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TITLE

DEVICE REGULATORY LABEL MODEL PA97000 PATIENT ASSISTANT

Doc. No.

p. 1 of 6

M976704A

Rev B

| REVISION | DESCRIPTION |
|----------|--|
| A | Initial release |
| В | Revise section 2 to reflect metric values, add tabs 002 through 006 to view 2, update to new template. |

| Hedtronic | DEVICE REGULATORY LABEL MODEL PA97000 PATIENT ASSISTANT | M976704A | REV. B | p. 2 of 6 |
|-----------|--|----------|--------|-----------|
|-----------|--|----------|--------|-----------|

1.0 TABLE OF CONTENTS

| 1.0 2.0 3.0 4.0 | Table of Contents Scope Component Identification Handling Requirement |
|--------------------------|--|
| 5.0 | Notification of Change |
| 6.0 | Completion |
| 7.0 | Notes |

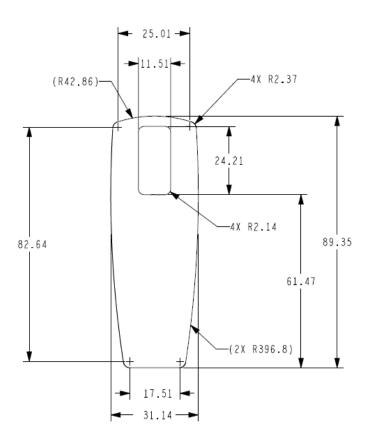
2.0 SCOPE

This specification shall identify the procurement source for Device Regulatory Label for the Model PA96000 Patient Assistant.

3.0 COMPONENT IDENTIFICATION

- 1. Material: (.125 mm) Thick velvet matte finish polycarbonate with PSA adhesive. Overall thickness excluding release liner (.185 mm) nominal.
- 2. Adhesive: (.06 mm) thick Acrylic PSA, 3M 467MP or Medtronic approved equivalent.
- 3. Colors: Background Dark Grey, Pantone 431. Graphics Black, Pantone Process Black.
- 4. See graphics file for artwork. Refer to associated artwork file (.eps file).
- 5. Packaging Kiss-cut on sheets with waste removed or die cut individual labels with release liner pull tab. Bulk package as to prevent damage and packaging waste.
- 6. All dimensions in View 1 are in millimeters unless otherwise noted. Tolerances are +/- .254 mm.
- 7. Radius tolerances are +/- .3 mm unless otherwise noted.
- 8. Identify each label package with the part number at a minimum.
- 9. All borders and window/s are represented by line-art. See the supplied artwork. Cut back the adhesive layer approx. (.508 mm) REF. from window border. No adhesive allowed in window area.
- 10. This component to be RoHS compliant with restrictions on hazardous substances.

View 1 – Dimensions – (not to scale)

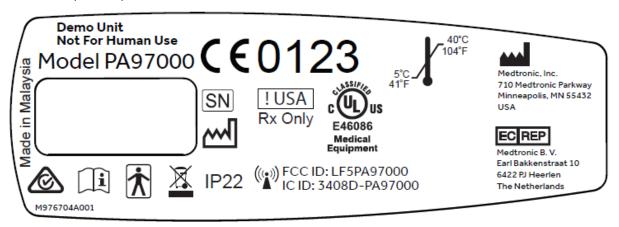


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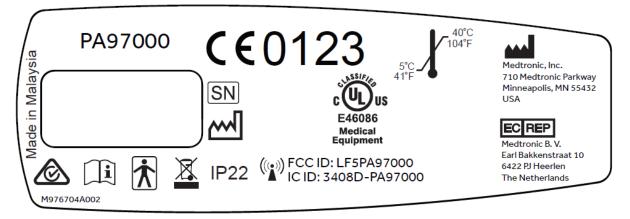
| at | DEVICE REGULATORY LABEL MODEL PA97000 | M076704A | | | |
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| Areatronic | PATIENT ASSISTANT | W970704A | 6704A REV. B | p. 4 of 6 | |

View 2 – Artwork Tabs (Reference use only not to scale)

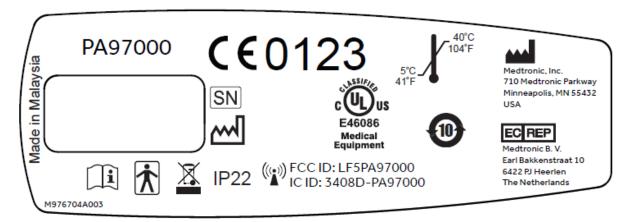
TAB -001 (DEMO)



TAB -002 AUS / NZ

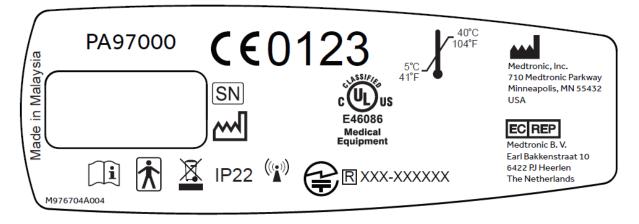


TAB -003 China

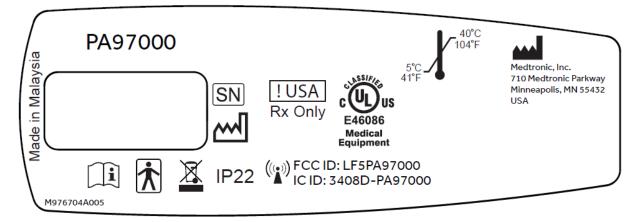


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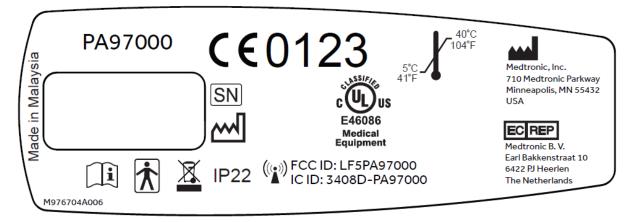
TAB -004 Japan



TAB -005 US / Canada



TAB -006 OUS



4.0 HANDLING REQUIREMENT

The manufacturer shall package and ship the component parts in a manner designed for protection from physical damage and, if electrically susceptible, from electrostatic discharge.

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| 🕀 Medtronic | PATIENT ASSISTANT | 101970704A | REV. D | p. 6 01 6 | |

5.0 NOTIFICATION OF CHANGE

Upon approval by Medtronic, Inc. of the initial design, any part, process changes or deviations considered by the manufacturer must be submitted to Medtronic, Inc. In writing for review, the information submitted should include a complete description of the change and effect the change will have on all characteristics of the device, material and /or process.

6.0 COMPLETION

This paragraph concludes this specification.

7.0 NOTES

Not applicable to this document.