

SPANDAN QUALITY CONTROL TEST REPORT

PART 1 - OVERVIEW

Device Information

Device ID	Manufacturing Date/Time	Production Plant ID	Batch ID	Firmware Version
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Stages Overview

Stage Name	Description	Operator ID	Remark
STAGE 1	PCB Programming		
STAGE 2	Connection and sampling test		
	Signal/trace accuracy test		
	ECG parameters accuracy test		
STAGE 3	Device Assembly		
STAGE 4	Barcode Generation		
STAGE 5	Chest Leads, USB Cables Entry		
STAGE 6	Connection and sampling test		
	Signal/trace accuracy test		
	ECG parameters accuracy test		

Final Assessment

Status :

Reason: -

ActionRequired: -

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PART 2a - QUALITY TEST TRACE ANALYSIS

Device Information

Device ID	Manufacturing Date/Time	Production Plant ID	Batch ID	Firmware Version
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Quality Test Analysis

■ Trace recorded by device ■ Standard signal

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PART 2b - QUALITY TEST PARAMETERS ANALYSIS

Device Information

Device ID	Manufacturing Date/Time	Production Plant ID	Batch ID	Firmware Version
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ECG Parameters

Parameter	CCV	Acceptance value	Tolerance	Difference	Result
PR Interval		130 ms	±10 ms		
QRS Interval		98 ms	±5 ms		
QT Interval		370 ms	±10 ms		
QTc Interval		402 ms	±10 ms		
RR Interval		1299 ms	±50 ms		
Heart rate		78 BPM	±1 bpm		
Q Amplitude		1.83 mV	±0.1 mV		
R Amplitude		3.22 mV	±0.1 mV		
S Amplitude		-2.9 mV	±0.1 mV		
Number of Samples obtained from the device (All values are in sample(s))					
V1		5000	±100		
V2		5000	±100		
V3		5000	±100		
V4		5000	±100		
V5		5000	±100		
V6		5000	±100		
Lead I		5000	±100		
Lead II		5000	±100		