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Quality Health Care Accessible To All

Urgent Field Safety Notice (FSN)**Medpro AccuFlo Elastomeric Infusion Pump,****FSCA-identifier: 05 MAY 2011****Type of action: Recall**

Date: **05 MAY 2011**

Attention: To Whom It May Concern**Details on affected devices:****Modelname: Medpro AccuFlo Elastomeric Infusion Pump****Concerned Product codes and Lot Numbers: CT-0020-240, CT-0015-240 and CT-0020-150**

Product Code	Lot No.
CT-0020-240	90713
	90918-17
	90942
	80605
CT-0015-240	90238
	90712
	90361
	90921
CT-0020-150	90941
	90912
	80711

The devices have been sold in Germany, Italy, France, Austria, UK, Spain, Portugal and Turkey

Description of the problem:

*As the devices described showed a higher flowrate than specified the manufacturer has decided to recall the concerned lots
The recall of the pumps listed is performed to eliminate the risk of significantly higher flow rate than designed that may result in
over-administration of drug solutions and to eliminate further risk and harm to the patients.*

The following malfunctions have been recognized:

- 1. Post anaesthesia, Fentanyl finished in 2 hours than expected 24 hours*
- 2. 5 FU 10,000mg NACL 0.9% 240 ml administered in significantly shorter time than the expected 120 hours*
- 3. 5 FU 5,000 mg/mL 5 h instead of 120 hours*

*Incomplete UV glue adhesion at the glass tube (outer diameter) and pvc tube (inner diameter) in a small portion of assemblies
resulted in this malfunction.*

Advise on action to be taken by the user:

The manufacture has decided to recall of the aforementioned lot numbers:

Pls. immediately identify and quarantine the affected lots.

Fill in the recall questionnaire supplied by the supplier and return the affected products to the supplier.

Transmission of this Field Safety Notice:

*This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the
potentially affected devices have been transferred.*

*Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective
action.*

This field safety corrective action had been submitted to the competent national authority.

Contact reference person:

Name / organisation, address, contact details.

Here the name of the contact person in the country is required. (Just a company name is not sufficient)

The undersign confirms that this notice has been notified the appropriate Regulatory Agency
(Closing paragraph)



Urgent Field Safety Notice (FSN)
Medpro AccuFlo Elastomeric Infusion Pump,
FSCA-identifier: 06 JUN 2011; Extension to the FSN 05 MAY 2011

Type of action: Recall

Date: 06 JUN 2011

Attention: To Whom It May Concern

Details on affected devices:

Modelname: Medpro AccuFlo and AccuFlux Elastomeric Infusion Pump
Concerned Product codes and Lot Numbers: see attached appendix A

The devices have been sold in Germany, Italy, France, Austria, UK, Denmark, Netherlands, Ireland, Hungary, Greece, Czech Republic, South Africa, Switzerland, Slovenia, Spain, Portugal and Turkey.

Description of the problem:

As the devices described showed a higher flow rate than specified the manufacturer has decided to recall the concerned lots
The recall of the pumps listed is performed to eliminate the risk of significantly higher flow rate than designed that may result in over-administration of drug solutions and to eliminate further risk and harm to the patients.

The following malfunctions have been recognized:

1. Post anaesthesia, Fentanyl finished in 2 hours than expected 24 hours
2. 5 FU 10,000mg NaCl 0.9% 240 ml administered in significantly shorter time than the expected 120 hours
3. 5 FU 5,000 mg/mL h instead of 120 hours

Incomplete UV glue adhesion at the glass tube (outer diameter) and pvc tube (inner diameter) in a small portion of assemblies resulted in this malfunction.

Advise on action to be taken by the user:

The manufacture has decided to recall of the aforementioned lot numbers:

Pls. immediately identify and quarantine the affected lots.

Fill in the recall questionnaire supplied by the supplier and return the affected products to the supplier.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

This field safety corrective action had been submitted to the competent national authority.

Contact reference person:

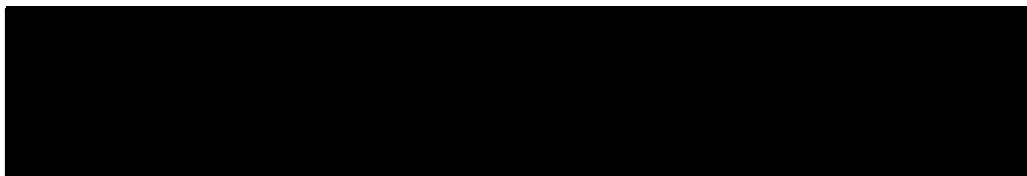
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The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.



Appendix A to FSN 03 JUNE 2011

Complete List of Lots to be Recalled

List of 4 May 2011 (11 lots)

Flow Rate	Model	Product Lot No.	Customer
1.5mL/hr	CT-0015-240	90238	pfm medical tpm gmbh
1.5mL/hr	CT-0015-240	90361	pfm medical tpm gmbh
1.5mL/hr	CT-0015-240	90712	pfm medical tpm gmbh
1.5mL/hr	CT-0015-240	90921	pfm medical tpm gmbh
1.5mL/hr	CT-0015-240	90941	pfm medical tpm gmbh
2.0mL/hr	CT-0020-150	80711	pfm medical tpm gmbh
2.0mL/hr	CT-0020-150	90912	pfm medical tpm gmbh
2.0mL/hr	CT-0020-240	90942	pfm medical tpm gmbh
2.0mL/hr	CT-0020-240	80605	pfm medical tpm gmbh
2.0mL/hr	CT-0020-240	90713	pfm medical tpm gmbh
2.0mL/hr	CT-0020-240	90918-1T	pfm medical tpm gmbh

List of 30 May 2011 (44 lots)

Flow Rate	Model	Product Lot No.	Customer
1.0 mL/hr	CT-0010-160	90359	pfm medical tpm gmbh
1.5mL/hr	CT-0015-180H	100916	pfm medical tpm gmbh
1.5mL/hr	CT-0015-240	90361	pfm medical tpm gmbh
1.5mL/hr	CT-0015-240	90851	pfm medical tpm gmbh
1.5mL/hr	CT-0015-240	90910	pfm medical tpm gmbh
1.5mL/hr	CT-0015-240	90917	pfm medical tpm gmbh
1.5mL/hr	CT-0015-240	90921	pfm medical tpm gmbh
1.5mL/hr	CT-0015-240	90941	pfm medical tpm gmbh
2.0mL/hr	CT-0020-048H	100413	pfm medical tpm gmbh
2.0mL/hr	CT-0020-048H	100527	pfm medical tpm gmbh
2.0mL/hr	CT-0020-048H	100835	pfm medical tpm gmbh
2.0mL/hr	CT-0020-050	90364	pfm medical tpm gmbh
2.0mL/hr	CT-0020-050	90927	pfm medical tpm gmbh
2.0mL/hr	CT-0020-050	90932	pfm medical tpm gmbh
2.0mL/hr	CT-0020-050	100407	pfm medical tpm gmbh
2.0mL/hr	CT-0020-050	100514	pfm medical tpm gmbh
2.0mL/hr	CT-0020-050	100627	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	80109	pfm medical tpm gmbh

Flow Rate	Model	Product Lot No.	Customer
2.0mL/hr	CT-0020-100	90239	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	90839	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	90913	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	91211	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	100210	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	100408	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	100516	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	100628	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	100827	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	110133	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	110142	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100	110316	pfm medical tpm gmbh
2.0mL/hr	CT-0020-100H	100604	pfm medical tpm gmbh
2.0mL/hr	CT-0020-150	100520	pfm medical tpm gmbh
2.0mL/hr	CT-0020-150	100828	pfm medical tpm gmbh
2.0mL/hr	CT-0020-200H	91216	pfm medical tpm gmbh
2.0mL/hr	CT-0020-200H	100716	pfm medical tpm gmbh
2.0mL/hr	CT-0020-200H	100837	pfm medical tpm gmbh
2.0mL/hr	CT-0020-240	90911	pfm medical tpm gmbh

Flow Rate	Model	Product Lot No.	Customer
2.0mL/hr	CT-0020-240	91208	pfm medical tpm gmbh
2.0mL/hr	CT-0020-240	100522	pfm medical tpm gmbh
2.0mL/hr	CT-0020-240	100715	pfm medical tpm gmbh
2.0mL/hr	CT-0020-240	100830	pfm medical tpm gmbh
2.0mL/hr	CT-0020-240	110134	pfm medical tpm gmbh
2.0mL/hr	CT-0020-240	110318	pfm medical tpm gmbh
2.5mL/hr	CT-0025-180 H	100530	pfm medical tpm gmbh