acurable

Acurable

Labelling (US)

AcuPebble SA100 sensor and accompanying software

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.

No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of Acurable. The information contained herein is subject to change without notice. Revisions may be issued advising of such changes and / or additions.

Copyright ©2018 Acurable Limited

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: Finsgate, 5-7 Cranwood Street, London EC1V 9EE

Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled

Document Control

Document Information

Document Name: Labelling (US)

Issue: 1.3

Published Date: 20-Sep-2021

Document Version History

Issue	Date	Author	Role	Description
0.1	18-Dec-2020	Elizabeth Dyer	Operations Manager	First version draft
1.0	12-Jan-2021	Emilio Sanz-Pereiras	CEO	Review and update
1.1	05-Mar-2021	Elizabeth Dyer	Operations Manager	Update software labels with Rx only symbol
1.2	18-May-2021	Elizabeth Dyer	Operations Manager	Update introductory sentence of web app label
1.3	20-Sep-2021	Elizabeth Dyer	Operations Manager	Update FCC ID number
1.4	10-Feb-2022	Elizabeth Dyer	Operations Manager	Add screens preceding mobile app label

Document Approval

Issue	Name	Role	Approval Outcome	Signature	Date
1.0	Emilio Sanz-Pereiras	Chief Executive Officer	Approved		12-Jan-2021
1.1	Emilio Sanz-Pereiras	Chief Executive Officer	Approved		05-Mar-2021
1.2	Emilio Sanz-Pereiras	Chief Executive Officer	Approved		18-May-2021
1.3	Emilio Sanz-Pereiras	Chief Executive Officer	Approved		20-Sep-2021
1.4	Emilio Sanz-Pereiras	Chief Executive Officer	Approved		10-Feb-2022

Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled

Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled

Table of Contents

1. INTRODUCTION **5**

2. APPLICABLE STANDARDS **5**

3. PRODUCT LABELS **6**

3.1 Label sensor enclosure 7
3.2 Label adhesives 8
3.3 Label packaging (external) 8
3.4 Label packaging (internal) 9
3.5 Label transport 9
3.6 Label mobile app 11
3.7 Label web app 12

Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled

1. INTRODUCTION

The AcuPebble SA100 medical device is accompanied by labelling 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 labelling 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 labelling, and the EU regulation 207/2012 for the online version of the Instructions for Use for healthcare professionals.
- The FDA requirements for labelling of medical devices, including 21 CFR part 801, and the FCC requirements for RF devices.

2. APPLICABLE STANDARDS

AcuPebble SA100 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, labelling 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 colours 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).

Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled

3. PRODUCT LABELS

AcuPebble SA100 labelling 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 sensor enclosure	AcuPebble SA100 sensor	AP-144	1.3
Label adhesives	AcuPebble SA100 adhesives	AP-163	1.2
Label packaging (external)	AcuPebble SA100 packaging (US version)	AP-257	1.4
Label packaging (internal)	AcuPebble SA100 packaging	AP-256	1.1
Label transport	Shipping outer packaging (US version)	AP-149	1.0
Label mobile app	AcuPebble SA100 mobile application (US version)	SAM-291	1.2
Label web app	AcuPebble SA100 web application (US version)	SAW-414	1.3

Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled

3.1 Label sensor enclosure

Label to be displayed (ie: printed) at the bottom of the AcuPebble SA100 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.

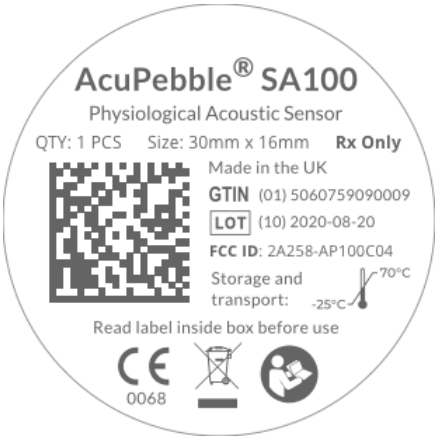
Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled

3.2 Label adhesives

Label to be displayed (ie: affixed sticker) on the AcuPebble SA100 adhesives container bag.

3.3 Label packaging (external)

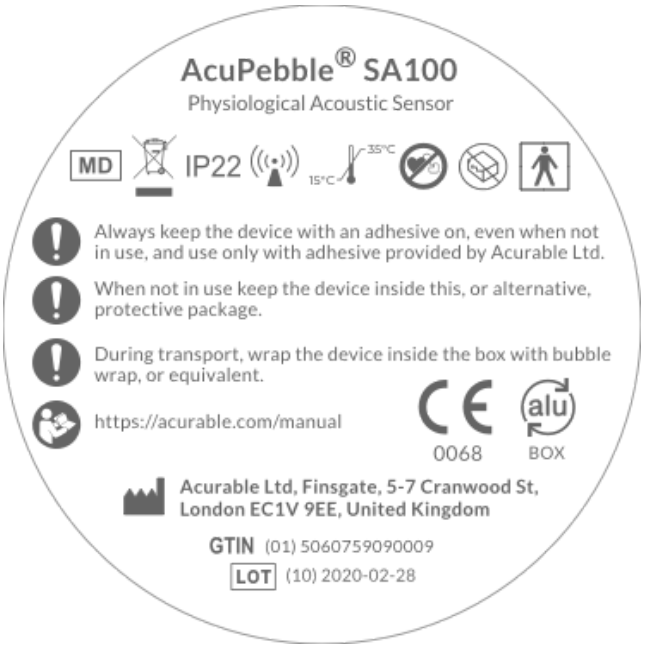
Label to be displayed (ie: affixed sticker) on the outside of the AcuPebble SA100 packaging box.



Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled

3.4 Label packaging (internal)

Label to be displayed (ie: affixed sticker) on the inside of the AcuPebble SA100 packaging box.



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.

Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled

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.

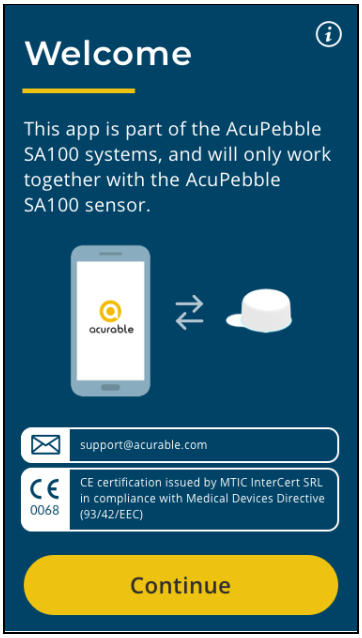
FCC ID: ABC0123456789

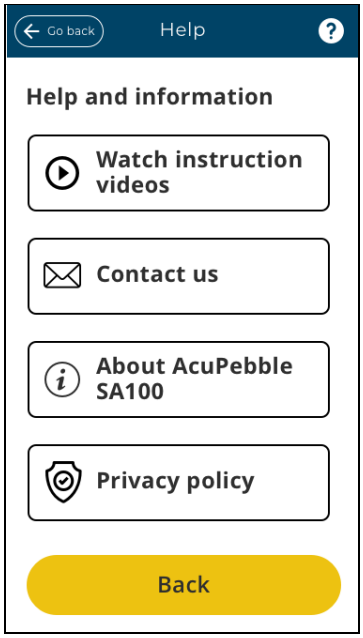
Note for transporter: This label must be included on the air waybill, when an air waybill is used.

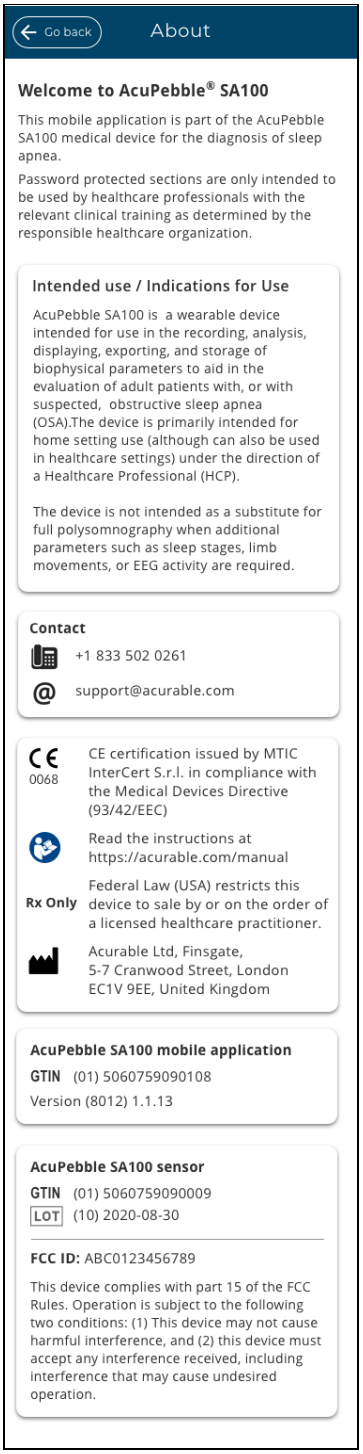
Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled

3.6 Label mobile app

Label to be displayed (ie: electronically) on the AcuPebble SA100 mobile application.



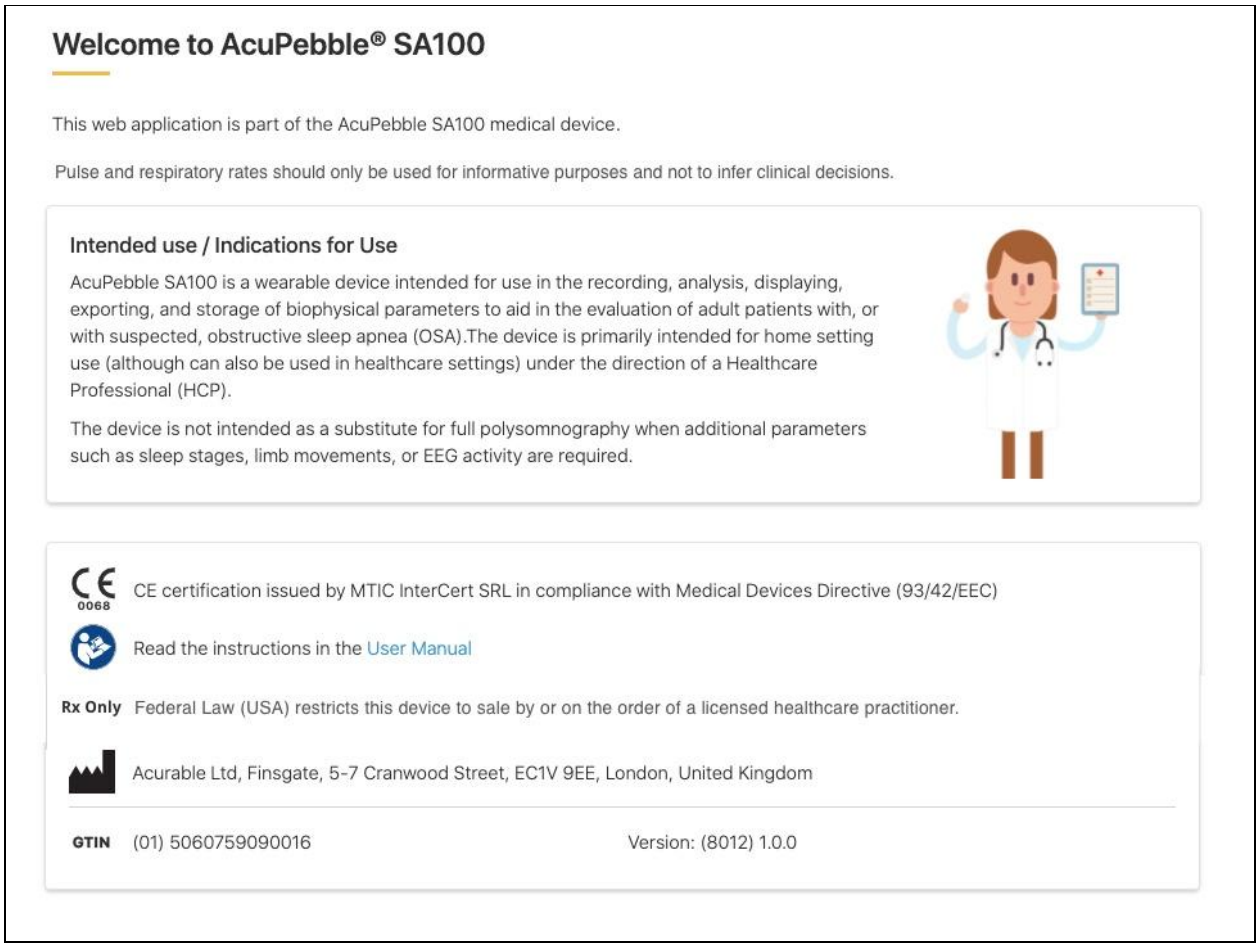




Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled

3.7 Label web app

Label to be displayed (ie: electronically) on the AcuPebble SA100 web application.



Copyright Acurable ©2018
All Rights Reserved
Printed copies are not controlled