

Customer Information Letter

Wireless Link for HeartStart MRx Monitor/Defibrillator could be unable to transmit data

Dear Customer,

This letter is to inform you of a product correction initiated by Philips Healthcare due to an issue when the Wireless Link is used to transmit data such as 12-Lead and Periodic Clinical Data Transmission (PCDT).

This Customer Information Letter is intended to inform you about:

- what the issue is and under what conditions it can occur
- the actions that should be taken by the customer/user in order to prevent risks for patients
- the corrective action planned by Philips to address the issue

Philips discovered during internal testing that the Wireless Link, when configured for a specific data flow, may be unable to transmit data (i.e., 12-Lead and PCDT). If this occurs, the MRx user will be informed of this inability to transmit data via visual notifications on MRx.

Please see the attached Customer Information Letter that provides information on how to identify affected devices and instructions on actions to be taken. Follow the "ACTION TO BE TAKEN BY CUSTOMER / USER" section of the notice.

A new version of software for Wireless Link will be provided to customers free of charge. A Philips Healthcare representative will contact you to arrange for installation of the Wireless Link software upgrade. We appreciate your patience as we work to schedule your upgrade as expeditiously as possible.

Philips sincerely apologizes for any inconvenience this may cause you. If you have questions regarding this notification or need any further information or support, please contact your local Philips representative or call us at <Philips representative contact details to be completed by the KM / country>.

Sincerely,



John Pardo
Director QA/RA, Emergency Care and Resuscitation

Customer Information Letter

Wireless Link for HeartStart MRx Monitor/Defibrillator could be unable to transmit data

AFFECTED PRODUCTS

Product: M3536A HeartStart MRx with Wireless Link Upgrade (861289)

Units Affected: Wireless Link units shipped by Philips between July and October 2013 for the following MRx serial numbers:

US00100253	US00547494	US00565643	US00567331	US00568772
US00100950	US00558361	US00565651	US00567332	US00568773
US00204282	US00560173	US00565652	US00567333	US00568774
US00210992	US00560174	US00565653	US00567334	US00568775
US00210993	US00560175	US00565655	US00567335	US00568776
US00210994	US00560176	US00565656	US00567336	US00568777
US00210995	US00560177	US00565657	US00567337	US00568778
US00210996	US00560178	US00565658	US00567338	US00568779
US00210997	US00561068	US00565660	US00567339	US00568780
US00210998	US00561724	US00565661	US00567340	US00568781
US00210999	US00563602	US00565662	US00567341	US00568782
US00211000	US00563603	US00565663	US00567720	US00568783
US00211001	US00563606	US00565664	US00567721	US00568784
US00212264	US00563607	US00565665	US00567722	US00568785
US00212265	US00565069	US00565666	US00567723	US00568786
US00212266	US00565414	US00566434	US00567724	US00568787
US00212267	US00565415	US00566564	US00568419	US00568788
US00212268	US00565416	US00567302	US00568656	US00568789
US00322574	US00565417	US00567303	US00568703	US00569520
US00322575	US00565418	US00567304	US00568704	US00569770
US00322876	US00565419	US00567305	US00568705	US00569778
US00322877	US00565420	US00567306	US00568706	US00569779
US00323134	US00565421	US00567307	US00568748	US00569780
US00323135	US00565422	US00567308	US00568749	US00569781
US00323137	US00565423	US00567309	US00568750	US00569782
US00323138	US00565424	US00567310	US00568751	US00569783
US00541205	US00565425	US00567311	US00568752	US00569784
US00541250	US00565427	US00567312	US00568753	US00569785
US00541254	US00565428	US00567313	US00568754	US00569786
US00541364	US00565429	US00567314	US00568755	US00569787
US00541370	US00565430	US00567315	US00568756	US00569788
US00541397	US00565446	US00567316	US00568757	US00569789
US00541402	US00565447	US00567317	US00568758	US00569790
US00541403	US00565448	US00567318	US00568759	US00569791
US00541405	US00565449	US00567319	US00568760	US00569792
US00543683	US00565450	US00567320	US00568761	US00570766
US00543684	US00565451	US00567321	US00568762	
US00543860	US00565452	US00567322	US00568763	
US00544078	US00565453	US00567323	US00568764	
US00544082	US00565454	US00567324	US00568765	
US00544089	US00565455	US00567325	US00568766	
US00544095	US00565456	US00567326	US00568767	
US00547383	US00565457	US00567327	US00568768	
US00547456	US00565458	US00567328	US00568769	
US00547457	US00565459	US00567329	US00568770	
US00547458	US00565642	US00567330	US00568771	

Customer Information Letter

Wireless Link for HeartStart MRx Monitor/Defibrillator could be unable to transmit data

PROBLEM DESCRIPTION	<p>Wireless Link may be unable to transmit data when configured for a specific data flow. This specific condition may only occur when the Wireless Link is configured to operate in access point mode in Data Management.</p> <p>If this issue occurs MRx will consistently display the message 'transmission failed, retry in XX seconds' after a 12-lead transmission is attempted or the connection failed symbol</p>  <p>when a periodic clinical data session is initiated. Please note that this notification will be displayed in other instances as well (e.g., when MRx is in a poor cellular coverage zone or is configured incorrectly).</p>
----------------------------	--

Customer Information Letter

Wireless Link for HeartStart MRx Monitor/Defibrillator could be unable to transmit data

<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>To identify an affected Wireless Link unit, locate the following information printed on labels on the back of the MRx:</p> <p>Wireless Link Upgrade # (861289) and MRx serial number on the upgrade label</p> <div data-bbox="402 659 1474 1213"> <p><i>Sample Primary Label</i></p> <p>The primary label contains the following information:</p> <ul style="list-style-type: none"> REF: M3536A PMS: 861289 OPT: ABAB0 (001) OPT KEY: B45500940 UDI: (01)00884838006652(21)US00571008 Service #: 861289 SN: US00571008 Wireless Link Option #: 001 MRx Serial Number: US00571008 Regulatory marks: SP-US, CE 0123, 50, and a crossed-out symbol. </div> <div data-bbox="402 1213 1474 1539"> <p><i>Sample Upgrade Label</i></p> <p>The upgrade label contains the following information:</p> <ul style="list-style-type: none"> REF: 860384 SN: US09123998 OPT: B7B228F1A OPT KEY: B7B228F1A 2014-02 M3535-84590 Rev C Production Order: 7582317 Wireless Link Upgrade #: 861289 MRx Serial Number: US09123998 </div>
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>While awaiting your software upgrade on Wireless Link, you may continue to use the Wireless Link with the MRx.</p> <p>If the issue occurs remove Wireless Link from service and contact the Philips Customer Care Solutions Center at <Philips representative contact details to be completed by the KM / country>.</p>

Customer Information Letter

Wireless Link for HeartStart MRx Monitor/Defibrillator could be unable to transmit data

ACTIONS PLANNED BY PHILIPS	<p>Philips has released a new version of Wireless Link software V2.0.0.3 sub1 that corrects the issue.</p> <p>Philips is initiating a correction to affected devices. The correction will consist of a software upgrade which will be provided free of charge to all units affected by this issue. A Philips Healthcare representative will contact customers with affected devices to arrange for installation of the software upgrade.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact the Philips Customer Care Solutions Center at <Philips representative contact details to be completed by the KM / country>.</p>