IMPORTANT PRODUCT INFORMATION

HARTMANN VivanoTec® ATMOS® S 042 NPWT

ID No:	FSN_11079-16-01
Type of measure:	Safety note
REF:	409 504 (Paul Hartmann AG) and 316.000.0 (ATMOS MedizinTechnik)
Serial number:	All currently used systems HARTMANN VivanoTec® and ATMOS® S 042 NPWT

Dear user of the HARTMANN VivanoTec® negative pressure unit and the ATMOS® S 042 NPWT negative pressure unit,

As manufacturer of negative pressure wound treatment systems listed above, we provide as part of the ongoing market monitoring by ATMOS MedizinTechnik GmbH & Co. KG this voluntary product information in order to explicitly draw attention to the following points:

- Update of the device software for all HARTMANN VivanoTec® vacuum units and for all ATMOS® S 042 NPWT vacuum units to version 1.3.
- Additional instructions for use in the respective operating instructions of the products listed above.
- The need to explicitly remind users of the importance of patient monitoring measures.

These changes and additional hints contribute to the reduction of avoidable user errors.

1. Description of the software changes

In the new software version **1.3** the following modifications have been made:

1.1 Immediate activation of the key lock after closing a warning message window

Hitherto, in the case of a warning (for example, "canister full", "hose blocked", ...), the key lock has been released in order to be able to acknowledge the warning message. The lock remained inactive for one minute to allow the user to change device settings. Market observations have shown that users or patients within this short time have, in some cases unconsciously, made changes in the device settings. Realizing this, the delayed activation of the key lock was removed, so that after acknowledgment of the warning message, the key lock is immediately active again.

1.2 *Optical highlighting of the start / stop button*

The control panel for starting and stopping the therapy - "Start / Stop button" on the touchscreen was coloured blue in the previous software versions. After switching on the device or after stopping the therapy an alternating colour change between light blue and dark blue indicated that the therapy must be restarted.

Market observations have shown that the users occasionally did not perceive this optical stimulus (alternating colour changes between light blue and dark blue) and therefore the start of therapy was delayed. From this knowledge, the operating area for starting and stopping the therapy ("start / stop button") was coloured green. The alternating colour change between light green and dark green now stands out clearly from the remaining blue coloured control surfaces and therefore ensures increased attention to the users. Illustrations in the operating instructions, which show this control surface, have been adapted accordingly.

1.3 *Changed time intervals in the operating mode "intermittent"*

In the operating mode "intermittent" a time interval between 1 to 10 minutes could be set. In the case of very short time intervals (e.g. 1 minute high target vacuum and 1 minute low target vacuum), a detected leakage and a related warning may have been reset by switching the mode from high to low target vacuum (or vice versa), and the indication window was only briefly displayed.

Market observations have shown that users have been irritated by the brief display of warnings in some cases. From this realization, the adjustable time interval has been adapted so that the user can set the desired target vacuum between 3 and 10 minutes. The display of the detected state as a warning sign remains visible for a longer time.

1.4 *Defective pump - additional warning*

The previous software versions cannot recognize a damaged pump in the device caused by external forces (for example, a fall). The users have noticed it during the prescribed control of the wound dressing when the set vacuum has not been reached

Market observations have shown that equipment has been used despite obvious external damage caused by fall or blow. From this finding, a check has been inserted into the software which can detect a damaged pump and then activates a warning message which prevents the use of a damaged device. The new warning message is: "Service required. Device cannot be operated! Have the device checked by service!"- connected to the symbol of a wrench. It has been inserted into the operating instructions as section "4.2.5 Service required".

2. Actions to be taken by the representative of the institution

The new software will be available from 01 April 2017. Prepare all devices for the software update (including decontamination) located in your facility and contact your responsible sales partner. ATMOS MedizinTechnik and / or Paul Hartmann AG will coordinate the software updates with you in your institution.

For the devices you will receive updated operating instructions from Index 14 (VivanoTec®) or Index 21 (ATMOS® S 042 NPWT).

Please make sure in your organization that, after the software update, all users of these products and other persons to be informed are trained before the first use of the device and are thus informed on the contents of this IMPORTANT PRODUCT INFORMATION. We recommend that you train all users with the help of your sales representative (Paul Hartmann AG or ATMOS MedizinTechnik GmbH & Co. KG) and to explicitly remind them of the importance of patient monitoring measures defined in your facility.

Please document the contents of your training courses carefully and ensure that all users of the equipment receive and confirm the training.

3. Contact information

If you have any questions about this product information, please contact your local medical device adviser or contact us at SiBaMP@atmosmed.de or by phone *+49 7653 689 -220 or -620*.

Best regards

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ATMOS MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Straße 16
79853 Lenzkirch / Germany
Phone: +49 7653 689-220
Fax: +49 7653 689-294
Mobile: +49 151 14550307