



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.



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

- ❖ Call 1-800-722-9377, Option 8 for 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.

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 to: +1 425-487-7478 or email to recall.response@philips.com

CUSTOMER ID: **86100187-A555**

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. This information has been distributed to our customer accounts.

CUSTOMER NAME (please print)

TITLE

CUSTOMER SIGNATURE

DATE

Please email the completed reply form to recall.response@philips.com or fax it to +1 425-487-7478 or your local Philips representative. If you experience difficulty carrying out the instructions contained in this communication, contact your local Philips representative.

HeartStart Q-CPR Adhesive Pads

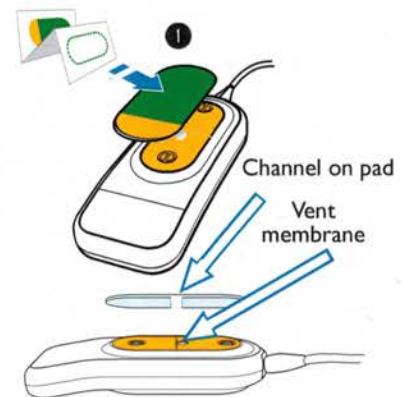
This document clarifies the section in your HeartStart MRx *Instructions for Use* related to attaching the adhesive pad to the CPR meter. It also replaces the HeartStart IFU Addendum dealing with Q-CPR Adhesive pad (Part number 453564528861). Keep this addendum with your *Instructions for Use*.

When using the CPR meter (or the earlier generation CPR sensor) for CPR feedback during an event, you must properly attach an adhesive pad to the rear cover of the device before using.

To attach the adhesive pad:

- 1 Open the package of adhesive pads. Peel one pad off the strip, exposing the adhesive surface on the underside. Align the bottom of the adhesive pad with the yellow patient-adhesive mount area of the rear cover of the CPR meter, making sure the channel on the adhesive pad is directly over the vent membrane. Press into place. See ❶
- 2 Do not peel off the green and yellow liner from the front of the pad until you are ready to apply the device to a patient.

For more information on the CPR Meter or sensor and its adhesive pads, see the *Q-CPR and Data Capture* chapter in the *HeartStart MRx Instructions for Use*.



WARNING: Properly performed CPR can result in the fracturing of a patient's ribs or other chest injuries, including external chest wall bruising or abrasion.* If patient rib or chest integrity has been compromised, continue to provide CPR in accordance with your local protocol.

CAUTION: As directed in the instructions, the CPR meter must be used with the adhesive pad in place and properly positioned.

* Black CJ, Busuttill A, Robertson C. Chest wall injuries following cardiopulmonary resuscitation. *Resuscitation*. 2004; 63:339-343.