

Electrogenic Laboratories Ltd



MOSkinTM Dosimetry System

Instruction For Use

LBL-001 Rev 03

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1 WARNINGS AND SAFETY PRECAUTIONS

The MOSkin™ System has been designed and constructed in accordance with international regulations and standards for operation of electrical equipment, electromagnetic compatibility, and stipulated safety requirements.

Improper use or handling, however, can result in damage and/or injury. To prevent damage to the equipment, please read these operating instructions carefully before using your MOSkin System. Keep these instructions in a safe place. Follow the instructions below to ensure safe and trouble-free operation of your system.



- **WARNING:** Any attempt to disassemble or modify the MOSkin System may result in unintended hazards. The MOSkin System can only be serviced by the manufacturer (Electrogenics Laboratories Ltd, ELL) or an ELL Authorized Service Center. Please contact your Product Specialist or Electrogenics Labs directly (support@electrogenicslabs.com) regarding any device that is not functioning correctly.
- **WARNING:** RDs are indicated for use on unbroken skin.
- **WARNING:** Hub contains permanent magnets. Do not use within six (6) inches (15.3 cm) of other magnetically susceptible medical devices.
- **WARNING:** increased cybersecurity risk if the MOSkin System is connected to a public and/or unsecured WiFi network.
- **WARNING:** Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment

- **WARNING:** This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- **CAUTION:** To reduce the cybersecurity risk to the MOSkin System only connect to a WiFi network when needed
- **CAUTION:** The MOSkin System shall be cleaned according to the instructions provided in this Instructions for Use.
- **CAUTION:** Folding or creasing the RD during use or cleaning may damage the RD and prevent correct baselining or reading of delivered dose.
- **CAUTION:** Do not handle the RD with forceps, tweezers or other mechanical devices as this may damage the RD. Use only gentle fingertip pressure in handling.
- **CAUTION:** Ensure time interval between RD baselining and dose reading does not exceed 2 hours to minimise effect of fading (<1% error within 2 hours).
- **CAUTION:** Examine the MOSkin System for damage or sharp edges prior to each use. If any damage or sharp edges are found, please contact customer service or your Product Specialist. Do not attempt to use the device.
- **CAUTION:** Any RD that has been calibrated by a MOSkin System user will be permanently modified from the factory calibration and accuracy may be affected.
- **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician

2 GENERAL

2.1 DEVICE DESCRIPTION

The MOSkin System is used for measuring radiation doses delivered to a patient by a separate system in a hospital or clinical environment. The output of the MOSkin System is not used to directly adjust the radiation dose.

The MOSkin System (Figure 1) consists of four elements:

- a. **Radiation Dosimeter (RD):** The RD detects radiation and stores the accumulated radiation received at the radiation sensor's location. When used for treatment the RD is attached to the patient and measures skin dose. The RD may also be used in combination with a build-up accessory to measure dose at specific below-skin depths.
- b. **HUB (HUB):** The HUB connects to RDs and converts the RD electrical parameters into a radiation dose measurement (unit: cGy) and transmits data to a Monitor tablet device running the Monitor Software.
- c. **Monitor:** The Monitor is used to display to the User the data generated by the System.
- d. **Monitor Software (MS):** The Monitor Software is software running on the Monitor, which receives data from the HUB and displays this information, allowing the user to interact with the system.



Figure 1 MOSkin System Components

2.1.1 Radiation Dosimeter (RD)



WARNING: RDs are indicated for use on unbroken skin.

The Radiation Dosimeter is a thin, flexible device that records the amount of radiation delivered to the patient. The RD is supplied clean, but non-sterile and does not need to be sterilized before use. The measurement component of the RD is located under the white dot on the tapered (purple) end of the device.



Figure 2 Radiation Dosimeter (RD)

The RD features a self-adhesive underside to facilitate placement on the patient.

2.1.2 Reader (HUB)

The HUB is a battery-powered device used to read information from up to four (4) RDs and communicate with the Monitor tablet and software.



Figure 3 HUB

The HUB features four slots on the top for reading RDs.

On the lower right side of the HUB top surface is the Action Button, which turns the HUB on and off. This button also houses an LED indicator that allows the user to determine the state of the HUB (see Section 8.1 for more information about LED indicators).

On the right side of the HUB is a USB-C port for power & battery charging.

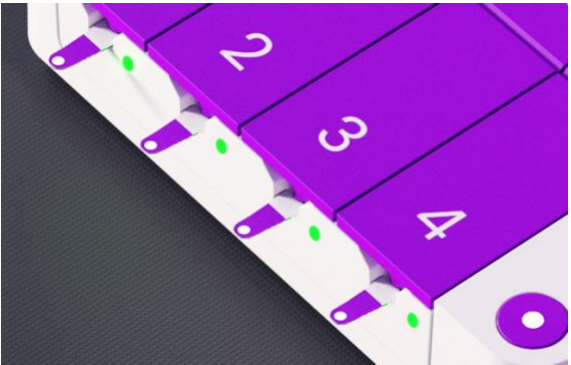


Figure 4 HUB Reading Slot

Each reading slot has a connector for each RD and an LED indicator to indicate connection status to the user.

2.1.3 Monitor

The Monitor is an Apple® iPad® commercial tablet for use with the MOSkin System. To interact with the MOSkin devices, the user will use the installed MOSkin Monitor Software.

Refer to the Instructions for Use of the computer tablet for information regarding the Monitor hardware, operation, and troubleshooting.



Figure 5 Monitor

2.1.4 Monitor Software

The Monitor Software is a proprietary application that is installed on the Monitor. See Section 3.5 for instructions on installing the Monitor Software.

The Monitor Software allows the MOSkin System user to initialize, read and allocate RDs to body areas. The Monitor Software also creates reports of the dosage data recorded by the MOSkin System during patient treatment.

2.2 INDICATIONS FOR USE

The MOSkin radiation measurement system intended use is a dosimeter to measure radiation dose delivered by a radiation source to the location of an RD sensor (RD) on the patient in a clinical use environment. The system is intended for the verification of the output of radiation producing devices. The output of the system is not used to directly adjust the radiation dose to the patient.

Radiation Dosimeters are indicated as single use ONLY.

2.3 CONTRAINDICATIONS

Do not use on broken skin.

2.4 INTENDED USER PROFILE

The system is intended for use by trained physicians, radiation therapists, nurses or technicians.

2.5 ADVERSE EFFECTS

There are no known adverse effects.

2.6 WARRANTY AND DISCLAIMERS

Electrogenics Laboratories, Ltd warrants the MOSkin System against defects in materials and workmanship for three (3) years from the date of purchase from Electrogenics Laboratories, Ltd (ELL) or its subsidiaries. This warranty is given only to the original purchaser of the MOSkin System. ELL's obligation under the warranty is to provide for repair, or at its option, to provide a replacement product. No other remedy is obligated by this warranty. All special, incidental and coincidental damages are excluded.

To request repair or replacement under this warranty, Purchasers should contact their local Customer Service.

Warranty conditions may differ in some countries. Contact your local Customer Service for warranty terms.

Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product. Products shipped by the Purchaser under this warranty shall be suitably packaged to protect the Product. If Purchaser ships a product to ELL in unsuitable packaging, any physical damage present in the Product on receipt and inspection by ELL, and not previously reported, will be presumed to have occurred in transit and will be the responsibility of the Purchaser.

Exclusions

This warranty is limited to defects and materials that can be attributed to a fault or defect within the MOSkin System.

This warranty does not extend to any Warranted Products or parts thereof: (a) that have been subject to misuse, neglect or accident, (b) that have been damaged by causes external to the Warranted Product, (c) that have been used in violation of the Instructions for Use, (d) on which the serial number has been removed or made illegible, (e) that have been modified by anyone other than ELL or an authorized service center,

unless authorized prior to such service by ELL, (f) that are equipment sold as used, or (g) that are exposed to any agents other than that recommended in Section 7.1.

Disclaimer of Additional Warranties

No distributor, dealer or other party is authorized to make any warranty on behalf of ELL, or to assume for ELL any other liability with respect to the MOSkin System.

The contents of these Instructions for Use do not constitute a warranty.

FCC Interference Statement (Part 15.105 (b))

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

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the manufacturer for help.

2.7 TABLE OF SYMBOLS

Symbol	Meaning	Reference
	Manufacturer's catalogue designation or number	ISO 15223-1: 2021 Reference no. 5.1.6. (ISO 7000-2493)
	Dispose of this equipment according to local regulations for electrical and electronic waste disposal	BS EN 50419 Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE) WEEE Directive 2012/19/EU
	Consult instructions for use	ISO 15223-1:2021 Reference no. 5.4.3. (ISO 7000-1641)
	Serial number	ISO 15223-1: 2021 Reference no. 5.1.7. (ISO 7000-2498)
	Lot Number	ISO 15223-1: 2021 Reference no. 5.1.5. (ISO 7000-2492)
	Country of manufacture	ISO 15223- 1:2021 Reference no. 5.1.11. (IEC 60417-6049)
	Caution or warning	ISO 15223-1: 2021 Reference no. 5.4.4. (ISO 7000-0434A)
	Medical Device	ISO/DIS 15223-1:2021 Reference no. 5.7.7

Symbol	Meaning	Reference
	Manufactured By	ISO 15223-1: 2021 Reference no. 5.1.1. (ISO 7000-3082)
	Prescription Only. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician	21 CFR Part 801.109
	Keep away from sunlight	ISO 15223-1: 2021 Reference no. 5.3.2. (ISO 7000-0624)
	Protect from heat and radioactive sources	ISO 15223-1: 2021 Reference no. 5.3.3.
	Keep dry	ISO 15223-1: 2021 Reference no. 5.3.4. (ISO 7000-0626)
	Do not use if package is damaged and the device inside appears physically broken, cracked, or does not charge and initialize following the Instructions for Use	ISO 15223-1: 2021 Reference no. 5.2.8. (ISO 7000-2606)
	Storage temperature range	ISO 15223-1: 2021 Reference no. 5.3.7. (ISO 7000-0632)
	Date of manufacture	15223-1: 2021 Reference no. 5.1.3. (ISO 7000-2497)

Symbol	Meaning	Reference
QTY	Quantity enclosed	
	Fragile, handle with care	ISO 15223-1: 2021 Reference no. 5.3.1. (ISO 7000-0621)
	Do not re-use	ISO 15223-1:2021 Reference no. 5.4.2. (ISO 7000- 1051)
	Open here	ISO 7000_3079 Reference no. 3079
	Meets FCC requirements per 47 CFR Part 15	47 CFR Part 15
FCC ID: OH2XXXX	Federal Communication s Commission Identifier (F ID #)	47 CFR Part 2 & 15
	DC input voltage symbol	IEC 60417 #5031 Direct Current

3 GETTING STARTED

3.1 UNPACKING AND INSPECTION



CAUTION: Examine the MOSkin System for damage or sharp edges prior to each use. If any damage or sharp edges are found, please contact customer service or your Product Specialist. Do not attempt to use the device.

After the MOSkin System components are unpacked, verify that there are no signs of damage. If there are signs of damage, contact your Product Specialist or Customer Service.

3.2 STORING SYSTEM COMPONENTS

Each component of the MOSkin System is labeled with the appropriate storage and use conditions.

Please refer to the individual package and device labels for current information.

3.3 FIRST TIME HUB POWER UP

The HUB is shipped in a low-power sleep mode to ensure that the system is not powered on during shipping and that the battery is not discharged.

To bring the HUB out of sleep mode, do the following:

1. Open the charging port on the side of the HUB.
2. Press the small button next to the USB-C port for 1 second.
3. The HUB can now be powered up normally as per Section 3.6.

3.4 POWERING & CHARGING THE SYSTEM

The HUB and Monitor tablet must be charged to operate. This section describes the steps to power and charge the system and the corresponding LED indicators.

3.4.1 Charging the HUB

Follow the steps below to charge the HUB :

1. Connect the HUB power adaptor to the mains power outlet.
2. Connect the HUB charging cable (USB-A end) to the power adaptor
3. Connect the HUB charging cable (USB-C end) to the power inlet on the right-hand side of the HUB.
4. Leave the HUB connected to the power adaptor for at least six (6) hours to completely charge the battery. See Section 8.1 for LED indicator details.

When fully charged, the HUB battery provides for approximately eight (8) hours of operation.

See Section 8.1 for LED indicator details including charging indicators.

3.4.2 Charging the Monitor

The Monitor also needs to be charged if the battery icon in the top-right corner of the status bar is red ().

Follow the steps below to charge the Monitor:

1. Connect Monitor to a power outlet using the included cable and power adapter.
2. Leave the Monitor connected to the power adaptor for at least three (3) hours to completely charge the battery or the battery percentage in the top-right corner of the status bar shows 100%.

3.5 INSTALLING THE MONITOR APPLICATION

The Monitor application may be downloaded and installed on the iPad via a custom Apple App Store® link that will be provided by Electrogenics Labs to the owner of the system upon purchase of the system.

1. Using the email address provided to Electrogenics Labs during the purchase of the MOSkin System, open the custom Monitor App link provided by Electrogenics Labs. This will open the App Store on the iPad.
2. Install the app and follow any instructions on-screen to complete the install process.

The Monitor App is now installed and ready to be used.

3.6 STARTING THE SYSTEM

To power on the HUB and the Monitor, follow these steps.



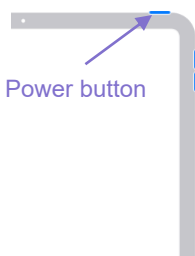
1. Press the Action Button in the lower right of the top face for two (2) seconds.

The HUB will then perform self-checks before being ready to use, this will take a few seconds.



If the HUB passes self-checks, and the battery is sufficiently charged the Action Button LED will start to flash white.

See Section 8.1 for more LED indicator details.



1. The Monitor can be turned on by pressing the Monitor's Power button.

From the home screen navigate to and open the MOSkin app.

If the Monitor fails to load refer to Troubleshooting (Section 8).



As the Application begins, a start-up screen is displayed. This screen shows the Global Trade Item Number (GTIN) of the product and the Version of the Monitor.

3.7 CREATING A USER ACCOUNT

The first user to create an account on the MOSkin System will become the system's **Super Administrator** by default. All following new users will have **Operator** privileges only unless created via the Admin User Manager (see Section 5.2). Also see Section 5.2.1 for details of different user types.

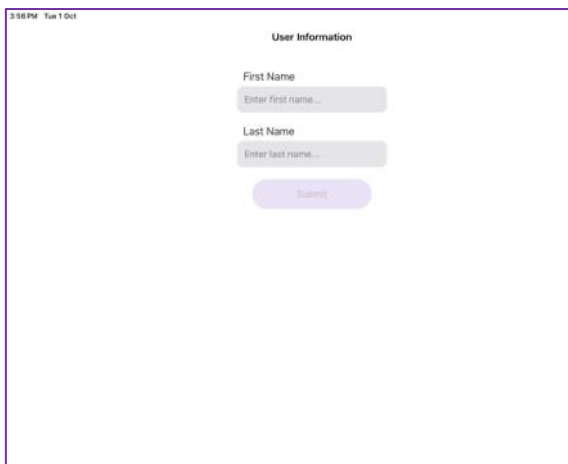
Follow these steps to create a new user account from the Sign In screen.



1. From the Welcome Screen, tap the **Create Account** button to be taken to the Sign Up Screen



2. Enter an email address that will become the account's username.
3. Enter and confirm a password as per the on-screen instructions.
4. Tap **Sign Up**



The screenshot shows a mobile application interface with a status bar at the top displaying '3:56 PM Tue 1 Oct'. The main content area is titled 'User Information' and contains two text input fields. The first field is labeled 'First Name' and has a placeholder text 'Enter first name...'. The second field is labeled 'Last Name' and has a placeholder text 'Enter last name...'. Below these fields is a blue button labeled 'Submit'.

5. Enter a first and last name and then tap **Submit**

Upon logging in, the Dashboard will be displayed.

3.8 SIGNING IN AND OUT

3.8.1.1 Signing In

If you have sign in credentials, follow these steps to Sign In to the MOSkin Monitor.

If you do not have login credentials, see Adding A New User in Section 5.2.3 for more information.

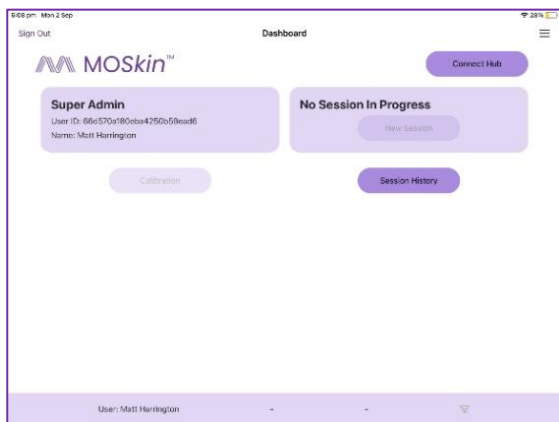


Once the MOSkin app is loaded, the Welcome Screen will be displayed.

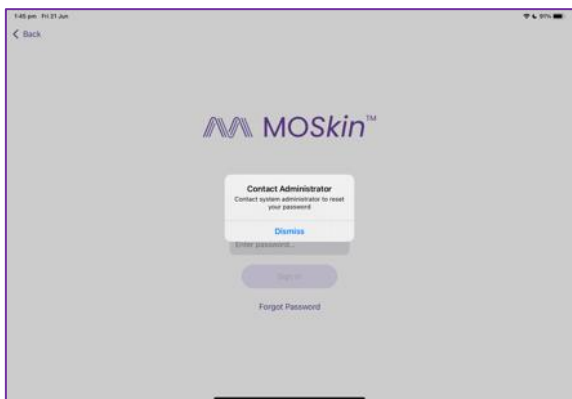
1. Tap on the **Sign In** button.



2. Enter your email and password into the Login Screen and tap **Sign In**.



If your credentials are accepted, you will be taken to the Dashboard.



If unsuccessful, you will be given another opportunity to enter the correct credentials.

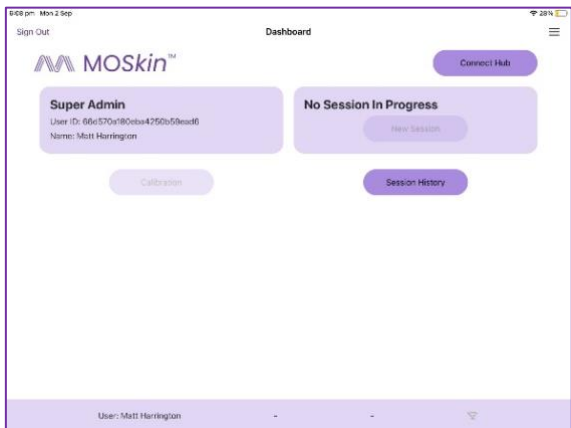
After five (5) unsuccessful attempts, the Monitor Application will lock-out.

Please refer to Troubleshooting (Section 8.8) for further information.

If you have forgotten your password, contact your MOSkin administrator.

3.8.1.2 *Signing Out*

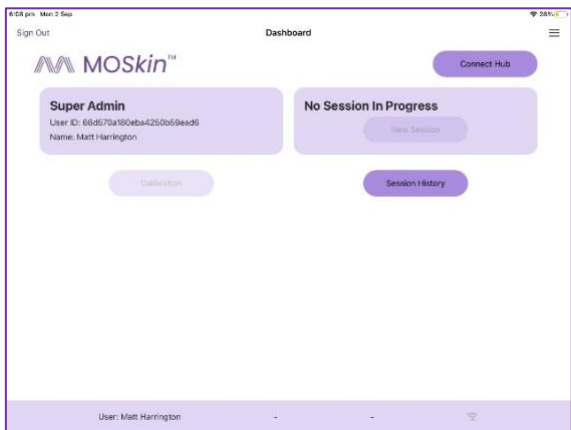
To Sign out, follow this step.



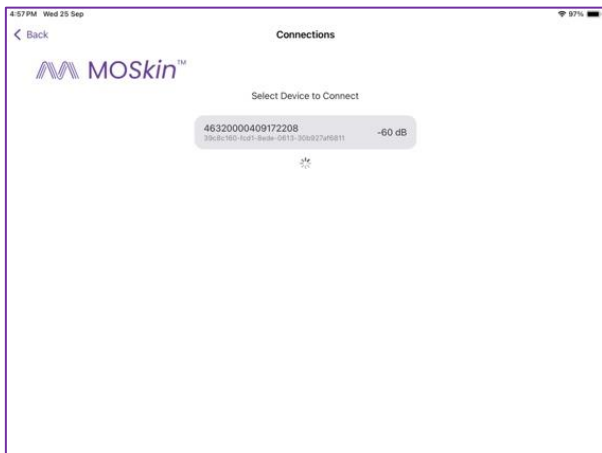
1. Tap **Sign Out** in the top-right corner of the Dashboard screen.

3.9 CONNECTING & DISCONNECTING A HUB

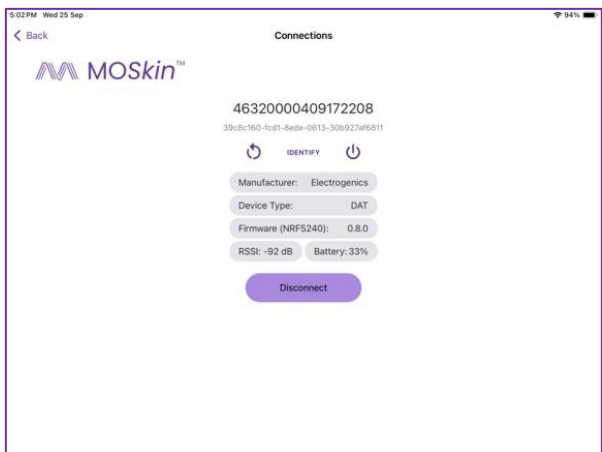
To connect the Monitor to the HUB, follow the following steps.



1. From the Dashboard Screen, tap on the **Connect Hub** button on the top right of the screen.



2. To connect, select the HUB you will be using from the list. The displayed name may found on the label on the underside of the HUB.

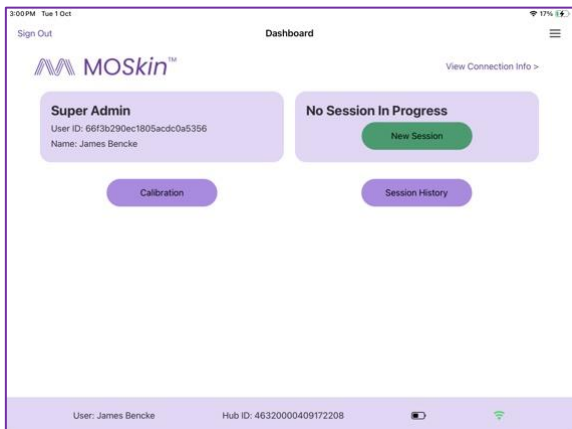


Connected hub information is displayed.

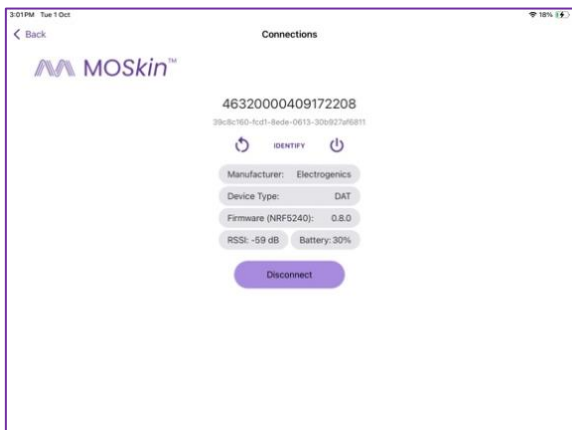
3. Tap on the **Back** button at the top-left of the screen to return to the Dashboard Screen.

If the desired HUB is not displayed, ensure it is powered on by checking that the LED indicator, see Section 8.1 for details.

To disconnect the Monitor from the HUB, follow these steps.



1. From the Dashboard, tap on the **View Connection Info** tab on the bottom of the screen to access the Connections Screen.



2. Tap **Disconnect** to disconnect the currently connected HUB.

3. Tap on the **Back** button to return to the Dashboard.

3.10 SHUTTING DOWN THE HUB

To shutdown the HUB and the Monitor, follow this steps.



1. Press the Action Button in the lower right of the top face of the HUB for five (5) seconds.

The slot LED indicators will illuminate White, indicating powering off in progress.

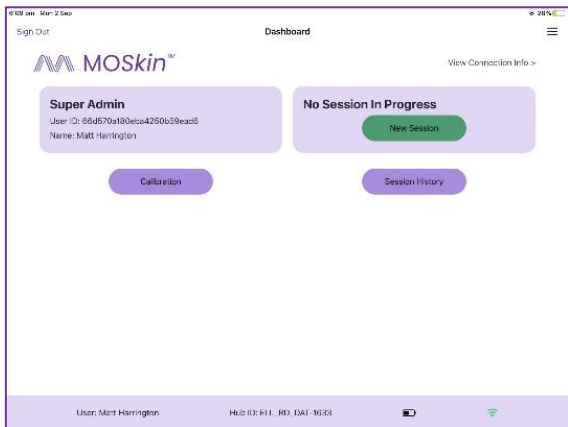
4 OPERATING INSTRUCTIONS

4.1 RUNNING A MOSKIN SESSION

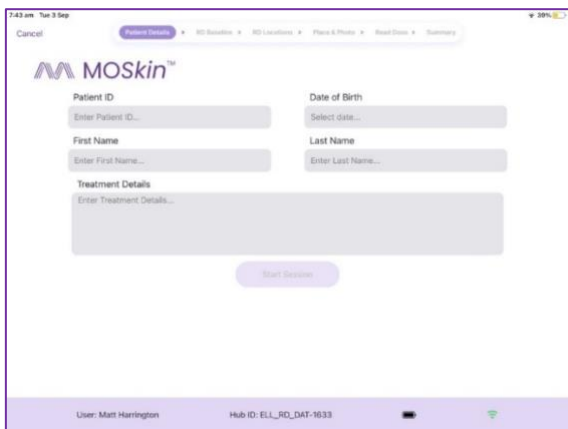
 Start MOSkin Session	Connecting a HUB. Create Patient session. Unpack & Baseline RDs. Assign RD locations.
 MOSkin Patient Treatment	Attach RDs & photograph locations. Treat patient per the prescribed Treatment Plan. Remove & clean RDs.
 Read MOSkin Dose	Read RD dose measurement results. Review results.
 Session Summary	Review & finalise session information. Generate and email report.

4.1.1 Start New Session

Before starting, ensure the Monitor is connected to the HUB intended to be used, as per Section 3.9.



1. From the Dashboard Screen, tap on the **New Session** button on right side of screen.



2. Input mandatory patient information (numeric ID, first and last names & date of birth).

3. Input optional treatment details as required (eg. according to user/clinic practices).

4. Tap the **Start Session** button to proceed.

4.1.2 Performing RD Baseline



RD.

WARNING: Folding or creasing the RD during use or cleaning may damage the

2:45 PM Thu 26 Sep

Pause Session

Patient Details • **RD Baseline** • RD Locations • Place & Photo • Read Done • Summary

MOSkin™

Patient ID: 123456789
Name: John Doe
DOB: 21 Apr 2024

Slot Number	RD ID	Connection Status	Baseline Status
1	-	☐	-
2	-	☐	-
3	-	☐	-
4	-	☐	-

Enter Operator Notes...

Baseline Read Proceed

User: James Bencke Hub ID: 46320000409172208

After the **Start Session** button is pressed (above), the Session Screen will be displayed.



1. Remove the required number of RDs from their packaging.



2. On the HUB, press down on the back of the slot to open it.

NOTE: Take care that the RD and HUB contacts are free of debris that may affect connection.

3. Insert required RDs into the HUB ensuring RD and HUB contacts are aligned.

As each RD is loaded, monitor the LED indicator.

The slot LED indicator will illuminate **GREEN** to indicate successful connection.

4. A **YELLOW** LED indicated incomplete connection, refer to Troubleshooting (Section 8.8) for further information.

2:46PM Thu 26 Sep 42%

Pause Session Patient Details RD Baseline RD Locations Place & Photo Read Dose Summary



Patient ID: 123456789
 Name: John Doe
 DOB: 21 Apr 2024

Slot Number	RD ID	Connection Status	Baseline Status
1	313430303432343231	■	—
2	—		—
3	—		—
4	—		—

Enter Operator Notes...

Baseline Read
Proceed

User: James Bencke
Hub ID: 46320000409172208

Each correctly placed and functional RD will appear marked with a **GREEN** square in the **Connection Status** column of the Monitor.

2:48PM Thu 26 Sep 40%

Pause Session Patient Details RD Baseline RD Locations Place & Photo Read Dose Summary



Patient ID: 123456789
 Name: John Doe
 DOB: 21 Apr 2024

Slot Number	RD ID	Connection Status	Baseline Status
1	313430303432343231	■	
2	333030303432343231	■	☼
3	—		—
4	—		—

Enter Operator Notes...

Baseline Read
Proceed

User: James Bencke
Hub ID: 46320000409172208

5. Tap the **Baseline Read** button to initialize the RDs.

RDs that have been read will appear with a **GREEN** check mark in the **Baseline Status** column.

2:50 PM Thu 26 Sep 39%

Pause Session Patient Details RD Baseline RD Locations Place & Photo Read Done Summary

MOSkin™ Patient ID: 123456789
Name: John Doe
DOB: 21 Apr 2024

Slot Number	RD ID	Connection Status	Baseline Status
1	313430303432343231	☒	☒
2	333030303432343231	☒	☒
3	-	☐	-
4	-	☐	-

Enter Operator Notes...

Baseline Read Proceed

User: James Bencke Hub ID: 46320000409172208

Once all RDs have been Baselined the Proceed button will illuminate.

6. Tap **Proceed** button to move to the next step.

4.1.3 Setting RD Locations



WARNING: RDs are indicated for use on unbroken skin.

It is advisable to check the condition of the patient's skin in the desired locations before detailing them in the Monitor workflow to ensure they are suitable.

If desired location is not suitable for RD attachment, consider different locations in consultation with suitable clinical team members.

Note: Location information can be amended at the end of the MOSkin session if needed.

2:56 PM Thu 26 Sep

Pause Session

Patient Details • RD Baseline • **RD Locations** • Place & Photo • Read Dose • Summary

MOSkin™

Patient ID: 123456789
Name: John Doe
DOB: 21 Apr 2024

☒ SLOT 1
ID: 313430303432343231
Location Description:*
Enter value...
Expected Dose (cGy):
Enter value (option...)

☒ SLOT 2
ID: 333030303432343231
Location Description:*
Enter value...
Expected Dose (cGy):
Enter value (option...)

☐ SLOT 3

☐ SLOT 4

Proceed

User: James Bencke Hub ID: 46320000409172208

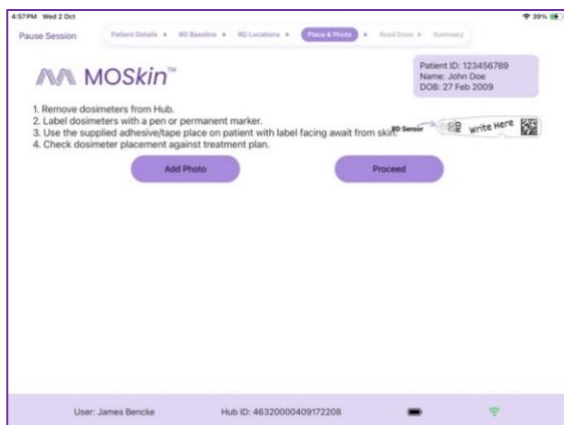
1. Fill out the Location details. Location Description is mandatory. **Expected Dose** is optional.

2. Press **Proceed** once information has been entered.

4.1.4 Placing and Photographing RDs on Patient

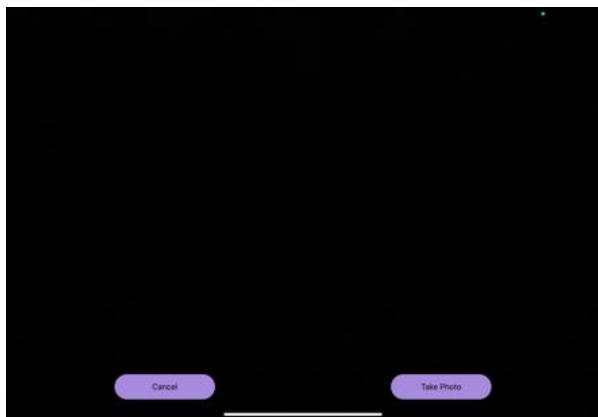


1. Remove the RD(s) from the HUB and label them using a permanent marker, if required.
2. Remove the remaining backing and using standard/localised clinical procedures, adhere the RDs onto the patient.



3. In the Monitor, tap **Add Photo** to begin photographing the RD placements, if desired.

Note: The MOSkin Application must have permission to access the tablet's Camera. A prompt will be displayed if permission is needed.



3. Tap the **Take Photo** button to document the RD locations.

Note: Photos are optional. If no photos are taken, an alternative text input field will be displayed for free text input.

The RDs are now baselined and placed on patient, and the prescribed radiation treatment may commence.

Observe clinical procedures for personnel and equipment radiation safety during radiation.

4.1.5 Removing the RDs from the Patient

Once the prescribed radiation treatment is complete, the RDs need to be removed from the patient, cleaned and then read by the MOSkin System to determine the accumulated dose.

Remove the RDs from the patient, and refer to “

Cleaning the RD After Patient Use” in Section 0 for more details of how to perform cleaning.

4.1.6 Reading the Delivered Dose



1. Insert RDs into the HUB as per before (see baseline step).

Note: The RDs do not need to be placed in the same reader slot as when they were Baselined.

5:12 PM Wed 2 Oct

43%

Pause Session

Patient Details

RD Baseline

RD Locations

Place & Photo

Read Dose

Summary

MOSkin™

Patient ID: 123456789
Name: John Doe
DOB: 27 Feb 2009

Slot Number	RD ID	Location	Expected Dose (cGy)	Connection Status	Read Status
1	-	-	Not Provided	☐	-
2	-	-	Not Provided	☐	-
3	-	-	Not Provided	☐	-
4	333030303432343231	hghg	Not Provided	☒	-

Take Dose Reading

Proceed

User: James Bencke

Hub ID: 46320000409172208

Each correctly placed and functional RD will appear marked with a **GREEN** square in the **Connection Status** column.

2. Tap the **Take Dose Reading** button to read the RDs.

5:14 PM Wed 2 Oct 43%

Pause Session Patient Details RD Baseline RD Locations Place & Photo **Read Dose** Summary

MOSkin™ Patient ID: 123456789
Name: John Doe
DOB: 27 Feb 2009

Slot Number	RD ID	Location	Expected Dose (cGy)	Connection Status	Read Status
1	-	-	Not Provided	☐	-
2	-	-	Not Provided	☐	-
3	-	-	Not Provided	☐	-
4	333030303432343231	hghg	Not Provided	☒	☒

Take Dose Reading Proceed

User: James Bencke Hub ID: 46320000409172208

Once all RDs have been read, the Proceed button will illuminate.

3. Tap **Proceed** button to move to the next step.

4.1.7 Session Summary

5:18 PM Wed 2 Oct 44%

< Back Patient Details RD Baseline RD Locations Place & Photo Read Dose **Summary**

MOSkin™ Patient ID: 123456789
Name: John Doe
DOB: 27 Feb 2009

Location	RD ID	Expected Dose (cGy)	Measured Dose (cGy)	Difference (%)
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-
knee	333030303432343231	20.000	0.000	-100.0

Photos Comment: jvjvh

Enter Operator Notes...

Amend Locations Email Report Finish Session

User: James Bencke Hub ID: 46320000409172208

The session summary is displayed showing Measured Dose and difference to Expected Dose.

4.1.8 Amending Location Details

Location details can be amended from the session Summary. To perform location amendments, follow these steps.

5:18 PM Wed 2 Oct 44%

Back Patient Details RD Baseline RD Locations Place & Photo Read Dose Summary

MOSkin™ Patient ID: 123456789
Name: John Doe
DOB: 27 Feb 2009

Location	RD ID	Expected Dose (cGy)	Measured Dose (cGy)	Difference (%)
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-
knee	333030303432343231	20.000	0.000	-100.0

Photos Comment: jvjvh

Enter Operator Notes...

Amend Locations Email Report Finish Session

User: James Bencke Hub ID: 46320000409172208

1. Tap **Amend Locations**, on the Summary screen.

5:24 PM Wed 2 Oct 45%

Cancel Patient Details RD Baseline RD Locations Place & Photo Read Dose Summary

MOSkin™ Patient ID: 123456789
Name: John Doe
DOB: 27 Feb 2009

SLOT 1

SLOT 2

SLOT 3

SLOT 4
ID:
333030303432343231
Location Description:*
knee
Expected Dose (cGy):
20

Do not remove RDs until locations have been saved.

Amend

User: James Bencke Hub ID: 46320000409172208

2. Make modifications to the Location Description and Expected Dose as needed.

3. Tab **Amend** to complete location amendments and return to session Summary.

4.1.9 Sharing Session Reports

Sharing session reports is achieved by emailing a Portable Document Format (PDF) file of the session report to desired recipient email address.

Note: The Monitor must be configured as per Section 8.7 in order to send the email and export the report.

To email a session report from the session Summary screen, follow these steps.

The screenshot shows the MOSkin Summary screen. At the top, there's a navigation bar with 'Back', 'Patient Details', 'RD Baseline', 'RD Locations', 'Place & Photo', 'Read Dose', and 'Summary'. The MOSkin logo is on the left. Patient details on the right include Patient ID: 123456789, Name: John Doe, and DOB: 27 Feb 2009. Below this is a table with columns: Location, RD ID, Expected Dose (cGy), Measured Dose (cGy), and Difference (%). The table has one row with data: knee, 333030303432343231, 20.000, 0.000, and -100.0. Below the table are fields for 'Photos Comment: jvjvh' and 'Enter Operator Notes...'. At the bottom are three buttons: 'Amend Locations', 'Email Report', and 'Finish Session'. The footer shows 'User: James Bencke' and 'Hub ID: 46320000409172208'.

Location	RD ID	Expected Dose (cGy)	Measured Dose (cGy)	Difference (%)
knee	333030303432343231	20.000	0.000	-100.0

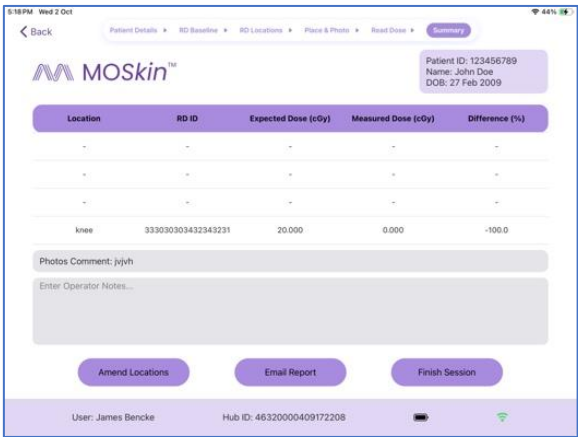
1. Tap **Email Report**, on the Summary screen.

The screenshot shows an email composition screen. The subject line is 'MOSkin Session Report for John Doe (123456789) - 2/10/2024, 10:53:08 AM'. The 'To' field is filled with a redacted email address. The 'Cc/Bcc, From' field shows 'imicslabs.com'. The subject line is repeated. The body of the email starts with 'Hello,' followed by 'Please find session report for John Doe (123456789) on 2/10/2024, 10:53:08 AM.' and 'From: James Bencke (jamesbencke@gmail.com)'. There is a PDF attachment icon labeled 'MOSkin - J... 2/10/2024 10:53:08 AM' with a size of '335 KB'. The footer shows 'User: James Bencke' and 'Hub ID: 46320000409172208'.

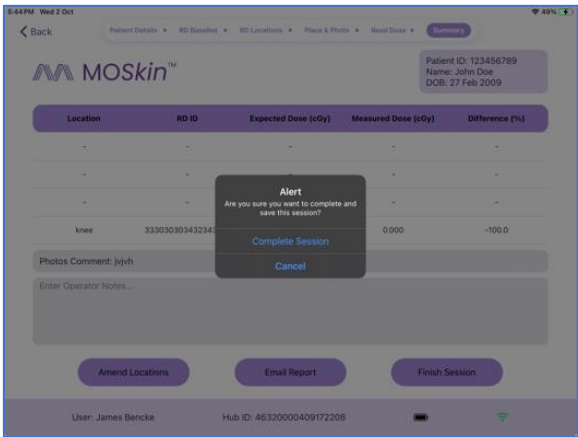
2. Enter recipient email address in the **To:** field. Default is the user's email address. Multiple recipients are accepted.

3. Tap the Send () button to send.

4.1.10 Finishing Up Session



1. Tap **Finish Session**, on the Summary screen.



2. Tap Complete Session to confirm that the session is to be closed and stored.

3. The MOSkin session has now been completed.

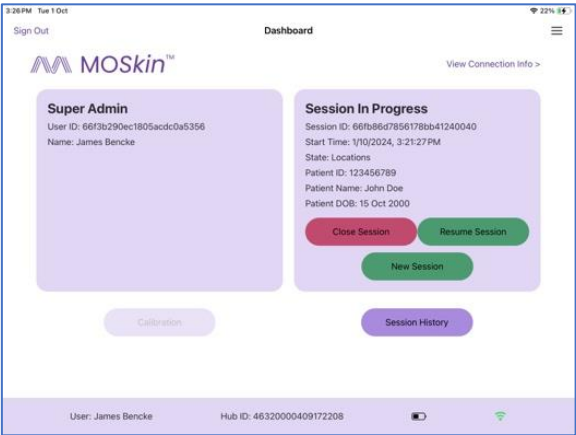
4.2 PAUSING AND RESUMING SESSIONS

At any stage throughout the MOSkin Session, the session can be paused. Paused sessions are stored on the Monitor and may be resumed to be completed or closed to be cancelled.

4.2.1 Pausing a Session



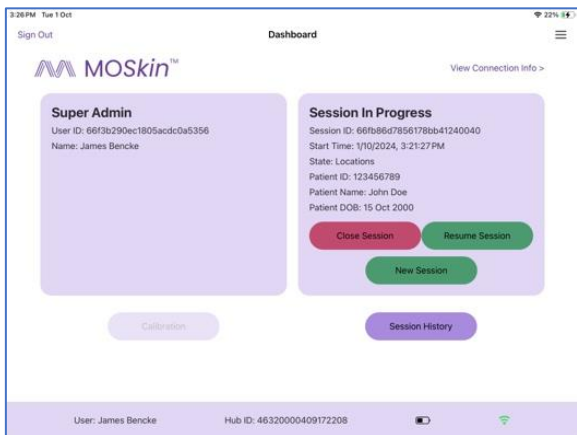
1. Press Pause Session in the top-left of the screen.



Returning to the Dashboard, the most recently paused session will appear in the Session In Progress section.

4.2.2 Resuming Last Session from Dashboard

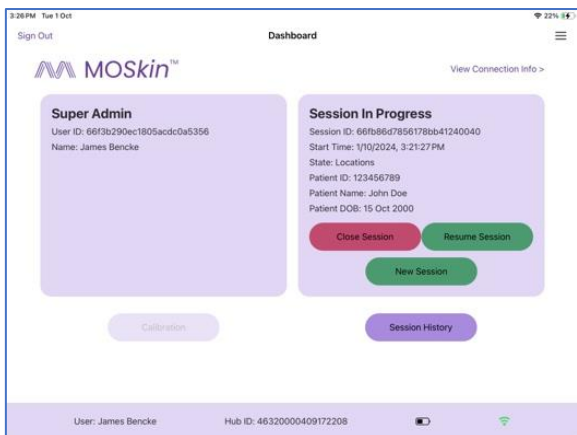
4.2.2.1 Resuming the Last Session



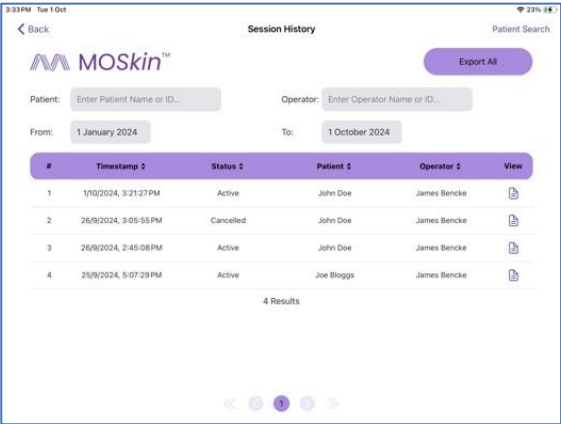
1. From the Dashboard, tap Resume Session from the Session In Progress section.

This will resume back to where the session was paused.

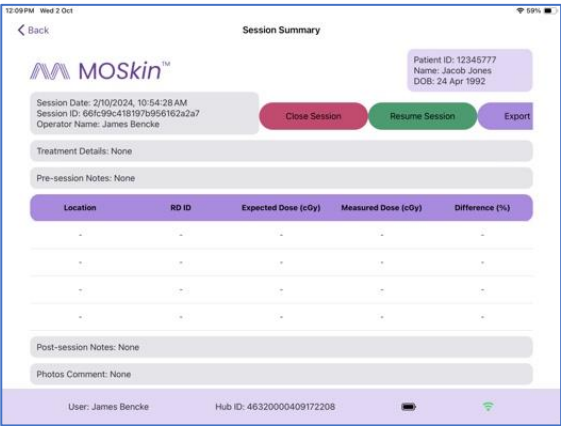
4.2.2.2 Resuming any Paused Session



1. From the Dashboard, tap Session History.



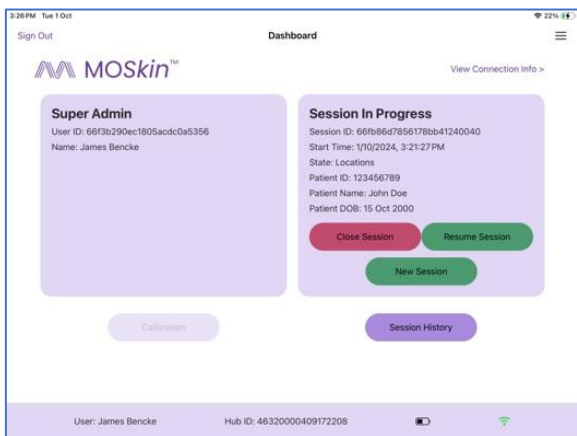
2. Select the Active session that is to be resumed from the list.



3. Tap Resume Session.

4.2.3 Closing a Session

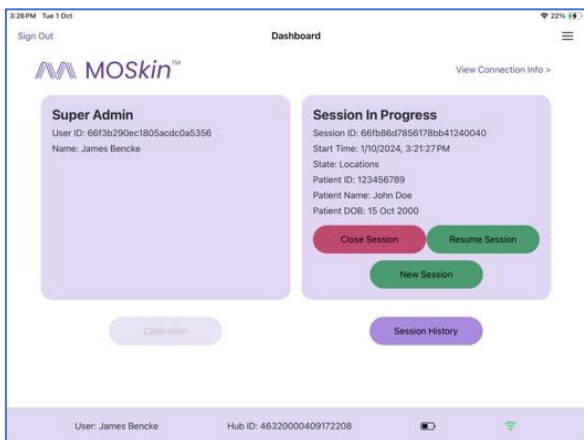
4.2.3.1 Closing the Last Session



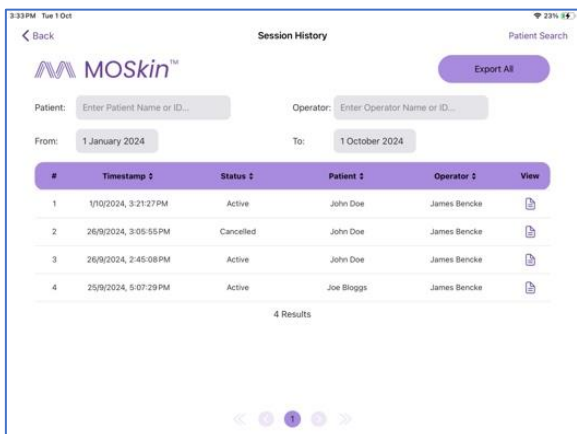
From the Dashboard, tap **Close Session** from the Session In Progress section.

This will cancel the most recently paused session.

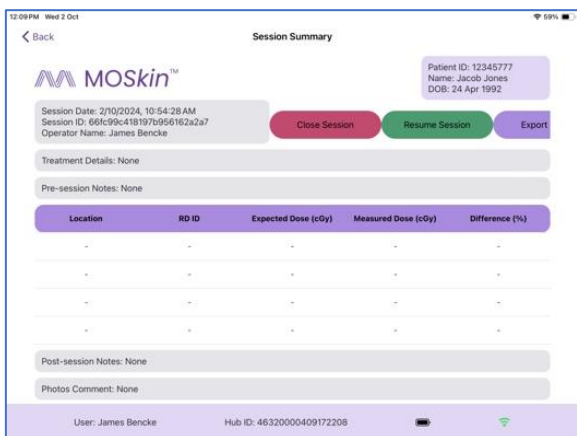
4.2.3.2 Closing any Paused Session



From the Dashboard, tap Session History.



1. Select the Active session that is to be closed and cancelled from the list.



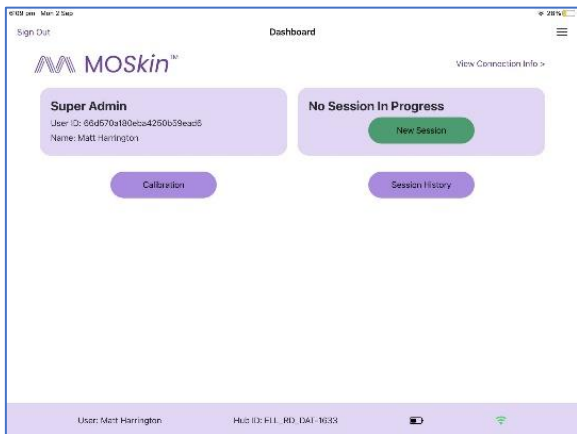
2. Tap **Close Session**.

3. This will cancel the selected session.

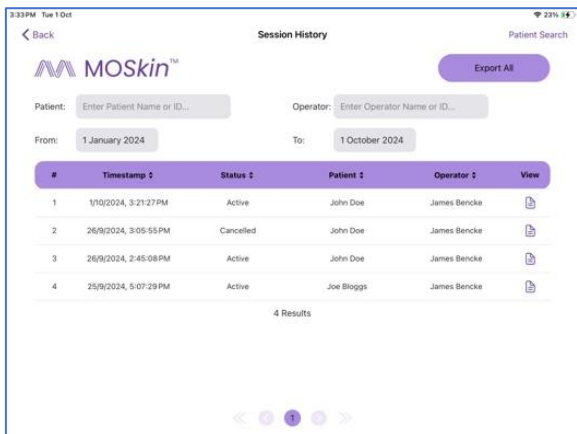
4.3 EXPORTING HISTORICAL SESSIONS

4.3.1 Export Individual Sessions

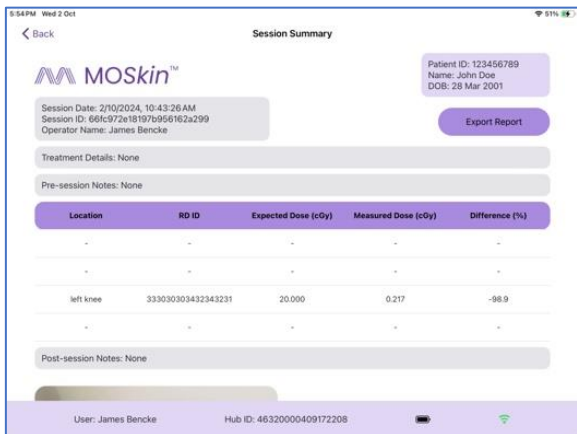
All prior sessions stored on the Monitor may be viewed and exported at any time. Follow these steps to export prior sessions.



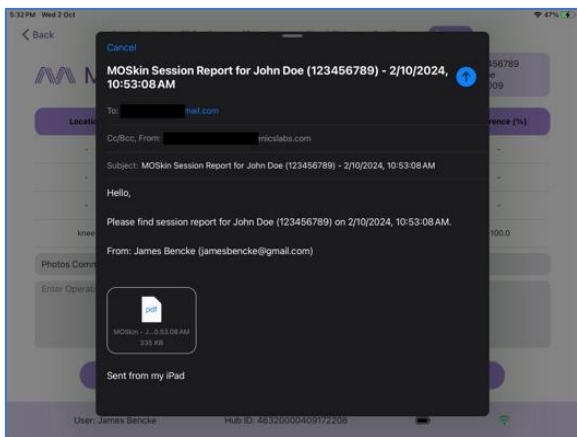
1. From the Dashboard Screen, tap on the green **Session History** button on right side of screen.



2. Search and select the desired session by clicking the document icon in the View column.



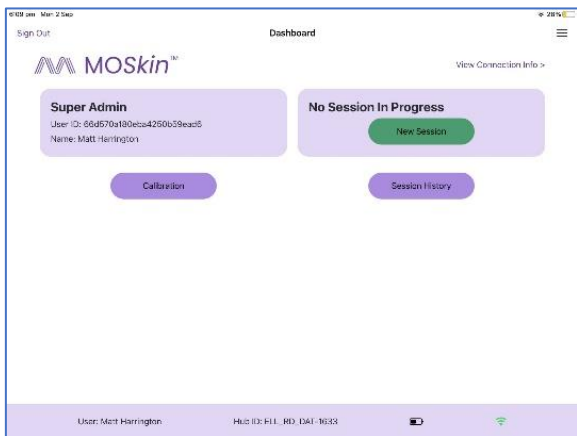
3. On the session Summary of the desired session, tap **Export Report**.



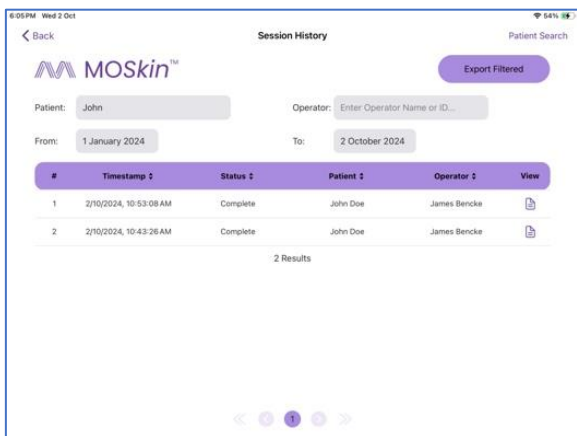
4. Enter recipient email address in the **To:** field. Default is the user's email address. Multiple recipients are accepted.

5. Tap the Send () button to send.

4.3.2 Export Multiple Sessions



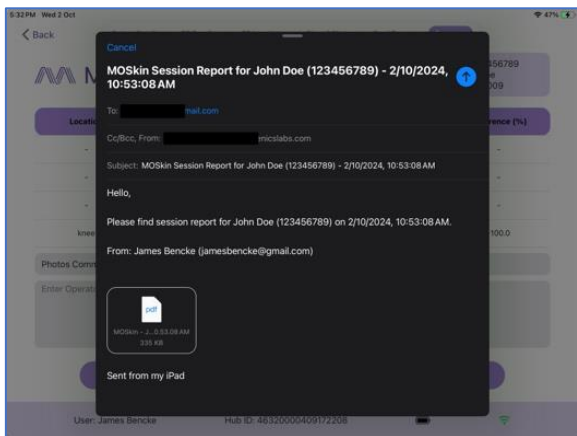
1. From the Dashboard Screen, tap on the **Session History** button on right side of screen.



Search for the desired sessions by using the filtering criteria at the top of the table.

2. On the session Summary of the historical session, tap **Export Filtered**.

Note: All reports can be exported by not filtering and tapping **Export All**.



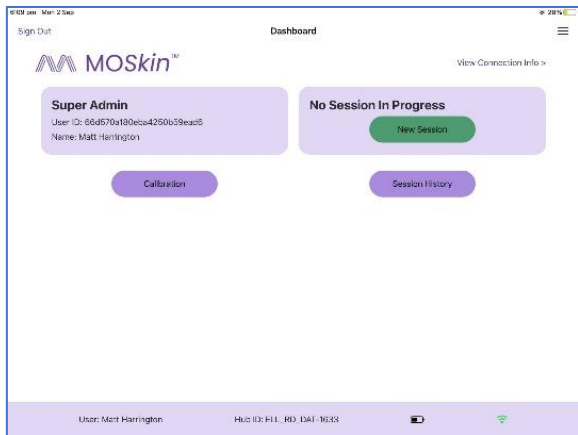
3. Enter recipient email address in the *To:* field. Default is the user's email address. Multiple recipients are accepted.

4. Tap the Send () button to send.

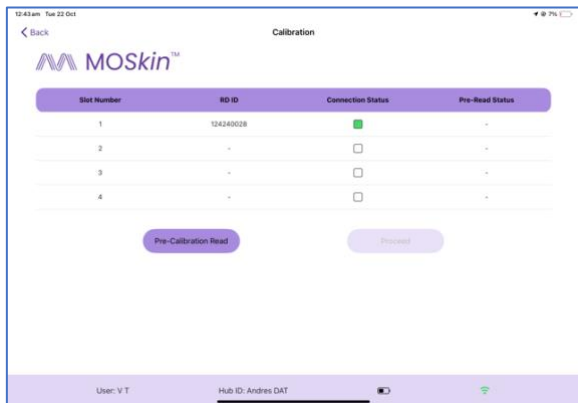
5 ADMINISTRATION OF THE MOSKIN SYSTEM

MOSkin Administrators have additional privileges and functionality which is detailed below.

5.1 MOSKIN SENSITIVITY CALIBRATION (ADMIN & TECHNICIAN)



1. From the Dashboard Screen, tap on the **Calibration** button.



Insert the RDs to be calibrated.

2. Once RDs are connected, tap **Pre-Calibration Read** to commence the calibration process.

Once all RDs have been read, the Proceed button will illuminate.

3. Tap **Proceed** to move to the next step.

The screenshot shows the MOSkin Calibration interface. At the top, it says "12:43 am Tue 22 Oct" and "Cancel Calibration". The title is "Calibration". Below the MOSkin logo, there is a field for "Calibration Dose (cGy) *" with the value "40". Below that is a section for "Additional Information" with a text area labeled "Enter notes...". A purple "Proceed" button is at the bottom. The footer shows "User: V T" and "Hub ID: Andres DAT".

4. Fill in Calibration Dose details and tap **Submit** at the bottom.

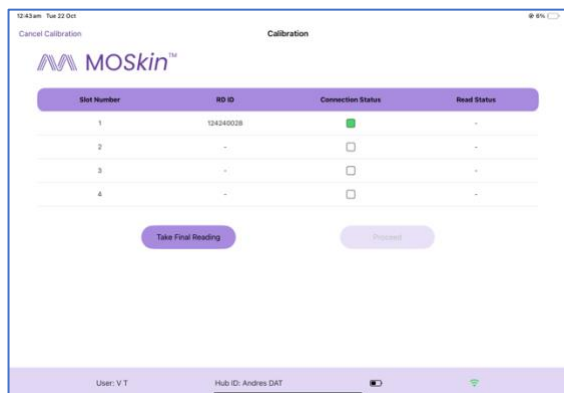
a. Calibration Dose (cGy) is mandatory.

b. Additional Information is an optional field.

The screenshot shows the MOSkin Calibration interface. At the top, it says "8:49 PM Wed 2 Oct" and "Cancel Calibration". The title is "Calibration". Below the MOSkin logo, there is a text instruction: "Place RDs in LINAC and Expose to Radiation". A purple "Proceed" button is at the bottom. The footer shows "User: James Bencke" and "Hub ID: 46320000409172208".

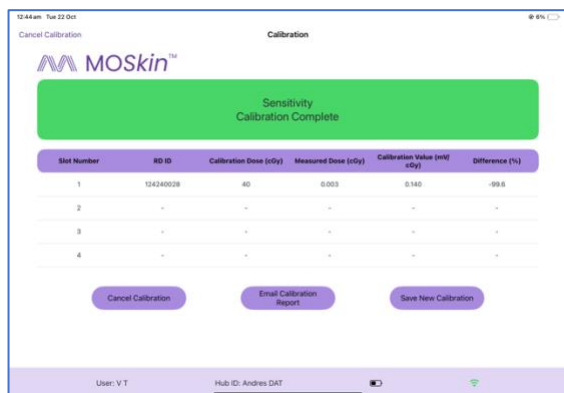
5. Remove RDs from HUB and place into LINAC (or reference dosing equipment) and expose to reference dose of radiation.

6. Once reference dose has been complete, tap **Proceed**.



7. Tap **Take Final Reading**, to read the RDs.

8. Once reading is complete, tap **Proceed**.



The Calibration process has completed BUT is not yet saved. The process can still be cancelled at this step.

To save and record the new calibration, do the following:

9. Tap **Email Calibration Report**, to export a detailed calibration report.

10. Tap **Save New Calibration**, to finalise the Calibration.

NOTE: Calibration reports are not saved on the Monitor, traceability is achieved via report export.

Sensitivity calibration for the connected RDs is now complete and required data has been written to the RDs.

CAUTION: Any RD that has been calibrated by a MOSkin System user will be permanently modified from the factory calibration.

5.2 USER MANAGER (ADMIN ONLY)

5.2.1 User Types

The table below identifies the various MOSkin Monitor Software operation permissions for each user type. There are four (4) user types of the MOSkin system, each with varying levels of features.

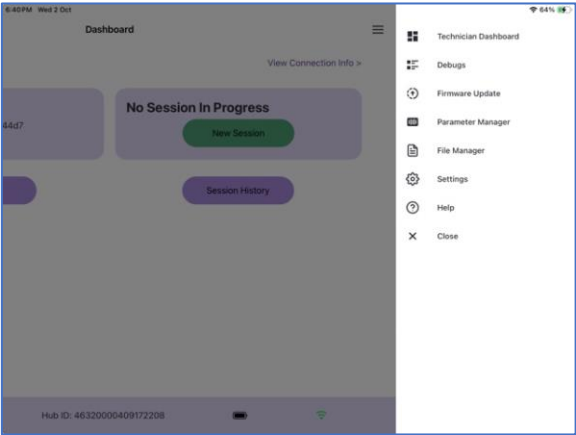
NOTE: There is only one Super Administrator on a MOSkin System, and this is designated as the first user to register in the system. This cannot be changed.

Function	Super Administrator	Technician	Administrator (e.g. Radiation Oncologist)	Operator (e.g. Radiation Therapist)
Ability to control DAT via debug terminal	Yes	Yes	No	No
Access to view debug terminal	Yes	Yes	No	No
Ability to perform an Over-The-Air software update of the DAT	Yes	Yes	No	No

Ability to view/modify DAT parameters	Yes	Yes	No	No
Ability to view RD parameters	Yes	Yes	No	No
Ability to retrieve/view DAT logged data (redundancy)	Yes	Yes	No	No
Access to User Management facilities	Yes	No	Yes	No
Ability to create new Users	Yes	No	Yes	No
Ability to delete/modify existing users	Yes	No	Yes	No
Ability to perform sensitivity calibration	Yes	Yes	Yes	No
Ability to run a MOSkin Session	Yes	Yes	Yes	Yes
Ability to view Session History Database	Yes	Yes	Yes	Yes
Ability to export Session	Yes	Yes	Yes	Yes

History database entries				
Ability to view and export Verbose Event Data from Session History	Yes	Yes	No	No
Ability to export and backup the full set of device data	Yes	Yes	No	No

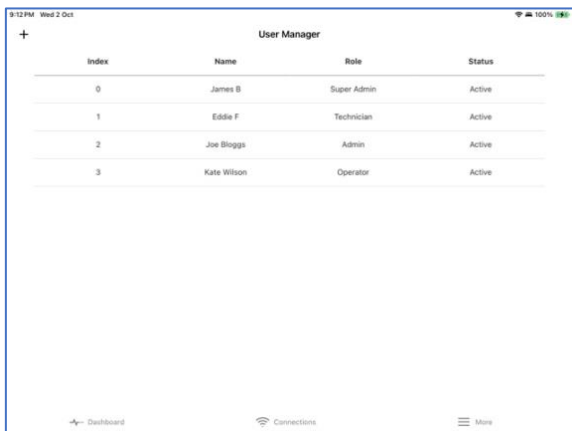
5.2.2 Accessing User Manager



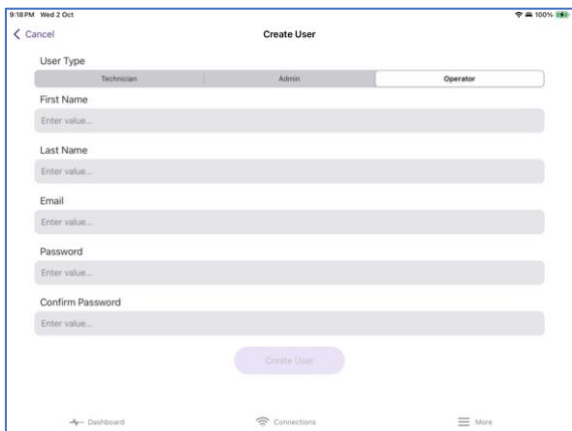
1. From Dashboard screen, click hamburger icon (≡) in top right corner and select *User Manager* from revealed menu.

All user of the MOSkin System are listed.

5.2.3 Adding a New User



2. On the User Manager screen, tap the + symbol in the top-left of the screen.



3. Select **User Type** at the top.

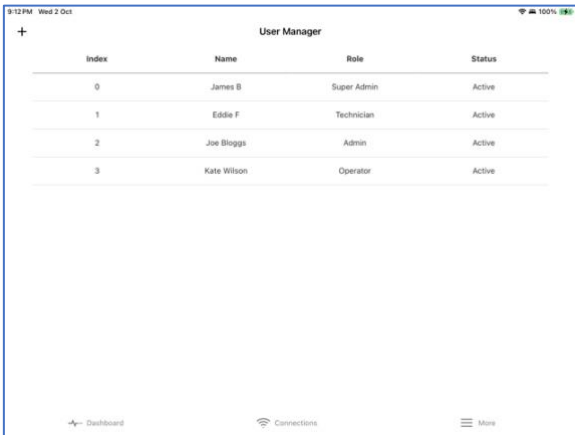
See Section 5.2.1 above, for details of user types.

4. Enter new user details and tap **Create User**.

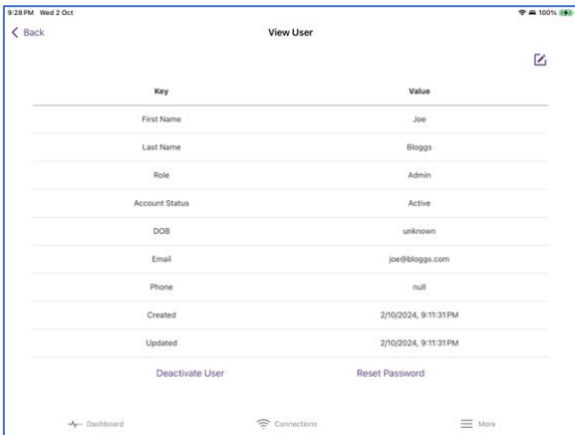
The new user will be created and will be listed in the User Manager.

5. Tap **Dashboard** at the bottom of the screen to return to the Dashboard Screen.

5.2.4 Viewing and Modifying Existing Users



1. On the User Manager screen, tap the row of the user to be viewed and/or modified.



The selected user’s details are listed.

2. To modify the user’s details, tap the edit icon () in the top-right of the screen.

9:34 PM Wed 2 Oct 100%

< Cancel Edit User

User Type

Technician Admin Operator

First Name

Joe

Last Name

Bloggs

Email

joe@bloggs.com

Save

Dashboard Connections More

3. Modify user details as needed and then tap **Save** to make changes.

Once complete, list of users will be presented on screen again.

4. Tap ***Dashboard*** at the bottom of the screen to return to the Dashboard Screen.

5.2.5 Deactivating and Reactivating Users

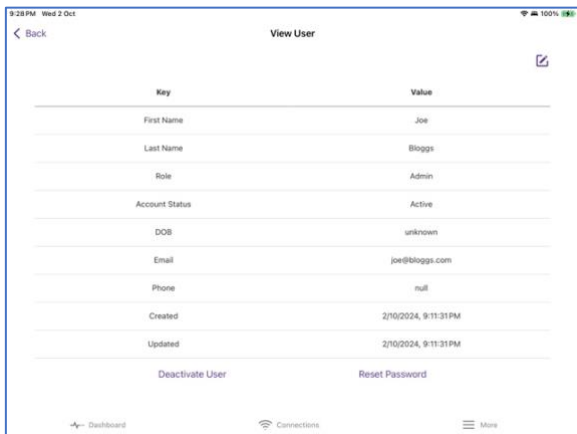
9:12 PM Wed 2 Oct 100%

+ User Manager

Index	Name	Role	Status
0	James B	Super Admin	Active
1	Eddie F	Technician	Active
2	Joe Bloggs	Admin	Active
3	Kate Wilson	Operator	Active

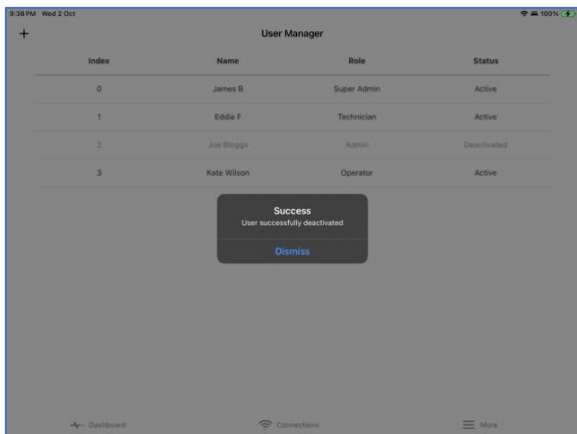
Dashboard Connections More

1. On the User Manager screen, tap the row of the user to be deactivated or reactivated.



The selected user's details are listed.

2. Tap Deactivate User or Reactivate User.

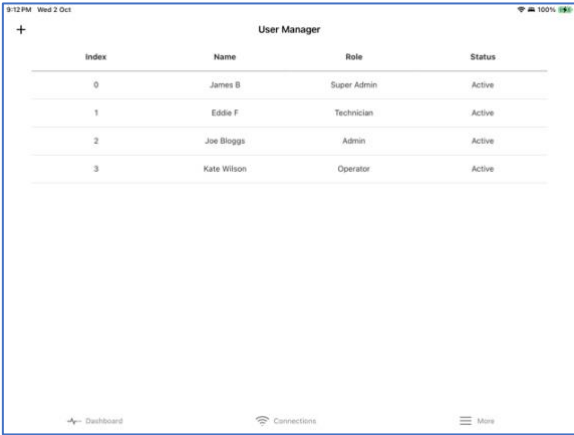


The user has now been deactivated or reactivated.

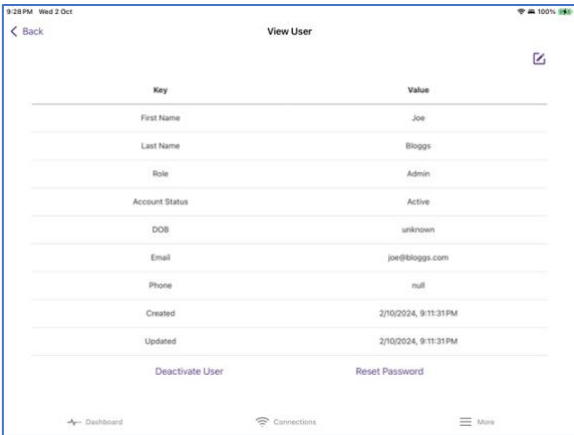
Deactivated users will no longer be able to use the MOSkin System.

3. Tap ***Dashboard*** at the bottom of the screen to return to the Dashboard Screen.

5.2.6 Resetting a User Password

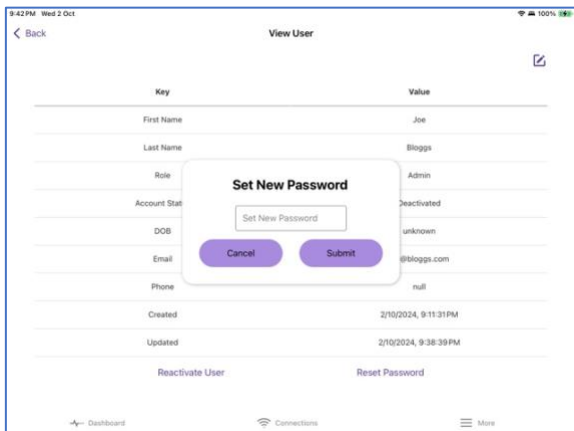


1. On the User Manager screen, tap the row of the user to be have their password reset.



The selected user’s details are listed.

2. Tap Reset Password.



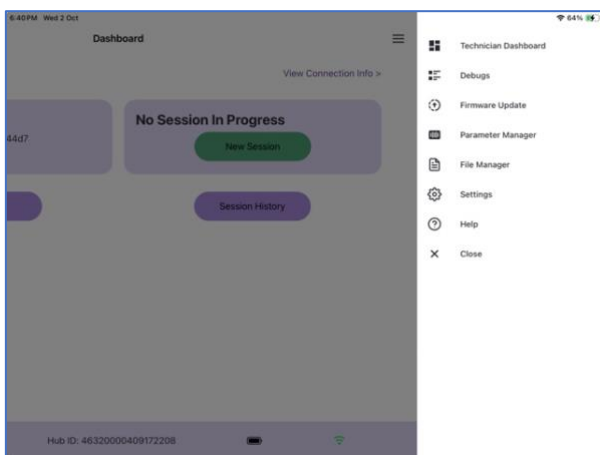
3. Enter a new password and tap **Submit**.

4. The new password will then need to be confirmed by re-entering. Tap **Submit** and confirm password reset.

The user's password has now been reset to the new password entered.

5. Tap **Dashboard** at the bottom of the screen to return to the Dashboard Screen.

5.3 TECHNICIAN DASHBOARD (TECHNICIAN ONLY)



1. Connect the HUB that is to be updated to the Monitor.

2. From Dashboard screen, click hamburger icon () in top right corner and select **Technician Dashboard** from revealed menu.



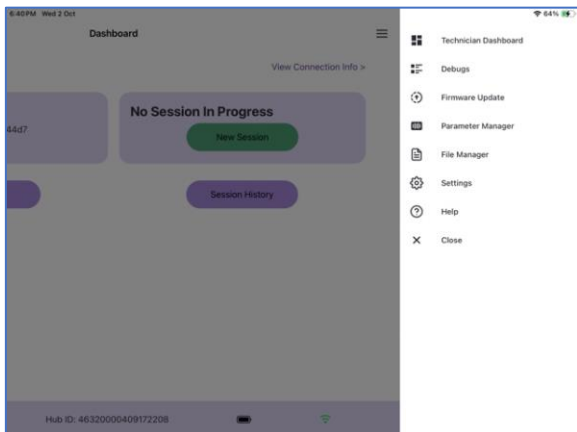
On this Dashboard, RD Baseline, Dose Reading and MOSFET Current setting can be performed by a technician.

Dosimeter Voltage (uV) and Current (uA) can be inspected along with calculated Dose Measurement (cGy).

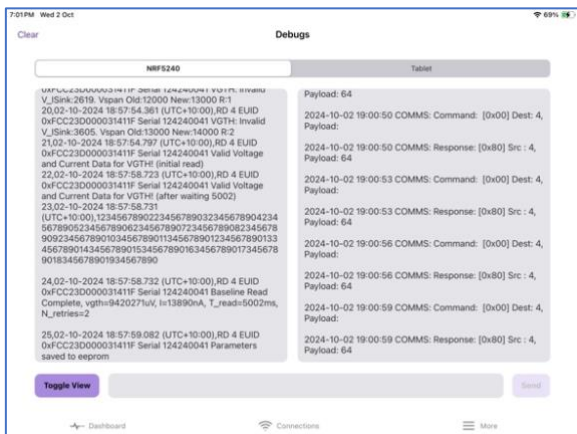
3. Tap **Dashboard** at the bottom of the screen to return to the Dashboard Screen.

5.4 DEBUGS (TECHNICIAN ONLY)

Detailed system debug logs can be inspected by a technician, follow these steps to access.



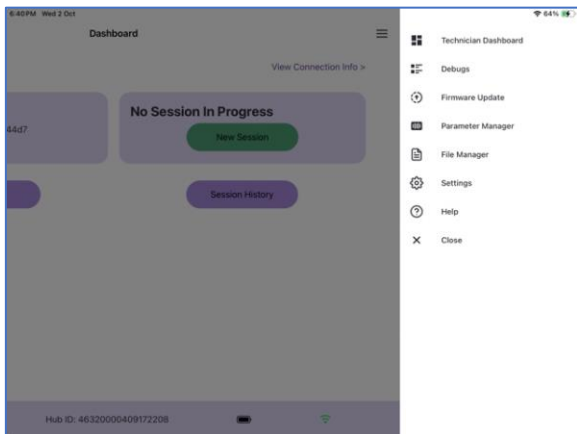
1. Connect the HUB that is to be updated to the Monitor.
2. From Dashboard screen, click hamburger icon () in top right corner and select **Debugs** from revealed menu.



3. Tap **Dashboard** at the bottom of the screen to return to the Dashboard Screen.

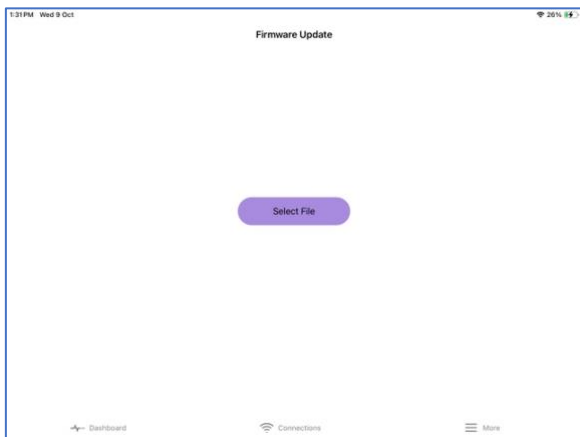
5.5 FIRMWARE UPDATE (TECHNICIAN ONLY)

The HUB firmware can be updated via the Monitor following these steps.



1. Connect the HUB that is to be updated to the Monitor.

2. From Dashboard screen, click hamburger icon (☰) in top right corner and select **Firmware Update** from revealed menu.



3. Click **Select File** then browse to latest software package provided by Manufacturer. The file will have the .zip extension.

Note: Firmware packages need to be obtained from the Manufacturer. Contact your local MOSkin representative.



4. Tap **Start Firmware Update**. Allow update to complete.

DO NOT TURN OFF HUB WHILE UPDATE IS IN PROGRESS.

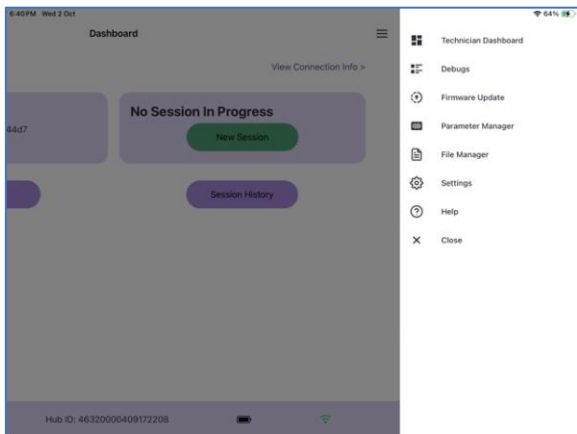
On completion, HUB firmware is updated.

5. Tap ***Dashboard*** at the bottom of the screen to return to the Dashboard Screen.

5.6 FILE MANAGER (TECHNICIAN ONLY)

The Monitor can retrieve and export HUB files and data via the File Manager.

To access and use the File Manager follow these steps.



1. Connect the HUB that contains the data to be retrieved to the Monitor.
2. From Dashboard screen, click hamburger icon () in top right corner and select **File Manager** from revealed menu.

The screenshot shows the File Manager screen at 1:32 PM on Wednesday, October 9th. It displays a table of files from a connected device. The table has three columns: Index, Filename, and Size. The files listed are:

Index	Filename	Size
0	Errors and Warnings Header	4096
1	Errors and Warnings Descriptor	4096
2	Errors and Warnings Data	327680
3	Binary Data Log Header	4096
4	Binary Data Log Data Descriptor	4096
5	Binary Data Log Data	307200
6	SelfTest Log Header	4096
7	SelfTest Log Descriptor	4096
8	SelfTest Log Data	98304
9	System Event Header	4096
10	System Event Header Descriptor	4096

The bottom navigation bar includes 'Dashboard', 'Connections', and 'More'.

All the available files on the connected HUB will be displayed.



3. To download all the files, scroll to the bottom of the screen and tap **Download All Files**.

4. To delete all the files on the connected device, scroll to the bottom of the screen and tap **Delete All Files**.

DO NOT TURN OFF HUB WHILE DOWNLOADING OR DELETING IS IN PROGRESS.

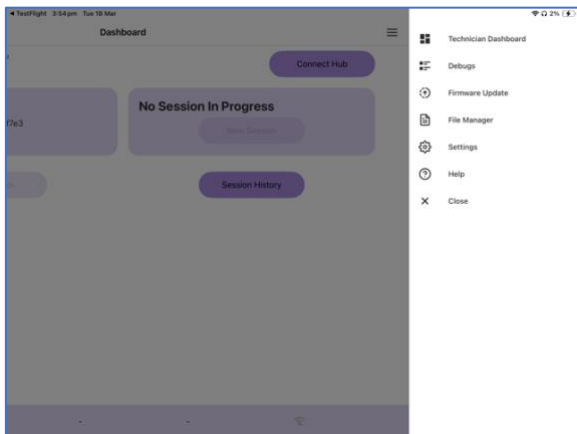
On completion, HUB firmware is updated.

Tap **Dashboard** at the bottom of the screen to return to the Dashboard Screen.

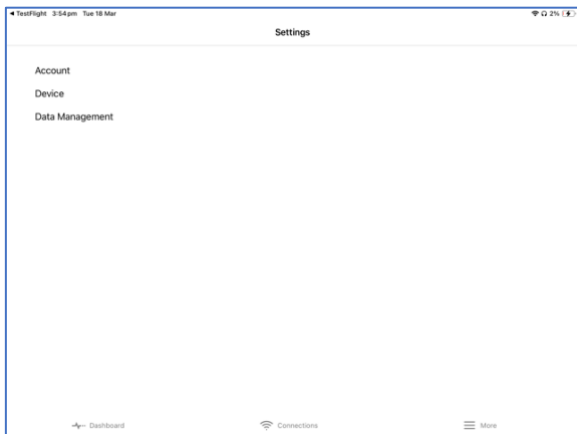
5.7 DATA BACKUP (ADMIN & TECHNICIAN)

All the Monitor's data can be backed up and exported from the Monitor in the case where the system is being reset and restored or decommissioned and the existing data is to be kept.

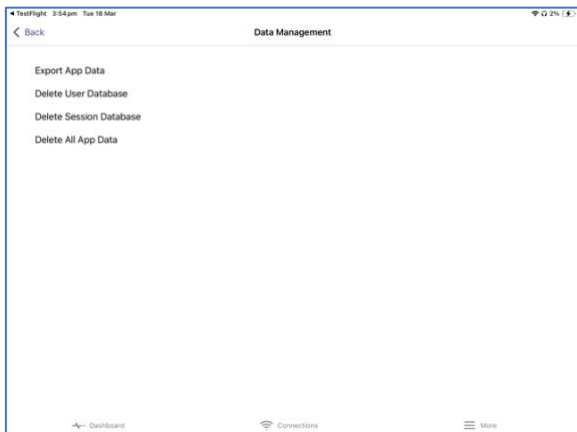
To back up the Monitor data, follow these steps.



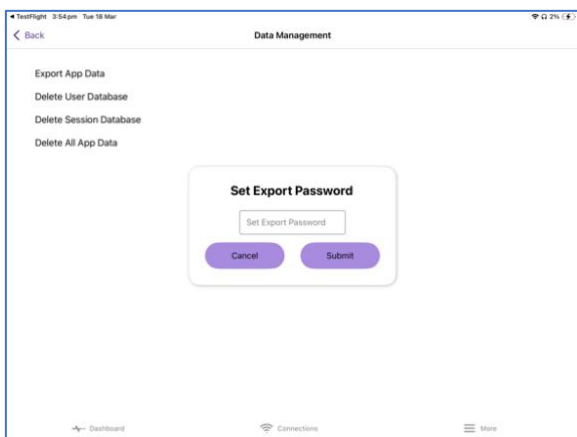
1. From Dashboard screen, click hamburger icon () in top right corner and select **Settings** from revealed menu.



2. Select **Data Management**.

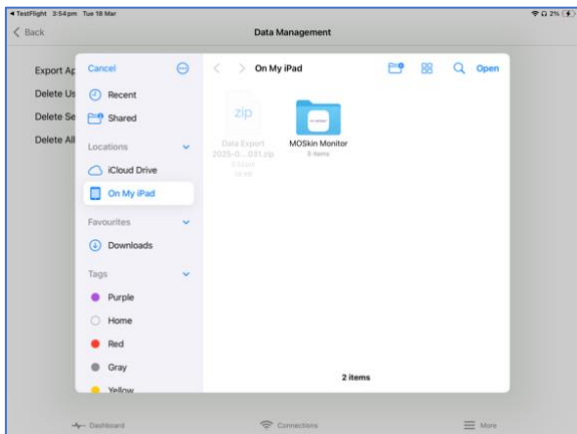


3. Select **Export App Data**.

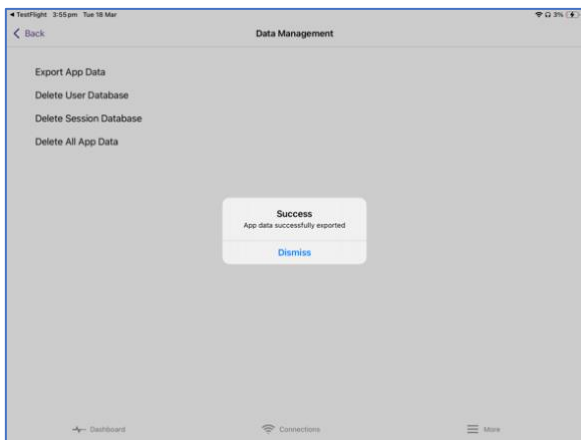


4. You will be prompted to set a password for the exported data archive.

Note: This password will be needed to open the archive (.zip) later.



5. Select location on the iPad to store the archive.

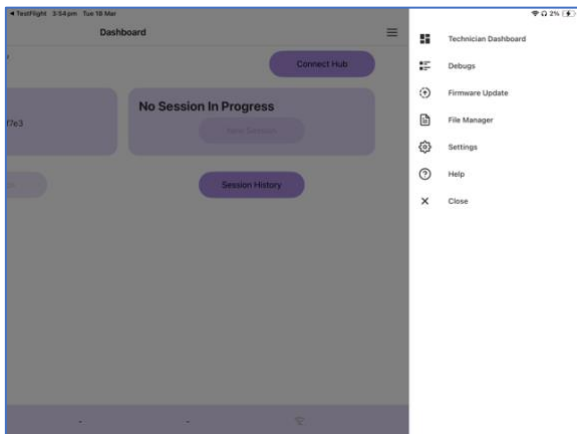


Back up is complete.

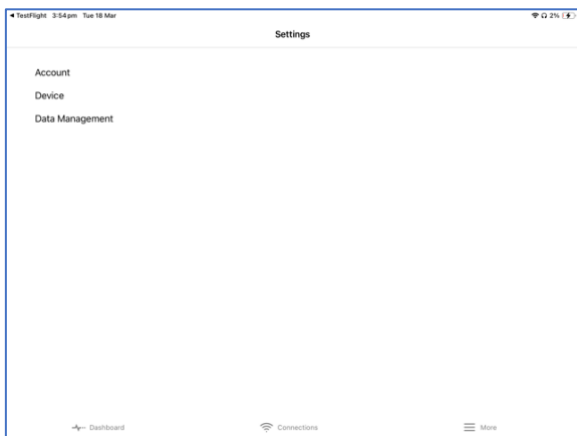
5.8 ERASE MONITOR DATA (TECHNICIAN ONLY)

The Monitor's data (sessions and users) can be erased from within the Monitor in the case where storage space needs to be freed up and the data is no longer needed or where the system is being decommissioned.

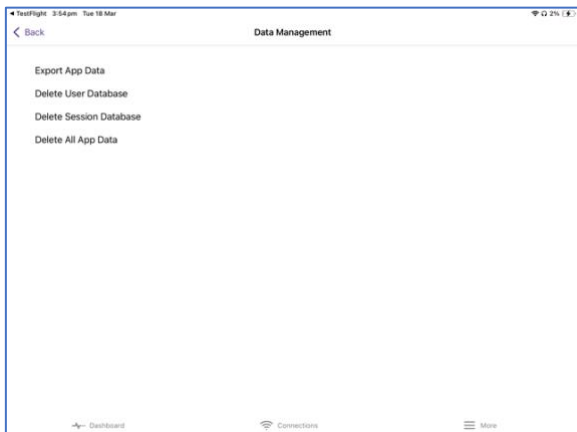
To erase Monitor data, follow these steps.



1. From Dashboard screen, click hamburger icon () in top right corner and select **Settings** from revealed menu.



2. Select **Data Management**.

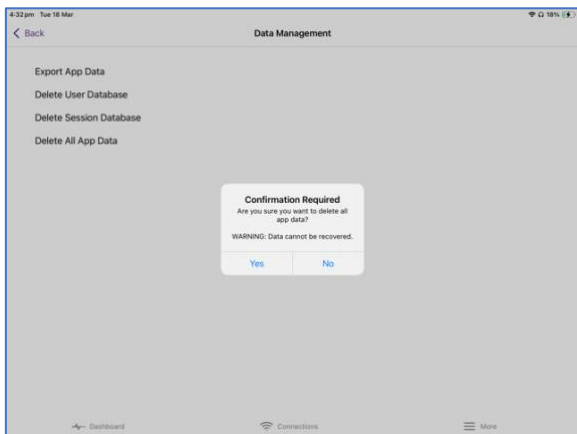


3. Select the desired option:

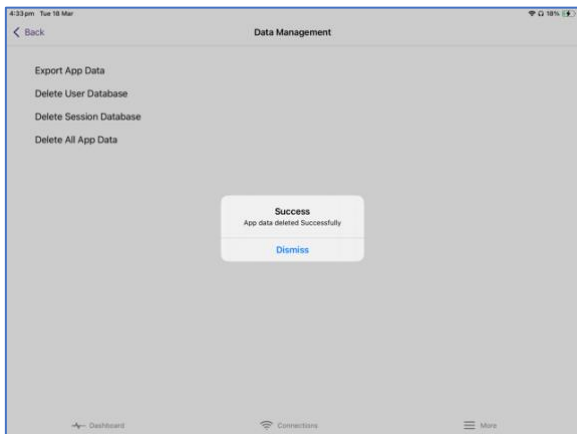
Delete User Database: deletes only the users from the system but keeps the session data.

Delete Session Database: deletes all sessions but keeps users.

Delete All App Data: deletes all data.



4. Select Yes to confirm the deletion of data.



Deleting of data is complete.

6 CYBERSECURITY

All connected devices face cybersecurity threats. When the MOSkin Monitor is connected to a Wi-Fi network, it is susceptible to a cyber-attack. This could be in the form of someone getting unauthorised access to data, malware or data breaches.

The MOSkin System has been designed to minimise these risks including the implementation of:

- No default passwords
- Enforcing strong passwords during password creation
- Only allowing authorised users to access data
- Automatic logoff if system sits idle for 10 minutes
- Data encryption of the device data transfers
- Means of performing software updates of all software elements
- Logging and audit trail (accessible to Technicians only)

Note: If you suspect that the MOSkin System has been impacted by a cyber-attack of any kind, you may report this to Electrogenics Laboratories; contact details are at the back of this Instructions for Use.

Follow the guidance below to minimise cybersecurity risks and to keep the MOSkin System secure.

6.1 WiFi NETWORKS



WARNING: There is an increased cybersecurity risk if the MOSkin System is connected to a public and/or unsecured WiFi network



CAUTION: To reduce the cybersecurity risk to the MOSkin System only connect to a WiFi network when needed

Only connect the MOSkin Monitor to known and secure WiFi networks. If you are unsure, consult with the IT department of the hospital or clinic in which the MOSkin System is to be used.

To further reduce cybersecurity risks, the MOSkin system can be used offline during sessions and only requiring connection to export session reports.

6.2 SOFTWARE UPDATES

The MOSkin System is comprised of three (3) distinct software and firmware components, each of which should be kept up to date.

- MOSkin Monitor Software
- MOSkin HUB Firmware
- Apple iPadOS Software (3rd party software)

6.2.1 MOSkin Monitor Software

The Monitor Software is managed by the Apple iPadOS App Store and when a new version of the Monitor Software is released, it will be updated automatically.

If automatic App updates are disabled within iPadOS, it is highly recommended it be enabled.

6.2.1.1 Enable automatic App Updates within the iPadOS Settings (recommended)

- Goto Settings > App Store
- Enable “App Updates”

6.2.1.2 Manually check for Monitor app updates periodically

- Goto App Store
- Locate and tap the Profile icon in the top right of the screen

- In the “Account” pop-up window, scroll down to see if there are available updates for the MOSkin Monitor app.

6.2.2 MOSkin HUB Firmware

Firmware updates for the MOSkin HUB will be distributed to the MOSkin Technician at the hospital or clinic that owns and operates the MOSkin system.

Refer to Section 5.5 for Technician instructions to perform the firmware update of the HUB.

6.2.3 Apple iPadOS Software

Apple iPadOS is the operating system that the MOSkin Monitor works with and it's important to ensure that it is kept up to date to minimise cybersecurity risks.

6.2.3.1 Update iPadOS Software

The iPadOS is automatically updated when a minor version update is available. For major version updates, the user will be prompted by the iPadOS to confirm the update.

If automatic updates are disabled, it is highly recommended that it be enabled.

To enable iPadOS automatic updates, follow these steps:

- Goto Settings > General > Software Update
- Tap Automatic Updates and ensure that “Install iPadOS Updates” is enabled.

Once iPadOS has been updated, it is recommended to check for MOSkin Monitor software updates, following Section 6.2.1 above.

6.2.3.2 Disable Beta iPadOS Software

It is highly recommended that beta iPadOS software is not used and should remain disabled.

If enabled, disable it by following these steps.

- Goto Settings > General > Software Update
- Beta Software and tap Off

6.3 MONITOR SECURITY

Basic cyber security measures should be implemented to reduce risks of improper use or access to the MOSkin System.

The following recommendations should be followed:

- Keep the MOSkin Monitor in a secure location when not being used and where possible, prevent it from being taken outside of the hospital and/or clinics in which it is used.
- The iPad should be configured to require a passcode to unlock it, and this passcode should not be easy to guess, i.e. not 1-2-3-4 or similar.
- Only share the passcode with personnel who need access to perform their job and have been trained to use the MOSkin system.
- Don't keep the passcode written on or stuck to the iPad.

6.4 BACKUPS

It is recommended that regular data backups are performed by the MOSkin system technicians to reduce the risk of lost data due to a cyber-attack.

To perform a data backup, follow the steps detailed in Section 5.7 above.

7 CLEANING

7.1 CLEANING OVERVIEW

The ONLY agent, cleaning or otherwise, that is recommended to come into contact with the MOSkin system is a fresh isopropyl alcohol (70%), non-foaming wipe.

The MOSkin System should never be exposed to the agents listed below. Use of these agents will void the product warranty.

The following agents are NOT to be used on the MOSkin system.

Benzene	Chlorohexane	Nitric acid 70%	Kerosene
Carbon Tetrachloride	Ethyl chloride	Trochloro- ethylene	Lacquer
Chlorobenzene	Freon	Perchloro- ethylene	Toluene
Chloroform	Gasoline	Naphtha	Xylene

This is not an exhaustive list of agents which may compromise the integrity of the MOSkin System, however is provided for guidance to users.

7.2 CLEANING INSTRUCTIONS

7.2.1 Cleaning the HUB

The HUB should be clean and dry before loading RDs.

Clean the HUB using a fresh, low-alcohol, non-foaming wipe applied to RD connection slots, exterior surfaces and charging cable.

Daily cleaning is recommended.

NOTE: Ensure the electrodes in the HUB slots and the gold connectors on the RDs are clean and free of any lint or debris to ensure reliable connection.

7.2.2 Cleaning the RD After Patient Use

The RD is provided clean and should **ONLY** be cleaned after it has been in contact with a patient.



WARNING: Folding or creasing the RD during use or cleaning may damage the RD and prevent correct Baselineing or reading of delivered dose.



WARNING: Do not handle the RD with forceps, tweezers or other mechanical devices as this may damage the RD. Use only gentle fingertip pressure in handling.

Clean the RD with a fresh low-alcohol, non-foaming wipe after removal from the patient.

Fold the wipe in half enclosing the RD. Wipe while holding one end of RD in fingertips. Move fingertips to the other end of the RD and repeat.

RD should be visually clean and dry before loading into the HUB for reading.

NOTE: Ensure the electrodes in the HUB slots and the gold connectors on the RDs are clean and free of any lint or debris to ensure reliable connection.

7.2.3 Cleaning the Monitor Tablet

Handle your Monitor Tablet with care to maintain its appearance. If you're concerned about

scratching or abrasion, you can use one of the many cases sold separately.

To clean the Monitor Tablet , unplug all cables and turn off the Monitor Tablet (press and hold the Power button, and then slide the onscreen slider).

Use a soft, slightly damp, lint-free cloth. Avoid getting moisture in openings. Don't use window cleaners, household cleaners, compressed air, aerosol sprays, solvents, ammonia, abrasives, or cleaners containing hydrogen peroxide to clean the Monitor Tablet. The Monitor Tablet has an oleophobic coating on the screen; simply wipe the Monitor Tablet screen with a soft, lint-free cloth to remove oil left by your hands. The ability of this coating to repel oil will diminish over time with normal usage, and rubbing the screen with an abrasive material will further diminish its effect and might scratch your screen.

Refer to the iPad User Guide for more information.

8 HELP AND TROUBLESHOOTING

8.1 LED INDICATORS

The following table details the different HUB indicator combinations what they mean.

Button Indicator	Slot Indicator	HUB Status and Actions
Off	Off	System powered off and not charging.
Flashing WHITE		HUB powered on and ready. Not connected to a Monitor.
Solid GREEN		HUB powered on and connected to a Monitor.
Flashing GREEN & YELLOW		LOW BATTERY, connect HUB power cable. HUB currently CONNECTED to Monitor.
Flashing WHITE & YELLOW		LOW BATTERY, connect HUB power cable. HUB currently DISCONNECTED to Monitor.
Flashing GREEN & PURPLE		CHARGING. HUB currently CONNECTED to Monitor.
Flashing WHITE & PURPLE		CHARGING. HUB currently DISCONNECTED to Monitor.

Flashing PURPLE		CHARGING. HUB currently OFF
Flashing GREEN		Indicates HUB that is connected to the Monitor where the user has tapped the IDENTIFY button.
Flashing YELLOW	Flashing YELLOW	HUB initialization has failed. Contact system administrator or technician for assistance.
	Solid WHITE	Slot OPEN
	Solid BLUE	RD CONNECTED and being initialized
	Solid GREEN	RD CONNECTED and READY
	Flashing GREEN	RD being read by the HUB
	Solid YELLOW	RD CONNECTION and/or failed INITIALIZATION

8.2 **MONITOR APPLICATION HELP**

The Monitor Application has a Help Menu to assist users during use of the MOSkin System.

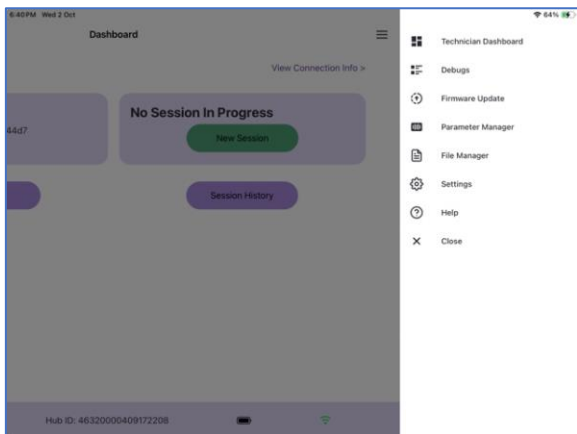
8.2.1 Determining Monitor Version Number

8.2.1.1 During Start Up



During Application start up, the Application version number and Unique Device Identifier will be displayed on the initial Splash Screen.

8.2.1.2 During Use



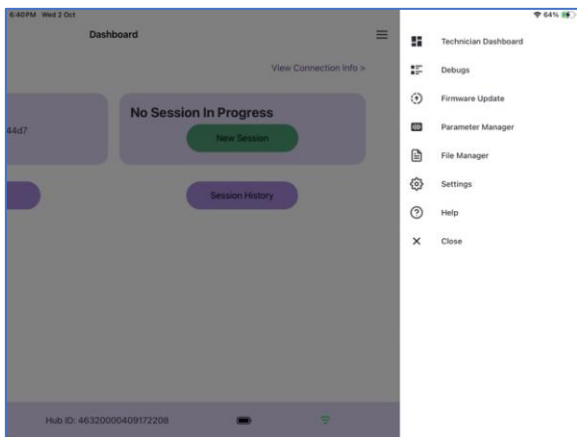
1. From Dashboard screen, click hamburger icon (≡) in top right corner and select **Help** from revealed menu.

Monitor software version and the product GTIN are listed on the presenting screen.

2. Tap on the ***Dashboard*** button at the bottom of the screen to return to the Dashboard Screen.

8.2.2 Terms & Conditions and Privacy Policy

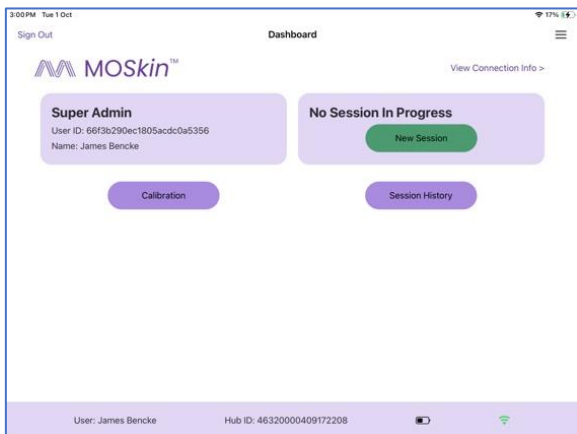
Terms and Conditions and a Privacy Policy are locate in the ***Help Menu***.



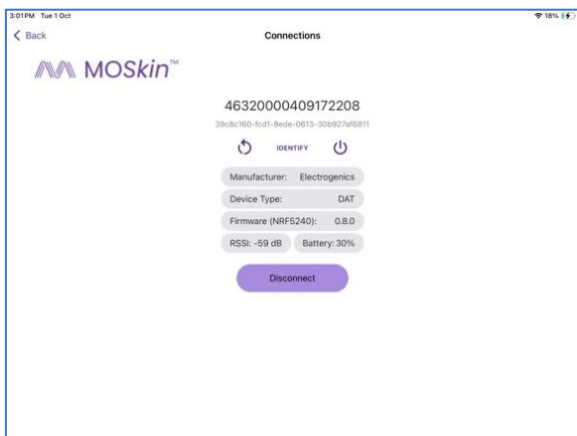
1. From Dashboard screen, click hamburger icon (**≡**) in top right corner and select ***Help*** from revealed menu.

Terms & Conditions and the Privacy Policy can be accessed from the Help Menu.

8.3 IDENTIFYING A DEVICE



1. From the Dashboard, tap on the **View Connection Info** tab on the bottom of the screen to access the Connections Screen.

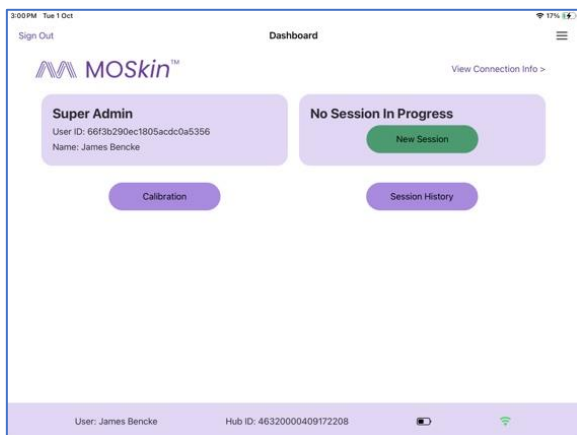


2. Tap **IDENTIFY** to blink a GREEN indicator on the currently connected HUB.

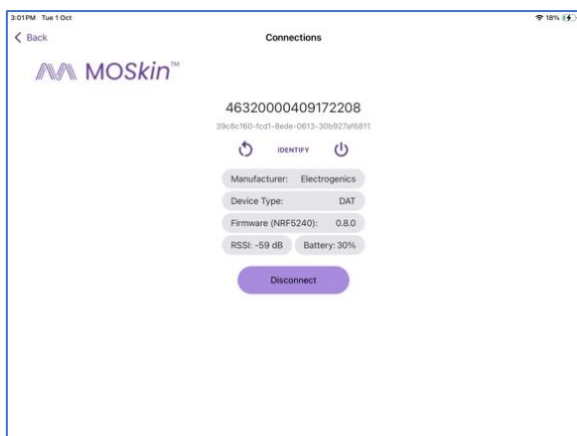
3. Tap on the **Back** button to return to the Dashboard.

8.4 ENTERING LOW POWER MODE

The HUB has a low power operations mode, where the battery capacity is conserved.



1. From the Dashboard, tap on the **View Connection Info** tab on the bottom of the screen to access the Connections Screen.



2. Tap the power icon  to power off and set the HUB into LOW POWER MODE. The HUB will disconnect from the Monitor.

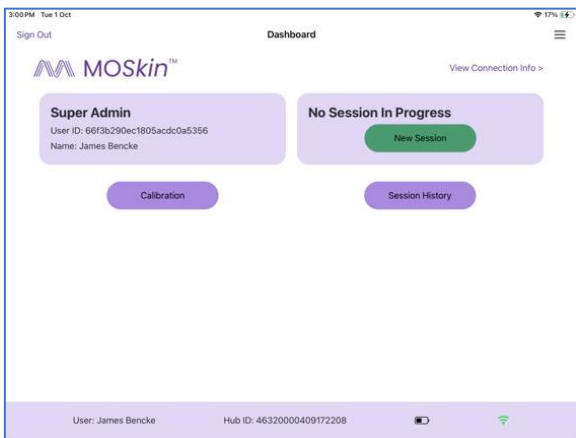
3. Tap on the **Back** button to return to the Dashboard.

8.5 REBOOTING A HUB

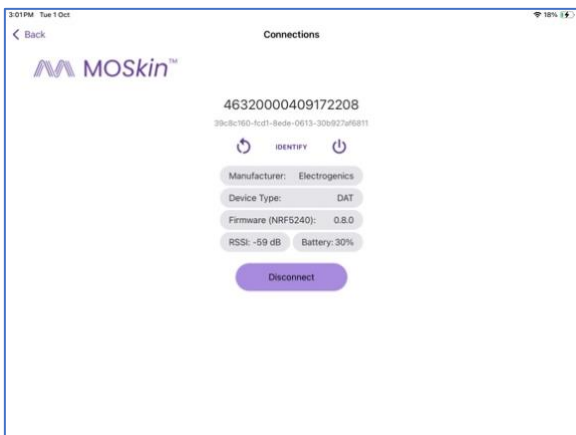
8.5.1 Hardware Reboot

If the MOSkin HUB requires a reboot, locate the reset button next to the USB-C charging port on the right side of the HUB. Press and hold for one (1) second.

8.5.2 Software Reboot



1. From the Dashboard, tap on the **View Connection Info** tab on the bottom of the screen to access the Connections Screen.

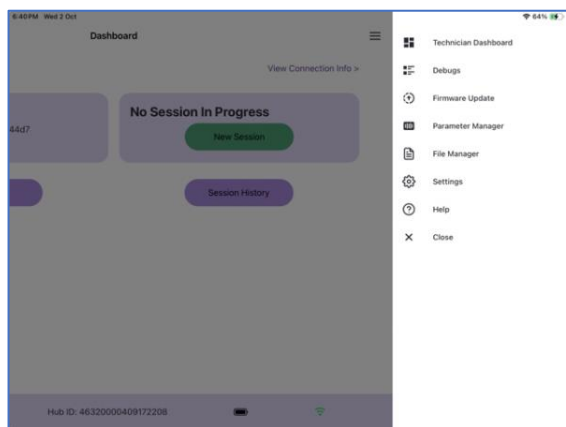


2. Tap the reboot icon . The HUB will disconnect from the Monitor.
3. Tap on the **Back** button to return to the Dashboard.

8.6 RESETTING A HUB TO FACTORY DEFAULTS

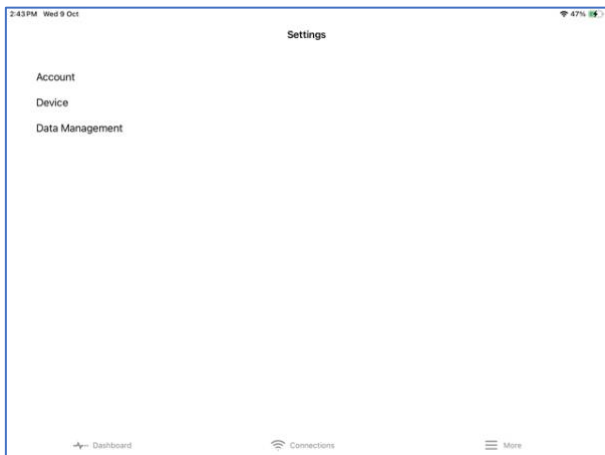
This provides a means to restore the HUB to the factory default settings. All settings will be reset. Any programmed settings will need to be reconfigured.

Note: this function can only be performed by MOSkin Technician users.

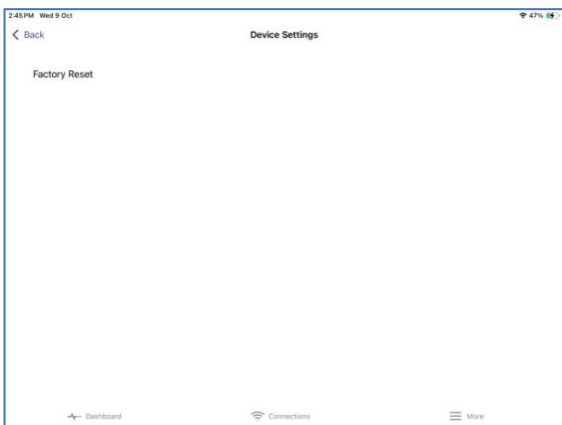


UXX-009 Dashboard Screen

1. From Dashboard screen, click hamburger icon () in top right corner and select **Settings** from revealed menu.



2. Tap Device.



3. Tap Factory Reset.

4. Confirm reset to Factory Default settings.

NOTE: This action CANNOT be undone.

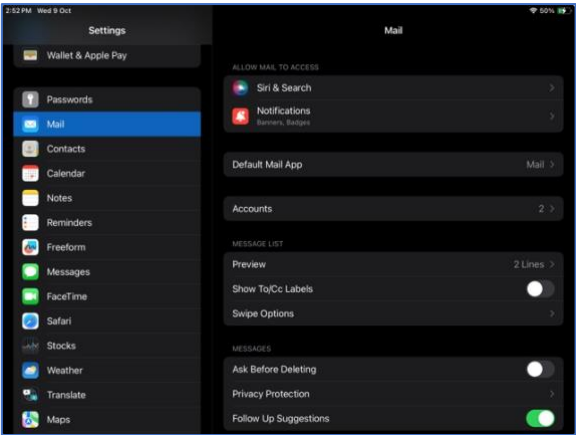
8.7 CONFIGURING EMAIL ON IPAD

Follow these steps to configure iPad email so that MOSkin reports can be exported.

Instructions are correct for iPadOS Version 18. Note that these steps may have changed slightly.

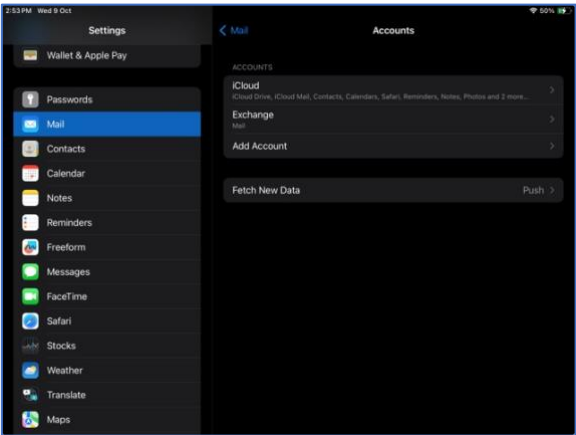


Goto iPad Settings



2. Select Mail from the left-hand side.

3. Select Accounts in the Mail panel.



4. Select Add Account and follow the on-screen steps to setup the email account that will be used to export reports from the Monitor.

NOTE: This action CANNOT be undone.

8.8 TROUBLESHOOTING

The following troubleshooting guide is to assist resolution to uncommon issues with the MOSkin System. If further assistance is needed, contact the system administrator and/or technicians.

Problem	System Component	Resolution
The HUB does not turn on.	HUB	Charge the MOSkin Reader per Section 3.4.1.
The device shuts off prior to recording a reading.	HUB	Charge the MOSkin Reader per Section 3.4.1.
Camera does not work	MONITOR	Permit Monitor app access to the camera. See iPad Settings.
RD connection error – YELLOW slot indicator illuminated Error code: 78	HUB, MONITOR & RD	Press rear of slot lid until LED indicator illuminates white. Release lid to retry connection. LED indicator should change to blue then fixed green. If persistent, remove & refit RD. If still persistent, apply light finger pressure to lid as soon as lid closes.

Problem	System Component	Resolution
RD connection error – YELLOW slot indicator illuminated Error code: 45	HUB, Montior & RD	Press rear of slot lid until LED indicator illuminates white. Release lid to retry connection. LED indicator should change to blue then fixed green. If persistent, remove & refit RD. If still persistent, apply light finger pressure to lid as soon as lid closes.
No indicator when RD inserted.	HUB & RDs	Reset lid and RD and try again. If still not working, remove RD and clean the eight (8) gold contacts on the back as per Section 0. Ensure RD is dry. Retry RD insertion. If still no indicator, visually inspect the HUB contacts under the lid. Clean contacts as per Section 7.2.1. Retry RD insert. If still no slot indicator, contact system administrator or technician.

Problem	System Component	Resolution
HUB unresponsive	HUB	Plug charging cable into the HUB and power on the charger, as per Section 3.4.1. If PURPLE indicator starts flashing, allow HUB to charge before trying again. If still unresponsive, contact system administrator or technician.
Unable to connect HUB to Monitor via Bluetooth or link drops out	HUB & Monitor	Move HUB and Monitor closer together or to an area with less interference.
Unable to connect Monitor to network via wifi or link drops out	Monitor	Monitor closer to your wireless router or to an area with less interference. Check with your institutions' Information Technology group to confirm the network login credentials are correct.

9

**GUIDANCE AND MANUFACTURER’S
DECLARATION – ELECTROMAGNETIC
EMISSIONS**

9.1

ELECTROMAGNETIC ENVIRONMENT

This data is included pursuant to IEC 60601 labelling requirements.

The MOSkin System is intended for use in the electromagnetic environment specified in Table 1 Electromagnetic Environment. The user of the MOSkin System should ensure that it is used in such an environment.

Table 1 Electromagnetic Environment

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR11	Group 1	The MOSkin System device uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class A	The MOSkin System is suitable for use in all electromagnetic environments.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

9.2 ELECTROMAGNETIC IMMUNITY

Table 2 Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 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	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	± 1 kV for input/output lines	N/A (unit does not contain any signal, control, or telecom lines)	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
	± 2 kV lines to earth	N/A (2-pin AC PSU only)	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip) for 0.5 cycle 0% UT (100% dip) for 1 cycles 70% UT (30% dip) for - 25 cycles <5% UT (>95% dip) for 250 cycles	0% UT (100% dip) for 0.5 cycle 0% UT (100% dip) for 1 cycle 70% UT (30% dip) for 25 cycles 0% UT (100% dip) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MOSkin System's charging system requires continued operation during power mains interrupts, it is recommended that the MOSkin System be powered from an uninterruptible power supply or a battery.

Table 2 Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment – Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 V _{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the MOSkin System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter, see Section 9.3.
	ISM Bands & Radio Amateur Bands	6 V _{rms}	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

9.3 SEPARATION DISTANCE

The MOSkin System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MOSkin System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MOSkin System as recommended below, according to the maximum output power of the communications equipment. The recommended separation distance between portable and mobile RF communications equipment and the MOSkin System is listed in Table 3 Separation Distance.

Table 3 Separation Distance

Separation distance according to frequency of transmitter (meters)			
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \cdot \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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 rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE: These guidelines may not apply in all			

situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

10 DISPOSAL OF SYSTEM COMPONENTS

10.1 RADIATION DOSIMETER DISPOSAL

The Radiation Dosimeters should be disposed of using your institution's protocols for disposal of patients contacting medical equipment, similar to used electrocardiogram electrodes.

10.2 HUB DISPOSAL

The HUB should be disposed of following your institution's process for recycling electronics equipment or returned to the manufacturer for disposal.

10.3 MONITOR DISPOSAL

If required, the MOSkin Monitor data can be backed up as per the instructions in Section 5.7 above.

Following any data backup, the iPad tablet should be erased using the process in the iPad User Guide, then disposed of following your institution's process for recycling electronics equipment or returned to the manufacturer for disposal.

11 SPECIFICATIONS

Item	Specifications
Applied Part	No applied (powered) parts interfacing with patient.
Hub Battery Life per Charge	3 hours (continuous operation)
Method of Cleaning	Clean the device as defined in Section 7.
Duty Cycle	Operator determined
Hub Power Source	Internal battery, rechargeable
Radiation Dose Measurement Range	10 to 400 centiGray (cGy) Photon MV energy.
Radiation Dose Measurement Accuracy	+/-5 cGY (<100 cGy) +/-5 % (100 to 400 cGy)
Angular Radiation Dose Measurement	0-15% offset of perpendicular beam dose measurement at angles 0-180-360°. Characterised as a fitted angular offset curve.
Angular Radiation Dose Measurement Accuracy	+/-5% of fitted angular offset curve at angles 0-180-360°.

Item	Specifications
Storage	The MOSkin System should only be stored at temperatures ranging from -20°F (-29°C) to 140°F (60°C) at 5% to 95% relative humidity (non-condensing).
Operating Conditions	The MOSkin System should only be operated at temperatures ranging from 59°F (15°C) to 95°F (35°C) at 5% to 95% relative humidity (non-condensing).
HUB AC Mains Voltage	100-240 V
HUB Mains Current	0.35 A
Monitor Tablet Minimum Requirements	Apple® iPad® 9th Generation (or newer) with a 10.2 inch screen (or larger). iPadOS® version 18.0, or later.

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