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
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
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.

The New Standard in High Flow Therapy

22 Industrial Drive  •  Exeter, New Hampshire 03833  •  T 603-658-0011  •  F 603-658-0181  •  www.vtherm.com
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 |

*The New Standard in High Flow Therapy*

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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
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.

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Potentially affected Lots</th>
</tr>
</thead>
<tbody>
<tr>
<td>PF-DPC-HIGH or FDE706</td>
<td>HF1402035, HF1404020, HF1405008, and HF1406004</td>
</tr>
<tr>
<td>PF-DPC-LOW or FDE707</td>
<td>LF1402030, LF1404017, LF1404018, LF1405004, LF1405005, LF1405035, LF1405036, LF1406009, and LF1406010</td>
</tr>
</tbody>
</table>

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
Construction of the Delivery Tube

Visual inspection of proximal end of delivery tube

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