PHILIPS

Philips Healthcare

URGENT Medical Device Recall
HeartStart FRx Automated External Defibrillator

Potential Relay Component Issue

Dear Philips HeartStart AED Customer,

This letter is to inform you that Philips Healthcare is conducting a voluntary recall of a limited number of HeartStart FRx automated external defibrillators (AEDs), model number 861304, manufactured by Philips in March 2010.

The recalled devices contain a component called a relay that may not meet Philips performance standards. The relays are from a single manufacturing lot. Possible contamination on the relay surface could compromise its performance over time and affect the AED's ability to make a therapy decision during use. Our records indicate that you have one or more of these recalled AEDs.

This issue was discovered during monitoring and analysis of our manufacturing processes in the factory. As of the date of this letter, we have received no reports of relay performance issues in the affected devices that have been shipped. However, as a precaution, we are proactively retrieving all units that may contain a relay from the affected lot.

Philips will be replacing the affected devices at no charge. Refer to the attached Field Safety Notice for instructions. The Field Safety Notice will also inform you about:

- What the issue is and under what circumstances it may occur
- Actions that you should take in order to mitigate risks for patients or users
- Actions planned by Philips to correct the issue

Please follow the "ACTION TO BE TAKEN BY CUSTOMER" section of the notice.

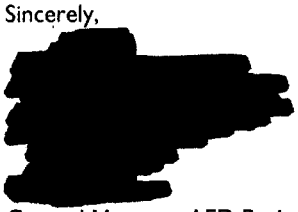
This document contains important information about this recall.
Please see attached Field Safety Notice for details.

Please review the following information with any AED owner or program manager who needs to be aware of the contents of this communication. It is important to respond to this Field Safety Notice.

This voluntary recall is being conducted with the knowledge of the FDA and all appropriate Regulatory Agencies.

Philips apologizes for any inconveniences this may cause. Your satisfaction with Philips products and with our response to this situation is very important to us.

Sincerely,



General Manager, AED Business
Philips Healthcare

Attachment

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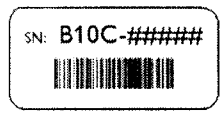
FIELD SAFETY NOTICE

AFFECTED PRODUCTS	HeartStart FRx automated external defibrillators (AEDs) model number 861304 manufactured in March 2010. A list of your affected serial numbers is attached.
ISSUE DESCRIPTION	The recalled AEDs contain a component called a relay that may not meet Philips performance specifications.
HAZARD INVOLVED	Possible contamination on the relay surface could compromise its performance over time and affect the AED's ability to make a therapy decision during use.
HOW TO IDENTIFY AFFECTED PRODUCTS	Our records indicate that you have received at least one of the affected devices. The serial numbers of your affected devices are provided on the attached list. The serial number is printed on a label on the back of your AED, as shown in the sample drawing below. A look-up tool of affected serial numbers is available at www.philips.com/HeartStartRelayAction. If a serial number does not begin with B10C, it was not manufactured in March 2010 and is not affected. 
ACTION TO BE TAKEN BY CUSTOMER	• **Check the serial number on your HeartStart FRx AED** against those provided in the attached list to confirm that you have one of the affected devices. If you have other HeartStart FRx AEDs with a serial number beginning with B10C, check them against the look-up tool of affected units available at www.philips.com/HeartStartRelayAction. • **Contact your local Philips representative** or **visit www.philips.com/ HeartStartRelayAction** to arrange for a replacement device to be shipped to you at no charge. • Please ensure that any owner or program manager of an affected device is made aware of this device recall immediately. If you have transferred the device to another person, please forward a copy of this notice to that person and notify us as soon as possible of the person's contact information. **Your AED should remain in service until you receive its replacement.**
ACTIONS PLANNED BY PHILIPS	Philips will replace all units involved in the recall free of charge with a replacement defibrillator of the same model. The replacement device will carry a full-term warranty.
FURTHER INFORMATION AND SUPPORT	For further information or support concerning this issue, please contact your local Philips representative or visit www.philips.com/HeartStartRelayAction for the serial number look-up tool and answers to frequently asked questions.

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Philips Healthcare

URGENT Medical Device Recall
HeartStart HS1 and HeartStart Home Automated External Defibrillators

Potential Relay Component Issue

Dear Philips HeartStart AED Customer,

This letter is to inform you that Philips Healthcare is conducting a voluntary recall of a limited number of HeartStart HS1 (model M5066A) and HeartStart Home (model M5068A) automated external defibrillators (AEDs) manufactured in March 2010.

The recalled devices contain a component called a relay that may not meet Philips performance standards. The relays are from a single manufacturing lot. Possible contamination on the relay surface could compromise its performance over time and affect the AED's ability to make a therapy decision during use. Our records indicate that you have one or more of these recalled AEDs.

This issue was discovered during monitoring and analysis of our manufacturing processes in the factory. As of the date of this letter, we have received no reports of relay performance issues in the affected devices that have been shipped. However, as a precaution, we are proactively retrieving all units that may contain a relay from the affected lot.

Philips will be replacing the affected devices at no charge. Refer to the attached Field Safety Notice for instructions. The Field Safety Notice will also inform you about:

- What the issue is and under what circumstances it may occur
- Actions that you should take in order to mitigate risks for patients or users
- Actions planned by Philips to correct the issue

Please follow the "ACTION TO BE TAKEN BY CUSTOMER" section of the notice.

This document contains important information about this recall.
Please see attached Field Safety Notice for details.
Please review the following information with any AED owner or program manager who needs to be aware of the contents of this communication. It is important to respond to this Field Safety Notice.

This voluntary recall is being conducted with the knowledge of the FDA and all appropriate Regulatory Agencies.

Philips apologizes for any inconveniences this may cause. Your satisfaction with Philips products and with our response to this situation is very important to us.

Sincerely,

[redacted]

General Manager, AED Business
Philips Healthcare

Attachment

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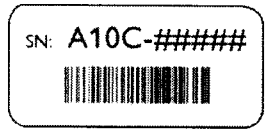
Philips Healthcare

FIELD SAFETY NOTICE

AFFECTED PRODUCTS	HeartStart HS1 (model M50666A) and HeartStart Home (M5068A) automated external defibrillators (AEDs), manufactured in March 2010. A list of your affected serial numbers is attached.
ISSUE DESCRIPTION	The recalled AEDs contain a component called a relay that may not meet Philips performance specifications.
HAZARD INVOLVED	Possible contamination on the relay surface could compromise its performance over time and affect the AED's ability to make a therapy decision during use.
HOW TO IDENTIFY AFFECTED PRODUCTS	Our records indicate that you have received at least one of the affected devices. The serial numbers of your affected devices are provided on the attached list. The serial number is printed on a label on the back of your AED, as shown in the sample drawing below. A look-up tool of affected serial numbers is available at www.philips.com/HeartStartRelayAction. If a serial number does not begin with A10C, it was not manufactured in March 2010 and is not affected. 
ACTION TO BE TAKEN BY CUSTOMER	• **Check the serial number on your HeartStart HS1 or HeartStart Home** against those provided in the attached list to confirm that you have one of the affected devices. If you have other HeartStart HS1 or HeartStart Home AEDs with a serial number beginning with A10C, check them against the look-up tool of affected units available at www.philips.com/HeartStartRelayAction. • **Contact your local Philips representative or visit www.philips.com/ HeartStartRelayAction** to arrange for a replacement device to be shipped to you at no charge. • Please ensure that any owner or program manager of an affected device is made aware of this device recall immediately. If you have transferred the device to another person, please forward a copy of this notice to that person and notify us as soon as possible of the person's contact information. **Your AED should remain in service until you receive its replacement.**
ACTIONS PLANNED BY PHILIPS	Philips will replace all units involved in the recall free of charge with a replacement defibrillator of the same model. The replacement device will carry a full-term warranty.
FURTHER INFORMATION AND SUPPORT	For further information or support concerning this issue, please contact your local Philips representative or visit www.philips.com/HeartStartRelayAction for the serial number look-up tool and answers to frequently asked questions.