# 1. REVISION HISTORY

<table>
<thead>
<tr>
<th>REVISION</th>
<th>AUTHOR</th>
<th>DESCRIPTION OF CHANGE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>00</td>
<td>John Fitzpatrick</td>
<td>Initial Release</td>
<td>08Mar19</td>
</tr>
</tbody>
</table>
| 01       | John Fitzpatrick              | • Replaced "Scripts Swap" sections with instructions for using the USB protocol import function.  
|          |                               | • Updated Genesis System Installation Kit from 250K Celsingles to 100K Celsingles.     | 28May19  |
|          |                               | • Removed UV Light Test.                                                              |          |
| 02       | Jason McCormick/John Fitzpatrick | • Updated Footer                                                                        | 17Jun19  |
|          |                               | • Formatted Dates with DDMMYY.                                                       |          |
| 03       | John Fitzpatrick              | • Updated document to reflect the use of the Genesis System GUI SW: v1.5.1 and FW: v7.5.0.  
|          |                               | • Updated log retrieval per v1.5.1 software.                                          | 18Jul19  |
|          |                               | • Updated 100K Installation Kit part Numbers                                          |          |
|          |                               | • Updated terminology from “chip” to “slide”.                                        |          |
|          |                               | • Updated Step 13.8                                                                 |          |
|          |                               | o Accurate volumes of buffer for Celsingle priming                                   |          |
|          |                               | o Updated protocol to “Advantage Program 100K Celsingle 3 Prime Kit v2.0”            |          |
|          |                               | o Fill 6 chambers of the reagent cartridge                                           |          |
| 04       | John Fitzpatrick              | • Qualification of the Genesis System is covered in the New docs G2-FSS-106a and G2-FSS-106b. | 26Jul19  |
| 05       | John Fitzpatrick              | • Changed title to “Genesis System Installation Qualification”                        | 06Aug19  |
|          |                               | • Added Thermal Evaluation and Genesis System Validation (burnin).                    |          |
|          |                               | • Referenced G2-FSS-021 Genesis System Validation                                    |          |
|          |                               | • Referenced G2-FSS-106a and G2-FSS-106b Genesis System Operational Qualification.   |          |
|          |                               | • Removed section describing procedure for establishing a remote connection; instead referenced G2-FSS-018 Genesis System Remote Access and File Transfer. |          |
|          |                               | • Updated format to align with support documents                                       |          |

## 2. PURPOSE

2.1 The purpose of this procedure is to describe the process for installing the Celsee® Genesis System at a customer site.

## 3. SCOPE

3.1 This procedure applies to any Celsee employee involved in the installation of a Genesis System at a customer site.

## 4. RESPONSIBILITY

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4.1 Field Service is responsible for installation of the Celsee Genesis System and for the maintenance of this procedure.

5. TRAINING
5.1 Personnel responsible for installation of the Celsee Genesis System will be trained on this procedure prior to performing installations at customer sites.

6. SAFETY
6.1 No special precautions are required.

7. ENVIRONMENTAL CONTROLS
7.1 No special environmental controls are required.

8. PERSONNEL PROTECTIVE EQUIPMENT (PPE)
8.1 Personnel performing this protocol shall use the following PPE:
   8.1.1 Gloves: silicone or plastic only. (No cloth/ fabric gloves.)
   8.1.2 Safety Glasses

9. DEFINITIONS
9.1 VM – Virtual Machine
9.2 OBQ – Out of Box Quality

10. REFERENCED DOCUMENTS
10.1 G2-FSS-018 Genesis System Remote Access and Remote File Transfer
10.2 G2-FSS-021 Genesis System Validation
10.3 G2-FSS-101 Genesis System Qualification Certificate
10.4 G2-FSS-102 Genesis System Installation Checklist
10.5 G2-FSS-106a Genesis System Operational Qualification (Celsingle)
10.6 G2-FSS-106b Genesis System Operational Qualification (Celselect)
10.7 QA-FSS-002 Customer Relationship Management

11. EQUIPMENT/ MATERIALS
11.1 Celsee Genesis System
11.2 External USB Hub
11.3 USB Keyboard
11.4 USB Flash Drive

12. OVERVIEW
12.1 This document provides the procedure for the following:
   12.1.1 General
   12.1.2 Out of Box Quality and Inventory
   12.1.3 Benchtop Installation of Components
   12.1.4 Thermal Evaluation
   12.1.5 Genesis System Validation (Burnin)
   12.1.6 Genesis System Qualification
   12.1.7 Establish Remote Access

13. PROCEDURE
13.1 General
13.1.1 During benchtop installation, electrical service for the Genesis System and other equipment may be provided from an uninterrupted power supply (UPS).

13.1.2 Any deviations from this installation procedure is to be documented in G2-FSS-102 Genesis System Installation Checklist and G2-FSS-101 Genesis System Qualification Certificate for the respective customer site.

13.2 Out of Box Quality (OBQ) and Inventory

13.2.1 Locate and unpack the boxes containing the Celsee Genesis System and ancillary materials. Unpack each box and ensure that the below materials have been delivered.

<table>
<thead>
<tr>
<th>Celsee Genesis System (1 Box)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Celsee Genesis System</td>
</tr>
<tr>
<td>• Power Supply (24V) and Cord</td>
</tr>
<tr>
<td>• Ethernet Cable (14’)</td>
</tr>
<tr>
<td>• Celsee Genesis System</td>
</tr>
<tr>
<td>Instruction Manual</td>
</tr>
<tr>
<td>• Barcode Scanner (wireless)</td>
</tr>
<tr>
<td>• Barcode Scanner Charging Station</td>
</tr>
<tr>
<td>• If applicable - Celsee Priming Genie</td>
</tr>
<tr>
<td>• If applicable - Celsee Priming Genie Power Cord</td>
</tr>
<tr>
<td>• Handheld Cartridge Piercer (1)</td>
</tr>
<tr>
<td>• Celsee Select Slide Plate (2)</td>
</tr>
<tr>
<td>• 100 – 250K Celsingle Slide Station (2)</td>
</tr>
<tr>
<td>• 100K Celsingle Lid (2)</td>
</tr>
<tr>
<td>• 250K Celksingle Lid (2)</td>
</tr>
<tr>
<td>• 100 – 250K Celsingle Replacement Gaskets (2)</td>
</tr>
<tr>
<td>• Rubber Mats for Waste Jar (2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Installation Kits (One Kit per Unit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Genesis System 100K Celsingle™ Installation Kit (4 Pack), PN 83001</td>
</tr>
<tr>
<td>• Genesis System Celselect™ Installation Kit (4 Pack), PN 83002</td>
</tr>
</tbody>
</table>

13.2.2 Remove all packing materials, desiccant packs, and tape from the instruments.

13.2.3 Inspect all equipment and materials for damage that may have occurred during shipping. If materials are found to be damaged, notify management and initiate an OBQ case in Sales Force per QA-FSS-002 Customer Relationship Management.

13.3 Benchtop Installation of Components

13.3.1 Don PPE per Step 8.

13.3.2 Ensure that sturdy immobilized benchtop space is available for the placement of the Celsee Genesis System.

13.3.2.1 A minimum of 6 inches of clear space is required on the left, right, and rear of the unit.

13.3.2.2 A minimum vertical clearance of 35 inches is required for full extension of the Genesis System’s lid.

13.3.3 Ensure that the bench where the Genesis System is to be installed is free of vibrating equipment.

13.3.4 Place the Genesis System on the benchtop.
13.3.5 Connect the power cord with 24V power supply into the Genesis System prior to plugging it into the electrical outlet, to prevent damage to electrical components.

13.3.6 Connect the barcode scanner charging station to the Genesis System.

13.3.7 If applicable, connect the ethernet cable to the Genesis System and to an active ethernet port at the installation site.

13.3.1 Turn on the Genesis System using the power switch located on the rear of the unit.

13.3.2 Scan the three barcodes below to program the wireless barcode scanner.

NOTE: Scanning these barcode enables the barcode scanner to read the custom Celsee QR codes.

---

**Add Enter Key (Carriage Return/Line Feed)**

---

**Disable Keypad Emulation**

---

**Enable GS1 Data Matrix (1)**
13.3.3 If necessary, scan the following barcode to reduce the volume of the barcode scanner.

![Barcode Image]

**Medium Volume**

13.4 **Thermal Evaluation**

13.4.1 Plug in the External USB Hub to the front USB port on the Genesis System.
13.4.2 Plug in the USB keyboard to the External USB Hub.
13.4.3 From the Genesis System GUI enter “Alt + Tab” to navigate to the VM terminal, and then enter “Ctrl + C” to kill the Genesis System GUI.
13.4.4 Right click on the desktop and logout of the VM terminal. See Figure 1.

![Virtual Machine Logout Image]

*Figure 1: Virtual Machine Logout*

13.4.5 Login to the VM with username “celsee_admin” and password “Celsee01”. See Figure 2.(next page)
13.4.6 Right click on the desktop of the VM and go to “Applications > Terminal Emulator”. See Figure 3.

13.4.7 From the VM terminal navigate to the “/home/celsee_admin” directory.

```bash
cd
```

13.4.8 Enter the following command and identify the target USB drive from the list displayed.

NOTE: This lists all storage devices connected to the Genesis System. A USB drive usually shows up as sdb1.

```bash
ls /dev/sd*
```

Figure 2: Virtual Machine Login

Figure 3: Virtual Machine Terminal Access
13.4.9 Make an empty directory titled “flash” if it does not already exist, then mount the USB drive to “flash”, assuming the target USB is “/dev/sdb1”.

```
sudo mkdir flash
sudo mount /dev/sdb1 flash
```

13.4.10 Navigate to the “celsee_admin” directory and open “testgui.py”.

*NOTE: A new window will appear with the testgui. See Figure 4.*

```
cd
python pyFreedom/testgui.py
```

![Figure 4: Testgui](image)

13.4.11 Ensure that the firmware version displayed at the bottom of the testgui is the most up-to-date version (Version 7.5.0). If not, refer to G2-FSS-017 Genesis System Software and Firmware Updates for instructions on how to update the Firmware on the Genesis System.

13.4.12 Click on the tab labeled “thermal eval”.

13.4.13 Click the “Run Thermal Eval” button on the testgui to execute an evaluation of the Genesis System’s thermal plates.

*NOTE: During a TEC Test the temperatures of the thermal plates will cycle between 100°C and 2°C. After the test, the testgui will display a pass or fail rating.*

13.4.14 Exit the testgui when the test is complete by pressing “Alt + Tab” and “Ctrl + c”.

13.4.15 Copy the newly created log files (thermal_eval_lane##-yyyy-mm-dd-tttt) from the “celsee_admin” directory to the USB drive mounted in the “flash” directory.

*NOTE: One log file will be created for each lane.*

```
sudo cp thermal_eval_lane0-yyyy-mm-dd-tttt ~/flash
sudo cp thermal_eval_lane1-yyyy-mm-dd-tttt ~/flash
```
13.5 **Genesis System Validation (Burnin)**
   13.5.1 Perform a Genesis System Validation per G2-FSS-021 Genesis System Validation.
   13.5.2 Ensure that the following is uploaded to the corresponding install case in Salesforce:
      13.5.2.1 Thermal Log (thermal_eval_lane0-yyyy-mm-dd-tttt)
      13.5.2.2 Thermal Log (thermal_eval_lane1-yyyy-mm-dd-tttt)
      13.5.2.3 Burnin Test file (burn_in_yyyy-mm-dd-tttt)

13.6 **Genesis System Qualification**
   13.6.1 Determine the core functionality of the customer’s Genesis System and qualify the system per the appropriate operational qualification SOP from the list below.
      13.6.1.1 G2-FSS-106a Genesis System Operational Qualification (Celsingle)
      13.6.1.2 G2-FSS-106b Genesis System Operational Qualification (Celselect)

13.7 **Establish Remote Access**
   13.7.1 If allowed at the customer site, test the internet connectivity and remote accessibility of the Genesis System per G2-FSS-018 Genesis System Remote Access and File Transfer.
   13.7.2 Complete G2-FSS-102 Genesis System Installation Checklist and then upload the file to the respective Salesforce installation case.
   13.7.3 Complete G2-FSS-101 Genesis System Qualification Certificate, provide a copy to the customer, then upload the file to the respective Salesforce installation case.