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Labelling

OxiPebble 100 sensor

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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:

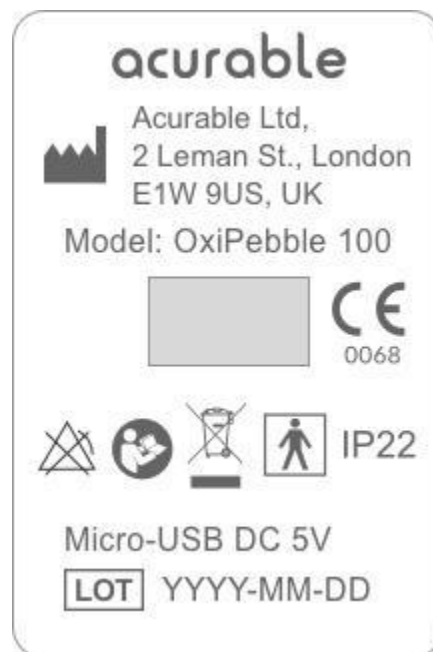
- BS EN ISO 15233-1:2021 - Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
- BS EN 60601-1:2006+A2:2021 - Medical electrical equipment. General requirements for basic safety and essential performance.
- BS ISO 7000:2004 - Graphical symbols for 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)

