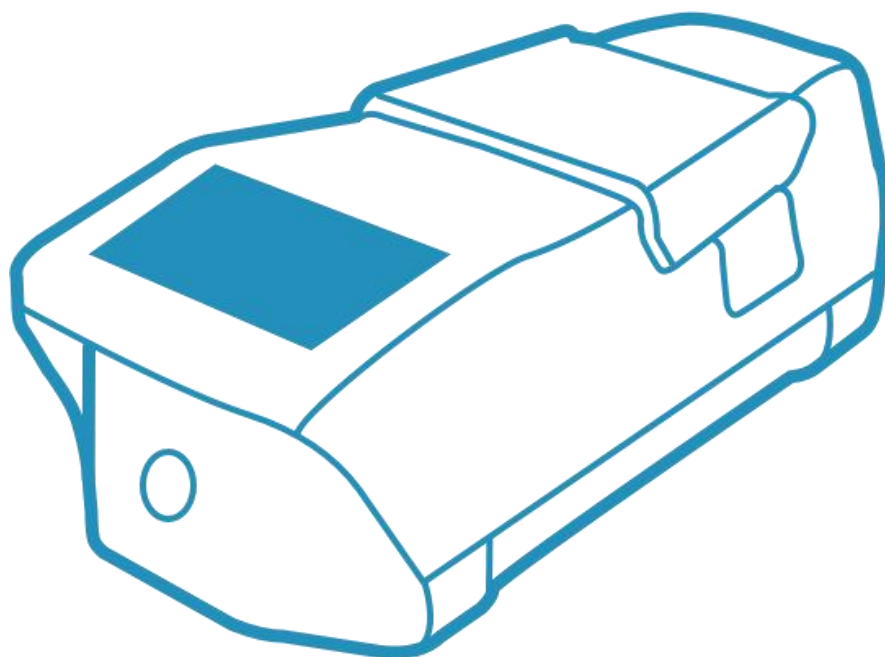


LePurseal[®]

全自动无菌封管机 II

Automatic Aseptic Sealer II

产品操作手册/User manual



目录

1. 通用	
1.1 公司简介	6
1.2 用户技术安全信息	8
1.3 免责声明	8
2. 介绍	
2.1 安全标识	9
2.2 安全须知	10
2.3 注意事项	10
2.4 故障描述	11
2.5 账号权限	12
2.6 产品介绍	13
2.6.1 参数	13
2.6.2 性能	14
3. 启动	
3.1 物品清单	16
4. 操作	
4.1 操作规范	17
4.2 菜单树	18
4.3 主界面图标介绍	19

4.4 “急停”功能	20
4.5 正确放入管子	21
4.6 触摸屏操作	22
4.6.1 开机自检	22
4.6.2 登录	24
4.6.3 封管	24
4.6.4 导出数据	27
4.6.5 用户管理	29
4.6.6 设置	31
4.6.7 修改密码	32
4.6.8 温度验证	33
4.6.9 本机信息	34
4.7 清洁	34
4.7.1 关于清洁	34
4.7.2 推荐使用	35
4.7.3 过程描述	35
5. 维护	36
5.1 维护	36

1.General	
1.1 Company Profile	37
1.2 User Technical Safety Information	38
1.3 Liability disclaim	39
2.Introduction	
2.1 Safety Sign	40
2.2 Safety Instructions	41
2.3 Notice	42
2.4 Error description	43
2.5 Account permissions	44
2.6 Product introduction	45
2.6.1Parameter	45
2.6.2 Performance	46
3 Start-up	
3.1 Accessories list	49
4.Operation	
4.1 Operating procedures	51
4.2 Menu	52
4.3 Introduction to main interface icons	53
4.4 Emergency stop	54
4.5 Properly insert the tubing	55
4.6 Touch screen	56

4.6.1Self-test	56
4.6.2Login	58
4.6.3Sealing	58
4.6.4Export Data	61
4.6.5User management	63
4.6.6Settings	65
4.6.7Change password	66
4.6.8 Temperature Validation	67
4.6.9Device Information	68
4.7Equipment Cleaning.....	68
4.7.1Cleaning instructions	68
4.7.2Recommended cleaning	69
4.7.3Process description	69
5.Maintenance	
5.1Maintenance	70

1. 通用

1.1 公司简介

上海乐纯生物技术股份有限公司，成立于 2011 年，是先行从事生物制药行业一次性使用耗材及设备的研发、生产和销售的高新技术企业。

作为国内最早一批提供生物制药工艺解决方案的企业，乐纯生物开创了国内生物制药行业一次性解决方案本土化的先河。乐纯生物十余年发力产业供应链创新和优质国产化替代，始终以客户为中心，质量至上，自强不息，不断开发新的一次性生物工艺应用产品。乐纯生物拥有多项生物制药工艺一次性使用产品相关专利技术，涵盖上游细胞培养、下游过滤、制剂灌装以及流体传输，均具有安全、可靠、易验证、低成本、环保等多重优势，从而帮助生物技术及制药企业保障药品工艺稳定性和药品质量。

乐纯生物以技术创新为驱动，充分发挥一次性技术的高效、安全、便捷、经济的优势，赋能生物医药，提供高品质工艺解决方案，致力于成为全球生物制药企业最信赖的合作伙伴。



1.2 用户技术安全信息

本手册包含本文所述产品的指定用途的所有必要信息，适用于技术合格人员。

合格人员是指由负责系统安全的人授权执行必要活动的人员，其中，这些人员具备相应的学历、经验和培训并了解相关标准、规范、事故预防条例和操作条件，并且能够识别并避免在这些活动中可能发送的危险。对于因事故而造成的设备或应用程序的任何损坏或后续损害，我们不承担任何责任。

1.3 免责声明

本手册中提供的信息如有更改，恕不另行通知。

本手册中的所有声明、信息准确和完整，但我们不为其提供任何明示或暗示的担保。

无论在本手册中是否作出了其他担保，本手册所有文档文件和软件仍有可能存在缺陷。我们不承诺所有明示或暗示的担保，包括（但不限于）对特定用途的适销性、适用性、非侵权性以及因交易、使用或商业惯例所衍生的担保。

在任何情况下，对于任何间接、特殊、连带发生或偶发的损坏，包括（但不限于）因使用或无法使用本手册而导致的任何利润损失或数据损失或其他损失，我们不对与使用本手册相关或因使用本手册而产生的附带或后果性损害负责，用户承担使用产品的全部责任。

本设备仅用于本手册规定的目的，未经我们事先书面同意，将本设备用于任何其他用途或对其进行变更均认为是操作不当。我们不对由此产生的任何损坏和损失承担责任，风险由操作人员承担。对于因事故而造成的设备或应用程序的任何损坏或后续损害，我们不承担任何责任。

2. 介绍

2.1 安全标识

 A yellow triangular warning sign with a black border. Inside the triangle, there are three wavy lines representing heat or steam, and a horizontal line below them.	<p>当心高温表面，小心烫伤。封管的加热片表面在工作过程中存在高温，不得随意触摸。</p>
 A yellow triangular warning sign with a black border. Inside the triangle, there is a black silhouette of a hand being crushed between two vertical lines, representing a hand injury hazard.	<p>当心夹手，注意手部安全，避免发生手部意外伤害。</p>
 A yellow triangular warning sign with a black border. Inside the triangle, there is a large black exclamation mark, representing a general warning or hazard.	<p>本说明以及装置带有“警示标志”的“警告”是指，如果不遵守相关要求，不采取相应措施，就存在有可能造成死亡或严重人身伤害的潜在危险。</p>

2.2 安全须知

*为了操作人员的人身安全以及设备使用安全，请仔细阅读以下信息。

- 开机前检查设备额定电压是否与当地电压一致。
- 本装置不适用于爆炸性环境。
- 不遵循制造商的操作手册说明可能导致不可靠，危险情况和安全干扰。
- 该装置是为实验室使用而开发的，必须防止任何类型的流体或蒸汽。
- 设备可在+18°C~ +40°C范围内工作。封管参数建议用于室温工况。
- 使用环境相对湿度要求为≤60%。
- 封管过程中，确保设备不处于关闭状态。
- 提高过程可靠性，确保有不间断电源(UPS)。
- 使用时确保没有异物进入内部的设备，以免造成设备的损坏。
- 确保使用完成后进行登出，否则另一个用户可以使用您的账户操作设备。
- 不遵循操作手册指示可能导致不可靠，危险情况和安全干扰。

2.3 注意事项

- 设备使用的电源必须有接地。
- 设备应保持洁净干燥，如有污损，应及时处理，以免影响设备的正常运行。
- 当设备发生故障时，应通知专业的维修人员检查维修。

- 封管过程中的中断可能导致问题，必须避免。一定要严格遵守操作说明。
- 设备在送到供应商或制造商之前必须进行消毒。

2.4 故障描述

代号	说明	解决方法
ERR1	表示电机运动机构故障	如果在设备运行过程中遇到任何异常情况，请立即关机并停电再重启。如果问题仍然存在，请联系我们的工程师以获得支持和帮助。
ERR2	表示固定端加热机构异常	
ERR3	表示移动端加热机构异常	
ERR4	表示固定端加热机构不升温	
ERR5	表示移动端加热机构不升温	
ERR6	表示降温冷却超时报警（冷却系统异常）	

2.5 账号权限

	ADMIN	操作员	查看者	Example
封管	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
导出数据	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
用户管理	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
设置	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
修改密码	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
本机信息	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
温度验证	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* “Example” 为一键登录功能，无需密码即可登录。

2.6 产品介绍

2.6.1 参数

电源	100~240VAC, 50/60Hz
系统功率	120W
热封时间	封管 3~5.5 min
适用管路规格型号	外径 6.4 mm ~ 25.4 mm (1/4"~1") , 可封带液或不带液的热塑管/BPT 等 *其中湿热管放置 24 小时再使用, 以避免出现封管外观不良
外形尺寸	长 * 宽 * 高: 37.5*16*15.5 cm
净重	5.5 kg
使用环境	温度: 18°C~40°C ; 湿度 ≤ 60%RH
材质	底座: 304 不锈钢, 外壳: ABS 工程塑料, 翻盖: PMMA
噪音	≤ 65dB
外壳处理	高温烤漆、耐消毒剂擦拭
权限管理	三级权限管理

2.6.2 性能

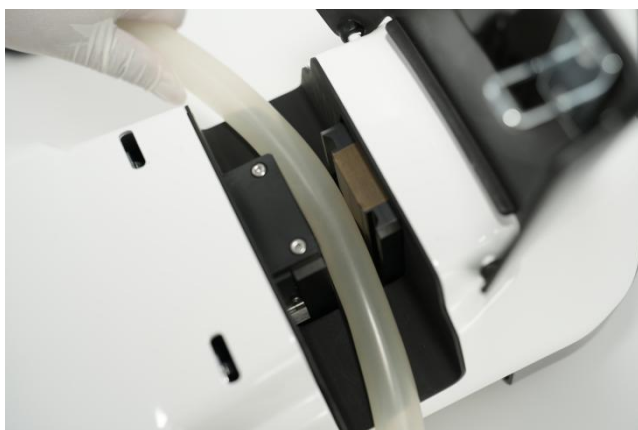
(1) 工作原理:

LePurseal®全自动无菌封管机 II 具有对应两个加热板，将管路放在两个加热板中间，通过夹紧后加热，在高温和压力的作用下，使管内壁熔合，冷却后管路即在中段完全密封，断开时可以用剪刀从中间的裁切线位置剪断。



(2) 适用性:

LePurseal®全自动无菌封管机 II 适用于外径 6.4 mm-25.4 mm 热塑性管路的热封，热封过程无需另外使用易耗品和一次性技术产品，如一次性生物反应器、一次性储液袋等配合使用，经济高效。



(3) 温度档位调节及管子选择程序:

LePurseal®全自动无菌封管机 II 可以封合不同品牌、不同材质的热塑管路，由不同的温度设置来适应不同的管路材质，本机器提供多个品牌、不同种规格管路的程序，在订货时我们便会根据确认的管路材质设置相应的参数与之适应。

品牌与管路型号对应关系详见下表:

管径 (Le-Flex®)	
1/8"-1/4"	3/16"-5/16"
1/4"-3/8"	1/4"-7/16"
1/4"-1/2"	3/8"-5/8"
1/2"-3/4"	3/4"-1"

管径 (Advanta Flex®)	
1/8"-1/4"	1/4"-3/8"
1/4"-7/16"	3/8"-5/8"
1/2"-3/4"	5/8"-7/8"
3/4"-1"	

管径 (C-Flex®)	
1/8"-1/4"	1/4"-3/8"
1/4"-7/16"	3/8"-5/8"
1/2"-3/4"	3/4"-1"

管径 (消泡剂)
消泡剂

管径 (BPT)
BPT

3. 启动

3.1 物品清单

物品名称	数量	选项
LePurseal® 全自动无菌封管机 II	1 台	<input checked="" type="checkbox"/>
电源线	1 份	<input checked="" type="checkbox"/>
产品操作手册	1 份	<input checked="" type="checkbox"/>
电源适配器	1 份	<input checked="" type="checkbox"/>

4. 操作

4.1 操作规范



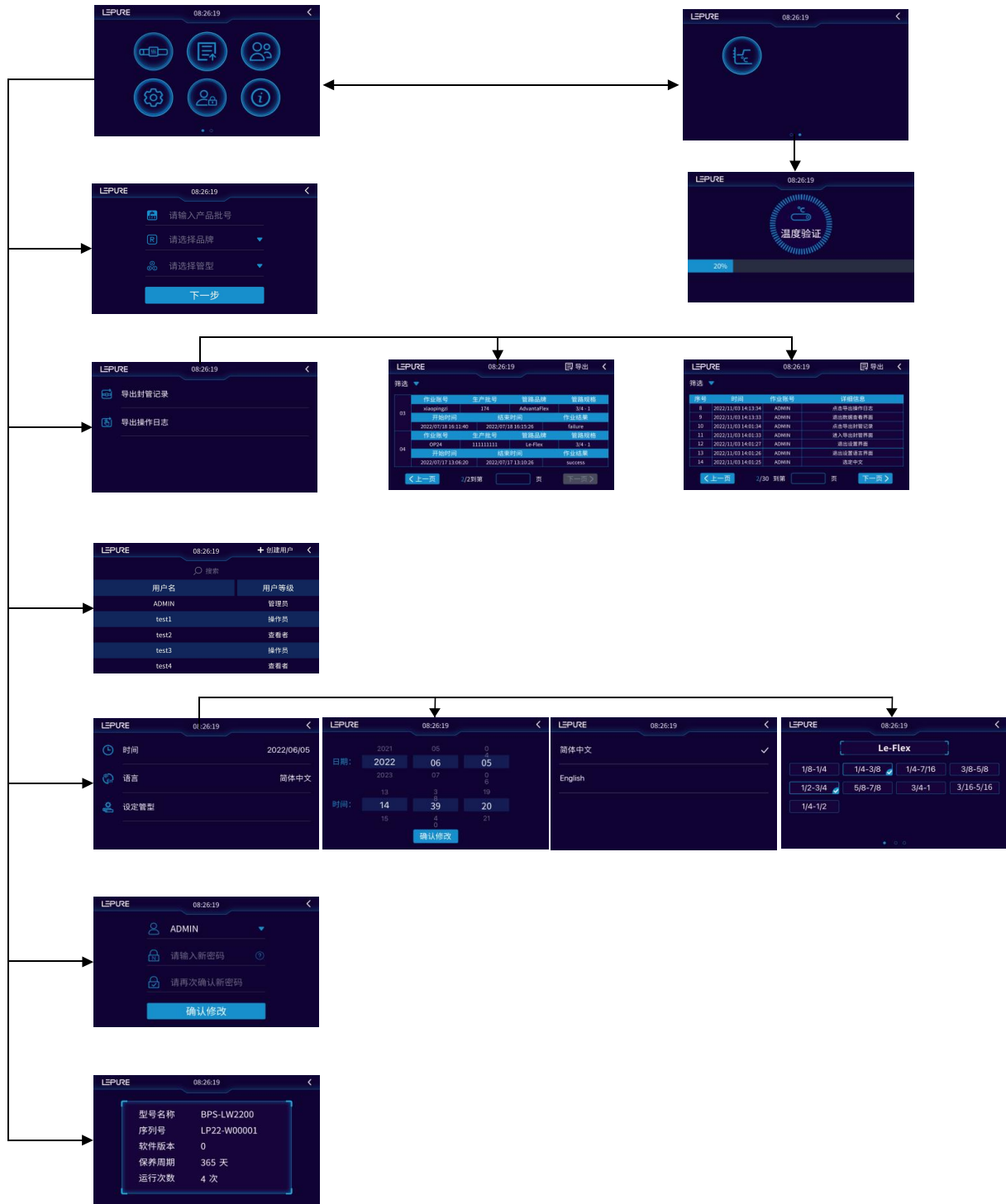
本仪器有热源，请注意各部位的温度，以免烫伤！



保持封管区域内干净，不得有污染物，定时清理干净。加热片上如果有污染物则会
影响温度，导致温度不均匀，从而影响封管质量！



4.2 菜单树

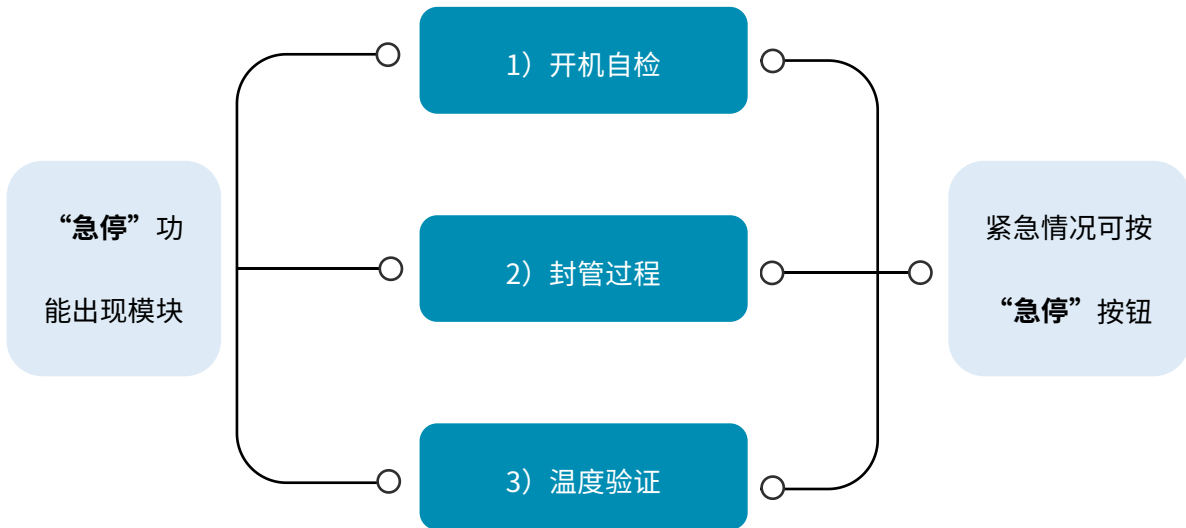


4.3 主界面图标介绍

	“封管”入口
	“数据导出”入口
	“用户管理”入口
	“设置”入口
	“修改密码”入口
	“本机信息”入口

	“温度验证”入口
---	----------

4.4 “急停”功能



4.5 正确放入管子

*请按以下方向放入管子，并合上保护盖:



4.6 触摸屏操作

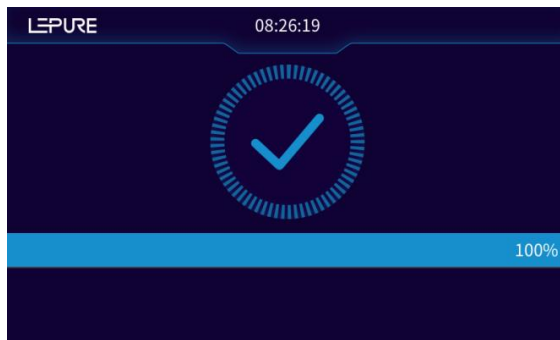
4.6.1 开机自检

界面图片	描述
 The image shows the main splash screen of the LEPURE machine. It features the brand name 'LEPURE' in large white letters, with '全自动无菌封管机 II' (Fully Automatic Sterile Capping Machine II) below it. The background is dark blue with a glowing grid pattern and some light blue particles.	step1 插入电源插头，打开电源开关。
 The image shows a screen with a dark blue background and a glowing blue border. At the top, it says 'LEPURE' and '08:26:19'. The main text reads: '开始自检前 请移除夹管区域内所有物品 并合上保护盖!' (Before starting self-check, please remove all items from the clamping area and close the protective cover!).	step2 防护盖自动弹出，出现左侧界面。 *本机通电开机后，如果长时间不进行自检，本机将会进入保护状态，需断电重启封管机。
 The image shows the same screen as step 2, but with a blue button labeled '开始自检' (Start Self-check) at the bottom center.	step3 合上防护盖，界面出现“开始自检”按钮。



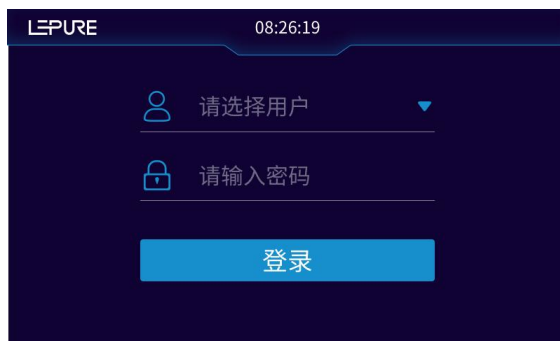
step4

在按下“开始自检”按钮后，设备将开始进行自检过程。



step5

当自检完成后，出现左侧界面。




step6

登录界面跳出后，输入正确的账户信息，进入相应的账户进行操作。

4.6.2 登录

界面图片	描述
	<p>在输入正确登录密码后，您将能够登录到相应的级别并执行操作。</p> <p>*ADMIN:初始密码 ADMIN；Example:一键登录；其他权限需要 ADMIN 创建。</p>

4.6.3 封管

界面图片	描述
	<p>step1</p> <p>在主界面上点击“封管”入口，将进入左侧界面。</p>
	<p>step2</p> <p>请输入批号，并从下拉菜单中选择品牌和管型。</p> <p>。</p>



step3

在确认好品牌和管型后； 点击“下一步”按钮，出现左侧界面。



step4

把管子放入到管托的中间位置。盖好防护盖后，然后点击“开始夹紧”按钮。

*请先将管子放置平整并贴平于黑色放管平台，再执行封管。



step5

在进行封管之前，需要进行预夹紧操作。



step6

在进行封管之前，系统给出的提示。

*弹出此界面后，请您执行两侧夹管。



step7

封管过程，预热阶段。



step8

封管过程，封管阶段。



step9

封管过程，冷却阶段。



step10

封管完成。

- ◇ 再次封不同品牌和管型选“重选管型”
- ◇ 再次封相同品牌和管型选“继续封管”

4.6.4 导出数据

界面图片

描述



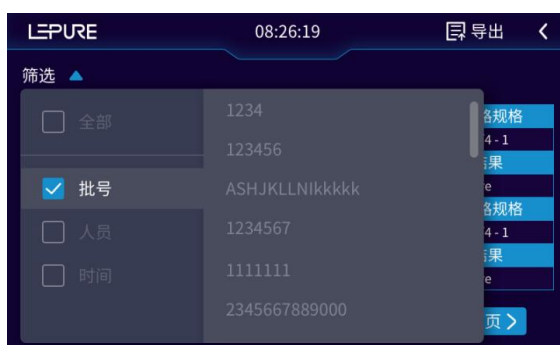
1) 在主界面上点击“导出数据”入口，将进入左侧界面。您可以在该界面上查看和导出封管记录和操作日志。



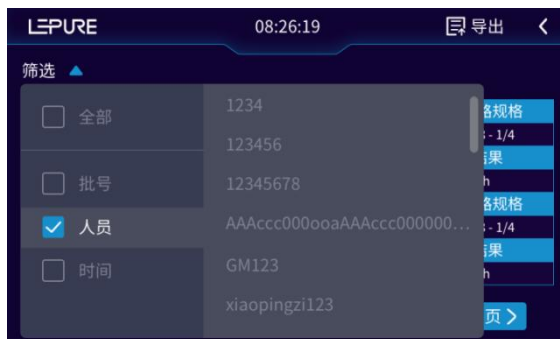
2) 点击“导出封管记录”后，您将进入左侧界面。使用“上一页”和“下一页”按钮可以在不同页之间进行切换，点击底部中间的输入框，可以快速搜索并定位到指定界面列表。



3) 导出方式有如下筛选项；点筛选下拉框，选择“全部”选项，即可导出全部数据。



4) 点击筛选下拉框，选择“批号”选项，即可按批号条件进行筛选。



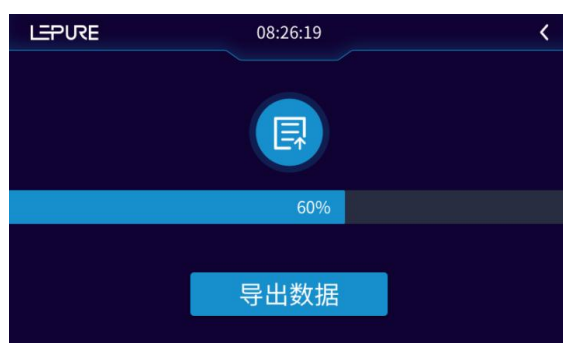
5) 点击筛选下拉框，选择“人员”选项，即可按人员条件进行筛选。



6) 点击筛选下拉框，选择“时间”选项，即可按时间条件进行筛选。



5) 点击“导出操作日志”后，您将进入左侧界面。使用“上一页”和“下一页”按钮可以在不同页之间进行切换，点击底部中间的输入框，可以快速搜索并定位到指定界面列表。



9) 点击图“7)”右上角“导出”按钮，您将进入左侧界面。插入 U 盘后，点击“导出数据”按钮，即可将数据导出到 U 盘中。

4.6.5 用户管理

界面图片

描述



在主界面上点击“用户管理”入口，将进入左侧界面。只有具有管理员权限的用户（ADMIN）才能进入此界面，并可以创建或删除其他用户。

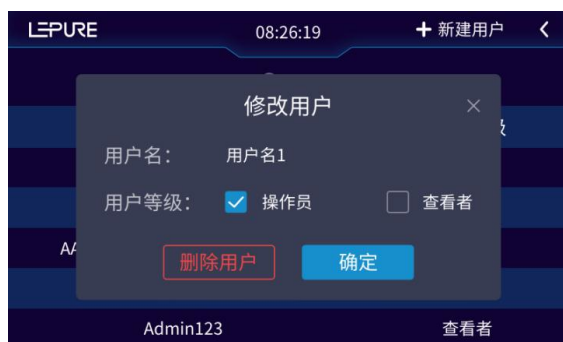
*此界面仅 ADMIN 可进入



2) ADMIN 账户具有唯一性,无法删除或更改。



3) 点击图“2)”右上角“+ 创建用户”按钮,进入左侧界面。输入对应的内容,即可创建新用户。
*账号是唯一的,曾使用过的账号,不能再创建。



4) 点击管理列表,进入左侧界面。您可以在此界面上修改和删除用户。

4.6.6 设置

界面图片	描述
	1) 在主界面点击“设置”入口，将进入左侧界面。您可以在此界面上对时间、语言和管型进行设定。
	2) 此界面可以设定时间。
	3) 此界面可以设定语言。



4) 此界面可以设定管型。

- ✧ 用户根据实际需求,可以选择适合的管型。

4.6.7 修改密码

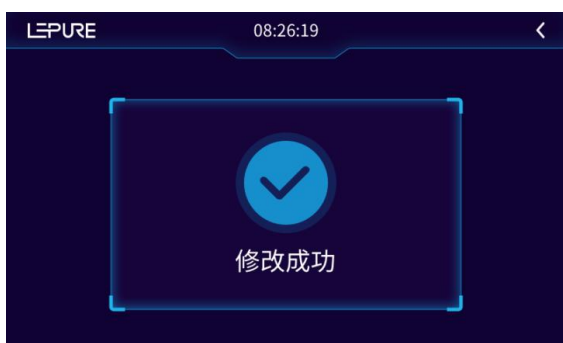
界面图片

描述



- 1) 在主界面上点击“修改密码”入口,将进入左侧界面。您可以选择相应的账户后,然后进行密码修改。。

*密码规则: 1~18 位任意字符



- 2) 当您成功修改密码后,系统给出的提示。




- 3) 当您失败修改密码后,系统给出的提示。

4.6.8 温度验证

界面图片	描述
	<p>step1</p> <p>在主界面上点击“温度验证”入口，将进入左侧界面。</p> <p>*仅管理员有权限操作，建议由乐纯验证工程师完成。</p>
	<p>step2</p> <p>放入验证工具，合上防护盖后，界面出现“开始温度验证”按钮。</p>
	<p>step3</p> <p>在按下“开始温度验证”按钮，您可以进行温度验证。</p>
	<p>step4</p> <p>温度验证完成后，显示左侧界面。</p>

4.6.9 本机信息

界面图片	描述
	<p>在主界面上点击“本机信息”入口，进入左侧界面。您可以查看部分设备信息。</p>

4.7 清洁

4.7.1 关于清洁

- 设备不能用喷洒或蒸汽的方式进行清洁。喷洒或蒸汽清洁会减少单个部件的使用寿命或者损坏单个部件。
- 设备清洁用无尘布蘸酒精对设备进行消毒清洁（如图 1、图 2）



(图 1)



(图 2)

4.7.2 推荐使用

- 乙醇 70% (如 Klericide 杀菌剂 70/30)
- 次氯酸钠 6% (如 Klericide 杀菌剂-CR)

4.7.3 过程描述



step1

设备自检完成，维持黑色盖子打开状态清

洁整个封管区域；



step2

使用清洁剂浸泡的洁净纸巾对压合位置

进行擦拭（建议使用无纺布）；

5. 维护

5.1 维护

- 应每周对设备进行清洁，每次使用前用喷适量酒精的无尘布清洁外表面。
- 应经常检查封管区域是否有污物，有污物请立即清洁。可用蘸适量酒精的无尘布清洁封管区域。
- 应定期检查设备运行状态，如有异常，请及时联系当地的销售和售后人员。
- 设备如需返厂维修请使用我司专用包装，否则会造成运输损坏，如开箱包装丢失，请联系当地销售购买。
- 每年对设备进行一次校验和维护。
- 售后服务热线：400-902-0506。

1.General

1.1 Company Profile

Shanghai LePure Biotech Co., Ltd., established in 2011, is a high-tech enterprise engaged in the research and development, production, and sales of disposable consumables and equipment for the biopharmaceutical industry.

As one of the earliest domestic enterprises providing biopharmaceutical process solutions, LePure Biotech pioneered the localization of disposable solutions in the Chinese biopharmaceutical industry. For more than a decade, LePure Biotech has been committed to innovation in the industrial supply chain and high-quality domestic alternatives, always putting customers first and striving for excellence. LePure Biotech continuously develops new disposable bioprocess application products with a focus on quality. LePure Biotech holds multiple patents and technologies related to disposable bioprocess products for biopharmaceutical processes, covering upstream cell culture, downstream filtration, formulation filling, and fluid transfer. These products have multiple advantages, including safety, reliability, easy verification, low cost, and environmental friendliness, which help ensure the stability of drug processes and drug quality for biotechnology and pharmaceutical companies.

LePure Biotech is driven by technological innovation, fully leveraging the advantages of disposable technology in terms of efficiency, safety, convenience, and economy,

empowering biopharmaceuticals, providing high-quality process solutions, and committed to becoming the most trusted supplier for global biopharmaceutical companies.



1.2 User Technical Safety Information

This manual contains all the necessary information for the designated use of the product described in this document and is intended for technically qualified personnel. Qualified personnel are those authorized by the responsible person of system safety to perform necessary activities, who have the appropriate education, experience, and training, understand relevant standards, regulations, accident prevention ordinances, and operating conditions, and can identify and avoid hazards that may arise during these activities. The manufacturer is not liable for any damage or subsequent damage to the equipment or applications caused by accidents.

1.3 Liability disclaimer

The information provided in this manual is subject to change without prior notice. All statements and information in this manual are accurate and complete, but we do not provide any warranties or implied warranties for them.




Regardless of any other warranties made in this manual, all documents, files, and software in this manual may still have defects. We do not make any warranties, expressed or implied, including (but not limited to) warranties of merchantability, fitness for a particular purpose, non-infringement, and warranties arising from trade, use, or customary practices.

In no event shall we be liable for any indirect, special, consequential, or incidental damages, including (but not limited to) any loss of profits, data, or other losses resulting from the use or inability to use this manual. The user assumes full responsibility for the use of the product.

This equipment is intended solely for the purposes specified in this manual, and any unauthorized use or modification of this equipment without our prior written consent is considered improper operation. We shall not be liable for any damages or losses resulting from such actions, and the risk is assumed by the operator. We are not responsible for any damages or subsequent losses to the equipment or applications caused by accidents.

2.Introduction

2.1 Safety Sign

 A yellow triangular warning sign with a black border, containing three wavy lines representing heat.	<p>Be careful of the hot surface and avoid scalding. The heating surface of the sealing tube has high temperature during operation and should not be touched without authorization.</p>
 A yellow triangular warning sign with a black border, containing a hand being pinched by a mechanical part.	<p>Be careful not to pinch your hands and pay attention to hand safety to avoid accidental hand injuries.</p>
 A yellow triangular warning sign with a black border, containing a large exclamation mark.	<p>This notice and the "warning" with a "warning sign" on the device indicate that if you do not comply with the relevant requirements and take corresponding measures, there is a potential danger of death or serious personal injury.</p>

2.2 Safety Instructions

For the personal safety of operators and the safety use of the equipment, please read the following information carefully.

- Before turning on the machine, check if the rated voltage of the equipment is consistent with the local voltage.
- This device is not suitable for explosive environments.
- Not following the manufacturer's instructions may result in unreliability, dangerous situations, and safety interferences.
- This device is developed for laboratory use and must prevent any type of fluid or steam.
- The device can operate within the range of +18°C to +40°C. The sealing parameters are only applicable to room temperature conditions.
- The optimal relative humidity for sealing is $\leq 60\%$.
- Ensure that the equipment is not in a closed state during the sealing process.
- To improve process reliability, ensure that there is an uninterrupted power supply (UPS) available.
- Ensure that no foreign objects enter the internal components of the equipment during use to prevent damage.
- Make sure to log out after use, otherwise another user may use your account to operate the equipment.
- Not following the instructions in the manual may result in unreliable, hazardous situations, and safety interference.

2.3 Notice

- The power supply used for the equipment must be grounded.
- The equipment should be kept clean and dry. If it is dirty, it should be cleaned promptly to avoid affecting the normal operation of the equipment.
- When the equipment malfunctions, professional maintenance personnel should be notified to inspect and repair it.
- Interruptions during the sealing process can lead to issues and must be avoided. It is essential to strictly follow the operating instructions.
- The equipment must be disinfected before being sent to the supplier or manufacturer.

2.4 Error description

Code	Description	Solution
ERR1	Electric motor motion mechanism malfunction.	If any abnormal situation occurs during the operation of the device, please immediately turn off the power and restart it. If the problem persists, please contact our engineers for support and assistance.
ERR2	Anomaly in the fixed-end heating mechanism.	
ERR3	Abnormality in the mobile-end heating mechanism.	
ERR4	The fixed-end heating mechanism is not heating up.	
ERR5	The mobile-end heating mechanism is not heating up.	
ERR6	Cooling timeout alarm (cooling system abnormal).	

2.5 Account permissions

	ADMIN	Operator	Viewer	Example
Sealing	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Exporting data	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
User management	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Settings	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Change Password	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Device Information	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Temperature Validation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* "Example" is a one-click login feature that allows you to log in without a password.

2.6 Product introduction

2.6.1 Parameter

Power	100~240VAC, 50/60Hz
System power	120W
Heat sealing time	Sealing tube for 3~5.5 minutes
Applicable pipeline specifications and models	<p>Thermoplastic tubing/BPT with an outer diameter of 6.4 mm ~ 25.4 mm (1/4" ~ 1") that can be sealed with or without liquid</p> <p>*The steam sterilized tubing should be left in place for 24 hours before use in case of any undesirable appearance caused by sealing.</p>
Dimension	Length * Width * Height: 37.5*16*15.5 cm
Net weight	5.5 kg
Operating environment	Temperature: +18°C ~ 40°C; Humidity ≤ 60%RH
Material	Base: 304 stainless steel, Housing: ABS engineering plastic, Flip cover: PMMA

Noise	≤65dB
Housing treatment	High-temperature baking paint 、 resistant to disinfectant wiping
Permission management	Three-level authority management

2.6.2 Performance

(1) Working principle

LePure Aseptic Sealing Machine has two corresponding heating plates. The tubing is placed between the two heating plates, clamped and heated. Under high temperature and pressure, the inner wall of the tubing is fused. After cooling, the tubing is completely sealed in the middle section. It can be cut with scissors at the cut line position in the middle when needed.



(2) Applicability

LePure Biotech aseptic tube sealing machine is suitable for heat sealing thermoplastic tubing with an outer diameter of 6.4 mm-25.4 mm. The heat sealing process does not require additional consumables and disposable technical products, such as disposable bioreactors and disposable storage bags, to be used in conjunction, which is economical and efficient.



(3) Temperature setting and tubing selection procedure

LePure aseptic sealing machine can seal different brands and materials of thermoplastic tubing, and adapt to different tubing materials through different temperature settings. The machine provides programs for multiple brands and different sizes of tubing. When ordering, we will set the corresponding parameters according to the confirmed tubing material to adapt to it.

The correspondence between brands and tubing models is detailed in the table

below:

Le-Flex®	
1/8"-1/4"	3/16"-5/16"
1/4"-3/8"	1/4"-7/16"
1/4"-1/2"	3/8"-5/8"
1/2"-3/4"	3/4"-1"

Advanta Flex®	
1/8"-1/4"	1/4"-3/8"
1/4"-7/16"	3/8"-5/8"
1/2"-3/4"	5/8"-7/8"
3/4"-1"	

C-Flex®	
1/8"-1/4"	1/4"-3/8"
1/4"-7/16"	3/8"-5/8"
1/2"-3/4"	3/4"-1"

BPT
BPT

Defoamer
Defoamer

*The steam sterilized tubing should be left in place for 24 hours before use in case of any undesirable appearance caused by sealing.

3 Start-up



3.1 Accessories list

Accessory name	Quantity	Option
Automatic Aseptic Sealer II	1	<input checked="" type="checkbox"/>

Power cord	1	<input checked="" type="checkbox"/>
Product manual	1	<input checked="" type="checkbox"/>
Power adapter	1	<input checked="" type="checkbox"/>

4.Operation

4.1 Operating procedures

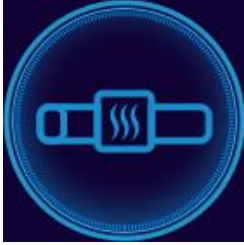





-  This device has a heat source, please pay attention to the temperature of each part to avoid burns!
-  Keep the clamping chamber clean and free of contaminants, clean it regularly.If there is contamination on the heating plate, it will affect the




4.2 Menu

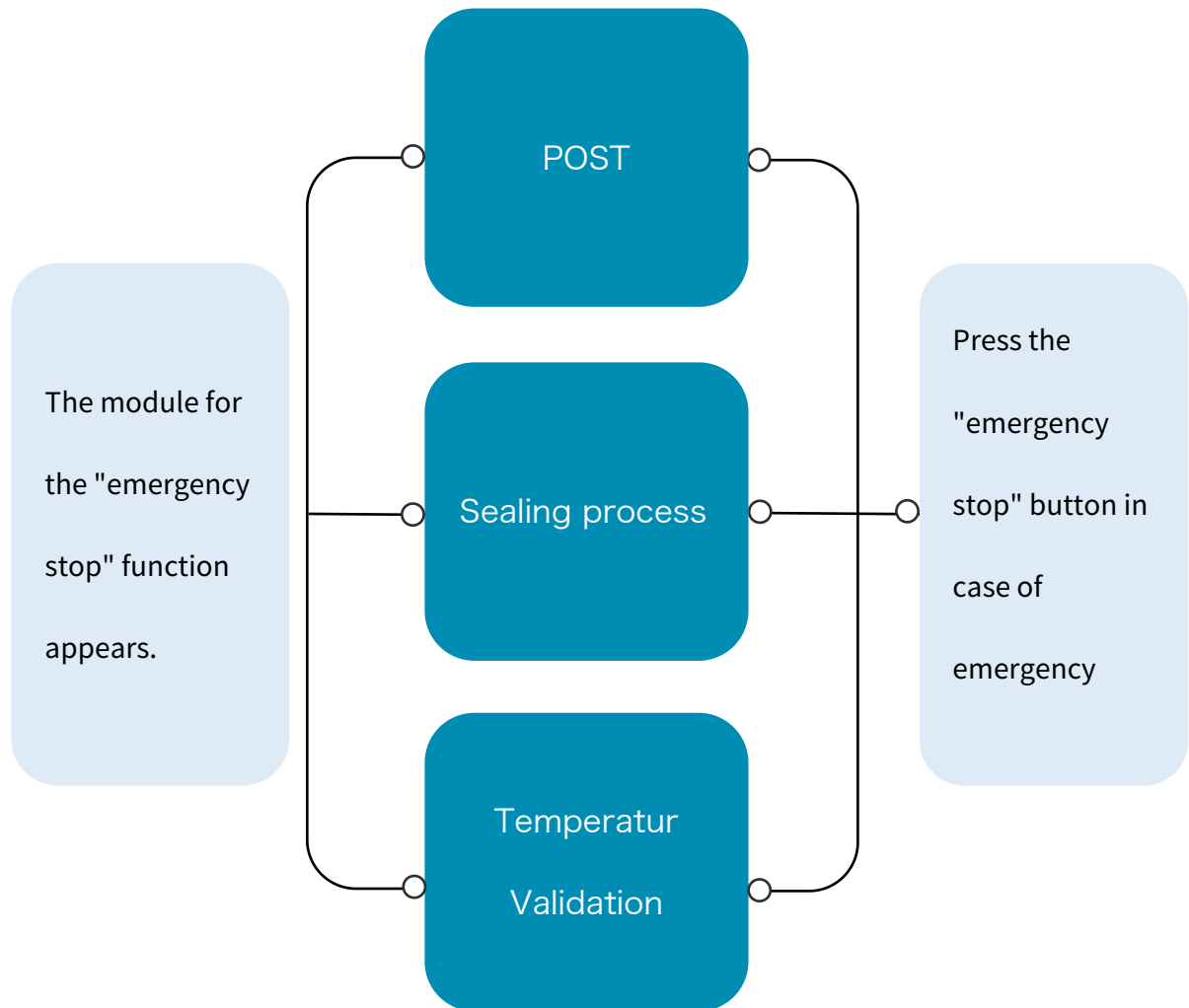


4.3 Introduction to main interface icons

	Tube sealing
	Export data
	User management
	Settings
	Change password
	Device Information

 A circular icon with a blue glow, containing a stylized graph with a temperature symbol (°C) and a checkmark.	Temperature Validation
---	------------------------

4.4 Emergency stop




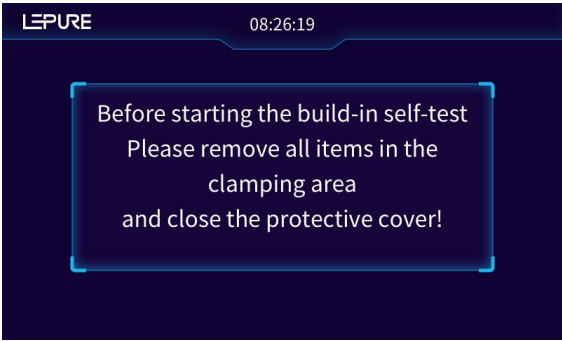
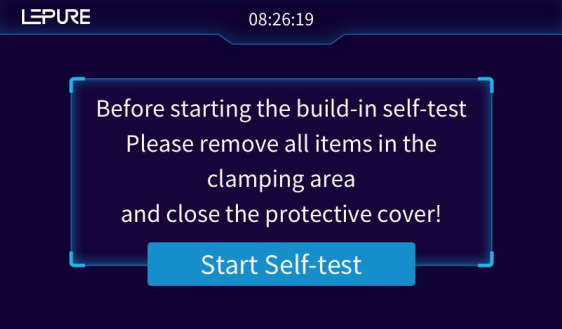
4.5 Properly insert the tubing

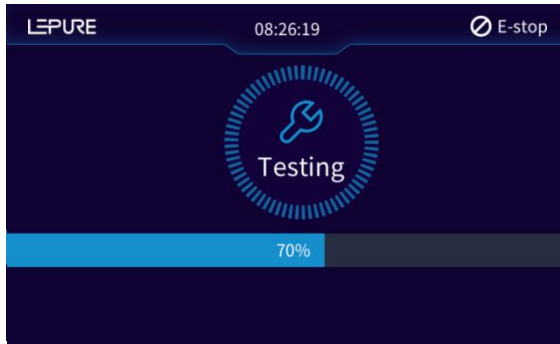
*Please insert the tubing according to the following orientations:



4.6 Touch screen

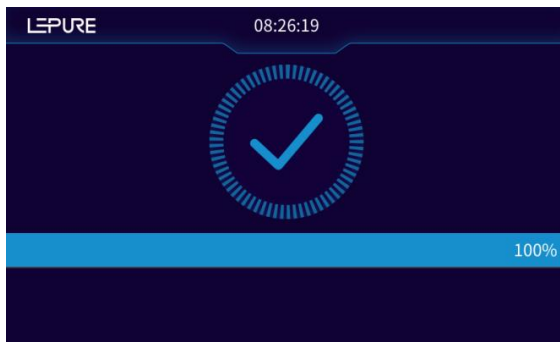
4.6.1 Self-test

Interface picture	Describe
 The image shows the main logo screen of the LEPURE Automatic Aseptic Sealer II. The background is dark blue with a grid of glowing blue lines and dots, suggesting a technical or digital theme. The text 'LEPURE' is prominently displayed in a large, white, sans-serif font, with 'Automatic Aseptic Sealer II' written below it in a smaller, white font.	<p>step1</p> <p>Plug in the power supply and turn on the power switch.</p>
 The image shows a touch screen interface with a dark blue background. At the top, 'LEPURE' is on the left and '08:26:19' is on the right. A central white box with a blue border contains the text: 'Before starting the build-in self-test Please remove all items in the clamping area and close the protective cover!'. The text is centered and uses a white, sans-serif font.	<p>step2</p> <p>The protective cover pops up automatically, and the left interface appears.</p>
 The image shows the same touch screen interface as in step 2, but with an additional blue button at the bottom center labeled 'Start Self-test' in white text. The rest of the screen content remains the same.	<p>*After the machine is powered on, if it does not perform a self-test for a long time, it will enter a protection state and require powering off and restarting the tube sealing machine.</p> <p>step3</p> <p>Close the protective cover, and the 'Start Self-Check' button will appear on the interface.</p>



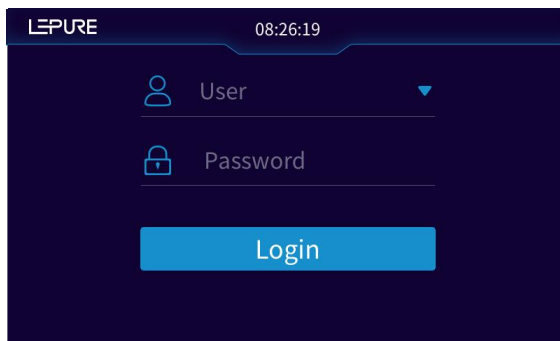
step4

After pressing the 'Start Self-check' button, the device begins to self-check.



step5

Self-check completed, left interface prompts.



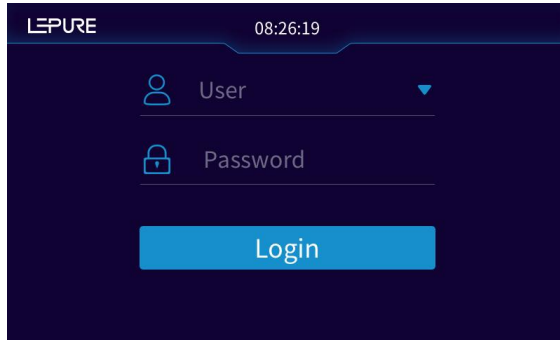
step6

The login interface pops up, allowing access to the corresponding account for operation.

4.6.2 Login

Interface picture

Describe



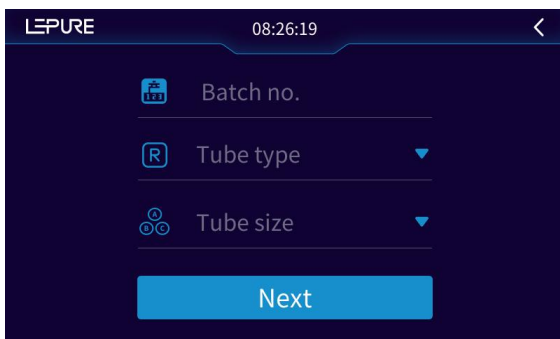
After entering the login password, you can log in to the corresponding level and perform operations.

*ADMIN: Initial password is ADMIN; Example: One-click login; Other permissions need to be created by ADMIN.

4.6.3 Sealing

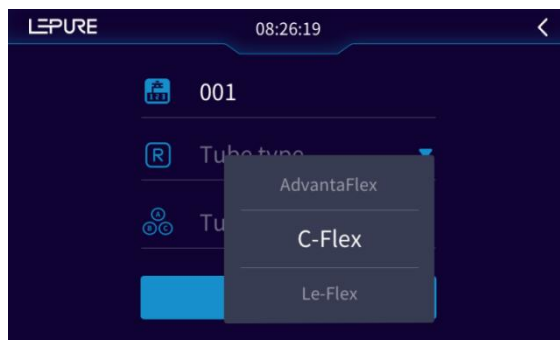
Interface picture

Describe



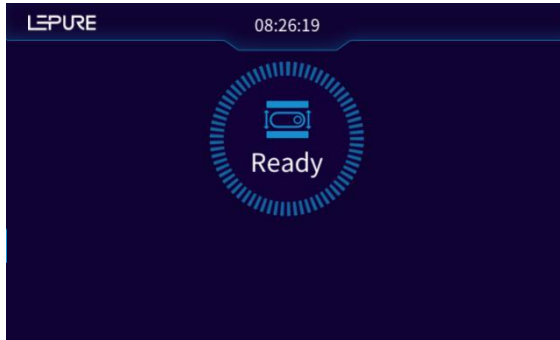
step1

Click on the 'Seal Tube' entrance on the main interface to enter the left interface.



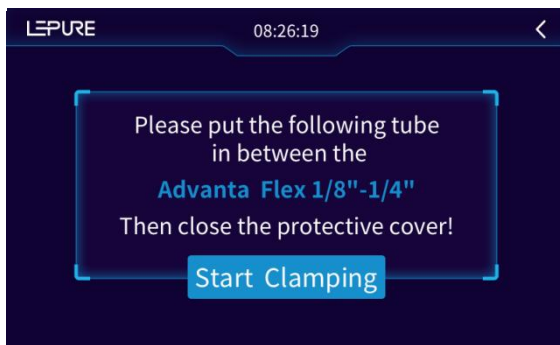
step2

Please enter the batch number and select the brand and tube type from the drop-down menu.



step3

After confirming the brand and tube type, click 'Next' to display the left interface.



step4

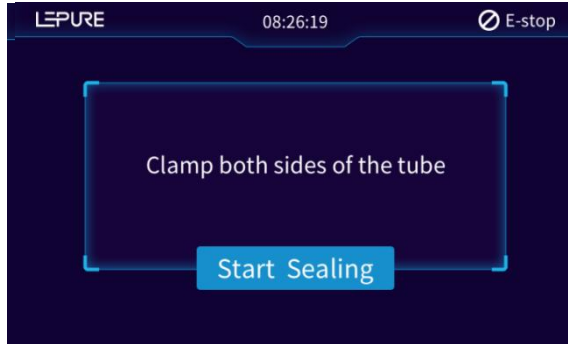
Place the tube in the middle position of the tube holder. After covering the protective cover, click 'Start clamping'.

*Please place the tube flat and adhere it to the black tube placement platform before sealing the tube.



step5

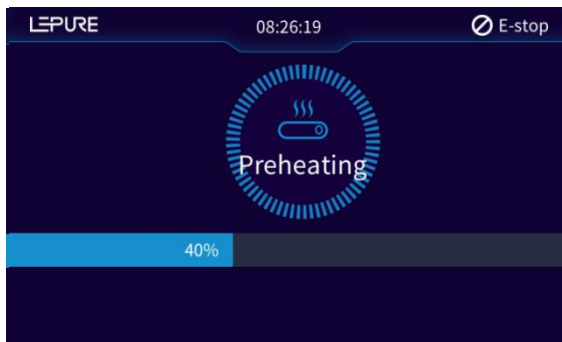
Pre-clamp before sealing the tube.



step6

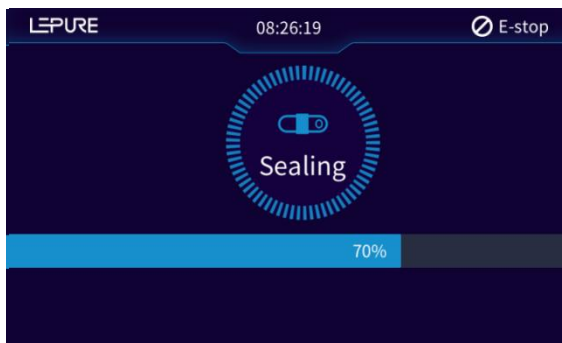
Tips before sealing the tubes.

*While on this screen, Please confirm that both sides of the tube have been clamped.



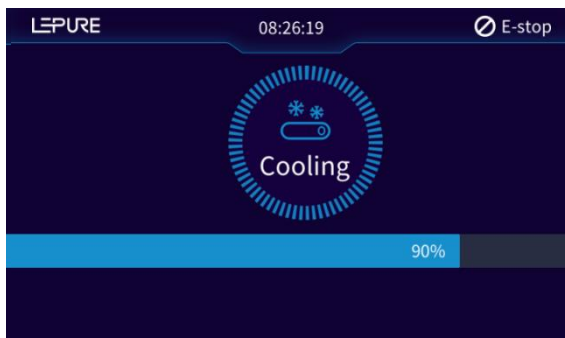
step7

Start preheating.



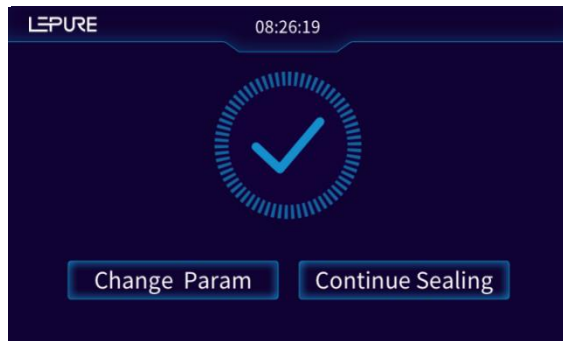
step8

Start sealing the tubes.



step9

Start cooling.



step10

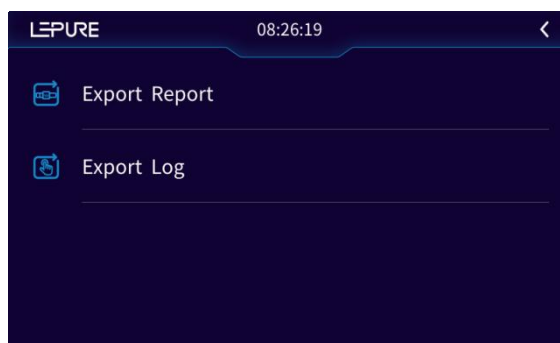
Sealing completed.

- ✧ To seal with a different brand or tube type, select 'Select Tube Type' again.
- ✧ To seal with the same brand and tube type, select 'Continue Sealing'.

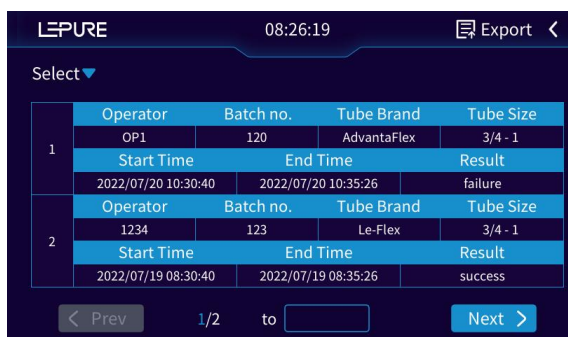
4.6.4 Export Data

Interface picture

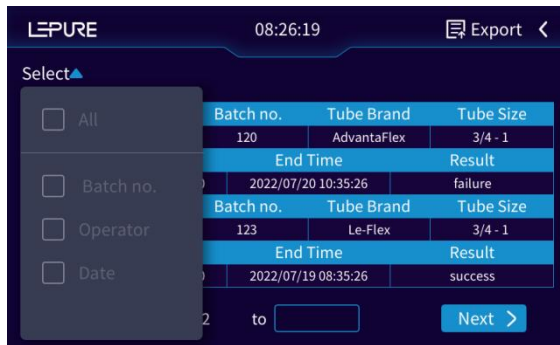
Describe



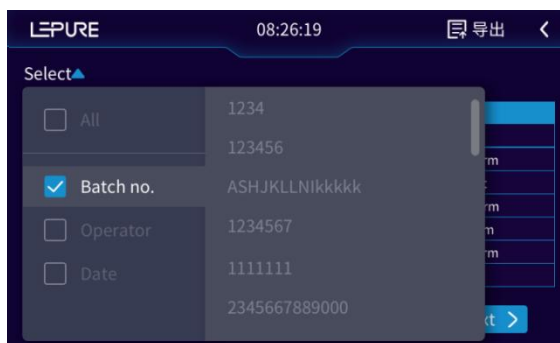
1) Click on the 'Export Data' entrance on the main interface to enter the left interface. You can view and export sealing records and operation logs.



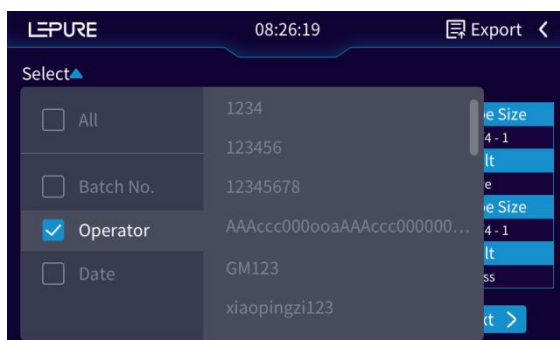
2) Click on 'Export Sealing Records' to enter the left interface. Select 'Previous Page' and 'Next Page' to switch between the previous and next page lists. Click on the input box in the middle of the bottom to quickly search for the specified page list.



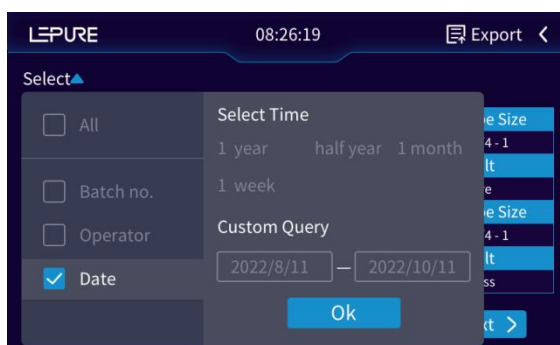
3) The export options include the following filter selections; click the filter dropdown box, Select the 'All' option to export all the data.



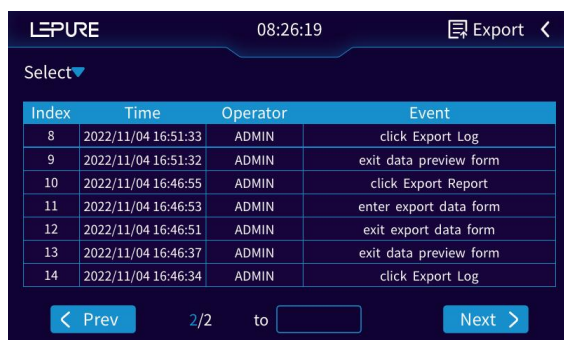
4) Click on the filtering dropdown menu and select the "Batch Number" option to filter by batch number.



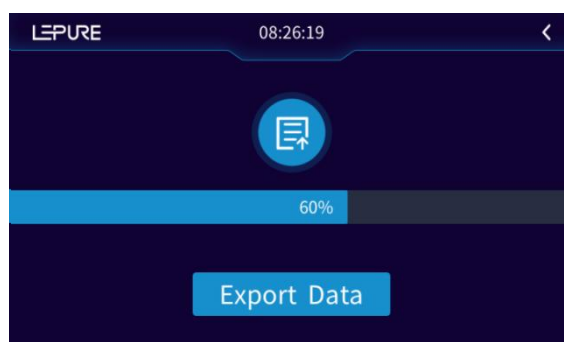
5) Click on the filtering dropdown menu and select the "Personnel" option to filter by personnel.



6) Click on the filtering dropdown menu and select "Time" option to filter by time.



7) Click on "Export Operation Log" to access the left-hand interface. Use the "Previous Page" and "Next Page" buttons to switch between pages of the list. The input box at the bottom center can be used to quickly search for a specific page in the list.

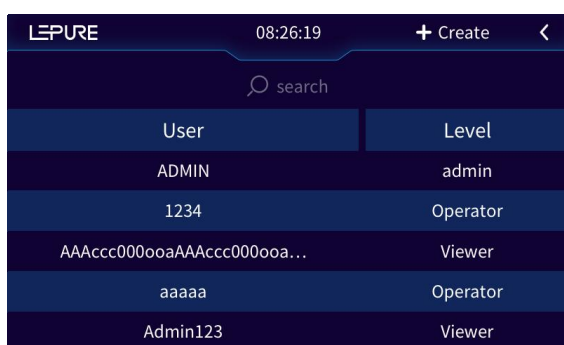


8) Click on the "Export" button in the upper right corner of step 7 to access the left-hand interface. Insert the USB flash drive and click on the "Export Data" button to export the data.

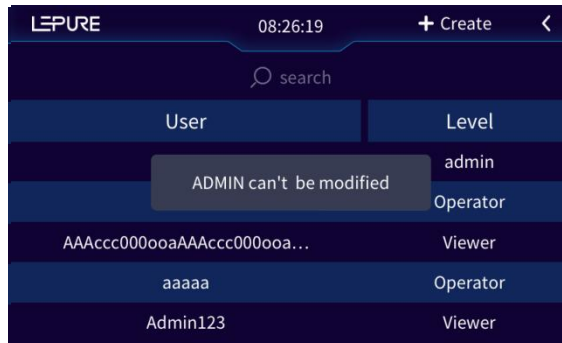
4.6.5 User management

Interface picture

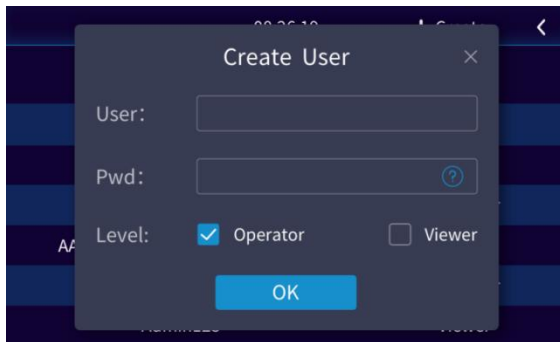
Describe



1) Click on the "User Management" entry on the main interface to access the left-hand interface. Users with ADMIN privileges can access this interface and have the authority to create or delete users.

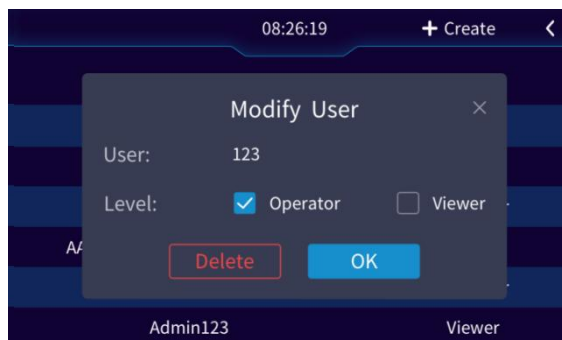


2) ADMIN is unique and cannot be deleted or modified.



3) Click on the "+ Create User" button in the upper right corner of Figure "2)" to enter the left interface. Enter the corresponding information to create a new user.

*The account number is unique. Accounts that have been used cannot be recreated.

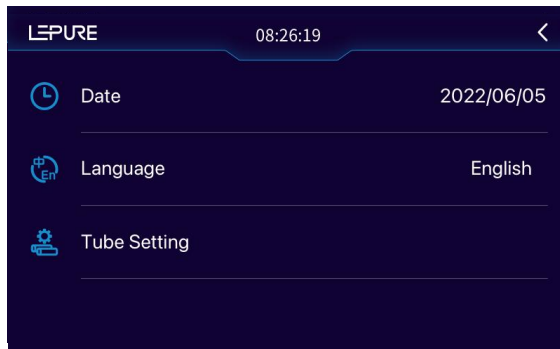


4) Click on the management list to enter the left interface. You can modify and delete users from there.

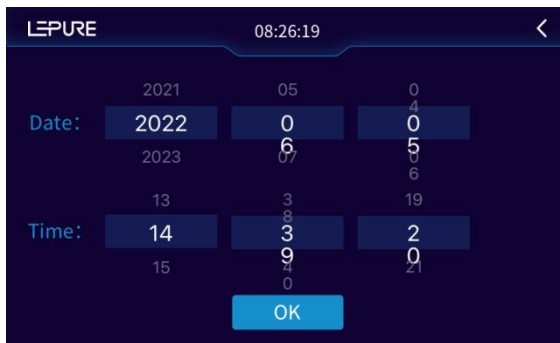
4.6.6 Settings

Interface picture

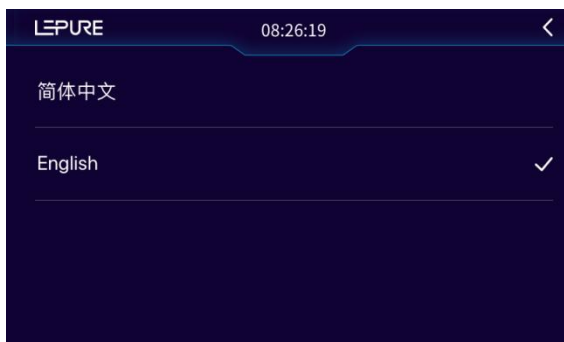
Describe



1) Click the "Settings" button on the main interface to enter the left-hand interface. You can set the time, language, and tube type.



2) Time setting.



3) Language setting.

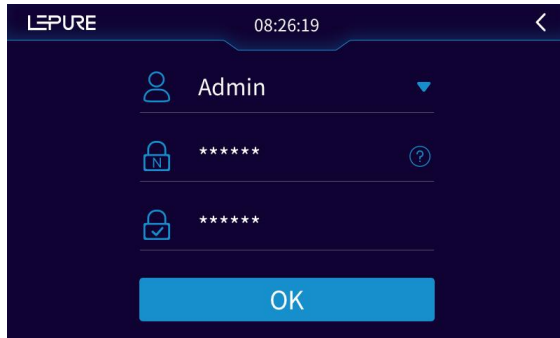


4) Management type setting.

4.6.7 Change password

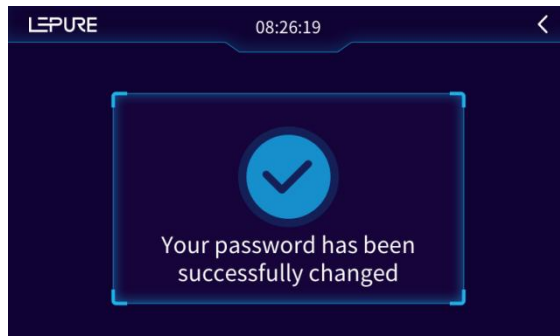
Interface picture

Describe

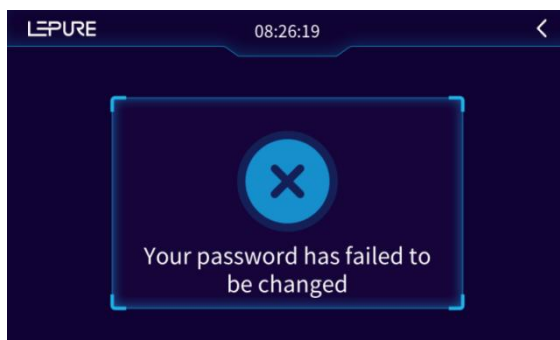


1) Clicking on the "Change Password" button on the main interface will take you to the left-hand side interface. You can select your account and then proceed to change your password.

Password rules: 1-18 characters of any type



2) Password change success prompt.



3) Password change error prompt.

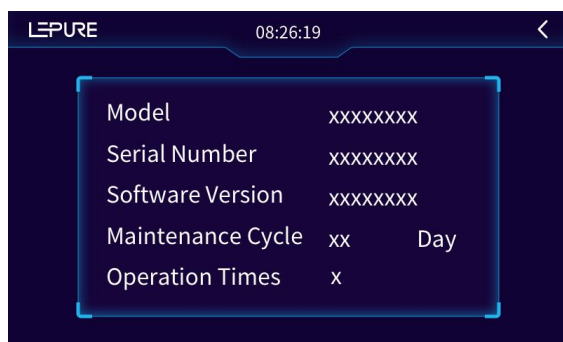
4.6.8 Temperature Validation

Interface picture	Describe
	<p>step1</p> <p>Click the "Temperature Validation" entry on the main interface to enter the left interface.</p>
	<p>step2</p> <p>Close the protective cover, and the 'start Temp. Validation' button will appear on the interface.</p> <p>*Only administrators have the authority to operate, and it is recommended that it be completed by a Lepure validation engineer.</p>
	<p>step3</p> <p>Press the 'Start Temp. validation' button to perform temperature validation.</p>
	<p>step4</p> <p>After the temperature validation is completed, the left interface will be displayed.</p>

4.6.9 Device Information

Interface picture

Describe



Click on the 'Device Information' entry to enter the left interface, where you can view some device information.

4.7 Equipment cleaning

4.7.1 Cleaning instructions

- The Automatic Aseptic Sealer II may not be cleaned with a spray- or steam procedure. Spray- or steam cleaning can cause a reduced life time of single components or lead to damage of single components.
- Clean the equipment using a lint-free cloth dipped in alcohol for disinfection and cleaning (refer to Figure 1 and Figure 2)



(图 1)



(图 2)

4.7.2 Recommended Items

- Ethanol 70% (e.g. Klericide 70/30)
- Sodium hypochlorite 6% (e.g. Klericide-CR)

4.7.3 Process description



step1

The equipment self-check is complete. Keep the black cover open to clean the entire sealed area.



step2

"Wipe the sealing position with a clean tissue soaked in a cleaning agent (preferably non-woven fabric is recommended).

5.Maintenance

5.1Maintenance

- The equipment should be cleaned weekly, and the outer surface should be wiped with a dust-free cloth sprayed with alcohol before each use.
- Regularly check the sealing area for dirt and clean it immediately if any. Clean the sealing area with a lint-free cloth dipped in an appropriate amount of alcohol.
- The equipment's operation status should be checked regularly, and if any abnormalities are found, please contact the local sales and after-sales
- Perform annual equipment verification and maintenance.
- If the equipment needs to be returned to the factory for repair, please use our dedicated packaging to avoid transportation damage. If the unpacking package is lost, please contact the local sales representative for purchase.
- After-sales service hotline: 400-902-0506.

*Please contact your sales engineer for device maintenance and upkeep plans.

LEPURE



微信公众号



官方网站

LEPURE

上海乐纯生物技术股份有限公司

Shanghai LePure Biotech Co., Ltd.

网站: www.lepure-bio.com

上海市松江区云振路 410 号 3 栋

邮箱: marketing@lepure-bio.com