August 20th, 2014

MEDICAL DEVICE RECALL - UPDATE

Vapotherm Precision Flow, Disposable Patient Circuit:

PF-DPC-High, PF-E-DPC-High, PFH-DPC-High, PF-NODPC-High,
PF-DPC-Low, PF-E-DPC-Low, PFH-DPC-Low, PF-NODPC-Low

Dear Customer/Distributor,

The purpose of this update is to simplify the identification of lot numbers affected by the recall. We have removed the table of individual lot numbers and instead are providing you with a bracket of lot numbers. The affected lots span 1402021 through 1406010, excluding lots 1402024 through 1402028 and 1404003. These numbers are applicable regardless of the prefix preceding them (i.e. HF, HFE, HFH, HFN, LF, LFE, LFH or LFN).

The purpose of the original letter was to advise you that Vapotherm, Inc. has received a small number of complaints involving a defect in the Disposable Patient Circuit that allows water to leak into the center gas lumen that is beyond what would be attributed to normal condensation.

In more than half the complaints, the defect was observed prior to use on patients, and in those where patients were involved, none of the complaints has resulted in serious injury or death. Our internal investigation indicates that this defect is easily detectable during normal use and the probability of serious injury or death is remote. However, this letter is being sent to raise awareness of the recent increase in incidence rate of this issue.

The leak into the center lumen occurs during the warm-up time after the Disposable Patient Circuit is connected to the Precision Flow hardware unit. This leak is significantly different than normal condensation and is visibly detectable by the amount of water exiting the distal end of the delivery tube. Our complaint rate for this defect is approximately 0.015%.

The operating manual requires that the cannula be connected to the patient only after the set temperature is reached. Please remind users of this requirement, and advise your

patient care personnel not to use, or to discontinue use of any Disposable Patient Circuit if water is observed leaking into the center lumen or from the cannula. Replace the device and report the defect to Vapotherm immediately for further investigation. Vapotherm will replace any defective product.

Our investigation has revealed that the cause for the leak is inadequate solvent bonding between the tubing and the connector. Our investigation to date has shown that the defect may be limited to the following lot numbers: 1402021 through 1406010 excluding lots 1402024 through 1402028 and 1404003.

We are pursuing corrective actions to increase the capability of the bonding process to reduce the occurrence of these defects in the future.

We apologize for any inconvenience you may experience that is associated with this issue.

Should you have any questions please contact our technical support team at

Email: ts@vtherm.com
(US) 855.557.8276
(INT'L) 1-603.658.5121

Sincerely,

Som Kovvuri,
VP, Regulatory & Quality

VAPOTHERM®

Dear Valued Customer/Distributor,

Recently we have received a small number of complaints involving a defect in the Disposable Patient Circuit Delivery Tube. The defect allows water to leak into the center lumen of the delivery tube, the gas line to the patient. The root cause appears to be an insufficient solvent bonding of the delivery tube to the connector where the delivery tube mates with the disposable water path. None of the complaints has resulted in patient injury. Our complaint rate for this defect is approximately 0.015%.

An internal investigation of the defect indicates that the fault condition is easily detectable and typically occurs while the device is coming up to the set temperature and is easily visible. Vapotherm recommends that you follow the Precision Flow instructions for use, which requires that the cannula be connected to the patient only after the set temperature is reached. If you identify a defective Delivery Tube please discontinue use and contact Vapotherm immediately. Vapotherm will replace all defective products at no additional cost to the customer. To report a complaint and receive replacement product please do the following:

1. Contact Vapotherm Technical Support 855-557-8276 (US) 1-603-658-5121 (International) or ts@vtherm.com
2. Indicate that you have experienced a DPC leak in the center lumen of the Delivery Tube and indicate the lot number of the DPC

Our investigation to date has shown that the defect has been detected in lot numbers of DPCs spanning February through early June. Because of the low incidence rate and ability to easily detect the defect there is no requirement that you proactively return the sets. Please refer to the formal recall notification for detailed information.

We apologize for any inconvenience this may cause you and your patients. If you have any questions please contact Vapotherm at ts@vtherm.com or 855-557-8276 (US), 1-603-658-5121 (International).

Sincerely,
Glenn Hanner, Precision Flow Global Product Manager
Som Kovvuri, VP, Regulatory & Quality

VAPOTHERM

August 13th, 2014

MEDICAL DEVICE RECALL

Vapotherm Precision Flow, Disposable Patient Circuit:

PF-DPC-High, PF-E-DPC-High, PFH-DPC-High, PF-NODPC-High,
PF-DPC-Low, PF-E-DPC-Low, PFH-DPC-Low, PF-NODPC-Low

Dear Customer/Distributor,

The purpose of this letter is to advise you that Vapotherm, Inc. has received a small number of complaints involving a defect in the Disposable Patient Circuit that allows water to leak into the center gas lumen that is beyond what would be attributed to normal condensation.

In more than half the complaints, the defect was observed prior to use on patients, and in those where patients were involved, none of the complaints has resulted in serious injury or death. Our internal investigation indicates that this defect is easily detectable during normal use and the probability of serious injury or death is remote. However, this letter is being sent to raise awareness of the recent increase in incidence rate of this issue.

The leak into the center lumen occurs during the warm-up time after the Disposable Patient Circuit is connected to the Precision Flow hardware unit. This leak is significantly different than normal condensation and is visibly detectable by the amount of water exiting the distal end of the delivery tube. Our complaint rate for this defect is approximately 0.015%.

The operating manual requires that the cannula be connected to the patient only after the set temperature is reached. Please remind users of this requirement, and advise your patient care personnel not to use, or to discontinue use of any Disposable Patient Circuit if water is observed leaking into the center lumen or from the cannula. Replace the device and report the defect to Vapotherm immediately for further investigation. Vapotherm will replace any defective product.

Our investigation has revealed that the cause for the leak is inadequate solvent bonding between the tubing and the connector. Our investigation to date has shown that the defect may be limited to the following lot numbers:

PF-DPC-High Lot Numbers

HF1402031	HF1403019	HF1404032	HF1405020
HF1402032	HF1404009	HF1404033	HF1405021
HF1402033	HF1404010	HF1404039	HF1405027
HF1402034	HF1404011	HF1404040	HF1405028
HF1402035	HF1404012	HF1404041	HF1405029
HF1403010	HF1404013	HF1404042	HF1405030
HF1403011	HF1404019	HF1404043	HF1405031
HF1403012	HF1404020	HF1405006	HF1406002
HF1403013	HF1404021	HF1405008	HF1406003
HF1403014	HF1404022	HF1405009	HF1406004
HF1403015	HF1404023	HF1405010	HF1406005
HF1403016	HF1404029	HF1405017	
HF1403017	HF1404030	HF1405018	
HF1403018	HF1404031	HF1405019	

PF-E-DPC-High Lot Numbers

HFE1403001	HFE1406001

PFH-DPC-High Lot Numbers

HFH1402041	HFH1402042

PF-NODPC-High Lot Numbers

HFN1402021	HFN1402029	HFN1403009

PF-DPC-Low Lot Numbers

LF1402030	LF1404004	LF1404036	LF1405022
LF1402036	LF1404005	LF1404037	LF1405023
LF1402037	LF1404014	LF1404038	LF1405024
LF1402038	LF1404015	LF1405001	LF1405025
LF1402039	LF1404017	LF1405002	LF1405026
LF1402040	LF1404018	LF1405003	LF1405032
LF1403003	LF1404024	LF1405004	LF1405033
LF1403004	LF1404025	LF1405005	LF1405034
LF1403005	LF1404026	LF1405012	LF1405035
LF1403006	LF1404027	LF1405013	LF1406008
LF1403007	LF1404028	LF1405014	LF1406009
LF1404001	LF1404034	LF1405015	LF1406010
LF1404002	LF1404035	LF1405016	

PF-E-DPC-Low Lot Numbers

LFE1403002

PFH-DPC-Low Lot Numbers

LFH1402022	LFH1402023	LFH1403008

PF-NODPC-Low Lot Numbers

LFN1404008	LFN1405011

We are pursuing corrective actions to increase the capability of the bonding process to reduce the occurrence of these defects in the future.

We apologize for any inconvenience you may experience that is associated with this issue.

Should you have any questions please contact our technical support team at

Email: ts@vtherm.com
(US) 855.557.8276
(INT'L) 1-603.658.5121

Sincerely,

Som Kovvuri,
VP, Regulatory & Quality

Solus Medical Ltd

Field Safety Corrective Action
Vapotherm Precision Flow Disposable Patient Circuits

The manufacturer, Vapotherm, has reported that some of the Disposable Patient Circuits recently sent to you may have a defect that may allow water to leak into the centre gas lumen during the warm-up time after the Disposable Patient Circuit is connected to the Precision Flow device.

This issue has not been reported in the United Kingdom and the probability of serious injury or death is remote. However, the manufacturer has recorded a 0.015% failure rate internationally and so this Field Safety Corrective Action notice is being issued to ensure you are aware of this issue.

This leak is significantly different than normal condensation and is will be clearly visible to the eye and detectable by water exiting the distal end of the delivery tube.

What do I need to do?

The instructions for use indicate that the cannula be connected to the patient only after the set temperature is reached. Please remind end users of this requirement and advise them not to use, or to discontinue use of, any Disposable Patient Circuit if water is observed leaking into the centre lumen or from the distal end of the delivery tube.

The manufacturer has advised that only circuits manufactured between February and June 2014 are likely to be affected and as the failure is only 0.015% it is very unlikely you will encounter this issue. However, if you do detect a faulty circuit please retain it and report the issue to Solus Medical by emailing info@solusmedical.com or calling 0845 305 8098. Solus Medical will arrange for the faulty circuit to be collected and replaced.

How to detect the fault (if present)

After the device has reached the set temperature, and before connecting the patient cannula, visually check the proximal end of the delivery tube. If the circuit is faulty water will be clearly visible in the centre lumen, just below the Disposable Water Path Connector (see overleaf).

If detect a faulty circuit please retain it and report the issue to Solus Medical by emailing info@solusmedical.com or calling 0845 305 8098. Solus Medical will arrange for the faulty circuit to be collected and replaced.

Potentially Affected Lots

The manufacturer has eliminated the defect in recently shipped circuits but has advised that circuits manufactured between February and June 2014 may be affected, the potentially affected lot numbers are shown below.

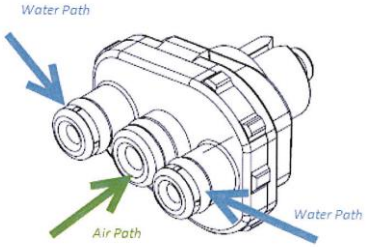
Product Code	Potentially affected Lots
PF-DPC-HIGH or FDE706	HF1402035, HF1404020, HF1405008, and HF1406004
PF-DPC-LOW or FDE707	LF1402030, LF1404017, LF1404018, LF1405004, LF1405005, LF1405035, LF1405036, LF1406009, and LF1406010

Lot numbers are provided for information only and as the reported failure is 0.015% you are unlikely to encounter this issue. **It is not necessary to quarantine or return the potentially affected circuits noted above unless a defect has been detected.**

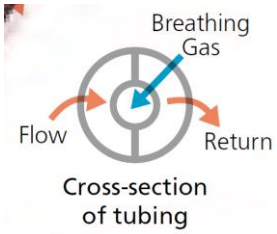
If you have any questions about this please contact us by emailing info@solusmedical.com or by calling 0845 305 8098

2 Dryden Loan, Bilston Glen Industrial Estate, Loanhead, EH20 9HR
Tel: 0845 305 8098 Fax: 0845 305 8099 E-mail: info@solusmedical.com Company No SC370398

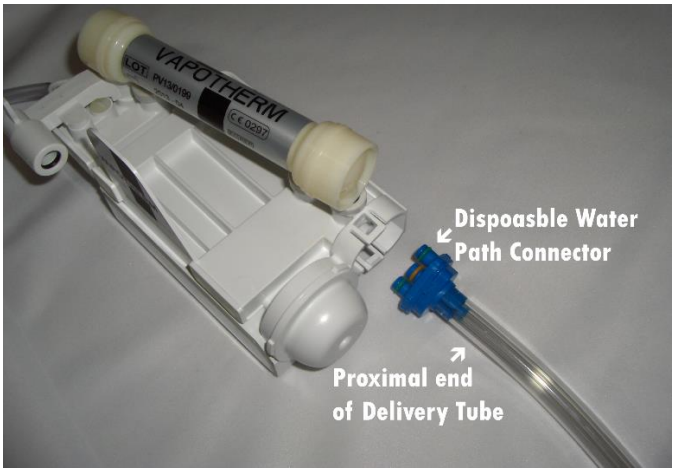
Construction of the Delivery Tube



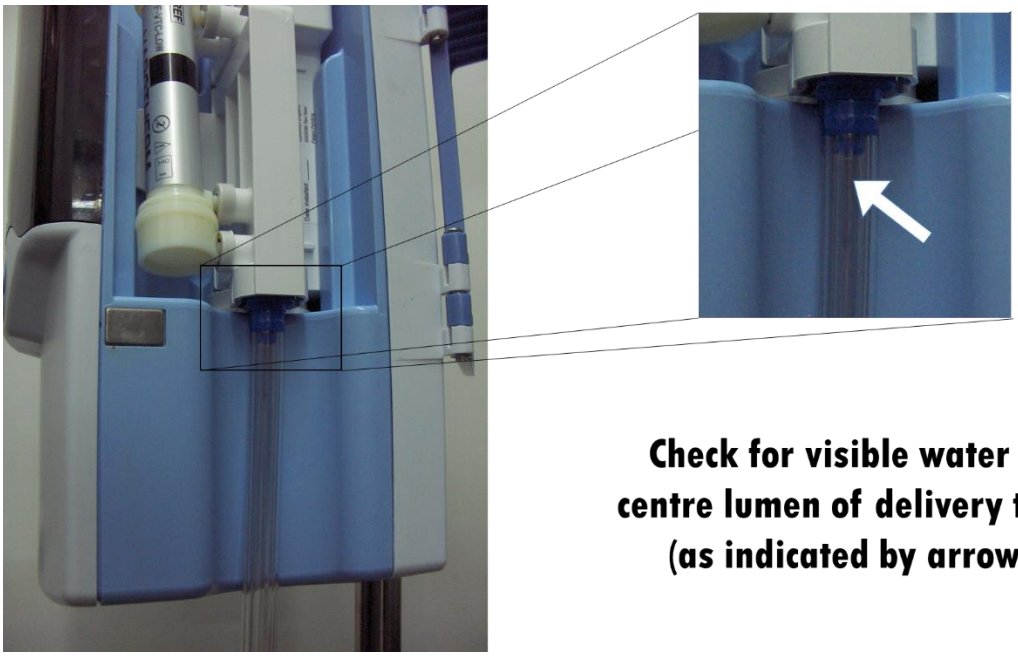
Disposable Water Path Connector



Cross-section of tubing



Visual inspection of proximal end of delivery tube



Check for visible water in centre lumen of delivery tube (as indicated by arrow)

2 Dryden Loan, Bilston Glen Industrial Estate, Loanhead, EH20 9HR
Tel: 0845 305 8098 Fax: 0845 305 8099 E-mail: info@solusmedical.com Company No SC370398