PHILIPS

January 19, 2018

FSN86100187A

Medical Device Recall / Labeling Correction

Philips HeartStart MRx and FR3 Monitor/Defibrillator

And HeartStart FR3 AED Used With

Q-CPR Meter or CPR Sensor

Dear HeartStart MRx and FR3 Owner,

1. Reason for this Voluntary Action:

- Philips is sending this letter as a formal notice of a Medical Device Labeling Correction
  - To ensure HeartStart MRx customers have access to the *HeartStart MRx Addendum* as a supplement to the MRx Instructions for Use (IFU)
  - To ensure HeartStart FR3 customers whose Q-CPR Meters are used on an MRx are aware that certain information contained in the FR3 AED Instructions for Administrators (IFA) and the FR3 Q-CPR Meter Instructions for Use (IFU) also applies to use of the Q-CP Meters with the MRx.

2. Product Information:

The Q-CPR meter can be used with the following devices:

Device	Device Model #	Q-CPR Model #
HeartStart FR3	861388 and 861389	989803149941
HeartStart MRx	M3535A and M3536A	453564145481, 453564257691, 989803162401 and M4761A

When attached to the bare chest of a suspected victim of Sudden Cardiac Arrest (SCA), the Q-CPR meter provides real-time feedback on the depth and frequency of CPR compressions in accordance with current CPR guidelines. These devices are intended for use by persons professionally trained in CPR, to assure proper use and the delivery of optimal CPR to the victim.

The disposable adhesive pad must be present and properly positioned when the Q-CPR Meter is used.

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3. Action Taken by Philips

- In August, 2015, Philips distributed a Q-CPR Addendum to the MRx Instructions for Use (IFU). This information was already available in the HeartStart FR3 Instructions for Administrators (IFA) and the FR3 Q-CPR Meter Instructions for Use (IFU).

- The addendum for the MRx addressed feedback received from customers about two specific issues:

    - Correct placement of the disposable adhesive pad on the Q-CPR meter
        - ❖ Philips provided an in-color graphic with instructions to clarify the positioning of the adhesive pad.

    - Types of injuries associated with the proper performance of CPR
        - ❖ Philips included a WARNING in the Addendum, calling out the types of injuries that may result from properly performed CPR.

4. Risk to Health:

- Tissue damage, bone breakage, etc. are well-known complications of CPR and are seen when CPR is correctly administered with or without the use of the Q-CPR Meter and CPR Sensor. The Q-CPR Meter and CPR Sensor when used as directed facilitate the administration of CPR and resulting tissue damage may still occur.

5. Action to be Taken by Customer

- For MRx customers, ensure that your copy of the MRx IFU contains the Addendum.
- For FR3 customers, ensure that the IFU for any MRx with which your Q-CPR Meter may be used contains the Addendum.
- Inform all staff who may use the Q-CPR Meter with an MRx of the information in the Addendum, regardless of whether the Q-CPR Meter was originally sold for use with an FR3 or MRx.
- Immediately return the attached reply card indicating whether your firm continues to possess an MRx or FR3, which is used with the Q-CPR Meter or CPR Sensor.

6. Technical Support

- ❖ Philips is committed to providing products and services of the highest quality. If you require further information or support regarding this notice, please contact your local Philips representative. <Philips representative contact details to be completed by the KM / country>.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Customer Reply for FSN86100187A:

HeartStart MRx Monitor/Defibrillator and FR3 AED

Used with Q-CPR Meter or CPR Sensor

Please complete and fax or email to: <Philips representative contact details to be completed by the KM/country>.

Contact Name:	
Telephone Number:	
Email Address:	
Facility Name:	
Street Address City, State, Zip:	

Please fax or email this completed form to the number or email address provided above.

CUSTOMER ACKNOWLEDGEMENT

The letter and IFU Addendum was read and understood by staff who may use the Q-CPR Meter with an MRx. The IFU Addendum, regardless of whether the Q-CPR Meter was originally sold for use with an FR3 or MRx, is now contained within any MRx IFU with which the Q-CPR Meter may be used.

_____ _____

CUSTOMER NAME (please print) **TITLE**

_____ _____

CUSTOMER SIGNATURE **DATE**

Please fax or email the completed reply form to <Philips representative contact details to be completed by the KM / country>. If you experience difficulty carrying out the instructions contained in this communication, contact your local Philips representative.

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<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN
CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Corrective Order pertaining to the <product name> due to FCO XXXXXXXX . Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: XXXXXX, XXXXXX, XXXXXXX, XXXXXX

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:

Customer Name/Signature:

Company Name/Stamp:

Date:

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