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Labelling (US)

AcuPebble Ox100 sensor and accompanying software

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Registered Company

Acurable Limited is registered in England and Wales No. 10310661

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Document Control

Document Information

Document Name: Labelling (US)

Issue: 1.2

Published Date: 01-Aug-2023

Document Version History

Issue	Date	Author	Role	Description
0.1	15-Feb-2022	Elizabeth Dyer	Operations Manager	First version draft
1.0	22-Jul-2022	Emilio Sanz-Pereiras	CEO	Review and update
1.1	19-Jul-2023	Elizabeth Gilmore	Operations Manager	Update FCC ID on packaging labels and final version of oximeter label
1.2	01-Aug-2023	Elizabeth Gilmore	Operations Manager	Add regulatory information for Canada

Document Approval

Issue	Name	Role	Approval Outcome	Signature	Date
1.0	Emilio Sanz-Pereiras	Chief Executive Officer	Approved		22-Jul-2022
1.1	Emilio Sanz-Pereiras	Chief Executive Officer	Approved		19-Jul-2023
1.2	Emilio Sanz-Pereiras	Chief Executive Officer	Approved		01-Aug-2023

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1. INTRODUCTION

The AcuPebble Ox100 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

AcuPebble Ox100 labels have been designed in compliance with the following standards:

- BS EN ISO 15233-1:2016 - Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
- BS EN 60601-1:2006+A12:2014 - Medical electrical equipment. General requirements for basic safety and essential performance.
- BS ISO 7000:2004 - Graphical symbols for use on equipment
- BS EN ISO 7010:2012+A7:2017 - Graphical symbols — Safety colors and safety signs — Registered safety signs.
- IEC 60878:2015 - 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 50419:2006 - Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE).

3. PRODUCT LABELS

AcuPebble Ox100 labeling is composed of the Instructions for use (aka: User Manual) and several labels displayed on each one of the product components visible by the user.

Title	Component	Key	Version
Label neck sensor enclosure	AcuPebble Ox100 neck sensor	AP-144	1.0
Label finger sensor enclosure	AcuPebble Ox100 finger sensor	OX-1	1.1
Label adhesives	AcuPebble SA100 adhesives	AP-163	1.0
Label packaging (external)	AcuPebble Ox100 packaging	AP-257	1.2
Label packaging (internal)	AcuPebble Ox100 packaging	AP-256	1.1
Label transport	Shipping outer packaging (Ox100)	AP-149	1.1
Label mobile app	AcuPebble Ox100 mobile application	SAM-291	1.1
Label web app	AcuPebble Ox100 web application	SAW-414	1.0

3.1 Label sensors enclosure

AcuPebble Ox100 is composed of two fully independent sensors, one that is to be placed on the neck and another one on the finger. The sensor on the neck is exactly the same as the previously cleared device “AcuPebble SA100” (K210480), hence the label on the sensor is identical to this one and has been previously cleared by the FDA. For completeness, however, it is also presented in the paragraph below.

Neck sensor label (identical to previously cleared K210480)

Label to be displayed (ie: printed) at the bottom of the AcuPebble Ox100 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.

Finger sensor label

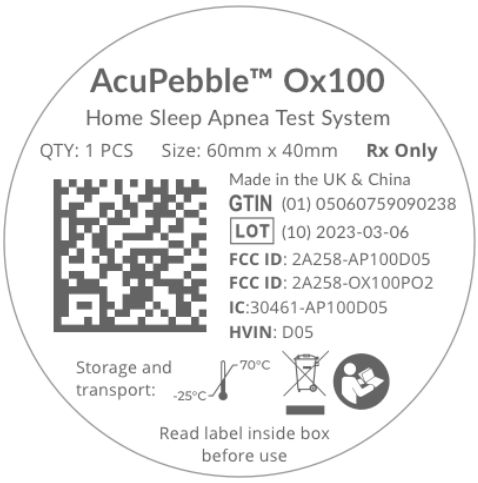
3.2 Label adhesives

The adhesives, including their label, were already cleared as part of K210480. The only change with respect to the previous one is the name of the device on the top. The description is below for completeness.

Label to be displayed (ie: affixed sticker) on the AcuPebble 100 adhesives container bag.

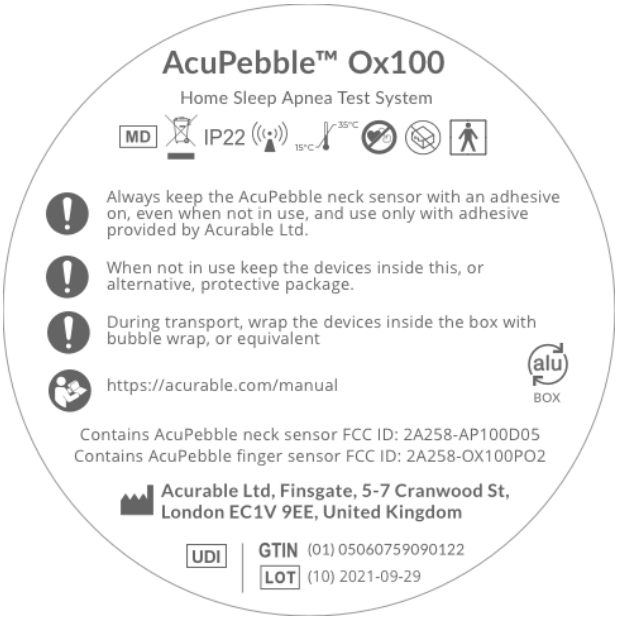
3.3 Label packaging (external)

Label to be displayed (ie: affixed sticker) on the outside of the AcuPebble Ox100 packaging box (Note, this is identical to the label of the previously cleared “AcuPebble SA100, K210480”, with the exception of the name and product size.)



3.4 Label packaging (internal)

Label to be displayed (ie: affixed sticker) on the inside of the AcuPebble Ox100 packaging box Note, this is identical to the label of the previously cleared “AcuPebble SA100, K210480”, with the exception of the name and the addition of the FCC ID for the finger sensor.



3.5 Label transport

Labels to be displayed (ie: affixed stickers) on the generic shipping outer packaging.

Instructions

- For all transport methods, the shipping box should have affixed the UN3481 handling mark.
- For air transport, the shipping box should also have affixed a Transport Document containing a General warning statement and an Air-waybill notice.

UN3481 label

Transport Document label

Li-Po batteries, in compliance with Section II of PI967

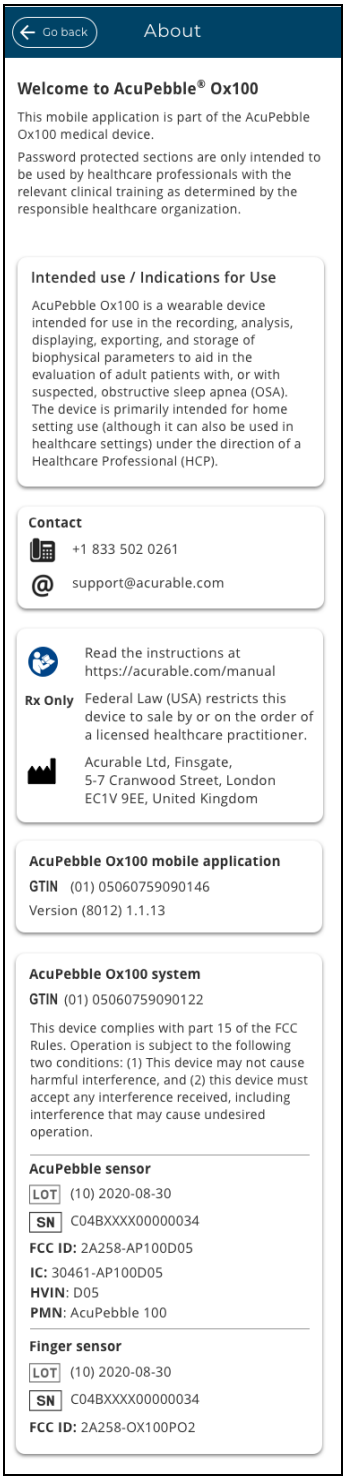
The package contains Li-Po cells or batteries; the package must be handled with care and a flammability hazard exists if the package is damaged. Special procedures must be followed in the event the package is damaged, to include inspection and repacking if necessary. For additional information, contact Acurable Ltd on +1 833 502 0261.

FCC ID: 2A258-AP100D05
FCC ID: 2A258-OX100PO2

Note for transporter: This label must be included on the air waybill, when an air waybill is used.

3.6 Label mobile app

Label to be displayed (ie: electronically) on the mobile application



3.7 Label web app

Label to be displayed (ie: electronically) on the AcuPebble Ox100 web application