

STANDARD OPERATING PROCEDURE/WORK INSTRUCTION		
Document Title	Document Description	Version No.
WI-109	Work Instructions for Acquiring and Applying Reflex Labels	2

1 PURPOSE

To define the process for acquiring and adhering some of the labels for the Reflex product.

2 SCOPE

This Work Instruction covers the following labels for Reflex:

- R30061: Emergency Stop Label
- R30062: FCC ID Label
- R30064: Reflex UDI Label
- R30065: Reflex Device Safety Label

3 RESPONSIBILITIES

Operations / Manufacturing	• Procuring and tracking inventory of labels • Following procedures for assembly
Engineering	• Designing labels and locations
Quality	• Document control of labels and instructions
Regulatory	• Ensuring labels adhere to relevant regulations

4 RECORDS

No additional records are generated from this process.

5 RELATED ITEMS

See Section 2	See documents (labels) listed under Section 2: Scope

6 PROCEDURE/WORK INSTRUCTION

6.1 General Instructions

This Work Instruction is referenced by one or more Reflex build documents (PRs, WIs, etc.). Follow instructions carefully in the governing document(s) and see the sections below for acquiring and adhering specific labels.

6.2 Emergency Stop Label

Emergency Stop labels (R30061) are purchased from an outside vendor and come on a sheet.

1. Obtain label sheet, R30061.
2. Clean the surface of the Reflex cover directly below the E-Stop with alcohol.
3. Adhere one label in the position shown. Note: The image shows a prototype label; the final version will be clear.

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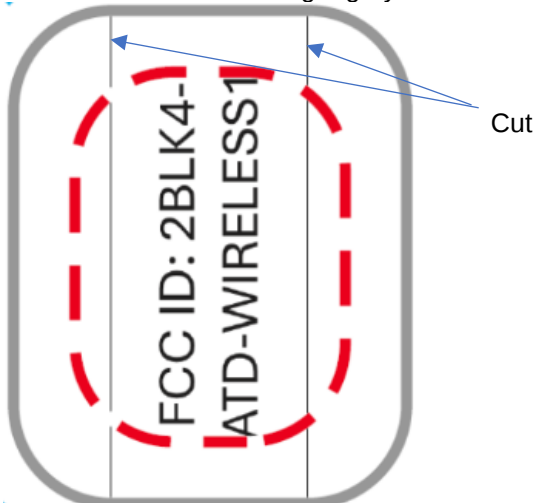


- Return label sheet to inventory.

6.3 FCC ID Label

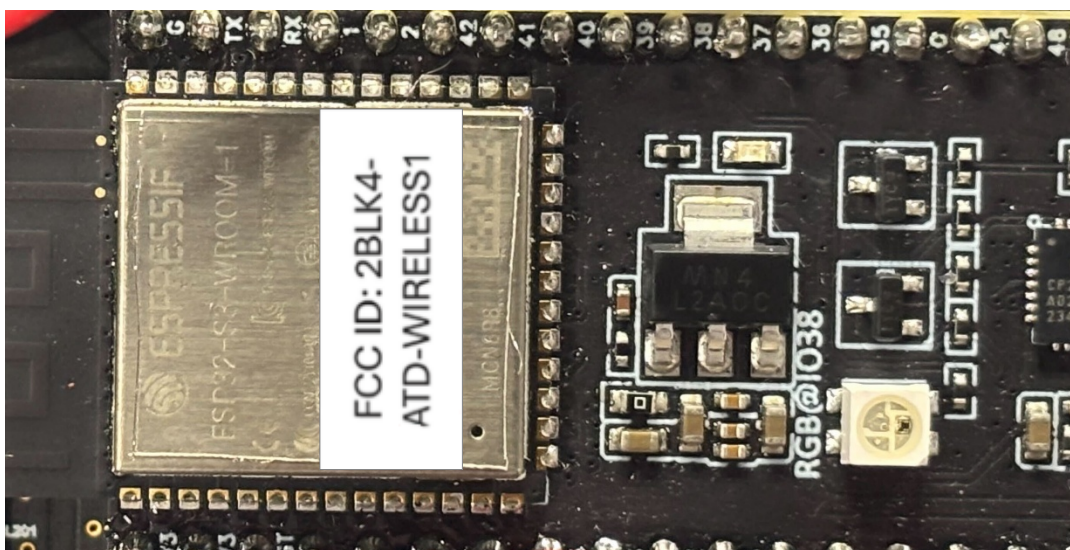
FCC ID labels (R30062) are purchased from an outside vendor and come on a sheet.

- Obtain label sheet, R30062.
- Clean the top surface of the ESP-32, if needed.
- Cut one label inside the light gray vertical lines shown below (red dashed line will not be on label):



- Adhere label in approximate position shown:

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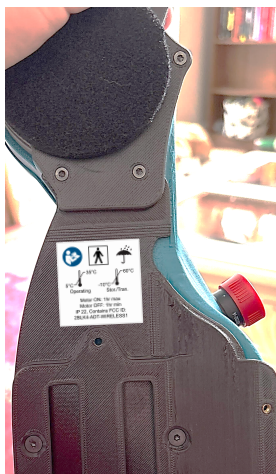


- Return label sheet to inventory.

6.4 Reflex Safety Label (R30065)

Reflex Safety labels (R30065) are purchased from an outside vendor and come on a sheet.

- Obtain label sheet, R30065.
- Clean the bottom surface of the Reflex with alcohol in the location shown.
- Adhere label in approximate position shown:



- Return label sheet to inventory.

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6.5 Reflex UDI Label (R30064)

Reflex UDI labels (R30064) are developed in-house and printed externally on a laser printer. Follow the instructions below:

1. Follow the detailed instructions in R30064: Reflex UDI Label to create and print the UDI label. Note the smaller label created (0.95" x 3.0") is for the device while the larger label is for the device package. Note this process is best done in batches for several Reflex devices.
2. Verify the data on the UDI label matches the serial number and handedness of the Reflex (see R30064 for details).
3. Clean the surface of the Reflex with alcohol, as needed, in the location shown.
4. Adhere label in position shown:



7 CHANGELOG

Describe changes below. It is acceptable to enter "See GG" in any of the name and date fields below. The Author and Reviewer shall electronically sign the document in the electronic QMS.

Ver.	Brief description of changes	Author	Date	Reviewer	Date
0	Original issue	D. Wilkinson	See GG	T. Roberts	See GG
1	Removed mentioned of other labels (shipping safety and UDI) as they will be in different docs	D. Wilkinson	See GG	T. Roberts	See GG
2	Added UDI label back in	D. Wilkinson	See GG	T. Roberts	See GG

Approved By:

[\(CO-155\) CO: accompanying docs and labeling instructions](#)

Description

WI-109: See changelog R30043: Changed App. A to include all variables; added more details to App. B re: EMC, other minor clarification changes. R30047: Updated assembly figure to call out angle of thigh strap.

Justification

WI-109: Added UDI here (instead of separate WI) for consolidation of docs. R30043: Compliance with regulations and general clarifications. R30047: Clarification on assembly.

Assigned To:	Initiated By:	Priority:	Impact:
David Wilkinson	David Wilkinson	High	Minor

Version History:

Author	Effective Date	CO#	Ver.	Status
David Wilkinson	March 26, 2025 1:18 PM PDT	CO-155	2	Published
David Wilkinson	March 23, 2025 10:03 AM PDT	CO-151	1	Superseded
David Wilkinson	March 15, 2025 2:35 PM PDT	Not Available	0	Superseded