visionflex
Equality healthcare

ProEX System

CLINICAL USER MANUAL

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

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

VFPXMANCLIN1.07

1 PRODUCT DESCRIPTION

The **ProEX 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 visualisations.

Featuring a high-end multi-core processor and advanced electronic design, the **ProEX 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 via USB.

2 SYSTEM CONTENTS

There are several variants of the ProEX System available to order. Included with all variants are the following:

All ProEX Systems contain the following common parts:	**Part Number** **UDI***	**Quantity**
Pre-installed Linux based software	N/A	1
ProEX System Medical Grade Power Supply Unit	PXEL0030	1
Remote Control	VFPXREMOTE1	1
ProEX System User Manual	VFPXMANCLIN2	1
Footswitch	VFS100	1
Mains Power Cable (Country depending)***	PXEL00XY	1
ProEX Variants *	**Part Number** **UDI-DI***	**System Number** **UDI***
ProEX Standalone unit	VFPROEX21.03 09352527001161	VFPROEXKIT21.03 09352527000768
ProEX System (FSC2 Version PAL)	VFPROEX22.03	VFPROEXKIT22.03

	09352527001178	09352527001291
ProEX System (GEIS Version)	VFPROEX23.03 09352527001185	VFPROEXKIT23.03 09352527001307
Camera Cradle Variants**		
FSC2 Cradle	PSXU0009	
GEIS Cradle	PXSU0010	
Mains Power Cable Variants***		
AU Mains Power Cable	PXCB0031	
US/CANADA Mains Power Cable	PXCB0032	
UK Mains Power Cable	PXCB0038	
EU Mains Power Cable	PXCB0039	

*Where applicable

Figure 1
Legend: ProEX Front

- A Touchscreen
- B Face camera
- C Built in microphone
- D Recording LED
- E Optional camera cradle accessory
- F Power button
- G USB 2.0
- H Microphone / socket
- I Headphone

Figure 2
Legend: ProEX Rear

- 1 Audio in/out
- 2 LAN
- 3 USB video
- 4 USB 3.0 (x2)
- 5 HDMI in/out
- 6 Remote control
- 7 Remote control holder
- 8 Power
- 9 Foot switch
- 10 S-Video in
- 11 Composite in
- 12 DVI in/out

3 BASIC SAFETY INSTRUCTIONS

Before using the **ProEX System**, users must read this User Manual in its entirety.

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

- Only use the product in a fault-free condition.
- Heed all cautions and warnings in these instructions.
- Although this device has been designed to the current state of the art, 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.
- 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; or does not operate normally; or has been dropped.
- Keep the original packaging. Transport the device in its original packaging and use it to return goods if service support is required.

WARNING: Unauthorised modifications to the device may result in risk of serious injury to persons. Do not make any unauthorised 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 System with any other power supply.

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

WARNING: To avoid the risk of electric shock, do not operate the device with the covers removed. 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 System.

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 System with electrical devices from different manufacturers and connecting type BF accessories ensure these are compliant with either IEC 60950 (general electrical equipment) or IEC 60601-1 and the entire system created complies with Clause 16 of IEC 60601-1.

WARNING: When using devices from different manufacturers and when operating an endoscope and/or endoscopic accessories with electrical medical devices, it must be ensured that the applied part is properly isolated (in accordance with the requirements for BF/CF applied parts defined in IEC 60601-1).

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.

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 System is 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: To avoid the risk of fire, short circuit or electric shock, peripheral devices should be connected prior to powering on the device.

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 the use of multiple sockets.

CAUTION: Only connect a Schoelly FSC2 endoscope to the front endoscope socket (FSC2 variant only)

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

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.

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: Handle the device with appropriate care. Do not kink, crush or sharply bend the camera cable. If the device is dropped or subject to high mechanical stress, stop using it and send into the manufacturer for inspection.

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 System including cables specified by Visionflex. Otherwise, degradation of the performance of this equipment could result.

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

NOTE: The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR class B). It shall not be used in residential areas.

NOTE: The unit is designed for safe operation at or below 2,000 m above sea level only.

NOTE: The ProEX System and its accessories are intended to be used within the patient environment.

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 INDICATIONS FOR USE

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 life;

- 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 ON-SITE SET UP

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 is plugged into a socket with a fully functioning earth connection as per locally applicable medical safety standards and regulations.
- The ventilation slots are not obstructed.
- Disconnection from the mains power is readily accessible.

The device is now properly installed.

5.2 CONNECTING THE ACCESSORIES

5.2.1 CONNECTING PROBES AND SCOPES

The device may be combined with Visionflex approved peripherals from other manufacturers. Connect probe connector to the connection point on the front panel of the **ProEX System** prior to powering on the device.

 Consult probe/scope's user manual for instructions on attaching and removing the probes.

5.2.2 CONNECTING MONITORS

Multiple monitors can be connected.

 Observe the instructions for use of the monitor.

Proceed as follows:

- Connect monitor to rear panel using cable (not supplied)
- Secure the connection cables at both ends to prevent them from being pulled out inadvertently
- When routing cables, ensure they do not present a trip or entanglement hazard

5.2.3 CONNECTING A FOOTSWITCH

- Only connect footswitches that have ingress protection IPX1 or higher.
- Connect the footswitch cable to the rear panel footswitch socket
- When routing the cables, ensure they do not present a trip or entanglement hazard.

5.2.4 CONNECTING TO THE MAINS POWER

Only connect the power supply to the mains after connecting all peripheral devices per above instructions.

The use of an uninterruptable power supply (UPS) is recommended to protect against input power interruptions or surges.

Proceed as follows:

- Check that the mains voltage at the site of operation corresponds to that in the User Manual.
- Insert the 12 V DC power cord of power supply into the corresponding power socket on the rear of the device.
- Connect the supplied power cord to the power supply and to the mains supply
- Ensure the mains 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.

6 OPERATION

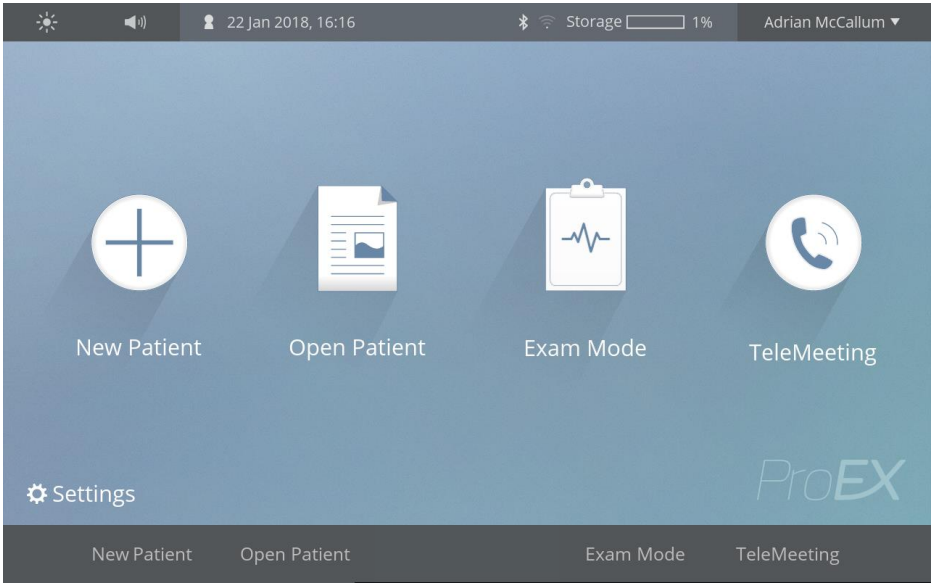
6.1 ADMINISTRATOR ACCESS: DEFINING USER ACCOUNTS

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 System** by pressing the power button on the front panel. The power button illumination will change from white to green and the **ProEX System** will power up (this may take a few seconds).
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 creation of a new patient, opening an already existing patient, entering exam mode directly or entering Telemeeting mode directly.

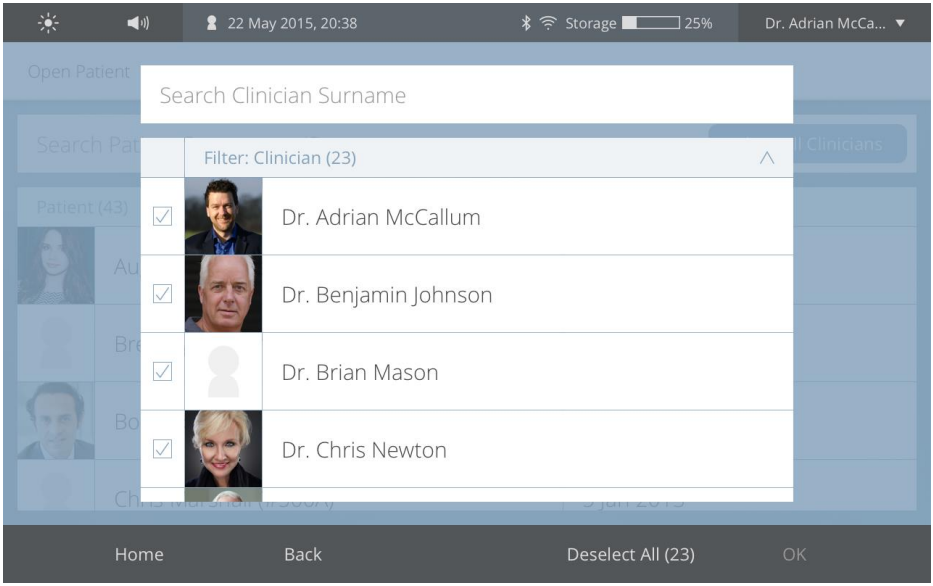
6.4 CREATING NEW OR OPENING EXISTING PATIENTS

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.



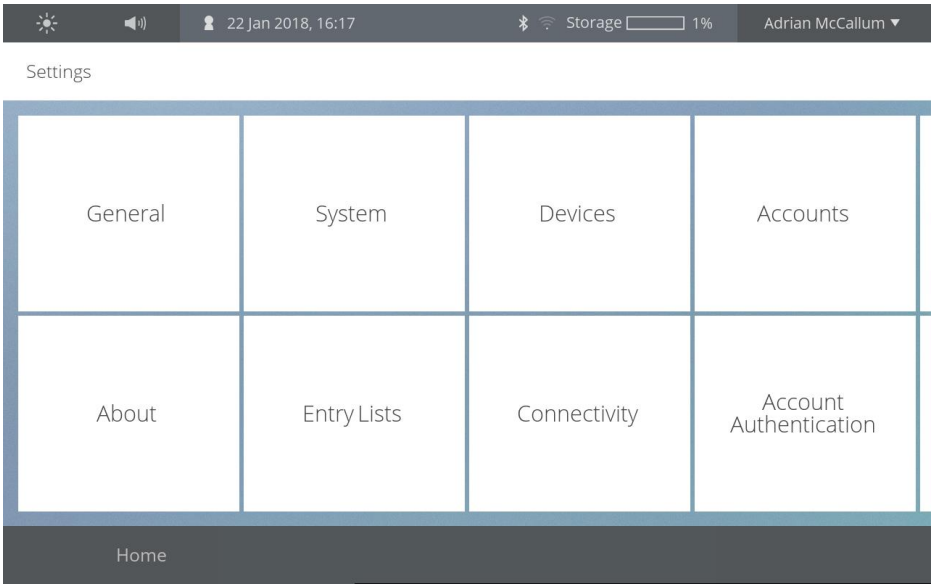
Once a patient is selected, the Exam Mode screen will appear where you can select the type of examination that you will be performing e.g. live video.

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. Settings Menu

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

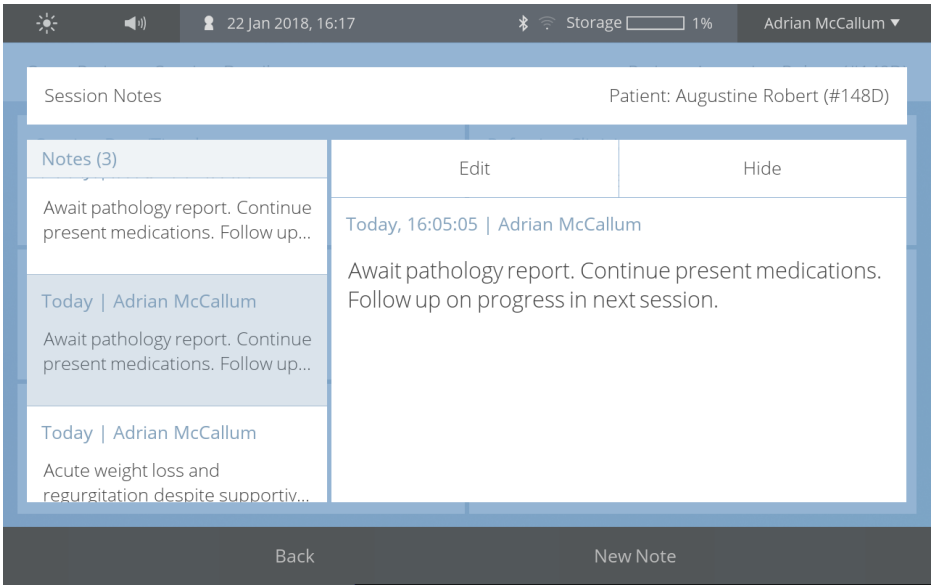


In the **Accounts** section you can manage the user accounts for your **ProEX System** device. You can also Enable/Disable the **Access Control** function and match the appropriate access level for each user account.

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.

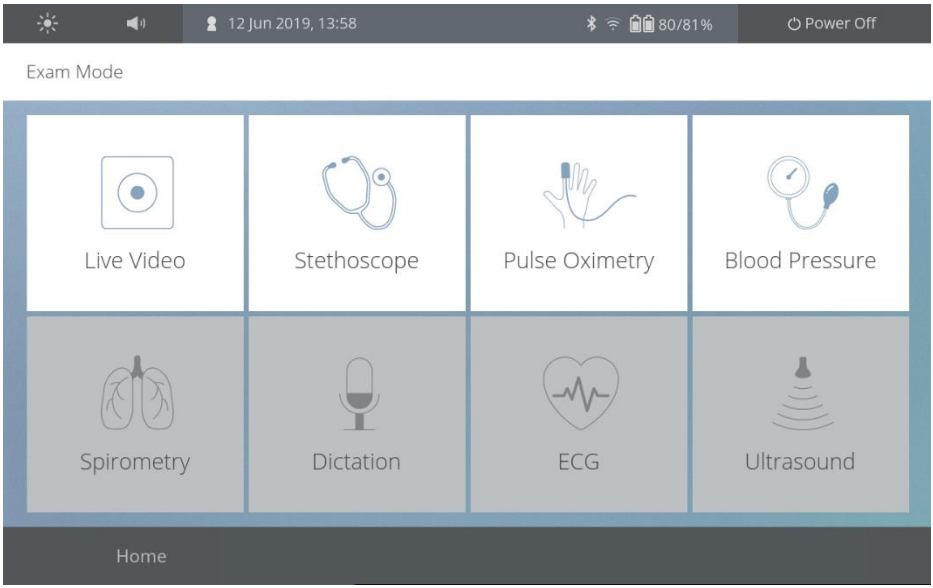
Existing Notes can be viewed and edited, or new Notes added against the ***Session***.



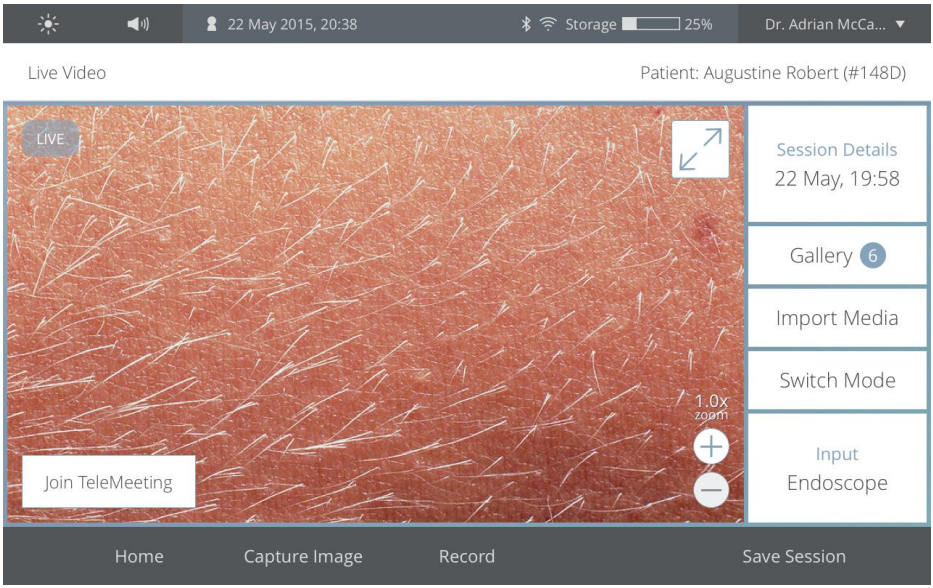
New Notes are saved by selecting ***Done*** on the touch screen or soft touch buttons.

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.



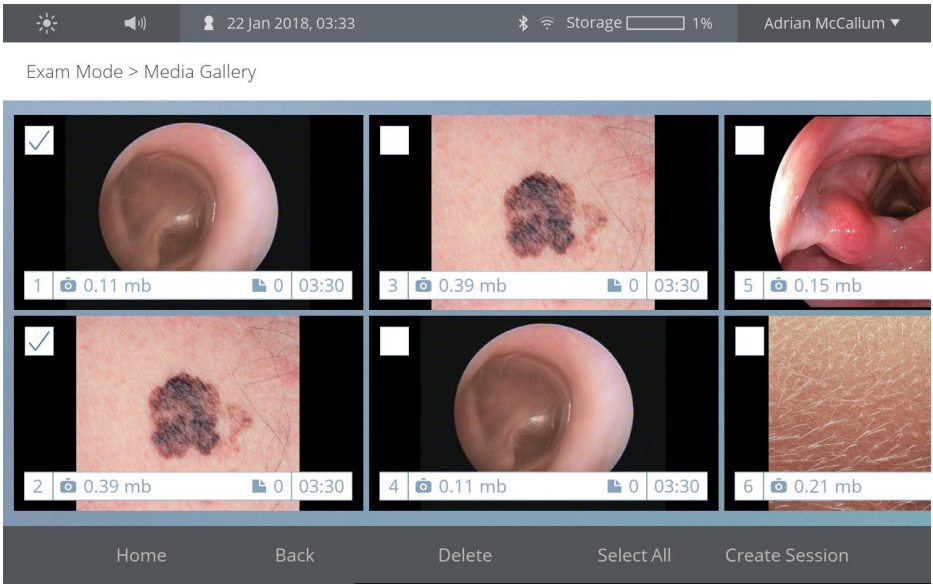
To capture still images and record video:

> ***Images***: When you see an image on the display that you want to capture, select the "***Capture Image***" option. The image will then be saved in the gallery. Pressing the footswitch or the 'Image Capture' button on the remote control will also capture still images.
>
> ***Recording:*** If you want to record a video clip, select the "***Record***" option to start recording. 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. The blue recording LED on the right side of the face camera indicates whether recording is in progress.

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.

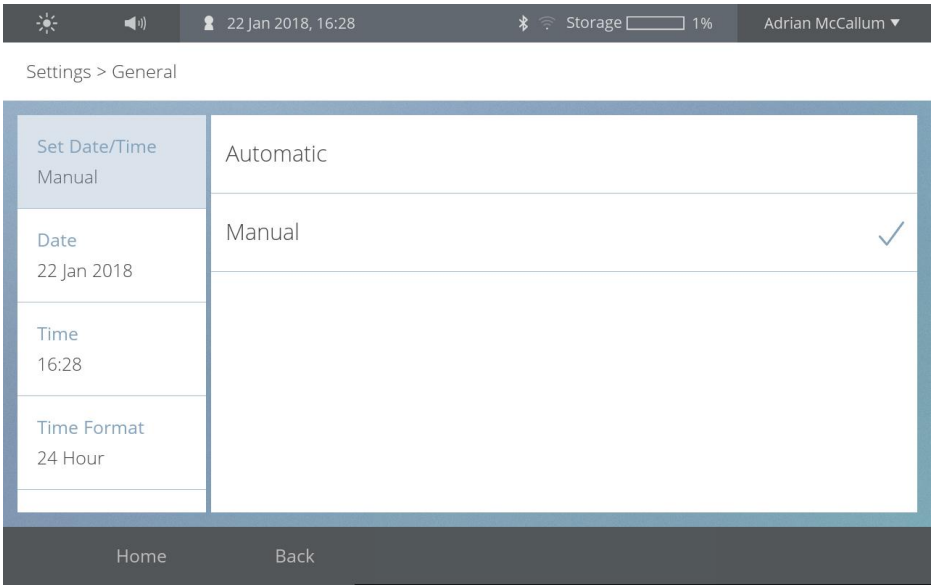


6.5.3 REVIEWING IMAGES AND VIDEO CLIPS

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 of the settings, 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 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 System** enables users to export media to a USB Memory Stick 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.

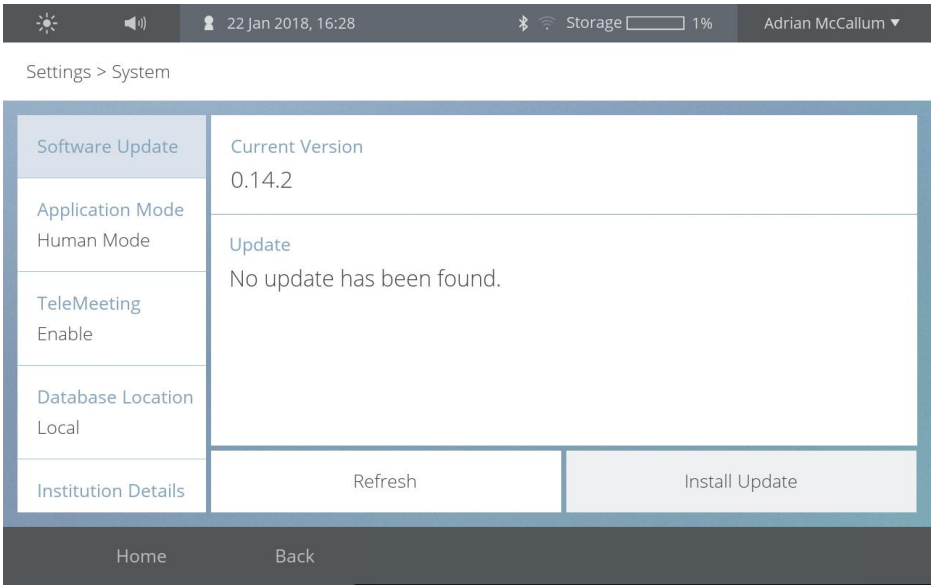
6.7 CHANGING USER PROFILE

You have the option to logout and change the **User profile** at any time an active session is not running, without restarting your **ProEX 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

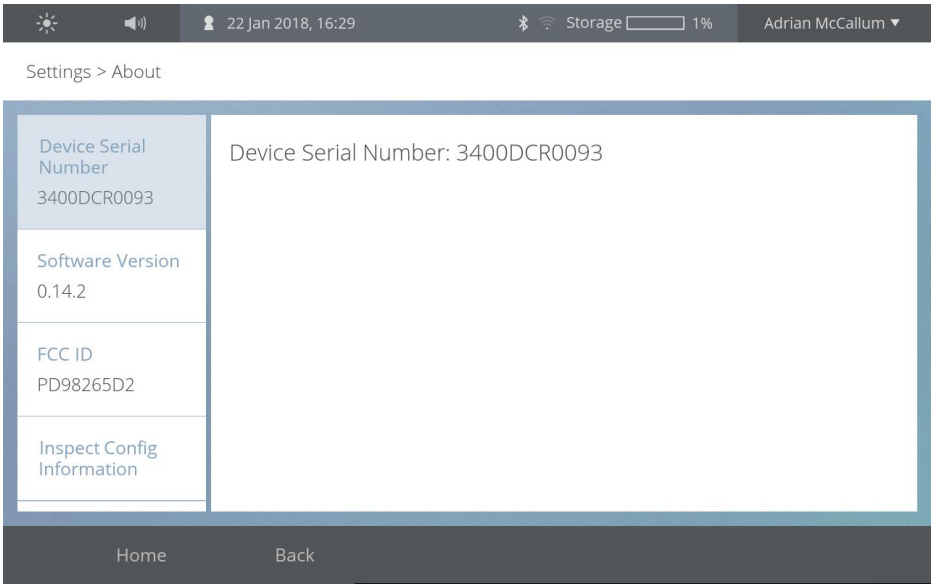
In the **System** section of the Settings Menu, you can check the current version of the Software and also install software updates by downloading the latest update file to a USB stick. You can choose between local and remote databases.

CAUTION: 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.

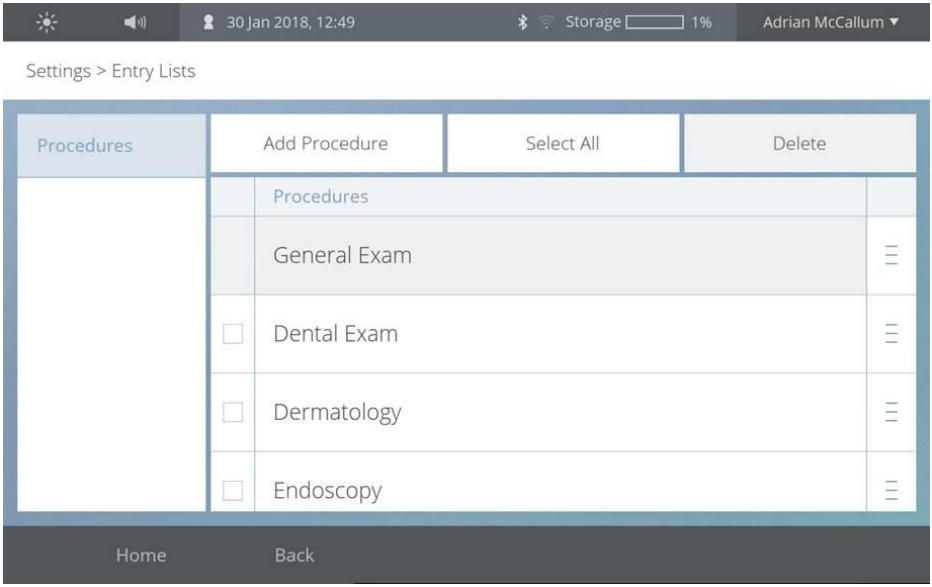


In the **Devices** section you will find the custom settings for all your attachable devices.

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



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

7 POWERING OFF

The **ProEX System** can be powered off using the front power button (item 'F') in Figure 1 (on page 6). The Power Off option is also available on the top toolbar from any screen. A message will appear asking the user if they are sure they wish to shut down?

The ProEX System should be shutdown properly through the software or by pressing the power button and following the prompts. Power to the unit should never be removed without first shutting down the ProEX.

***NOTE:** Unplug the power supply unit to disconnect the unit from mains voltage.*

8 CLEANING AND DISINFECTION

8.1 CLEANING OF THE **PROEX SYSTEM**

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

WARNING: The **ProEX System** Unit 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 can be wiped with:

- Clinell Universal Wipes,
- a soft, lint-free dry cloth,
- a soft cloth moistened with a small amount of 96 % ethanol (C_2H_6O) or 70% isopropyl alcohol (C_3H_8O) when required for infection control.

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 mains power supply to the ProEX System again after all cleaned parts are totally dry.

8.2 CLEANING OF THE **PROEX SYSTEM** REMOTE CONTROL

All exterior surfaces of the **ProEX System** Remote Control device can be wiped with a soft cloth. Clean the unit using a clean, soft cloth dry or moistened with a small amount of ethanol (C_2H_6O) or isopropyl alcohol when required for infection control.

Do NOT use other cleaners or solvents, they could damage the paint or labels on the Remote Control housing. Do not use wet sponges or cloths since this could lead to liquid reaching the electrical parts which could lead to damage to the device. Only use the Remote Control again after all cleaned parts are totally dry.

9 MAINTENANCE

The **ProEX System** has no user replaceable internal serviceable parts. If for any reason the **ProEX System** device fails, please contact Technical Support, contact details at the end of the manual.

10 PRODUCT DATA

10.1 COMPATIBILITY WITH OTHER MEDICAL / ELECTRICAL 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 System clinical mode (variant as per 'System Contents')
Case	Plastic housing, flame rated to UL 94V-0
LCD Display	10.1" full colour, 1280 x 800-pixel resolution with capacitive touch panel
Built-in Speakers	Menu selectable volume control (for audio confirmation only, not for diagnosis)
Video Input	CVBS (composite video) (PAL/NTSC) S-Video (PAL/NTSC) DVI-D HDMI v1.4
Video Output	DVI-D HDMI v1.4
Audio Input	Line In: Standard 3.5mm stereo jack socket Microphone jack: Standard 3.5mm mono jack socket

Audio Output	Headphone jack: Standard 3.5mm stereo jack socket Line Out: Standard 3.5mm stereo jack socket
USB Support	**Front panel (for use with patient peripherals):** 2 x USB3.0 powered 5V @ 500mA **Rear panel:** 2 x USB 3.0 for additional options, including backup drives
Footswitch	For hands-free capture (compatible with footswitches that have ingress protection rating IPX1). Standard 3.5mm mini jack socket, maximum voltage 250V/10A
Power	12 Vdc, 7 A Plug Pack (use only the approved power pack supplied)
Fuse Rating (internal, Service Personnel only)	Fuse rating FF10AH125V
Image Formats	JPEG
Video Formats	MPEG4
Audio Format	MP3, WAV, OPUS
FCC ID ProEX	Specified in Software (Home – Settings – About)
FCC ID Remote Control	Printed on rear of remote control
Dimensions (W x H x D)	ProEX System with cradle (FSC2 or GEIS): 320 (W) x 260 (D) x 130 (H) mm ProEX System without cradle: 280 (W) x 260 (D) x 130 (H) mm
Weight	ProEX System+ Remote Control (inc batteries), approximately 3.7kg ProEX System+ Remote Control (inc batteries) + power supply, approximately 4.3kg
Power Supply Rating	Powerbox ATM090T-A120, 100-240 VAC, 50-60 Hz, Medical grade, Continuous Output 12VDC,7.0A, 84W Max. For class II solutions: Powerbox ATM090T-P120, 100-240 VAC, 50-60 Hz, Medical grade, Continuous Output 12VDC,7.0A, 84W Max.
System Voltage	110-240 VAC using an external power supply
Protection class acc. To IEC 60601-1	Class I

Ingress Protection (IP) rating	IP21
Interfaces	Ethernet, Bluetooth v4.0, WiFi (802.11 a/b/c/n)
Protection type	Insulated case
Classification	Class I medical device (US, EU, AU) Class II medical device (CA)

Relevant Standards	
EN ISO 13485:2016/AC:2016	Medical devices – Quality Management System Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN 60601-1:2006 / A1:2013 / A11:2011 / A12:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance Ed. 3.1
EN 60601-1-2:2014	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 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

Transport and storage conditions	
Temperature	-25 +75°C
Rel. air humidity	Up to 95% RH (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa
Operating conditions	
Temperature	0 – 40°C
Rel. air humidity	Up to95% RH (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa Note: The ProEX System is not designed to be operated at over 2,000m above sea level

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 200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2/Hz$
Shock tests, 3 shocks per direction per axis	15g peak acceleration (11 msec. duration) / operation, half-sine,

11 TECHNICAL SUPPORT AND REPAIR

Should you need to arrange a repair or technical support for 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 a fast processing of your service requests, please return the product with the following information: **Return authorisation number, model number, serial number & detailed description of the problem.**

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

WARNING: For the protection of your staff as well as the staff at the repair centre, 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

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

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

13 DISPOSAL

When disposing of or recycling the device and its components, the applicable national regulations governing waste disposal and recycling must be adhered to.

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

These instructions for use must be stored in a defined location so that the user group may easily access it.

In the event of the sale of the device or its relocation, this document must be handed over 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”
	**Non-ionising radiation:** To indicate equipment that contain RF emitters
	Manufacturer
	Serial number
	Footswitch – to identify the connection for a footswitch
	Microphone
	Headphones
	Local Area Network (LAN) Connection
	Audio In Connection

	Audio Out Connection
	Direct Current
	Separate collection for WEEE (Waste 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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EC REP

CE

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