

6.2.2 ต้องทดสอบและตรวจสอบการทำงานของเครื่องมือแพทย์ก่อนการตรวจรับ





Bender GmbH & Co. KG
Londorferstra? 65
D-35305 Gr?berg

Device protocol

Device ID : BM1

Serial number	-	City	-
Manufacturer	BIONET	Street	-
Designation	-	Building	-
Test costs	-	Department	-
Client	-	Room	-
Comment	01088092769436201124013121DRC1ENA0003		

Test specification

Name : BM1

Standard	IEC 60601-1:2005-12	Protection class	C I
Manufacturer	BIONET	Date	6/21/2022
Designation	-		

Applied part

Group 1 Type CF Socket 1-2

Visual inspection

- ✓ Required documentation is available and reflects the current revision of the ME equipment, ME system
- ✓ Safety-related markings, labels and labelling are legible and complete
- ✓ Cord anchorage and cord guard of the power supply cord are free from defects
- ✓ Relevant accessories of the ME equipment are OK (e.g. cable, patient connections, tubings)
- ✓ Access covers which can be opened without the use of a tool are in good working order
- ✓ Functional earth terminal must not be used as a protective earth connection
- ✓ No hazards arising from component attachments or inadvertent loosening of cord connections
- ✓ Guiding rollers for insulated cords and the insulation of internal cord connections are in good condition
- ✓ The mains terminal devices comply with the general requirements and directives
- ✓ The fixing and connection of mains terminals are carried out properly
- ✓ Appropriate device fuses (nominal current, nominal voltage, breaking characteristics)
- ✓ Connections and accessible plug-in devices are designed to prevent incorrect wiring
- ✓ Connecting leads within a ME system are protected against mechanical damage
- ✓ The connection of the equipotential bonding conductor can be removed without the use of a tool and is protected against inadvertent loosening
- ✓ PE connections will not be interrupted when removing parts from ME systems

Electrical test steps

Voltage 264 volts (Ref. for measured current values)

No.	Meas. value	Limit value	Group: AP	
✓ 103	0.067 Ω	0.200 Ω		PE resistance, permanently attached cord (25A EPS800)
✓ 80	0.040 A	-		Load current
✓ 81	212 V	-		Operating voltage
✓ 82	0.008 kVA	-		Power consumption
✓ 7	0.033 mA	5.000 mA		Earth leak, curr. NC
✓ 9	0.032 mA	5.000 mA		Earth leak, curr. NC AP->PE
✓ 310	< 0.001 mA	0.100 mA		Touch current NC
✓ 312	< 0.001 mA	0.100 mA		Touch current NC AP->PE
✓ 326	0.033 mA	0.500 mA		Touch current SFC PE-O
✓ 328	0.033 mA	0.500 mA		Touch current SFC PE-O AP->PE
✓ 400	< 0.001 mA	0.010 mA	1: 1	Applied part leak, curr. NC DC
✓ 400	< 0.001 mA	0.010 mA	1: 2	Applied part leak, curr. NC DC
✓ 401	< 0.001 mA	0.010 mA	1: 1	Applied part leak, curr. NC AC
✓ 401	< 0.001 mA	0.010 mA	1: 2	Applied part leak, curr. NC AC
✓ 424	< 0.001 mA	0.010 mA	1: 1	Applied part leak, curr. NC DC NEP

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No.	Meas. value	Limit value	Group: AP	
✓ 424	< 0.001 mA	0.010 mA	1: 2	Applied part leak, curr. NC DC NEP
✓ 425	< 0.001 mA	0.010 mA	1: 1	Applied part leak, curr. NC AC NEP
✓ 425	< 0.001 mA	0.010 mA	1: 2	Applied part leak, curr. NC AC NEP
✓ 416	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC DC PE-O
✓ 416	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC DC PE-O
✓ 417	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC AC PE-O
✓ 417	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC AC PE-O
✓ 440	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC DC NEP PE-O
✓ 440	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC DC NEP PE-O
✓ 441	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC AC NEP PE-O
✓ 441	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC AC NEP PE-O
✓ 550	0.003 mA	0.050 mA	1: 1	Applied part leak, curr. SFC U-AP
✓ 550	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC U-AP
✓ 554	0.006 mA	0.050 mA	1: 1	Applied part leak, curr. SFC Ph-r U-AP
✓ 554	0.003 mA	0.050 mA	1: 2	Applied part leak, curr. SFC Ph-r U-AP
✓ 558	0.006 mA	0.050 mA	1: 1	Applied part leak, curr. SFC U-AP NEP
✓ 558	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC U-AP NEP
✓ 562	0.007 mA	0.050 mA	1: 1	Applied part leak, curr. SFC Ph-r U-AP NEP
✓ 562	0.003 mA	0.050 mA	1: 2	Applied part leak, curr. SFC Ph-r U-AP NEP
✓ 250	< 0.001 mA	0.010 mA	1: 1	Patient auxiliary current NC DC
✓ 251	< 0.001 mA	0.010 mA	1: 1	Patient auxiliary current NC AC
✓ 266	< 0.001 mA	0.050 mA	1: 1	Patient auxiliary current SFC DC PE-O
✓ 267	< 0.001 mA	0.050 mA	1: 1	Patient auxiliary current SFC AC PE-O
✓ 8	0.032 mA	5.000 mA		Earth leak, curr. NC Ph-r
✓ 10	0.032 mA	5.000 mA		Earth leak, curr. NC AP->PE Ph-r
✓ 311	< 0.001 mA	0.100 mA		Touch current NC Ph-r
✓ 313	< 0.001 mA	0.100 mA		Touch current NC AP->PE Ph-r
✓ 327	0.033 mA	0.500 mA		Touch current SFC PE-O Ph-r
✓ 329	0.033 mA	0.500 mA		Touch current SFC PE-O AP->PE Ph-r
✓ 402	< 0.001 mA	0.010 mA	1: 1	Applied part leak, curr. NC DC Ph-r
✓ 402	< 0.001 mA	0.010 mA	1: 2	Applied part leak, curr. NC DC Ph-r
✓ 403	< 0.001 mA	0.010 mA	1: 1	Applied part leak, curr. NC AC Ph-r
✓ 403	< 0.001 mA	0.010 mA	1: 2	Applied part leak, curr. NC AC Ph-r
✓ 426	< 0.001 mA	0.010 mA	1: 1	Applied part leak, curr. NC DC NEP Ph-r
✓ 426	< 0.001 mA	0.010 mA	1: 2	Applied part leak, curr. NC DC NEP Ph-r
✓ 427	< 0.001 mA	0.010 mA	1: 1	Applied part leak, curr. NC AC NEP Ph-r
✓ 427	< 0.001 mA	0.010 mA	1: 2	Applied part leak, curr. NC AC NEP Ph-r
✓ 418	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC DC PE-O Ph-r
✓ 418	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC DC PE-O Ph-r
✓ 419	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC AC PE-O Ph-r
✓ 419	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC AC PE-O Ph-r
✓ 442	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC DC NEP PE-O Ph-r
✓ 442	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC DC NEP PE-O Ph-r
✓ 443	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC AC NEP PE-O Ph-r
✓ 443	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC AC NEP PE-O Ph-r
✓ 551	0.003 mA	0.050 mA	1: 1	Applied part leak, curr. SFC U-AP Ph-r
✓ 551	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC U-AP Ph-r
✓ 555	0.006 mA	0.050 mA	1: 1	Applied part leak, curr. SFC Ph-r U-AP Ph-r
✓ 555	0.002 mA	0.050 mA	1: 2	Applied part leak, curr. SFC Ph-r U-AP Ph-r
✓ 559	0.006 mA	0.050 mA	1: 1	Applied part leak, curr. SFC U-AP NEP Ph-r
✓ 559	0.002 mA	0.050 mA	1: 2	Applied part leak, curr. SFC U-AP NEP Ph-r
✓ 563	0.007 mA	0.050 mA	1: 1	Applied part leak, curr. SFC Ph-r U-AP NEP Ph-r
✓ 563	0.003 mA	0.050 mA	1: 2	Applied part leak, curr. SFC Ph-r U-AP NEP Ph-r
✓ 252	< 0.001 mA	0.010 mA	1: 1	Patient auxiliary current NC DC Ph-r
✓ 253	< 0.001 mA	0.010 mA	1: 1	Patient auxiliary current NC AC Ph-r
✓ 268	< 0.001 mA	0.050 mA	1: 1	Patient auxiliary current SFC DC PE-O Ph-r
✓ 269	< 0.001 mA	0.050 mA	1: 1	Patient auxiliary current SFC AC PE-O Ph-r
✓ 15	0.044 mA	10.000 mA		Earth leak, curr. SFC SC-O
✓ 17	0.044 mA	10.000 mA		Earth leak, curr. SFC SC-O AP->PE

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No.	Meas. value	Limit value	Group: AP	
✓ 318	< 0.001 mA	0.500 mA		Touch current SFC SC-O
✓ 320	< 0.001 mA	0.500 mA		Touch current SFC SC-O AP->PE
✓ 408	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC DC SC-O
✓ 408	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC DC SC-O
✓ 409	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC AC SC-O
✓ 409	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC AC SC-O
✓ 432	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC DC NEP SC-O
✓ 432	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC DC NEP SC-O
✓ 433	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC AC NEP SC-O
✓ 433	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC AC NEP SC-O
✓ 258	< 0.001 mA	0.050 mA	1: 1	Patient auxiliary current SFC DC SC-O
✓ 259	< 0.001 mA	0.050 mA	1: 1	Patient auxiliary current SFC AC SC-O
✓ 16	0.056 mA	10.000 mA		Earth leak, curr. SFC SC-O Ph-r
✓ 18	0.055 mA	10.000 mA		Earth leak, curr. SFC SC-O AP->PE Ph-r
✓ 319	< 0.001 mA	0.500 mA		Touch current SFC SC-O Ph-r
✓ 321	< 0.001 mA	0.500 mA		Touch current SFC SC-O AP->PE Ph-r
✓ 410	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC DC SC-O Ph-r
✓ 410	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC DC SC-O Ph-r
✓ 411	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC AC SC-O Ph-r
✓ 411	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC AC SC-O Ph-r
✓ 434	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC DC NEP SC-O Ph-r
✓ 434	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC DC NEP SC-O Ph-r
✓ 435	< 0.001 mA	0.050 mA	1: 1	Applied part leak, curr. SFC AC NEP SC-O Ph-r
✓ 435	< 0.001 mA	0.050 mA	1: 2	Applied part leak, curr. SFC AC NEP SC-O Ph-r
✓ 260	< 0.001 mA	0.050 mA	1: 1	Patient auxiliary current SFC DC SC-O Ph-r
✓ 261	< 0.001 mA	0.050 mA	1: 1	Patient auxiliary current SFC AC SC-O Ph-r

Functional test

✓ Functional test

Test PASSED



Test engineer KIM HAN SU
Test date 1/31/2024

Signature



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