PHILIPS

Philips Healthcare

URGENT Medical Device Recall
HeartStart HS1, HeartStart First Aid, HeartStart Home Automated External Defibrillators

Capacitor Failure

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 and HeartStart First Aid (models M5066A) and HeartStart Home (model M5068A) automated external defibrillators (AEDs) manufactured in October 2009.

The recalled devices contain a component called a capacitor that may not meet Philips performance standards. Failure of the capacitor during use could prevent the AED from delivering effective defibrillation therapy when indicated. Our records indicate that you have one or more of these recalled AEDs.

This issue was discovered during the monitoring and analysis of our manufacturing processes. At this time, we have received no reports of capacitor failure in the affected devices that have been shipped. As a precaution, however, we are proactively retrieving all units that may contain a defective capacitor.

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

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 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

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

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

Sincerely,

[redacted]

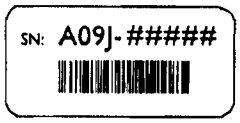
PHILIPS

Philips Healthcare

[redacted]
General Manager, AED Business
Philips Healthcare

Attachment

FIELD SAFETY NOTICE

AFFECTED PRODUCTS	HeartStart HS1 and HeartStart First Aid (model M50666A) and HeartStart Home (model M5068A) automated external defibrillators (AEDs), manufactured in October 2009. Only certain units manufactured in October 2009 are affected, which can be identified by the serial number, as described below.
PROBLEM DESCRIPTION	The recalled AEDs contain a capacitor that may not meet Philips performance specifications.
HAZARD INVOLVED	Failure of this component during use could prevent the AED from delivering effective defibrillation therapy when indicated.
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 all affected serial numbers is available at www.philips.com/HeartStartCapacitorAction. If a serial number does not begin with A09J, it was not manufactured in October 2009 and is not affected. 

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ACTION TO BE TAKEN BY CUSTOMER	• **Check the serial number on your HeartStart HS1, HeartStart First Aid, or HeartStart Home AED** against those provided in the attached list to confirm that you have one of the affected devices. If you have other HeartStart HS1, HeartStart First Aid, or HeartStart Home AEDs with a serial number beginning with A09J, check them against the look-up tool of all affected units available at www.philips.com/HeartStartCapacitorAction. • **Contact your local Philips representative** or **visit www.philips.com/ HeartStartCapacitorAction** to arrange for a replacement device to be shipped to you at no charge. • Please ensure that all users of an affected device are made aware of this device recall immediately. If you have transferred the device to another user, please forward a copy of this notice to that user and notify us as soon as possible of the user's contact information. If it is needed in an emergency, your AED should be used prior to 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.
FURTHER INFORMATION AND SUPPORT	For further information or support concerning this issue, please contact your local Philips representative or visit www.philips.com/HeartStartCapacitorAction for the serial number look-up tool and answers to frequently asked questions.

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Philips Healthcare

Cardiac Care -1/3- FSN86100086 2009 NOVEMBER 02

URGENT Medical Device Recall
HeartStart FRx Automated External Defibrillator

Capacitor Failure

Dear Philips HeartStart AED Customer,

This letter is to inform you that Philips Healthcare is conducting a voluntary recall of a limited number of the model 861304 HeartStart FRx automated external defibrillator (AED) manufactured in October 2009.

The recalled devices contain a component called a capacitor that may not meet Philips performance standards. Failure of the capacitor during use could prevent the AED from delivering effective defibrillation therapy when indicated. Our records indicate that you have one or more of these recalled AEDs.

This issue was discovered during the monitoring and analysis of our manufacturing processes. At this time, we have received no reports of capacitor failure in the affected devices that have been shipped. As a precaution, however, we are proactively retrieving all units that may contain a defective capacitor.

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

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 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

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

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

Sincerely,

[redacted]

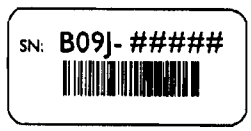
PHILIPS

Philips Healthcare

[redacted]
General Manager, AED Business
Philips Healthcare

Attachment

FIELD SAFETY NOTICE

AFFECTED PRODUCTS	HeartStart FRx (model 861034) automated external defibrillator (AED), manufactured in October 2009. Only certain units manufactured in October 2009 are affected, which can be identified by the serial number, as described below.
PROBLEM DESCRIPTION	The recalled AEDs contain a capacitor that may not meet Philips performance specifications.
HAZARD INVOLVED	Failure of this component during use could prevent the AED from delivering effective defibrillation therapy when indicated.
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 all affected serial numbers is available at www.philips.com/HeartStartCapacitorAction. If a serial number does not begin with B09J, it was not manufactured in October 2009 and is not affected. 

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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 B09J, check them against the look-up tool of all affected units available at www.philips.com/HeartStartCapacitorAction. • **Contact your local Philips representative** or **visit www.philips.com/ HeartStartCapacitorAction** to arrange for a replacement device to be shipped to you at no charge. • Please ensure that all users of an affected device are made aware of this device recall immediately. If you have transferred the device to another user, please forward a copy of this notice to that user and notify us as soon as possible of the user's contact information. If it is needed in an emergency, your FRx should be used prior to 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.
FURTHER INFORMATION AND SUPPORT	For further information or support concerning this issue, please contact your local Philips representative or visit www.philips.com/HeartStartCapacitorAction for the serial number look-up tool and answers to frequently asked questions.