stryker

Urgent Recall

HeartSine® samaritan® Public Access Defibrillator 350P/360P/500P

10th JULY, 2025

To: Owners of HeartSine® Defibrillators

Model	Serial Numbers
350P 360P 500P	To view the list of all serial numbers included in this recall, please refer to the Appendix attached or visit the website linked below: https://www.stryker.com/us/en/emergency-care/product-notices/heartsine/index.html If your device is listed, please follow the instructions provided in this letter.

Stryker has initiated a serial-specific Urgent Recall for the devices listed in the table above. This device recall notification is being issued to alert customers with HeartSine® samaritan® PAD 350P/360P/500P devices of a potential device malfunction issue.

Product Description

The HeartSine® samaritan® PAD is a small, lightweight, portable, battery operated Automated External Defibrillator (AED) designed to treat victims of cardiac arrest.

Product Problem

It was determined during internal quality testing that a manufacturing process issue related to a circuit board component **may** impair the device's ability to function or cause failure. This failure could occur at any point when the device is holding a charge in preparation to deliver therapy, while delivering a shock, or after shock delivery. The device becomes inoperable after the failure occurs.

Potential Hazards & Harms

If this issue occurs, the device **may** fail to deliver the intended therapy during use, potentially leading to a delay in treatment or no treatment being delivered during use. **The issue was observed during quality testing and the issue was not observed during patient use. There have been no adverse events reported related to this issue.** If your device experiences this issue during use, please seek an alternative defibrillator.

Stryker's Planned Actions:

The company is notifying all customers who have received HeartSine® samaritan® PAD devices within the identified range of potentially affected devices to perform the actions outlined below. Once your response is received, Stryker will be in contact to arrange the next steps for a replacement device.

End Customer Actions Required:

Inform individuals within your organisation who need to be aware of this action.

1. Immediately inspect inventory and identify impacted devices. Instructions for where to locate device serial numbers are found in Appendix A. Identify impacted devices by verifying the device serial numbers are included in the Appendix attached or link below.

   https://www.stryker.com/id/en/emergency-care/product-notices/heartsine/fa318-t3.html

2. Please complete the Acknowledgement Form on Page 4 and return the form to **CERT Academy Sdn Bhd** via email to **account@certacademy.com.my** as soon as possible. **Even if you do not have any affected product, please return a signed form.** You can also access the form online by scanning the QR code or visiting the link provided on page 4.
3. Until a replacement is available, Stryker recommends keeping your HeartSine samaritan PAD in service if you do not have an alternative public access defibrillator. This recommendation is based internal testing demonstrating a low probability of failure due to this product manufacturing issue.
4. Maintain awareness of this communication internally and near the affected unit until all required actions have been completed within your facility and the unit has been replaced.
5. If your organisation has transferred any affected items to another location, please immediately let them know of this recall and notify **CERT Academy Sdn Bhd** via email to **account@certacademy.com.my**.
6. **CERT Academy Sdn Bhd** is also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep **CERT Academy Sdn Bhd** informed of any adverse events associated with this product by emailing **account@certacademy.com.my**.

On behalf of Stryker, we thank you sincerely for your help and support in submitting your response latest by **25th July 2025**. We regret any inconvenience that may be caused and would like to reassure you that we are committed to meeting our high internal quality standards and your expectations.

Yours sincerely,

Nurfarah Athira Binti Mat Noh

Account Executive

CERT Academy Sdn Bhd

No.8-2, The Wharf, Prima Biz Hub

Jalan Tasik Prima 5/1, Taman Tasik Prima

47150 Puchong, Selangor

M: +603-8066 8665

End Customer Acknowledgement Form

Please inspect your inventory for affected devices. In the table below, please identify the affected devices on hand. *Appendix A* provides instructions on where to locate Serial Number/Model information.

Product	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
SAM 350P						
SAM 360P						
SAM 500P						

Have you further distributed any affected product: _____ YES _____ NO
Please include recipient information in your email to ***account@certacademy.com.my*** *notifying* ***CERT Academy Sdn Bhd*** *of further distribution.* ***CERT Academy Sdn Bhd*** *will work with you to ensure recipients are notified appropriately.*

Acknowledgement

By signing below and returning to ***CERT Academy Sdn Bhd***, you acknowledge that you have received and understand the enclosed notification, and that all requested actions have been completed.

Form completed by:

Name **Title**		**Company Name**	
Signature		**Email**	
Date		**Phone**	

Please return a scanned copy via email account@certacademy.com.my

Privacy

Stryker is collecting your personal information in this Acknowledgement Form so that we can conduct this Urgent Recall and organise replacement of affected products. If you do not provide us with the requested personal information, we may not be able to confirm whether you or your organisation have affected product on hand, or organise replacements. We may disclose your personal information:

1. To our related companies and third party service providers used in conducting our business (including those located overseas such as the United States of America and United Kingdom);
2. Where we are required or authorised by law to do so.

Further information about how we handle your personal information, including details of your rights (which depending on your jurisdiction, may include the right to request access to and rectification or erasure of your personal information) can be found in our Privacy Statement at Global Policy Statement | Stryker or by contacting us at globalprivacy@stryker.com

Appendix A

HeartSine samaritan PAD 350P/360P/500P

Instructions to Identify Impacted Devices

1) To find your device serial number and model number, see the labels on the rear of your device as shown below:

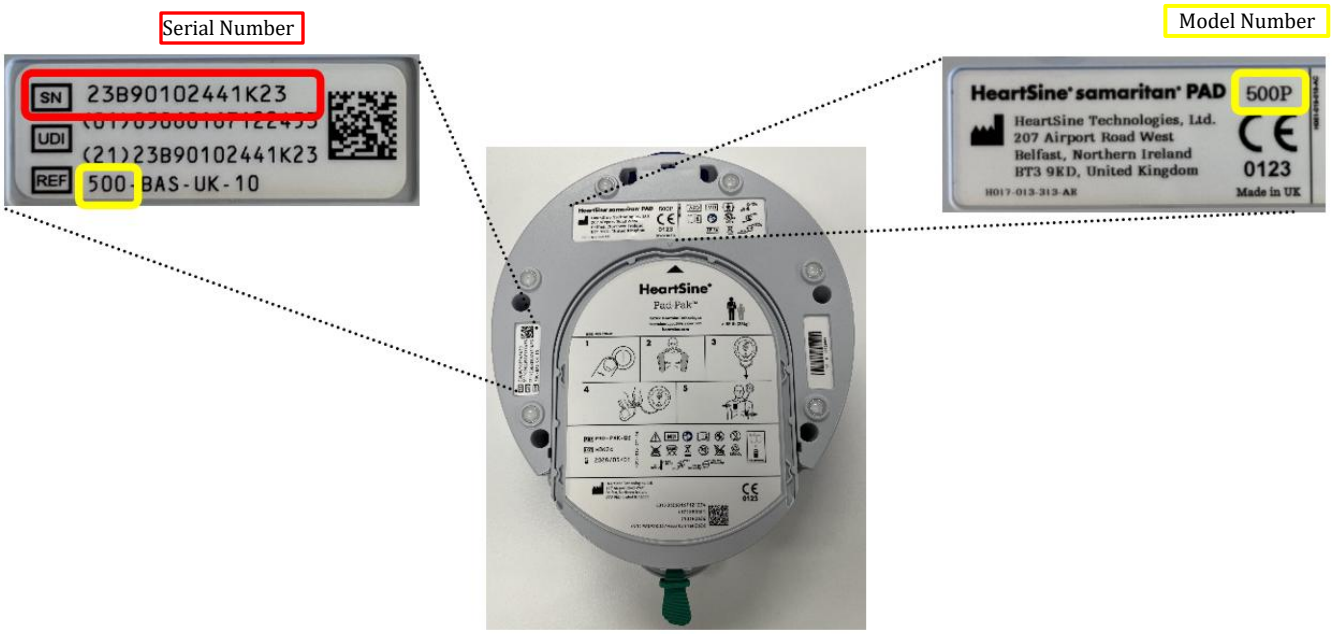

Figure 1 – Serial & Model Number location

Impacted devices are:

- Model numbers 350, 360, 500
- Impacted serial numbers: To view the list of all serial numbers included in this recall, please refer to the list attached or website linked below:
  https://www.stryker.com/us/en/emergency-care/product-notices/heartsine/index.html

Appendix B: List of affected device in Malaysia

The following list of Serial Numbers affected only includes the LOCAL affected identifiers in Malaysia **based on shipment records. Alternatively, you may visit the website linked below:**
https://www.stryker.com/us/en/emergency-care/product-notices/heartsine/index.html

For other Serial Numbers affected globally, please verify with Stryker or visit the website linked below:
https://www.stryker.com/us/en/emergency-care/product-notices/heartsine/index.html

<<List of Serial number effected>>

stryker

Urgent Recall

HeartSine® samaritan® Public Access Defibrillator 350P/360P/500P

10th JULY, 2025

To: Owners of HeartSine® Defibrillators

Model	Serial Numbers
350P 360P 500P	To view the list of all serial numbers included in this recall, please refer to the Appendix attached or visit the website linked below: https://www.stryker.com/us/en/emergency-care/product-notices/heartsine/index.html If your device is listed, please follow the instructions provided in this letter.

Stryker has initiated a serial-specific Urgent Recall for the devices listed in the table above. This device recall notification is being issued to alert customers with HeartSine® samaritan® PAD 350P/360P/500P devices of a potential device malfunction issue.

Product Description

The HeartSine® samaritan® PAD is a small, lightweight, portable, battery operated Automated External Defibrillator (AED) designed to treat victims of cardiac arrest.

Product Problem

It was determined during internal quality testing that a manufacturing process issue related to a circuit board component **may** impair the device's ability to function or cause failure. This failure could occur at any point when the device is holding a charge in preparation to deliver therapy, while delivering a shock, or after shock delivery. The device becomes inoperable after the failure occurs.

Potential Hazards & Harms

If this issue occurs, the device **may** fail to deliver the intended therapy during use, potentially leading to a delay in treatment or no treatment being delivered during use. **The issue was observed during quality testing and the issue was not observed during patient use. There have been no adverse events reported related to this issue.** If your device experiences this issue during use, please seek an alternative defibrillator.

Stryker's Planned Actions:

The company is notifying all customers who have received HeartSine® samaritan® PAD devices within the identified range of potentially affected devices to perform the actions outlined below. Once your response is received, Stryker will be in contact to arrange the next steps for a replacement device.

End Customer Actions Required:

Inform individuals within your organisation who need to be aware of this action.

1. Immediately inspect inventory and identify impacted devices. Instructions for where to locate device serial numbers are found in Appendix A. Identify impacted devices by verifying the device serial numbers are included in the Appendix attached or link below.

   https://www.stryker.com/id/en/emergency-care/product-notices/heartsine/fa318-t3.html

2. Please complete the Acknowledgement Form on Page 4 and return the form to **MediCERT Supplies Sdn Bhd** via email to **account@medicert.com.my** as soon as possible. **Even if you do not have any affected product, please return a signed form.** You can also access the form online by scanning the QR code or visiting the link provided on page 4.
3. Until a replacement is available, Stryker recommends keeping your HeartSine samaritan PAD in service if you do not have an alternative public access defibrillator. This recommendation is based internal testing demonstrating a low probability of failure due to this product manufacturing issue.
4. Maintain awareness of this communication internally and near the affected unit until all required actions have been completed within your facility and the unit has been replaced.
5. If your organisation has transferred any affected items to another location, please immediately let them know of this recall and notify **MediCERT Supplies Sdn Bhd** via email to **account@medicert.com.my**.
6. **MediCERT Supplies Sdn Bhd** is also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep **MediCERT Supplies Sdn Bhd** informed of any adverse events associated with this product by emailing **account@medicert.com.my**.

On behalf of Stryker, we thank you sincerely for your help and support in submitting your response latest by **25th July 2025**. We regret any inconvenience that may be caused and would like to reassure you that we are committed to meeting our high internal quality standards and your expectations.

Yours sincerely,

Nurfarah Athira Binti Mat Noh

Account Executive

MediCERT Supplies Sdn Bhd

No.7-2, The Wharf, Prima Biz Hub

Jalan Tasik Prima 5/1, Taman Tasik Prima

47150 Puchong, Selangor

M: +603-8066 8665

End Customer Acknowledgement Form

Please inspect your inventory for affected devices. In the table below, please identify the affected devices on hand. *Appendix A* provides instructions on where to locate Serial Number/Model information.

Product	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
SAM 350P						
SAM 360P						
SAM 500P						

Have you further distributed any affected product: _____ YES _____ NO
Please include recipient information in your email to ***account@medicert.com.my*** *notifying* ***MediCERT Supplies Sdn Bhd*** *of further distribution.* ***MediCERT Supplies Sdn Bhd*** *will work with you to ensure recipients are notified appropriately.*

Acknowledgement

By signing below and returning to ***MediCERT Supplies Sdn Bhd,*** you acknowledge that you have received and understand the enclosed notification, and that all requested actions have been completed.

Form completed by:

Name **Title**		**Company Name**	
Signature		**Email**	
Date		**Phone**	

Please return a scanned copy via email account@medicert.com.my

Privacy

Stryker is collecting your personal information in this Acknowledgement Form so that we can conduct this Urgent Recall and organise replacement of affected products. If you do not provide us with the requested personal information, we may not be able to confirm whether you or your organisation have affected product on hand, or organise replacements. We may disclose your personal information:

1. To our related companies and third party service providers used in conducting our business (including those located overseas such as the United States of America and United Kingdom);
2. Where we are required or authorised by law to do so.

Further information about how we handle your personal information, including details of your rights (which depending on your jurisdiction, may include the right to request access to and rectification or erasure of your personal information) can be found in our Privacy Statement at Global Policy Statement | Stryker or by contacting us at globalprivacy@stryker.com

Appendix A

HeartSine samaritan PAD 350P/360P/500P

Instructions to Identify Impacted Devices

1) To find your device serial number and model number, see the labels on the rear of your device as shown below:

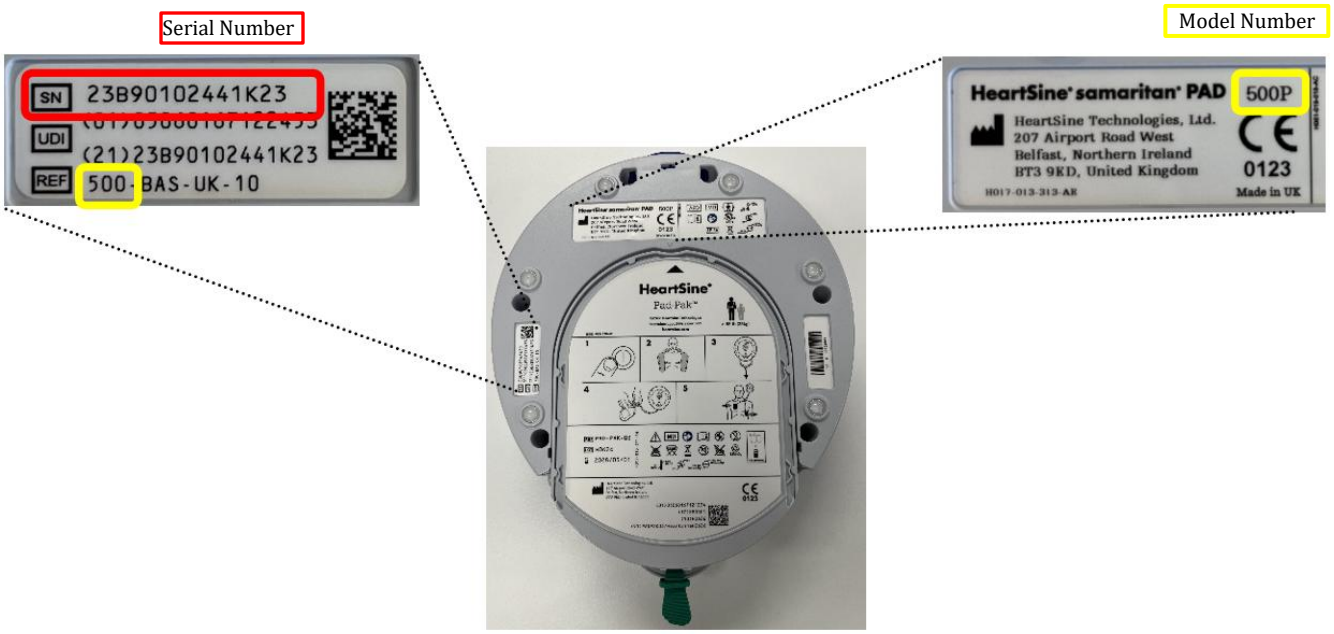

Figure 1 – Serial & Model Number location

Impacted devices are:

- Model numbers 350, 360, 500
- Impacted serial numbers: To view the list of all serial numbers included in this recall, please refer to the list attached or website linked below:
  https://www.stryker.com/us/en/emergency-care/product-notices/heartsine/index.html

Appendix B: List of affected device in Malaysia

The following list of Serial Numbers affected only includes the LOCAL affected identifiers in Malaysia **based on shipment records. Alternatively, you may visit the website linked below:**
https://www.stryker.com/us/en/emergency-care/product-notices/heartsine/index.html

For other Serial Numbers affected globally, please verify with Stryker or visit the website linked below:
https://www.stryker.com/us/en/emergency-care/product-notices/heartsine/index.html

<<List of Serial number effected>>