



Nufer Medical – let's find the best solutions

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Certified according to ISO 13485

Test Record

TEST PASSED

Test Performed

Date: 07.02.2018
Record: 151231117.mtr
Template: 34.002.2_Endkontrolle
Wärmestrahler.mtt
Template Version: 34.2.9

Ansurs Components Used

Ansurs Version 3.1.3
Plug-In: AVPI Version 2.4.11
Plug-In: ESA620 Version 1.2.6

Test Setup

Selections

Service Events Performed	Standards Performed
	User defined IEC 60601

Device under test

Serial number	151231117	Type	Säuglingswärmestrahler
Appliance code	NM	Model	Ceratherm 600-3
Group	1800223	Location	Viamed Limited
Status		Address 1	15 Station Road / Cross Hills
Manufacturer	Nufer Medical AG	Address 2	BD20 7DT Keighley, W. Yorks - GB

MTI Data

Test Instrument	Serial Number	Firmware Version
ESA 620	1247007	v2.11

Signatures

Test Result

Test Element	Test Type	Fail
Mechanischer Check/ Mechanical check /Test mécanique	Checklist	
Result: Sichtkontrolle / Visual check / Contrôle visuel Zubehör komplett / Accessories complete / Acc. complets Gerät gereinigt / Equipment cleaned / Appareil nettoyé Fahrgestell arretierbar und höhenverstellbar / Mobile floor stand lockable and height adjustable / Pied mobile verrouillable et hauteur réglable Halterung / support / crochet	Recorded Value Pass Pass Pass Not Applicable Pass	
Funktionstest / Function control / Contrôle de fonctionnement	Checklist	
Result: Hauptschalter prüfen / Check main switch / Contrôle interrupteur principal Tasten und Anzeigen prüfen / Check buttons and label / Contrôle les boutons et l'autocollone Heizungen 4 Stufen wählbar / Heater (4 steps) / Chauffage (4 pos.) LED-Lampe (2Stufen)/ LED lamp (2 levels)/ Lampe LED (2 niveau)	Recorded Value Pass Pass Pass Pass	
1. Alarme / Alarms / Alarme	Numerical List	
Limits: Ansur - User defined Akustisch und optisch nach / Acoustical and optical after / Acoustique et Optique après Result: Akustisch und optisch nach / Acoustical and optical after / Acoustique et Optique après	High Value 15 Recorded Value 15	Low Value 15 min
2. Alarme / Alarms / Alarme	Checklist	
Result: Alarm-Rückstellung Erinnerungs-Alarm/ Reminder-Alert Mute/ Alarm acquiter Akustisch und optisch Netzausfallalarm / Acoustical and optical powerlose-alarm / Acoustique et Optique alarm panne de courant	Recorded Value Pass Pass	

Test Element	Test Type				Fail
Result: Alarm-Rückstellung Netzausfallalarm/ Powerlose-alarm mute/ Alarm panne de courant acquiter	Recorded Value Pass				
Diverses / Miscellaneous / Divers	Checklist				
Result: Material Komplet (gem. Auftragsbestätigung) / Material complete / Matériel complet Gerät in VoM aufgenommen / Equipment recorded / Appareil enregistré Seriennummer-Etikette vorhanden / Serial no. / No. de série Piktogramm beidseitig vorhanden / Pictogram / Pictogram Fahrgestell Warnhinweis "Standortwechsel" / Mobile floor stand, warning label "displace" / Pied mobile, signal de danger "déplacer" Bedienungsanleitung / User's Manual / Manual d'utilisation Service Anleitung / Service Manual / Manual de service	Recorded Value Pass Pass Pass Pass Not Applicable Pass Not Applicable				
Electrical Safety Test IEC 60601-1 - Class 1 Typ B	Auto Sequence				
Procedure: (1) Ceratherm 600-2 an ESA620 Netzstecker und Poag anschliessen. (2) Sicherstellen, dass das Gerät eingeschaltet ist. (3) Start Test drücken um den Elektrischen Sicherheitstest zu starten.					
Result: Test Group	Value 2.7	Unit A	High Limit	Low Limit	Standard IEC 60601 User defined
Mains Voltage	Mains Voltage				
Live to Neutral	Mains Voltage Live to Neutral				
Result: Live to Neutral	Value 227.9	Unit V	High Limit	Low Limit	Standard IEC 60601 User defined
Neutral to Earth	Mains Voltage Neutral to Earth				
Result: Neutral to Earth	Value 0.3	Unit V	High Limit	Low Limit	Standard IEC 60601 User defined
Live to Earth	Mains Voltage Live to Earth				
Result: Live to Earth	Value 228.7	Unit V	High Limit	Low Limit	Standard IEC 60601 User defined
Earth Resistance	Earth Resistance				

Test Element	Test Type					Fail
Result: PE Resistance1	Value 0.053	Unit Ohm	High Limit 0.2 0.2	Low Limit	Standard IEC 60601 User defined	
Equipment Current	Equipment Current					
Procedure: Gerät muss auf Stufe 4 laufen!						
Result: Equipment Current	Value 2.7	Unit A	High Limit 2.9 2.9	Low Limit 2.4 2.4	Standard IEC 60601 User defined	
Insulation Resistance	Insulation Resistance					
Mains to Protective Earth	Insulation Resistance Mains to Protective Earth					
Result: Mains to Protective Earth	Value 99999	Unit MOhm	High Limit	Low Limit 2 2	Standard IEC 60601 User defined	
Earth Leakage Current	Earth Leakage Current					
Normal Condition	Earth Leakage Current Normal Condition					
Result: Normal Condition	Value 61.1	Unit uAAC+DC	High Limit 5000 5000	Low Limit	Standard IEC 60601 User defined	
Open Neutral	Earth Leakage Current Open Neutral					
Result: Open Neutral	Value 118.5	Unit uAAC+DC	High Limit 10000 10000	Low Limit	Standard IEC 60601 User defined	
Normal Condition, Reversed mains	Earth Leakage Current Normal Condition, Reversed mains					
Result: Normal Condition, Reversed mains	Value 59.7	Unit uAAC+DC	High Limit 5000 5000	Low Limit	Standard IEC 60601 User defined	
Open Neutral, Reversed Mains	Earth Leakage Current Open Neutral, Reversed Mains					
Result: Open Neutral, Reversed Mains	Value 118.7	Unit uAAC+DC	High Limit 10000 10000	Low Limit	Standard IEC 60601 User defined	
Enclosure Leakage Current	Enclosure Leakage Current					
Normal Condition	Enclosure Leakage Current Normal Condition					
Result: Normal Condition	Value 0.6	Unit uAAC+DC	High Limit 100 100	Low Limit	Standard IEC 60601 User defined	
Open Neutral	Enclosure Leakage Current Open Neutral					
Result: Open Neutral	Value 0.6	Unit uAAC+DC	High Limit 500 500	Low Limit	Standard IEC 60601 User defined	

Test Element	Test Type				Fail
Open Earth	Enclosure Leakage Current Open Earth				
Result: Open Earth	Value 58.7	Unit uAAC+DC	High Limit 500 500	Low Limit	Standard IEC 60601 User defined
Normal Condition, Reversed mains	Enclosure Leakage Current Normal Condition, Reversed mains				
Result: Normal Condition, Reversed mains	Value 0.5	Unit uAAC+DC	High Limit 100 100	Low Limit	Standard IEC 60601 User defined
Open Neutral, Reversed Mains	Enclosure Leakage Current Open Neutral, Reversed Mains				
Result: Open Neutral, Reversed Mains	Value 0.6	Unit uAAC+DC	High Limit 500 500	Low Limit	Standard IEC 60601 User defined
Open Earth, Reversed Mains	Enclosure Leakage Current Open Earth, Reversed Mains				
Result: Open Earth, Reversed Mains	Value 59.7	Unit uAAC+DC	High Limit 500 500	Low Limit	Standard IEC 60601 User defined