

# CellSeal<sup>®</sup>

**AUTOMATED THAWING SYSTEM**

**REF** CATS-100

**REF** G47268

The CellSeal Automated Thawing System is for thawing the content of 2ml and 5ml CellSeal Closed-System Cryogenic Vials.

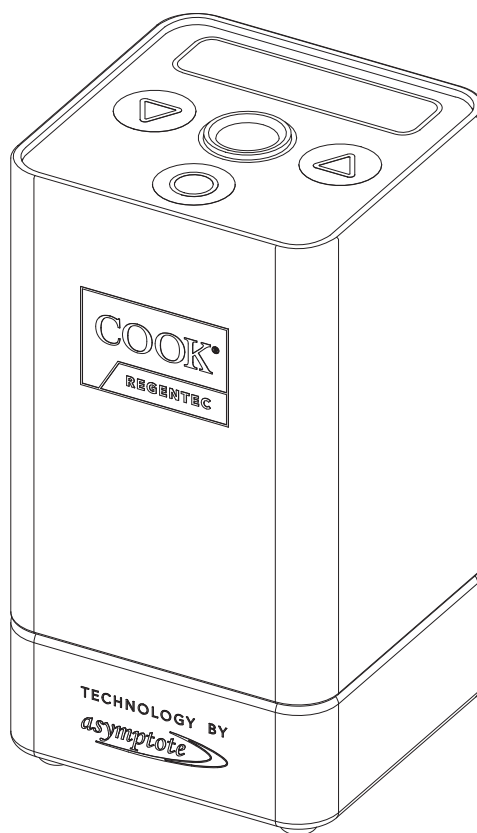
## User Manual

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## 1. Revision History

Revision	Details	Date	Author
1	Initial issue	12/08/16	DMM/SMilne

## Document Scope

This manual is intended as a guide for the operation, care and maintenance of the CellSeal Automated Thawing System (hereinafter referred to as “the Thawing System”). The information contained herein is based upon technical data that has been validated and is believed to be appropriate for the intended use of the product.

## Intended Audience

This manual is intended for use by personnel with a thorough understanding of the products, procedures, and safety requirements for processing and handling of biologic products.

## Application

The CellSeal® Automated Thawing System is for thawing the content of 2ml and 5ml CellSeal® Closed-System Cryogenic Vials.

## Exclusions and Limits of Liability

Neither Cook Regentec, nor Asymptote make any warranties, expressed or implied, and assume no liability in connection with any use of this information. If the Thawing System or its related procedures are used for purposes other than those stipulated herein, validation of the specific application should be obtained, otherwise Cook Regentec and Asymptote assume no liability or obligation not guarantee product performance. Personnel using the Thawing System do so at their own discretion and risk.

## Proprietary Information

All rights are reserved. Copying of the protected designs associated with the Thawing System is strictly prohibited without the prior written consent of Cook Regentec and Asymptote.

## User Alerts

Throughout this document WARNINGS, CAUTIONS and NOTES are employed to notify the user of important and/or critical information.

**WARNING:** A Warning indicated a condition or procedure that could result in improper thawing or possible injury to the user. A Warning is enclosed with a bold-line box.

**CAUTION:** A Caution indicated a condition or procedure that could result in damage to the unit. A Caution is enclosed with a single-line box.

**NOTE:** A Note indicates important and/or useful information.

## Safety Symbols



Caution, risk of electric shock



Caution



Protective Earth (P.E.)

## CE Mark Information

For inquiries related to the CE marking of this product, please contact:

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## 2. Introduction

Thank you for purchasing a CellSeal® Automated Thawing System.

This manual describes the operation of the Thawing System, as well as cleaning and routine maintenance procedures. For details of how to set up remote access to your thawing profiles and data logs, please visit <http://my.cryochain.com/cellseal>

The Thawing System tightly controls the heating of cryopreserved samples stored in CellSeal® Closed-System Cryogenic vials until it automatically detects that they are fully thawed. Multiple contact and non-contact temperature sensors constantly monitor the condition of the sample to determine when melting is complete. The system operates without the use of water or any other fluid to minimise the risk of sample contamination. A complete record of the thawing process is stored on the device itself and can also be uploaded to the my.cryochain web platform for real-time remote access. Further details can be found in the Technical specifications section 0 of this document.

NOTE: This product is intended solely for use in a laboratory environment, for the processing of cryogenically stored vials. This product is not certified for use as a medical device.

### 3. Safety

When used correctly, the Thawing System poses very limited safety risks. To ensure their safe operation please follow these instructions. Use other than as intended, modification or integration other than as designed for by Asymptote could result in impairment of safety mechanisms.

#### Mains electricity

**WARNING:** The Thawing System operates from a 24VDC 3.75A SELV power supply separate from the main unit. It is important that the correct approved power supply unit (PSU) as supplied by Asymptote is used, to avoid hazards arising from fire, electric shock or electromagnetic interference.



**WARNING:** Disassembly, servicing or modification of the Thawing System or the PSU supplied is not permissible by users. Doing so can invalidate the warranty and give rise to risk of electric shock.



**WARNING:** Ensure that suitable Portable Appliance Testing (PAT) procedures are undertaken regularly throughout the life of the PSU. This will also ensure that plugs and leads are correctly earthed, should they have been changed or damaged.



**WARNING:** Use with a de-rated mains supply cord gives rise to potential hazards. Asymptote recommend against the use of mains supply cords not correctly rated for the product.





**WARNING:** Disassembly, servicing or modification of the Thawing System or the PSU supplied is not permissible by users. Doing so can invalidate the warranty and give rise to risk of electric shock.



**WARNING:** The PSU provided is an earthed SELV power supply. Use only with mains outlets with a ground connection.



## Disconnecting the Thawing System

Disconnection or switching off of the Thawing System from the electricity supply can be achieved by pulling the concentric plug out from the base.

The mains adaptor disconnecter is its mains plug which must be easily accessible when plugged into the wall socket (power outlet).

## Lifting and carrying

Take care when lifting and carrying the Thawing System. Ensure that all precautions are taken to lift in a safe manner and follow your company's lifting and handling procedures.

The Thawing System is light so can be lifted and carried by a single user.

## Hot surfaces

The surfaces exposed at the vial warming location can be up to 50°C in normal operation. This is not hot enough to cause immediate injury.

## Cold surfaces

Since the Via Thaw is intended to be used with cryogenically cold samples, users should take adequate measures to ensure their ability to safely handle said samples.

## Personal protective Equipment

Since this device is to be used with cell cultures and therapies, and to mitigate the risks associated with potential rapid ejection of the vials following very heavy use over a long lifetime, it is recommended that users only operate the device while wearing safety glasses and gloves.

## 4. WiFi

### EC regulations

The WiFi has been verified in accordance with EC regulation, and tested by notified body "Eurofins Product Service" CE0681.

### United States FCC Regulations

The Cook VIA Thawer Contains Transmitter Module FCC ID: OA3RN1723, a certified WiFi module for integration into equipment.

*This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:*

- *Reorient or relocate the receiving antenna*
- *Increase the separation between the equipment and receiver*
- *Connect the equipment into an outlet on a circuit different from that to which the*

*receiver is connected*

- *Consult the dealer or an experienced radio/TV technician for help*

## Industry Canada regulations

The Cook VIA Thawer contains transmitter module IC: 7693A-RN1723, a certified WiFi module for integration into equipment.

*This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.*

*Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.*

*Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.*

*Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.*

## 5. Getting started

### Before switching on

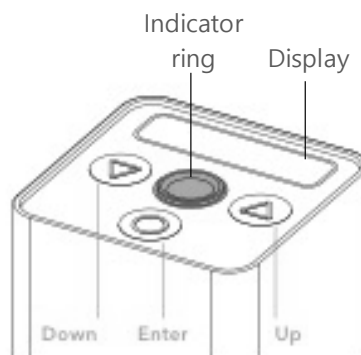
1. Site the Thawer on a suitable table or work-surface. Keep thawer and PSU away from liquids, and maintain good access to device and building electrical supply sockets.
2. The outlet vents for fluids from condensation or ice thawing and the loudspeaker are on the bottom so ensure that the work-surface is firm and free from debris. Do not run the system on a soft surface such as a carpet.
3. Plug the supplied IEC C5 cable into the supplied PSU and the 5.5mm DC jack into the Cook VIA Thaw. The PSU used MUST be the 24VDC 3.75A LPS SELV variant supplied with the Thawing System.

### Attaching to Ethernet

4. If a wired connection to a local network is required for a my.Cryochain connection, then plug an Ethernet cable from the local area network into the RJ45 socket at the back of the Thawer. It is important that the Ethernet in your facility complies with the ELV directive, or TNV standards to ensure safety.

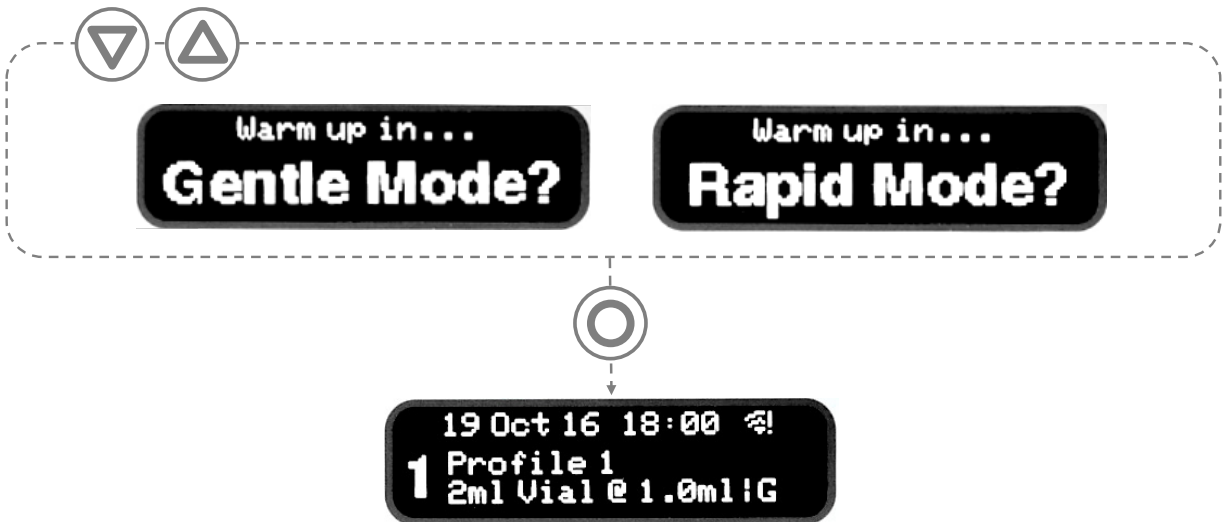
NOTE: The Ethernet cable MUST be a screened variety to ensure correct operation.

### Introducing the user interface



## Switching on and warming up

The device will power up as soon as the PSU is plugged in and powered up, and after a few seconds presents the following choice. Use the arrow buttons to switch modes and press the enter button to confirm your selection.



**NOTE:** **Gentle mode** limits the temperature of all internal parts to a maximum of 37°C making the system inherently safe from risks of heating cells above this temperature.

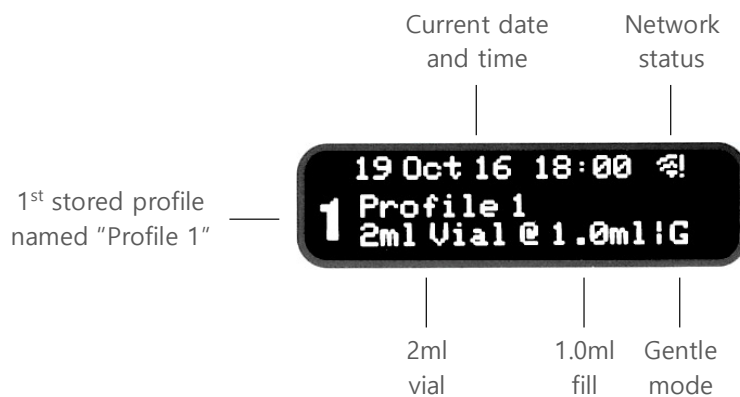
**Rapid mode** allows some internal parts to reach 50°C to more closely match water bath thawing allowing for the different heat transfer characteristics of the metal chucks. Control circuits ensure that the core temperature of the vial contents should never exceed 37°C.

Initially after switching on the indicator ring will be orange and the vial clamping chucks will be closed indicating that the system is not ready to accept frozen vials. Once the choice of mode has been made the indicator ring will remain orange until the internal temperature has stabilised. At this point the indicator ring will turn green and the jaws will open ready to accept a vial for thawing.

## Self-tests during power up

During each power on cycle the Thawing System performs a sequence of internal tests to verify correct operation. If any problems are detected an error screen will be shown with an error code. Please make a note of this error code and be ready to provide it when contacting technical support..

## Introducing the home screen

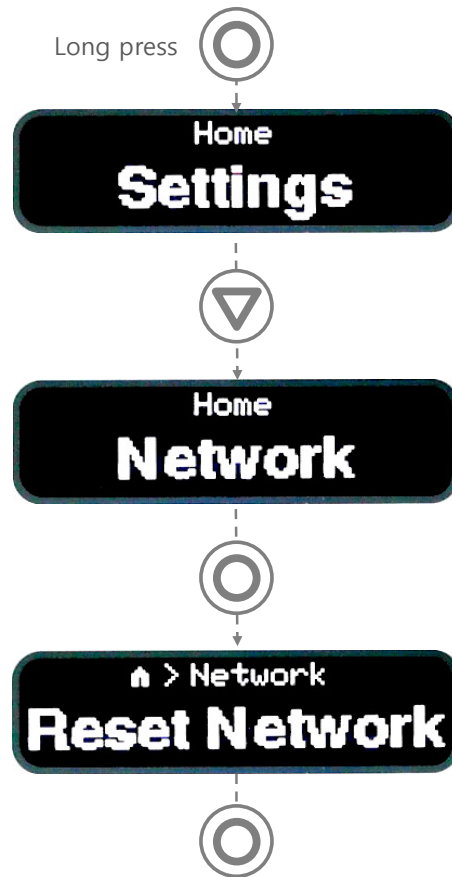


## Setting the time

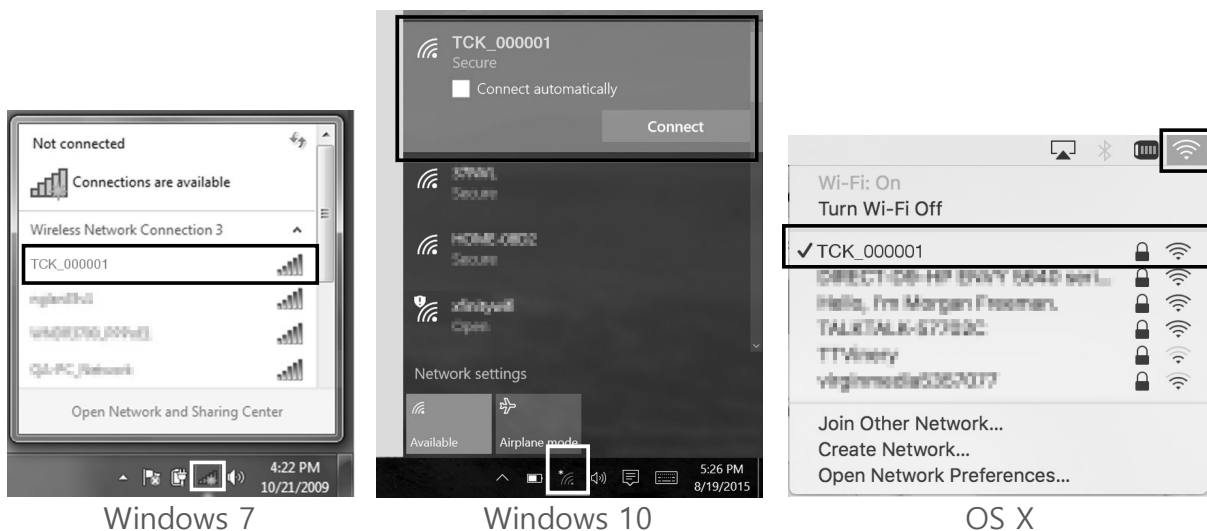
It is important for accurate thaw logs that the time on the device is set correctly. If a network connection is provided, the device will set the time automatically. If not, it is the user's responsibility.

## Setting up the network

To change network settings, first clear any existing settings using the following sequence.



The Thawing System will now automatically re-boot and then presents a new WiFi network with an SSID matching the system's serial number. Connect to this new WiFi network from a Windows or Apple computer as follows:



Once successfully connected to the Thawing System WiFi network, launch your web browser and visit **192.168.1.1**. The following page will be presented:

**Settings**

IP address	<input type="text" value="0.0.0.0"/>
Gateway	<input type="text" value="0.0.0.0"/>
DNS Server	<input type="text" value="0.0.0.0"/>
Netmask	<input type="text" value="0.0.0.0"/>
Use my.CryoChain?	<input checked="" type="checkbox"/>
Device API Password	<input type="text"/>
my.CryoChai	<input type="text" value="n.com"/>
WiFi SSID	<input type="text" value="none"/>
WiFi Password	<input type="text" value="none"/>

To set a static IP address complete the following fields:

- **IP address** *e.g. 200.54.182.32*
- **Gateway** *e.g. 200.54.182.1*
- **DNS Server** *e.g. 200.54.182.1*
- **Netmask** *e.g. 255.255.255.0*

To connect the Thawing System to a my.CryoChain instance:

- **Use my,Cryochain** (✓)
- **Device API Password** *e.g. 6axDICoxaANmHyLQ0z0nMA*
- **my.Cryochain Domain** *e.g. cook.cryochain.com*

To set the Thawing System to connect to a local WiFi network

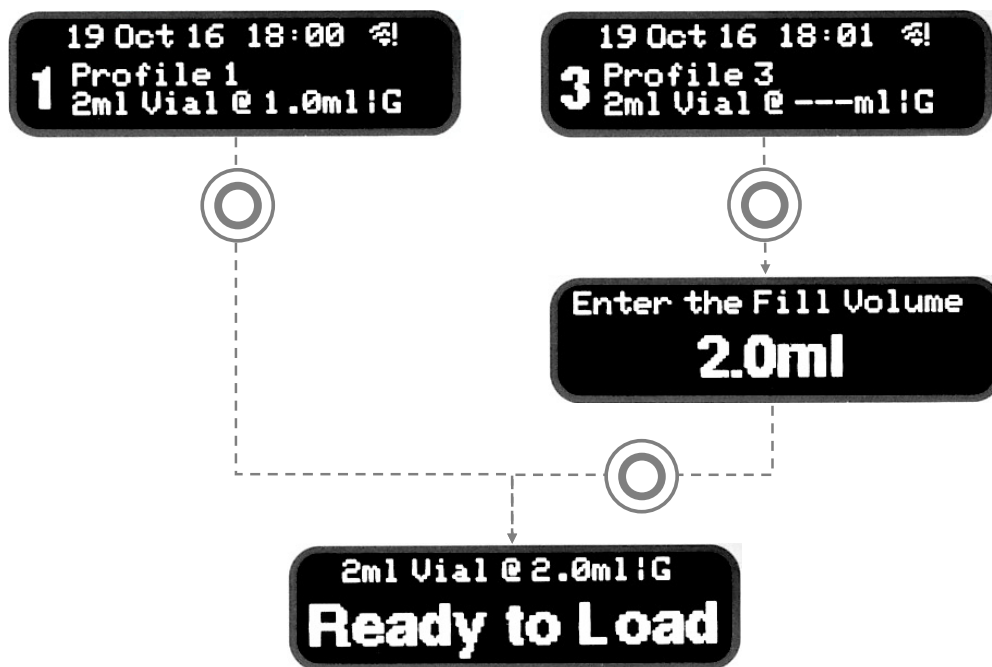
- **WiFi SSID** *e.g. PublicWiFi*
- **WiFi Password** *e.g. Password*



## 6. Thawing Procedure

Note: Ensure the indicator ring is green before attempting to load a vial.

Browse to the desired thawing profile using the arrow keys and the press enter to select. If the selected thawing profile is dependent on further user input, the ring indicator will remain orange, and the chucks will remain closed until the required information is provided. An example of a fully specified profile is shown on the left below, and an example requiring operator input of fill volume is shown on the right.



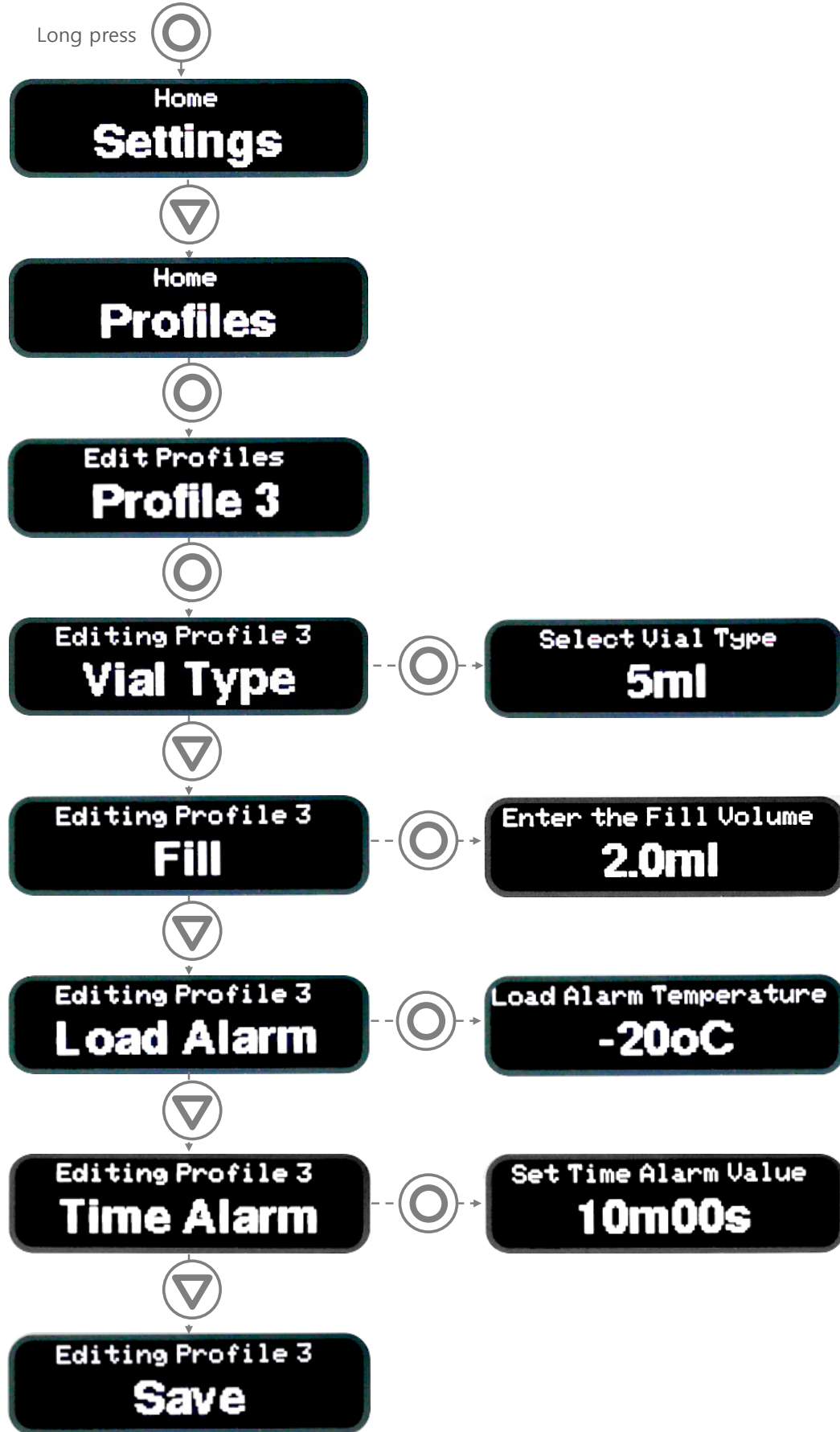
Now insert the appropriate vial. Holding by the top, press the vial down and hold until the device clamps. The indicator will glow purple when the vial is at the correct depth.



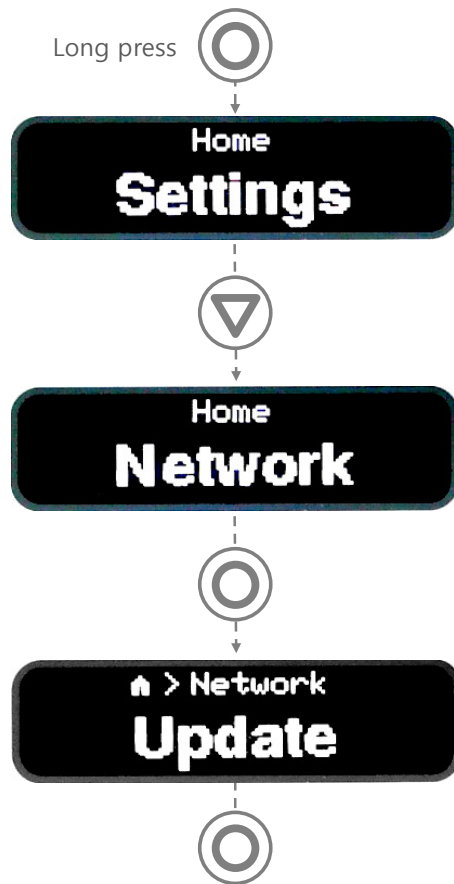
Thawing begins right away and after a short period of analysis; progress is indicated on the display. When the thaw is complete, the vial is ejected and the indicator ring will glow green if successful. If unsuccessful, the indicator will glow orange.



## 7. Editing and creating thawing profiles



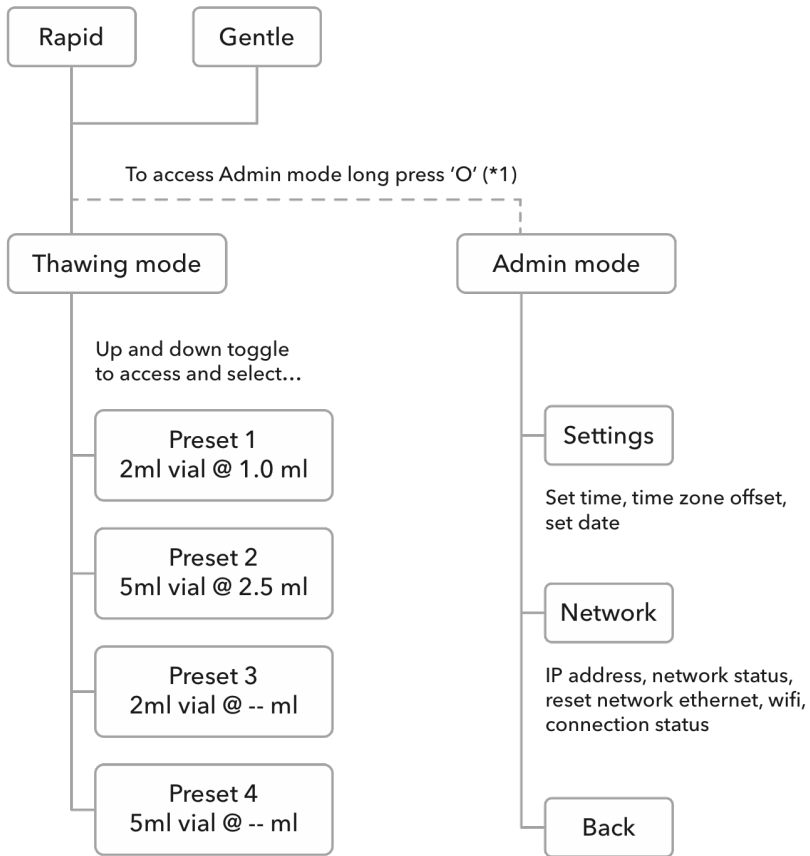
## 8. Updating Thawing System Firmware



Wait while the unit checks for, then downloads the update. It will display "Updating...". This step can take quite some time and varies depending on the network connection but 10 minutes is typical.

When the unit says "Restart Now!", turn the Thawing System off, wait until the display is blank, then turn it back on again. The Thawing System will appear to be inactive for up to another 10 minutes: this is normal! When it is finished the unit will restart and run the new software.

## 9. Menu structure



## 10. Cleaning and Decontamination

Appropriate decontamination procedures should be carried out if hazardous material is spilled on/into the equipment.

Cleaning and decontamination should be carried out using alcohol wipes, or a cloth dampened with ethanol/IPA.

Avoid spraying, pouring or otherwise allowing cleaning or sterilisation fluids into the internal cavities or sockets.

The use of corrosive or strong solvent products to clean the product can result in cosmetic damage to the paint and plastic top, or potentially functional damage to the circuitry within.

Do not use cleaning or decontamination agents which could cause a hazard if used on the device. In case of doubt, contact Cook Regentec for assistance.

## 11. Maintenance and Service

There are no user serviceable parts inside this product. Servicing and repairs must be carried out by Asymptote or its authorised representatives. Please contact Cook Regentec to arrange any necessary repairs or maintenance.

## 12. Disposal

At the end of the life of the Thawing System, please contact Cook Regentec or Asymptote to arrange disposal and recycling.

The product contains metals that can be recycled and should not be disposed of in general waste.

### 13. Specifications and dimensions

MODEL NUMBER	TCK_30001
THAWING FORMATS	2ml CellSeal® vial filled from 0.1-2ml 5ml CellSeal® vial filled from 0.1-4.7ml
AMBIENT OPERATING TEMPERATURE	+5°C to +30°C
OPERATING VOLTAGE	100V to 240V (PSU) 24VDC (Thawing System)
MAXIMUM INPUT CURRENT	1.2A at 100Vac (PSU) 3.75A at 24VDC (Thawing System)
PORTS	RJ45 Ethernet (for use with screened cable ONLY) WiFi connectivity 5.5mm DC jack, IEC 60130 type A IEC C5 socket (PSU input)
EXTERNAL DIMENSIONS (W X D X H)	7.7cm x 7.7cm x 14.6cm (3.0" x 3.0" x 5.75") (Thawing System) 12.9cm x 5.4cm x 3.2cm (5.1" x 2.1" x 1.3") (PSU body)
NET WEIGHT	0.925kg (Thawing System) 0.360kg (PSU, excluding IEC lead)
FUSE	In regions where a fused IEC 60320 mains cable is used, a 1A to 5A fuse is acceptable.