

Certificate of Calibration & Performance

Certificate No.: K60-AK001-0316

The here stated device was calibrated using standards with accuracy guidelines traceable to the National Institute of Standards & Technology (NIST) or have been derived from formulas of physical constants, or have been derived by ratio/ self calibration techniques. Evidence of traceability is on file at our service center.

Client Name: El-Mahy Trading Company.
Client Address: 12 El Sheikh Ali Youssef St., El Sayeda Zeinab , Cairo.

Calibration Data

Calibration Eng.:	STE-20	Test Date:	16-03-2016
Calibration Device:	Infant Incubator Tester Electrical Safety Analyzer	Model:	Model: INCU 601PRO
		S.N:	6050183 204368
Calibration Method:	MECL-WI-09 MECL-WI-01	Attachments:	3 pages

Equipment Data

Equipment Type:	Infant Incubator	Serial No.:	1507572
Model:	CHS-i1000	Manuf. Year:	N.A
Manufacturer:	JW Medical	Prev. Calib.:	N.A
Location:	N.A	Next Calib. On:	16-03-2017
Date of receipt:	16-03-2016		

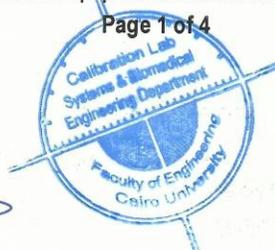
Environmental conditions

Temperature:	19.3°C	Relative Humidity:	30 %
Test Location:	MECL		
Issue date/ Issue No:	16-03-2016/01		

Test results & uncertainties are stated in the attached test report.
This report should not be reproduced without written approval by
Medical Equipment Calibration Lab.

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Quality Manager



Technical Manager

Certificate Number:	K60-AK001-0316	Page 2 of 4
Test Name:	Electrical Safety Test	
Test code	MECL-WI-01	
Date:	16/03/2016	

ENVIRONMENTAL CONDITIONS

Temperature	19.3 °C	Humidity	30 %
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Visual Inspection

	Parameter	Status
1	Chassis/Case	Pass
2	Mechanical connections	Pass
3	Controls and switches	Pass
4	Indicators and Displays	Pass
5	Visual and audible alarms	Pass
6	Accessories	Pass

Electrical Safety*

Class: I

Type: BF

I. No applied Parts **

Test Description	Limit	Reading	Status
1. Mains Voltage (Line Voltages) [V]	CI,II		
Line1-Earth	NL	234.3	Pass
Line2-Earth	NL	0.8	Pass
Line1-Line2	NL	233.9	Pass
2. Protective Earth Resistance (PER) [Ω]***	CI		
Protective Earth Resistance	0.2	0.063	Pass
3. Insulation Resistance [$M\Omega$]****	CI,II		
(L1-L2) to Earth	2	Over	Pass
4. Current Consumption [A]	CI,II		
Current in L2	NL	0	Pass
5. Earth Leakage [μA]	CI,II		
Normal Polarity, Earth open	500	38	Pass
Normal Polarity, Earth open, L2 Open	1000	54	Pass
Reverse Polarity, Earth Open	500	17	Pass
Reverse Polarity, Earth Open, L2 Open	1000	55	Pass
6. Enclosure Leakage [μA]*****	CI		
Normal Polarity	100	0	Pass
Normal Polarity, L2 Open	500	0	Pass
Normal Polarity, Earth Open	500	38	Pass
Reverse Polarity	100	0	Pass
Reverse Polarity, L2 Open	500	0	Pass
Reverse Polarity, Earth Open	500	17	Pass

* The test is done in Auto mode

** Applied Parts are the patient connections, if exist the second part of electrical safety test is done which includes additional 3 parameters.

*** The limit for PER is dependant upon DUT: 0.2 Ω for devices with a non-detachable power supply cord; 0.1 Ω for devices with appliance inlet

**** Limits for Insulation Resistance are not specified in IEC-601. It is here as stated in HEI 95

***** The limits have been removed for Enclosure Leakage test with Class IP due to the fact that zero readings are always expected



Certificate Number:	K60-AK001-0316	Page 3 of 4
Test Name:	Incubator Performance Test	
Test code	MECL-WI-09	
Date:	16/03/2016	

I. Incubator Performance Test

Incubator Functional Checkout

Test	Checked	Status	Notes
Power Fail Alarm Check	√	Pass	-----
Warm Up Time (max. — min.)	√	Pass	-----
Air Mode Temp. Stability*	√	Pass	-----
Air Temp. Hi Alarm	√	Pass	-----
Air Temp. Low Alarm	√	Pass	-----
Skin Mode Temp. Stability**	N/A	-----	-----
Skin Temp. Hi Alarm	N/A	-----	-----
Skin Temp. Low Alarm	N/A	-----	-----
Sensor Open Alarm	N/A	-----	-----
Fan Alarm	N/A	-----	-----

Incubator Settings***

	Temperature Setting	Humidity Setting
Setting 1	32	N.A
Setting 2	36	N.A

Test Parameters

I Incubator Readings

Test Parameter	Reading	
	Setting 1	Setting 2
Tinc	32	36
Tskin	N.A	N.A
Warm Up Time (min.)	50	30

II .Analyzer Readings

Testing Parameter	Reading					
	Setting 1			Setting 2		
	Min.	Max.	Avg.	Min.	Max.	Avg.
T1 (°C)	31.7	31.9	31.8	35.9	36	35.9
T2 (°C)	32.5	32.7	32.7	36.6	36.9	36.8
T3 (°C)	32	32.3	32.1	36.1	36.3	36.1
T4 (°C)	33.8	36.2	35.6	37.9	40.6	39.8
Humidity (%)	N.A	N.A	N.A	N.A	N.A	N.A
Air Flow (m/s)	0	0	0	0	0	0
Sound (db)	50.5	56.9	53.9	50.3	58.5	53.4

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Test Name:	Incubator Performance Test	
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Date:	16/03/2016	

Test Parameters	Limit****	setting 1		setting 2	
		Reading	Status	Reading	Status
T1max - T1min.	≤ ±0.5	0.2	Pass	0.1	Pass
T2max .- T2min.	≤ ± 0.5	0.2	Pass	0.3	Pass
T3max.- T3min.	≤ ± 0.5	0.3	Pass	0.2	Pass
T2avg. - T1avg.	≤ ±1	0.9	Pass	0.9	Pass
T2avg. -T3avg.	≤ ±1	0.6	Pass	0.7	Pass
T2avg. - Tinc.	≤ ± 0.8	0.7	Pass	0.8	Pass
T2avg. - TSkin.	≤ ± 0.3	N.A	-----	N.A	-----
T2avg. - Tsetting	≤ ± 1.5	0.7	Pass	0.8	Pass
Warm Up - Warm Upspec.	± 20% Warm Upspec	50	Pass	30	Pass
Overshoot	≤ 2° C (30-34)	N.A	-----	N.A	-----
Havg.- Hsetting	≤ 0.01*Hset.	N.A	-----	N.A	-----
Sound Level Avg.	≤ 60 db	53.9	Pass	53.4	Pass
Sound Alarm In	≤ 80 db	73.4	Pass	73.4	Pass
Air Flow Avg.	≤ 0.35 m/s	0	Pass	0	Pass

TABLE OF UNCERTAINTIES

	Parameter name	Uncertainty*****	
		32 °C	36 °C
	Setting Temperature		
1	Temperature	± 0.70	± 0.70
2	Air Flow	± 0.19	± 0.19
3	Sound	± 5.79	± 5.79
4	Humidity	N.A	N.A

REMARKS:

* The Air Temperature should remain within 0.5 °C of the set point

** The Skin Temperature should remain within 0.5 °C of the set point

*** Test Duration at least 1 Hours for each setting

****The accepted range is calculated according to the ANSI/AAMI I151-1996 , IEC 60601-2-19 & IEC 60601-2-20

*****The reported expand standard uncertainty is based on NIST international standard multiplied by a coverage factor = 2 providing a level of confidence of approximately 95 %

CONCLUSION:

Tested equipment ONLY passed all tests and related parameters stated in this report.



الصور أعلاه هي نتائج معايرة حضانة الاطفال

Mami CHS-i1000

من شركة JW Medical

و هذا الملف من مرفقات المقال الخاص بنا عن حضانات الأطفال المبتسرين على
الموقع الرسمي www.etcomed.com

لمعلومات أكثر عن المنتج:

[/http://etcomed.com/ar/products/infant-incubator-chs-i1000-ar](http://etcomed.com/ar/products/infant-incubator-chs-i1000-ar)

أو الاتصال بالأرقام التالية:

[+201154003565](tel:+201154003565) القاهرة .

[+201145503381](tel:+201145503381) القاهرة .

[+2011582884](tel:+2011582884) المنصورة .

[+201120040115](tel:+201120040115) أسبوط .