

Project: P-0000461

Document title: WREM Marking and Labeling Report

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Approvals: *This document is electronically signed. Please refer to record approval.*

Document history:

Revision	Date	By	Description
1	05/18/2021	EALF	Initial Release
2	12/13/2023	CHBZ	Update with corrections to overall project, Updated Left and Right for Amplified Speaker, Report title error. Corrected.

Table of Contents

1	Introduction	3
1.1	Purpose	3
1.2	Scope	3
1.3	References	3
1.4	Definitions of terms	3
2	System overview	4
2.1	Type label	4
2.1.1	First revision of label	5
2.1.2	Second revision of label	5
2.1.3	Actual revision of label	7
2.2	Other parts delivered with the MedRx WREM	9
2.3	Position of label on device	10
2.4	Shipping Label	12
3	Attachments	14

1 Introduction

1.1 Purpose

This document is intended to define the label and labelling requirements for the MedRx Wireless REM. The document will define the layout of labels, the content and their placement on the device.

1.2 Scope

This requirement specification is valid for all variants of the MedRx WREM.

1.3 References

Project name: MedRx WREM.

- 1) EN ISO 15223-1:2016
- 2) ANSI/AAMI 60601-1:2005 (3rd edition)
- 3) EU Medical Device Regulation
- 4) EU Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EU 4. July 2012)
- 5) Q-MBP-22 Classification, Labelling & Traceability

1.4 Definitions of terms

Term	Definition
MDR	EU Medical Device Regulation
FCC	Federal Communications Commission
OSHA	United States Occupational Safety and Health Administration
ETL	Electrical Testing Laboratories listed mark to North American safety standards
NRTL	National Recognized Test Laboratory
ATM	Authorization to mark (according to ETL)

2 System overview

MedRx, Inc. manufactures the Wireless REM. The device and stickers are labelled accordingly:

MedRx, Inc.

1200 Starkey Rd., STE 105

Largo, FL. 33771

The WREM is a wireless real ear measurement.

Device base system:

WREM Base Unit

Accessories/Transducers:

WREM Probes

WREM Probe Bow

Disposables:

None

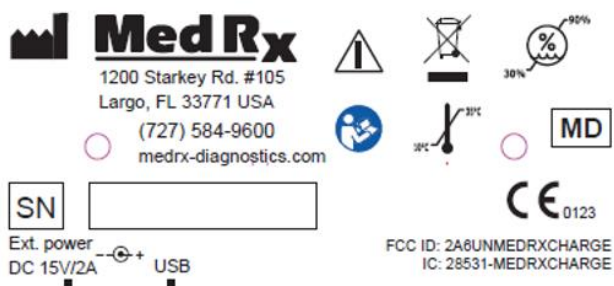
2.1 Type label

The labelling of the MedRx Wireless REM is described below, the progression from the first draft to the final approved revision is described for future reference. The detail of the final approved revision is described.

WREM Marking and label Report

2.1.1 First revision of label

Bottom of MedRx WREM



Type

Figure 1 The first revision of silk screen on the WREM

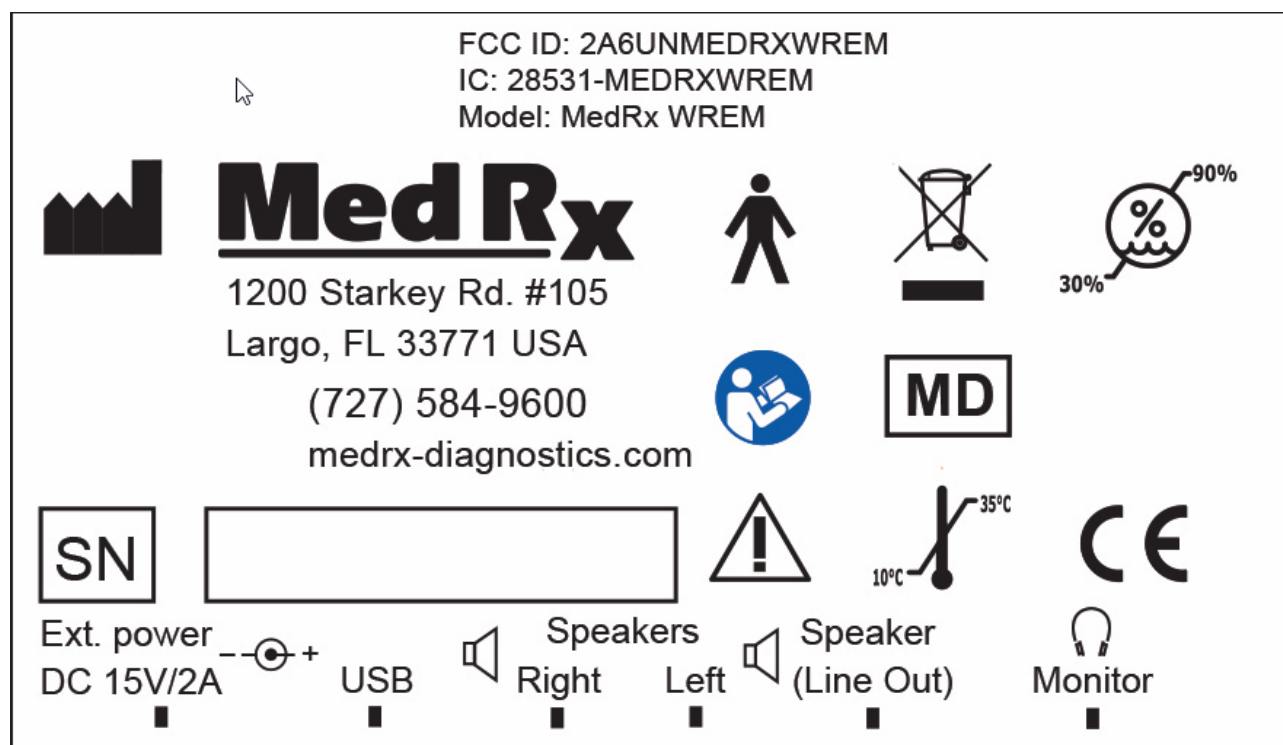
This is the first revision of the label and the review of this raised the following comments below:

Comments:

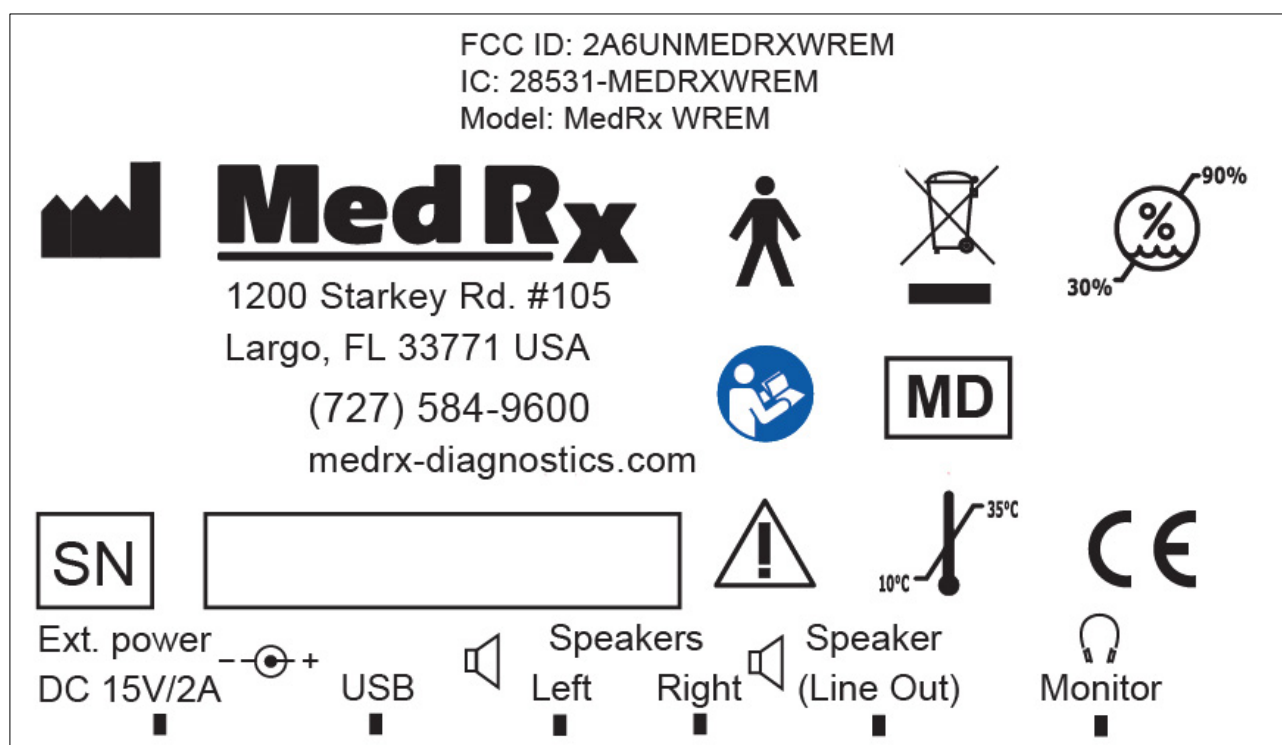
Actions in next revision

- New layout for REM Amp and line out
- CE0123 -> CE
- Monitor
- FCC ID and IC Updated for WREM

2.1.2 Second revision of label



2.1.3 Third revision of label



Probe Mic

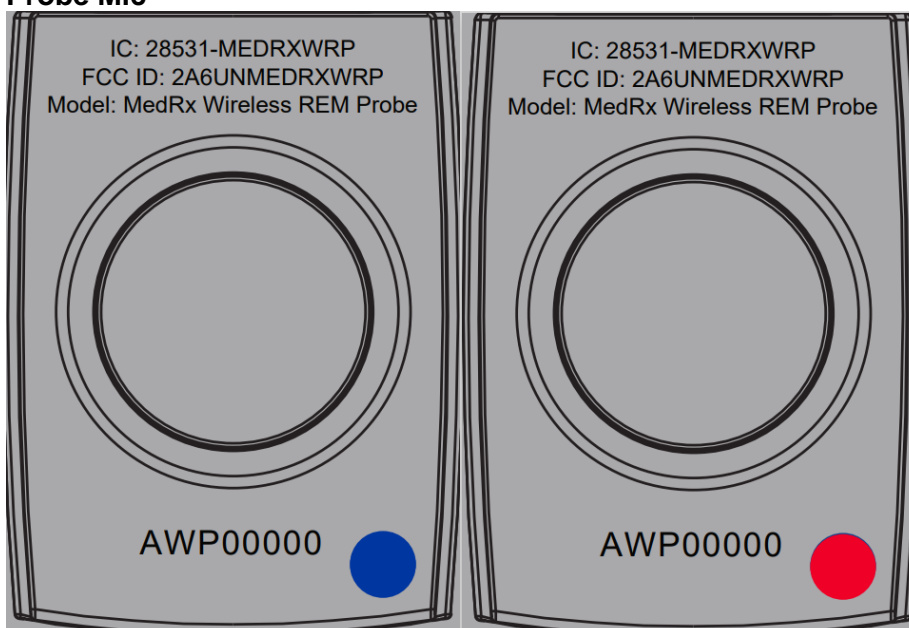


Figure 2 The final revision of probe mic back

This is the first revision of the label and the review of this raised the following comments below:

Comments:

The Serial Number will be etched into the probe mics.

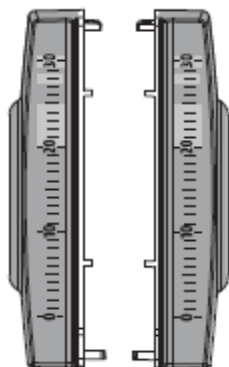
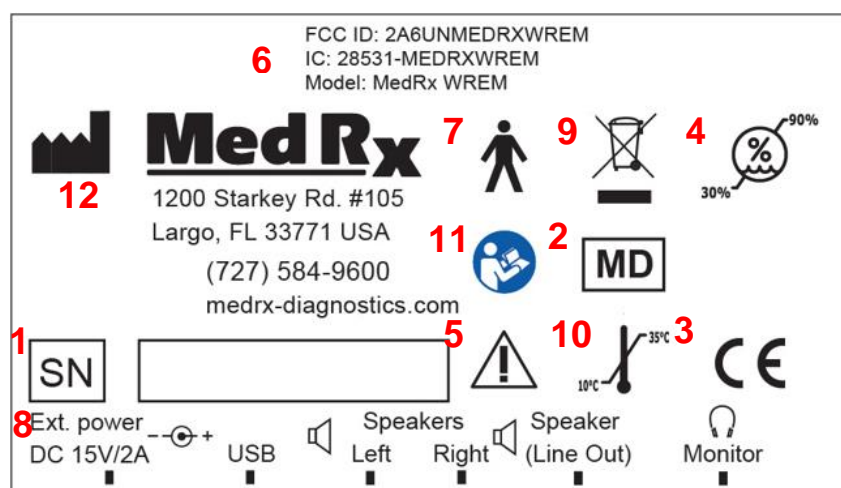
Probe Mics Side View

Figure 3 The final revision of probe mic side

Probe Bow

Figure 4 The final revision of Probe Bow

2.1.4 Actual revision of label

The present working revision of the label:

Figure 2 Present

The printed information contains the following symbols and data:

- 1) Product Serial Number
- 2) Medical Device Regulation Label

- 3) The MedRx WREM is manufactured in conformity with the European regulations for medical devices 93/42/EEG and carries the CE mark (Class I).
- 4) Transportation and storage temperature -20C to 50C
- 5) Indicates: Caution (not warning) that if precautions are not taken it may cause moderate injury.
- 6) Indicates: FCC identification number – US, IC identification number – CAN, Model
- 7) The symbol indicates that the MedRx WREM fulfills the requirements of ref. 2 EN 60601-1 as application device Type B.
- 8) Specification of the supply of energy to the product.
- 9) Indicates that the device must not be disposed of in normal household garbage.
- 10) Transportation and storage humidity limits -10C to 35C
- 11) This safety sign requires that the operator of the equipment must read the User Manual and follow the instructions on safety, operation, and cautions.
- 12) Manufacturer's identification and address.

2.2 Other parts delivered with the MedRx WREM

The label of the (table, pc, screen) are beyond the scope of this report.

2.3 Position of label on device

The position of the type label on the device is shown in **Error! Reference source not found..** Wearability of the label is ensured by the placement of the label.

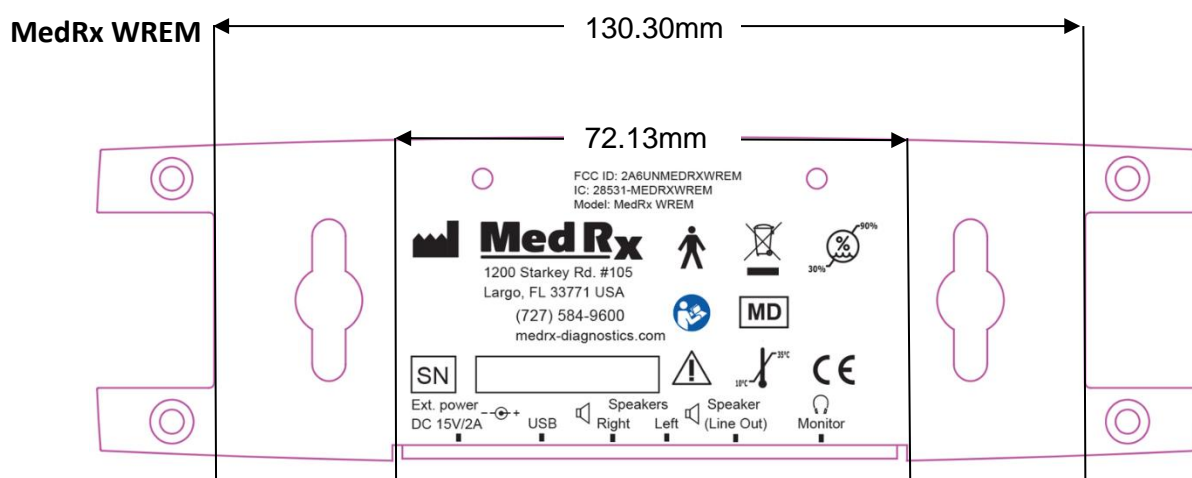


Figure 8 The position of the label on the Base Station device

Probe Mic

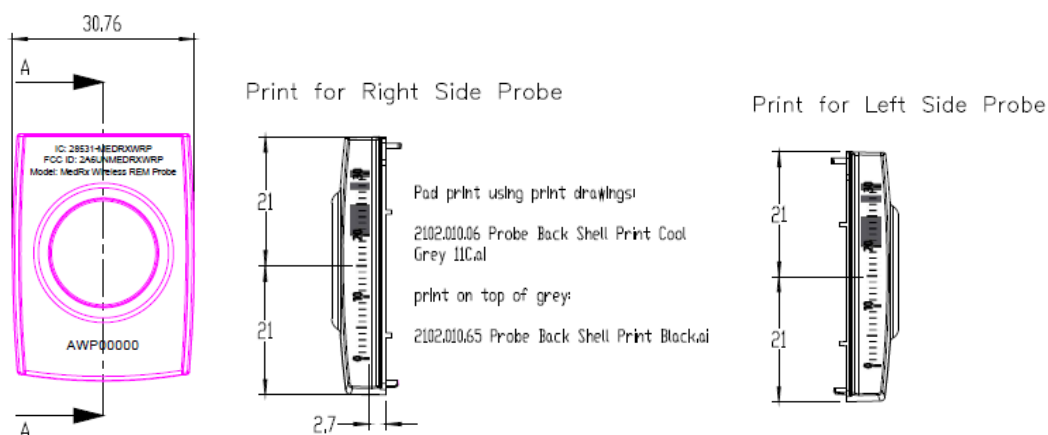


Figure 9 The position of the label on the probe mics

AWRC Probe Bow

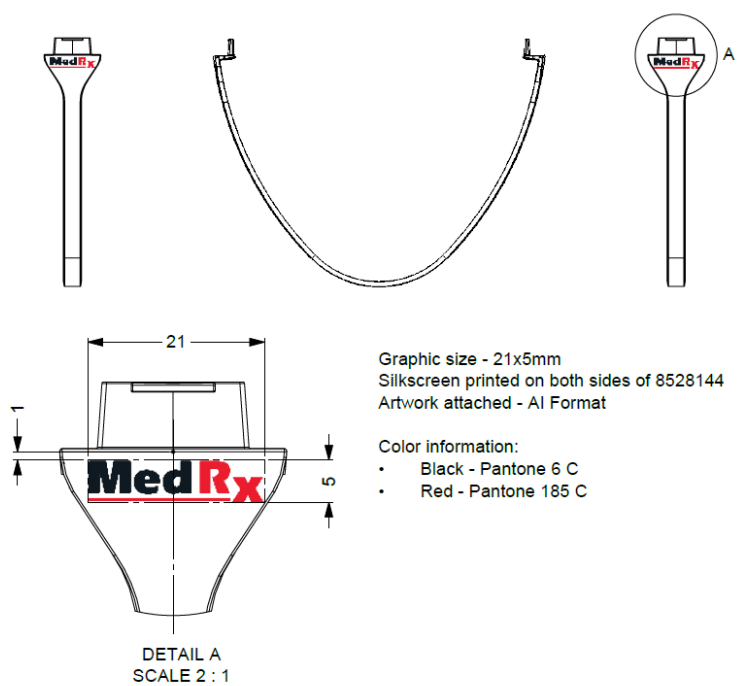
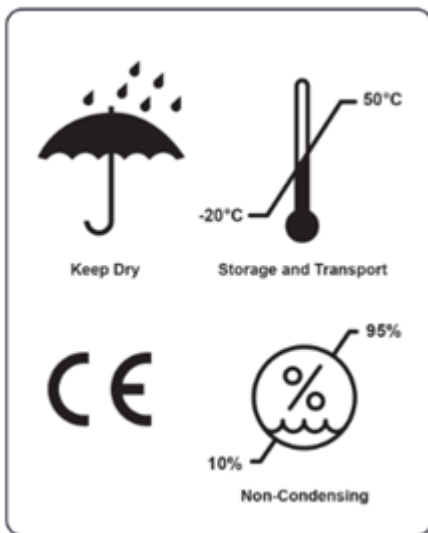


Figure 10 The position of the label on the AWRC Probe Bow

2.4 Shipping Label

When the device is shipped it will bear a packing label as shown:



8514974 – Storage Information Label “CE”



8100219 – Bumper Sticker Shipping Label



8505026 – International Safe Handling Broken Glass “Fragile” Label



8535515 - Lithium Battery Handling, Symbol Only, 4 5/8 x 5

3 Attachments

None