

## **URGENT - Medical Device Correction M3535A/M3536A HeartStart MRx**

### **Internal Memory Cards in Some Units May Cause Device Restart**

Dear Customer,

This letter is to inform you that Philips Healthcare is conducting a voluntary correction of approximately 500 HeartStart MRx Monitor/Defibrillators. Philips has determined that these devices may contain defective internal memory cards that can cause the devices to exhibit one or more of the following behaviors:

- Device repeatedly restarts approximately every 20 seconds.
- Slow device start-up of approximately 15 seconds or more. During this time, the MRx displays either a blank screen or the Philips HeartStart MRx Start-up screen prior to displaying the selected mode of operation (i.e. Monitor, AED, Pacing or Manual Defib mode).
- "Internal Memory Failure" INOP message when attempting to print an event from the Data Management screen.
- When printing from the Data Management screen, a patient's Event Summary prints with some clinical events missing.

**This document contains important information for the continued safe and proper use of your equipment**

Please review the information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Our records indicate that you have received at least one of the affected devices, which were originally shipped from Philips' manufacturing facility in the first half of 2008. Please see the table on page 2 of this notice, which provides information on how to identify affected devices and instructions on actions to take.

Philips has traced the source of the problem to one group of potentially defective internal memory cards, and we are voluntarily initiating a correction of affected devices by replacing these cards. Philips will replace the cards free of charge.

We apologize for the inconvenience that this will cause you. Ensuring that you have the highest quality defibrillators is our top priority. Your satisfaction with Philips products, as well as with our response to this problem, is very important to us.

If you need any further information or support concerning this issue, please contact your local Philips Response Center at 0180 3333544.

Sincerely,



Director, Quality & Regulatory Affairs, Philips Cardiac Care

This notice has been reported to the appropriate Regulatory Agency.



Philips Healthcare

Cardiac Resuscitation

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<b>AFFECTED PRODUCTS</b>	<p><b>Product:</b> Philips HeartStart MRx Monitor/Defibrillators, Models M3535A and M3536A.</p> <p><b>Units Affected:</b> See Units Affected List on pages 3 and 4.</p> <p><b>Manufactured and Distributed by:</b> Philips Healthcare, 3000 Minuteman Road, Andover, MA 01810</p>
<b>PROBLEM DESCRIPTION</b>	<p>Devices with defective internal memory cards can exhibit one or more of the following behaviors:</p> <ul style="list-style-type: none"><li>• Device repeatedly restarts approximately every 20 seconds.</li><li>• Slow device start-up of approximately 15 seconds or more. During this time, the MRx displays either a blank screen or the Philips HeartStart MRx Start-up screen prior to displaying the selected mode of operation (i.e. Monitor, AED, Pacing or Manual Defib mode).</li><li>• "Internal Memory Failure" INOP message when attempting to print an event from Data Management.</li><li>• When printing from the Data Management screen, a patient's Event Summary prints with some clinical events missing.</li></ul>
<b>HAZARD INVOLVED</b>	<p>Devices exhibiting the repeated restarts behavior are unusable for monitoring, defibrillation, and pacing.</p>
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	<p>To determine whether you have an affected device, locate the serial number on the back of the MRx, in battery bay B, and determine if it is on the Units Affected List on pages 3 and 4 of this notice.</p>
<b>ACTIONS PLANNED BY PHILIPS</b>	<p>Philips will replace the internal memory cards in affected MRx Monitor/Defibrillators free of charge.</p> <p>A Philips Healthcare representative will contact customers with devices on the Units Affected List to arrange for replacement of the internal memory card.</p>
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	<p>During the interim period, as you await the upgrade for your device, you may continue to use the HeartStart MRx. However, it is advised that you have a readily available backup defibrillator to use should the restart behavior occur.</p> <p>Devices that exhibit the repeated restart or slow start-up should be removed from service. Devices that exhibit the incomplete Event Summary or Internal Memory Failure printing behavior may remain in service if your application does not require the information in the Event Summary.</p> <p>Additionally, Philips recommends that users check the Status Log for an error "0x80000102" at each shift check and remove the device from service if the error is present. This error indicates the potential for the restart behavior. Instructions for accessing the Status Log are on page 5 of this Medical Device Correction Notice.</p>
<b>FURTHER INFORMATION AND SUPPORT</b>	<p>If you need any further information or support concerning this issue, please contact your local Response Center at 0180 3333544.</p>



**Philips Healthcare**

**Cardiac Resuscitation**

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**Units Affected List**

US00100694	US00324718	US00324854	US00324948	US00325664	US00325781
US00100695	US00324720	US00324855	US00324949	US00325674	US00325787
US00101003	US00324727	US00324856	US00324950	US00325675	US00325788
US00101148	US00324728	US00324858	US00324951	US00325676	US00325789
US00101277	US00324729	US00324859	US00324952	US00325677	US00325790
US00101427	US00324730	US00324860	US00324954	US00325678	US00325795
US00101443	US00324731	US00324861	US00324956	US00325679	US00325796
US00101696	US00324734	US00324862	US00324957	US00325680	US00325797
US00101876	US00324736	US00324863	US00324958	US00325681	US00325799
US00102033	US00324744	US00324864	US00324959	US00325682	US00325800
US00102552	US00324748	US00324865	US00324961	US00325683	US00325804
US00102602	US00324749	US00324866	US00324962	US00325684	US00325806
US00202756	US00324751	US00324867	US00324963	US00325685	US00325807
US00202955	US00324754	US00324868	US00324964	US00325686	US00325808
US00203505	US00324756	US00324869	US00324965	US00325687	US00325810
US00203923	US00324758	US00324870	US00324966	US00325688	US00325812
US00204295	US00324759	US00324871	US00324967	US00325689	US00325813
US00204347	US00324760	US00324872	US00324968	US00325690	US00325814
US00204361	US00324761	US00324873	US00324970	US00325692	US00325816
US00204423	US00324763	US00324874	US00324971	US00325694	US00325817
US00204438	US00324764	US00324875	US00324973	US00325696	US00325818
US00204490	US00324765	US00324876	US00324974	US00325697	US00325819
US00204648	US00324767	US00324877	US00324975	US00325698	US00325820
US00205100	US00324768	US00324878	US00324979	US00325699	US00325821
US00205625	US00324769	US00324879	US00324980	US00325700	US00325822
US00205636	US00324771	US00324880	US00324982	US00325701	US00325823
US00205650	US00324773	US00324881	US00324984	US00325703	US00325827
US00205651	US00324775	US00324882	US00324986	US00325704	US00325828
US00205660	US00324777	US00324883	US00324997	US00325705	US00325830
US00205666	US00324779	US00324884	US00325003	US00325706	US00325831
US00205688	US00324780	US00324885	US00325005	US00325707	US00325832
US00205751	US00324781	US00324886	US00325007	US00325708	US00325833
US00205839	US00324782	US00324887	US00325008	US00325709	US00325834
US00205994	US00324783	US00324888	US00325010	US00325710	US00325835
US00206144	US00324784	US00324889	US00325023	US00325711	US00325836
US00206531	US00324785	US00324890	US00325024	US00325712	US00325837
US00206641	US00324786	US00324891	US00325028	US00325713	US00325838
US00207021	US00324788	US00324892	US00325031	US00325714	US00325847
US00207313	US00324789	US00324893	US00325032	US00325715	US00325848
US00207485	US00324802	US00324894	US00325035	US00325716	US00325851
US00207604	US00324803	US00324895	US00325038	US00325717	US00325852
US00207924	US00324804	US00324896	US00325040	US00325718	US00325853
US00207930	US00324805	US00324897	US00325041	US00325719	US00325856
US00208087	US00324806	US00324898	US00325042	US00325720	US00325858



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Units Affected List (continued)

US00208140	US00324807	US00324899	US00325043	US00325721	US00325859
US00208752	US00324808	US00324900	US00325045	US00325722	US00325861
US00208789	US00324809	US00324901	US00325048	US00325723	US00325863
US00208790	US00324810	US00324902	US00325049	US00325724	US00325867
US00209355	US00324811	US00324903	US00325054	US00325725	US00325870
US00209715	US00324812	US00324904	US00325055	US00325726	US00325871
US00210183	US00324813	US00324905	US00325056	US00325728	US00325873
US00210304	US00324814	US00324906	US00325057	US00325729	US00325874
US00210783	US00324815	US00324907	US00325062	US00325730	US00325875
US00210982	US00324816	US00324908	US00325063	US00325731	US00325877
US00212242	US00324817	US00324909	US00325064	US00325734	US00325878
US00212790	US00324818	US00324910	US00325066	US00325735	US00325889
US00315280	US00324819	US00324911	US00325068	US00325736	US00325903
US00315447	US00324820	US00324912	US00325069	US00325737	US00325908
US00315464	US00324821	US00324913	US00325081	US00325738	US00325909
US00316930	US00324822	US00324914	US00325082	US00325739	US00325943
US00318057	US00324823	US00324915	US00325085	US00325740	US00325957
US00318523	US00324824	US00324916	US00325086	US00325741	US00325979
US00318538	US00324825	US00324917	US00325087	US00325742	US00325994
US00319936	US00324826	US00324918	US00325094	US00325744	US00326002
US00321428	US00324827	US00324919	US00325095	US00325745	US00326008
US00324554	US00324828	US00324920	US00325096	US00325746	US00326034
US00324581	US00324829	US00324921	US00325166	US00325748	US00326043
US00324582	US00324830	US00324922	US00325231	US00325749	US00326058
US00324583	US00324831	US00324923	US00325534	US00325750	US00326061
US00324584	US00324832	US00324924	US00325535	US00325751	US00326062
US00324586	US00324833	US00324925	US00325583	US00325752	US00326063
US00324614	US00324834	US00324926	US00325584	US00325753	US00326064
US00324615	US00324835	US00324927	US00325585	US00325754	US00326065
US00324616	US00324836	US00324928	US00325586	US00325755	US00326069
US00324619	US00324837	US00324929	US00325587	US00325757	US00326073
US00324620	US00324838	US00324932	US00325612	US00325758	US00326074
US00324622	US00324841	US00324933	US00325613	US00325759	US00326075
US00324624	US00324842	US00324934	US00325616	US00325762	US00326079
US00324625	US00324843	US00324935	US00325621	US00325763	US00326084
US00324627	US00324844	US00324936	US00325623	US00325766	US00326225
US00324642	US00324845	US00324937	US00325624	US00325767	US00326248
US00324645	US00324847	US00324938	US00325628	US00325768	US00326350
US00324646	US00324848	US00324939	US00325651	US00325770	US00326505
US00324659	US00324849	US00324940	US00325654	US00325771	
US00324680	US00324850	US00324941	US00325655	US00325773	
US00324707	US00324851	US00324942	US00325661	US00325774	
US00324712	US00324852	US00324944	US00325662	US00325775	
US00324713	US00324853	US00324947	US00325663	US00325780	

## Instructions for Checking the Status Log

Check the HeartStart MRx Status Log through Service Mode.

**CAUTION: Do not access Service Mode while the HeartStart MRx is connected to a patient.**

To access the Status Log:

1. Turn the HeartStart MRx Therapy Knob to Monitor
2. Press the Menu Select button
3. Use the Navigation arrows to highlight **Other** and press the Menu Select button
4. From the Other Menu highlight **Service** and press the Menu Select button
  - You are now leaving normal operating mode and need to press the Menu Select button to acknowledge the on-screen message
5. Enter the password (27689) by using the Navigation arrows to scroll through the list of numbers until the desired number is highlighted. Press the Menu Select button to activate each selection
6. Once you have entered all five numbers, select **Done** and press the Menu select button
7. Once in Service Mode, press the Menu Select button to activate the Service Menu. Use the Navigation arrows to highlight **Status Log** and press the Menu Select button
8. If the IntelliVue Net option is installed, then you will be offered a choice between the Device Status Log and Network Status Log. Select Device Status Log.
9. The Status Log will appear on screen. Press the **Print Log** softkey to print the report

To exit the Status Log and ...

- return to Monitor Mode: Press the **Main Service** softkey and then **Exit Service** softkey
- turn the HeartStart MRx off: Turn the Therapy Knob to the Off position

**NOTE:** The Status Log is generally for use by trained service personnel and factory engineers. There may be many status messages in the log. Usually these messages are benign and do not require intervention. If your MRx displays an hour glass in the Ready For Use Indicator, these messages should be of no concern, other than the 0x80000102 message identified in this notice.