

Philips Healthcare

Emergency Care and Resuscitation

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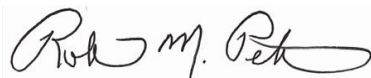
Customer Information Letter
Philips HeartStart MRx Monitor/Defibrillator with Q-CPR
Additional Information to Instructions for Use

Dear Customer,

Philips has updated the HeartStart MRx's Instructions for Use associated with Q-CPR meter and CPR sensor via an addendum. The addendum has instructions on application of the disposable adhesive pads, which are used with the Q-CPR meter, including a diagram which illustrates proper placement and orientation of this pad. In addition, the addendum includes general information on the types of injuries, which may occur during CPR.



Please refer to the following page, which provides additional information about these updates. Please follow the instructions provided in the "Actions to be taken by Customer/User" section. If you need any further information or support concerning this update, please contact your local Philips representative : **<Philips representative contact details to be completed by the KM / country>**

Sincerely,



Bob Peterhans
General Manager, Emergency Care and Resuscitation

Attachments

AFFECTED PRODUCTS	<p>Product: Q-CPR meter and CPR sensor used with Philips HeartStart MRx Monitor/Defibrillator with Q-CPR option.</p> <p>Units Affected: All Q-CPR meter and CPR sensor, models 453564145481, 453564257691, and M4761A are affected.</p>
REASON FOR UPDATE	<p>Adhesive Pads: During internal review, Philips identified that the instructions on attaching the Q-CPR meter adhesive pad to the Q-CPR meter could be improved.</p> <p>Patient chest injury: Instructions did not inform the users that properly performed CPR can result in injuries to the patient.</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>Q-CPR meter or CPR sensor used with Philips HeartStart MRx Monitor/Defibrillator with Q-CPR Option are affected.</p> <p>Q-CPR meter Model # 453564145481 and 453564257691 CPR sensor Model # M4761A</p> <p>The model number is printed on the back of the meter and sensor, as shown below:</p> <div data-bbox="630 951 1507 1602" style="display: flex; justify-content: space-around;"><div data-bbox="630 951 945 1602" style="text-align: center;"><p>CPR Sensor</p></div><div data-bbox="1133 951 1507 1602" style="text-align: center;"><p>Q-CPR meter</p></div></div>

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ACTIONS TO BE TAKEN BY CUSTOMER / USER	Provide the information in the attached HeartStart MRx IFU Addendum to users.
ACTIONS PLANNED BY PHILIPS	Philips is issuing an Addendum to the HeartStart MRx IFU to provide additional guidance on proper use of the Q-CPR meter and CPR sensor.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>