

Device Test Report

Manufacturer: Stockert

Model: EP-SHUTTLE

Serial Number: ST-0612

Work Sheet: 19634

Page 1 of 5

Check List

Adjustment/Linearity	= OK
Analogue Filter	= OK
Cleanliness	= OK
Connectors	= OK
CoolFlow connection	= OK
Display	= OK
Foot Pedal connection	= OK
Frontpanel secured	= OK
Functional Tests	= OK
Global Port connection	= OK
Impedance reading	= OK
Indif. Electrode detection	= OK
Keypad	= OK
Label JJ	= OK
Labels/Inscriptions	= OK
Main Fuses	= OK
Optocoupler NIS board calibration	= OK
Output Power test	= OK
Package	= OK
PM Label	= OK
Power decrease after Temp. setpoint	= OK
Power increase after Start	= OK
Power Label/SW match	= OK
Remote Function	= OK
RF-Ramp NIS Check	= OK

IM 08.06.15 A

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Page 2 of 5

Safety Test Completed	= OK
Screwings	= OK
Selector Knob	= OK
Self Test	= OK
Signals Analogue ECG	= OK
Signals Digital ECG	= OK
SN Label/SW Match	= OK
Temp CTRL Ablation 4mm	= OK
Temp CTRL Ablation 8mm	= OK
Temp. increase after Start	= OK
Visual Inspection	= OK

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Page 3 of 5

Measured Values

Impedance 0 Ohm [0-12]	= 3
Impedance 100 Ohm [95-105]	= 102
Indiferent 47 Ohm (only for CPU Impedance SW>=04.01) [410-450]	= 432
Indiferent Close [0]	= 0
Indiferent Open [816-1.02]	= 1.02
Power delivery 100 W [99-101]	= 99
Power Version W	= 100
Revision Nr.	= 18
RF Current at 50W [710-730] mA	= 720
RF Voltage at 50W [71-73] V	= 71
SW Check (C0) CPU Master 0 (min. 02.01)	= 0.2/0.1
SW Check (C1) CPU Master 1 (min. 34.01)	= 3.5/0.1
SW Check (C2) CPU Impedance (min. 02.01)	= 0.4/0.1
SW Check (C3) CPU ECG (min. 04.01)	= 0.4/0.1
SW Check (C4) CPU Multi Temp (min. 02.02)	= 0.2/0.2
SW Check (C6) CPU Display (min. 05.01)	= 0.5/0.1
SW Check (C7) CPU Docu (min. 06.03)	= 0.8/0.3
SW Version	= 1.035
Temp Dual TC1 25°C [24-26]	= 25,3
Temp Dual TC1 90°C [88-92]	= 90,8
Temp Dual TC2 25°C [24-26]	= 25,3
Temp Dual TC2 90°C [88-92]	= 91,3
Temp. TC 25°C [24-26]	= 25,2
Temp. TC 90°C [88-92]	= 90,3
Temp. THR 25°C [24-26]	= 24,2

IM 08.06.15 A

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Work Sheet: 19634

Page 4 of 5

Temp. THR 90°C [90-94]

= 90,4

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Customer: Fakultni Nemocnice Ostrava-Poruba
 I. Interni Klinika
 70852 Ostrava
 Czech Republic

Failure Reported: During procedure generator re-starts (DC/DC converter defective); 1 board rail broken

Work done: DC/DC converter replacement; Board rail replacement; MDV board calibration; Dual Temp board calibration; PM and full system tests

Test Passed *Signature* 

Test done at: 30-10-2007 **Next Test:** 30-10-2008

P.S.: Safety Test Report Attached

Legend for safety test 'Applied Parts Leakage':

- AP1 = Catheter TIP
- AP2 = Catheter Ring2
- AP3 = Catheter Ring3
- AP4 = Catheter Ring4
- AP5 = Indifferent Electrode

S A F E T Y T E S T R E P O R T

E P - S H U T T L E 1 0 0 W

Device No. : ST-0612

Safety test was performed in accordance with standards: DIN EN 60601-1, DIN EN 60601-2-2 and the work instructions AA1030021.

The safety test was performed with the measuring device:

GMN;Secutest SIII A00 D00;M7010;MH 998262 0001;01;XXXXXXXXX;0C;22;GMC V 6.5

MD was checked with Secutest device test box.

OK

Visual inspection

OK

Short circuit check

OK

Ground resistance enclosure socket PE connection to

	Measurement	Tolerance	Standard	Status
Cover bottom	+0,021 Ohm	0.005-0.03 Ohm	< 0.1 Ohm	OK
Cover top	+0,021 Ohm	0.005-0.03 Ohm	< 0.1 Ohm	OK
POAG	+0,021 Ohm	0.005-0.03 Ohm	< 0.1 Ohm	OK

Insulation resistance

	Measurement	Tolerance	Standard	Status
PE-N,L (R _{ISO})	>+310,0 MOhm	100-500 MOhm	> 70 MOhm	OK
PE-Tip	>+310,0 MOhm	100-500 MOhm	> 70 MOhm	OK
PE-Ring2	>+310,0 MOhm	100-500 MOhm	> 70 MOhm	OK
PE-Ring3	>+310,0 MOhm	100-500 MOhm	> 70 MOhm	OK
PE-Ring4	>+310,0 MOhm	100-500 MOhm	> 70 MOhm	OK
PE-Ring5	>+310,0 MOhm	100-500 MOhm	> 70 MOhm	OK
PE-Ring6	>+310,0 MOhm	100-500 MOhm	> 70 MOhm	OK
PE-THR	>+310,0 MOhm	100-500 MOhm	> 70 MOhm	OK
PE-TC1	>+310,0 MOhm	100-500 MOhm	> 70 MOhm	OK
PE-Indif	>+310,0 MOhm	100-500 MOhm	> 70 MOhm	OK

High voltage test

	Measurement	Tolerance	Standard	Status
Adjustment = 1.5 kV; 60 s	1520V	1.5-2 kV	> 1.5 kV	OK

Earth leakage current

	Measurement	Tolerance	Standard	Status
NC L/N DC	+0,000 mA	0-6 µA	< 0.5mA	OK
NC N/L DC (pol changing)	+0,000 mA	0-6 µA	< 0.5mA	OK
NC L/N AC	+0,010 mA	5-35 µA	< 0.5mA	OK
NC N/L AC (pol changing)	+0,009 mA	5-35 µA	< 0.5mA	OK
SFC N disconnected	+0,019 mA	5-35 µA	< 1 mA	OK

Enclosure leakage current

	Measurement	Tolerance	Standard	Status
NC L/N DC	+000,0 uA	0-10 µA	< 100 µA	OK
NC N/L DC (pol changing)	+000,0 uA	0-10 µA	< 100 µA	OK
NC L/N AC	+000,0 uA	0-10 µA	< 100 µA	OK
NC N/L AC (pol changing)	+000,0 uA	0-10 µA	< 100 µA	OK
SFC PE L/N DC	+000,2 uA	0-10 µA	< 500 µA	OK
SFC PE N/L DC (pol changing)	+000,2 uA	0-10 µA	< 500 µA	OK
SFC PE L/N AC	+010,2 uA	1-40 µA	< 500 µA	OK
SFC PE N/L AC (pol changing)	+009,8 uA	1-40 µA	< 500 µA	OK

Patient leakage current

	Measurement	Tolerance	Standard	Status
Tip NC DC	+000,2 uA	0-10 µA	< 10 µA	OK
Tip NC AC	+000,0 uA	0-10 µA	< 10 µA	OK
Tip SFC PE DC	+000,2 uA	0-10 µA	< 50 µA	OK
Tip SFC PE AC	+002,3 uA	0.5-15 µA	< 50 µA	OK
Tip SFC N disconnected	+000,0 uA	0-10 µA	< 50 µA	OK
Ring2 NC DC	+000,2 uA	0-10 µA	< 10 µA	OK
Ring2 NC AC	+000,0 uA	0-10 µA	< 10 µA	OK
Ring2 SFC PE DC	+000,2 uA	0-10 µA	< 50 µA	OK
Ring2 SFC PE AC	+002,2 uA	0.5-15 µA	< 50 µA	OK
Ring2 SFC N disconnected	+000,0 uA	0-10 µA	< 50 µA	OK
Ring3 NC DC	+000,2 uA	0-10 µA	< 10 µA	OK
Ring3 NC AC	+000,0 uA	0-10 µA	< 10 µA	OK
Ring3 SFC PE DC	+000,2 uA	0-10 µA	< 50 µA	OK
Ring3 SFC PE AC	+002,2 uA	0.5-15 µA	< 50 µA	OK
Ring3 SFC N disconnected	+000,0 uA	0-10 µA	< 50 µA	OK
Ring4 NC DC	+000,2 uA	0-10 µA	< 10 µA	OK
Ring4 NC AC	+000,0 uA	0-10 µA	< 10 µA	OK
Ring4 SFC PE DC	+000,2 uA	0-10 µA	< 50 µA	OK
Ring4 SFC PE AC	+002,1 uA	0.5-15 µA	< 50 µA	OK
Ring4 SFC N disconnected	+000,0 uA	0-10 µA	< 50 µA	OK

Patient leakage current	Measurement	Tolerance	Standard	Status
Ring5 NC DC	+000,2 uA	0-10 uA	< 10 uA	OK
Ring5 NC AC	+000,0 uA	0-10 uA	< 10 uA	OK
Ring5 SFC PE DC	+000,2 uA	0-10 uA	< 50 uA	OK
Ring5 SFC PE AC	+000,9 uA	0.5-15 uA	< 50 uA	OK
Ring5 SFC N disconnected	+000,0 uA	0-10 uA	< 50 uA	OK
Ring6 NC DC	+000,2 uA	0-10 uA	< 10 uA	OK
Ring6 NC AC	+000,0 uA	0-10 uA	< 10 uA	OK
Ring6 SFC PE DC	+000,2 uA	0-10 uA	< 50 uA	OK
Ring6 SFC PE AC	+000,8 uA	0.5-15 uA	< 50 uA	OK
Ring6 SFC N disconnected	+000,1 uA	0-10 uA	< 50 uA	OK
Indif NC DC	+000,2 uA	0-10 uA	< 10 uA	OK
Indif NC AC	+000,0 uA	0-10 uA	< 10 uA	OK
Indif SFC PE DC	+000,2 uA	0-10 uA	< 50 uA	OK
Indif SFC PE AC	+002,3 uA	0.5-15 uA	< 50 uA	OK
Indif SFC N disconnected	+000,1 uA	0-10 uA	< 50 uA	OK
Mains on applied parts	Measurement	Tolerance	Standard	Status
Applied parts SFC L/N	+018,5 uA	10-35 uA	< 50 uA	OK
Applied parts SFC N/L	+018,5 uA	10-35 uA	< 50 uA	OK
Patient auxiliary current	Measurement	Tolerance	Standard	Status
Tip NC DC	+000,2 uA	0-10 uA	< 10 uA	OK
Tip NC AC	+000,0 uA	0-10 uA	< 10 uA	OK
Tip SFC PE DC	+000,2 uA	0-10 uA	< 50 uA	OK
Tip SFC PE AC	+000,0 uA	0-10 uA	< 50 uA	OK
Ring2 NC DC	+000,2 uA	0-10 uA	< 10 uA	OK
Ring2 NC AC	+000,0 uA	0-10 uA	< 10 uA	OK
Ring2 SFC PE DC	+000,2 uA	0-10 uA	< 50 uA	OK
Ring2 SFC PE AC	+000,0 uA	0-10 uA	< 50 uA	OK
Ring3 NC DC	+000,2 uA	0-10 uA	< 10 uA	OK
Ring3 NC AC	+000,0 uA	0-10 uA	< 10 uA	OK
Ring3 SFC PE DC	+000,2 uA	0-10 uA	< 50 uA	OK
Ring3 SFC PE AC	+000,0 uA	0-10 uA	< 50 uA	OK
Ring4 NC DC	+000,2 uA	0-10 uA	< 10 uA	OK
Ring4 NC AC	+000,0 uA	0-10 uA	< 10 uA	OK
Ring4 SFC PE DC	+000,2 uA	0-10 uA	< 50 uA	OK
Ring4 SFC PE AC	+000,0 uA	0-10 uA	< 50 uA	OK
Ring5 NC DC	+000,2 uA	0-10 uA	< 10 uA	OK
Ring5 NC AC	+000,0 uA	0-10 uA	< 10 uA	OK
Ring5 SFC PE DC	+000,2 uA	0-10 uA	< 50 uA	OK
Ring5 SFC PE AC	+000,0 uA	0-10 uA	< 50 uA	OK
Ring6 NC DC	+000,2 uA	0-10 uA	< 10 uA	OK
Ring6 NC AC	+000,0 uA	0-10 uA	< 10 uA	OK
Ring6 SFC PE DC	+000,2 uA	0-10 uA	< 50 uA	OK
Ring6 SFC PE AC	+000,0 uA	0-10 uA	< 50 uA	OK
Indif NC DC	+000,2 uA	0-10 uA	< 10 uA	OK
Indif NC AC	+000,0 uA	0-10 uA	< 10 uA	OK
Indif SFC PE DC	+000,2 uA	0-10 uA	< 50 uA	OK
Indif SFC PE AC	+000,6 uA	0-10 uA	< 50 uA	OK

High frequency leakage current

The safety test was performed with the METRON QA-ES measuring device MG042.

	Measurement	Tolerance	Standard	Status
Tip (IEC 60601-2-2 picture 103)	90,0 mA	60-100 mA	< 150 mA	OK
Indif (IEC 60601-2-2 picture 103)	48,0 mA	30-100 mA	< 150 mA	OK

Safety check was recorded in the final test protocol. The final test protocol is filed in the device history record.

Device has passed the test

YES

Gerät hat die Prüfung bestanden

JA

Company *Johnson & Johnson Medical*
 Date 30.10.2007 11:24
 Tested by LM
 Next test 29.10.2008
 Signature