acurable

Acurable

Labelling

OxiPebble 100 sensor

Notice

Acurable Limited cannot accept any financial or other responsibilities that may be the result of your use of information, software or devices provided by Acurable, including direct, indirect, special or consequential damages or loss of profits. There are no warranties extended or granted by this document or software material. You should be very careful that the use of information, software and devices provided by Acurable complies with the laws, rules, and regulations of the jurisdictions with respect to which it is used.

Trademarks

AcuPebble is a trademark of Acurable Limited. All trade names referenced are the service mark, trademark, or registered trademark of the respective organisation.

Registered Company

Acurable Limited is registered in England and Wales No. 10310661

Registered address: 2 Leman Street, London E1W 9US, United Kingdom

Document Control

Document Information

Document Name: Labelling

Issue: 1.0

Published Date: 1-September-2024

Document Version History

Issue	Date	Author	Role	Description
0.1	1-Sep-2024	Elizabeth Gilmore	Operations and Quality Manager	First version draft
1.0	1-Sep-2024	Anas Imtiaz	CTO and Deputy CEO	Review and update
1.1	07-Feb-2025	Jessica Burbidge	Product Development Coordinator	Update enclosure FCC ID

Document Approval

Issue	Name	Role	Approval Outcome	Signature	Date
1.0	Anas Imtiaz	CTO and Deputy CEO	Approved		1-Sept-2024
1.1	Anas Imtiaz	CTO and Deputy CEO	Approved		07-Feb-2025

Table of Contents

1. INTRODUCTION

The AcuPebble Ox200 medical device is accompanied by labeling that provides the information needed to use the device safely and properly, taking account of the training and knowledge of the potential users, and identifies the device and the manufacturer.

This labeling is compliant with:

- The Essential Requirements in Annex I section 13 of the European Medical Device Directive (MDD) 93/42/EEC which provides the specific requirements for the content of the product labeling, and the EU regulation 207/2012 for the online version of the Instructions for Use for healthcare professionals.
- The FDA requirements for labeling of medical devices, including 21 CFR part 801, and the FCC requirements for RF devices.

2. APPLICABLE STANDARDS

OxiPebble 100 labels have been designed in compliance with the following standards:

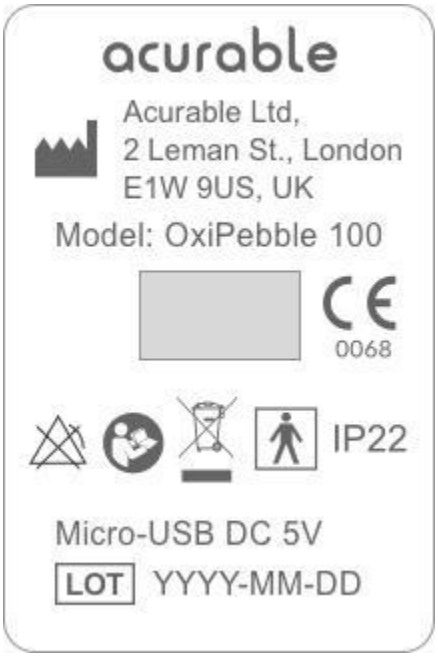
- BS EN ISO 15233-1:2021 - Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
- BS EN 60601-1:2006+A2:2021 - Medical electrical equipment. General requirements for basic safety and essential performance.
- BS ISO 7000:2004 - Graphical symbols for use on equipment
- BS EN ISO 7010:2020+A6:2023 - Graphical symbols — Safety colors and safety signs — Registered safety signs.
- IEC 60878:2022 - Graphical symbols for electrical equipment in medical practice
- BS EN 80416-3:2002+A1:2011 - Basic principles for graphical symbols for use on equipment. Guidelines for the application of graphical symbols.
- EN 50419:2022 - Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE).
- ISO 80601-2-61:2019 - Particular requirements for basic safety and essential performance of pulse oximeter equipment

3. PRODUCT LABELS

3.1 Label sensor enclosure (CE mark)

Label to be displayed (ie: printed) at the bottom of the OxiPebble 100 sensor enclosure.

- Note that the sensor label does not have the full UDI (GTIN) because there is not enough space due to the very small size of the device (29mm in diameter). Note the label can only be printed on the sensor enclosure base, because the other surfaces (ie: sides and top) are not flat and cannot be printed on.
- The full UID and FCC ID are displayed on the sensor packaging and on the accompanying mobile application instead (see sections below).
- Note that the sensor can be visually identified from the Model and LOT information on the label.



3.2 Label sensor enclosure (FDA)