FreMon SCIENTIFIC

ZipThaw™ 202 System

User Manual

FDA CLEARED

UL LISTED

CE

ISO

Revision 06
Revision date Jan. 2020

Fremon Scientific, Inc.
5724 La Jolla Blvd., Suite # 304
La Jolla, CA 92037
USA
TEL: (916) 669-9330
FAX: (512) 535-6103

1. TABLE OF CONTENTS

2. TABLE OF FIGURES

3. INTRODUCTION

This document contains the Instructions for Use (IFU) and technical description of the ZIPThaw™202 system based on system requirements that have been derived from several sources, including customer voice, marketing requirements and previous system generations.

These instructions are intended for use by medical professionals in hospitals.

3.1 INDICATIONS FOR USE

The FMS ZipThaw™ 202 is a thawing device intended for the following applications:

- thawing of Fresh Frozen Plasma (FFP)
- thawing of Plasma Frozen within 24 Hours after Phlebotomy (PF24)

WARNING

The device cannot be used to warm previously thawed Cryoprecipitate AHF, Platelets and Granulocytes.
This device is not intended for the thawing of, but not limited to, Red Blood Cells, Hematopietic Progenitor Cells or Umbilical Cord Blood.

3.2 IMPORTANT

These instructions use the following pictograms, symbols and words to highlight warnings and special advice:

WARNING	A warning alerts the user to the possibility of a danger to persons associated with misuse of the device
CAUTION	A caution alerts the user to the possibility of a problem with the device which could pose danger to property, the device or basic device functions

These instructions are intended for use by medical professionals.

You must follow the instructions and safety information contained in this user manual at all times when using the device. This will prevent risks to patients and users as well as prevent damage to equipment.

FreMon Scientific can accept no liability for damage caused as result of failure to follow these instructions.

WARNING

These instructions for use must be retained throughout the life of the product and handed to any subsequent user.

WARNING

Medical Electrical devices are subject to safety measures regarding electromagnetic compatibility (EMC). The device must be installed and operated in accordance with the EMC advice contained in these instructions.

3.3 TERMS & ABREVIATIONS

Temp	Temperature	**DC**	Direct current
CRT	Control Rate Thawing	**W**	Watt
GUI	Graphical User Interface	**V**	Volt
EIS	Electronic Information Systems	**Amp**	Ampere
Min.	Minute(s)	**HMI**	Human Machine Interface
FEC	Front End Controller	**Chamber**	The well where the plasma bag is being processed
AC	Alternating Current	**SOM**	System on a Module computer
CMC	Chamber Module Controller	**TCM**	Thawing Chamber Module
SMP	System Management Processor	**BIT**	Built-in-Test: a diagnostics program that checks system functions.

4. DEVICE DESCRIPTION

The ZipThaw™ 202 platform has a modular architecture that allows configuration flexibility.

4.1 ZIPTHAW™ SYSTEM MODULES

The ZipThaw™ is built with universal-basic modules:

4.2 THAWING CHAMBER MODULE (TCM)

This is a universal module that utilizes a closed warming chamber, agitation mechanism and temperature monitoring. It mechanically and wirelessly connects to ZipSleeve™ .

The TCM contains two heating cushions, each filled with 300ml water-based gel, that are sealed. Each cushion is affixed to heating element and being controlled by a temp sensor and Chamber Module Controller (**CMC**). In addition, each heating element has its own heating sensor for overheating protection.

Overall overheating protection is accomplished by utilizing an independent temperature sensor that shuts down power in case of cushion overheating.

4.3 SYSTEM MANAGEMENT PROCESSOR (SMP)

System Management Processor unit (**SMP**) that can control up to 4 CMCs. The **SMP** is a high-level CPUs that controls and monitors system function, drives a touch-screen GUI module, and external memory media.

4.4 CHAMBER MODULE CONTROLLER (CMC)

Chamber Module Controller: a universal chamber control module. It controls one Chamber unit (i.e. sensors, agitation, limit switches and heating) and communicates with the SMP for data/status synchronization.

4.5 ZIPSLEEVE™

A basic overwrap sleeve that has embedded wireless temperature sensor that measures the thawed Bag substance temperature and will signal the CMC to stop heating once the sensor temperature reading reaches the “Target Temperature” of 33 °C (91.4 °F).

4.6 POWER SUPPLY

Universal, medical grade AC/DC power supply that fits international power system and supplies the necessary power to drive up 2 pockets modules.

4.7 ZIPTHAW 202™ FRONT VIEW

FIGURE 1. ZIPTHAW™ 202 FRONT VIEW

4.8 ZIPTHAW 202™ REAR VIEW

FIGURE 2.: ZIPTHAW™ 202 REAR VIEW

4.9 ZIPSLEEVE™ :

FIGURE 3.: ZIPSLEEVE™ VIEW

4.10 HOW DOES IT WORK?

The plasma frozen bag is placed inside a ZipSleeve™, a smart overwrap bag and inserted into the Thawing Chamber Module (**TCM**).

During the thawing process, the plasma bag is thawed by the Chamber's heating cushions.
The heating cushions temperature are controlled by the system to maintain a heating temperature of 37 °C (98.6 °F).

The plasma frozen bag temperature is monitored by the ZipSleeve™ temperature sensor and will signal the system to stop heating once the sensor temperature reading reaches the "Target Temperature" of 33 °C (91.4 °F) while the ZipThaw™ system controls the agitation mechanism to ensure homogeneous mixing and heat distribution.

4.11 DEFAULT TEMPERATURE SETTING

The final, "Target Temperature" for thawed plasma is fixed at 33 °C (91.4 °F) as a factory setting. The ZipSleeve™ sensor monitors the temperature of the frozen plasma bag and will signal the system to stop heating once the sensor reaches 33 °C (91.4 °F).

Note:
The user cannot modify the "Target Temperature".

4.12 LABELING AND SYMBOLS

4.12.1 REAR PANEL

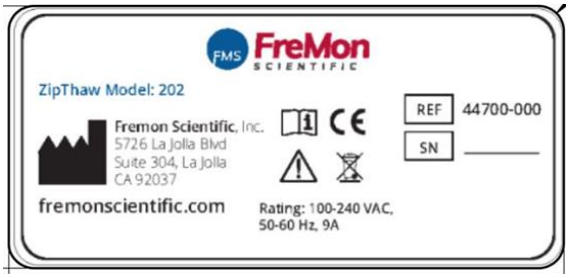


FIGURE 4.: ZIPTHAW™ 202 LABEL

4.12.2 SYMBOLS USED IN THIS USER MANUAL:

No.	Symbol	Description
1	CE	CE MARK
2		ATTENTION, CONSULT ACCOMPANYING DOCUMENTS.
3		WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE) COMPLIANCE SYMBOL
4		MANUFACTURER
5	EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN UNION
6	10A, 250V~	FUSE
7	LOT	PI LOT NUMBER
8	CAT	CATALOG NUMBER
9	Rx	FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PROFESSIONAL

No.	Symbol	Description
10		HIGH TEMPERATURE WARNING

4.13 COMPLIANCE WITH FCC, 47 C.F.R. PART 18

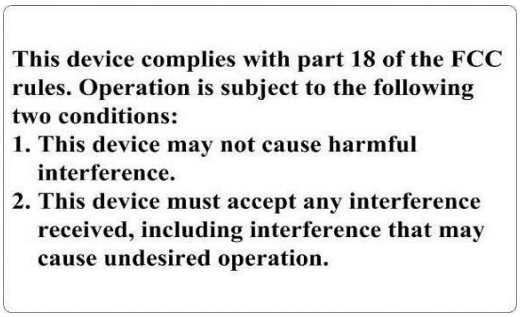


FIGURE 5.: COMPLIANCE WITH 47 C.F.R. PART 18

5. CONTRAINDICATIONS

Other than those substances described in the Intended Purpose (see Section 3.1), the ZipThaw™ is not intended to thaw, heat or keep warm any blood product or other substance, including but not limited to red blood cells, hematopoietic progenitor cells, umbilical cord blood, previously thawed Cryoprecipitate AHF, Platelets, and Granulocytes.

There are no known contraindications for thawing or heating blood products.

6. SAFETY ADVICE

⚠ WARNING

Read the instructions contained in this user manual and any other user documentation before using the device.

This device is class I electrical equipment.

Only use the device according to the instructions in this user manual.

Do not exceed heating temperature and time limit when heating blood and blood products.

If the device has a fault, do not use it and contact FreMon Scientific.

Electrical installations must comply with the applicable regulations and standards.

Only use the power cord supplied by FreMon Scientific to connect to the main power source.

To ensure complete isolation of the device from the power main source, the cord's mains plug must be removed from the power mains socket.

Do not attempt to repair the device by yourself. Repairs and modifications may only be carried out by Fremon Scientific or authorized personnel.

The influence of strong magnetic fields can cause malfunctions in the ZIPThaw™. If electromagnetic interference occurs, increase the distance between the ZIPThaw™ and the device causing the interference. The ZIPThaw™ works within the limit values set in the EN 60601-1-2 standard, and can be influenced outside these limit values.

Portable and mobile HF communication equipment can affect the device.

Do not use the device near:

Flammable materials

Flammable mixtures of anesthetic substances with air, oxygen or nitrous oxide whose flashpoint is below 50 °C (122 °F).

7. OPERATION

7.1 DEVICE PLACEMENT AND POWER CONNECTION.

1. Ensure there is enough space for the ZipThaw™ 202 to be placed on the bench.
2. Leave at least 10cm (4”) between the rear side of the ZipThaw™ 202 and a wall to allow easy access to power ON/OFF main switch located as part of the IEC socket.
3. Leave clear at least 40cm (15.7”) from each side to allow loading and unloading of bags into/from the chambers.
4. Connect the power cable to the ZipThaw™ 202 IEC socket, located at the back and plug the cord into a power outlet.
5. Always use the power cord supplied by FreMon Scientific to connect to the main power source.

7.2 DOORS STATUS

During the system-operations if any Chamber door is opened or unproperly locked, the following error message will be displayed:

FIGURE 6. DOOR OPEN ERROR POP-UP SCREEN

Close Chamber Door and Press “OK” will clear the message

7.3 POWER UP

Flip the power switch at the back of the device to "**ON**" position to provide power to the system.
(see Figure 2).
The system goes through self-diagnostics and setup cycles (pre-heating) that may take up to 3 minutes.

FIGURE 7. ZIPTHAW™ 202 POWER-UP SCREEN

7.3.1 POWER UP FAILURE

If the self-diagnostics and setup cycles fail, an error beep will sound for 1 second, and the touch screen will display a system error message.
Switch off the device and contact FMS service!

FIGURE 8. SYSTEM ERROR POP-UP SCREEN

7.3.2 BIT FAILURE

During the self-diagnostic tests, the system will determine whether both Chambers are functioning or one or both of the Chambers has a fault and must be disabled. The system will disable the faulty Chamber(s) but will allow the device to fully function if one Chamber is functioning.

The following error message will appear:

FIGURE 9.: CHAMBER ERROR POP-UP SCREEN

Pressing "**OK**" will make the error message disappear and the following screen will be displayed where the faulty Chamber will be disabled and will have a grayed-out graphic appearance.

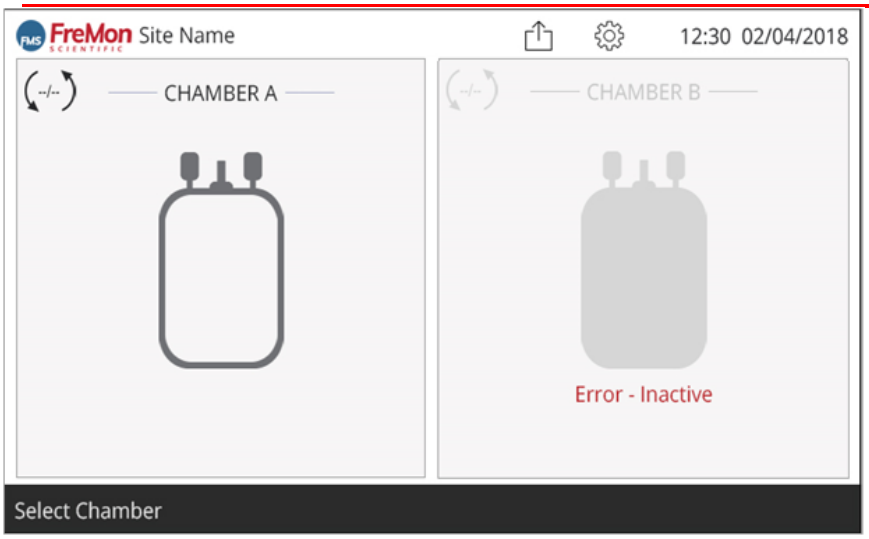


FIGURE 10.: HOME SCREEN WITH CHAMBER ERROR

7.3.3 SYSTEM RESET RECOVERY

In case that the system defaults to an unexpected “Reset” mode, upon successful BIT , the home screen will appear and the system will recover in to pre-thawing state see 7.3.2.

Note:
It is the user’s descresion to start a new thawing cycle, using these bags or discarding them.

To continue a new thawing cycle proceed to 7.3.2.

7.3.4 SUCCESSFUL POWER UP

Upon successful pre-heating cycle, the home screen will appear,. The screen will prompt: “**Select Chamber**” as shown below.

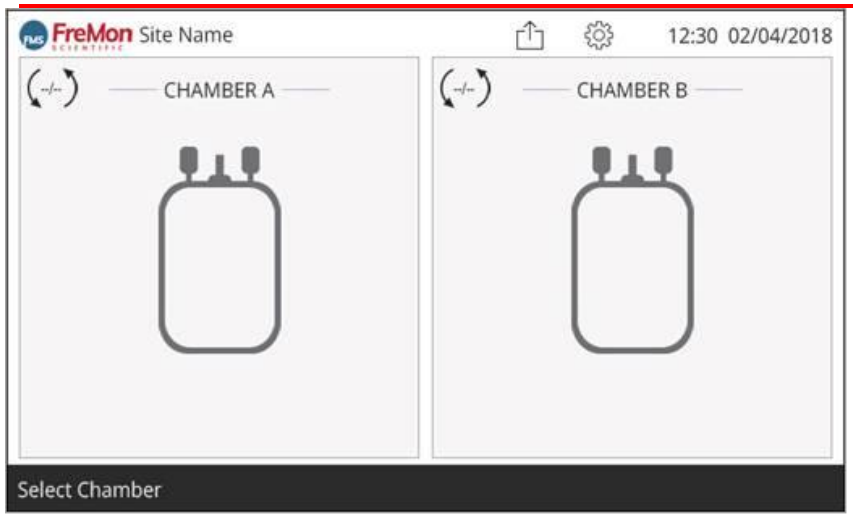


FIGURE 11. HOME SCREEN

7.4 MAIN SCREEN DESCRIPTION

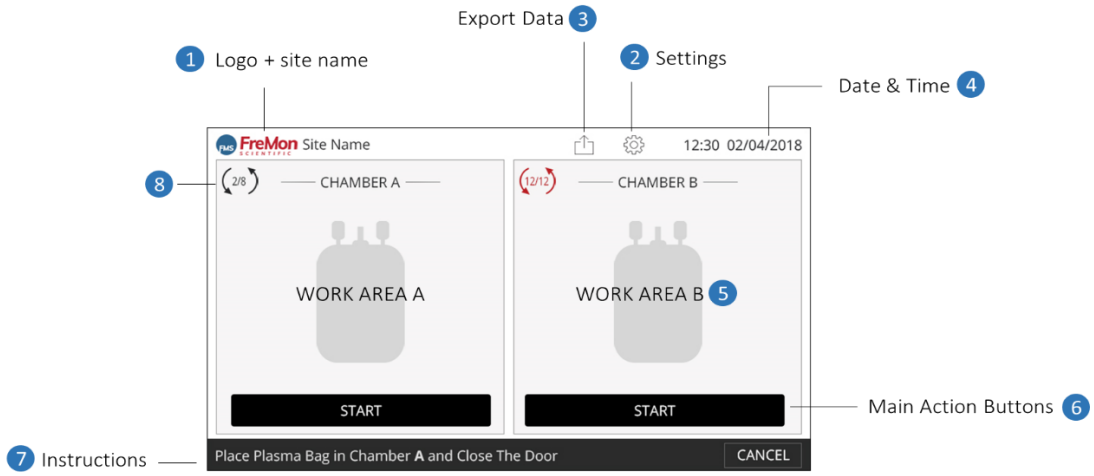


FIGURE 12. HOME SCREEN

1	FreMon logo+ site name	5	Work Area A+B - the user main area interaction.
2	Settings.	6	Main Action Buttons.
3	Data Export.	7	Instructions for active Chamber.
4	Date & Time.	8	Number of ZipSleeve™ uses indicator.

7.5 SETTINGS

Pressing the "**Settings**" button will open the settings screen. **This screen is for the device administrator and technical support use only.**

Entering the settings screen requires an administrator password.
The administrator will have a default password (**45253**, factory default) that can be changed in the setting screen.

FIGURE 13. LOGIN TO THE SETTINGS SCREEN

Note:
If the administrator password is forgotten, the password may only be reset by a certified technician.

Upon entering the correct administrator password and pressing "**OK**", the following setting screen will appear:

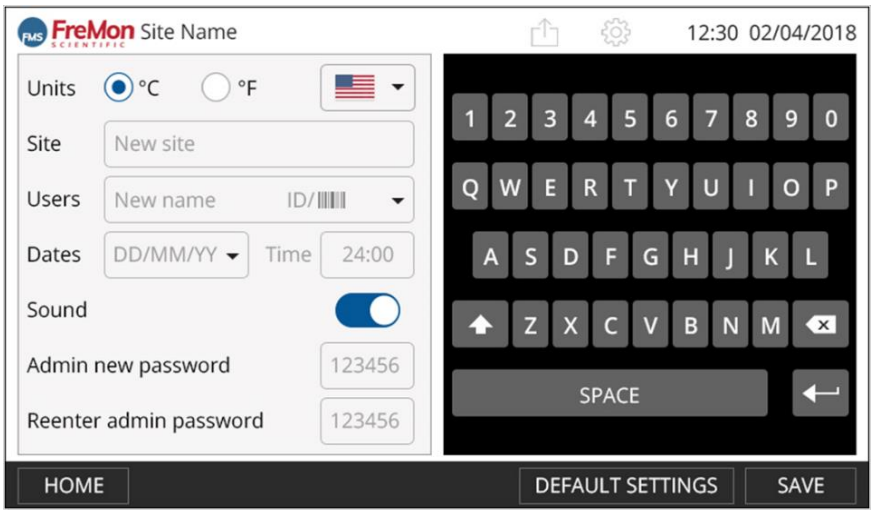


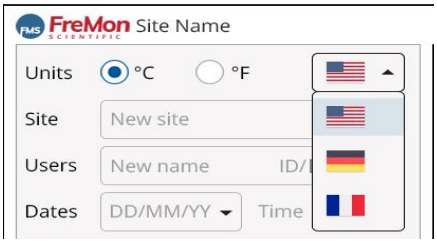
FIGURE 14. SETTINGS SCREEN

7.5.1 KEYS DESCRIPTIONS

HOME	Pressing this key will revert back to the home screen without saving.
DEFAULT SETTINGS	Pressing this key will revert back to factory settings.
SAVE	Pressing this key will save settings and go to the home screen.
↵	"**ENTER**" key.

7.5.2 SELECTING LANGUAGE

Upon touching the displayed flag button a drop down menu opens with images of additional flags allowing the user to choose the language represented by the flag.

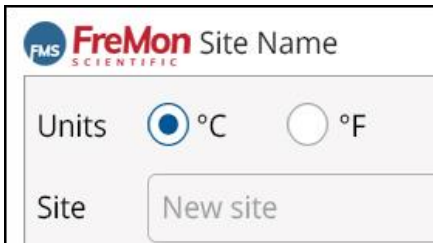


Upon touching the chosen flag the drop-down menu will close, the language will change, and the chosen flag will be displayed.

Note: Default Language is English represented by the American flag icon.

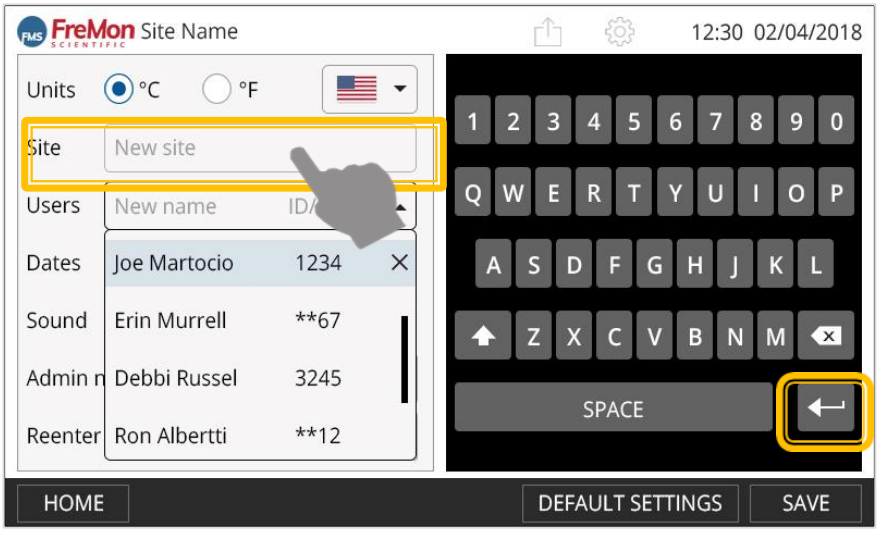
7.5.3 SELECTING TEMPERATURE UNIT

The administrator can select which temperature unit will be displayed (i.e., Celsius or Fahrenheit) by thouching the corresponding radio button.



7.5.4 ENTERING SITE NAME

To enter the site's name touch the the screen at the "New Site" location to highlight it and use the keyboard to type the site's name. The typed name will appear at the header upper left, next to the FreMon Scientific logo.



Note: This field is limited to 25 characters.

7.5.5 SETTING THE DATE & TIME

To set the date, touch the Date field. A dropdown menu will open. Select the desired date format (i.e., DD/MM/YY or MM/DD/YY), and then, use the displayed keyboard to type the current date.

To set the time, touch the Time field. The time format is 24:00.
Use the keyboard to enter the current time.

Note: If the typed information is incorrect, the field will be marked red

7.5.6 ENABLING AUDIO

To enable audio alerts turn “Sound” ON or OFF by sliding the corresponding switch.

ON
OFF

7.5.7 ADDING NEW USER

Touching the Users field enables typing a new user name by either typing it into the “New name” field by using the display keyboard or, scanning the new user’s ID into the “ID/barcode” field.

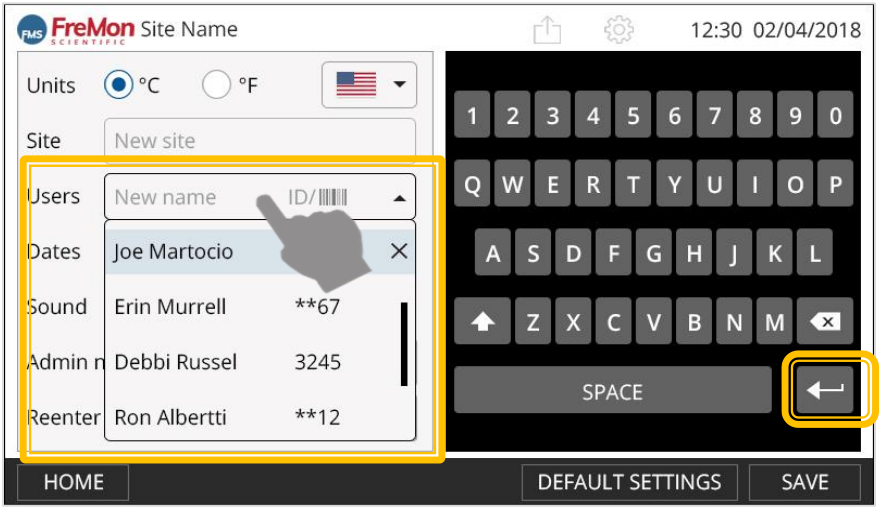


FIGURE 15. ADDING NEW USER SCREEN

When pressing the ID/barcode icons the built-in barcode reader is enabled (i.e., you will see the barcode reader’s red beam light up) and the user can either scan the ID or type it using the displayed keyboard.
To confirm new user press ↵ - the new name and ID will be added to the list.

7.5.8 EDITING USER LIST

- Mark the "Users" (i.e. touching) the drop-down list will be displayed.
- To delete a user name from the list, press the "**X"** icon on the right side of the user ID.
- To add a newly added user press the "**ENTER**" key.
- When finished editing the whole screen, to save the data entry press "**SAVE**".
- To return to the home screen press the "**HOME**" key.

FIGURE 16. ADDING NEW USER SCREEN

7.6 GETTING STARTED

From the home screen select a Chamber, A or B, by touching the screen area, as shown below.

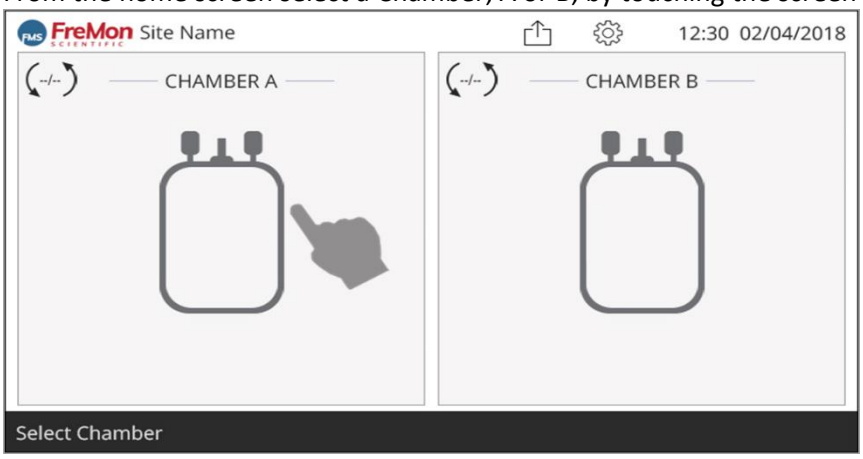


FIGURE 17. SELECT CHAMBER FROM HOME SCREEN

Selecting a Chamber will open the "Insert Data Screen".

7.7 INSERT THAWING DATA

Data can be entered:

- Using the built-in barcode reader.
- Manually typing the data.

7.7.1 BARCODE DATA ENTRY

Place the plasma bag in front of the barcode reader and aim the red beam to the upper barcode field (1) of the plasma bag label. Once you hear a beep, move to next bar code field (i.e., 2,3,4), one at a time.

Verify that the correct data was entered, especially the donor identification number (DIN) (i.e., field marked 1).

User ID should be entered by either scanning the user's ID card or manually, as described below (7.7.2).

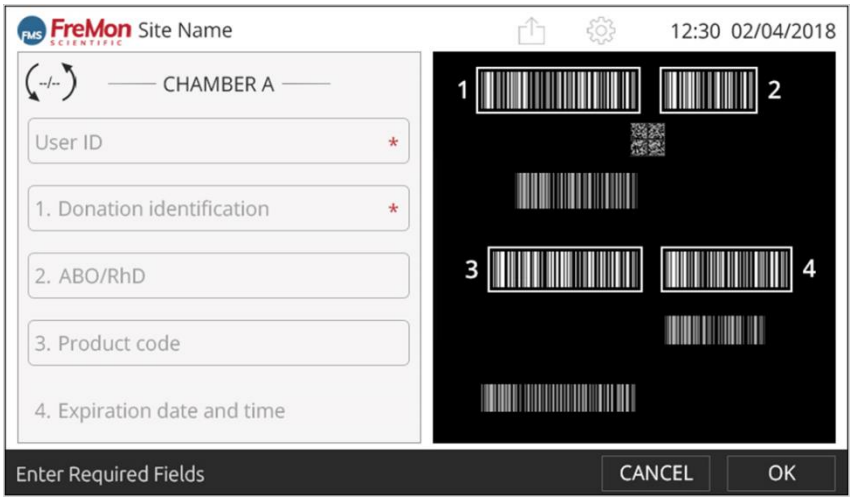
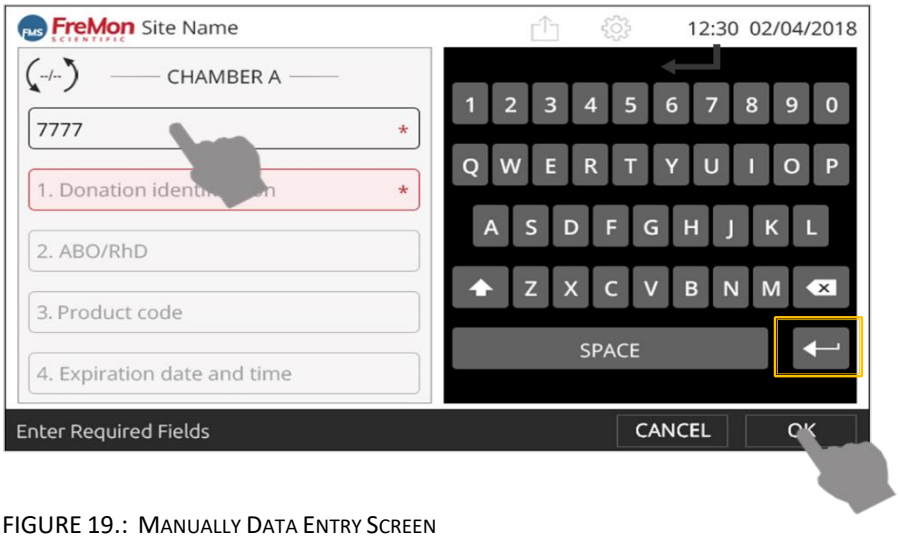


FIGURE 18.: BARCODE, INSERT DATA SCREEN

7.7.2 MANUALLY DATA ENTER

To enter data manually, Touch the relevant field: The following screen will appear:



*Mandatory data fields are marked by * (i.e. User Name/ID, Donation ID).*

FIGURE 19.: MANUALLY DATA ENTRY SCREEN

- Touching the fields opens the keyboard. Pressing **"OK"** inserts the data, closes the keyboard and moves to the next field.
- User ID: Up to 25 characters when scanning.
  Typing should allow 4 characters (user ID code).

- DIN: Up to 16 characters.
- ABO/RhD: 4 characters.
- Product Code: 8 characters.
- Expiration Date/time: 10 characters.

Once data is entered,

- To accept data entry and return to the Home Screen, press the "**OK**" key.
- To cancel and return to the home screen press "**CANCEL**".

If "**OK**" was pressed **BUT** a mandatory field was not filled, the system will mark the unfilled field for the user to complete the data entry and a pop-up screen will be displayed. Press "OK" to continue.

FIGURE 20. MANDATORY FEILDS DATA ENTRY ERROR

If no data entry errors occur, and the "**OK**" button was pressed, the system will default to the home screen as shown below:

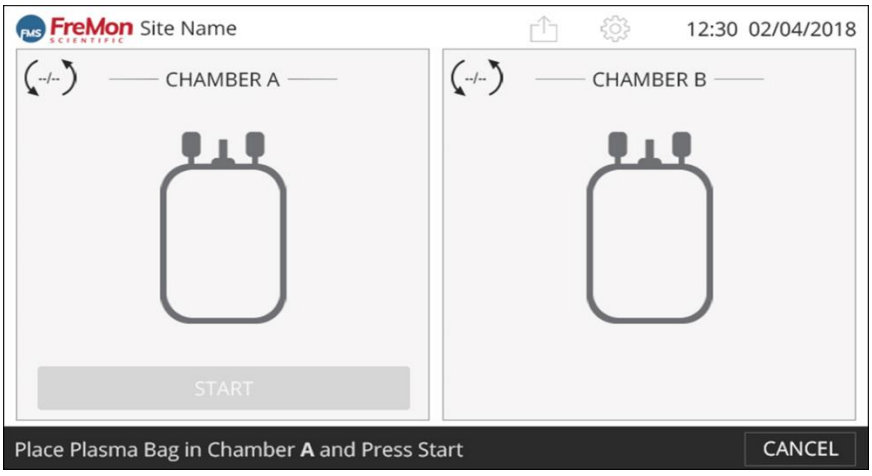


FIGURE 21. HOME SCREEN AFTER DATA ENTRY (CHAMBER A)

7.8 STARTING A THAWING CYCLE

7.8.1 LOADING FROZEN PLASMA BAG INTO A ZIPSLEEVE

Place the frozen plasma bag inside a new or used ZipSleeve™ overwrap bag.
Insert the frozen bag with the label facing the clear side of the ZipSleeve™.

Note:
Once the ZipThaw™ system verifies that a valid ZipSleeve™ overwrap bag is placed inside the device (i.e. # of uses is less or equal to 8) it will enable the device to begin a thawing cycle.

Note:
ZipSleeve™ Maximum Number of Uses is 8

FIGURE 22.: ZIPSLEEVE™ ORIENTATION.

7.8.2 LOADING THE ZIPSLEEVE INTO THE CHAMBER

Open the Chamber door and place the loaded ZipSleeve™ inside the Chamber.

[*Please note that the ZipSleeve™ can be loaded only in the orientation indicated by the hard plastic strip at the top of the ZipSleeve™*].

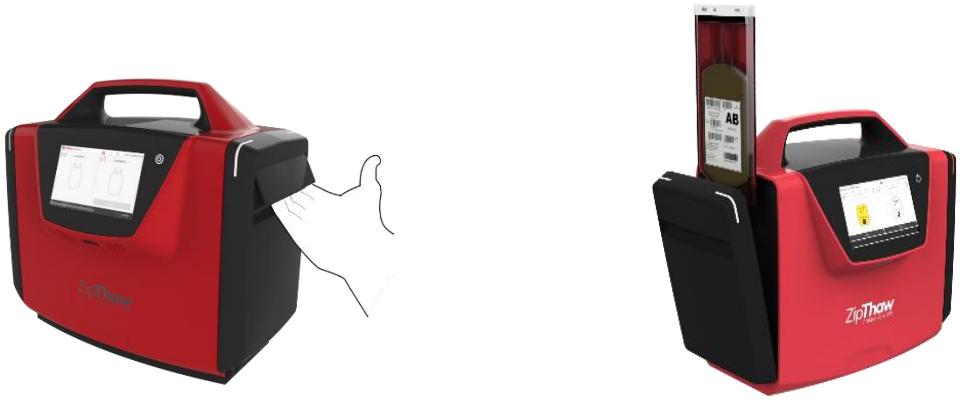


FIGURE 21. DEVICE OPEN DOOR

Close the Chamber door.

Upon Chamber door closing, the ZipThaw™ system will verify that a valid ZipSleeve™ overwrap bag is placed inside the device (i.e. number of uses is less or equal 8) before the "START" key is enabled.
If the ZipSleeve™ was used 8 times the system will display the following screen:

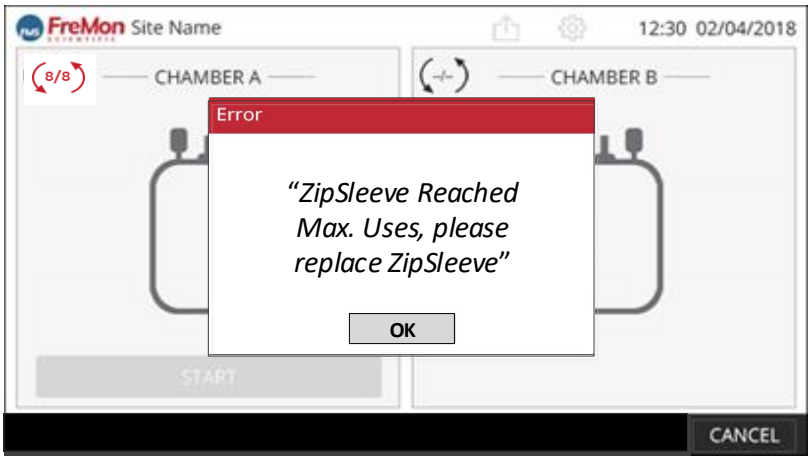
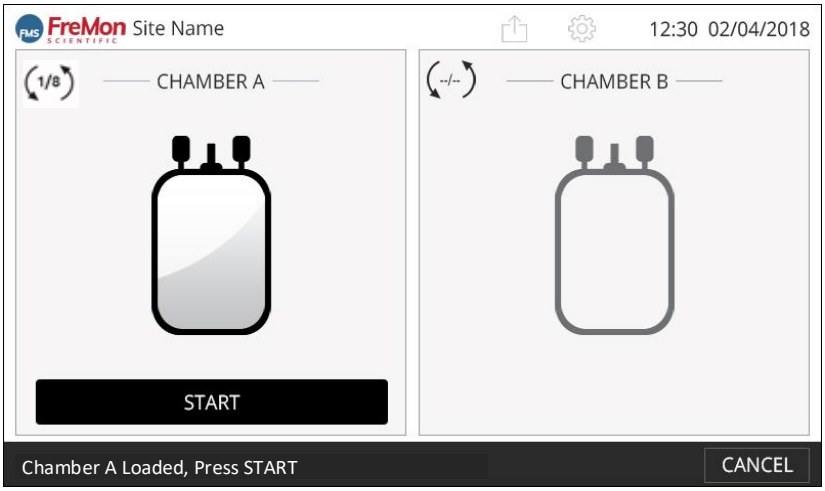


FIGURE 23.: REPLACE ZIPSLEEVE™ DUE TO NUMBER OF USES SCREEN.

Replace the ZipSleeve™ , as described above (7.8.1, 7.8.2).
Upon Chamber door closing with a valid ZipSleeve™, the GUI will display the following screen:



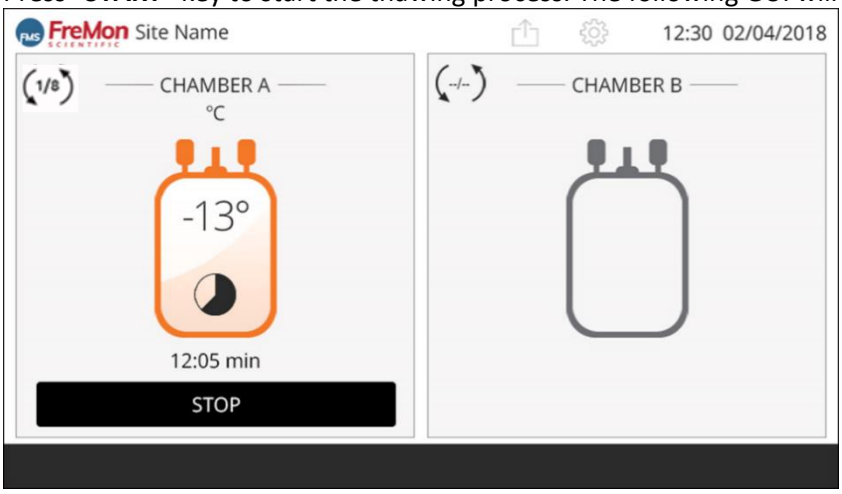
The "START" key becomes active and the bag GUI image will be emphasized.

FIGURE 24. CHAMBER A LOADED, READY TO START THAWING SCREEN.

Pressing "**Cancel**" will disable the "**START**" key and the thawing process. The Screen will default to the home screen (i.e. after Data Entry).

7.8.3 STARTING

Press "**START**" key to start the thawing process. The following GUI will be displayed:



When The Thawing Cycle Begins:

- ***The Bag GUI Turns ORANGE.***
- ***The Plasma Temperature, Progress Pie Thawing Elapsed Time Parameters are Displayed***
- ***The LED indicator Turns ORANGE***

FIGURE 25. CHAMBER A THAWING SCREEN.

Note:
Agitation will start automatically, once the thawing cycle commences.

7.8.4 INTENTIONAL THAWING STOP

In some cases the thawing cycle may be stopped at a verified substance liquid stage (i.e. ice cristals free). Once the chamber temperature reaches +15°C/59°F, the thawed substance (i.e. plasma) is thawed to a liquid stage. To abort the thawing cycle, at any stage, press the "**STOP**" key. The following message screen will appear:

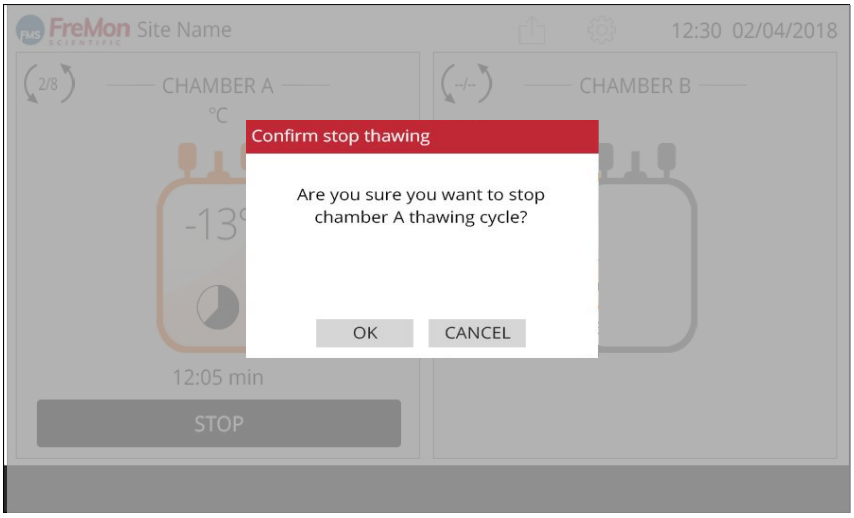


FIGURE 26. THAWING CYCLE INTENTIONAL STOP PROMPT

To confirm thawing cycle stop press "**OK**" or to continue the thawing cycle press "**Cancel**".

7.8.5 RUNNING THAWING USING THE SECOND CHAMBER B

The ZipThaw™ system enables thawing in both Chambers simultaneously but independent of each other.

Simply tap on the Chamber B icon, the screen will be updated:

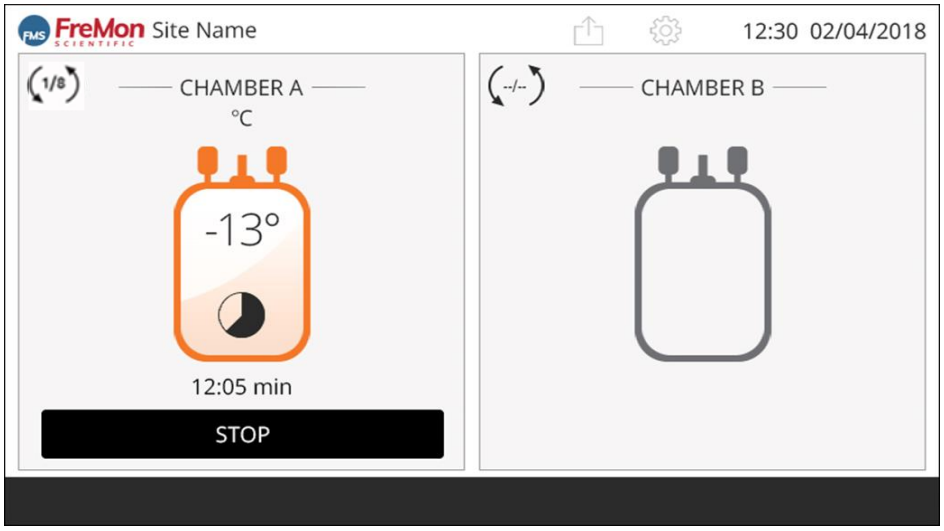
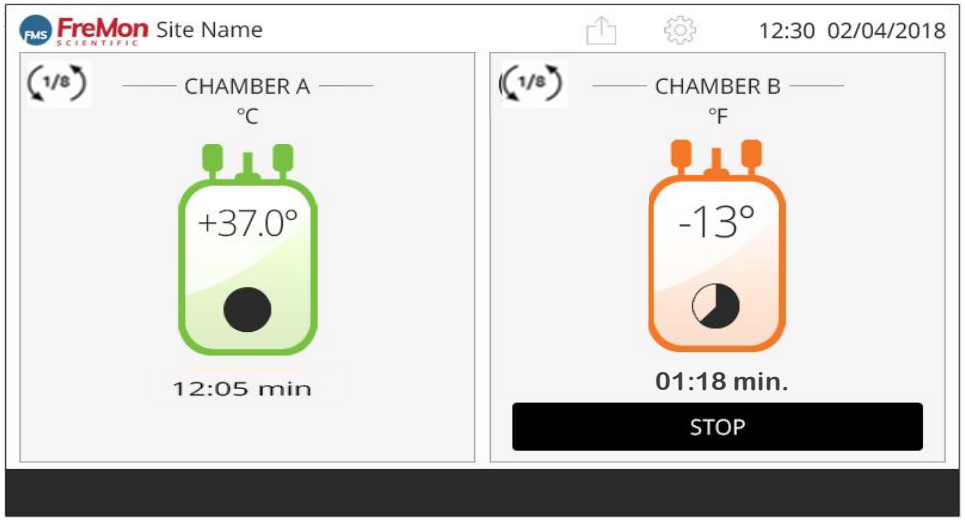


FIGURE 27. THAWING CYCLE CHAMBER A RUNNING & CHAMBER B READY SCREEN

Repeat **7.8.1 to 7.8.4** with respect to Chamber B.

7.9 END OF THAWING CYCLE

Upon thawing cycle completion of Chamber A, the following screen will be displayed:



- ***The Bag icon turns GREEN.***
- ***A One Time Alarm will be sounded for 1 Sec.***
- ***Chamber LED turns Green***

FIGURE 28. THAWING CYCLE CHAMBER A RUNNING & CHAMBER B LOADED AND START READY SCREEN

Open the Chamber door and remove the ZipSleeve™ from the Chamber and than take out the thawed plasma bag.

Note:
If the bag is left inside the chamber, the system starts to count the time post End-of-Thawing Cycle and will alert the user (i.e. sound and LED light will flicker) once, for 1 second, after 5minutes .

7.10 TIMEOUT THAWING CYCLE

The ZipThaw™ system has a timeout mechanism that stops the thawing cycle in cases where the thawing process doesn't reach the target temp (i.e. 33°C).

Note:
Currently, the timeout is set to 40 minutes for each thawing cycle.

In case of a timeout, the system will display the following message:

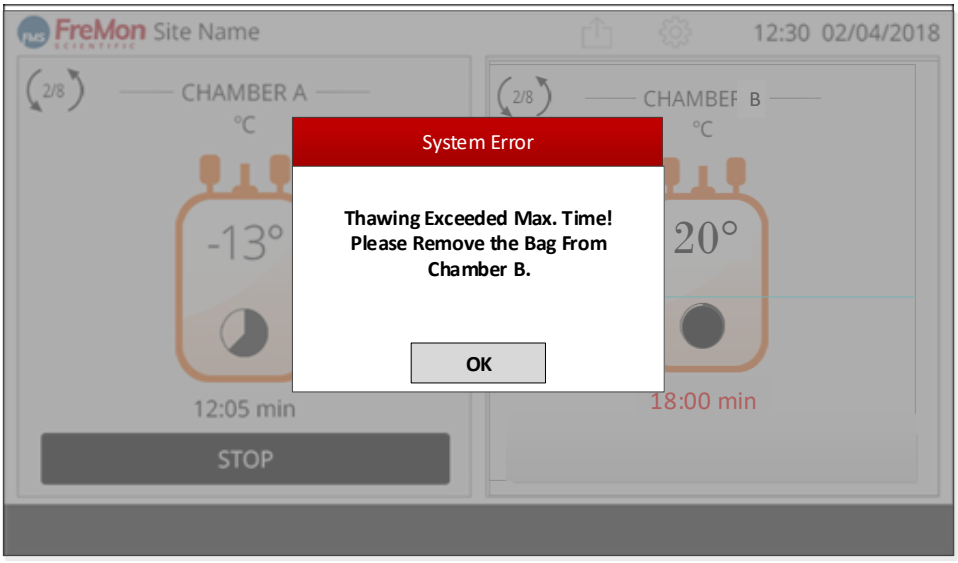


FIGURE 29. TIMEOUT SCREEN

Press "**OK**" and open the chamber door and remove the ZipSleeve™ from the chamber and than take out the thawed plasma bag.

8. EXPORTING DATA

At the end of a thawing session or before starting a thawing session, logged data can be export onto USB media.
Press the "Export Data" icon, the following GUI will be displayed

FIGURE 30. EXPORT DATA SCREEN

When entering the screen, the user will Scan/Enter his ID. (barcode will be lit when entering the screen and shut after scanning or after the user will type his ID and press enter)

Export data button will be idle until the ID is entered

The user then connects a USB drive and presses "**EXPORT FILES**". A pop-up with a progress bar will appear while downloading.

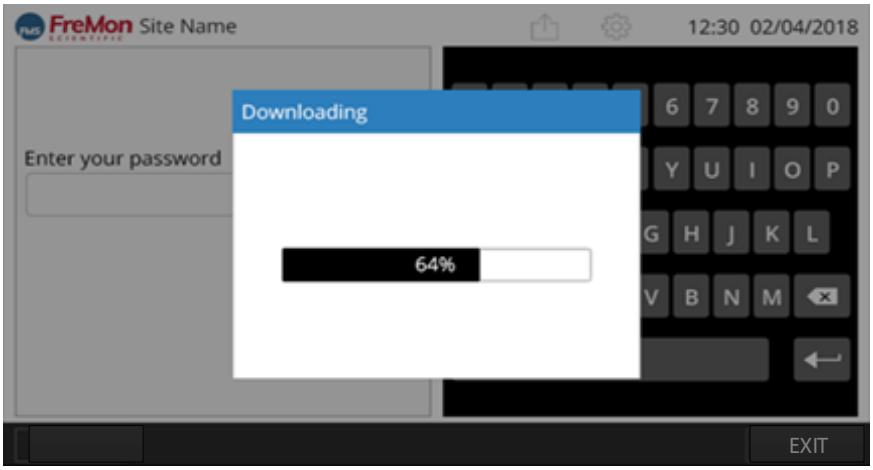


FIGURE 31.: DOWNLOADING DATA SCREEN

When finished exit the screen by pressing "**EXIT**".

The device exports a copy of all records stored on the device (2000 records possible). The user is not able to sort the records stored on the device.

The ZIPThaw™ keeps the most recent 2000 thawing session records. When the device's record storage space is full and a new record is created, the oldest record is deleted.

8.1 EXPORTING DATA STRUCTURE

The exported file will have the following fields.
The file will have comma-separated values (CSV) format.

#	date	start time	end time	user ID	bag ID	duration	extra time after finish	initial bag temp	final bag temp	error 01	error 02	error 03	error 04	Bag TEMP at 00:30	Bag TEMP at 01:00	Bag TEMP at 01:30	.....	... Bag TEMP at 60:00
Log number (between 1-1999)	Thawing date (MM/DD/YYYY)	Thawing start time	Thawing end time (when cycle stopped or finished)	User ID as inserted in the insert data screen 24:00 format	Bag ID as inserted in the insert data screen	From START until end of thawing Cycle (33°C/Green ICON)	Extra Time of bag inside the chamber after thawing cycle ended / cancel	First thawed bag Temp reading	Last thawed bag Temp reading	Errors that happened during thawing cycle (relevant chamber)				Temp is sampled -twice a minute - until taking the bag out				

9. POWERING DOWN

9.1 STANDBY MODE

To power down the system (standby mode) located on the front panel (see Figure 1), press the .
The screen will display the following prompt:

FIGURE 7-33: DEVICE SHUTDOWN PROMPT FIRST SCREEN

► To cancel and return to the previous screen press “CANCEL”.
► To continue power down press “OK”, the following pop up message will appear:

FIGURE 32.: DEVICE POWER DOWN PROMPT SCREEN

► Press “**CANCEL**” to cancel and return to the previous screen.
► Press “**YES**” to confirm standby mode.

The system will enter a standby mode.
Pressing the power button will wake the system and a power up process will be initiated as described above (see Section 7.3).

9.2 TURN-OFF MODE

To turn the ZIPThaw™ 202 off completely (i.e., disconnect the power), flip the **On-Off** switch located at the back of the device.

10. USERS MESSAGES

The ZIPThaw™ 202 system will prompt the user with operational and error messages as follows:

PHASE	MESSAGE	DESCRIPTION	BUZZER	SYSTEM RESPONSE	ACTION NEEDED
POWER UP SCREEN	"***Chamber A Door is Open. Please Close Chamber Door***"	Warning Message: Chamber Door A is open.	NO	A warning Pop-Up message that the Chamber Door is Open.	1. Close the door to resume power-up sequence. 2. Pop-Up massage will disappear OR when pressing "**OK**".
	"***Chamber B Door is Open. Please Close Chamber Door***"	Warning Message: Chamber Door B is open.	NO	A Warning Pop-Up message that the Chamber Door is Open.	1. Close the door to resume power-up sequence. 2. Pop-Up massage will disappear OR when pressing "**OK**".
	"***System Error, FMS Technical Support Required*** "	Error Messages: Error found during system BIT Testing.	YES	A System Error Pop-Up message. Operational Halt.	Require Technical Support assistance!
	"Chamber A Error, Use Chamber B"	Error Messages: Error found during system BIT Testing: Chamber A malfunction.	YES	A System Error Pop-Up message. Chamber A will be disabled.	1. Pressing "OK" will close the popup. 2. Follow IFU regarding Technical Support assistance!
	"Chamber B Error, Use Chamber A"	Error Messages: Error found during system BIT Testing: Chamber B Malfunctioning.	YES	A System Error Pop-Up message. Chamber B will be disabled and the specific Chamber GUI will be modified.	1. Pressing "OK" will close the popup. 2. Follow IFU regarding Technical Support assistance!
SELECT CHAMBER SCREEN	"***Select Chamber***"	System Prompt: Indicating User choice to use the available Chamber.	NO	None	Follow IFU
PHASE	**MESSAGE**	**DESCRIPTION**	**BUZZER**	**SYSTEM RESPONSE**	**ACTION NEEDED**
INSERT DATA SCREEN	"***Enter Required Fields***"	System Prompt: User to enter required thawing cycle data.	NO	A System Pop-Up message.	Pressing "**OK**" will close the popup. Follow IFU.
	" ***Incorrect ID, Please Re-Enter ID***"	System Warning: When an wronge ID was typed.	NO	A System Pop-Up message.	Pressing "**OK**" will close the popup. Follow IFU.

	"Data is Incorrect or Missing, Please Recheck Data"	System Prompt: When entering wrong barcodes OR not filling the mandatory fields.	NO	A System Pop-Up message.	Pressing "**OK**" will close the popup. Follow IFU.
INSERT PLASMA BAG SCREEN	***"Place Plasma Bag in Chamber A and Press Start"***	System Prompt: Operational instructions.	NO	A System Prompt Message.	Follow IFU.
	"Place Plasma Bag in Chamber B and Press Start"	System Prompt: Operational instructions.	NO	A System Prompt Message.	Follow IFU.
	"ZipSleeve Reached Max. Uses, please replace ZipSleeve"	System Prompt: Indicates that the ZipSleeve has reached its maximum number of uses.	NO	1. A System Pop-Up message. 2. Operation Halt 3. GUI Change indicating (N/N).	1. Pressing "**OK**" will close the popup and allow the user to use a new ZipSleeve. 2. Follow IFU and Replace ZipSleeve.
	"Door A is Open, Please Close Chamber Door"	Warning Message: Chamber Door A is not properly closed.	NO	1. A System Pop-Up message. 2. System will disable Chamber A thawing operation until the Chamber door is closed properly.	1. Pressing "OK" will close the popup message. 2. Close Chamber A Door Properly.
	"Door B is Open, Please Close Chamber Door"	Warning Message: Chamber Door A is not properly closed.	NO	1. A System Pop-Up message. 2. System will disable Chamber B thawing operation until the Chamber door is closed properly.	1. Pressing "OK" will close the popup message. 2. Close Chamber A Door Properly.
	"No ZipSleeve Detected in Chamber A, Please Insert ZipSleeve"	Warning Message: Indicating that a ZipSleeve was not loaded at the intendent Chamber A.	NO	1. A System Pop-Up message. 2. Chamber A Operational pause.	1. Pressing "**OK**" will close the popup message. 2. Follow IFU and load a ZipSleeve in the intendent Chamber.
	"No ZipSleeve Detected in Chamber B, Please Insert ZipSleeve"	Warning Message: Indicating that a ZipSleeve was not loaded at the intendent ChamberB.	NO	1. A System Pop-Up a message. 2. Chamber B Operational pause.	1. Pressing "**OK**" will close the popup message.

					2. Follow IFU and load a ZipSleeve in the intendent Chamber.
THAWING IN PROGRESS	***"Chamber A Failure, Technical Support Required"***	**Error Message:** Indicating that upon thawing cycle "START", Chamber A malefunctioned.	YES	1. A System Pop-Up a message. 2. The system disables Chamber A, after 3 test trials. 3. The System allows Chamber B to continue.	1. Pressing "**OK**" will close the popup message. 2. Follow IFU regarding Technical Support assistance!
	"Chamber B Failure, Technical Support Required"	**Error Message:** Indicating that upon thawing cycle "START", Chamber A malefunctioned.	YES	1. A System Pop-Up a message. 2. The system disables Chamber B, after 3 test trials. 3. The System allows Chamber A to continue.	1. Pressing "**OK**" will close the popup message. 2. Follow IFU regarding Technical Support assistance!
	"Chamber Door A Opened" "Resume Thawing?"	Warning Message: Indicating that Chamber A Door was opened during thawing cycle.	YES	1. A System Pop-Up a message. 2. The system pause thawing at Chamber A.	1. Close Chamber Door. 2. Pressing "**YES**" will resume thawing. 3. Pressing "**NO**" will abort the thawing cycle.
	"Chamber Door B Opened" "Resume Thawing?"	Warning Message: Indicating that Chamber B Door was opened during thawing cycle.	YES	1. A System Pop-Up a message. 2. The system pause thawing at Chamber B.	1. Close Chamber Door. 2. Pressing "**YES**" will resume thawing. 3. Pressing "**NO**" will abort the thawing cycle.
	"Thawing Exceeded Max. Time! Please Remove the Bag From Chamber A/B"	**Error Message:** Indicating that the system timeout the thawing cycle due to failure to thaw the bag to the target temperature within a predefined-timeouttime.	YES	1. A System Pop-Up a message. 3. The system terminate the thawing process at the said chamber.	4. Press "**OK**" and open the chamber door and remove the ZipSleeveTM from the chamber and than take out the thawed plasma bag.

POST THAWING CYCLE	***"Chamber A Door Opened, Thawing Cycle Stopped!"***	**Error Message:** Indicating that Chamber Door A was left open for more than 5 minutes.	YES	1. A System Pop-Up a message. The system terminates thawing at Chamber A.	1. Pressing "**OK**" will close the popup message. 2. Chamber A GUI will revert to "Select Chamber" screen.
	"Chamber B Door Opened, Thawing Cycle Stopped!"	**Error Message:** Indicating that Chamber Door B was left open for more than 5 minutes.	YES	1. A System Pop-Up a message. 2. The system terminates thawing at Chamber B.	1. Pressing "**OK**" will close the popup message. 2. Chamber B GUI will revert to "Select Chamber" screen.
ADMINISTRATOR SCREEN	***"Password Incorrect"***	**Error Message:** Indicating that incorrect password was typed.	YES	1. A System Pop-Up a message.	1. Pressing "**OK**" will close the popup message. 2. Re-Enter the correct password.
	"Incorrect Data, Please Re-Enter Data"	Warning Message: Indicating that the two administrator passwords entered, are not the same	NO	1. A System Pop-Up a message. 2. The incorrect fields will be marked red.	1. Pressing "**OK**" will close the popup message. 2. Re-Enter correct passwered.
	"***Incorrect Data, Please Re-enter Data***" -OK	Warning Message: Indicating that date and time were not filled correctly.	NO	1. A System Pop-Up a message. 2. The incorrect fields will be marked red.	3. Pressing "**OK**" will close the popup message. 4. Re-Enter correct date & time.
	"The Device Will Go to Default Settings All Users Will be Erased. Are You Sure ?"	Warning Message: When pressing the default settings button.	NO	A System Pop-Up a message.	1. pressing "**YES**" will delete changed settings and go back to "Home" screen. 2. Pressing "**NO**" will close the pop up and return to the setting/Admin. screen.
	"Exit the Screen Without Saving. Are You Sure ?"	Warning Message: When pressing "Home" after changing the settings. the data will not be saved	NO	A System Pop-Up a message.	1. Pressing "**YES**" will delete changed settings and go back to factory settings. 2. Pressing "**NO**" will close the pop up and go back to the screen.

EXPORT DATA	***"Scan/Enter Your ID, then Insert USB and Export"***	System Prompt: when entering the Export Data screen.	NO	None.	
	"Incorrect ID, Re-Enter ID" -OK	**Error Message:** Indicating that an incorrect ID was entered.	YES	A System Pop-Up a message.	1. Pressing "**OK**" will close the popup. 2. Re-Enter the password.
	"Downloading..."	System Prompt: While downloading	NO	massage disappear automatically when downloading is finished	None.
	"No USB Media Identified, Please Insert USB Media"	Warning Message: Indicating that the user didn't plug a USB media into it's socket.	NO	A System Pop-Up a message.	1. Pressing "OK" will close the popup
	"Downloading Failure "	Warning Message: Indicating that the downloading of data failed.	NO	A System Pop-Up a message.	1. Pressing "OK" will close the popup
	"Media Memory Full"	Warning Message: Indicating that the Media disk-on-key is full	NO	A System Pop-Up a message.	**1.** Pressing "OK" will close the popup
SYSTEM ON /OFF	***(*) "Turning OFF ZIPThaw" "Are You Sure?"***	Warning Message: Indicating that the ON/OFF push-button was pressed.	NO	A System Pop-Up a message.	1. Pressing "**NO**" will clear the pop up and resume previous system status. 2. Pressing "**YES**" will turn the system OFF.
	(**) "System Shutdown! Thawing Cycle Will be Stopped"	Warning Message: Indicating that the ON/OFF push-button was pressed, While a thawing cycle is in progress.	YES	1. A System Pop-Up a message (**). 2. Thawing Cycle paused. 3. IF a "YES" was selected by the user: the (*) message will appear.	1. Pressing "**NO**" will clear the pop up and resume Thawing. 2. Pressing "YES" will pop-up message (*). 3. Pressing "NO" will clear the pop up and resume previous system status. 4. Pressing "YES" will turn the system OFF.

11. CLEANING

11.1 EXTERNAL CLEANING AND DISINFECTING

To clean the ZipThaw™ 202 please use commercial santiatizing, disinfecting wipes or spray that has the ability to both clean and sanitise and works on a broad spectrum of pathogens including bacteria, yeasts / moulds and viruses.

11.2 DISPLAY CLEANING

To clean the device touch-screen please Lens-Wipes containg water, Isopropyl/Alcohol, Detergent and Anti-Static.

11.3 EMPTING THE DRAINAGE TRAY

A daily routine should be inspecting and empting the Drainage Trays prior to power up.
The Drainage Trays are accessed from the ZipThaw™ 202 rear by, opening the drainage covers and oull out the disposable trays.
Note:
Fluids inside the drainage containers indicates that the heating cushion may have a leak which requires technical support advisement.

12. WARRANTY

Three years full replacement warranty.

13. CUSTOMER SERVICE

For maintenance and repairs, please contact FreMon Scientific:

Moni Shavit
USA: +1-916-467-6377
IL: +972-50-695-4413
moni@fremonscientific.com

Please return faulty devices to FreMon Scientific for appropriate disposal.

The device must be cleaned and disinfected before returning it to FreMon Scientific for repairs or disposal.

14. SPECIFICATIONS

Thawing Technology:	Electrical power, disposable pocket
Typical Thawed Bag Capacity:	Single or Dual Bags
Cushions Heating Temperature: **Idel (Standby):** **Thawing:**	 36.5°C±0.5°C 36.5°C±0.5°C
ZipSleeve Sensors Cutoff Temperature:	33°C
Average Thawing Time (Minutes), single or dual Bag	100ml - ≤ 10 250ml - ≤ 16 450ml - ≤ 40
Agitation Method:	Electronic control mechanical Movement
Agitation Parameters :	Cycle: 2.2 c/sec. Amplitude: ±32mm
Visual Display/User Interface:	7" Touch Screen with Graphical User Interface
System:	**Main CPU:** VAR-SOM-SOLO/Dual: Freescale i.MX6 • High performance 1.0 GHz Single and Dual Core Cortex-A9™ • 1GB DDR3, 1GB SLC NAND and 64GB eMMC • Full HD 1080p video encoding/decoding capability • Vivante GPU providing 2D/3D acceleration **Chamber Control:** STMicroelectronics, STM32L073, MCU 32BIT 192KB
Interface & Network:	**USB** • USB 2.0 OTG • USB 2.0 Host
Memory Bank:	Internal for 2,000 thawing records
Internal Power Supplies:	Medical grade, isolating power-supply • ***Input:*** 100-240Vac**,** maximum rated current 2.5A • ***Outputs***: 2 X 24VDC, 12.5A maximum current
Heating Power:	Max. 400W, each Chamber
Electrical Rating (V/Hz/A):	100-240Vac, 50/60Hz 2.5Amp
Size: [W x D x H]	cm: 47.1 x 27.6 x 41.6 (including the top handle) inch: 18.5 x 10.9 x 16.4 (including the top handle)
Weight: [Lb/Kg] **Portable:**	24.2lb/11Kg Yes
Environmental Requirements:	
Ambient Operating Temp: **Ambient Humidity:** **Storage Temperature (in original packaging):**	10°C to 32°C (50°F to 86°F) 20% to 70% non-condensing -20°C to 70°C -4°F to 158°F)
Storage humidity (non-condensing):	30% - 90% non-condensing

15. PROTECTION AGAINST HARMFUL INTERFERENCE

15.1 EMC SAFETY

- The device has been tested and found to comply with the limits for the medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical clinical installation. This device generates uses and can radiate radio frequency energy. If not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that the interference to other devices, which can be determined by turning the device off and on, is caused by this instrument.

  The user is encouraged to try to correct the interference by one or more of the following measures:

  - Reorient or relocate the receiving device.
  - Increase the separation between the devices.
  - Connect the device into an outlet on a circuit different from that which was previously used.
  - Consult FreMon Scientific's service personnel for help.

  Interference to the device may be caused by portable and mobile RF communication equipment. In case of an interruption, beware of such a device in the vicinity.

- Use of the system with any accessory, transducer or cable other than those specified may result in increased EMISSIONS or decreased IMMUNITY than those specified.
- The system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions		
The ZIPThaw™ 202 is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIPThaw™ 202 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The ZIPThaw™ 202 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ZIPThaw™ 202 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly
Harmonic emissions IEC 61000-3-2	Not Applicable	

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ZIPThaw™ 202 or shielding the location.

Guidance and manufacturer's declaration – electromagnetic immunity

The ZIPThaw™ 202 is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIPThaw™ 202 should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 2 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	>95 % dip for 10ms 60 % dip for 100ms 30 % dip for 500ms 95 % dip for 5000ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ZIPThaw™ 202 requires continued operation during power mains interruptions, it is recommended that the ZIPThaw™ 202 be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE - U_T is the AC mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity			
The ZIPThaw™ 202 is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIPThaw™ 202 should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,7 GHz	[3] V [3] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ZIPThaw™ 202, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ZIPThaw™ 202 is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ZIPThaw™ 202. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the ZipThaw 202

The ZIPThaw™ 202 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ZIPThaw™ 202 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ZIPThaw™ 202 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
0,01	**0.12**	**0.12**	**0.23**
0,1	**0.37**	**0.37**	**0.74**
1	**1.17**	**1.17**	**2.33**
10	**3.69**	**3.69**	**7.38**
100	**11.67**	**11.67**	**23.33**

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

15.2 ELECTRICAL SAFETY

HERMON LABORATORIES

ACCREDITED

Hermon Laboratories Ltd.
P.O.Box 23
Binyamina 30500, Israel
Tel.+972 4 628 8001
Fax.+972 4 628 8277
e-mail: mail@hermonlabs.com

839.01
Electrical

IEC/EN 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No. ..... :	FRESAF_EN.30272
Date of issue ..... :	04 January, 2017
Total number of pages ..... :	134
CB Testing Laboratory ..... :	Hermon Laboratories Ltd
Address ..... :	HaTachana road, P. O. Box 23, Binyamina 30500, Israel
Applicant's name ..... :	FreMon Scientific Inc.
Address ..... :	1 Financial Center, Boston MA 02111 USA
Test specification:	
Standard ..... :	EN 60601-1: 2006 + A11:2011 + A1:2013 IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	
Test Report Form No. ..... :	IEC60601_1K (modified)
Test Report Form Originator ..... :	UL(US)
Master TRF ..... :	2015-11

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

HERMON LABORATORIES

CERTIFICATE

CERTIFICATE OF CONFORMITY

With EN 60601-1-6:2010 + A1:2015, IEC 60601-1-6:2010 (Third Edition) + A1:2013 for use in conjunction with IEC 62366:2007 (First Edition) + A1:2014 standards

Certificate Number FRESAF_EN.31414-6C

This certificate of conformity has been granted to the applicant based on the results of tests and evaluations, performed by Hermon Laboratories 26 June – 16 July, 2019 on representative samples of the specified products.

Product description

Tested item:	Plasma thawing and warming device
Model:	ZipThaw™ 202
Serial number:	0006
Hardware version:	VER-B
Software release:	V1.20

Applicant/Manufacturer details

Name:	FreMon Scientific Inc.
Address:	5726 La Jolla Blvd., Suite 304, La Jolla, CA 92037 USA

This is to certify that the tested product sample satisfies the requirements of the above listed standard/s.

Measurement/test results are contained in the test report: FRESAF_EN.31414-6.
The comments in the associated test report shall be taken into account and used in conjunction with this certificate

Michael Brun,
Product Safety Group Manager
Hermon Laboratories Ltd.
September 18, 2019

Page 1 of 1

EXPERTS IN GLOBAL COMPLIANCE SOLUTIONS

EMC Radio Telecom Environmental Product Safety International Approvals

Hermon Laboratories Ltd.
Hatachana St., POB 23, Binyamina 30500 Israel
Phone: +972 4 628 8001, Fax: +972 4 628 8277
Email: mail@hermonlabs.com, www.hermonlabs.com

15.3 UL MARK

NOTICE OF COMPLETION
AND
AUTHORIZATION TO APPLY THE UL MARK

2020-01-30

FreMon Scientific Inc.
Farideh Z. Bischoff
5726 La Jolla Blvd Suite 304
La Jolla, CA, 92037 USA

Our Reference:	File E513424, Vol. D1	Project Number:	4789289418
Your Reference:	Model ZipThaw 202, Plasma thawing and warming device		
Project Scope:	UL Listing to the following standard(s):		
	UL 61010-1, 3rd Edition, May 11, 2012, Revised April 29 2016, CAN/CSA-C22.2 No. 61010-1-12, 3rd Edition, Revision dated April 29 2016		

Dear Farideh Z. Bischoff:

UL has completed the investigation under the above project and confirmed compliance of your product(s) with UL requirements. We appreciate that you have a choice of certification providers and thank you for choosing UL.

This letter temporarily supplements the UL Follow-Up Services Procedure and serves as authorization to apply the UL Mark at the factory location(s) identified on the Authorization Page of UL File E513424, Vol. D1. You are required to send a copy of this letter to all manufacturing locations authorized under UL File E513424, Vol. D1. Products that bear the UL Mark must be identical to those submitted to UL for evaluation and found to be compliant with UL requirements.

Since you have Manufacturing factories that manufacture this product at a different location than above, please inform each factory listed below that they need to access their UL FUS Procedure via myUL, or have them contact us to email the Procedure to them.

ARAN RESEARCH & DEVELOPMENT LTD

Additional requirements related to the responsibilities of the Applicant and Manufacturer can be found under Additional Resources at https://www.ul.com/fus.

The Follow-Up Services Procedure covering your product(s) will typically be provided by UL within 10 business days. Any information and documentation provided to you involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

A UL certification is a valuable marketing tool meaning your product or company has successfully met stringent requirements. We encourage you to use your UL Mark and certification in your marketing activities. You can find information on how to accurately promote your UL certification at https://www.ul.com/marketing.

If you have any questions, please contact me or any of our customer service representatives. And, congratulations again on your achievement!

Very truly yours,

Seth De Sota (Project Handler)
763.586.3586
Staff Engineer
Seth.DeSota@ul.com

Reviewed by:

Bruce Mahrenholz
CPO Director
Certification Program Office
UL LLC

This is an electronically generated letter. Signatures are not required for this document to be valid.

Page 1 of 1

15.4 FDA CLEARANCE

U.S. FOOD & DRUG ADMINISTRATION

December 18, 2019

Fremon Scientific, Inc.
Attention: Mr. Yoram Levy
QSite
31 Haavoda Street
Binyamina 3054431
Israel

Re:	BK190401
Device Name:	ZipThaw™ 202
Regulation Number:	21 CFR 864.9205
Regulation Name:	Blood and plasma warming device
Regulatory Class:	Class II
Product Code:	KZL
Dated:	November 28, 2019
Received:	November 29, 2019

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

U.S. FOOD & DRUG ADMINISTRATION

December 18, 2019

Fremon Scientific, Inc.
Attention: Mr. Yoram Levy
QSite
31 Haavoda Street
Binyamina 3054431
Israel

Re:	BK190401
Device Name:	ZipThaw™ 202
Regulation Number:	21 CFR 864.9205
Regulation Name:	Blood and plasma warming device
Regulatory Class:	Class II
Product Code:	KZL
Dated:	November 28, 2019
Received:	November 29, 2019

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Orieji Illoh -S

Digitally signed by Orieji Illoh -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Orieji Illoh -S, 0.9.2342.19200300.100.1.1=2000420941
Date: 2019.12.18 16:12:38 -05'00'

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure
Indications for Use