

## Table of contents

1. Purpose.....	2
2. Scope .....	2
3. Roles and responsibilities.....	2
4. Bill of Materials .....	2
5. Drawing of components .....	2
6. Specifications .....	2
7. Shipping, Handling and Packaging Requirements.....	3
8. Test Plan .....	3
9. Certificate of Conformance.....	4
10. Goods In Inspection and Acceptance Criteria.....	4
11. Appendices.....	4
12. Revision history.....	6

## 1. Purpose

- 1.1. The purpose of this document is to provide all critical details of the *HeartSine Pad-Pak Insert – Multilingual, H017-013-363* supplied by *any approved printed material supplier*. This document will include Details of *HeartSine Pad-Pak Insert – Multilingual, H017-013-363*, Bill of Materials, Drawings of components, Specifications, Shipping & Handling Requirements, Goods in Acceptance Criteria, Certificate of Conformance, where applicable.

## 2. Scope

- 2.1. This document applies to component *H017-013-363* supplied by *any approved printed material supplier*.

## 3. Roles and responsibilities

- 3.1. HeartSine shall populate this template to ensure all critical information is documented.
- 3.2. The approved printed material supplier shall review the *HeartSine Pad-Pak Insert – Multilingual*, to ensure content is correct.

## 4. Bill of Materials

- 4.1. This section shall provide a list of raw materials or each individual component and the quantities of each needed to manufacture the final product.

N/A as applicable

## 5. Drawing of components

- 5.1. This section shall provide design specifications and a schematic drawing and/or product images that visually illustrate the product and its individual components. This drawing should include clear labels, noting distinguishing characteristics.

Refer to Appendix A

## 6. Specifications

- 6.1. This section shall provide Stryker specifications detailing critical defining information about the product and components. Design specifications should be included where appropriate. This section shall define temperature and environmental conditions for manufacture.

<b>SPECIFICATION</b>	<b>Finished Size</b>	110 x 142mm (+/-2mm)
	<b>Flat Size</b>	440 x 710 mm folded to 110 x 142mm
	<b>Page Count</b>	2 Pages (Front and Back) including 40 Panels
	<b>Print Method</b>	Offset Lithograph or Digital Print.
	<b>Colour Ref</b>	Black Pantone 294U 1 Process Inks + 1 Pantone Ink (P294U) both sides.
	<b>Stock</b>	60gsm Bond
	<b>Binding</b>	N/A
	<b>Work Flow</b>	Trim, Folded and Box Suitably.

<b>PREPRESS</b>	<b>Print Ref on Artwork</b>	Refer to Artwork
	<b>Artwork Submission</b>	Approved PDF supplied by E-mail
	<b>Proofing Requirement</b>	Pre-flight Artwork. Issue Ripped Printers Proof

<b>PACKING</b>	<b>Packing</b>	Standard CoC
	<b>Non-Kits</b>	Pack in corrugated boxes. <u>Labelling to include:</u> Part No/Description/Qty in box/Batch (HeartSine Label) <u>Weight Restriction:</u> <10kgs Standard or Euro pallet acceptable. <u>Height restriction on pallet:</u> <200cms Mixed product ok on pallet. But ensure each box is labelled

<b>NOTES</b>	<b>File Naming</b>	When artwork is updated the ending sequence of the filename will be updated
	<b>Sampling</b>	<u>Production Sampling:</u> <u>Print Production:</u> First and Last of batch of print run. <u>Finished Product:</u> First and Last of batch run <u>If Kitted:</u> First and last of kitted batch. Samples labelled and inserted into sample envelopes.

## 7. Shipping, Handling and Packaging Requirements

7.1. This section shall detail shipping and handling requirements of the *HeartSine Pad-Pak Insert – Multilingual, H017-013-363*, to ensure safety and quality of product. Shipping of dangerous goods require appropriate documentation, labels and must include MSDS information. This section shall also include packaging information, box type, box weight, quantity of units per box.

Requirements					
Part No.	Shipping	Handling	Packaging	Quantity units per box	Reusable Container
H017-013-363	Supplier Courier	Less than 10kgs per shipper box	Packed in labelled double walled corrugated box	As agreed with supplier	N/A

## 8. Test Plan

8.1. This section shall state whether test plans or test specifications are required for the *HeartSine Pad-Pak Insert – Multilingual, H017-013-363*. These may be provided to the supplier by HeartSine or may be developed between HeartSine and *any approved printed material supplier*. This section shall detail agreed test plans or test specifications.

N/A as applicable

---

## 9. Certificate of Conformance

A certificate of conformance certifies the *HeartSine Pad-Pak Insert – Multilingual, H017-013-363* received from *any approved printed material supplier* are tested to specifications defined by HeartSine. HeartSine requires a certificate of conformance from all critical component suppliers.

N/A as applicable

## 10. Goods In Inspection and Acceptance Criteria

This section shall detail the level of inspection required by HeartSine Goods in team and the acceptance criteria for incoming product(s).

Part Number	Part Description
H001-003-075	Appendix 1 to the Goods Inwards and Stores Procedure
H006-004-271	Manual Goods In Work Instruction

## 11. Appendices

- 11.1. Appendix A, the *HeartSine Pad-Pak Insert – Multilingual, H017-013-363*

## Appendix A

*HeartSine Pad-Pak Insert – Multilingual, H017-013-363*

## 12. Revision history

Rev	Description
AC	<p>Address changed from “203 Airport Road” to “207 Airport Road” , “9ED” to “9LF” and “United Kingdom” to “Northern Ireland”</p> <p>“U.S./Latin America Customer Support” changed to “Distributed in U.S. by:”</p> <p>Added “HeartSine samaritan PAD” before UL Classification</p> <p>Changed Date of issue to “2021/01”</p> <p>Changed copyright year to 2021</p> <p>Updated part number revision to “AC”</p> <p>Arabic language code changed from AB to AR</p> <p>Czech language code changed from CZ to CS</p> <p>Estonian Language code changed from EE to ET</p> <p>Japan language code changed from JP to JA – within Japanese body of text updated text to match the user manual</p> <p>Updated Portuguese language code from PT to PT-PT</p> <p>Updated Polish language code from PO to PL</p> <p>Updated Brazilian language code from BZ to PT-BR</p> <p>Updated mandarin language code from MD to ZH-CN</p> <p>Updated Cantonese language code from HK to ZH-TW</p>
AD	<p>Postcode changed from '9LF' to '9ED'</p> <p>DOI changed from '2021/01' to '02/2021'</p> <p>Rev changed from 'AC' to 'AD'</p> <p>Spanish Code updated to 'ES-ES'</p>
AE	<p>Addition of ‘United Kingdom’ to Belfast address</p>

Rev	Description
AF	<p>The following changes have been made to the supplier spec:</p> <ul style="list-style-type: none"> <li>- Updated rev to AF</li> <li>- flat size updated to: <b>440 x 710 mm folded to 110 x 142mm</b></li> <li>- page count updated to: <b>2 Pages (Front and Back) including 40 Panels</b></li> <li>- added to colour ref: <b>1 Process Inks + 1 Pantone Ink (P294U) both sides</b></li> <li>- Stock updated to: <b>60gsm Bond</b></li> <li>- Workflow updated to: <b>Trim, Folded and Box Suitably.</b></li> </ul> <p>The following changes are impacting the artwork:</p> <ul style="list-style-type: none"> <li>- Removed Step 6 image</li> <li>- Added Disposal after use section and image</li> <li>- Reorganized image/step flow from left to right, to down the first column and then second column</li> <li>- Moved CE 0123 next to manufacturing symbol and updated size per RED @ 5 mm</li> <li>- Added addresses for Stryker Australia: <ul style="list-style-type: none"> <li>Stryker Australia Pty Ltd</li> <li>8 Herbert St</li> <li>St Leonards NSW 2065</li> <li>Australia</li> </ul> </li> <li>- Added Stryker European Operations: <ul style="list-style-type: none"> <li>Stryker European Operations B.V.</li> <li>Herikerbergweg 110</li> <li>1101 CM Amsterdam</li> <li>Netherlands</li> </ul> </li> <li>- Updated footer content: <ul style="list-style-type: none"> <li>Date of issue: 11/2022</li> <li>© 2022</li> <li>H017-013-363-AF</li> </ul> </li> <li>- Removed Rx only logo</li> <li>- Updated language code EN to EN-UK</li> <li>- Step 2 updated to state: <ul style="list-style-type: none"> <li>2. Place HeartSine samaritan PAD (<b>AED</b>) face up on a flat surface and slide in Pad-Pak or Pediatric-Pak.</li> </ul> </li> <li>- Updated step 4 to state: <ul style="list-style-type: none"> <li>4. Verify that green status indicator is blinking, indicating the <b>AED</b> is ready for use.</li> </ul> </li> <li>- Updated and merged step 5 and 6 to say:</li> </ul>

Rev	Description
	<p>5. Turn on <b>AED</b>. You should hear expected language and should not hear a warning message. <b>Turn off AED.</b></p> <ul style="list-style-type: none"> <li>- Indications for use section - Removed periods at end of both bullets on all translations.</li> <li>- New sections: <ul style="list-style-type: none"> <li>- <b>Disposal after use</b> Remove Pad-Pak. Cut wires. Stick pads together. Dispose of pads as infectious waste. Recycle lithium battery separately per local regulations.</li> <li>- <b>Intended purpose</b> The Pad-Pak or Pediatric-Pak accessory contains the battery to power the HeartSine samaritan PAD and two electrode pads to provide the electrical connection to the patient's chest for delivery of defibrillation shock. The delivery of a defibrillation shock can stop disruption to the heart's normal rhythm and restore blood flow.</li> <li>- <b>Contraindications</b> Do not use if patient is responsive or conscious.</li> </ul> </li> <li>- In cautions section, changed device to AED: Single use ONLY. Reuse may cause <b>AED</b> to be unable to deliver therapy leading to a failure to resuscitate.</li> <li>- Update to: "<del>This also</del> can be found at <a href="https://heartsine.com">https://heartsine.com</a>" to be "<b>Each</b> can be found at heartsine.com"</li> <li>- Changed three paragraphs under Notes into bullets and removed periods from the ends.</li> <li>- Added: <b>Please report any serious incident that occurs with this device to HeartSine Technologies, Ltd. and to your national competent authority or other local regulatory authority as per local regulations.</b></li> <li>- Removed Adult child symbol from all RoW text at end of first "Note" and added it as an asterisk at the bottom of page 1 for better fit.</li> <li>- Updated alpha order on the following languages: <b>ET, PT-BR</b></li> <li>- Added new section for "<b>ES-AM (Estados Unidos solamente)</b>" before ES based on updated EN-US text which can be found below at end of changes below</li> <li>- <b>ES-ES changed to ES</b></li> <li>- <b>In LT, added quote marks to "Pediatric-Pak":</b></li> <li>- <b>In NO, used sentence case for "Merknader"</b></li> <li>- <b>In PL, updated "Pediatric-Pak: Jest"</b></li> <li>- <b>In RO, Updated bullet sub-heads to bold: <b>Cartușul Pad-Pak:</b> and <b>Cartușul Pediatric-Pak:</b></b></li> </ul>



Rev	Description
	<p>Added entire new panel for EN-US before EN-UK panel as follows:</p> <p><b>EN-US (US only)</b></p> <p><b>Set-up</b></p> <ol style="list-style-type: none"> <li>1. Remove from packaging.</li> <li>2. Place HeartSine samaritan PAD (AED) face up on a flat surface and slide in Pad-Pak or Pediatric-Pak.</li> <li>3. Listen for “double click” to indicate it is properly inserted.</li> <li>4. Verify that green status indicator is blinking, indicating the AED is ready for use.</li> <li>5. Turn on AED. You should hear expected language and should not hear a warning message. Turn off AED.</li> </ol> <p><b>Disposal after use</b></p> <ul style="list-style-type: none"> <li>• Remove Pad-Pak. Cut wires. Stick pads together. Dispose of pads as infectious waste. Recycle lithium battery separately per local regulations</li> </ul> <p><b>Pad-Pak and Pediatric-Pak contain:</b></p> <ul style="list-style-type: none"> <li>• Pair of disposable single use defibrillation pads</li> <li>• LiMnO<sub>2</sub> (18V – 1500mAh) non-rechargeable battery</li> </ul> <p><b>Indications for use</b></p> <p>The Pad-Pak and Pediatric-Pak, when used with a HeartSine samaritan PAD, are indicated for use on victims of cardiac arrest. See the AED user manual or user handbook for the exhibiting signs of cardiac arrest specific to each device.</p> <ul style="list-style-type: none"> <li>• Pad-Pak: Intended for use on adults or children &gt; 8 years or &gt; 25 kg (55 lb)</li> <li>• Pediatric-Pak: Intended for use on children between the age of 1-8 years or &lt; 25 kg (55 lb)</li> </ul> <p><b>Battery capacity</b></p> <p>&gt;60 shocks or 6 hours battery use.</p> <p><b>Warnings</b></p> <p>DO NOT USE if expiry date is exceeded.</p> <p>DO NOT USE if the pouch is opened or damaged. This may result in the electrode gel being dry.</p>

Rev	Description
	<p><b>Cautions</b></p> <p>Single use ONLY. Reuse may cause AED to be unable to deliver therapy leading to a failure to resuscitate. It may also lead to cross-infection between patients.</p> <p>DO NOT PULL the green tab on the Pad-Pak during set-up.</p> <p>If you hear a warning message when you turn on your HeartSine samaritan PAD, consult the troubleshooting section of the HeartSine samaritan PAD user manual or user handbook.</p> <p>For full instructions for use, indications for use, contraindications and safety information, and disposal instructions, refer to your HeartSine samaritan PAD user manual or user handbook. Each can be found at <a href="http://heartsine.com">heartsine.com</a>.</p> <p><b>Notes</b></p> <ul style="list-style-type: none"> <li>• Pediatric-Pak is only suitable for use with HeartSine samaritan PADs with the symbol</li> <li>• The TSO/ETSO-certified Pad-Pak must be used on board commercial fixed wing aircraft</li> <li>• DO NOT STORE the Pediatric-Pak next to magnetically sensitive storage media as it contains a magnetic component (surface strength 6500 gauss)</li> </ul> <p>Please report any serious incident that occurs with this device to HeartSine Technologies, Ltd. and to the U.S. Food and Drug Administration as per local regulations.</p>

**Note:** If this section is used, list no more than five (5) previous revisions.