软件需求说明书 Software requirement specification

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历 史 修 订 记 录 Revision History

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目录 Content

1 介绍 Introduction

1.1 对象文档 Object Document

本文档描述对软件需求分析，以确保每个需求得到满足所使用的方法，是根据设备系统需求而形成软件需求，为软件设计，软件测试提供依据，是整个设备的一部分。

This document describes the method used to analyze the software requirements to ensure that each requirement is met. The Software requirement comes from the system requirement of the equipment and it provides the basis for software design and software testing, it is a part of the whole equipment.

项目相关文档：Project Relevant Document:

1） 需求说明 Requirements Instruction

2） 系统设计 System Design

3） 测试报告 Test Report

4） 产品使用说明书 User Manual

5）项目周报 Project Weekly Report

1.2 参考文献 References

编号 Document No.	文件 Document	根源 Source
[1]	EN 62304:2006	国际标准 International Standard
[2]	EN ISO 14971:2012	国际标准 International Standard
[3]	EN 60601-1-10：2008	国际标准 International Standard

2 产品说明 Description of Product

2.1 工作原理 Work Principle

这个设备是婴儿培养箱，该培养箱为早产儿和成熟婴儿提供受控环境。它可以控制温度、湿度和氧气浓度。可用于任何新生儿和婴儿护理医院科室，包括各级NICU、婴儿特护病房、高级托儿所、新生儿科和儿科。该设备不是为家庭使用而设计的。

This device is an Infant Incubator which provides a controlled environment for the premature and mature infants. It can control the temperature, humidity and oxygen concentration. And it can be used in any hospital departments of neonatal and infant care including NICU at all levels, infant intensive care unit, advanced nursery, neonatology department and pediatric department. It is not designed for the home use.

婴儿培养箱通过加热棒和散热器加热空气。离心风机将加热区的热风带入罩内达到设定温度。加湿器中的另一根加热棒将水烧开，水蒸汽被吸入加热区。因此，水蒸汽加入循环空气以增加罩中的湿度。舱内传感器模块实时收集箱体温度、湿度和婴儿体温，并将这些数据传输到微处理器。因此微处理器可以通过比较实时数据和用户设置来相应地调整加热棒的输出。

The Infant Incubator heating the air through the heating bar and radiator. The centrifugal fan brings the hot air in the heating area into the inside hood to reach the set temperature. The another heating bar in the humidifier boils the water and the steam is drown into the heating area. Therefore, the steam is involved into the air circulating system to increase the inside hood humidity. The inside hood sensor module collects the real time inside hood temperature, humidity and the infant body temperature value and then transmits these data to the microprocessor, therefore the microprocessor can adjust the output of the heating bar accordingly by the comparing of the inside hood real time data with user setting.

伺服控制的氧气系统包括气压传感器、调节器、比例阀和氧气电池。来自医院供气系统或煤渣的氧气从氧气入口进入培养箱。气压传感器检查入口氧气压力以确保其在安全范围内。调节器将氧气压力调节到适合比例阀的一定水平。氧气电池安装在婴儿舱内，它将婴儿舱的氧气浓度数据传输到微处理器。并由微处理器控制比例阀调节氧气流量，最终使婴儿舱内的氧气浓度保持在设定范围内。

The servo controlled Oxygen system includes air pressure sensor, regulator, proportional valve and Oxygen cell. Oxygen from the hospital air supply system or cinder enters the incubator from the oxygen inlet. The air pressure sensor checks the inlet Oxygen pressure to ensure it is within the safe range. The regulator adjusts the Oxygen pressure to a certain level which is suitable for a certain level of the proportional valve. The Oxygen cell is installed inside the hood to transmit the inside hood Oxygen concentration to the microprocessor. The microprocessor controls the proportional valve to adjust the Oxygen flow which to make sure the inside hood Oxygen concentration remains at the setting level.

2.2 预期用户 Intended User

Medical Personnel, Neonatal Intensive Care Unit (NICU) staff, neonatologists, pediatricians, neonatal nurses, and respiratory therapists.

2.3 术语和定义 Terms and Defination

条款 Item	描述 Description
液晶显示器 LCD display	液晶显示器 LCD display
用户 User	在 2.2 中描述的预期用户 The intended user descripted in 2.2

3 编程环境的要求 Programing Environment Requirement

- 编程语言 Programing language：C,C++
- 编程软件 Programing software：Qt Creator（Qt 集成开发和调试工具 Qt Integrated development and debugging tools），Keil（单片机集成开发和调试工具 SCM integrated development and debugging tool）
- 程序调试工具 Program debugging tool：Qt Creator（Qt 集成开发和调试工具 Qt Integrated development and debugging tools），Keil（单片机集成开发和调试工具 SCM integrated development and debugging tool）
- 操作系统 Operating system：Linux 4.19 及以上版本 Linux 4.19 and above

4 操作平台要求 Operating Platform Requirement

4.1 硬件要求 Hardware requirement

- MCU：STM32F103，主频 48MHz 以上，配置在 Cortex M0 以上 FLASH 大于 8Kbit

  MCU: STM32F103, with the main frequency above 48mhz, configured above cortex M0, and flash greater than 8kbit
- 核心板：iMx6ul，主频 800M，RAM 512M，ROM 8G

  Core board: imx6ul, main frequency 800m, RAM 512M, Rom 8g
- 传感器：温度传感器 192-103LET-A01，体温探头 ODM-W0008A，相对湿度传感器 HIH-5031-001，氧气浓度传感器 AA844-210

  Sensors: temperature sensor 192-103let-a01, body temperature probe odm-w0008a, relative humidity sensor hih-5031-001, oxygen concentration sensor aa844-210
- 电池：锂电池 UR1865ZM2

  Battery: Lithium battery UR1865ZM2
- 显示：液晶屏 EJ080NA-05B

  Display: LCD Screen EJ080NA-05B
- 触控：触摸屏 XWT3301

  Touch sensitive: Touch Screen XWT3301
- 输入按钮：触摸按钮

  Input button: Touch button

4.2 计算机系统要求 Computer system requirements

本软件的运行环境为独立设计和制造，本软件的中央处理单元为 iMx6ul。中央处理单元运行的软件是公司研发的控制程序。本软件的操作不需要其他计算机软件的支持。

The running environment of this software is independently designed and manufactured and the central processing unit of the software is imx6ul. The software of the central processing unit is the control procedure which developed by company. The operation of this software is no need the supporting of other computer software.

5 软件输入和输出要求 Software Input and Output Requirement

5.1 软件输入 Software input：

输入内容 Input information	输入要求和功能 Input requirement and function
热敏电 Thermal resistor	输入要求：25℃=10K Input requirement: 25℃=10K 功能：采集婴儿体温 Function: Collect infant temperature
K 型热电偶 K type thermocouple	输入要求：5mV=1℃ Input requirement: 5mV=1℃ 功能：温度过高报警

	Function: The over temperature alarm
相对湿度传感 Relative humidity sensor	输入要求：相对湿度=采集数值/(1.546-0.00216*T) Input requirement relative humidity= acquisition value/(1.546-0.00216*T) 功能：检测相对湿度 Function: Detection of relative humidity
氧气浓度传感器 Oxygen sensor	输入要求：0%~100%氧气浓度 Input requirement: 0%-100% Oxygen concentration 功能：检测氧气浓度 Function: Detection of oxygen concentration
光电开关 Photoelectric switch	输入要求：高电平/低电平 Input requirement: High electrical level/low electrical level 功能：检测模块盒是否插入 Function: Check whether the module box is inserted
循环风扇霍尔传感器 Circulating fan Hall sensor	输入要求：转速检测信号 Input requirement : Speed detection signal 功能：检测循环风扇风机转速是否正常 Function: Check whether the rotating speed of circulating fan is normal
微动开关 Inches switch	输入要求：低电平 Input requirement: Low electrical level 功能：检测抽屉是否在位 Function: Check whether the drawer is in place
按键 button	输入要求：高电平/低电平 Input requirement: High electrical level/low electrical level 功能：用户信息输入 Function: User information input

5.2 软件输出 Software output:

输出结果 Output result	输出功能说明 Output function description	输出对象 Output object
箱体温度设定 Air Temperature Setting Value	显示设定的温度值 Display Air Temperature Setting Value	液晶屏 LCD
皮肤温度设定 Skin Temperature Setting Value	显示设定的皮肤温度值 Display Skin Temperature Setting Value	液晶屏 LCD
箱体相对湿度设定 Relative Humidity Setting Value	显示设定的相对湿度值 Display Relative Humidity Setting Value	液晶屏 LCD
箱体氧气浓度设定 Oxygen Concentration Value	显示设定的氧气浓度值 Display Oxygen Concentration Setting Value	液晶屏 LCD

箱体温度实时数值 Actual Air Temperature Value	显示实时箱体温值 Display Actual Air Temperature Value	液晶屏 LCD
箱体湿度实时数值 Actual Relative Humidity Value	显示实时箱体湿度值 Display Actual Relative Humidity Value	液晶屏 LCD
箱体氧气浓度实时数值 Actual Oxygen Concentration	显示实时氧气浓度值 Display Actual Oxygen Concentration Value	液晶屏 LCD
皮肤温度实时数值 Actual Skin Temperature	显示实时皮肤温度值 Display Actual Skin Temperature	液晶屏 LCD
趋势图 Trend	显示历史趋势图 Display Trend	液晶屏 LCD
报警提示 Alarm Prompt	提示系统故障报警、空气温度报警、皮肤温度报警等 Display System Error Alarm, Air Temperature Alarm, Skin Temperature Aiarm etc	液晶屏、报警灯，喇叭 LCD, ALARM Lamp, Speaker

6 软件性能和功能要求 Software Performance and Functional Requirements

6.1 功能要求 Functional requirement

编号 No.	SRS 功能 SRS function	SRS 描述 SRS description
SR1	温度控制 Temperature control	1．温度 sensor 实时收集箱体温度数据，婴儿体温数据。 1.The temperature sensor collects the real time inside hood temperature value and the infant temperature value. 2．数据经过 ADC，平滑滤波，曲线耦合处理后得到实时温度数据。 2.The real-time temperature data is obtained after ADC, smooth filtering and curve coupling processing 3．MCU 通过比较实时数据和用户设置数据之间的差异，调整循环空气加热棒的输出功率，最终使婴儿舱内的温度保持在设定范围内，从而实现温度控制。 3.By comparing the difference between the inside hood real time data and user setting data, MCU adjusts the output power of the circulating air heating bar to keep the inside hood temperature within the setting level finally, in this way to realize the temperature control.
SR2	湿度控制	1．相对湿度 sensor 实时收集箱体相对湿度数据。

<table>
<tr><td></td><td>Humidity control</td><td>1.The relative humidity sensor collects the real time inside hood relative humidity data.
2．数据经过 ADC 处理，平滑滤波，湿度计算后得到实时相对湿度数据。
2.The real time relative humidity data is obtained after ADC processing, smooth filtering and curve coupling processing.
3．MCU 通过比较实时数据和用户设置数据之间的差异，通过调整水箱加热棒的输出功率，实现调节空气中的水蒸气比例，最终使婴儿舱内的湿度保持在设定范围内，从而实现湿度控制。
3.By comparing the difference between the real time data and the user setting data, MCU can adjust the proportion of the steam in air by adjusting the output power of the heating bar in water tank to make the inside hood humidity remains at the setting range finally which can realize the humidity control.</td></tr>
<tr><td>SR3</td><td>氧气浓度控制
Oxygen control</td><td>1．氧气浓度sensor实时收集氧气浓度数据。
1.Oxygen concentration sensor collects the real time oxygen concentration data.
2．数据经过ADC处理，平滑滤波，曲线耦合处理后得到实时氧气浓度数据。
2.The real time oxygen concentration data is obtained after the ADC processing, smooth filtering and curve coupling processing.
3．MCU通过比较实时数据和用户设置数据之间的差异，控制比例阀调节氧气流量，最终使婴儿舱内的氧气浓度保持在设定范围内，实现氧气浓度控制。
3.By comparing the difference between the real time data and the user setting data, MCU controls the proportional valve to adjust the oxygen flow to make the inside hood oxygen concentration remains at the setting data in which can realize the control of the oxygen concentration.</td></tr>
<tr><td>SR4</td><td>趋势图
Trend</td><td>1．能到画出 2、4、8、12、24 小时间隔的趋势图。
1.Display trend with 2, 4 8, 12 and 24 hours interval.
2．趋势图有皮肤 1，皮肤 2，箱体温度，箱体相对湿度，加热功率。
2.Trend display includes: skin 1, skin 2, air temperature, humidity, heating power.</td></tr>
<tr><td>SR5</td><td>用户设置
User Set</td><td>1．用户设置列表 User Set Table
<table><tr><th>序号 N</th><th>可选项目 Option Items</th><th>设置范围 Range</th><th>出厂默认设置</th></tr></table></td></tr>
</table>

<table>
<tr><td></td><td></td><td>
<table>
<tr><th>o.</th><th></th><th></th><th>值 Default Setting</th></tr>
<tr><td>1</td><td>Humidity Option</td><td>Yes/No</td><td>No</td></tr>
<tr><td>2</td><td>Oxygen Option</td><td>Yes/No</td><td>No</td></tr>
<tr><td>3</td><td>Oxygen Cal Level</td><td>21%/100%</td><td>21%</td></tr>
<tr><td>4</td><td>Skin temperature alarm limit</td><td>1.0℃/0.5℃</td><td>1.0℃</td></tr>
<tr><td>5</td><td>Skin mode</td><td>Yes/No</td><td>Yes</td></tr>
<tr><td>6</td><td>Air set temperature</td><td>20.0°C to 39.0°C (increments of.1°C)</td><td>35.0℃</td></tr>
<tr><td>7</td><td>Skin set temperature</td><td>34.0°C to 38.0°C (increments of.1°C)</td><td>36.5℃</td></tr>
<tr><td>8</td><td>Temp Unit</td><td>℃/℉</td><td>℃</td></tr>
<tr><td>9</td><td>Humidity set value</td><td>30%-95% RH</td><td>50%</td></tr>
<tr><td>10</td><td>Oxygen set value</td><td>21%-65%</td><td>21%</td></tr>
<tr><td>11</td><td>Alarm sound</td><td>1 to 8</td><td>4</td></tr>
<tr><td>12</td><td>Language</td><td>English, Chinese</td><td>English</td></tr>
<tr><td>13</td><td>Screen Calibration</td><td>OFF/Start</td><td>OFF</td></tr>
</table>
2．下次开机能够响应用户设置的值
The setting is saved even restart the device.
</td></tr>
<tr><td>SR6</td><td>报警
Alarm</td><td>报警级别：高级，中级，低级；
Alarm level: High, Medium and Low;
报警类型：灯光报警，声音报警，报警信息。
Alarm type: Light alarm, sound alarm, alarm information
各报警类型级别呈现方式：
Presentation mode of each alarm type and level:
1.灯光报警 Light Alarm：
高级报警：红色，模块盒灯光闪烁频率 0.3 秒。
Advanced alarm: Red color, module box light flashes at a frequency of 0.3 seconds.
中级报警：黄色，模块盒灯光闪烁频率 0.9 秒。
Intermediate alarm: Yellow color, module box light flashes at a frequency of 0.9 seconds.
低级报警：黄色，模块盒报警灯常亮。
Low level alarm: Yellow color, the module box</td></tr>
</table>

		alarm light is always on. 当多个不同级别的报警同时发生时，响应最高级别的灯光。 When multiple alarms of different levels occur at the same time, respond to the highest level of light. 2.声音报警 Sound alarm： 高级报警：嘟-嘟-嘟- -嘟-嘟- - - -嘟-嘟-嘟- -嘟-嘟 Advanced alarm: du-du-du- -du-du- - - -du-du-du- -du-du 中级报警：嘟-嘟-嘟 Medium level alarm: du-du-du 低级报警：嘟 Low level alarm: du 当多个不同级别的报警同时发生时，响应最高级别的声音。 When multiple alarms of different levels occur at the same time, respond to the highest level of light. 3.报警信息 Alarm information 高级报警：报警提示+红色背景。 Advanced alarm: Alarm information + Red background. 中级报警：报警提示+黄色背景。 Medium level alarm: Alarm information + Yellow background. 低级报警：报警提示+黄色背景。 Low level alarm: Alarm information + Yellow background. 当多个不同级别的报警同时发生时，提示信息以一秒间隔轮流显示。 When multiple alarms of different levels occur at the same time, respond to the highest level of light. 具体报警信息见章节 8 See Chapter 8 for specific alarm information
SR7	按键功能 Key Function	1．按键功能描述如下 The button functions are described as below：

序号 No.	按键名称 Button Name	功能 Function
1	报警静音键 Alarm mute key	如当前有可被静音的报警被触发，点击报警静音键，报警被静音。 If an alarm that can be muted is triggered, click the alarm mute key to mute the alarm
2	功能选择键 Function choose button	选择对应的参数或菜单，具体描述如下： Select the corresponding parameter or menu, the specific description as below: 1. 当前页面位于主页面 1： 1. When the current page is on the main page 1: （1）点击按键 1，进入空气温度设置菜单页面 Press the button 1, enter the air temperature setting menu page （2）点击按键 2，进入皮肤温度设置菜单页面 Press button 2, enter the skin temperature setting menu page （3）点击按键 3，进入湿度设置菜单页面 Press button 3, enter the humidity setting menu page （4）点击按键 4，进入氧气设置菜单页面 Press the button 4, enter the oxygen setting menu page 2. 当前页面位于主页面 2： 2.When the current page is on the main page 2: （1）点击按键 1，进入趋势图菜单页面 Press button 1, enter the trend menu page

					（2）点击按键 2，进入称重菜单页面 Press the button 2, enter the weight scale page （3）点击按键 3，切换温度单位（℃/°F）Press the button 3, change the temperature unit (℃/°F) （4）点击按键 4，进入系统设置菜单，系统设置菜单的功能按键描述如下： Press button 4, enter the system setting menu, the function of system setting menu described as below: a）用户设置菜单 User setting menu b）工厂设置菜 Factory setting menu c）版本信息菜单 Version information menu d）主界面菜单 Main page menu.
			3	页面切换键 Page switch button	用于主页面 1，主页面 2 之间切换。 Used for the page switch between page 1 and page 2. 主页面 1，2 详细描述见 10.1.2.5 功能选择区域 The specification description of page 1, 2 please see 10.1.2.5 function selection area.
			4	上下选择键 Selection choice for the up and down button	上下选择键用于设置数字或移动光标 The up and down selection button are used to set numbers or move the cursor

			5	锁屏键 Lock screen button	点击锁屏键，操作面板上除报警静音按键以外的按键全部被锁死，锁屏指示灯亮起。或者一段时间不操作，系统也会自动锁屏，锁屏指示灯自动亮起。 Click the lock screen button, all the button on the operation panel are locked except for the alarm mute button, and the lock screen indicator light is on. And if there is no operation of the panel for a while, the system will lock the screen by itself, and the lock screen indicator light is on automatically. 当锁屏指示灯亮起，报警静音按键可正常工作，其他按键无效。 When the lock screen indicator light is on, the alarm mute button can work normally while the other buttons are invalid. 当点击其他按键时，屏幕弹窗提示“Keypad Locked-Press  ”，弹窗持续时间 5 秒。 在任何的操作页面下，点击锁屏键，页面恢复主页面，如果有弹窗，弹窗退出。氧气校准和称重过程中自动锁屏功能被屏蔽，防止过程被中断。 When click other buttons, the screen will pop up with the prompt " keypad locked press  ", and the information lasts for 5 seconds. Under any operation page, click the lock screen key to restore the main page. If there is a pop-up window, the pop-up window will exit. During oxygen calibration and weighing, the automatic screen locking function is shielded to prevent the process from being interrupted.
			6	电源键 Power button	系统电源键位于面板左下角，开关打开状态系统上电，开关关闭状态系统下电。 The system power key is located at the lower left corner of the panel. The system is powered on when the switch is on and powered off when the switch is off.

<table>
<tr><td>SR8</td><td>显示
UI</td><td>具体描述见章节 10
See Chapter 10 for details</td></tr>
<tr><td>SR9</td><td>LED 指示灯</td><td>LED 指示灯描述如下：
LED indicators are described as below:
 

<table>
<tr><th>序号 No.</th><th>指示灯名称 Name of the indicator</th><th>功能 Function</th></tr>
<tr><td>1</td><td>报警静音指示灯 Alarm mute indicator</td><td>如当前有可被静音的报警被触发，点击报警静音键，报警静音指示灯亮起。
If an alarm that can be muted is triggered, click the alarm mute key and the alarm mute indicator will light up</td></tr>
<tr><td>2</td><td>锁屏指示灯 Lock screen indicator</td><td>点击锁屏键，操作面板上除报警静音按键以外的按键全部被锁死，锁屏指示灯亮起。或者一段时间不操作，系统也会自动锁屏，锁屏指示灯自动亮起。
Click the lock screen button, all the button on the operation panel are locked except for the alarm mute button, and the lock screen indicator light is on. And if there is no operation of the panel for a while, the system will lock the screen by itself, and the lock screen indicator light is on automatically.
当锁屏指示灯亮起，报警静音按键可正常工作，其他按键无效。</td></tr>
</table></td></tr>
</table>

					When the lock screen indicator light is on, the alarm mute button can work normally while the other buttons are invalid. 当点击其他按键时，屏幕弹窗提示“Keypad Locked-Press  ”，弹窗持续时间 5 秒。 在任何的操作页面下，点击锁屏键，页面恢复主页面，如果有弹窗，弹窗退出。氧气校准和称重过程中自动锁屏功能被屏蔽，防止过程被中断。 When click other buttons, the screen will pop up with the prompt "keypad locked press  ", and the information lasts for 5 seconds. Under any operation page, click the lock screen key to restore the main page. If there is a pop-up window, the pop-up window will exit. During oxygen calibration and weighing, the automatic screen locking function is shielded to prevent the process from being interrupted.
			3	>37℃指示灯 >37℃ indicator	当设置空气或皮肤温度≥37.1℃（大于37℃指示灯为黄色） When set the air and skin temperature ≥37.1℃ (The indicator light above 37 ℃ is yellow)
			4	交流电指示灯 AC indicator	交流电接通，打开交流电源开关后，交流电指示灯亮起。 When the AC power is turn on, the AC indicator light is on after the AC power switch is turned on.
			5	锂电池指示灯 Battery indicator	当存在锂电池时，锂电池指示灯亮起。 When the battery is present, the battery indicator light is on.
SR10	称重 Weight scale	具体描述见章节 6.4 称重 See chapter 6.4 for the weighting specification description			
SR11	氧电池（氧气浓度传感器）校准	具体描述见章节 6.5 氧电池（氧气浓度传感器）校准			

	Oxygen cell (Oxygen concentration sensor) calibration	See chapter 6.5 for the specification description.

6.2 性能要求 Performance Requirement

编 号 No.	SRS 功能 SRS function	SRS 描述 SRS description
SR12	参数控制精度 Parameter control accuracy	1．箱体温度控制精度（均培养箱温度与控制温度之间差异）Air Mode Control Temperature Accuracy（Difference between average incubator temperature and setting temperature）：±0.5℃ 2．皮肤温度控制精度 Skin Mode Control Temperature Accuracy：±0.3℃ 3．湿度控制精度 Humidity Control Accuracy：±5% 4．氧气浓度控制精度 Servo Oxygen Control Accuracy: ±2%
SR13	参数显示 Parameter display	1．箱体温度显示 Air Temperature Display： （1）箱体温度显示范围 Air Temperature Display Range：20-42℃ （2）箱体温度显示分辨率 Air Temperature Display Resolution：0.1℃ （3）箱体温度显示精度 Air Temperature Display Accuracy: ±0.3℃ 2．皮肤温度显示 Skin Temperature Display： （1）皮肤温度显示范围 Skin Temperature Display Range：20℃-40℃ （2）皮肤温度显示分辨率 Skin Temperature Display Resolution：0.1℃ （3）皮肤温度显示精度 Skin Temperature Display Accuracy: ±0.3℃ 3．湿度显示 Humidity Display： （1）湿度显示范围 Humidity Display Range：0%-100%RH （2）湿度显示分辨率 Humidity Display Resolution：1%RH （3）湿度显示精度 Humidity Display Accuracy：±5%RH 4．氧气显示 Oxygen Concentration Display： （1）氧气浓度显示范围 Oxygen Display Range：10%-100% （2）氧气浓度显示分辨率 Oxygen Display Resolution：1% （3）氧气浓度显示精度 Oxygen Display Accuracy：±5%（21%氧气校准 Oxygen calibration）,±3%（100%氧气校准 Oxygen calibration） 5．称重显示 Weight Display：

		(1) 称重显示范围 Weight display Range：300 g to 8 kg (2) 称重显示分辨率 Weight display resolution：1 g (3) 称重显示精度 Weight display accuracy：±5g

6.3 数据定义和数据库要求 Data Definition and Database Requirement

数据名称 Data Name	含义 Meaning	数据类型 Data Type	数据格式 Data Format	数据 Data	备注 Remark
温度 Temperature (℃)	温度的数值 Temperature Value	输入数据 Input data	整型数据 Integer Data	20-42	
相对湿度 Relative Humidity (%)	相对湿度的数值 Relative Humidity value	输入数据 Input data	整型数据 Integer Data	10-100	
功率百分比 Heating Power Percentage (%)	加热功率百分数值 Heating Power value	输入数据 Input data	整型数据 Integer Data	0-100	

本设备软件设计没有应用到数据库 This device software does not have database.

6.4 称重 Weight Scale

6.4.1 选配称重 Optional function of weight scale

称重模块插拔检测，插入称重模块后，“Weight”变为绿色。如果设备上并未插入称重模块，“Weight”显示为灰色，且不可操作。

The weighing module is plugged in and out for detection. After inserting the weighing module, "weight" turns green. If the weighing module is not inserted into the equipment, "weight" is gray and inoperable.

6.4.2 锁屏 Lock Screen

在称重过程中，为了避免自动锁屏把称重程序打断，进入称重菜单后，自动锁屏功能被屏蔽。但如果用户手动按锁屏，系统锁屏，并跳回主界面，显示进入称重前的趋势图或血氧图，菜单区域也跳回第一面。

During the weighing process to avoid the interrupting of the weighting procedure by the automatic lock screen function, the automatic lock screen function is shielded after enter the weight scale menu. However, if the user manually presses the lock screen, the system locks the screen and jumps back to the main interface to display the trend or SpO2 trend before entering the weighing, and the menu area also jumps back to the first side.

6.4.3 称重 Weight Scale

读取称重模块（称重传感器）数据，若去皮重量在称重范围内（0~8kg），显示测试结果，若去皮重量大于 8kg，提示“体重过重（Too much weight）”。

Read the Weight scale module (Weight scale sensor) data, If the peeled weight is within the weighing range (0 ~ 8kg), the test result will be displayed. If the peeled weight is greater than 8kg, it will prompt "too much weight".

6.4.4 称重校准 Weight Scale Calibration

如果系统检测到增加的重量超出 5000g±10%，系统提示 Scale Cal Fail。此时，用户可以再次点击 Cal 进行校准，如果系统检测到增加的重量在 5000g±10%的范围之内，则提示 Scale Cal Pass。

If the system detects that the added weight exceeds 5000g ± 10%, the system prompts scale cal fail. At this time, the user can click cal again for calibration. If the system detects that the increased weight is within the range of 5000g ± 10%, it will prompt scale cal pass.

6.5 氧电池（氧气浓度传感器）校准 Oxygen Cell(Oxygen Concentration sensor) Calibration

将输出氧浓度分别设定为 21%和 100%，然后调节氧电池增益，使测量值和设置值保持一致，待两点定标完成后，在 21%和 100%输出范围内，多点比较氧浓度设定值与显示值，如果偏差在 5%以内，说明氧电池控制和监测没有问题，氧电池校准成功，提示“Oxygen Cal Pass”，否者氧电池校准失败，提示“Oxygen Cal Fail”。

Set the output oxygen concentration to 21% and 100% respectively, then the gain of the oxygen battery is adjusted to keep the measured value and setting value at the same level. After two point calibration is completed, the oxygen concentration setting value and the display value are compared at various points within 21% and 100% output range. If the deviation is less than 5%, there is no problem in the control and monitoring of the oxygen battery, and the oxygen battery calibration is successful and prompt "oxygen cal pass". Otherwise, if the oxygen battery calibration fails, prompt "oxygen cal fail".

7 软件系统与其他系统之间的接口 Interface between the Software System and other Systems

软件被编写在芯片内部，芯片被焊接到 PCB 上。软件系统与其他系统之间无接口

The software is written inside the chip and the chip is welded to the PCB. There is no interface between the software system and other systems.

8 软件驱动的警报、警告和操作员信息 Software driven alarms, warnings, and operator information

通过液晶显示屏和蜂鸣器提示本软件的报警、报警和操作员信息，详见信息如下：

The alarm, alarm and operator information of the software are prompted through the LCD and buzzer. See the information below for details:

报警名称 Alarm Name		报警级别 Alarm Class	报警静音时间 Alarm Silence Time	处理动作 Action	触发条件 Trigger
英文 English	中文 Chinese				
Stuck Key	按键不灵 Key failure	高级 High	NA	NA	按键出现故障 Keyboard error
Sensor Disconnect	模块盒断开 Module box disconnected	高级 High	NA	关闭-加热、加湿 Switch Heater, evaporator	模块盒线材断开 Sensor module cable disconnected
Sensor Module Failure3	模块盒风扇停转 Module box fan stalls	高级 High	NA	关闭-加热、加湿 Switch Heater, evaporator	模块盒的循环风扇不转 Sensor module fan failure
Sensor Module Failure6	环境探头故障 Environment probe failure	高级 High	NA	关闭-加热、加湿 Switch Heater, evaporator	环境温度探头短路，断路 Ambient temperature sensor short or broken circuit
Low Air Flow	气流过低 Airflow too low	高级 High	NA	关闭-加热、加湿 Switch Heater, evaporator	气流 K 型热电偶温度值 > 65℃ Air K type thermocouple value > 65℃
Air Flow Probe Failed	气流探头故障 Airflow probe failure	高级 High	NA	关闭-加热、湿度 Switch Heater, evaporator	风速 K 型热电偶短路、断路 Air K type thermocouple short or broken circuit
Humidity Heater Failed 1	加湿器故障 1 Humidifier fault	高级 High	NA	关闭加湿 Switch evap	加湿器 K 型热电偶温度值 250℃Evaporator K t

	1			orator	ype thermocouple valu e ＞250℃
High Skin Tempera ture	皮肤温度过高 Skin temperatur e too high	0.5/中级 Mediu m 1/高级 High	0.5/15min 1/5min	关闭加热 S witch Heat er	皮肤模式，显示的温度低于设定温度 1℃或 0.5℃（1 或 0.5 是根据用户的选择） Skin Mode, display ski n temperature 1℃ or 0.5℃ higher than setti ng temperature(1 or 0.5 choosen by users)
Low Skin Tempera ture	皮肤温度过低 Skin temperatur e too low	0.5/中级 Mediu m 1/高级 High	0.5/15min 1/5min	NA	皮肤模式，显示的温度低于设定温度 1℃或 0.5℃（1 或 0.5 是根据用户的选择）Skin Mode, displ ay skin temperature 1℃ or 0.5℃ lower tha n setting temperature (1 or 0.5 choose by u sers)
Remove Skin2 Pro be	取下“皮肤 2”探头 Remove the "sk in 2" probe	中级 Medium	NA	关闭加热 S witch Heat er	皮肤模式下，插入“皮肤 2”探头；Connect Skin 2 temperature sensor on skin mode
Skin Probe Discon nect	皮肤探头断开 Skin probe disc onnected	前 30 秒/中级/后高级 Before 30s Med ium/After 30s High	5min	关闭加热 S witch Heat er	在皮肤模式下：“皮肤 1”温度探头从传感器上取下 Disconnect skin 1 t emperature sensor on skin mode
Motor Failed	电机故障 Motor failure	高级 High	NA	关闭-加热、湿度 Switch Heater, ev aporator	风机停转 Motor stuck
Add Water	水箱缺水 The water tank is short of wa ter	低级 Low	NA	关闭-湿度 S witch evap orator	加湿器 K 型热电偶温度＞105℃ Evaporator K type the rmocouple value ＞10 5℃
Power Failure	AC 断电 Ac power off	Before 30s Med ium/After 30s High	NA	关闭-加热、加湿 Switch Heater, ev aporator	交流电未插入 AC powe r disconnect
High Temp CutOut	高温断开 High temperatu re disconnected	高级 High	5min	关闭-加热 S witch Heat er	1、 空气模式到达 38℃（未启动＞37℃） Air temperature ＞38 ℃

					2、 空气模式到达 40℃（启动＞37℃） Air temperature ＞40 ℃ under overide 3、皮肤模式，只要培训箱温度到达 40℃， 注：温度到达 40℃，40-39 存在，低于 39 才解除 Skin mode, air temperature ＞40 ℃. Once temperature drops between 39-40, alarm still occur. Alarm stop unitl temperature drops to 39.
High Air Temperature	空气温度过高 Air temperature too high	中级 Medium	15min	关闭-加热 Switch Heater	显示温度＞设定温度 1.5℃ Display temperature 1.5℃ higher than setting temperature
Low Air Temperature	空气温度过低 Air temperature too low	中级 Medium	15min	NA	显示温度＜设定温度 2.5℃ Display temperature 2.5℃ lower than setting temperature 注：开机屏蔽 40 分钟此报警，改变值屏蔽最长分钟数，默认为 15 分钟此报警 Everytime turn on the machine, this alarm is disable for 40 mins. Everytime decrease setting temperature, this alarm is disable for 15 mins.
Low Humidity	湿度过低 Humidity too low	中级 Medium	15min	NA	显示的湿度值低于设定湿度值＞10%； Display humidity is 10% lower than setting humidity. 注：开机屏蔽 30 分钟此报警，改变值屏蔽最长分钟数，默认为 15 分钟此报警

					Everytime turn on the machine, this alarm is disable for 40 mins. Everytime decrease setting humidity, this alarm is disable for 15 mins.
High Skin1 Temperature	“皮肤 1”温度过高 "Skin 1" temperature too high	中级 Medium	15min	NA	1、空气模式 air mode，＞38℃（Not started＞37℃） 2、空气模式 air mode，＞39℃（Not started＞37℃） Override
High Skin2 Temperature	“皮肤 2”温度过高 "Skin 2" temperature too high	中级 Medium	15min	NA	1、空气模式 air mode，＞38℃（Not started＞37℃） 2、空气模式 air mode，＞39℃（Not started＞37℃） Override
Battery Disconnect	电池断开 Battery disconnected	高级 High	NA	NA	电池断开或者损坏 Battery is disconnected or damaged
Sensor Out of Position	模块盒不在位 Sensor module is out of position	高级 High	NA	关闭-加热、加湿 Switch Heater, evaporator	模块盒被拔出 Sensor module is slided out
Reservoir Out of Position	水箱不在 Water tank is out of position	5 分钟/提示/后中级 Before 5 mins Prompt/After 5 mins Medium	15min	关闭加湿 Switch evaporator	水箱被拔出 Water reservoir is pull out
Access Panel Open	侧门开启 Side door open	5 分钟/提示/后中级 Before 5 mins Prompt/After 5 mins Medium	15min	NA	侧门被打开 Access door open
Heater Failed1	加热器故障 1 Heating bar failure 1	高级 High	NA	关闭-加热 Switch Heater	加热棒旁边的 K 型热电偶超过 160℃ Heater K type thermocouple value ＞160℃
Heater Failed2	加热器故障 2 Heating bar failure 2	高级 High	NA	关闭-加热 Switch Heater	加热器 K 型热电偶断路，数据显示异常 Heater K type thermocouple broken circuit, data error
Air Probe Failed	温度传感器故障	中级 Medium	NA	NA	传感器模块中，两个温度

	Temperature sensor failure				探头所测得的温度差距大于 0.8℃ Two air temperature sensors value differ bigger than 0.8℃
Humidity Heater Failed 2	加湿器故障 2 Humidifier fault 2	高级 High	NA	关闭-加湿 Switch evaporator	加湿器 K 型热电偶断路，数据显示异常 Evaporator K type thermocouple broken circuit, data error

提示内容 Prompt	触发条件 Trigger	备注 Remark
程序自检 Self Testing	设备开机，自行进行自检 Turn on the product	
键盘被锁，请解锁 Keypad Locked -Press 	键盘被锁住，用户按其它键时，提示此信息 Keypad is locked while try to press keypad	
皮肤模式关闭 Skin Mode Disabled	用户设置关闭皮肤模式，用户点击皮肤模式，提示此信息 user presee skin mode while skin mode is disable in user setting	

9 安全要求 Security Requirement

无安全要求 No security requirement

10 通过软件实现的用户界面要求 User Interface Requirements Implemented by Software

10.1 开机界面 Start up Interface

开机过程中，显示开机 logo。 During startup, the startup logo is displayed.

10.2 显示界面 Display Interface

10.2.1 主界面 Main interface

如图示 1 所示，主界面分为如下 6 个区域 As shown in Figure 1, the main interface is divided into the following six areas

1) 信息提示区域 Information prompt area

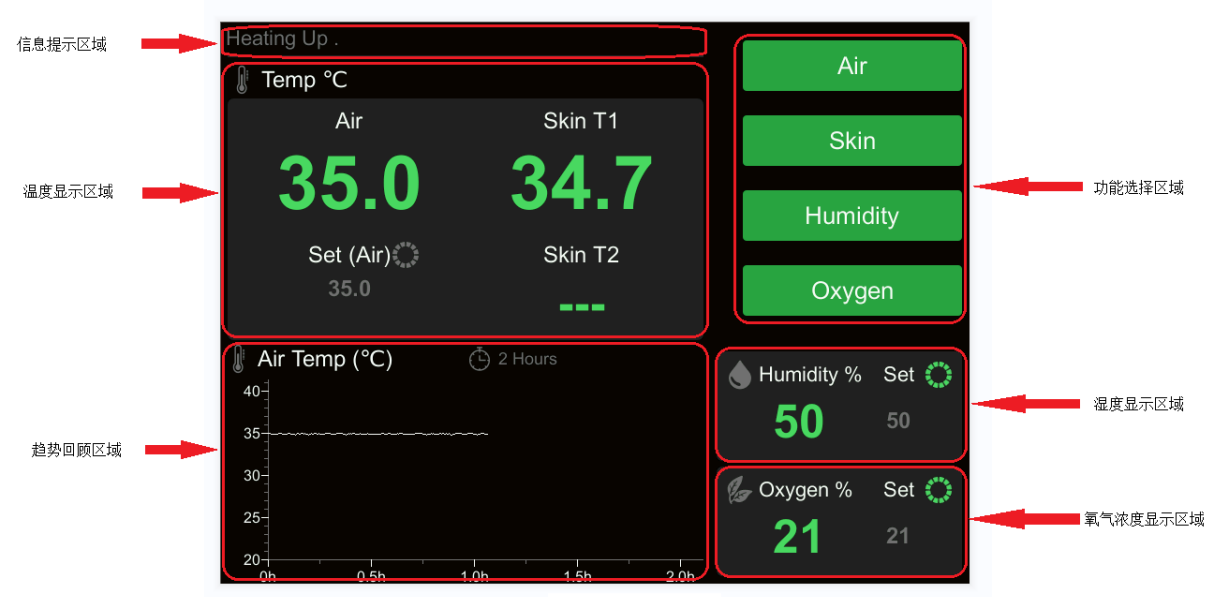
2) 温度显示区域 Humidity display area

3) 趋势回顾区域 Trend review area

4) 功能选择区域 Function choose area

5) 湿度显示区域 Humidity display area

6) 氧气浓度显示区域 Oxygen concentration display area



图示1

10.2.1.1 信息提示区域 Information prompt area

信息显示区域主要显示加热信息（Heating Up），报警静音图标，侧门开启图标，报警信息和提示信息，电池图标。

The information display area mainly displays heating up information, alarm mute icon, side door opening icon, alarm information and prompt information, and battery icon.

取消薄膜按键上的电池指示灯，用屏幕上的图标代替。机器版本分带电池和不带电池的，带电池的显示电池图标，不带电池的不显示电池图标。出厂前在出厂设置里配置是否带电池，不需要自动识别。

Cancel the battery indicator on the membrane button and replace it with the icon on the screen. The machine version is divided into those with battery and those without battery. The battery icon is displayed for those with battery, and the battery icon is not displayed for those without battery. There is no need to be identified if the machine with or without battery before the delivery in the factory set.

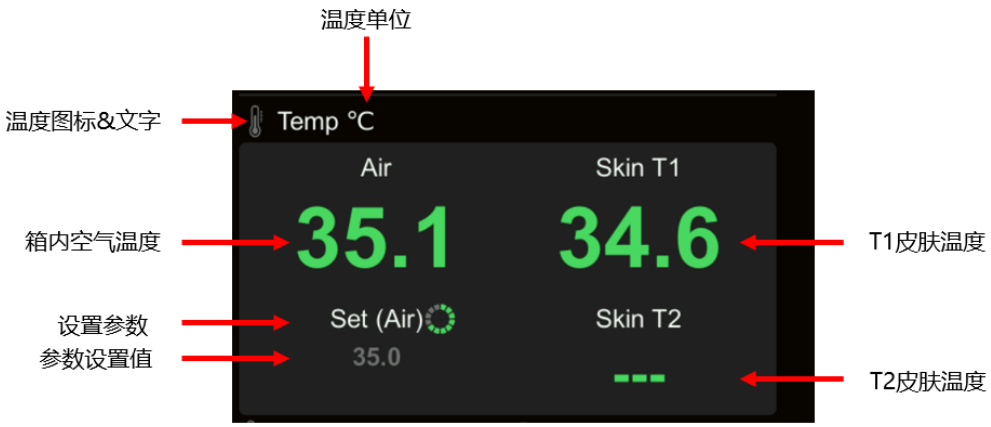
电池满电状态和充电状态需要用不同的图标。

Different icons are required for battery full state and charging state

报警静音图标使用新设计的图标。有报警被静音显示为  。没有报警被静音显示为  。

The alarm mute icon uses the newly designed icon. If alarm is muted the display is  . No alarm is muted the display is  .

10.2.1.2 温度显示区域 Humidity Display Area



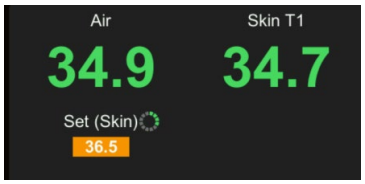
图示4

如图示 4，温度显示区域包含如下内容

As shown in Figure 4, the temperature display area includes the following contents

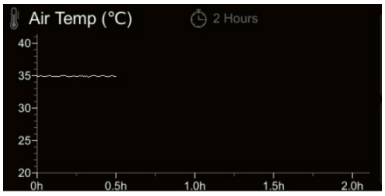
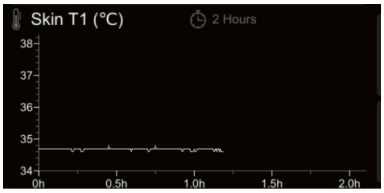
	名称 Name	内容 Content
1	温度图标&文字 Temperature icon & content	只显示，没有任何变化 Only display, no any change

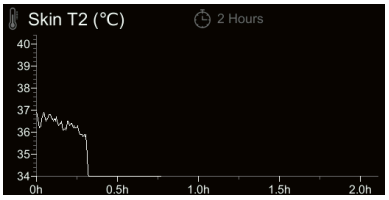
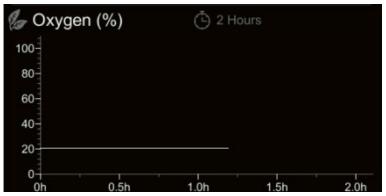
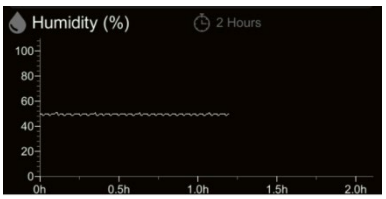
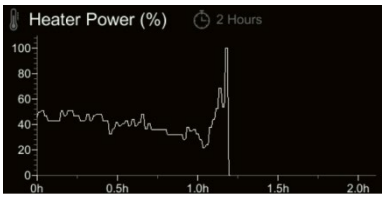
2	温度单位 Temperature unit	用户可在摄氏度和华氏度之间切换 Temp °F The ℃ and °F is switchable by user Temp °F
3	箱内空气温度 Inside hood air temperature	空气温度显示范围 20℃-42℃，步进 0.1℃。当温度≤19.9℃，显示 LOW，当温度≥42.1℃，显示 HIGH。 The display range of air temperature is 20 ℃ - 42 ℃ in steps of 0.1 ℃. When the temperature is ≤ 19.9 ℃, it displays low; when the temperature is ≥ 42.1 ℃, it displays high. 空气温度显示需做柔化处理，避免短时间内频繁跳动。 The air temperature display needs to be softened to avoid frequent jumping in a short time. 空气温度显示刷新频率为 3 秒一次。（是下位机 3 秒才发送数据给上位机） The refresh frequency of air temperature display is once every 3 seconds. (The lower computer sends data to the upper computer after 3 seconds)
4	设置参数 Set temperature	箱温模式显示“Set(Air)”，肤温模式显示“Set(Skin)” The inside hood temperature mode displays as “Set(Air)”, The air temperature mode display as “Set(Skin)”.
5	参数设置值 Parameter setting value	箱温&肤温设置范围见参数表，步进 0.1℃ The setting range of the inside hood temperature and the skin temperature is shown in parameter table, with a step of 0.1℃.
6	T1 皮肤温度 T1 Skin temperature	T1 皮肤温度显示范围 20℃-42℃，步进 0.1℃。当温度≤19.9℃，显示 LOW，当温度≥42.1℃，显示 HIGH。（需讨论是实际温度，还是经过柔化处理的温度。） T1 skin temperature display range: 20 ℃ - 42 ℃, step 0.1 ℃. When the temperature is ≤ 19.9 ℃, low information is displayed, and when the temperature is ≥ 42.1 ℃, high information is displayed. (It needs to be discussed whether it is the actual temperature or the temperature after softening.) T1 皮肤温度显示需做柔化处理，避免短时间内频繁跳动。

		T1 skin temperature display needs to be softened to avoid frequent beating in a short time. T1 皮肤温度显示刷新频率为 3 秒一次。（是下位机 3 秒才发送数据给上位机） The refresh rate of T1 skin temperature display is once every 3 seconds. (The lower computer sends data to the upper computer after 3 seconds). T1 皮肤探头未插入时显示“---” "--" is displayed when T1 skin probe is not inserted.
7	T2 皮肤温度 T2 Skin temperature	同上 Same as above 肤温模式下“Skin T2”及 T2 数值不显示，也不显示“---”，空白。如下图。 In skin temperature mode, "Skin T2" and T2 values are not displayed, nor "---" is displayed, and it is blank. As shown below. 

10.2.1.3 趋势回顾区域 Trend review area

趋势回顾及血氧区域可分别显示如下内容 The trend review and SpO2 area can display the following contents respectively.

	内容 Content	图片 Picture
1	箱温趋势回顾 ”Air Temp(℃)” Trend review of the inside hood “Air Temp(℃).”	
2	皮肤温度 T1 趋势回顾” “ Skin T1 (℃)” Trend review of the Skin temperature T1 “Skin T1 (℃)”	

3	皮肤温度 T2 趋势回顾"“ Skin T2 (℃)” Trend review of the Skin temperature T 2 “Skin T2 (℃)”	
4	氧气浓度趋势回顾 “Oxygen(%)” Trend review of the Oxygen concentrati on “Oxygen(%)”	
5	湿度趋势回顾 “Humidity(%)” Trend review of the Humidity review “Humidity(%)”	
6	加热功率趋势回顾 “Heater Power (%)” Trend review of the heater power “Hea ter Power (%)”	

10.2.1.4 功能选择区域 Function choose area

功能选择区域包括如下菜单 The function choose area including the following menu：

主页面 1 Main menu 1

- Air 菜单 Air Menu
- Skin 菜单 Skin Menu
- Humidity
- Oxygen

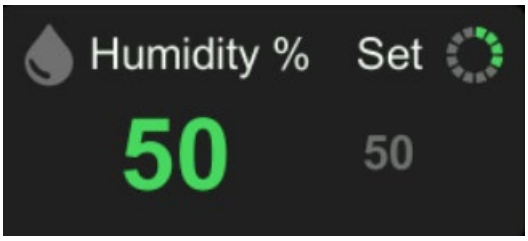
主页面 2 Main Menu 2

- Trend 菜单 Trend Menu
- Weight 菜单 Weight Menu
- °C/°F
- System 菜单 System Menu

10.2.1.5 湿度显示区域 Humidity display area

湿度显示区域显示湿度的检测值和设置值

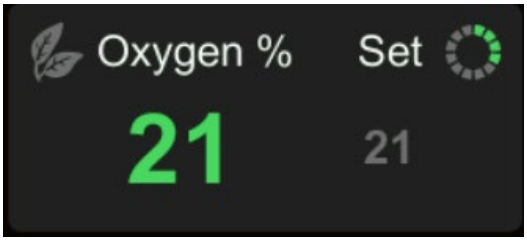
The humidity display area displays the detected value and set value of humidity



10.2.1.6 氧气浓度显示区域 Oxygen concentration display area

氧气浓度显示区域显示氧气浓度的检测值和设置值

The Oxygen concentration display area or the detected value and set value of the oxygen concentration



10.2.2 图示 Illustration

婴儿培养箱中使用下列图示 Use the following illustration in the infant incubator

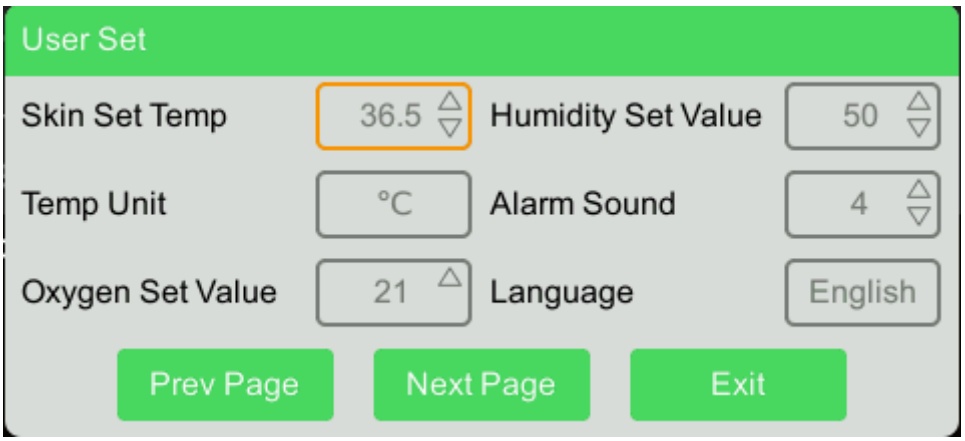
	图片 Picture	说明 Description
1		温度图示，出现在温度显示区域及温度相关的趋势回顾。 Temperature icon, which appears in the temperature display area and the trend review which is related to the temperature.
2		工作图示，动态图示，表示箱温（皮肤）控制，湿度控制或氧气浓度控制正在工作。只要上述功能开启，即便加热棒在某一时刻并没有通电加热或者某以时刻并没有氧气输入，图标都显示并伴随光标环绕闪动。 Working icon, dynamic diagram, which means the inside hood (Skin temperature) control, humidity control or the oxygen concentration control is working. As long as the above function started the icon will display and there will be flash around with the cursor even the heating bar is not powered on for heating at a certain tim

		e or there is no oxygen input at a certain time.
3		时间图示，出现在趋势回顾区域，表示回顾的时间间隔。（横坐标的总时间）。 Time icon, which appears in the trend review area, indicates the time interval of review. (Total time of Abscissa)
4		湿度图示 Humidity icon
5		氧气浓度图示 Oxygen concentration icon
6		称重图示 Weight scale icon
9		报警被静音图标 The alarm muted icon
10		报警未被静音图标 The alarm not muted icon
11		核心温度图标 Central temperature icon
12		外周温度图标 Peripheral temperature

10.3 软按键功能描述 Software button function description:

10.3.1 用户设置界面软按键 User setting interface software buttons

用户设置界面软按键布局如下 The user setting interface software button layout as follows:



“  ”：前一页按键，点击后，用户设置界面切换到前一页

The Previous page button, after click, the user setting interface changes to previous page

“ 

”：后一页按键，点击后，用户设置界面切换到后一页。

The next page button, after click, the user setting interface changes to next page.

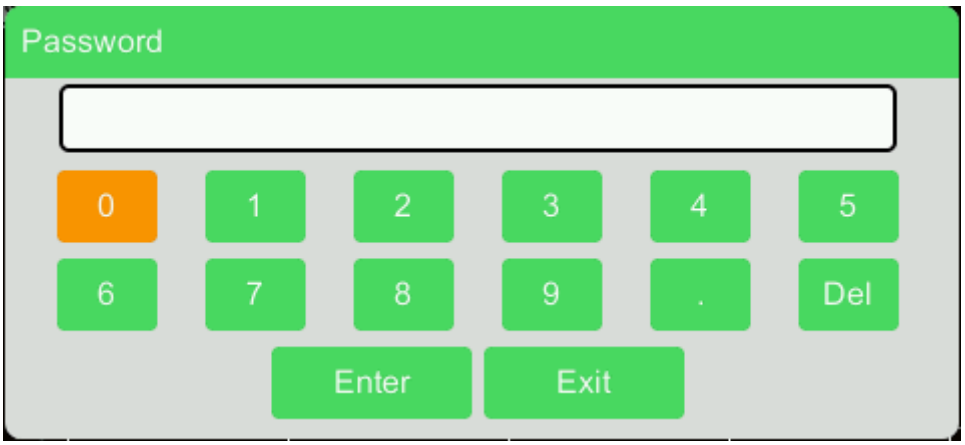
“ 

”：退出按键，点击后，退出当前菜单界面。

The Exit button, after click, the current interface menu exit.

10.3.2 工厂设置界面软按键 Factory setting interface software button

工厂设置界面软按键布局如下 The factory setting interface software button layout as follows：



“0~9”：数字按键，点击后，按键编辑框输入对应数字。

“0~9”: Press the number key. After clicking, press the button to enter the corresponding number in the edit box.

“ 

”：小数点按键，点击后，编辑框输入“.”。

Press the decimal point button and click it to enter in the edit box.

“ 

”：删除按键，点击后，编辑框当前光标退格并删除一个字符。

Delete key. After clicking, the current cursor in the edit box will be backspace and a character will be deleted.

“ 

”：确定按键，点击后，校验工厂设置密码，密码正确进入工厂设置界面，出错误，编辑框内提示密码错误。

Press the OK button and click it to verify the factory setting password. If the password is correct, enter the factory setting interface, an error will appear, and the password error will be

prompted in the edit box.

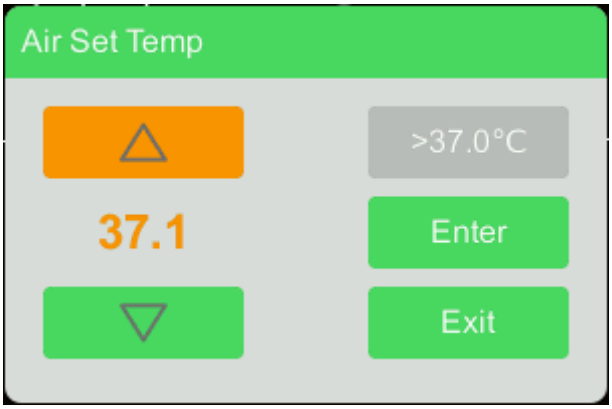
“ 

”：退出按键，点击后，退出当前菜单界面。

Exit button, after clicking, the current menu interface exits.

10.3.3 空气/皮肤温度设置菜单页面按键 Buttons of Air/Skin temperature setting menu

空气/皮肤温度设置菜单界面按键布局如下 The buttons of Air/Skin temperature setting menu l ayout as follows：



“ 
”：向上按钮，点击后，空气/皮肤温度设定值增加 0.1。

Up button, Click the up button, and the set value of air / skin temperature will increase by 0.1.

“ 
”：向下按钮，点击后，空气/皮肤温度设定值减小 0.1。

Down button, Click the down button, and the set value of Air/Skin temperature will decre ase by 0.1.

“ 

”：启用按钮，点击后，设置温度启用“>37℃”设置且按钮置灰。

Start button, after clicking, the“>37℃”temperature set function started and the button turn into grey.

“ 

”：确定按键，点击后，确实设定值并退出当前设置菜单界面。

Enter button, Press the Enter button and click to confirm the setting value and exit the c urrent setting menu interface.

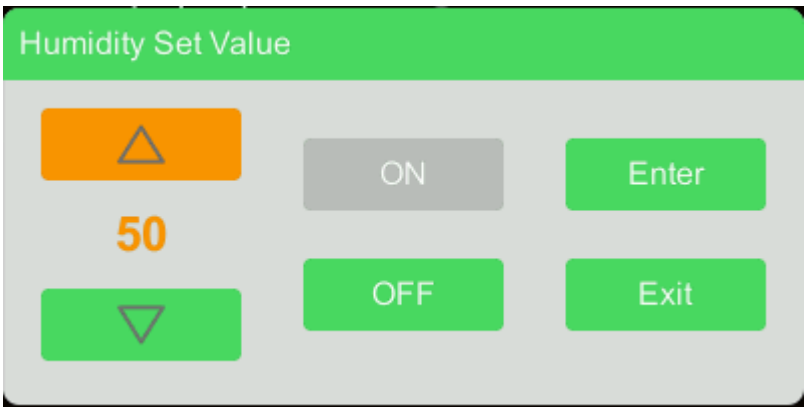
“ 

”：退出按键，点击后，退出当前菜单界面。

Exit button, press the exit button to exit the current menu interface.

10.3.4 湿度设置菜单页面按键 Humidity setting menu interface button

湿度设置菜单界面按键布局如下 Humidity setting menu interface button layout shows as bell ow：



“△”：向上按键，点击后，湿度设定值增加 1。

Up button, after clicking, the humidity value increased by 1.

“▽”：向下按键，点击后，湿度设定值减小 1。

Down button, after clicking, the humidity value decrease by 1.

“ON”：开启按键，开启设置湿度的显示。

Start button, start the display of humidity setting.

“OFF”：关闭按键，关闭设置湿度的显示。

Close button, close the display of humidity setting.

“Enter”：确认按键，点击后，确实设定值并退出当前设置菜单界面。

Confirm button, after clicking, the set value is confirmed and the current interface setting menu exited.

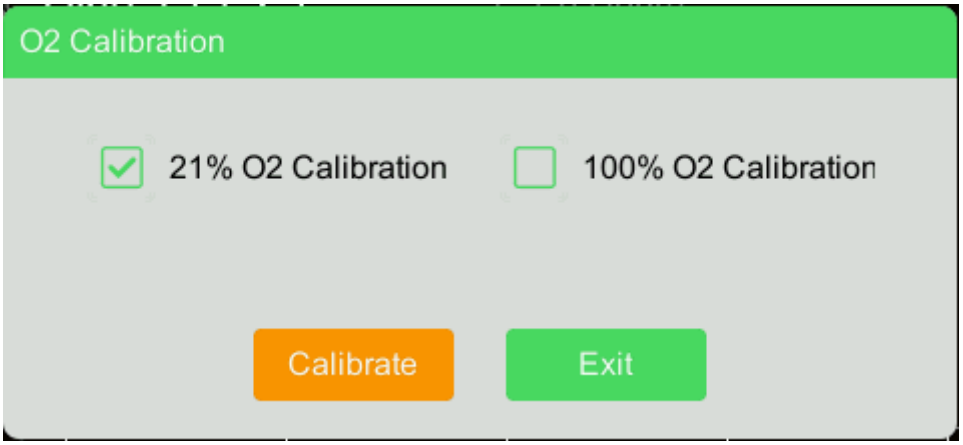
“Exit”：取消按键，退出当前菜单界面。

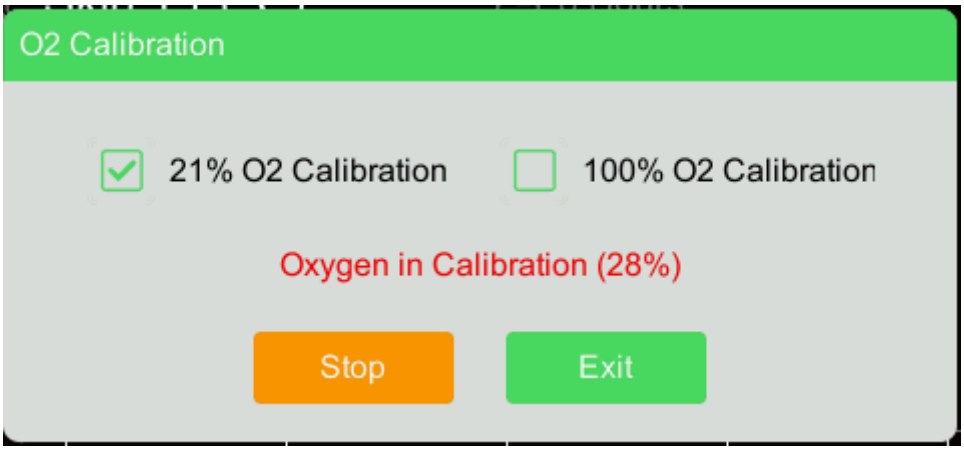
Cancel button, press the exit button to exit current menu interface.

10.3.5 氧气浓度校准菜单页面按键 Oxygen concentration calibration menu button

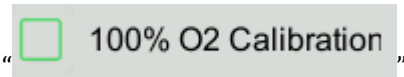
氧气浓度校准菜单界面以及校准过程菜单界面按键布局如下：

The Oxygen concentration calibration menu and the calibration process interface button lay out shows as follow:





“  ”：21%氧气校准复选按钮，点击后，氧气校准使用 21%浓度进行校准。 21% oxygen calibration check button. After clicking, oxygen calibration uses 21% concentration for calibration.

“  ”：100%氧气校准复选按钮，点击后，氧气校准使用 100%浓度进行校准。100% oxygen calibration check button. After clicking, oxygen calibration uses 100% concentration for calibration

“  ”：校准按键，点击后，进入氧气校准流程。

Calibration button, after clicking, the oxygen calibration process starting.

“  ”：停止校准按键，点击后，停止当前氧气校准流程。

Calibration stoop button, after clicking, the oxygen calibration process stopped.

“ 

”：氧气校准进度显示。Oxygen calibration progress display.

“ 

”：退出当前菜单界面。Exit the current interface menu.

11 所交付的医疗设备软件在运维现场的安装和验收要求 Installation and acceptance requirements of delivered medical equipment software at operation and maintenance site

软件被编写在芯片内部，芯片被焊接到 PCB 上，不需要额外的安装。

The software is written inside the chip, and the chip is welded to the PCB without additional installation.

12 有关操作和维护方法的要求 Requirements for operation and maintenance methods

软件操作方法需求分析 Software operation methods requirement analysis

1) 操作简单，方便 Easy and convenient to operate
2) 输出按键操作顺序要求：先按锁定/解锁按键，再进行其它操作。Keypad operation sequence: unlock first before other operation
3) 操作安全须知：使用说明书警示，设备标识，软件界面的报警信息 Safety instruction in the operation: check warning is the user manual, label, alarm information on the screen.
4) 通过使用说明书指导用户操作软件 Instruct users to operate in the user manual

13 有关 IT-网络方面的需求 IT-Network requirements

无网络功能. No network function

14 用户维护要求 User maintenance requirement

No need of the user maintenance. Software do not update.

15 监管要求 Regulatory requirements

Comply with the relevant Thailand regulations, Food and Drug Administration.

16 在软件要求中包括风险控制措施 The risk control measures included in the software requirement

详见以下风险控制管理报告。 See the risk control management report for details.