SMARTFREEZ CRYO

CELL

Qualification Manual

Installation Qualification document

Operational Qualification document

Version 2025-09

Table of Contents

Document approval for use

Prepared by	**DATE**
Carlos Completo, Project Engineer, SmartFreez Lda.	

Reviewed by	**DATE**
Andreia Duarte, Principal Scientist, SmartFreez Lda.	

Approved by	**DATE**
Rui Estrela, General Manager, SmartFreez Lda.	

1. Welcome

Thank you very much for purchasing a CELL unit from SmartFreez.

The Qualification Manual describes the Installation Qualification procedures and the Operational Qualification procedures.

Before start working with the unit, please read the User Manual, which describes the safety issues, technical specifications, and operating instructions of the unit. Strictly follow all the safety instructions in that manual.

SmartFreez is a specialized company on freeze/thaw technology and solutions for the biopharmaceutical industry. You can contact SmartFreez in the following ways:

Address:

SmartFreeZ, Lda

Av. Professor Doutor Cavaco Silva, Edifício Tecnologia 1.2, nº 21

2740-257 Porto Salvo

Portugal

Phone no.: +351 215 928 189

Email: info@smartfreez.com

Internet: www.smartfreez.com

2. Installation Qualification

2.1. Introduction

This Test Plan provides documented verification that the system has been produced and assembled in accordance with SmartFreez's specifications. The plan includes all the IQ test protocols for the parts of the system that are listed in this document.

2.2. Overview

Each test shall be performed by a qualified tester. The tests shall be signed by the tester. "N/A" should be marked for any item that is not applicable.

2.2.1. Equipment being tested

Table 1 – Equipment being tested.

Equipment being tested	
Description	Serial Number
CELL Machine v4	SN: 254 102

2.2.2. Protocol aims

The Installation Qualification protocol aims to confirm the following:

- That the product supplied matched the order specification of the customer.
- That all standard accessories are supplied.
- That any optional accessories are supplied.
- That the unit has been correctly unpacked and is not damaged.
- That the unit is correctly placed in a safe and suitable environment.
- That the unit is electrically safe.
- That the unit is installed correctly.
- That all supporting documentation is supplied.

2.3. Summary of the Installation Qualification test

Table 2 – Summary of the Installation Qualification tests.

Summary Results			
Test	**Result**	**Approval by**	**Date**
1			
2			
3			
4			

2.4. Installation Qualification test protocols

This document has been produced to include many commonly executed tests. It is at the sole discretion of the end user to determine which tests are applicable, necessary, or if additional testing is necessary in order to meet their requirements.

2.4.1. Test 1 – Packaging Verification

Test 1			
Objective: To verify that the unit and accessories are present.			
Procedure: 1. Check that the delivered transportation box is not damaged. 2. Open the box and verify that the unit and accessories are present.			
Sub-Test	**Description**	**Test Result**	**Acceptance**
1	• Box not damaged.		
2	• Main body of the unit.		
	• Power supply cord.		
	• F-T assembly, comprised of three parts: vials support, intermediate spacer, and top cover.		
	• Cold transportation box		
	• Ethernet cable.		
	• User manual.		
	• Qualification Manual.		
	• Best Practices Manual.		
	• Vials (optional)		
Comments:		**Signature:** **(tester)** **Date:**	

2.4.2. Test 2 – Model and Serial Number Verification

Test 2			
Objective: To verify that the unit is labeled with the correct model and serial number.			
Procedure: 1. Locate the serial number label attached on the rear panel of the unit. It should match the information shown in section 2.2.1.			
Sub-Test	**Description**	**Test Result**	**Acceptance**
1	• Model.	Model: _____	
2	• Serial Number.	SN: _____	
Comments:		**Signature:** **(tester)** **Date:**	

2.4.3. Test 3 – Parts Inspection

Test 3			
Objective: To verify that the unit and accessories are free of defects.			
Procedure: 1. Visually inspect the unit and accessories. The main body of the unit should be in good condition (no scratches; intact screen; the lid should open and close; etc.). 2. The parts of the F-T assembly should be in good condition (no damage; the four pins/feet of the support should be unbroken and move up when pressed and down when released). 3. The power supply cord and ethernet cable should be intact.			
Sub-Test	**Description**	**Test Result**	**Acceptance**
1	• Main body of the CELL unit.		
2	• F-T assembly, comprised of three parts: vials support, intermediate spacer, and top cover.		
3	• Power supply cord.		
	• Ethernet cable.		
Comments:		**Signature:** **(tester)** **Date:**	

2.4.4. Test 4 – Installation the Unit

Test 4			
Objective: To verify the correct installation of the unit according to the “User Manual” instructions.			
Procedure: 1. Install the unit as described in the “User Manual”. 2. Verify that the ethernet cable is easily connect to the port.			
Sub-Test	**Description**	**Test Result**	**Acceptance**
1	• CELL unit is installed in a levelled benchtop (up to 0.5°).		
2	• There is at least 20 cm of free space between the faces of the unit (excluding the bottom face).		
3	• The power cord is correctly connected to the power inlet at the rear of the unit.		
4	• The unit is connected to a grounded power outlet.		
5	• The ethernet cable connects to the port at the rear of the unit.		
Comments:		**Signature:** **(tester)** **Date:**	

3. Operational Qualification

3.1. Introduction

The CELL systems is designed to be used in scientific and industrial freezing and thawing applications.

This Test Plan provides documented verification that the system has been produced and correctly works in accordance with SmartFreez's specifications. The plan includes all the OQ test protocols for the system listed in this document.

3.2. Overview

Each test shall be performed by a qualified tester after reading the User Manual. The tests shall be signed by the tester. "N/A" should be marked for any item that is not applicable.

3.2.1. Equipment being tested

Table 3 – Equipment being tested.

Equipment being tested	
Description	Serial Number
CELL Machine	SN: 254 102

3.2.2. Protocol aims

The Operational Qualification protocol aims to confirm the following:

- That all the mechanical and electrical functions are operating correctly.
- That all programming functions are operating correctly.
- That the export data application is operating correctly.

3.3. Summary of the Operational Qualification tests

Table 4 – Summary of the Operational Qualification tests.

Summary Results			
Test	**Result**	**Approval by**	**Date**
A			
B			
C			
D			
E			
F			
G			
H			
I			

3.4. Operational Qualification test protocols

This document has been produced to include many commonly executed protocols. It is at the sole discretion of the end user to determine which tests are applicable, necessary, or if additional testing is necessary in order to meet their requirements.

3.4.1. Test A – Power on and boot verification

Test A			
Objective: To verify that the CELL unit switches on and that the software boots.			
Procedure: 1. Connect the CEL unit to the power supply (as specified in the User Manual). 2. Power on the CEL unit by switching on the switch button. 3. Wait for system to boot.			
Sub-Test	**Description**	**Test Result**	**Acceptance**
1	• Switch on the CELL unit. After a few seconds, a blue led switches on near the touchscreen.		
2	• During booting a series of screens appear in the touchscreen.		
3	• After a couple of minutes, the “Main screen” appears (see a snapshot of the “Main screen” in the *User Manual*.		
Comments:		**Signature:** **(tester)** **Date:**	

3.4.2. Test B – Piston movement verification – Part 1 of 2

Test B

Objective: To verify that the pistons on the lid move properly.

Procedure:

1. Switch on the CELL unit as specified in the User Manual (or Test A).
2. Open the CELL unit by pressing the lock and pulling the lid.
3. Press the “Settings” button in the touchscreen. It should appear on the “Settings screen”.
4. By pressing sequentially, several times, the “Cells up” and “Cells down” buttons check if the pistons move.

Sub-Test	Description	Test Result	Acceptance
1	• Press the “Cells down” button. The pistons should move continuously.		
2	• Press the “Cells up” button. The pistons should move and stop at the highest position.		

Comments:	**Signature:** **(tester)** **Date:**

3.4.3. Test C – Piston movement verification – Part 2 of 2

Test C

Objective: To verify that piston movement is not blocked by the F-T assembly.

Procedure:

1. Switch on the CELL unit and open the lid.
2. Go to the “Settings screen” and press the “Cells up” button.
3. Place the F-T assembly inside the chamber of the CELL unit (see the User Manual for more information about placing the F-T assembly).
4. Close the lid. The lock must produce a “click” sound. If necessary, pull the lock.
5. Go to the “Settings screen” and press sequentially the “Cells down” and “Cells up” buttons.
6. Check if the “Cells down” and “Cells up” buttons become both gray or any strange sound occurs. This means that the pistons are blocked due to a too high F-T assembly. If this is the case, remove immediately the F-T assembly and contact SmartFreez.

Sub-Test	Description	Test Result	Acceptance
1	• Register the FT-Assembly part numbers		
2	• Press “Cells down” button. Did the buttons blocked?		
3	• Press “Cells up” button. Did the buttons blocked?		
4	• Press “Cells down” button. Did the buttons blocked?		
5	• Press “Cells up” button. Did the buttons blocked?		

Comments:	**Signature:** **(tester)** **Date:**

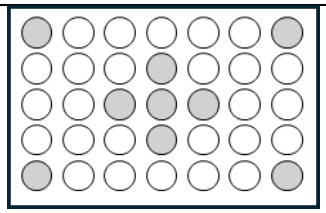
3.4.4. Test D – Freezing verification – Part 1 of 2

Test D

Objective: To verify that ice nucleates in the nucleation stage.

Procedure:

1. Prepare 10 mL of a 10% DMSO solution in Fetal Bovine Serum (FBS).
2. Fill nine 2 mL vials with 1 mL of DMSO solution (Check the User Manual on the type of vials to be used).
3. Put the vials and the F-T assembly in the refrigerator (between +2 °C and +6 °C for at least two hours).
4. Switch on the CELL unit.
5. Pour 25 mL of thermal contact fluid into the heat transfer plate (for more information on the thermal contact fluid, see Section *"Thermal contact fluid"* of the User Manual).
6. Load and start the "T02 Test T-profile" recipe.
7. Put the vials in the vials support and place the F-T assembly inside the CELL unit at the end of stage 1 of the recipe (without pushing the F-T assembly against the heat transfer plate).
8. Let the run finish the second stage of the recipe. As soon as the second stage of the recipe finishes (and the third stage begins) remove the vials from the CELL unit and check if ice nucleation has occurred.
9. Measure the height of nucleated ice layer on the lateral wall of the vials

Sub-Test	Description	Test Result	Acceptance
1	• Has ice nucleation occurred? How many vials? (mark the nucleated vials)		
2	• Was the height of the ice, on the lateral wall of the vial, between 1 and 2 mm? (Do not account with the plastic thickness of the vial's bottom surface)		

Comments:	Signature: (tester) Date:

3.4.5. Test E – Freezing verification – Part 2 of 2

Test E			
Objective: To verify that ice nucleates in the nucleation stage and that it doesn´t melt neither detaches from the bottom of the vial.			
Procedure: 1. Repeat the procedure of the Test D but, instead of analyzing the vials at the end of stage 2, remove and analyze the vials at the end of stage 3. 2. Let the run finish the third stage of the recipe (temperature increase from the nucleation temperature to -7 °C). As soon as the third stage of the recipe finishes (and the fourth stage begins) remove the vials from the CELL unit and check if the nucleated ice remains attached to the bottom of the vials.			
Sub-Test	**Description**	**Test Result**	**Acceptance**
1	• Did the nucleated ice remain attached to the bottom of the vial?		
Comments:		**Signature:** **(tester)** **Date:**	

3.4.6. Test F – Application for data retrieval – Part 1 of 2

Test F			
Objective: To verify that the user can access the application for data retrieval.			
Procedure: 1. Switch on the CELL unit. 2. Switch on a computer and connect it to the CELL unit via Ethernet ports. 3. Configure the Ethernet connection according to the User Manual. 4. Access the application for data retrieval, as described in the User Manual.			
Sub-Test	**Description**	**Test Result**	**Acceptance**
1	• Did the login page appeared?		
2	Using the correct credentials, did the user enter the “Home” page of the application?		
Comments:		**Signature:** **(tester)** **Date:**	

3.4.7. Test G – Application for data retrieval – Part 2 of 2

Test G			
Objective: To verify that the user can retrieve data from an experimental run.			
Procedure: 1. Login to the application according to the User Manual. 2. Expand the left menu tree “Reporting → Export → Tasks”, as described in the User Manual. 3. Click the magnifying glass. 4. Retrieve a data log file, in the logs table, by clicking the download button. 5. Open the retrieved data log file in a spreadsheet software.			
Sub-Test	**Description**	**Test Result**	**Acceptance**
1	• Did the data log file downloaded?		
2	• Do the data log file presents the data fields described in the User Manual?		
Comments:		**Signature:** **(tester)** **Date:**	