**Field Safety Corrective Action Report Form**
**Medical Devices Vigilance System**
**(MEDDEV 2.12/1 rev 5)**

**v.04/07**

| **1. Administrative Information** | |
|---|---|
| Destination<br>Medicines & Healthcare Products Regulatory Agency<br>151 Buckingham Palace Road<br>Victoria<br>London<br>SW1W 9SZ | **Stamp box for the Competent Authority** |
| **Date of this Report**<br>25-Jul-2011 | |
| **Reference Number Assigned by Manufacturer**<br>2183502-05/10/11-005-C | |
| **Incidence Reference No. and Name of the Coordinating NCA Competent Authority (if applicable)**<br>N/A | |
| **Identify to What Other Competent Authorities this Report was Also Sent**<br>Canada, United Arab Emirates, Argentina, Australia, Aruba, Belgium, Bulgaria, France, Greece, Hong Kong, Ireland, Israel, Lebanon, Malaysia, Netherlands, New Zealand, Philippines, Qatar, Saudi Arabia, Singapore, El Salvador, Thailand, United Kingdom, South Africa | |
| **2. Information on Submitter of the Report** | |
| **Status of submitter**<br>☐ **Manufacturer**<br>☒ **Authorised Representative within EEA**<br>☐ **Others: (identify the role):** | |
| **3. Manufacturer Information** | |
| **Manufacturer Name**<br>Smiths Medical International Ltd. | |
| **Manufacturer's Contact Person**<br>Mick Boydon | |
| **Address**<br>Bramingham Business Park, Enterprise Way | |
| **Postal Code**<br>LU3 4BU | **City**<br>Luton |
| **Phone**<br>+44 (0)1582 430307 ext. 4770307 | **Fax**<br>+44 (0)1582 430001 |
| **E-mail**<br>Mick.Boydon@smiths-medical.com | **Country**[2]<br>United Kingdom |
| **4. Authorised Representative Information** | |
| **Name of Authorised Representative**<br>Smiths Medical International Ltd | |
| **The Authorised Representative's Contact Person**<br>Franz Korner | |
| **Address** | |

| | |
|---|---|
| **Postal Code**<br>TN25 4BF | **City**<br>Ashford, Kent |
| **Phone**<br>+49 (0)89 242959 345 | **Fax**<br>+49 (0)89 242959 327 |
| **E-mail**<br>eu.rep@smiths-medical.com | **Country**[2]<br>United Kingdom |

**5. National Contact Point Information**

| | |
|---|---|
| **National Contact Point Name** | |
| **Name of the Contact Person**<br>Franz Korner | |
| **Address**<br>Bretonischer Ring 3 | |
| **Postal Code**<br>85630 | **City**<br>Grasbrunn |
| **Phone**<br>+49 (0)89 242959 345 | **Fax**<br>+49 (0)89 242959 327 |
| **E-mail**<br>eu.rep@smiths-medical.com | **Country**[2]<br>Germany |

**6. Medical Device Information**

**Class**

| | |
|---|---|
| ☐ AIMD Active Implant | |
| ☐ MDD Class III | ☐ IVD Annex II List A |
| ☒ MDD Class IIb | ☐ IVD Annex II List B |
| ☐ MDD Class IIa | ☐ IVD Devices for Self-Testing |
| ☐ MDD Class I | ☐ IVD General |

**Nomenclature System (preferable GMDN)**
GMDN

**Nomenclature Code**
Omnifuse – 13217
Omnifuse PCA - 35932

**Nomenclature Text**
Omnifuse – Infusion Pump, Syringe
Omnifuse PCA – Infusion Pump, Analgesic, Patient-Controlled

**Commercial Name/ Brand Name / Make**
Omnifuse Pumps and Omnifuse PCA Pumps

**Model Number**
0152, 0153, 0157, 0158, and 0159

**Serial Number(s) or Lot/ Batch Number(s)**
All Serial Numbers

**Software Version Number (if applicable)**
N/A

**Manufacturing Date/ Expiry Date (if applicable)**

N/A

**Accessories/ Associated Device (if applicable)**

N/A

**Notified Body (NB) ID Number**

0473

**7. Description of FSCA**

**Background Information and Reason for the FSCA:**

Smiths Medical is initiating this FSCA because of the possible impact of significant vibration or jarring to Omnifuse and Omnifuse PCA Pumps in inducing a System Fault Code, causing the Pump to alarm and stop delivery of the infusion. This is due to sensitivities of the precision accuracy detection mechanisms within these Pumps.

The type of vibration or jarring that can induce a System Fault Code can include the type of vibration or jarring that can occur when transporting Pumps across block paving, uneven flooring, or other rough surfaces.

Smiths Medical has also become aware that under certain circumstances, Omnifuse or Omnifuse PCA Pumps ("Omnifuse Pump") may experience a loss of the last infusion data from the totaliser displayed totals on the pump screen. This can only occur when:

- A system fault occurs during ongoing infusion activity and the pump is restarted; or
- The battery is allowed to run to zero power during ongoing infusion activity and the pump is restarted.

In both of these situations, the totaliser display does not update to show the ongoing infusion, although the ongoing infusion details are still available in the downloadable memory. Smiths Medical will provide information to customers to enable users to correctly and safely manage the reset process to remove the possibility that the displayed data can be misinterpreted.

**Description and Justification of the Action (Corrective/ Preventive):**

Smiths Medical will issue all Omnifuse and Omnifuse PCA Pump Customers the Urgent Field Safety Notice (FSN) and Customer Information Bulletin (see attached).

Smiths Medical is in the process of making changes to the Instructions Manuals supplied with these Pumps to provide users with information on the impact of significant vibration or movement to the operation of the Omnifuse Pump, including the addition of a new Warning.

Within this change, full instructions and warnings will be provided to enable the user to correctly and safely manage the reset process and to zero the incorrect displayed totaliser data.

When the pump battery is running low on power, it will first alarm with a low battery condition (providing audible and visual alarms) and then it will eventually alarm with a continuous audible alarm to alert the user that the battery is exhausted and the pump must be connected to a mains supply immediately or the pump will automatically shut off. It would be highly irregular and unlikely for clinicians in clinical practice to ignore such an alarm event. Because this type of event is highly irregular and unlikely to occur in clinical practice, and because only 1 complaint of this nature has been reported within the last 3 years, it has been decided that the current Instruction Manual provides sufficient information to the customer to avoid this issue. Within the current Manual, there are various instructions that describe the low battery and battery exhausted alarms, and there is also a Warning that addresses battery management: "Correct management of battery charging is essential to make sure that the pump can operate on batteries for the time specified. Failure to do so may lead to impaired functioning of the pump, resulting in patient injury or death".

The updated Instructions Manuals will be sent to customers upon release of the updated version. These will be sent according to the received information requested in the FSN Confirmation Form.

**Advice on Actions to be Taken by the Distributor and the User:**
Subject to this Urgent Field Safety Notice, Smiths Medical is requesting its customers to follow the instructions when using the pumps, both on the Urgent Field Safety Notice and on the CIB. Users are instructed to heed the following warnings:

Possible Impact of Significant Vibration or Jarring to Omnifuse Pumps
Due to sensitivities of the precision accuracy detection mechanisms within Omnifuse Pumps, certain levels of vibration or jarring during transport can induce a system fault code. An example of the type of vibration or jarring that may induce a System Fault Code would be transporting a pump across an uneven surface (e.g., block paving).

When transporting a patient during operation of an Omnifuse Pump, users should discontinue use of the Pump during transport and restart the Pump once transport is completed; or when no alternative is available, be aware that vibrations during transport may trigger a System Fault Code, causing the Pump to alarm and stop delivery of the infusion. If a System Fault Code occurs during transport, the user can follow the instructions on the attached Customer Information Bulletin ("CIB") for resetting the Pump to clear the System Fault and continue with the infusion.

Affect on the Totaliser Display - After Resetting the Pump to Clear a System Fault
If a System Fault Code occurs during an infusion and the Pump is reset (as described in the attached CIB), the totaliser display will not include the most recent infusion data.

Therefore, if the clinician chooses to clear the System Fault and continue with the infusion, the totaliser must be reset and the manual records referenced to prevent using incorrect medication delivery totals. The downloadable history on the Pumps still maintains the correct medication delivery totals. However, the downloadable history is only accessible through the Pump's PC software program, typically maintained by the facility's biomedical department.

Smiths Medical is in the process of making changes to the Instruction Manuals supplied with these Pumps, to provide users with this new information regarding System Fault Codes and the operation of these Pumps, including the addition of two new Warnings:

> **WARNING:** When transporting a patient during operation of an Omnifuse or Omnifuse PCA Syringe Pump, users should either: a) discontinue use of the Pump during transport and restart the Pump once transport is completed; or b) be aware that vibrations during transport may trigger a System Fault Code, causing the Pump to alarm and stop delivery of the infusion. A delay or interruption in therapy may result in patient injury or death.
>
> **WARNING:** Failure to reset the cumulative total as advised in the 'clearing system fault codes' process may result in inaccurate infusion data being displayed by the totaliser function. The use of inaccurate infusion data in clinical decisions may result in inappropriate or unnecessary clinical intervention which could lead to patient injury or death.

**Advice on Action to be Taken by the User:**

1) Circulate this Field Safety Notice and Customer Information Bulletin to all end users of Omnifuse Pumps;

2) Be aware that when transporting a patient during operation of an Omnifuse Pump, users should either: a) discontinue use of the Pump during transport and restart the Pump once transport is completed; or b) be aware that vibrations during transport may trigger a System Fault Code, causing the Pump to alarm and stop delivery of the infusion, and take appropriate precautions. A delay or interruption in therapy may result in patient injury or death;

3) Maintain good clinical practice by keeping manual records of infusions;

4) Be aware that failure to reset the cumulative total when following the 'clearing system fault codes' process will result in inaccurate infusion data being displayed in the totaliser function. The use of inaccurate infusion data in clinical decisions may result in inappropriate or unnecessary clinical intervention. Failure to reset the cumulative total following a system fault code may lead to patient injury or death; and

5) Complete and return the attached Confirmation Form (see Attachment 1) by Fax to +44 (0) 1582 430001 or by email to Omnifusevib@smiths-medical.com

**Attached Please Find**
☒ Field Safety Notice (FSN) in English ☐ FSN in National Language
☒ Others (please specify) Customer Information Bulletin, Risk Analysis Summary

**Time Schedule for the Implementation of the Different Actions:**
Consignees will be mailed the FSN, Response Form, and CIB commencing 25-July -2011.
Consignees will be mailed the updated Instructions Manuals commencing 22-Sep-2011.

**These Countries Within the EEA Are Affected by this FSCA:**
**-within the EEA and Switzerland**
☐AT ☒BE ☒BG ☐CH ☐CY ☐CZ ☐DE ☐DK ☐EE ☐ES
☐FI ☒FR ☒GB ☒GR ☐HU ☒IE ☐IS ☐IT ☐LI ☐LT
☐LU ☐LV ☐MT ☒NL ☐NO ☐PL ☐PT ☐RO ☐SE ☐SI ☐SK

**Candidate Countries:** ☐CR ☐ TR

☐ ALL EEA, Candidate Countries and Switzerland

**Others:** None

**These Countries Outside the EEA and Switzerland are Affected by this FSCA:**
Canada, United Arab Emirates, Argentina, Australia, Aruba, Hong Kong, Israel, Lebanon, Malaysia, New Zealand, Philippines, Qatar, Saudi Arabia, Singapore, El Salvador, Thailand, South Africa

**8. Comments:**
As Smiths Medical's Notified Body, Intertek, is located in the UK, Smiths Medical recognizes the MHRA as the Lead Competent Authority for this product. All other competent authorities listed in this document will also receive a copy of this Report and the FSN.

I affirm that the information given above is correct to the best of my knowledge.

Signature

2nd August 2011
Date

Franz Korner
Name

Grasbrunn
City

Submission of this report does not, in itself, represent a conclusion by the manufacturer and / or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.