintenance-free membrane pump driven by an electric motor. Thanks to the negative pressure which is generated during operation of the pump in the wound dressing, tube line system and exudates container, exudates can be extracted by suction. The negative pressure unit automatically generates, regulates and monitors the set therapy values. The exudate is collected in the VivanoTec Secretion Canister intended for this. Special filter technology prevents the penetration of fluids, bacteria and odours into the interior of the device. Therapy settings can be applied by means of a touch screen. VivanoTec NPWT is fitted with a rechargeable lithium-ion storage battery. A microprocessor-controlled electronic charging system inside the negative pressure unit ensures that the storage battery is securely charged.

VivanoTec NPWT is delivered with the following components: a VivanoTec Carrying Shoulder Strap, a country specific main adapter, a charger and operating instructions and eventually a VivanoTec Case.

Atmos Medizintechnik GmbH is legal manufacturer of VivanoTec NPWT. VivanoTec NPWT carries the CE-mark according to EU directive 93/42/ EEC for medical devices. The product is classified as a class IIa medical device.

A conformity assessment has been performed for VivanoTec NPWT and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use and effectiveness of VivanoTec NPWT therefore, is ensured if the product is used in line with the intended purpose.



2. Application / Indication

Indications

VivanoTec NPWT has only to be used in combination with Vivano System.

Application notes

- 1) Connect VivanoTec Secretion Canister to VivanoTec NPWT.
- 2) Switch on VivanoTec by touching the On/Off Key during two seconds
- 3) Chose the appropriate therapy modus (continuous or intermittent) by touching the screen.
- 4) Set up the desired therapy pressure
- 5) Start the therapy by touching the start key on the screen.


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3. Technical data



Voltage	100- 240 V~, 50/60 Hz Mains socket IEC320 Type C8
Current consumption	max. 1.5 A
Power consumption	max. 50 W
Charger	Manufacturer: GlobTek, Inc. Model: GTM91099-6015-3.0-T2
DV voltage	12 V DC +/- 2 %, max. 5 A via cable 1.2 m in length with plug 5.5 x 2.5 x 11 mm, alternatively via motor vehicle cable from the cigarette lighter jack
Storage battery, incorporated	Li-Ion, 14,4 V nominal, 2250 mAh
Operation time	Charging time approximately 2.0 hours at up to 20° C ambient temperature (temperature > 25° C longer charging time), automatic switching to maintenance charge, operation up to 16 hours at 80 mmHg and 0.4 l/min leakage, capacity indication in the display continuous operation on mains supply
Pump	Membrane pump, 1 pump head
Flow	max. 4.5 l/min free flow (without filter, damper or tubes)
Negative pressure	max. 500 mmHg (pump output at sea level) but limited mechanically and through electronic control
Negative pressure regulation	Electronically regulated, max. 250 mmHg, min. 20 mmHg in steps of 5 mmHg, requires exudate canister to be connected for stable negative pressure regulation
Display	Graphic display, colour, with backlighting with adaption to ambient light and automatic switch-off (power saving mode)
Operating modes	Continuous or intermittent, optional simultaneous storage battery charging and operation
Data memory	Internal memory for therapy data: 4 MB
Intermittent mode	Time upper vacuum: Range 1 minute to 10 minutes Time lower vacuum: Range 1 minute to 10 minutes Setting range for lower vacuum:

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	Range 20 mmHg to 230 mmHg* Setting range for upper vacuum: Range 40 mmHg to 250 mmHg* *The set minimum vacuum value between Hi and Lo, is 20 mmHg Default: Hi. 3 min. 120 mmHg Lo. 3 min. 20 mmHg
Earth leakage current	Max. 0.5 mA
Ambient conditions for transport and storage	-25...+70°C 5...93 % air humidity without condensation t air pressure of 700...1060 hPa
Ambient conditions in operation	+5...+40°C 15...93 % air humidity without condensation t air pressure of 700...1060 hPa
Dimension H x W x D	164 x 206 x 95 mm without exudate canister Depth with 300 ml: max. 115 mm Depth with 800 ml: max. 153 mm
Weight: - Negative pressure unit (without canister) - Exudate canister 300 ml - Exudate canister 800 ml - Mains charger and mains cable	1.20 kg 0.16 kg 0.18 kg 0.50 kg
Recurring safety checks	Maintenance including safety check must be carried out every two years.
Protection class (EN 60601-1)	Device: II Charger: II
Applied part (The applied part of the suction device ist he tube-canister system)	Type BF 
Type of protection	IP 22
Classification acc. to Appendix IX EC Directive 93/42/EEC	IIa
CE mark	CE 0124
UMDNS code	Suction Unit Wound 10-223

Sound intensity ≤ 39 dB (A) at 125 mmHg

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4. Presentations

Article	Article-No.	Unit per box
VivanoTec NPWT	409 504	1
VivanoTec Russia	409 502	1

5. Labelling

Each unit is labelled with a Serial Number SN with 9-digit code:
e.g. 100000421

6. Packaging

VivanoTec NPWT are packaged in shipping carton acc. DIN, sealed with adhesive tapes.

Date: 2015-09-01

PAUL HARTMANN AG
- Product Development Advanced Wound Care
- Development NPWT (CMO-DNP)

i. V.



Dr. Axel Eckstein