**Protocol for Provisional Acceptance Verification of**

**ZipThaw Device**

**Presented by:**

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**Document Number:** FM-112018-0003

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# Version Control

|  |  |  |  |
| --- | --- | --- | --- |
| **Version Number** | **Created By** | **Release Date** | **Changes Summery** |
| Ver 1.0 | Moni Shavit | November 2018 | Draft version |
|  |  |  |  |
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|  |  |  |  |
|  |  |  |  |

# Objective

To set a provisional protocol for testing the ZIPThawTM 202 device functionality that will enable performance of a coagulation lose rest, as per FM-112018-0001.

## ****Terms & Abriviations****

|  |  |  |  |
| --- | --- | --- | --- |
| **Temp** | Temperature | **DC** | Direct current |
| **CRT** | Control Rate Thawer | **W** | Watt |
| **GUI** | Graphical User Interface | **V** | Volt |
| **EIS** | Electronic Information Systems | **Amp** | Ampere |
| **LAN** | Local Area Network | **HMI** | Human Machine Interface |
| **WAN** | Wide Area Network | **PLC** | Programmable Logic Controller |
| **FEC** | Front End Controller | **Pocket** | The Pocket where the plasma/blood bag is being processed |
| **AC** | Alternating Current | **FFP** | Fresh Frozen Plasma |
| **ATP** | Acceptance Test Protocol/Procedure |  |  |
|  |  |  |  |
|  |  |  |  |

## Note:

Validation of the ZIPThawTM 202 device follows FDA’s devices Quality System Regulation (QSR) Requirements for Medical Device Manufacturers for FDA 21 CFR 820 Compliance to obtain a 510K clearance (i.e. Use of FDA-Recognized Standards with a Declaration of Conformity Under Section 514(c) and AABB COI 1113 - FOR THE USE OF HUMAN BLOOD AND BLOOD COMPONENTS

## Statement of Intended 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)

The FreMon Scientific ZIPThawTM202 Thawing device is intended to be used in hospitals, trauma centers, blood banks and laboratories where it is required to thaw up to 2 units of Plasma, specifically Fresh Frozen Plasma (FFP), Cryoprecipitate AHF or Plasma Frozen Within 24 Hours After Phlebotomy (PF24) for future infusion into a patient.

ZIPThawTM 202 device is not intended, currently, for thawing of, but not limited to, Red Blood Cells, Hematopoietic Progenitor Cells or Umbilical Cord Blood.

# Acceptance Protocol

## General

For ATP testing, we recommend that no less than 25 frozen bags filled with 200ml substance will be used for each device.

### Equipment Needed:

1. ZIPThawTM 202 device
2. 2 x 30 bags filled with substance = 180ml±10ml salted distilled water (180ml H2O + 10gr NaCl)
3. Freezer space (-20°C)
4. Results Tables
5. Thermometer, wireless: 59 MAX Infrared Thermometer

### Materials Required:

Ns - Number of bags: 450ml container bags to be filled with 180ml±10ml substance and to be used as Validation Group 1(VG).

### determining the Number of Samples:

Based on the assumption that all tests will be acceptable, the sample size:

For 90% Confidence & 90% Reliability is:

Ns = = 22

Therefore, Ns will be **25**.

# Validation Process

## Pre-Freeze Visual Inspection

1. Obtain 25 bags of FFP/saline water, in a 450ml container-bags with volume of 180ml±10ml.
2. Inspect the FFP bags visually for any spots that potentially cause cracks during and/or post freezing;  
   In case of a crack or leak, discard sample).

## Freeze process

Freeze all bags to -20°C for at least 24 hours.

## Validation Process

### Pre-Freeze Visual Inspection

* 1. Inspect the FFP bags visually for any spots that potentially cause cracks during and/or post freezing;
  2. Number the bags (i.e. 1,2,3…25) using, RED permanent marker.

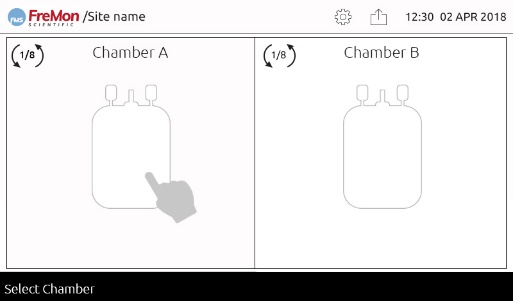
### Freeze process

Freeze all bags at -20°C for 24 hours.

### Test Preparation

* 1. Turn on the device allowing warming up, as per operation manual.   
     Please note that the ZIPThawTM202 does require a short diagnostics and heat stabilizing period upon power up and will prompt when it is ready unless an error occurred during power up diagnostic run.
  2. Cushion temp setup to 37.0°C.
  3. The ZIPThawTM202 will be preset at factory or at site by FMS technical support, to thaw within average Tc (cycle time) of 15 min. and not exceed substance temperature 37.0°C.
  4. Take out from the freezer 2 bags, at a time, to be thawed by the ZIPThawTM202 device.
  5. Inspect bags for cracks and defects.
  6. Discard defective bags and replace them with new ones from the freezer.

### Test Process Bags:

* 1. Verify that the ZIPThawTM202 is in READY mode (Hone screen).  
       
     
  2. Insert the frozen bags into a ZipSleeve bag and place them in Chamber A and B and close the door (light Red 🡪 Green).
  3. Press tab A to display Chamber A screen and verify that ZipSleeve NoU is valid.
  4. Then press “**START**” to start the thawing process.
  5. Repeat 3, 4 for chamber B.
  6. Upon completion of the thawing cycle (Buzzer, light flashing and display message), open the "chamber" door and take out the ZipSleeve containing the thawed bag and extract the thawed bag. Inspect that there was no leak. If a leak is observed discard the bag.
  7. Using the Non-Contact Infrared Thermometer such as Fluke 59 MAX+, IR Thermometer, measure the bag temp on central lower mass locations. The Fluke 59 MAX+ will Calculate the average temperature (Tave) to be compared with the ZIPThawTM 202 preset and displayed bag temperature.  
       
     
  8. Repeat process 2 to 7 for all bags.
  9. Record results in the tables located in APPENDIX A.



1. ATP Process

## results

Record results of group using Table 2.

## Acceptance and authorization

### Temperature criteria:

For 450m container Bags filled with 180ml ± 10ml plasma:

**Pass:**

1. Averagethawing temperatures **TAx** are between 30°C – 37.0°C

**AND** **TAXmax** ≤ 37.0°C.

1. **AND**, The Variance between the average displayed thawing temperature T**Ad** and the measured T**A1** is ±3%

**Fail:** Otherwise.

### Thawing Cycle Time Criteria:

**Pass**: Average thawing cycle **tA** is between 0– 16 minutes

**AND** **tmax** ≤ 16. min.

Fail: Otherwise

## conclusion & recomendations

If The above results are met:

1. Compose a validation report.
2. Conduct DR to authorize acceptance of system design
3. Modify DHF.
4. Approve Device performance for the Coagulation Lose rest in SD.

Else:

1. Conduct a fail analysis process
2. CAPA

Repeat validation.

## Table 2: Post-Freezing Temperature and Thawing Duration results

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sa mple #** | **Measured Weight/Volume**  **(gr.)** | **Initial Temp**  **(°C)** | **Device Display**  **Td (°C)** | **Average Measured T1**  **(°C) \*** | **Thawing Time**  **[min.]** | **Performed by/Date** | |  | **Remarks** |
| 1 | 180 | -8 | 31 | 31.5 | 15 | koby | 26 |  | side b: no heating  PRE-HEATING 33 only  cushion temp. 36 |
| 2 | 180 | -6.4 | 30 | 30 | 17 |  |  |  | doora make noise |
| 3 | 180 | -1 | 31 | 31 | 16 |  |  |  | ver 126 |
| 4 | 180 | -9.7 | 30 | 30 | 18 |  |  |  |  |
| 5 | 180 | 0 |  |  |  |  |  |  | Reset button |
| 6 | 180 | 0 | 31 | 30.6 | 15.13 |  |  |  |  |
| 7 | 180 | 0 | 31 | 30.2 | 15.0 |  |  |  |  |
| 8 |  |  | 31 | 31 | 16.20 |  |  |  |  |
| 9 |  |  | 31 | 30.8 | 15.31 |  |  |  |  |
| 10 |  |  | 31 | 31 | 15 |  |  |  |  |
| 11 |  |  | 31 | 31 | 16 |  |  |  |  |
| 12 |  | -6 | 32 | 35 | 14.30 |  |  |  | reset button no light  display is not tight  revise screen  subtitel |
| 13 | 180 | -6 | 32 | 31.6 | 14.1 | koby | 27 |  |  |
| 14 | 180 | -10 | 31 | 31.3 | 15 |  |  |  | version 31 |
| 15 | 180 | -10 | 32 | 31.5 | 14 | koby | 27 |  | version 31 |
| 16 |  |  |  |  |  |  |  |  | som ver:12  this machin(2) go to usa |
| 17 | 180 | -18 | 32 | 31.5 | 15 | koby | 28 |  |  |
| 18 | 180 | -20 | 31 | 31.2 | 15.30 |  |  |  |  |
| 19 | 250 | -18 | 31 | 31.5 | 23 |  |  |  |  |
| 20 | 180 | -16 | 31 | 30.5 | 15.20 |  |  |  |  |
| 21 | 180 | -18 | 32 | 31.5 | 17 |  |  |  |  |
| 22 | 180 | -20 | 31 | 31.6 | 17.30 |  |  |  |  |
| 23 | 180 | -16 | 31 | 31.6 | 15.20 | koby | 28 |  |  |
| 24 |  |  |  |  |  |  |  |  |  |
| 25 |  |  |  |  |  |  |  |  |  |

### 

## Thermoeter appovals & Specs:

Tecnimed Thermofucus 0070a2

```1111111111111111<https://www.accessdata.fda.gov/cdrh_docs/pdf3/k033790.pdf>

Fluke IP Thermometer Specifications:

<http://en-us.fluke.com/products/thermometers/fluke-59-max-thermometer.html#techspecs>