

Model: PG1000



SN

0344

FCC ID: RW6PG1000TRX

Cyberonics, Inc.

IP22

26-0008-7400/0

Specification, Label, ProGuardian
Sensor

Label Location



[illegible]

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1. PURPOSE

This specification establishes the requirements for the label that will be adhered to the **bottom** of the *ProGuardian Sensor*.

2. APPLICABLE DOCUMENTS

61-0004-2000	Procedure, Receiving Inspection, Proofreading
61-0004-2300	Procedure, Receiving Inspection, Label, Die Cut, Adhesive
70-0000-1600	Workmanship Standard, Requirements, Printed Materials

3. DEFINITIONS

Proof — (1) a test copy of the printed document file that is made for examination and/or correction; (2) to compare the test document to the approved artwork to determine that it matches

Proofread — to read and mark corrections on the document copy

4. REQUIREMENTS

The supplier shall produce and deliver the labels according to the following requirements.

4.1 Artwork

4.1.1 Artwork file "26-0008-7400 ART" shall be used by the supplier to generate the label. Cyberonics will provide the supplier with the software file.

4.1.2 The die cut shall cut completely through the face stock. The matrix shall not be stripped.

4.1.3 The "die" lines on the artwork shall not be printed.

4.1.4 All printed text and graphics shall be legible and completely inside the die-cut lines.

4.2 Supplier's Responsibilities

4.2.1 It shall be the supplier's responsibility to ensure that all supplier-related requirements of this specification are met.

4.2.2 The supplier shall produce one (1) original color proof (mock-up) from the artwork and shall inspect for legibility, print quality, size, and construction using the criteria outlined in this specification.

4.2.3 The supplier shall file the artwork. On receiving a repeat order for this manual, the supplier may re-use the artwork only if the revision number is the same. If a repeat order specifies a different revision, the artwork on hand shall be destroyed and new artwork shall be provided by Cyberonics.

4.3 Cyberonics' Acceptance Responsibilities

4.3.1 **Printer Proof (Optional)** — If applicable, Cyberonics Receiving Inspection (R/I) will inspect (proofread) the proof in accordance with 61-0004-2000 and 70-0000-1600. A signed Proofreading Acceptance Form will be sent/faxed to the supplier. It will indicate whether the proof is:

- ◆ Approved As Is
- ◆ Approved with changes noted
- ◆ Not approved

If acceptable, the labels will be approved for printing. No changes shall be made to the artwork after approval by Cyberonics. The vendor is not required to provide a subsequent proof if the proof has been "Approved with Changes Noted."

If rejected, the vendor shall correct the problem and provide one (1) subsequent proof for Cyberonics' inspection.

4.3.2 **Lot Inspection (Mandatory)**— Cyberonics R/I shall inspect (proofread) a sample of the printed labels in accordance with 61-0004-2300 and 70-0000-1600. For label tolerances, defer to tolerances as outlined in Section 4.4 below. If acceptable, the labels will be approved by Cyberonics and placed into stock.

4.4 Label, Paper and Ink Requirements

Sheet Size	Supplier will provide labels on a Roll. Note: The carrier sheet will extend outside the width of the label by the minimum amount needed to carry the label.
Label Stock	Autotype autotex F8 Graphic Overlay (.008), 3M 467MP Adhesive (.002), or equivalent
Overall Height, Excluding Backing	0.012" Max
Label Size	0.35 h x 0.87 w (See Figure 1)
Corner Radius	0.005"
Ink	Black
Lines	Do not print die-cut lines.
Die Registration Tolerance	0.01"
Label Cut Size Tolerance	0.005"
Serial Number	Helvetica 5pt Black Serial Numbers (XXXXXXXX) are to be assigned sequentially as specified in the purchase order.

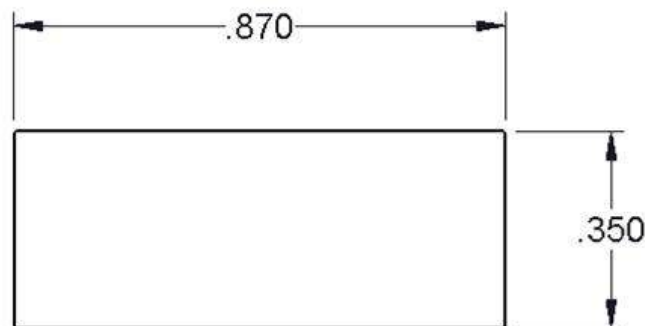


Figure 1. Finished Dimensions