Healthcare Technology International Ltd.
東莞保康電子科技有限公司

文件名稱（Doc Name）： Product Specification for #1628

产品名称（Product Name）: Smart Suction Cupping

文件編號（Doc No.）： PDS-1628-01

版本 (Rev) : Draft

Prepared by/Date: _____ Form reviewed by QS_____

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修改履歷（Revision History）

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A	First Released		N/A

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2. Responsibility Matrix

Product No.:	#1628	Customer No.:	**N/A**	
Product Name:	Smart Suction Cupping			
Client / Proj. Owner	Therabody			
Product Type:	□ OEM	▓ ODM	□ Open Item	□ Other: __
ROHS Compliance	▓ Yes	□ No		
Product Categories: Medical Devices Class #1				

Item	Task	Deliverables	Customer Responsible	HTI Responsible
1	Industrial Design	Rendering Drawing	TB	N/A
2	User Interface Design	User Interface spec.	TB	N/A
3	Electronic Design	Schematic and PCB Diagram (PDF)	N/A	HTI
4	Mechanical Design	2D/3D Parts Drawings (PDF)	N/A	HTI
5	Firmware Design	Firmware documents (Hex File)	N/A	HTI
6	Risk Analysis	D-FMEA Report (PDF)	TB	HTI
7	Materials Selection	Materials List	N/A	HTI
9	CE/FCC Apply and Other	CE/FCC Certificate	TB	N/A
10	Packaging Structural Design	2D /3D Drawing (PDF)	N/A	HTI
11	Labeling Requirement	Artworks and Specification	TB	N/A
12	Product Manual	PDF or Word file	TB	N/A

3. Introduction

3.1. Intended Use (including the needs of the user and patient)

The intended use of Smart Suction Cupping is to relieve stress and pain of the muscles. With providing a negative pressure attached on muscles with heat applied, this product can help increase the blood circulation and help sore and tightened muscles relax, which can also help eliminate the buildup of lactic acid waste. Cupping treatment can also be regarded to bring psychological reassurance to users which can enhance its analgesic properties.

This portable suction cupping has a simple interface to control the device with customizable suction, Heating and Vibration setting, including Bluetooth connectivity, which can synchronize with each other through App via Bluetooth.

3.2. Definitions, Acronyms

3.2.1. SSC- Smart Suction Cupping

3.2.2. PDS – Product Design Specification

3.2.3. DFMEA – Design Failure Mode and Effects Analysis

3.2.4. IFU – Instructions for use

3.2.5. NMPA- National Medical Products Administration

3.2.6. FDA – Food and Drug Administration

3.2.7. IEC – International Electro technical Commission

3.2.8. EN – European Norm

3.2.9. RMR – Risk Management Report

3.3. Reference documents

3.3.1. Design Input Requirements - PDI-1628-1

3.3.2. Customer UI

3.4. Overview Description: The suction cupping device of two items;

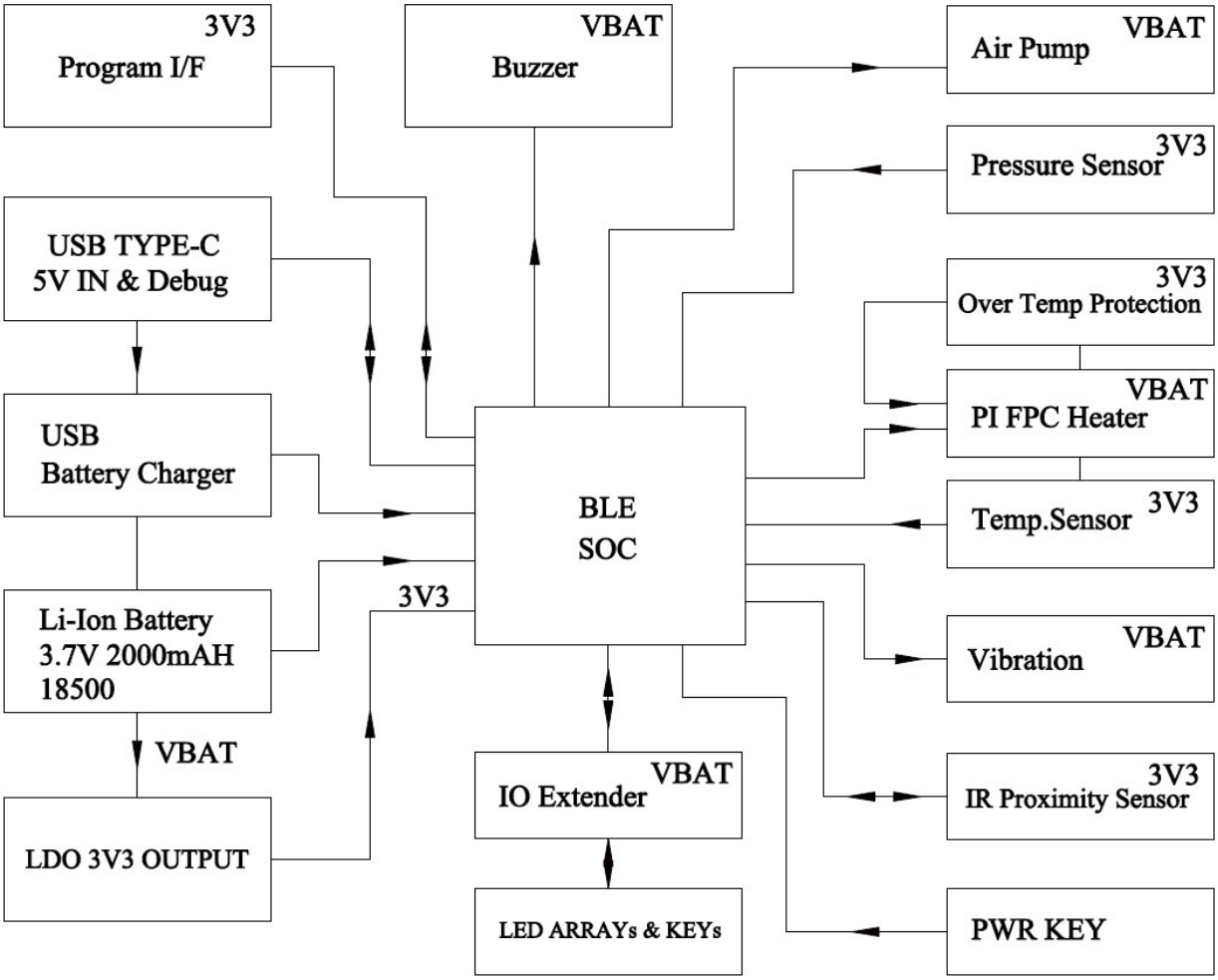
3.4.1. A heat controllable electrical suction cupping running under software control and safety overrides.

3.4.2. A wired power adapter

3.4.3.

4. System Requirements (Performance Characteristics/ Specifications)

4.1 Circuit Block Diagram of Suction Cupping （#1628）



4.2 Pump requirement:

Output Power: ~ 3 W

Rated Voltage: 3.7V ± 0.2 VDC

Operating Voltage: 3~6V ± 0.02

No Load Current: <0.20 A

Rated Current: ~0.6A Max

Suction Vacuum: -60kPa min (at 3.7 VDC)

Noise Less than </=57 dB

Operation temperature range: 0 ~ 40 °C

Ref. Size (mm): OD21 mm * L 45 mm

4.3 Sound setup Requirements:

4.3.1 The sound generating device should produce sounds with a frequency of 2 kHz ~ 4 kHz.

4.3.2 The fixed “Beep” voice level, ≥ 50 dB, sound will be used as an indicator to the user 30 CM away (Measure the decibel level at 30CM)

4.3.3 Key Button function sound ,(per pressing button);

4.3.4 Over temperature for alarm sound

4.3.5 Over suction for alarm sound

4.3.6 Over current for alarm sound

4.3.7 Low voltage alarm sound for battery pack

4.3.8 Size : L 7* W7 * T4mm

4.3.9 Operating Temperature: -10 ~ +60 °C

4.3.10 Relative Humidity: 5 ~ 90 %（Non-condensing）

4.4 Vibration motor requirement :

4.4.1 The operating voltage range : ≥ 3.0~ 4 VDC,

4.4.2 Rated voltage ： 3.7VDC

4.4.3 Operating current：</= 80mA

4.4.4 Motor speed : ~8000Rpm/min,

4.4.5 Stall Current : ~200mA

4.4.6 Stall Torque ： >/= 65 gf.cm

4.4.7 Insulation Resistance >/=10Mohm (min)

4.4.8 Vibration motor : OD 12* L22mm

4.4.9 Operating Temperature: -10 ~ +60 °C

4.4.10 Relative Humidity: 5 ~ 90 %（Non-condensing）

4.5 Power Adapter :

4.5.1 Input Voltage Range: 90 ~ 264 VAC,

4.5.2 Input Frequency: 47 ~ 63 Hz,

4.5.3 Input current: ~1 A rms@115 VAC 60 Hz, 1 A rms @ 230 VAC 50 Hz.

4.5.4 AC supply Power: ≥ ~5 W

4.5.5 DC Voltage Output: 5 VDC ± 0.2 V, ~ 1 A

4.5.6 Earth Leakage Current: < 150 µA

4.5.7 Touch Current: 100 µA Max.

4.5.8 Output port ： USB Type C

4.5.9 Efficiency: ~ 90 % Typical;

4.5.10 Operating Temperature: -10 ~ +60 °C

4.5.11 Relative Humidity: 5 ~ 90 %（Non-condensing）

4.5.12 Product Categories: Medical #2 (Meet the IEC60601-1 standard)

4.5.13 ESD test : Contact discharge ：8KV，Air discharge 15KV

4.6 Suction Range Settings:

4.6.1. The Suction Setting and Suction adjustment for this E-suction Cupping device

4.6.1.1. The pump drive system must have 3 fixed level settings, the designated maximum suction value: ～ -60 kPa Max.;

4.6.1.2. The suction detection circuit is used to collect signals, and PWM technology is used to adjust the speed of air pump, to realize suction and precision control

4.6.2. Suction Accuracy: about ± 3 kPa (For future ± 2 kPa)

4.6.3. The 3-levelized suction setting table (Default is set at level #1):

Setting Level	#1	#2	#3	Remarks
Suction Range (kPa)	-25 ± 2	-43 ± 2	-60 (Max)	
LED Indicator	LED#1	LED#2	LED#3	

4.7 Temperature Range Settings:

4.7.1. The heating temperature system must have 3 fixed level settings for this Electrical Cupping device, the designated maximum temperature: ~48 ℃,

4.7.2. The temperature Accuracy: ± 2 ℃

4.7.3. Temperature Response Time: < 1 s

4.7.4. Test environment temperature: 25+/-2℃

4.7.5. The 3-levelized heating temperature setting table (Default is set at level #1):

Setting Level	#1	#2	#3	Remarks
Temperature Range (℃)	43 ± 2	45± 2	48 ± 2	
LED Indicator	LED#1	LED#2	LED#3	

4.8 Vibration speed or Cycle Rrequency Requirements:

4.8.1. The speed control must have 3 fixed level settings for this Electrical Cupping device, the designated maximum Speed: 3000RPM/Min

4.8.2. The Speed Accuracy control: ± 10% ,at 3.7VDC

4.8.3. Test environment temperature: 25+/-3℃

4.8.4. Vibration Speed or Cycle frequency levels table

Vibration Level	#1	#2	#3	Remark
Rpm/Minutes	1800	2400	3000	
Or Vibration (Hz)	30	40	50	
LED Indicator	LED#1	LED#2	LED#3	

4.9 App Setting for Treatment Time Requirements:

4.9.1. Connect the smartphone through a Bluetooth APP and set different treatment times, The treatment time control must have 3 fixed level settings for this Electrical Cupping device, the designated maximum treatment time: 15 minutes , it's countdown mode

4.9.2. The treatment time accuracy control: ± 10 Seconds

4.9.3. Test environment temperature(Room Temp) : 23+/-3℃

4.9.4. Treatment Time table

Treatment Level	#1	#2	#3	**Remark**
Treatment Time (Minutes)	5	10	15	

4.10 Bluetooth Module Requirements:

4.11.1. 2.4Ghz Low power Bluetooth module with MCU is single or Dual mode V5.0 or V5.2,.

4.11.2. Operating DC Supply voltage : 2.0~3.6VDC

4.11.3. Transmit Consumption current : </=10mA

4.11.4. RX Consumption current: </=10 mA

4.11.5. Sleep current : <10 uA

4.11.6. Crystal frequency :16MHz

4.11.7. Data memory : 64KB

4.11.9. Programmable Flash :128K~500KB

4.11.10. Support the USB interface

4.11.11.. Instruction mode: Module can be configured by AT command by either APP or PC UART

4.11.12. Transmission distance : ~15 Meters

4.11.13. Receiver sensitivity :~ -70 dBm

4.11.14. Customer design the BT App. software

4.11 Battery Pack Requirements:

4.11.1. 1 Pcs 3.7 V 18500 Lithium Battery Pack of Electrical cupping device

4.11.2. Nominal Voltage: ~3.7 V

4.11.3. Nominal capacity: >/= ~1850 mAh Min

4.11.4. PCM circuit

4.11.5. Discharge Cut-off Voltage: ~2.8 V

4.11.6. Internal Impedance: < 80 mΩ

4.11.7. Standard & Discharge Charge current: 1C

4.11.8. Cycle Life: ≥ 500 Times （>/= 70% capacity ）

4.11.9. Charge Operation Temperature Range: 0~45 ℃

4.11.10. Discharge Operation Temperature Range: -10~60 ℃

4.11.11. The battery pack reference standards:

GB 31241, IEC62133, UN38.3, UL 2054 (Battery Cell UN1642);

4.12 LED indicator Content Requirements:

4.12.1. The LEDs for the **“Suction”**, **“Heating”, “Vibration ”**, **“Power On/Off”** , **“Battery Power”** , **“Bluetooth” and “Treatment Time”** function indicator

4.12.2. The LED will show the “**Heater temperature**” level strips, it’s respectively the #1, #2, #3, Strip, representing different temperature levels;

4.12.3. The LED will show the “**Suction**” level strips, it’s respectively the #1, #2, #3, Strip,

representing different "**Suction**" levels;

4.12.4. The LED will show the ""**Vibration**" level strips, it's respectively the #1, #2, #3Strip, representing different ""Vibration" levels;

4.12.5. The a LED will show the "**Treatment Time**" level strips, It defaults to the first treatment time ~ 5 minutes ;

4.12.6. If APP mode is used, Choose different treatment times through your smartphone , it's respectively the #1, (5 Minutes),#2(10 minutes), #3Strip (15 minutes);

4.12.7. Will have a LED for the **Power On** or **Off** and **Bluetooth** APP connection indicator

4.12.8. The a RGB LED includes the battery pack energy and charging indicator

4.12.9. The LED total ： **11** PCS

4.13 PI Heater Requirements:

4.13.1. The DC Resistance: ~5.0 Ω ± 10 %

4.13.2. Operating Voltage 3.0~5 VDC

4.13.3. Rated Voltage 3.7 VDC

4.13.4. Rated current : ~740mA +/- 10%

4.13.5. Power : ~.3.0W +/-0.3W

4.13.6. The heater size (Oval): OD28 mm * T0.2 mm (Approximately)

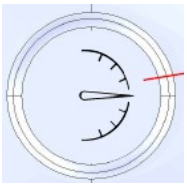
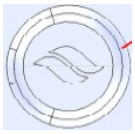
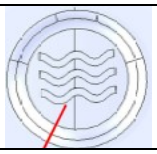
4.13.7. Rated operating temperature >/=120 °C

4.13.8. Insulation Voltage : 500VDC

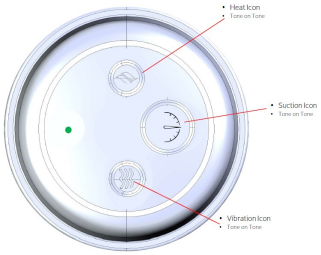
4.14 Function Buttons Requirements:

4.14.1. The 3 Buttons design of Electrical Cupping device: "**Power/ Suction**" Button, "**Heating**" Button, "**Vibration**" Button.

4.14.2. Function buttons show and description

Control Button and Icon	Function Description	Remarks
	**Suction Button**: **1**. Used to turn On/Off and suction of suction Cup. Device 2.Long Press 2S and release, Power ON ,Bluetooth automatically ON, the Bluetooth LED indication icon blinks 3. Short Press for the different suction setting or Exit , the suction LED indication on 4. The LED 3 white color bars for the Suction status indicator(Suction :-25 Kpa ,-43KPa ,-60Kpa Max) 5. Long Press 2S and release again, Power Off ,the all LEDs Off and Air bleed function	
	**Hetaing** button: 1.Used to be the different hetaing level and the Start Run or Stop of suction cup device; 2. The LED 3 white color bars for the heating status indicator (43C , 45C , 48C)	
	**Vibration Button** : Used to be the different Vibration level and the Start Run or Stop of cup device	
GRB LED for Battery Enelgy	**RGB for Battery Enelgy and Charging Indicators:** 1. LED Blue colour for the 70~100% battery capacity 2. LED Green colour for the 10~69% battery capacity 3. LED Red colour for the > 5 ~10% battery capacity 4. LED Red colour flashing < 5 % battery capacity	

Keys 2D for reference.:



4.14.3. The "**Power/Suction**" Button is designed for the turning On/ Off and Time of this suction Cupping device: With pressing and holding the "**Power**" button around 2 s, the device can be turned on , without running any functions (timing, suction and heating), the Heating & Suction function & Vibration are default at level #1 and the time is default at 5 minutes; the Time LED #1 On(blink) and automatically enter bluetooth search connection mode

4.14.4. Short pressing the "**Power/ Suction**" button around 0.5 s, setting the different suction and defaults 5 minutes for treatment time#1 ,the Time LED #1 On ~5minutes ,the Suction LED#1 on or LED# 1 and LED #2on ,or LED# 1 and LED #2on and LED #3 on ;

4.14.5. App for the treatment time setting : 5 Minutes the time LED #1, or ~10minutes or treatment time#2 , the treatment time LED #3 On ~15minutes ;

Treatment Time and Suction table

Treatment Level	#1	#2	#3	**Remark**
Defaults the Treatment Time (Minutes)	5	N/A	N/A	
App for the Treatment Time (Minutes)	5	10	15	
Treatment Time LED Indicator	LED#1	LED#2	LED#3	
Suction Range (kPa)	-25	-43	-60 Max	
Suction LED Indicator	LED#1	LED#2	LED#3	

4.14.6. Long press and hold the power button around 2 s and release , to turn off the power and Air bleed of suction cupping device

4.14.7. Short pressing the "**Heating**" button around 0.5s, select the heating function and setting heating for the 43℃，or 45℃，or 48℃ , continue to short it,and return to the 35℃, and has the corresponding Led indication , long pressing the "Heating " button around 2 s and release ,will exit the **Heating** mode;

The 3-levelized heating temperature setting table

Setting Level	#1	#2	#3	Remarks
Temperature Range (℃)	43± 2	45 ± 2	48 ± 2	Temp. tolerance+/-2℃,
Temp.LED Indicator	LED#1	LED#2	LED#3	

Note: form the 25 ℃ to 43 ℃ ＜～60S

4.14.8. Short Pressing the "**Vibration**" button around 0.5s, seltct the he Vibration function and setting speed for the 1800Rpm/minute or 30Hz,-→2400 Rpm/minute or 40Hz → 3000Rpm/minute (50Hz), continue to short it and return to the 1800 Rpm/minute, and has the corresponding Led indication，long pressing the "Vibration " button around 2 s and release ,will exit the **Vibration** mode;

Vibration Speed levels table

Vibration Level	#1	#2	#3	Remark
Rpm/Minutes or Vibration	1800 or ~30Hz	2400 or ~40Hz	3000 or ~50Hz	Vibration speed tolerance：+/-10%
LED Indicator	LED#1	LED#2	LED#3	

4.14.9. Auto exit Mode adjustment function if not pressing any button for around 2 s.

4.14.10. The summarized table of the ranges for the "Time" & "Heating" & "Suction" & "Vibration" settings mode of suction cupping device

The Factory Default Program Settings for Suction Cupping Device

No	Mode	Setting Level Range	Default program	Remarks
1	"Time" (minute)	5, 10, 15	5	It can be set anywhere from 5 to 15minutes; the tolerance should be less than 1 minutes
2	"Suction" (kPa)	,-25,-43,-60.	-25	It can be set from -25Kpa to -60 kPa Max, the tolerance should be than +/- ~3Kpa

3	“Heating” (°C)	43 ,45, 48.	43	It can be set from 43 to 48 °C, the tolerance should be less than +/- 2C;
4	“Vibration” (RPM/Minute)	1800(30Hz), 2400(40Hz), 3000(50Hz).	1800 (30Hz)	It can be set from 1800 to 3000 RPM/min, the tolerance should be than +/- 10%; at 3.7VDC

4.15 Electrical parameters Requirements:

4.15.1. Operation Voltage: 3 ~ 4.2 V ± 0.1 V

4.15.2. Cut-off Voltage: 3.0 V ± 0.1 V

4.15.3. Operation currents for heater and Suction and vibration function: ~1.6 Ah Max

4.15.4. Sleep currents: < 50 μA

4.15.5. Heater and Suction and Vibration function the Continuous operational time: >/= 30 minutes

4.15.6. Operational Time setting function

4.15.7. Low battery voltage warning: When the battery operating voltage is below 3.2 V ± 0.1 V, the battery LED will blink (beep sequence: 0.8 s on/ 0.8 s off). After 20 consecutive sounds, this cupping device shuts down.

4.15.8. Over temperature warning: During operation, if the measured temperature continues to exceed the designed temperature range for about 10 s (Example: #3 level >/=~50 ℃), the Heating warning mode will be activated, the heating LED will blink (blink sequence: 0.4 s on/ 0.4 s off) and Alarm sound. After 10 consecutive blink and alarm, this cupping device shuts down.

4.15.9. Over suction warning: During operation, if the measured suction continues to exceed the designed suction range for about 20 s (for example: #3 level -60 kPa Max), the over suction warning mode will be activated, the suction LED will blink (Blink sequence: 0.8 s on/ 0.8 s off) and Alarm sound. After 20 consecutive blink, this suction cupping device shuts down.

4.15.10. Over current warning: During operation, if the current continues to exceed the designed range for about 6 s, the Over current warning mode will be activated, the power LED will blink (Blink sequence: 0.8 s on/ 0.8 s off). After 10 consecutive blink, this cupping device shuts down.

4.16 Battery capacity indicator Requirements:

4.16.1. The operating Voltage range: 3.0 V ~ 4.2 V ± 0.1 V

4.16.2. 1 Pcs 3.7 V 18550 Lithium Battery pack

4.16.3. Battery Level Indicator Definition

4.16.3.1. Battery Voltage range: >= 3.8 V - 4.2 V (± 0.1 V):, 70 % to 100 %. the LED Blue on

4.16.3.2. Battery Voltage range: >=3.6 V – 3.7 V (± 0.1 V):, >10 % to 69 %. the LED Green on

4.16.3.3. Battery Voltage range: >=3.3~3.5 V (± 0.1 V):, >5%~10 %. the LED Red on

4.16.3.4. Battery Voltage range: 3.2 V (± 0.1 V):, <5 %. the LED Red blink , after flashlight 20 times (Blink sequence: 0.8 s on/ 0.8 s off) of Red LED and the product power will be turned off.

4.16.3.5. Battery pack capacity indicator for RGB LED

No	LED indicator	Battery Voltage (V)	Battery Capacity (%)
1	Blue	>= 3.8~4.2V	70%~100%
2	Green	>=3.6~3.7	10%~69%
3	Red	>=3.3~3.5	5~10%
4.	Red blink	< 3.3	< 5%

4.17 Charging Voltage Indication Requirements (Ref. Voltage tolerance about ± 0.1 V)

4.17.1. The RGB LED has represents the electrical energy of the product's battery pack.

4.17.2. When the battery voltage is between <3.3 V, in charging mode, the LED red blink on,

4.17.3. When the battery voltage is >=3.3~3.4 V, in charging mode, the LED red on,

4.17.4. When the battery voltage is >=3.5 ~3.6V, in charging mode, the LED Green blink on,

4.17.5. When the battery voltage is between ≥3.7 V, in charging mode, the LED green on

4.17.6. When the battery voltage is between >=3.8 V <~4.1V, in charging mode , the LED blue blink on,

4.17.7. When the battery voltage is between >4.1 V, in charging mode , the LED blue on,

4.17.8. Charging Voltage capacity indicator Battery pack for RGB LED

Battery pack charging indicator for RGB LED

No	LED indicator	Battery Voltage (V)	Battery Capacity (%)
1	Red blink	<~3.3	<5%
2	Red On	>=3.3~3.4	>5%< 10%
3	Green blink	>=3.5~3.6	10%<69%
4	Green On	>=3.7	>/=69%
5	Blue Blink	>3.7~4.1	>=70% <95%
6	Blue On	>4.1	>95 ~100%

4.18 Bluetooth indicator management

4.18.1. Connect/pair the smartphone to the device using the Bluetooth and 1 LED indicator after pair,

4.18.2. The Bluetooth LED indicator blinks for ~4s during the process of suction cupping device with the APP, Bluetooth LED indicator stops flashing when connected to the App.

418.3. The Bluetooth for the “Heating , Suction , Vibration “setting of suction cupping dvice

4.19 Pump drive management

4.19.1. Use the ~20 kHz PWM to control the speed of Pump.

4.19.2. Drive capacity: 0.8 A as minimum; Battery packet voltage: 3.7 VDC

4.19.3. The pump drive system must be able to supply maximum of ~ -60 KPa at the level #3; the drive voltage: 3.7VDC.

4.20 Energy saving mode Requirements

4.20.1. The product enters charging mode, after 5 seconds, ,the brightness of the LED brightness value should be adjusted to ~ 30%.

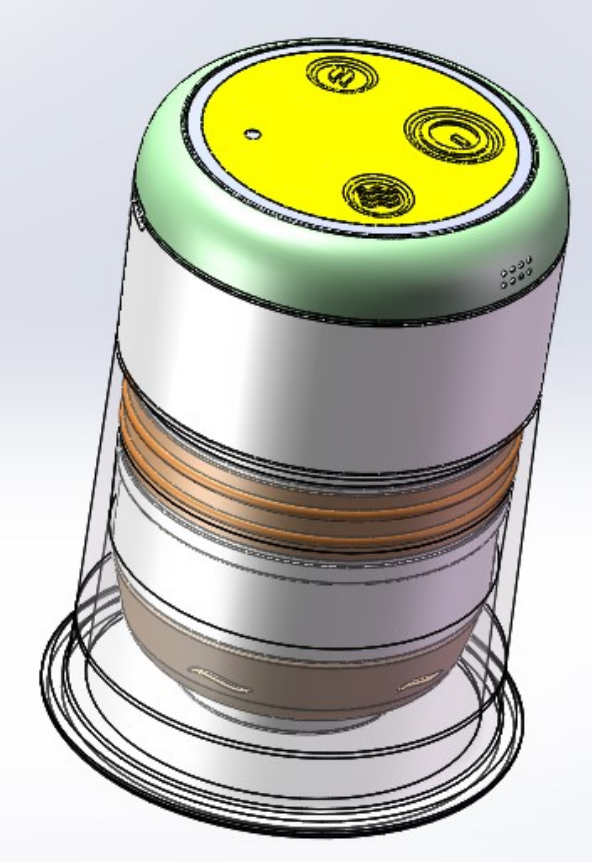
4.20.2. The Power should be cut off automatically if it is not under operation for 1 min. (i.e. no suction or heating function performed.)

4.21 . Self check mode Requirements

Power on , the product enters the self-check mode for the Battery, 3.3Vcc , Buttons, Pump I/O port ,Heat I/O port ,Vibration I/O port , Solenoid valve . (For software design)

4.22 Electrical Cupping device mechanical part

4.19.1 Appearance drawing for reference.



4.19.1.Electrical Cupping device body size: Ø 59 mm x T95 mm (Approximately, in oval shape)

4.19.2.The Cup Size: Ø 55 mm

4.19.3.Heat transfer part design (Antioxidation aluminum alloy material for reference)

4.19.4.The Electrical Cupping body must have a minimum fluid ingress of TBD.

4.19.5. The must be cleanable and shall tolerate water, saline, 20% Isopropyl alcohol, 5% sodium hypochlorite and water,

4. Application Procedure

Refer to customer's "User Interface" specification and User Manual

5. Ease of Use and Maintainability

N/A

6. Environment Requirements (e.g. Operating / Storage Temperature, Humidity)

Temperature, Operating	0 ~ 40 ℃
Temperature, Storage	-20 ~ 60 ℃
Relative Humidity, Operating	10 % ~ 90 % (Non-condensing)
Relative Humidity, Storage/Shipping	10 % ~ 90 % (Non-condensing)
Atmospheric Pressure	~86.0 kPa ～ 106.0 kPa

7. Noise Requirements

The system front 30 centimeter for the measurement, the Speed 6 Level full load: </= 57 dBa

8. Electrical Leakage current & Safety Testing Requirements

9.1 Leakage current testing (Ref.: Class 2 /Type BF equipment)

TBD

9.2 ESD Testing

9.2.1. Contact Discharge: ± 8 kV

9.2.2. Air Discharge: ± 15 kV

9.3 Hi-pot Testing for Adapter

AC input to GND: 2.5 KVAC, 60 s, ≤ 5 mA

10. Cleaning safety testing Requirements

10.1 The suction cupping" device must be cleanable and shall tolerate water, saline, 20% Isopropyl alcohol, 10% bleach solution, 5% sodium hypochlorite and water, methylated spirits, and body

fluids.

11. Electrical Cupping device Manufacturing and Test Requirements

11.1 Ref.IPC-A610 standard class 2 for the PCBA build.

11.2 PCBA Function test

11.3 Pump module test

11.4 Unit Function test

12. Labeling Requirements.

12.1 There shall be an operators' manual (Instructions for Use (IFU).

12.2 Information regarding how to verify proper device operation and service key components in case of damage or failure must available to device operators.

12.3 The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor." Ref. General labeling provision 21.CFR.801.1

12.4 The device, shall have a serial number, Manufacturer and date of manufacturer per FDA UDI

12.5 All shipping boxes shall be labeled with the device name, model number and quantity.

12.6 The device, shall have a serial number, Manufacturer and date of manufacturer per CFDA UDI

13. Packaging Requirements.

TBD

14. Applicable Standard and Regulatory Requirements (e.g. EMC, Safety, Medical device).

14.1 ISO 13485-2016 Quality Management Systems

14.2 ISO 14971-2012 Application of Risk Management to Medical Devices

14.3 ISO 10993- Evaluation and testing in the risk management process

14.4 ISO 10993-5 Tests for in vitro cytotoxicity

14.5 ISO-13732-1 Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces

14.6 GB16886 :材料生物相容性评价标准

14.7 GB16886-5 体外细胞毒性试验

14.8 IEC-60601-1 3.1 edition (IEC60601-1:2005&A1:2012) Electromagnetic compatibility Requirements and tests

14.9 AAMI ANAI ES60601-1:2005+A1. Type BF applied part

14.10 IEC 60601-1-6:2013 3.2 ed Medical electrical equipment –Part 1-6: General requirements for basic safety and essential performance –Collateral standard: Usability

14.11 IEC61000-4-2: Electrostatic discharge immunity test standards

14.12 GB 9706.1 – 2007 医用电气设备 第 1 部分：安全通用要

14.13 YY 0505-2012 医用电气设电磁兼容性要求和试验

14.14 IEC 61000-4-2 .Electrostatic discharge immunity test standards

14.15 IEC62366:2014 1.1ed. Medical devices. Application of usability engineering to medical devices

14.16 IEC 61058-1 Switches for appliances –part1 : General requirements

14.17 IEC-60601-1-2 Medical electrical equipment –General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests （CISPR11， Group1）

14.18 EN55011:2016 Scientific and medical equipment — Radio-frequency disturbance characteristics —Limits and methods of measurement (Ref. the Table 2 and Table 6 for Class A, group 1 equipment)

14.19 GB-T18153 机械安全 可接触表面温度 确定热表面温度限值的工效学数据参考标准

14.20 21 CFR Part 820 - Quality System Regulation

14.21 21.CFR.801.1 - General labeling provision

14.22 IEC-62304:2006&AA1:2015 Software the standard compliance (Software life cycle)

14.23 IEC60529:2013 2.2ed for Electrical Cupping IPX2

14.24 ROHS 2.0

14.25 IPC-A-610 Standard Class 1

15. Reliability and Life Testing Requirements

15.1 Reliability tests include the Shipping test, Drop test, Temperature and Humidity Range test.

15.2 Life test: The function button must be capable of running at a duty cycle of 10 s on and 4 s off for one cycle, in total: 100000 cycles.

16. Other Requirements

16.1 The exterior of the Electrical Cupping device must contain no sharp edges or pointed projections.

16.2 Uses life :2 years uses. (~500hr)

16.3 The suction cupping device enclosure must a have a mass of less than 0.23 kg.

16.4 Reference Customer UI