visionflex

Equality healthcare

ProEX MOBILE SYSTEM
USER MANUAL

Integrating capture, storage, and connectivity for quality patient images, video and audio

Please read this manual carefully before operating your **ProEX Mobile System** and retain it for future reference.

VFPMMAN1.09

TABLE OF CONTENTS

1. PRODUCT DESCRIPTION

The ProEX Mobile System facilitates patient examinations for screening purposes via high quality images derived from a range of medical examination accessories (not supplied with standard system). Examinations may also be streamed live through a video conferencing connection to a specialist for remote visualization.

Featuring a high-end multi-core processor and advanced electronic design, the ProEX Mobile System can record multiple types of data streams and store them in solid state memory inside the unit in an encrypted format, from where it can be sent to other clinicians via WiFi, over the Mobile Network, or via USB.

2. SYSTEM CONTENTS

The ProEX Mobile System (Part number EU/AUSTRALASIA VFPROEXMOBKIT2.01 UDI 09352527001352 US/CANADA VFPROEXMOBKIT1.01 UDI 09352527000676) includes following items:	Part Number UDI*	Quantity
ProEX Mobile Hardware – single device	Codes for EU/Australasia VFPROEXMOBILE2.01 UDI-DI 09352527001345 Codes for US/CANADA VFPROEXMOBILE1.01 09352527000669	1
Pre-installed Linux based software	VFD-1006-SW-0002	1
ProEX Mobile System Medical Grade Power Supply	VFPMPSU1	1
ProEX Mobile System User Manual (this document)	VFPMMAN1	1
Batteries for ProEX Mobile System(VF-ProEX-M-Battery)	VFPMBAT1	2

Mains Power Cable (Country depending)*	PXEL00XY	1
Optional accessories include the following:		
Vehicle VESA Mount with 12v PSU (VF-PVM)	VFPMPVM1	1
Simple VESA Mount (VF-SVM)	VFPMSVM1	1
Back-pack with wheels for ProEX Mobile System& Accessories	VFBPACK1	1
Mains Power Cable Variants*		
AU Mains Power Cable	PXCB0031	1
US/CANADA Mains Power Cable	PXCB0032	1
UK Mains Power Cable	PXCB0038	1
EU Mains Power Cable	PXCB0039	1

Figure 1
Legend:
ProEX Mobile Front

- A Power socket 12V DC
- B Ethernet
- C Power LED
- D Recording LED
- E LCD Display
- F Microphone
- G Front facing camera
- H Power button
- I Camera shutter button
- J USB 3.0
- K USB 2.0

Figure 2
Legend:
ProEX Mobile Rear

- A Battery test button and Indicator
- B Battery release button
- C Rear camera light
- D Rear camera
- E Speaker
- F Handle
- G Batteries

3. BASIC SAFETY INSTRUCTIONS

Before operating the ProEX Mobile, users must read this User Manual in its entirety.

If any faults or malfunctions are detected, Visionflex must be informed immediately.

1. Only use the product in a fault-free condition
2. Heed all cautions and warnings in these instructions.
3. Although this device has been manufactured to the highest and most current standards, hazards could still arise during initial installation, operation or maintenance. Therefore, it is important that users only use the product in accordance with its instructions for use and technical description.
4. Refer all servicing to qualified service personnel. Servicing is required when the apparatus has been damaged in any way, such as when a power supply cord or plug has been damaged, liquid has been spilled on the apparatus, objects have fallen onto the apparatus, the apparatus has been exposed to rain or moisture, does not operate normally or has been dropped.
5. Keep the original packaging. Transport the device in its original packaging and use it to return goods if service support is required.

WARNING: Unauthorized modifications to the device may result in risk of serious injury to persons. Do not make any unauthorized modifications.

WARNING: To avoid the risk of fire, short circuit or electric shock, the device should only be operated with the supplied power supply, within the voltage ratings specified in this User Guide. Do not power the ProEX Mobile System with any other power supply.

WARNING: To avoid the risk of fire, short circuit or electric shock, the device should not be charging at the same time as using an applied part.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

WARNING: Do not operate the device with the covers removed as there is a risk of electric shock. Do not open the device.

WARNING: To avoid the risk of electric shock, do not touch accessible parts (other than those intended for patient contact) and the patient simultaneously.

WARNING: To avoid excessive leakage current., do not use multiple socket outlet (power strip) or an extension cord with the ProEX Mobile.

WARNING: To avoid electromagnetic interference, do not place the device near imaging equipment such as CT scanners and Magnetic Resonance Imaging (MRI) scanners.

WARNING: To avoid risks from fire, short circuit or electric shock, when connecting the ProEX Mobile System with electrical devices from different manufacturers and connecting type BF accessories ensure these are compliant with IEC 60950 (general electrical equipment) or IEC 60601-1 clause 16.

WARNING: To avoid risk from fire, short circuit or electric shock, follow the manufacturer's installation instructions for medical electrical system installation. In instances where there is an element of doubt concerning the safety of the connected devices, the user must contact the manufacturers concerned or other informed experts such as biomedical engineers for proper use.

WARNING: Risk of damage to the device through improper handling, maintenance and use carries a risk to the patient, user and other persons, or can lead to reduced lifetime of the device. Do not kink, crush or strongly bend camera cable. If the device is dropped or subject to high mechanical stress, stop using and send to the manufacturer for inspection.

WARNING: To avoid the risk of suffocation, keep packaging material out of reach of children.

WARNING: To avoid the risk of fire, short circuit or electric shock, only use the unit in drip and splash-proof areas. Clean any liquid spills from the surface of the device immediately and never dip the housing into liquids.

WARNING: To avoid the risk of fire, short circuit or electric shock, routinely inspect all electrical connections. Defects like loose plugs, defective camera cables or others may interfere with safety and image quality and must be exchanged immediately

WARNING: Risk from installation in potentially explosive locations. Increased risk of fire or explosion in oxygen-enriched atmospheres. Device must be installed outside of potentially explosive locations and not near flammable substances.

WARNING: To avoid the risk of infection the ProEX Mobile Systemis not intended for use in a sterile environment. The unit contains cooling fans which could re-circulate contaminated material. Do not enclose the unit in a sterile drape.

WARNING: Risk of fire, short circuit or electric shock if electrical connections are installed improperly. Make sure that the electrical connections are installed in accordance with the national technical regulations

WARNING: Risk of fire, short circuit or electric shock if electrical connections are installed improperly. Make sure that the electrical connections are installed in accordance with the national technical regulations

WARNING: Risk of fire, short circuit or electric shock in use of multiple sockets. If required, use medically approved multiple sockets. Never connect multiple sockets in series. Do not cover sockets.

WARNING: To avoid the risk of explosion, the device should only be operated with the supplied batteries. Replace only with the same or equivalent type recommended by the manufacturer. Check or replace the battery pack every year.

CAUTION: Risk of damage to the device, use a damp lint free cleaning cloth when cleaning the outside of the device, do not use any abrasive cleaners or cleaners containing benzene or derivatives.

CAUTION: Applied parts are connected to the ProEX Mobile System USB ports. The ProEX Mobile System itself does not have an applied part. The USB ports on the device do not provide any patient isolation.

Electromagnetic Compatibility (EMC)

CAUTION: Risk resulting in electromagnetic radiation. Possible malfunctions and image interference. Use cables supplied or recommended by Visionflex. Ensure that all devices operated in the vicinity meet the EMC requirements required by the country of use. Perform a post-installation function check.

CAUTION: Use of accessories, transducers and cables other than those specified or provided by Visionflex could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.

CAUTION: Use of this equipment adjacent to or stacked with other equipment should be avoided unless explicitly approved by the manufacturer of this device.

CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennae) should be used no closer than 30 cm (12 inches) to any part of the ProEX Mobile System including cables specified by Visionflex. Otherwise, degradation of the performance of this equipment could result.

CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennae) should be used no closer than 30 cm (12 inches) to any part of the ProEX Mobile System including cables specified by Visionflex. Otherwise, degradation of the performance of this equipment could result.

CAUTION: Avoid subjecting the ProEX Mobile System to vibration or shock when in use and when in transit.

CAUTION: Disconnect the ProEX Mobile System from AC outlet before cleaning.

CAUTION: If the equipment is not in use for a long time, disconnect from the power source to avoid damage by transient over voltage.

CAUTION: Do not leave this equipment in an uncontrolled environment where the storage temperature is below – 20^0 C (-4 ^{0} F) or above 60^0 C (140 ^{0} F). It may damage the equipment.

FOR CANADA ONLY: This digital apparatus does not exceed the Class A limits for radio noise emissions from digital apparatus set out in the Radio Interference Regulations of the Canadian Department of Communications.

USA FCC CLASS A: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules.

Any serious incident that has occurred in relation to the device.
should be reported to the manufacturer, Authorized Representative, or the competent authority of the Member State in which the
user and/or patient is established; Please see contact details on the last page of this document.

4. INTENDED USE AND INDICATORS FOR USE

The ProEX Mobile System is intended to display, record, store and/or transfer data from diagnostic devices locally or remotely during medical procedures.

The ProEX Mobile System itself is not a diagnostic device.

4.1 INTENDED USERS

Intended for use by a lay operator or by trained healthcare personnel. The user should be familiar with computer-based equipment.

4.2 USE ENVIRONMENT

For clinical purposes, the device is intended to be used at medical facilities and home healthcare environments or via a remote connection. Note: The home healthcare environment includes:

- The dwelling place in which a patient live.
- Other places where patients are present both indoors and outdoors, excluding professional healthcare facility environments where operators with medical training are continually available when patients are present. See Technical Description (Section 10.2) for more details.

5. INSTALLATION

5.1 DEVICE SETUP

When installing the device, ensure that:

- It is positioned on a level, non-slip surface that can support its weight.
- It is protected from water drips and splashes.
- It will not be subjected to vibration during operation.
- The mains connector cable is plugged into a socket with a fully functioning earth connection as per locally applicable medical safety standards and regulations.
- Disconnection from the mains power is readily accessible. The device is now properly installed.

5.2 CONNECTING THE ACCESSORIES

The device may be combined with Visionflex approved peripherals from other manufacturers.


Observe the instructions for use of the applied part.

5.3 CONNECTING THE DEVICE TO MAINS POWER

Use of the ProEX Mobile System Medical Grade Power Supply and Cable is recommended.

Proceed as follows:

- Check that the mains voltage at the site of operation corresponds to that in the User Manual and check the Earth connection.
- Insert the DC power cord of power supply into the power socket on the left-hand side of the device.
- Connect the supplied power cord to the power supply and to the mains
- Ensure the power switch is readily accessible
- When routing cables, ensure they do not present a trip or entanglement hazard

The device is now properly connected to power. Before each use, check that the device and accessories to be used are free of damage and in full working order.

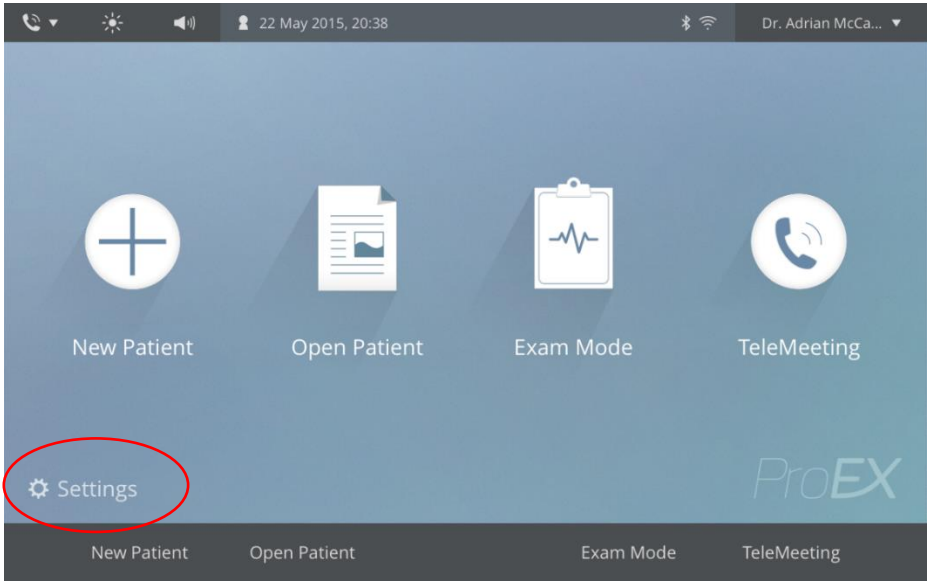

For compliance with IEC 60601-1-11: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment, the USB ports will not be active whilst the ProEX Mobile is connected to Mains.

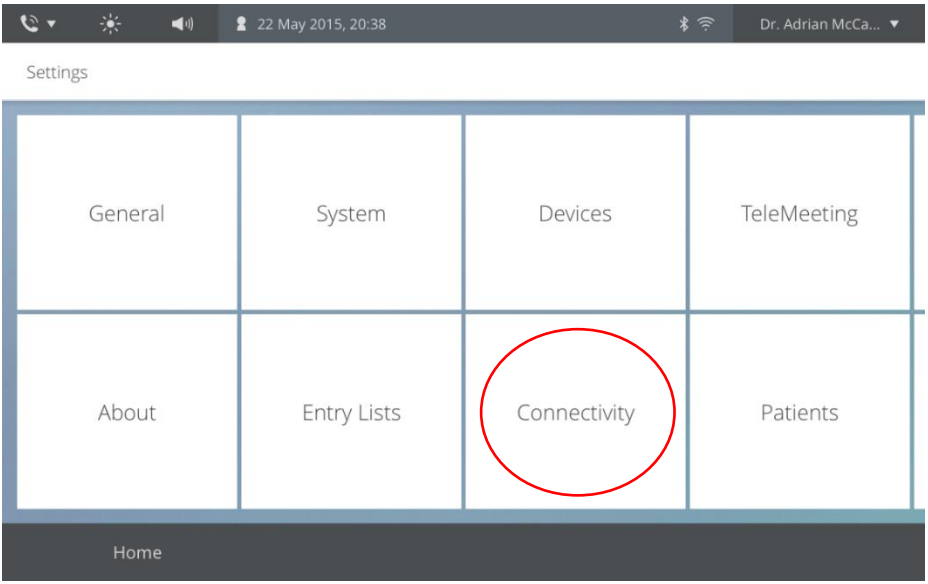
5.4 SIM CARD SETUP

5.4.1 TURN OFF MOBILE DATA

To receive a cellular mobile connection from your network provider the mobile data action must be turned off before installing your SIM card. To do this navigate to the

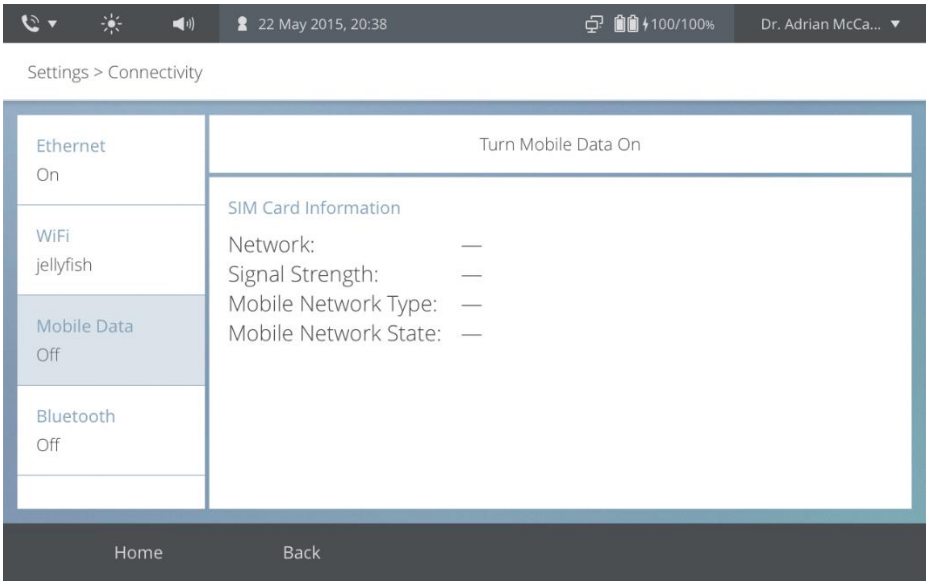
connectivity tile from your home screen by selecting **settings** and then push the **connectivity** tile.





Once on this page there are four bars on the left hand-side, Ethernet, Wi-Fi, Bluetooth and Mobile Data. Select the **Mobile Data** tab and turn off mobile data, press the **Home button** at the bottom and then turn off your ProEX Mobile. You can now proceed with installing the SIM card.

NOTE: Ensure your Mobile SIM service is activated on the chosen provider's network before installation.



5.4.2 SIM CARD REQUIREMENTS

The SIM card (Micro size SIM) should be a country specific SIM card or an Australian sim card (Australian Market).

Ensure you have the correct size card or card with adaptor 15mm x 12mm (Micro SIM Card).

Please note: Ensure your Mobile SIM service is activated on the chosen provider's network before installation

5.4.3 SIM CARD INSTALLATION

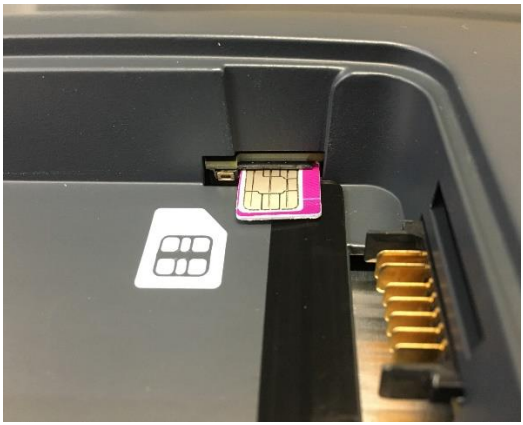
Ensure you have turned off Mobile Data in the **Settings** Menu. Turn off the ProEX Mobile and remove both batteries. To release a battery, slide the black button across and push the white button down simultaneously.

Locate SIM card installation slot in the left-hand battery slot.

Compare SIM card to supplied white SIM card image to ensure correct size and correct orientation for installation.

Insert SIM card below black guide, but above gold metal contact point as shown here. Press in until the SIM card clicks and holds inside the slot. It should be flush with the surface and not protruding:

Once complete, re-fit the batteries, turn ProEX Mobile ON, enter **Settings menu > Connectivity** and turn Mobile Data on.



For SIM card removal, ensure you push the SIM card further into the slot with a small object or fingernail (1-2mm until you hear or feel a click) and the spring will release the card.

5.4.4 ACTIVATING CELLULAR NETWORK

Now that you have installed the SIM card you can navigate back to connectivity, see the first step "**turn off mobile data"** and turn on the mobile data. The top right-hand corner of the ProEX Mobile should now display 4G and a signal strength meter

(stacked bar), confirming that the SIM card installation has been successful and there is a cellular signal detected.

6. OPERATION

6.1 ADMINISTRATOR ACCESS: DEFINING USER ACCOUNTS

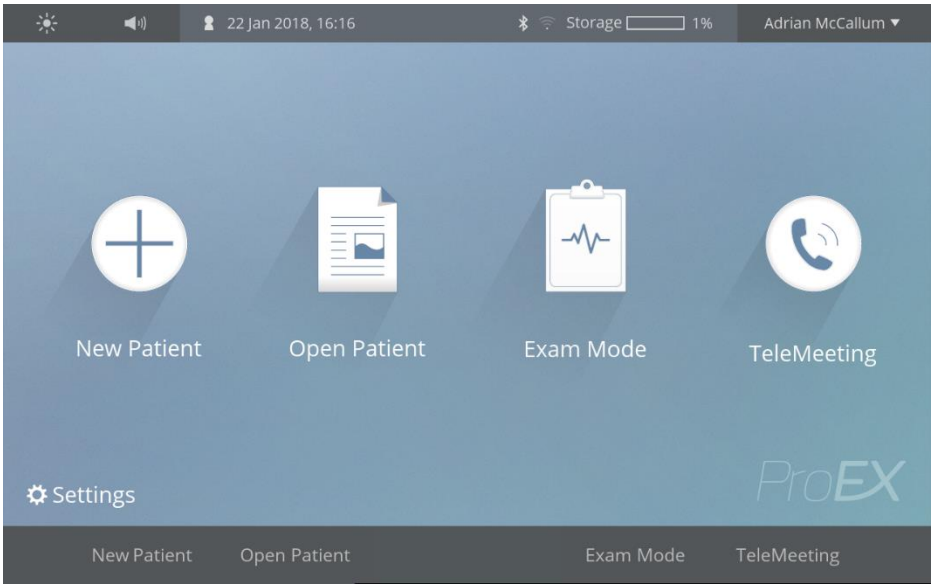
Administrators should initially define user accounts and decide on requirements for user account controls (PINs or passcodes).

6.2 START UP AND LOGIN

Turn on the **ProEX Mobile System** by pressing and holding the power button on the front panel, right side for 3 seconds. The **ProEX Mobile System** will vibrate on powering up.

Next, select login and enter your PIN or passcode if assigned by the administrator (change to your selected PIN or password after first login).

6.3 MAIN MENU AND BASIC WORKFLOW



- The main menu allows for the creation of a new patient, opening an already existing patient, entering exam mode directly or entering Telemeeting mode directly.

6.4 CREATING NEW OR OPENING EXISTING PATIENTS

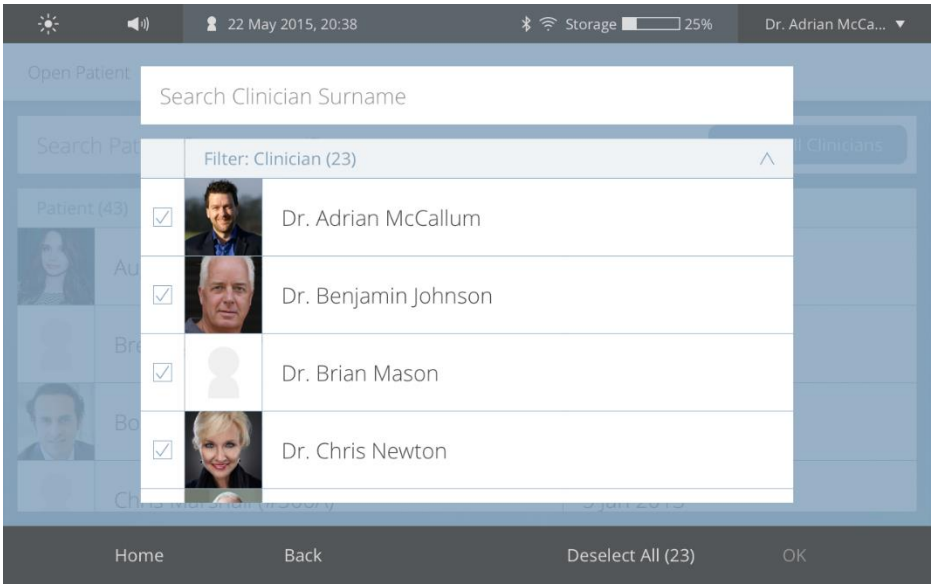
Once client details have been entered or a client profile opened, you can create a ***New Patient***, open an existing patient's data, ***Open Patient*** or go straight to ***Exam Mode*** using options on the touch screen or the buttons below.

The ***New Patient*** option allows you to enter and save a new patient's profile before creating a ***Session*** and proceeding to ***Exam Mode***.

The ***Open Patient*** option allows you to browse your existing patients. It comes with a search function for surname or patient ID.

From the ***Open Patient*** Overview screen, you can review previous patient ***Sessions*** and create new ***Sessions***.

Search filters are available for patient, clinician and procedure selection.

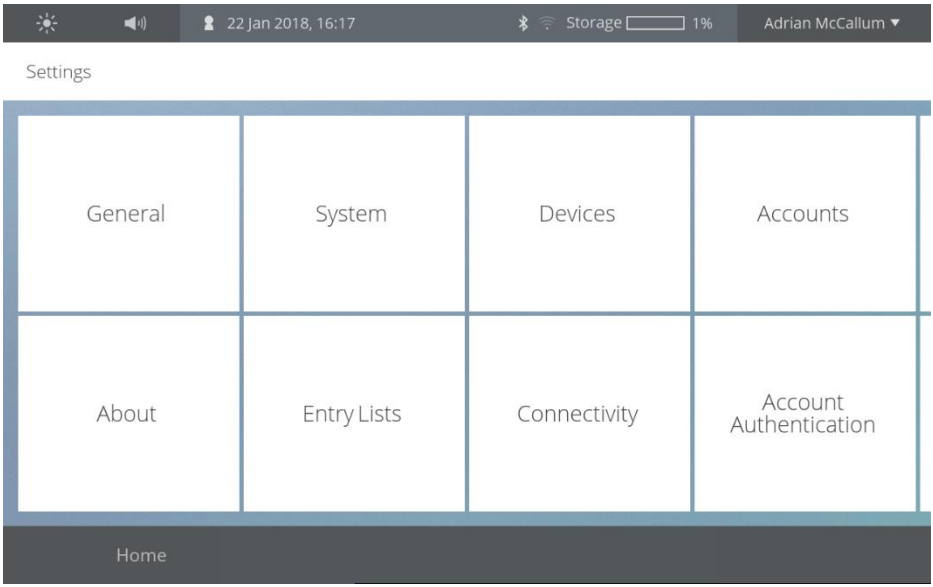


Once a patient is selected, the Exam Mode screen will appear where you can select the type of examination that you will be performing e.g. live video.

6.5 EXAM MODE

In the **Exam Mode** you can jump directly to the procedure you want to do next, for example, **Live Video** or **Stethoscope.** From the **Exam Mode** you have the option to capture still images or record video and/or capture images in a temporary storage gallery. When you are finished with recording, you can create a session for a new or existing patient and the new media will be automatically added to the session. You also have the option to create a new session before recording any media.

The Settings Menu of the **ProEX Mobile System** can be accessed from the Main Screen. It contains several different sections. You can use the settings menu to customize your **ProEX Mobile System** to suit your personal needs and preferences.

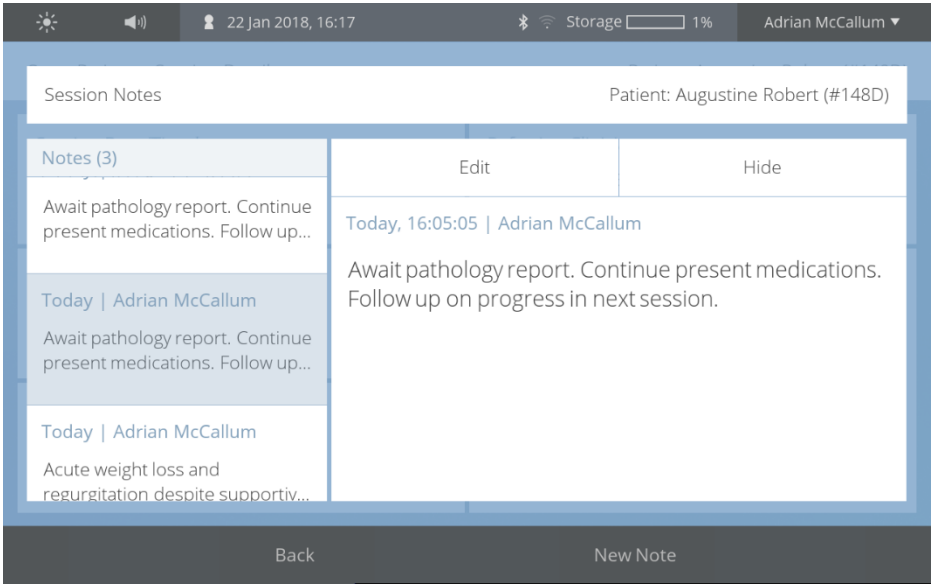


In the **Accounts** section you can manage the user accounts for your **ProEX Mobile System** device. You can also Enable/Disable the **Access Control** function and match the appropriate access level for each user account.

6.5.1 CREATING SESSIONS

Use the Home and Back keys to navigate back to the main menu or between Patient screens. Once you have entered the ***Session*** details you can add Notes under **Session Notes** or continue to the Exam Mode.

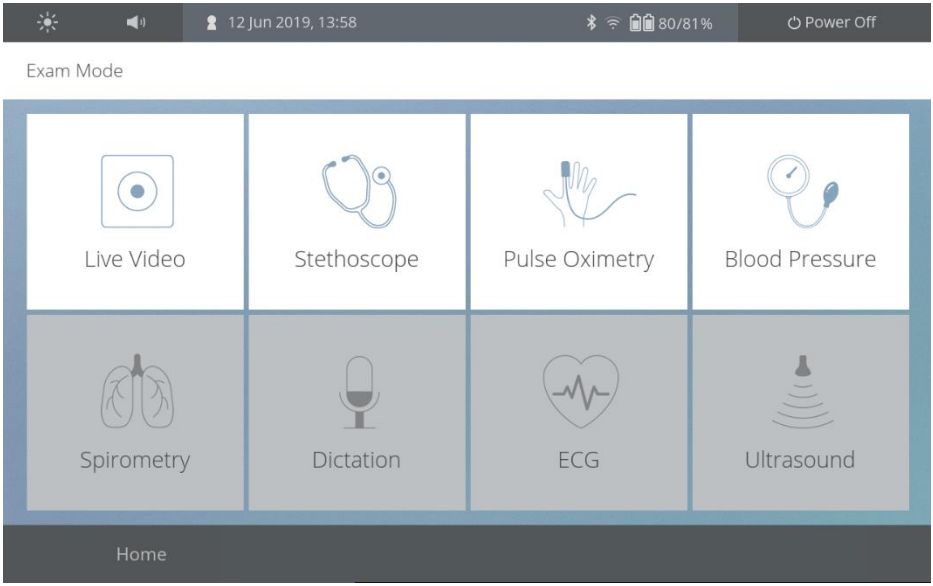
Existing Notes can be viewed and edited, or new Notes added against the ***Session***.



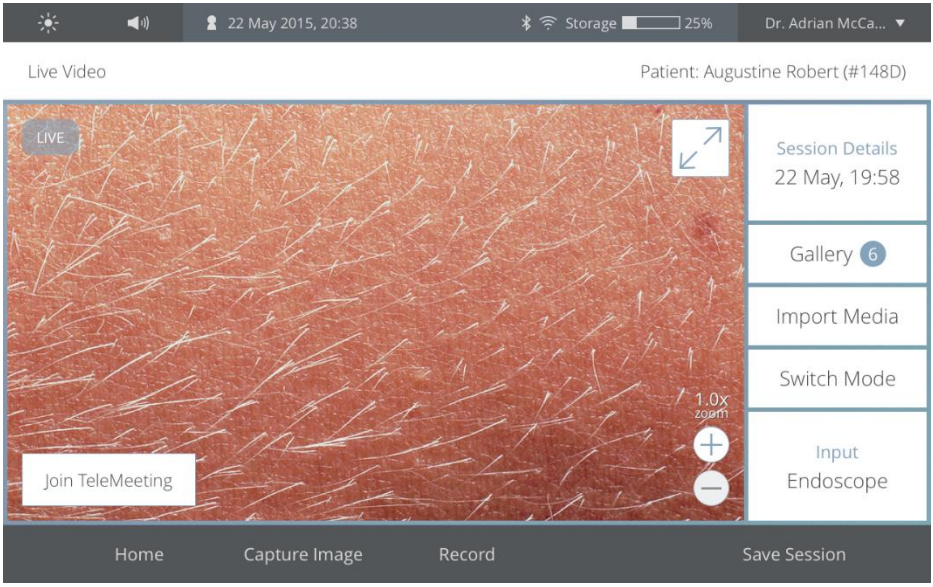
New Notes are saved by selecting ***Done*** on the touch screen or soft touch buttons.

6.5.2 CAPTURING STILL IMAGES AND RECORDING LIVE VIDEO

Enter the ‘Live Video’ function mode from the Exam Mode screen to capture media.



The Live Video screen will allow you to view video from the selected input. The video can be zoomed in or out by pressing the + & - buttons on the screen.



To capture still images and record video:

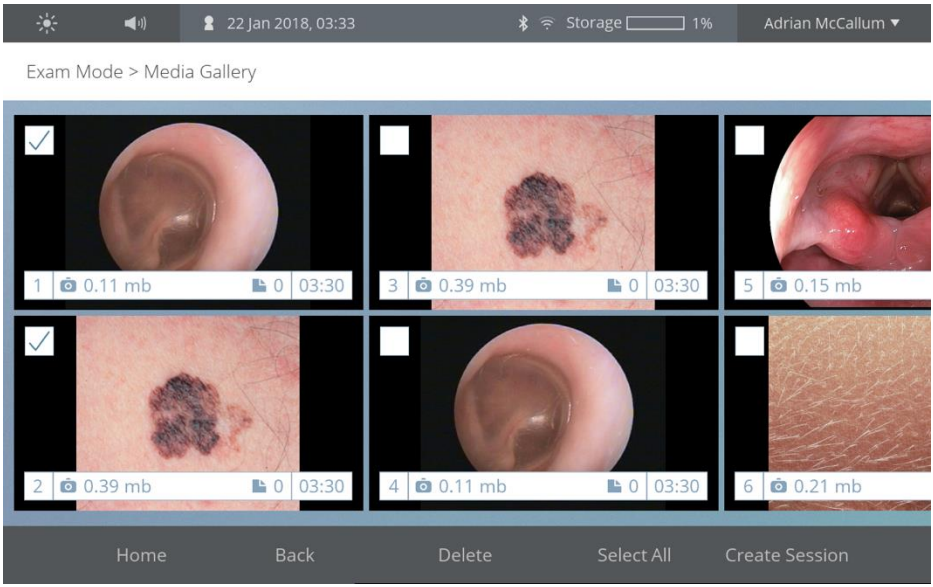
Images: When you see an image on the monitor that you want to capture, select the "***Capture Image***" option or press the Camera Shutter Button. The image will then be saved in the gallery.

Recording: If you want to record a video clip, select the "***Record***" option to start recording. The Blue Recording LED shall illuminate to indicate recording is in session. Select *"**Stop Recording**"* option to stop the recording. Recording can also be paused and re started. Recording can also be done from the remote control by pressing the 'Record' button. Once recording has been finalised the video file will be saved in the gallery.

IMPORTANT: When you **finish** capturing **all** the still images and video clips for your current patient, select the "***Save Session***" option and then select the "***New Patient***" option from the home screen to start capturing still images and videos for the next patient.

If images are being exported, a destination for the files can be selected.

The desired Images can be selected for viewing or ***exported*** to a storage device.

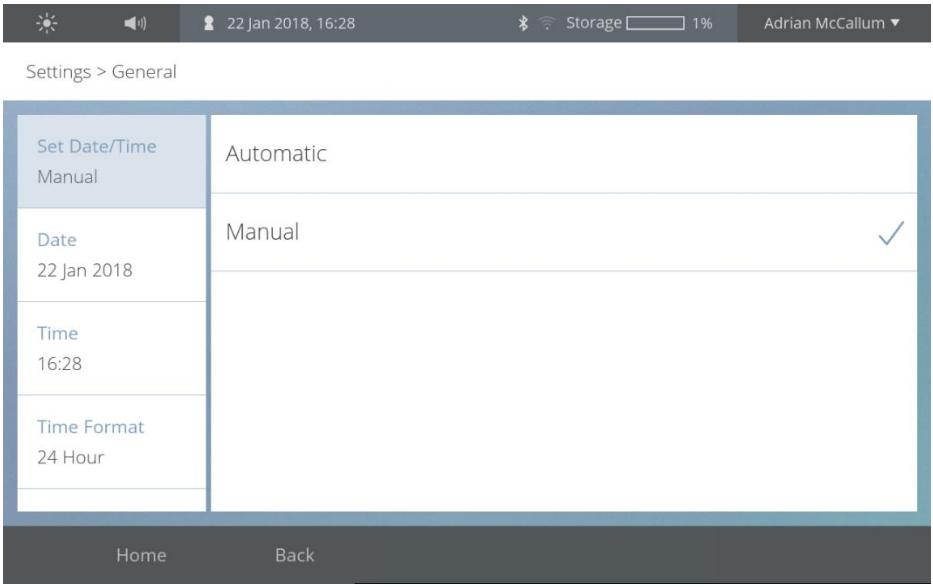


6.5.3 REVIEWING IMAGES AND VIDEO CLIPS

Image Review: To review images while in a 'Live Video' session, press on the gallery icon on the right side of the screen. Images and videos will be laid out in thumbnail form with the most recent images at the top. Images can also be reviewed from the patient screen by opening the desired session and scrolling through the available media. Pressing on any image will open the file for viewing. Images and video can be 'swiped' left or right to move to the next or previous image.

6.5.4 DATE / TIME:

In the **General** section you can set date and time. You have the option to set date and time by yourself or you can choose the Automatic option if you have an internet connection. When using the Automatic option, the **ProEX Mobile System** will set date and time on its own, furthermore you can choose if you want the time displayed in 12/24-hour format.



6.6 EXPORTING MEDIA

The **ProEX Mobile System** enables users to export media to a USB or network destination. To export media, tick the box of one or more media files in the gallery and press the **Export** button.

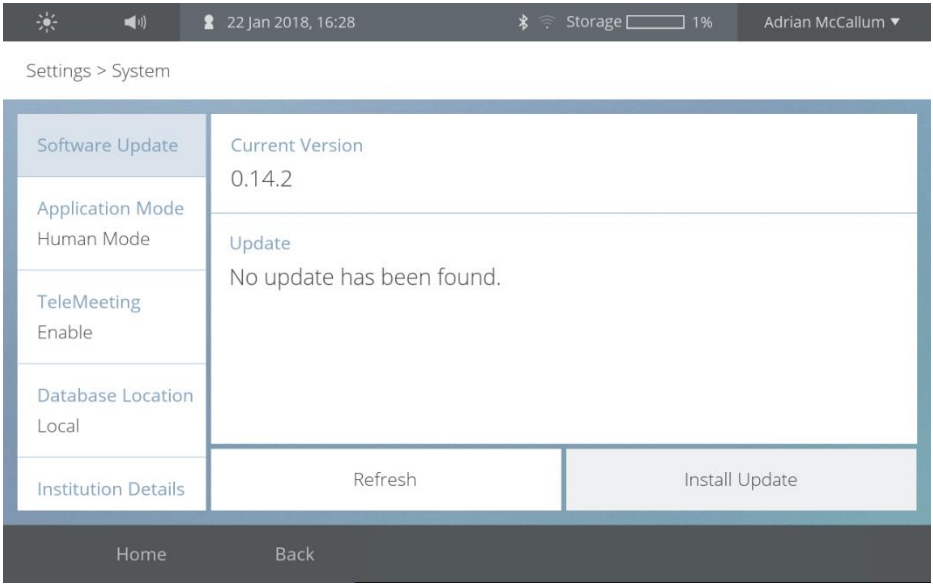
After pressing the **Export** button, the **Export** window will pop up. Here you can choose your destination and set an Encryption code for your files if desired.

6.7 CHANGING USER PROFILE

You have the option to logout and change the **User profile** at any time an active session is not running, without restarting your **ProEX Mobile System**. To change the **User Profile** tap on the currently active Login profile in the top right corner. A Logout-Field will appear in the top right corner. After tapping the Logout-Field, you can login with a different **User Profile**.

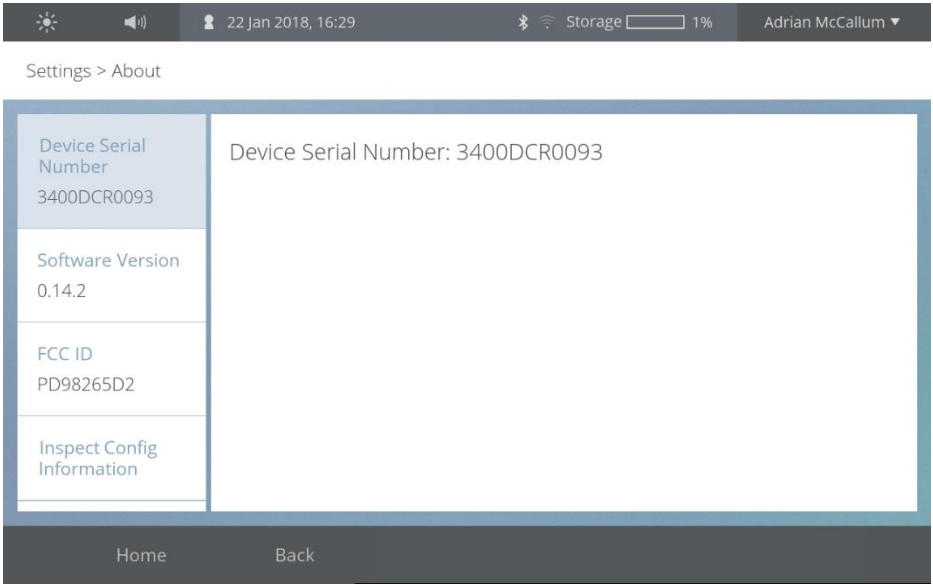
6.8 SOFTWARE VERSION AND UPDATES

In the **System** section of the Settings Menu, you can check the current version of the Software and also install software updates by downloading the latest update file to a USB stick. You can choose between local and remote databases. The **Format Database** option will delete all data from the local database, which includes accounts, patients and procedures data. You can reset the settings to "Factory Default" by executing the **Reset All Settings** option.

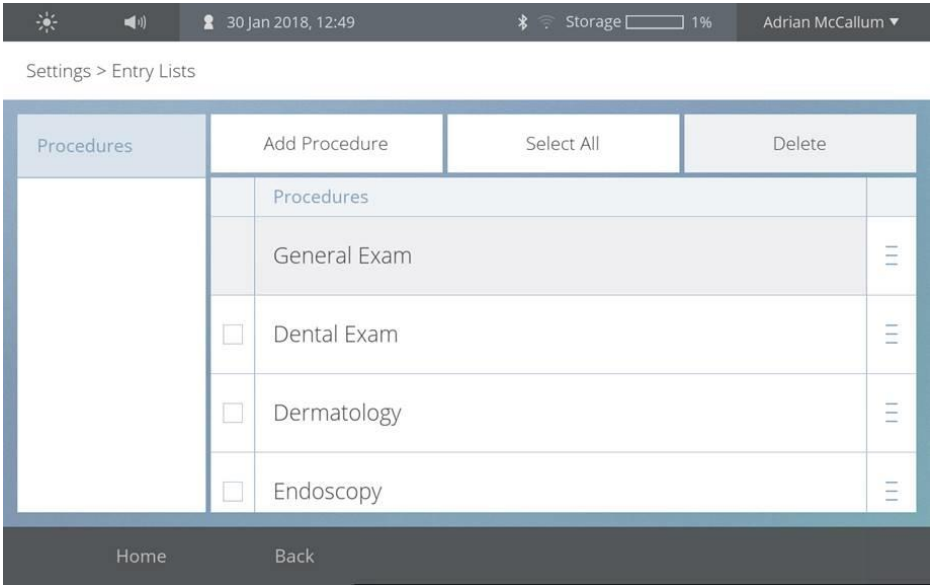


In the **Devices** section you will find the custom settings for all your attachable devices.

In the **About** section you will find the Serial Number of your **ProEX Mobile System**. Furthermore, you can inspect the configuration information.



In the **Procedure** section you can manage the procedures for your **ProEX Mobile System**. You can add new procedures and delete existing ones. The order of the procedures can also be changed by pressing on any one of the existing procedures for more than 2 seconds and then moving that procedure up or down to the desired location.



In the **Connectivity** section you can manage the Bluetooth, WiFi and Mobile Data settings of your **ProEX Mobile**. With a few easy steps you can connect Bluetooth devices (Keyboards, medical devices, etc.) to your **ProEX Mobile System** or connect your device to a WiFi or Mobile network.

7. POWERING OFF

The **ProEX Mobile System** can be powered off using the power button as indicated in Figure 1. The Power Off option is also available on the top toolbar from any screen. A message will appear on the screen asking the user if they are sure they wish to shut down?

The **ProEX Mobile System** should be shutdown properly through the software or by pressing the power button and following the prompts. ***NOTE:*** *Unplug the power supply unit to disconnect the unit from mains voltage***.**

8. CLEANING AND DISINFECTION

8.1 CLEANING OF THE **PROEX MOBILE**

The **ProEX Mobile System** housing and touchscreen can be cleaned by wiping with a dry cloth. Do not insert the **ProEX Mobile System** into liquids.

WARNING: The **ProEX Mobile System** should be disconnected from its power supply during cleaning.

Do NOT attempt to sterilise the device (e.g. through autoclaving or irradiation or ethylene oxide).

All exterior surfaces of the **ProEX Mobile System** can be wiped with a soft cloth. Clean the unit using a clean, soft cloth dry or moistened with a small amount of disinfectant when required for infection control.

The following cleaning disinfectants are tested and verified for use:

- Clinell Universal Wipes,
- CIDEX, Viraguard, Control III Disinfectant Germicide, Caviwipes, Dispatch Disinfectant Cleaner CLH69101 and Puregreen 24 Disinfectant.

Do NOT use other cleaners or solvents, they could damage the paint or labels on the housing. Do not use wet sponges or cloths since this could lead to liquid reaching the electrical parts which could lead to injury and cause damage to the device.

Only connect the unit again after all cleaned parts are totally dry.

9. MAINTENANCE

The ProEX Mobile System device has no user replaceable internal serviceable parts. If for any reason the ProEX Mobile System fails, please contact the manufacturer as per details at the end of the manual.

10. PRODUCT DATA

10.1 COMPATIBILITY WITH OTHER MEDICAL DEVICES/EQUIPMENT

The device may be combined with Visionflex approved peripherals from other manufacturers. The list of approved peripherals is available on the Visionflex website.

There is a pop-up message displayed on the device that indicates if the peripheral is not approved; User is to contact Visionflex for more information.

It is the User's responsibility to check and make sure that the system is and remains fully operational. Contact our service department if you have any questions regarding compatibility.

10.2 TECHNICAL DESCRIPTION

Model	ProEX-Mobile
Case	3mm ABS + PC TYPE Plastic Housing with a Magnesium rear cover
Power Supply	Input: 100-240V AC @ 50-60 Hz Output: 12V, 7.5A, 90W max. (use only the power pack supplied)
Image Formats	JPEG
Video Formats Audio Formats	MPEG4/MP4 MP3
Dimensions (W x H x D)	312 (W) x 239 (H) x 37 (D) mm
Weight	ProEX Mobile, approximately 1.8 kg
Protection class acc. To IEC 60601 – 1	Class I
Ingress Protection (IP) rating	IP54
Network Interfaces	Ethernet Gigabit LAN, 3G/4G/LTE, WiFi (802.11 a/b/c/n)
Classification	• Class I medical device: US, EU and AU • Class II medical device: Canada only
Battery Type	Lithium-ion
Battery Capacity	Capacity 4545 mAh x2
Battery Run Time	Approx. 5 hrs
Speaker	2W x 1

Relevant Standards	
EN ISO 13485:2016	Medical devices – Quality Management System Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance Ed. 3.1
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability Ed 3.1
EN 60601-1-11:2015	Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 62366:2006	Medical devices – Part 1: Application of usability engineering to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied part 1 General Requirements.
EN 1041:2008	Information Supplied by the Manufacturer of Medical Devices

10.3 AMBIENT CONDITIONS

Operating, Transport and Storage Conditions

Operating Temperature	0 to 40°C
Operating Humidity	Up to 75% RH, non-condensing
Operating Pressure	700 hPa to 1060 hPa
Storage Temperature	-25°C + 70°C (-13° + 158°F)
Storage Humidity	Up to 95%, non-condensing
Storage Pressure	700 to 1060 hPa
Vibration tests 30 min per perpendicular axis (3 total)	10 Hz to 100 Hz: 1,0 $(m/s^2)^2/Hz$
	100 Hz to 200 Hz: - 3 db per octave
	100 Hz to 200 Hz: - 3 db per octave
Shock test, 3 shocks per direction per axis	30g peak acceleration (11 msec. duration) / operation, half-sine,
Drop (with packaging)	80cm, (1 Corner, 3 Edge, 6 Surface)
EMI / Safety	CE/FCC Class B, UL60601-1, EN60601-1, E1, EN1789

11. TECHNICAL SUPPORT AND REPAIR

To arrange for repair of the device, please visit www.visionflex.com.au or call 1300 059 926 (toll free within Australia) or +61 2 8438 9898 (from outside Australia).

NOTE*:* For fast processing of service requests, please return the product with the following information: **Return authorisation number, model number, serial number and detailed description of the problem.**

Guarantee and warranty claims will not be accepted if the user or a non-authorized repair centre effects maintenance or repair on its own.

WARNING: For the protection of staff, thoroughly clean and disinfect the product (and if applicable, sterilize accessories) before shipment.

The repair centre can refuse the repair of contaminated product due to safety reasons.

12. WARRANTY

The Manufacturer commits to a 12 month 'Back to Base' guarantee on the functioning of the ProEX Mobile. This guarantee is restricted to claims presented within the guarantee period starting from the date of the purchase of the ProEX Mobile System giving details about repairs along with the invoice number.

This guarantee is only applicable to defects that cannot be attributed to normal wear and tear, misuse or incorrect handling, lack of proper care or Acts of God.

13. DISPOSAL

Any product carrying this symbol must be disposed of separately through dedicated electrical and electronic devices recycling. Within the EU, such disposal is taken care of by the manufacturer free of charge.

14. INFORMATION ABOUT THIS DOCUMENT

These instructions are an integral component of the device and contain all the information required by users for safe and proper use.

These instructions must be stored in a defined location so that they may be accessed at all times by the target group.

In the event of the sale of the device or its relocation, this document must be provided to the new owner.

15. KEY TO SYMBOLS

Symbol	Title
	**WARNING:** Indicates the need for the user to consult the user manual for important warnings that cannot be presented on the medical device itself.
	**CAUTION:** Indicates the need for the user to consult the user manual for important cautionary information that cannot be presented on the medical device itself.
	Refer to instruction manual/booklet Note: On ME Equipment “Follow instructions for use”
	Permissible storage and transport temperature
	Manufacturer
	Serial number
	Separate collection for WEEE (waste of electrical and electronic equipment)

	Packaging widely recycled - The universal recycling symbol (U+2672 ♲ UNIVERSAL RECYCLING SYMBOL in Unicode) is internationally recognized for recycling activity
	CE mark. The device satisfies the requirement of Council Directive 93/42/EEC
	Authorised Representative
	Industrial Design Registered in Canada
	Medical Device

MD

visionflex
Equality healthcare

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