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TEST REPORT IEC 60601-2-21 Medical electrical equipment Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	
Report Number	170912056GZU-002
Date of issue	08 Nov 2017, Modification 1: 15 Jun 2019
Total number of pages	29
Name of Testing Laboratory preparing the Report	Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
Applicant's name	REER GMBH
Address	MUEHLSTRASSE 41, 71229 LEONBERG, GERMANY
Test specification:	
Standard	IEC 60601-2-21:2009, AMD1:2016
Test procedure	Test Report
Non-standard test method	N/A
Test Report Form No.	IEC60601_2_21D
Test Report Form(s) Originator	Intertek
Master TRF	Dated 2017-09-25
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Test item description :	Radiate heater
Trade Mark :	Reer
Manufacturer	Same as Applicant
Model/Type reference :	1920, 1922, 1926, 1928, 19030, 19033, 19034, 19037, 19040, 19050, 19060, 19070, 19300, 19310, 19320, 19330, 19131, 19133, 19130, 19134, 19137, 19035
Ratings :	Model: 1920, 1922, 1926, 1928, 19030, 19033, 19034, 19037, 19300, 19310 19131, 19133, 19130, 19134, 19137,19035 230 V ~, 50 Hz, 800 W Model: 19040, 19050, 19060, 19070, 19320, 19330 230 V ~, 50 Hz, 500 W

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
Testing location/ address :		Block E, No.7-2 Guang Dong Software Science Park, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China
Tested by (name, function, signature) :		Bin Zhong, Engineer
Approved by (name, function, signature) .. :		Raymond Yin, Asst. Technical Manger
<hr/>		
<input type="checkbox"/>	Testing procedure: CTF Stage 1:	N/A
Testing location/ address :		
Tested by (name, function, signature) :		
Approved by (name, function, signature) .. :		
<hr/>		
<input type="checkbox"/>	Testing procedure: CTF Stage 2:	N/A
Testing location/ address :		
Tested by (name + signature)..... :		
Witnessed by (name, function, signature) . :		
Approved by (name, function, signature) .. :		
<hr/>		
<input type="checkbox"/>	Testing procedure: CTF Stage 3:	N/A
<input type="checkbox"/>	Testing procedure: CTF Stage 4:	N/A
Testing location/ address :		
Tested by (name, function, signature) :		
Witnessed by (name, function, signature) . :		
Approved by (name, function, signature) .. :		
Supervised by (name, function, signature) :		

List of Attachments (including a total number of pages in each attachment):	
Appendix 1: Product photos (pages: 14)	
Summary of testing:	
Tests performed (name of test and test clause): Follow clause was performed: 201.10.6 Infrared radiation 201.12.1.102 accuracy of distribution of irradiation to the mattress	Testing location: Intertek Testing Services Shenzhen Ltd. Guangzhou Branch Block E, No.7-2 Guang Dong Software Science Park, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China
Summary of compliance with National Differences (List of countries addressed): None	
<input checked="" type="checkbox"/> The product fulfils the requirements of <u>clause 201.10.6 and clause 201.12.1.102 of IEC 60601-2-21:2009, AMD1:2016.</u>	

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



Remark: Other models have the same label except model, power.

Test item particulars :	
Classification of installation and use :	Transportable
Supply Connection	Non-detachable cord
..... :	
Possible test case verdicts:	
- test case does not apply to the test object..... :	N/A
- test object does meet the requirement..... :	P (Pass)
- test object does not meet the requirement..... :	F (Fail)
Testing :	
Date of receipt of test item	12 Sep 2017
Date (s) of performance of tests	12 Sep 2017 – 30 Sep 2017
General remarks:	
<p>"(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report.</p> <p>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</p> <p>Determination of the test conclusion is based on IEC Guide 115 in consideration of measurement uncertainty.</p> <p>This report is for the exclusive use of Intertek's Client and is provided pursuant to the agreement between Intertek and its Client. Intertek's responsibility and liability are limited to the terms and conditions of the agreement. Intertek assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this report. Only the Client is authorized to permit copying or distribution of this report and then only in its entirety. Any use of the Intertek name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by Intertek. The observations and test results in this report are relevant only to the sample tested. This report by itself does not imply that the material, product, or service is or has ever been under an Intertek certification program.</p> <p>The test report only allows to be revised only within the report defined retention period unless standard or regulation was withdrawn or invalid.</p> <p>This report is replacing the previous report 130206014GZU-002 and the report 130206014GZU-002 is superseded.</p> <p>Modification 1: this report is based on and superseded original report 170912056GZU-002, dated on 08 Nov 2017, with below modified:</p> <ol style="list-style-type: none"> 1. Added model 19300,19310,19320,19330 is the same as 1926,1928,19040,19050 respectively. 2. Added model 19131, 19133, 19130, 19134, 19137,19035 is the same as 1928 except enclosure colour. 3. Model 19300,19310,19320,19330 used power cord with a british standard plug. 4. Added Figure 13 –Figure 22. 5. Updated labelling. 	

Manufacturer's Declaration per sub-clause 4.2.5 of IEC60335-2-11:

<p>The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not applicable</p>
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When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies) : Same as Applicant

General product information and other remarks:

Model Similarity:

All these models have the following differences:

- 1) 1920, 1922, 1926, 1928, 19030, 19033, 19034, 19037 are the same radiate heater.
- 2) 1920 and 1926 are wall mounted type; 1922 and 1928 are portable type.
- 3) 1926 and 1928 are with timer and 1920 and 1922 are without timer.
- 4) 1928, 19030, 19033, 19034, 19037 are the same radiate heater with timer. Their plastic parts have different color. (See Appendix 1)
- 5) 19040, 19050, 19060 and 19070 are the same radiate heater. 19040 and 19050 have timer but 19060 and 19070 are without timer. 19040 and 19060 are wall mounted type; 19050 and 19070 are portable type. (See Appendix 1)

1920, 1922, 1926, 1928, 19030, 19033, 19034 and 19037 have two heating tube with 800 W power and 19040,19050, 19060 and 19070 have a heating tube with 500 W power.

IEC 60601-2-21			
Clause	Requirement + Test	Result - Remark	Verdict

201.10	PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS		P
201.10.6	The maximum irradiance level at any point on the mattress does not exceed 60 mW/cm ² in the total infra-red spectrum	See below	P
	Measured maximum irradiance level (mW/cm ²)	7.6 mW/cm ² for 800 W (dated 30 Sep 2017) 5 mW/cm² for 500 W	P
	The maximum irradiance level does not exceed 10 mW/ cm ² in the near infra-red spectrum (760 nm to 1 400 nm)	See below	P
	Measured maximum irradiance level in the near infra-red spectrum (mW/cm ²)	Less than 7.6 mW/cm ² for 800 W (dated 30 Sep 2017) 5 mW/cm² for 500 W	P

201.12	ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS		P
201.12.1.1 02	The difference between the MID- POINT AVERAGE TEMPERATURE and the TEST DEVICE AVERAGE TEMPERATURE of any of the other devices comprising the TEST LOAD does not exceed 2°C	See also appended Table 201.12.1.102	P

IEC 60601-2-21			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.102		TABLE: Accuracy of operating data					P
Air velocity, (m/s)	Ambient temp., (°C)	Temperature control settings, (°C)					
		MANUAL MODE			BABY CONTROLLED MODE		
< 0.1	23.04	P			N/A		
reading number (n)	individual temperature readings taken of TEST DEVICES, t_n (°C)					SKIN SENSOR reading, (°C)	
	1	2	3	4	M	—	
1	35.73	36.82	35.59	36.32	36.01	N/A	
2	35.68	36.86	35.24	36.06	36.03	N/A	
3	36.01	37.06	35.18	35.98	36.00	N/A	
4	36.05	36.72	36.68	35.93	36.00	N/A	
5	35.99	36.57	35.66	35.77	36.01	N/A	
6	35.92	36.48	35.83	35.82	36.03	N/A	
7	35.94	36.50	35.73	35.78	36.01	N/A	
8	36.03	36.51	35.74	35.79	36.02	N/A	
9	36.12	36.57	35.81	35.85	36.03	N/A	
10	36.07	36.52	35.73	35.77	36.01	N/A	
11	36.11	36.56	35.68	35.76	36.00	N/A	
12	36.14	36.59	35.71	35.81	36.00	N/A	
13	36.18	36.63	35.89	35.93	36.04	N/A	
14	36.15	36.62	35.83	35.89	36.02	N/A	
15	36.07	36.59	35.76	35.86	36.02	N/A	
16	36.00	36.57	35.74	35.85	36.00	N/A	
17	35.90	36.51	35.77	35.78	36.00	N/A	
18	35.99	36.45	35.82	35.88	36.00	N/A	
19	36.01	36.43	35.80	35.84	36.00	N/A	
20	35.98	36.17	35.92	35.93	36.00	N/A	
TEST DEVICE AVERAGE TEMPERATURES, T_n	36.00	36.59	35.76	35.88	36.01	—	
Max. difference between TEST DEVICE AVERAGE T_n & T_M	-0.01	+0.59	-0.24	-0.12	—	—	

IEC 60601-2-21						
Clause	Requirement + Test	Result - Remark				Verdict
Max. difference between the SKIN SENSOR temperature and CONTROL TEMPERATURE	—	—	—	—	—	N/A
Supplementary information: In EQUIPMENT with a BABY CONTROLLED MODE the SKIN TEMPERATURE SENSOR is attach to the centre of the upper surface of the TEST DEVICE "M"						
Supplementary Information:						
Measurement was conducted at a distance of 80 cm from the heater for 800 W radiate heater.						

IEC 60601-2-21			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.102	TABLE: Accuracy of operating data (additional form, dated 28 Sep 2017)					P
Air velocity, (m/s)	Ambient temp., (°C)	Temperature control settings, (°C)				SKIN SENSOR reading, (°C)
		MANUAL MODE		BABY CONTROLLED MODE		
< 0.1	24.995	P		N/A		
reading number (n)	individual temperature readings taken of TEST DEVICES, t_n (°C)					SKIN SENSOR reading, (°C)
	1	2	3	4	M	—
1	35.73	34.62	35.27	34.80	36.09	N/A
2	35.62	34.46	35.14	34.73	35.99	N/A
3	35.61	34.47	35.15	34.68	35.96	N/A
4	35.63	34.54	35.21	34.72	35.95	N/A
5	35.68	34.64	35.25	34.72	36.02	N/A
6	35.67	34.61	35.27	34.74	36.00	N/A
7	35.64	34.66	35.30	34.69	35.99	N/A
8	35.53	34.55	35.24	34.62	35.95	N/A
9	35.54	34.62	35.25	34.61	35.95	N/A
10	35.51	34.63	35.24	34.60	35.98	N/A
11	35.52	34.67	35.32	34.59	35.97	N/A
12	35.51	34.67	35.34	34.59	35.99	N/A
13	35.49	34.72	35.37	34.59	35.98	N/A
14	35.52	34.73	35.37	34.56	35.99	N/A
15	35.45	34.71	35.40	34.58	35.96	N/A
16	35.45	34.74	35.38	34.51	35.99	N/A
17	35.42	34.71	35.40	34.57	35.99	N/A
18	35.44	34.76	35.44	34.5	36.00	N/A
19	35.44	34.75	35.45	34.55	36.01	N/A
20	35.53	34.89	35.54	34.56	36.07	N/A
TEST DEVICE AVERAGE TEMPERATURES, T_n	35.56	34.66	35.32	34.62	35.99	—
Max. difference between TEST DEVICE AVERAGE T_n & T_M	-0.44	-1.34	-0.68	-1.38	—	—

IEC 60601-2-21						
Clause	Requirement + Test	Result - Remark				Verdict
Max. difference between the SKIN SENSOR temperature and CONTROL TEMPERATURE	—	—	—	—	—	N/A
Supplementary information: In EQUIPMENT with a BABY CONTROLLED MODE the SKIN TEMPERATURE SENSOR is attach to the centre of the upper surface of the TEST DEVICE "M"						
Supplementary Information:						
Measurement was conducted at a distance of 96 cm from the heater for 500 W radiate heater.						

Appendix 1: Product photos



Figure 1 1920



Figure 2 1922



Figure 3 1926



Figure 4 1928



Figure 5 19030



Figure 6 19033



Figure 7 19034



Figure 8 19037



Figure 9 19040



Figure 10 19050



Figure 11 19060



Figure 12 19070



Figure 13 19300



Figure 14 19310



Figure 15 19320



Figure 16 19330



Figure 17 19035



Figure 18 19130



Figure 19 19131



Figure 20 19133



Figure 21 19134



Figure 22 19137

****END OF REPORT****