CAPA DETAILS

Report Filters			
Hospital	Cypress Testing	**Department**	Resource Managament
Title	Policies		

CAPA Details	
CAPA No	uiCAPA0017
Title	Policies
Reported On	13-Oct-2025
Reported By	Siddhesh
Criticality	2
CAPA Type	Supplier
CAPA Against	Product
CAPA Source	Audit
Department	Resource Managament
Owner	Siddhesh
Problem Reported	not supported
Root Cause	SOPs (Standard Operating Procedures) for CAPA handling
How to Prevent?	response
Status	Open
Plan Details	
Investigation Assignee	NA
Investigation Due Date	-
Implementation Assignee	NA
Implementation Due Date	-
Completion Assignee	NA
Completion Due Date	-
Investigation Details	
Initial Risk	NA
Final Risk	NA
Occurance Date	-
Detection Rating	NA
Implementation & Completetion Details	
Action Taken	NA
Action Taken On	-
Completed By	NA
Turnaround Time	00 Days

Feedback Details

User	Department	Designation	Feedback Rating	Feedback Date

CAPA DETAILS

FDA Code 21 CFR Part 11 Compliance

Labcare is a truly “paperless” monitoring and recording service. All electronic records are fully FDA 21 CFR part 11 compliant and **securely stored on mirrored servers in two different geographical locations for up to 30 years.**

The service Labcare fully meets the exacting requirements of the FDA code which includes the use of unique electronic signatures specifically linked to operator names that are fully traceable. In addition our IT servers and databases are regulated and managed through the Company’s ISO9001:2008 quality management system.

FDA 21 CFR part 11 specifically regulates the secure creation, storage and management of electronic temperature records, Instrument logs under a strict electronic signature policy that is the gold standard for data compliance in the field of monitoring systems.

Through our rigorous data security protocols, coupled with our 24/7 global data access via web-browser interfaces; our customers enjoy unprecedented data security, access and control of their monitoring processes.

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Whenever electronic records are generated the importance of protecting the integrity, security and traceability of the records is critical to any business operating in a regulatory environment.

Since the publication by the FDA of 21 CFR part 11 code, electronic records and signatures can now be assumed to be equivalent to paper records and hand written signatures.

Due to the nature of the Labcare remote monitoring service, compliance with code 21 CFR part 11 is easily achieved as fundamentally all data records are stored and maintained securely at an off-site ‘Cloud’ location where system access to the records is securely managed.

Naturally the FDA code 21 CFR part 11 and subsequent issues of guidelines are open to interpretation. However, the key intention and requirements of this code are very clear.

It is the users responsibility to manage the usage of issue of electronic signatures, generated doc, However Shivani/ Labcare system will not be responsible for any perpetual tampering of data using a 3rd party software/ converter.

Labcare system access limited to authorized individuals via individual unique ID and password. However Shivani/ Labcare will not be responsible for user sharing the user related to credential with any other individual.

Labcare system user credential is binded to single system and user cannot log into other instrument or system until logged out. However user can opt out of this feature where Shivani/ Labcare system will not be responsible of any accidental accessing by any other user.

Labcare provides values of various parameter collected from different instrument trough their communication protocol or parameters collected through various sensor and do not manipulate the data, but the data do not assure the unit to be working accurately as per standards, which need to be periodically verified by a Third party audit.

Labcare captures and stores the data, audit trails or reports for period of 3years only after which it will be deleted, but user can opt for higher retention period trough by a subscription fee.

This white paper is intended to assist our existing and potential Labcare monitoring systems customers to satisfy themselves that the systems installed in their facilities are fully compliant with the FDA code.