# Vivano®Tec Pro

**General Product Description/Intended Purpose**

The Vivano®Tec Pro negative-pressure unit is used to create and control a sub-atmospheric (i.e., negative) pressure at the site of an acute or chronic wound during negative-pressure wound therapy (NPWT).

The controlled, negative pressure established by the system drains wound exudate and skin fragments away from the surroundings of the wound into a wound dressing and an associated tube system for collection in a designated exudate canister attached to the negative-pressure unit. In addition, negative pressure stimulates cell growth and blood circulation in the wound.

The Vivano® System is meant for use only on 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.

The Vivano®System may be used only by a physician or a qualified person, in accordance with a physician's instructions, but may be deployed in hospital, residential-care and home-care settings.

Vivano®Tec Pro is intended for use only in conjunction with the Vivano® System by PAUL HARTMANN AG. In particular, in order to establish a functional NPWT, at least the following other components are required:

- Vivano®Med Foam
- Hydrofilm®
- Vivano®Tec Port
- Vivano®Tec Exudate Canister

Vivano®Tec Pro is a medical device class IIa.

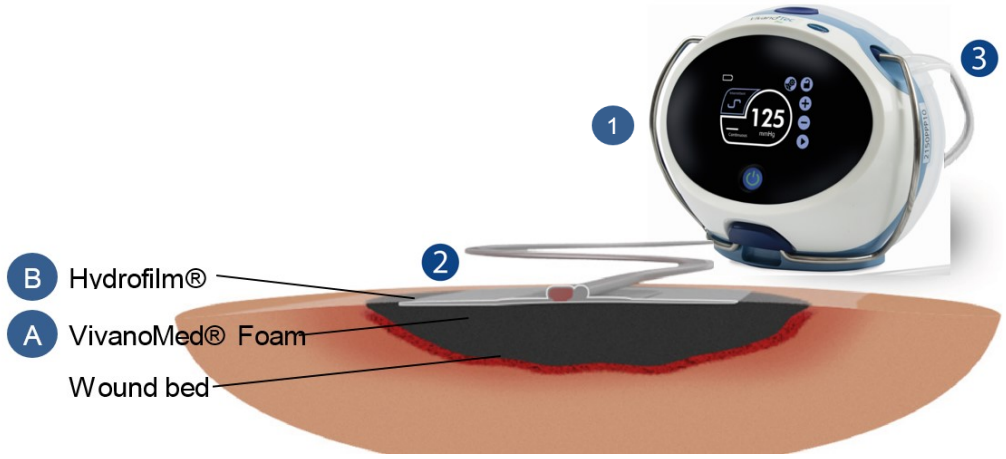


Figure 1: Vivano® negative pressure wound therapy (NPWT) system:
1) Vivano®Tec Pro Unit, 2) Vivano®Tec Port (+tubing), 3) Vivano®Tec Exudate Canister,
A) Vivano®Med Foam, B) Hydrofilm®

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**Application/Indication**

The Vivano® System is used in wounds with injured tissue to support healing by secondary intention. Vivano®Med 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.
Vivano®Tec Pro is used to establish controlled negative pressure at the site of an acute or chronic wound.

**Reference Numbers**

| Article | Article-No. | Units per box |
|---|---|---|
| **Vivano®Tec Pro (all countries except Russia)** | 409508/0 | 1 |

**Contraindications**

Contraindications for the use of the Vivano® System:
- malignant tumor wounds
- non-enteric/unexplored fistulas
- untreated osteomyelitis
- necrotic tissue

**Warnings and special precautions**

Special precautions should be taken in the context or associated with the risk of:
- bleeding
- application of the VivanoMed Foam on nerves, anastomosis points, blood vessels or organs
- infected wounds
- blood vessels and organs
- bone fragments or sharp edges
- surgical incisions
- enteric fistulas
- spinal cord injuries with the development of autonomic hyperreflexia
- magnetic resonance imaging (MRI)
- defibrillation
- hyperbaric oxygen therapy (HBO)
- external heat sources
- presence of flammable or explosive gases and/or liquids
- electrical safety

For more information on important safety instructions, special and general precautions, please refer to the Warnings and Precautions sections in the Vivano®Tec Pro instructions for use document.

# Vivano®Tec Pro

**Product Disposal**

To minimize the risk of potential infection hazards, or environmental pollution, Vivano®Tec Pro should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards. For more information on product disposal, please refer to the disposal section in the Vivano®Tec Pro instructions for use document.

**Incident Reporting**

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU 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 authorized representative and to your national authority.

**Product Characteristics / Technical Data**

| Property | Characteristics |
|---|---|
| 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. |
| VivanoTec Pro power supply | Input: 100-240 V ac, 1.1 A, 50-60 Hz<br>Output: 24 V dc 2.01 A<br>- Manufacturer: XP Power Limited<br>- Model: AFM45US24C2-XE1047 |
| 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. 2.0 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 |

# Vivano®Tec Pro

| | |
|---|---|
| Intermittent mode | Time interval: 2 - 10 minutes in each case<br>Upper pressure<br>value: 40 - 200 mmHg<br>Lower pressure<br>value: 20 - 80 mmHg<br>The preset minimum pressure difference between upper pressure and lower pressure value is 20 mmHg<br>Standard values for the upper pressure range: 5 min. 125 mmHg<br>Standard values for the lower pressure range: 2 min. 20 mmHg |
| Continuous mode | Standard value 125 mmHg; pressure range: 20 to 200 mmHg |
| Warning message signal | 3 pulses of 200 ms and 150 ms pause, with 2.5 seconds separation sound pressure level: 47 dB (A) |
| Transport and storage conditions | Temperature: -25 to +60 °C<br>Relative Humidity: 15 to 90 %, non-condensing |
| Ambient conditions in operation | Temperature: +5 to +40 °C<br>Relative Humidity: 15 to 90 %, non-condensing<br>Pressure: 700 hPa to 1060 hPa |
| Dimensions | H x W x D 172x214x105 mm without exudate canister<br>Depth with 300 ml exudate canister: max. 117 mm<br>Depth with 800 ml exudate canister: max. 148 mm |
| Weight | Negative pressure unit (without canister) 1.2 kg<br>Exudate canister 300 ml 0.25 kg<br>Exudate canister 800 ml 0.29 kg<br>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 millimeters 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 Rechargable Li-ion Battery 14.40 – 14.52 V, 2 A, 2600 - 2700 mAh, 38.00 - 38.88 Wh |

# Vivano®Tec Pro

**Product Performance Characteristics**

| Property | Test method | Test results |
|---|---|---|
| Medical electrical equipment<br>**General requirements for basic safety and essential performance** | IEC 60601-1 | compliant |
| Medical electrical equipment<br>**Systems used in the home healthcare environment** | IEC 60601-1-11 | compliant |
| Medical electrical equipment<br>**Electromagnetic disturbances - Requirements and tests** | IEC 60601-1-2 | compliant |
| Medical electrical equipment.<br>**Usability** | IEC 60601-1-6 | compliant |
| Medical electrical equipment<br>**Tests and guidance for alarm systems in medical electrical equipment and medical electrical systems** | IEC 60601-1-8 | compliant |

**Labelling**

Reference-No.
e.g.: REF 409508/0

Serial-No. with 9-Digit Code
e.g.: SN 216010001

Manufacturing Date
e.g.: 2020 year, 07 month, 31 day

Medical Device

MD

Unique Device Identifier (UDI)

UDI

**Latest Date of Revision:** 2020-07-20