

Technical Specification

Equipment Specifications for “Freeze Marker” for transportation of freeze sensitive vaccine

1. Product Description (Purpose and function)

Freeze Marker is required for transportation of freeze sensitive vaccine to ensure the maintenance of cold chain. Battery operated electronic irreversible freeze indicator, with integrated temperature sensor (+/- 0.5°C accuracy) that changes display from [Good] to [BAD] when exposed to -0.5°C for 60 minutes or more, to indicate exposure to FREEZING range.

2. Operational Requirements

The exposure duration should be NON-CUMMULATIVE (Not a sum of multiple exposures to - 0.5°C, totaling 60 minutes or more).
A blinking LED or a blinking (Once in 5 seconds or less) dot on LCD display is required to suggest that device is functioning.

3. Technical Specifications, including accessories, spares, consumables

1. Material- ABS casing/ dust & moisture proof sealed construction.
2. Temp range- -20°C - +55°C
3. Humidity range - 95%RH
4. Accuracy - +/- 0.5°C or better
5. Minimum logging interval- 1 minute (Preset)
6. Display- LCD screen 10mm x 10mm or bigger/shows battery is working/unit activated/ exposure within safe range/ exposure to freezing range.
7. Display contrast- Should be clearly visible at 100 lux.
8. Weight- Not critical.
9. Size- Not exceeding 10 cm x 5 cm x 2.5 cm
10. Programming- Factory programmed
11. Battery life- Minimum 3 years including Post-activation operational battery life.
12. User activation- Required.
13. Provision to stop/ reset by user- No.
14. Sticker on the back describes activation procedure/description of display for battery/ activation/ good or bad status.
15. IP rating-64/67
16. Product should have self-adhesive tap/ eyelet to mount device with vaccine load/ inside ILR.
17. Individually packed, with user instructions / essential product details in English and Hindi.

4. PQS, standards, calibration/ certification

1. ISO-9001: 2008
2. Product should qualify WHO PQS standard E006/007 E006/009 (Freeze Alert) along with E006/007 (Freeze Tag) [Specification reference-WHO PQS E06/IN03.1]

5. Configuration/ user programming

Non-programmable, irreversible design, with one start button/ no stop button.

6. Environmental/ safety factors/ disposal guidance

1. Conformity to Montreal protocol/ non-utilization of hazardous chemicals.
2. As per WHO PQS guidance.

7. Quality Assurance/ Product verification/ Testing protocol/ methods and checklists of tests

1. Independent third party Quality Assurance/ Product verification/ Testing laboratory
2. Product specification verification protocol- WHO PQS E06/IN03.VP.1 and associated standards.

8. Training, demonstration, and documentation / manuals

1. User instructions / essential product details in English and Hindi on unit/ as instruction sheet.
2. Training- Colored brochure and CD/DVD with easy to understand Video on product features/ activation, display and interpretation (English & Hindi) - one set for each 200 units' / standard packing.

9. Warrantee management/ liability

1. One year replacement warrantee against manufacturing defects.

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