OPERATORS MANUAL

Smith+Nephew
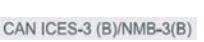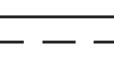
INTELLIO◇

Tablet

Glossary of Symbols
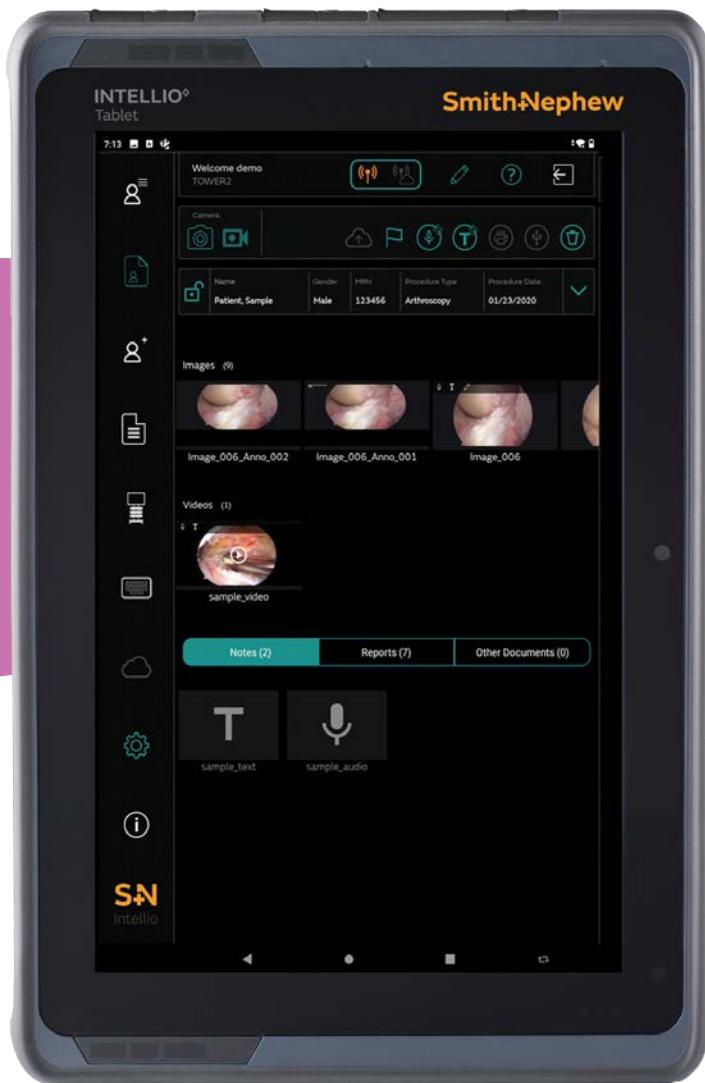
Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Follow instructions for use		Keep dry		Radio Frequency Identification (RFID)
CE	CE Mark	IP65	Ingress Protection		BSMI (Taiwan) R33138 RoHS
REF	Catalog number	SN	Serial number	VCI	VCCI (Japan)
	Stand-by		EU: Not for general waste	FC	Federal Communications Commission
	This way up		Date of Manufacturer		Class II electrical equipment
ifu.smith-nephew.com	Consult instructions for use	!	Caution	CAN ICES-3 (B)/NMB-3(B)	ICES (Canada)
	Electrical Equipment Safety System (EESS)	!	General Warning Sign	CMIIT ID: 2018AJ5950	China Wireless ID
EC REP	Authorized representative in the European community	LOT	Batch Code	CCC	China Compulsory Certification (CCC)
	Manufacturer	Rx only	Prescription use only	10	Environment Use Period
CLASSIFIED C UL US	UL certification		INTELLIO° Tablet		Importer
	USB output		GITEKI		Danger Voltage
85% 15 %	Humidity limitation	((•))	Wi-Fi		Direct Current
106 kPa 70 kPa	Atmospheric pressure	MD	Medical Device	MADE IN	Made In
140° F 60° C -4° F -20° C	Temperature limitation	UDI	Unique Device Identifier		Non Ionizing Electromagnetic Radiation
	Alternating Current	MR	MR Unsafe		

Device Interface Icons

InterAction with INTELLIO◊ Tablet

	Image Capture		Video Capture (Start/Stop)
	Create User		Close Procedure
	Selected item		Record Audio Annotation
	Create Text Annotation		Auto Print Active
	Auto Print Idle		USB
	Delete		Create Image Annotation
	Share Patient Data		E-mail
	Save to Camera Roll		PDF S (Secure pdf Report)* *De-identified
	PDF F (Full pdf Report)		Undo – on image Annotation
	Redo – on image Annotation		Pen tool
	Draw a line		Erase Content
	Choose color		Draw a filled or empty circle or rectangle
	Set opacity and width		Rewind
	Play		Pause
	Forward		Screen shot
	Full Screen		Integration Broker
	Create Patient(s) from Worklist		Worklist Active
	Pull Worklist – Patient(s) data		Worklist Error
	Worklist Idle		Cloud Upload
	Cloud Sync Status		

InterAction with DYONICS◊ POWER II

	Up button
	Down button
	Forward – clockwise direction of shaver rotation (distal view)
	Reverse – counterclockwise direction of shaver rotation (distal view)
	Oscillate – alternating forward reverse direction of shaver rotation
	Mode button – change Oscillation

InterAction with WEREWOLF◊

	Ablation
	Tone Volume Control
	Lo Mode Ablation
	Med Mode Ablation
	Hi Mode Ablation
	Coagulation
	Ambient
	Ambient Audio Notification

InterAction with DOUBLEFO◊ Pump

	Pressure setting mmHg
	Lavage suction value
	Rinse setting
	Shaver suction setting
	Shaver greyed out - inflow only

Note: (Green = Active / Orange = Inactive). Red (no displayed code) = over pressure for; mmHg and Lavage.

Preface

This manual contains general information, together with the operation instructions for the Smith+Nephew INTELLIO◊ Tablet. It is essential that all materials in this manual be read and understood before any attempt is made to operate the medical device.

Note: The System specification contains content, which is essential in assisting you with storage management.

Note: The Admin Considerations section contains information that should be considered when installing device with the Integration Broker.

Smith+Nephew Compatible Devices

Refer to the U.S. Approval/Clearance section in this document for a listing of the devices.

U.S. Approval/Clearance

Table 1 provides a list of the U.S. Approval/Clearance technologies, that are used in the Smith & Nephew Compatible Devices.

Technologies	Smith+Nephew Compatible Devices		Respective 510K number
Camera/Camera Control Unit	72205059	LENS 4K CAMERA CONTROL UNIT	(K191177)
	72205707	INTELLIO◊ 4K CAMERA CONTROL UNIT	(K221740)
Mechanical Resection	72200873	DYONICS◊ POWER II CONTROL UNIT	(K062849)
Fluid Management	72205352	DOUBLEFLO◊ Pump	(K203480)
RF Coblation	72290105	WEREWOLF◊ COBLATION◊ System	(K162074)

Table 1. Compatible Devices

Table of Contents

Device Description

The INTELLIO◊ Tablet is an optional medical device tablet with Smith+Nephew software for use with the LENS 4K or INTELLIO 4K Surgical Imaging Systems. The INTELLIO Tablet provides the ability to remotely control Smith+Nephew device settings, manage patient information, establish surgeon preferences, and support temporary storage of images and video.

The INTELLIO Tablet is used in conjunction with the following systems:

- INTELLIO 4K Camera Control Unit (CCU) IFU, (REF 10601603). Herein called INTELLIO 4K CCU throughout the IFU.
- LENS 4K Camera Control Unit (CCU) IFU, (REF 10601350).
- DYONICS◊ POWER II Control Unit IFU, (REF 10600181).
- WEREWOLF◊ System IFU, (REF 64999.EN).
- DOUBLEFLO◊ Pump IFU, (REF 202078 EN).

Refer to the System Specifications section listed in this document for more information.

Upon request, a copy of the medical grade tablet hardware IFU (REF 10601768) is available. Contact Smith+Nephew Customer Service.

Intended Users

The Smith+Nephew INTELLIO Tablet is intended for use by healthcare professionals in accordance with these Instructions for Use. The use environment is professional healthcare facility.

Intended Use

The Smith+Nephew INTELLIO Tablet is intended for use for wired or wireless remote control of compatible Smith & Nephew surgical and endoscopic devices.

Indications for Use

The Smith+Nephew INTELLIO Tablet is indicated for use to provide wired or wireless remote control of Smith+Nephew compatible surgical and endoscopic devices within the operating room including camera/camera control unit, patient information system, mechanical resection system, fluid management system and RF coblation system. These controls consist of adjusting parameter settings only.

Contraindications

None known.

Target Patient Group

The targeted patient population for the INTELLIO Tablet is patients requiring endoscopic surgical procedures as determined necessary by the prescribing healthcare professionals.

Adverse Event Reporting

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

complaints@smith-nephew.com

⚠️ Warnings

- It is the health care professional's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Read these instructions completely prior to use.
- DANGER: Risk of explosion if used in the presence of flammable anesthetics.
- Use aseptic technique in accordance with standard operating room procedures.
- To prevent electric shock, do not remove any covers or screws from the INTELLIO Tablet. There are no user-serviceable components inside the INTELLIO Tablet its accessories. Dismantling the equipment will void the warranty.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1, install an appropriately rated IEC 60601-1 approved isolation transformer with a minimum of 1000 VA and retest the system.
- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety. Consider the following when choosing accessory devices:
  - Use of the accessory in the patient vicinity.
  - Evidence that the safety certification of the accessory has been performed in accordance with IEC 60601-1.
- Connect only accessory items that have been specified as part of the System or have been specified as compatible. Use of accessories and cables with this equipment, other than those specified by Smith+Nephew, could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.
- Do not use this device in oxygen rich environments (>25%).
- To avoid the risk of electric shock, this equipment must only be connected to with the Power Adapter (FSP / FSP065-DBCM1) provided.

Warnings

- Only use the power cord with following specification: 18AWG min., type SJT, 125V/10A, UL/CSA listed, 3m max.

- Electrical Interference. This equipment is designed to be used as a stand-alone, or in proximity to other medical equipment. Although this equipment is designed and tested to minimize interference with, or by, other electrical equipment; interference may occur. If interference occurs with other equipment it may be corrected by one or more of the following measures:
  - Reorient or relocate this equipment, the other equipment, or both.
  - Increase the separation between the pieces of equipment.
  - Connect the pieces of equipment into different outlets or circuits.
  - Consult a biomedical engineer.

- This device shall not be permanently affixed such that removal or opening is impossible without using a tool.

- Disturbances may be manifested by failure to maintain communication with the Connected Tower.

- High Frequency (HF) Interference: This equipment was designed and tested to be used with HF Electrical Surgical Unit (ESU) equipment. If interference occurs with other equipment it may be corrected by one or more of the following measures:
  - Reorient or relocate this equipment, the other equipment, or both.
  - Increase the separation between the pieces of equipment.
  - Connect the pieces of equipment into different outlets or circuits.
  - Consult a biomedical engineer.

- Portable and mobile RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the INTELLIO° Tablet, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

  Field strengths from RF transmitters, such as base stations for radio, (cellular/cordless) telephones, land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts cannot be predicted. The Professional Healthcare Facility must assess the electromagnetic environment due to RF transmitters; an electromagnetic site survey should be considered to ensure compatibility with the immunity levels contain in IEC/EN 60601-1-2.

  The INTELLIO Tablet normal operation is for general surgical purposes throughout the duration of orthopedic and arthroscopy applications.

- When networking with electrical devices, the operator is responsible for ensuring that the resulting system meets the requirements set forth by the following standards:
  - EN 60601-1 (IEC 60601-1)Medical electrical equipment Part 1: General requirements for safety

  - EN 60601-1-2 (IEC 60601-1-2) Medical electrical equipment Part 1-2: General requirements for safety Collateral standard: Electromagnetic compatibility; Requirements and tests

- This equipment shall not be used as a life support system.

Battery

- Danger of explosion if the battery is incorrectly replaced. Replace only with the same type recommended by the manufacturer, discard a used battery according to the manufacturer's instructions.

- Mistreatment of the battery used in this device may present a risk of fire or chemical burn.

- Do not dispose of a battery in a fire and check with local authorities for disposal instructions.

- The INTELLIO° Tablet can only be equipped with standard battery pack with Getac, AIM-BAT-10, 2300mAH Lithium-Ion Battery provided. Use of another battery may present a risk of fire or explosion.

- Please charge the battery once every month or remove the battery pack if the device has not been used for some time.

- When charging the battery, it is important to consider the environment temperature of the Lithium-Ion battery pack. The process is more efficient at normal room temperature or slightly cooler. It is essential that you charge the battery within a temperature range of 50° to 77° F (10° to 25° C). Charging the battery outside of the specified range could damage the battery and shorten their charging life cycle.

- Although a charged Lithium-Ion battery may be left unused for several months, their capacity may be depleted due to the buildup of internal resistance. If this happens, they will require recharging prior to use. A Lithium-Ion battery may be stored at temperatures between -4° to 140° F (-20° to 60° C), however they may be depleted more rapidly at the high end of this range. It is recommended to store the INTELLIO Tablet battery within normal room temperature ranges.

- Battery system, equipotential pin, metal wiring on equipotential pin, wheels and brake shall be replaced/send back to maintain by the manufacturer every two years, risks of function failure, electrical shock, equipment damage, environment pollution etc., may occur if not doing so.

- Make sure the user does not allow contact between SIP/SOPs and the patient at the same time.

- Maintenance: to properly maintain and clean the surfaces, use only the approved products or clean with a dry applicator.

- Do not place the power cord where it is difficult to disconnect and may be stepped on by another person

- Do not modify this equipment without authorization of the manufacturer.

- Remove the power cord to fully turn off the device when the battery pack is empty.

Precautions

R̲X̲ only U.S. Federal law restricts this device to sale by or on the order of a physician.

- To ensure maximum performance, safe operation, and full warranty protection of the INTELLIO◊ Tablet, read and follow these precautions.

- Read these instructions completely prior to use.

- Each time you choose a file to delete, the INTELLIO Tablet will alert you. The file will be immediately deleted from the mobile device storage and is irretrievable.

- Once a patient file is locked, it cannot be unlocked.

- Once the file is locked it cannot be modified. Please ensure that you have completed all annotation prior to locking the file.

- Do not leave this equipment in an uncontrolled environment where the Storage temperature is below (-4° F or -20° C), or above (140° F or 60° C). This may damage the equipment.

- The INTELLIO Tablet is used with the Qualified & certificated power adapter (REF 72205611). Refer to the System Specifications section listed in this document for more information.

- Environmental Protection: This equipment contains electronic printed circuit assemblies. At the end of the useful life of this equipment, it should be disposed of in accordance with any applicable national or institutional policy relating to obsolete electronic equipment.

- If a secure pdf report is desired, ensure the patient information is not visible on the image or in a secure report. Refer to the Report Settings section listed in this document.

- Disconnect the power cord before cleaning.

- Do not immerse or rinse, spill liquids, or allow fluids to enter the device. If liquid enters the unit through the vents, permanent damage may result.

- Do not spray cleaning agent on the INTELLIO Tablet.

- Do not use disinfectants that contain phenol.

- Do not autoclave or clean the INTELLIO Tablet or its peripherals with strong aromatic, chlorinated, ketone, ether, or ether solvents, sharp tools, or abrasives. Never immerse electrical connectors in water or other liquids.

- Electrical safety testing should be performed by a biomedical engineer or other qualified person.

- **Caution!** To prevent shock. Do not remove cover. No user serviceable parts inside. Refer servicing to qualified personnel.

- IC (Industry Canada) Statement (IC: 20634-INTELLIO) Antenna Statement
Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication. Canadian Department of Communications Compliance Statement CAN ICES-3(B)/NMB-3(B)

- FCC compliance (FCC ID: 2AEAJ-INTELLIO)

- 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.

- Only use with preinstalled software, please contact the manufacturer for further assistance.

- 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. These limits are designed to provide reasonable protection against harmful interference in an industrial installation. This equipment generates and can receive 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:
  - Re-orient or relocate the console or shield the location.
  - 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 dealer or an experienced radio/TV technician for help. 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.

- Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

- All users should create their own PIN and password.

- Do not operate at line voltages other than those stipulated on the back of the unit.

- Handle the unit with care. If the unit is damaged in any way, it must be returned immediately for service.

- Once a patient file is locked, it cannot be unlocked to add additional media. However, the user can delete the patient file when desired.

- The e-mail will include a password protected zip file, as well as the password to open the file. Remove the password from the email and provide it to the intended recipient through another communication method.

- This product contains Nickel (Ni) which may cause allergic reactions.

Accessories

Refer to the Ordering Information section in this manual for more information.

System Controls

Front Overview

Figure 1. Front Overview

	Front Panel Control	Function	
A	LED System Indicator		Green when **ON**; 100%.
			Charging
			Blinks, Low Battery (10%)
B	Light Sensor	Ambient light sensor. **Note:** Detects the light quality and intensity.	
C	Speaker	Speaker volume is adjustable.	
D	Battery Cover and Latch	On rear - item not shown	
E	Rear Camera with LED Flash	On rear - item not shown. Camera is functional and is only accessible to the Admin.	

Note: The front camera is non-functional and not shown in Figure 1.

Multiple Side Overview

Figure 2. Multiple Side Overview

	Rear Panel Connections	Function
A	Power Button	Turns the INTELLIO◇ Tablet on and off.
B	Volume Key (Up/Down)	Two volume keys (Up / Down)
C	USB Door	3.0 Type C
D	DC-IN	DC Jack
E	Docking Connector	Connects to VESA 75 x 75 mm mount

Note: Tampering with the SD slot (not shown) will result in data loss and damage to the device.

Interface Overview

The INTELLIO◊ Tablet user interface provides various controls, including icons, sliders, radio buttons, drop down menus, data entry fields, active text fields, and controls to identify activities and options to the user. The icons and controls used for specific operations are identified in the sections for those operations. The general icons and controls available in multiple different views are presented here. This section discusses the coloration (active, inactive, disabled), and other features in standard use for the software. Any information unique to a particular feature operation will be discussed in the section on that feature.
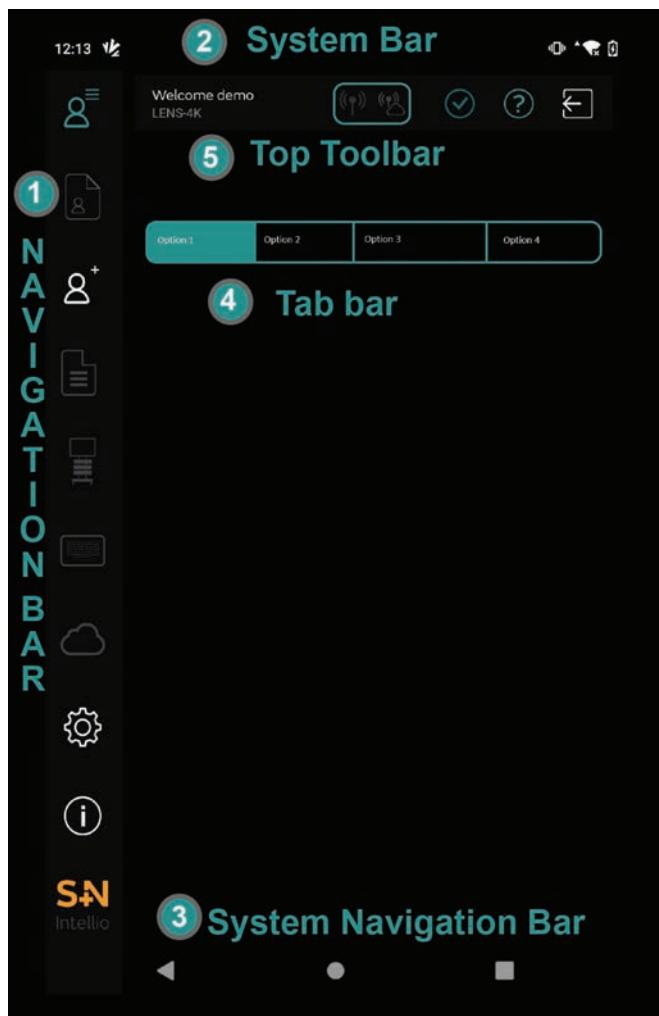
The User Interface screen contains the following:

1	Navigation Bar:	The Navigation Bar provides assess to key features including Patient List, Work List, Tower, and MY. INTELLIO◊ Cloud.
2	System Bar:	The System Bar is located at the top and displays system status, battery, connectivity, and user's local time zone. Up/Down arrows will display transfer direction.
3	System Navigation Bar:	The System Navigation Bar allows the user to press the left arrow to return to the Home screen. **Note:** The Admin has access to the other two functions; Admin Home and Home mode.
4	Tab Bar:	The Tab bar is used in a number of screens including but not limited to the Snapshot, Device Upgrade, and Tower Connection Settings view. This Tab bar allows the user to select between different sub-menus for the item.
5	Top Toolbar:	The Top Toolbar of the provides access to Help, Logout, and other features.

Interaction with INTELLIO◊ Tablet - Navigation Bar

	Current Patient - Indicates the current patient file you are viewing.
	Patient List - Displays a list of created patient files.
	Create Patient - Tap to create a new patient file.
	Worklist - Displays the Worklist data when Integration Broker is configured. This icon is greyed out when not configured or active. When Integration Broker is enabled and there is an active network connection, the icon is a teal color.
	Tower - Displays status of connected medical devices. The INTELLIO TOWER icon on the INTELLIO Tablet, turns grey when there is no connection to a Medical Device, and turns teal when there is.
	Remote Keyboard - Used to control the control unit functions. The icon is greyed out when not connected to the Smith+Nephew compatible equipment.
	MY. INTELLIO Cloud Software Browser - Provides access to cloud web portal. **Note:** Applicable only in the US.
	Settings - Provides access to various user functions, for the purpose of user customization.
	Tool Tips - Displays the name of a icon.

Installation

Unpacking and General Inspection

Prior to using the INTELLIO◇ Tablet, it is essential that all system components be inspected for damage, which can negatively impact the system's performance. Inspection should include all equipment to be used in surgery, including cables and peripheral devices.

1. Remove the INTELLIO Tablet and accessories from the shipping container. Be certain to open and inspect all boxes and sealed plastic bags to ensure that all components are accounted for.

   If any parts are missing or damaged, contact an authorized Smith+Nephew representative. Save the carton and packing materials in the event that a component needs to be returned for repair.

INTELLIO Tablet

The following parts included with every INTELLIO Tablet kit received. **Note:** All the accessories are optional.

REF	Description
72205455	INTELLIO Tablet
72205608	INTELLIO Tablet Rechargeable Battery (pre-installed)
72205607	INTELLIO Tablet, 4-Battery Charger (optional)
72205611	INTELLIO Tablet Replacement AC/DC adaptor
72205606	INTELLIO Tablet, VESA Mount

Setup

Note: Smith+Nephew recommends charging the INTELLIO Tablet for at least one hour before using for the first time.

VESA Docking Station

1. Mount the Vesa Mount to the boom arm attached to the Arthroscopic Tower.

2. Place the INTELLIO Tablet onto the VESA docking station.

3. Connect power adapter to the docking station to start using the device.

Connecting the Power Cord

The INTELLIO Tablet can be powered by AC/DC power adapter. Be sure to always handle the power cords by holding the plug ends only.

Follow these procedures in order:

1. Connect the DC plug of the power adapter to INTELLIO Tablet product DC in connector.

2. Connect the 2-pin male plug of the power cord to an electrical outlet.

Power On the INTELLIO Tablet

1. Press the Power Button for 2~3 seconds to start the INTELLIO Tablet.

2. While the INTELLIO Tablet is running:
   - Push the Power Button for 1 second to disable the LCD backlight for power saving.
   - Push the Power Button again to enable the backlight again.

3. Press the Power Button for 10 seconds while the INTELLIO Tablet is running to power down.

Note: The INTELLIO Tablet can either be connected to the CCU via USB or Wi-Fi.

Network Connectivity

INTELLIO Tower Wi-Fi Connectivity

Connecting to Wi-Fi via the Tablet.

1. Tab on the INTELLIO◇ Tablet icon, (Figure 3) to open the software.

INTELLIO Tablet

Figure 3. INTELLIO Tablet icon

2. From the Navigation Bar, tap on the **Settings** icon.

3. Tap on **Wireless Settings**.

4. Tap the **Wi-Fi** icon and confirm to shift to the Tower Wi-Fi.

5. Tap **Scan** to see available Networks.

6. Tap **Connected Tower Network** and select preferred Network.

7. Enter the **Network PW** (password**)** for the INTELLIO Tower.

8. Tap Save to save the password for the preferred INTELLIO Tower.

Tether the INTELLIO Tablet to the CCU

The INTELLIO◇ Tablet can connect via Wi-Fi or tether on both CCU's. INTELLIO 4K has dedicated USB for tablet (mini), and the LENS 4K has the Type B connector.

1. Inspect the Mini USB tethering port is functioning, (if used).

2. Connect the tether cable (REF 72205455) to either the USB-A port on the front panel or the USB-A port on the rear panel of the INTELLIO 4K CCU.

3. Open the USB Door on the INTELLIO Tablet and attach the other end of the tethering cable.

INTELLIO 4K CCU

The INTELLIO Tablet can connect to the INTELLIO 4K CCU via Wi-Fi or USB. Use the Type B to USB Type C cable to connect the INTELLIO 4K CCU to the INTELLIO Tablet.

LENS 4K CCU - USB

The INTELLIO Tablet can connect to the LENS 4K CCU via Wi-Fi or USB. Use the Type B to USB Type C cable to connect the LENS 4K CCU to the INTELLIO Tablet.

Connection to the Internet for MY.INTELLIO◊ connectivity

When utilizing the Wi-Fi connectivity option.

1. From the INTELLIO Tablet, tap the **Settings** icon.
2. Tap the **Wi-Fi** tab.
3. Tap the **Wi-Fi** network associated with your facility's Wi-Fi network to connect to the Internet.
4. Enter the *username* and *security password* for the network.

Note: The network password only needs to be entered the first time the INTELLIO Tablet is connected to the network. The device will automatically remember the network password.

Service Life Checklist

Perform a performance check for the installation and before each use case begins.

Check the following items to ensure that they function properly, and the system is ready to use.

☐ Check the INTELLIO Tablet is fully charged or connected to a power source.

☐ Inspect the Mini USB tethering cable is functioning, (if used).

☐ Check to confirm connection to the Wi-Fi (if enabled).

☐ Check the status bar to confirm that the USB device is detected, (if utilized).

☐ Check screen for cracks.

☐ Check the device for visible damage.

Process

User Accounts

Each INTELLIO◊ Tablet has one (1) Admin User and supports up to 32 personal user accounts. The Admin's role is to set-up the INTELLIO Tablet for each facility and create each user's initial personal account.

It is the responsibility of each user to physically protect the INTELLIO Tablet. Mobile devices are often lost or stolen due to their portable nature. Controls such as encryption at rest are in place to protect sensitive data, however, users are advised to keep these devices physically secure. Recommendations include:

- Never leaving the mobile device unattended, placing it in a secure area such as a locked drawer when not in use.
- Locking the screen when finished using.
- Backing up patient data refer to MY.INTELLIO◊ Cloud Settings.
- Purging patient data when no longer needed refer to Delete Existing Patient File sections in this document.

Admin User

Quick Start

1. Turn on the tablet by pressing the **Power button** located on top right side.
2. From the Android lock screen, tap on the **Admin** (Owner) icon, (Figure 4).
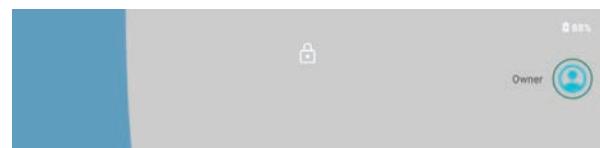
Figure 4. Android lock screen

3. **Log in** into the Owner account.
4. **Enter** the default PIN is 930313 in the keyboard.
5. The INTELLIO Tablet prompts the user to change the default password, (Figure 5).

   Note: The user must complete this step; the tablet is not usable until this step is complete. A numeric PIN or alpha-numeric password.

Figure 5. Reset Factory Password

User Accounts

6. Once the password is changed successfully, the user will be sent to the lock screen, (Figure 6).
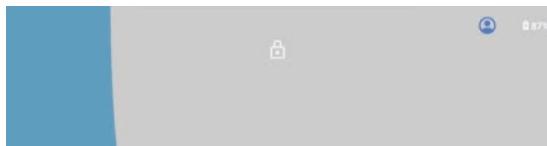
Figure 6. Lock Screen

7. Unlock the tablet with a newly set password.
8. The INTELLIO Tablet HOME displays, (Figure 7).
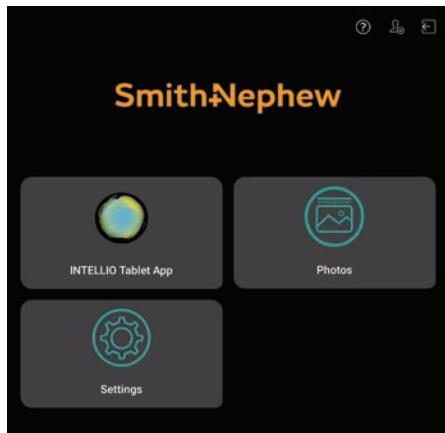
Figure 7. INTELLIO Tablet Home

Create New OS User

1. From the Home software, (Figure 7), tap on the **Create User icon** located in the top right corner.
2. Tap on **Multiple Users**, (Figure 8).
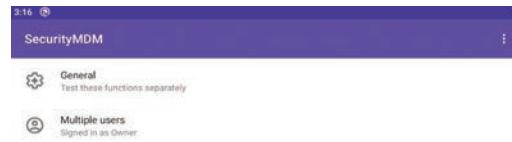
Figure 8. Multiple Users

3. Tap on **Add User**, (Figure 9).

Figure 9. Add user

4. Enter the *username*, (Figure 10), and tap **OK** to create a new user.
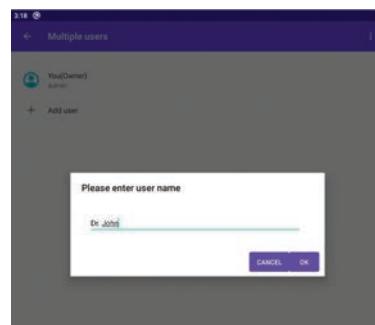
Figure 10. Username

5. Allow a few seconds for the new user icon to be created and appear, (Figure 11) .
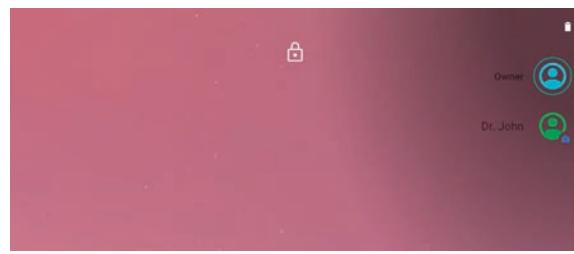
Switching between users

Figure 11. Switching between users

6. Tap on the **Power button** to lock the tablet.
7. Tap on the **Power button** again to activate the lock screen.
8. Tap on the **user icon**, (Figure 11) to switch between the users.

9. Repeat steps 3 to 6 to create another the new user setup.

New Application User Setup

The software can support up to 64 application user accounts. Each user must create a personal user account. It is the responsibility of each user must change his or her password after the first login, refer to Change an Existing Password section in this document.

- **WARNING: Each user is required to change the user password after the first login, the risk of retaining the default password is not advised as it can lead to unauthorized access.**

Create a personal user account

1. Tap the **INTELLIO Tablet** icon (Figure 3) to open the software.
2. The Login screen, (Figure 12) appears.
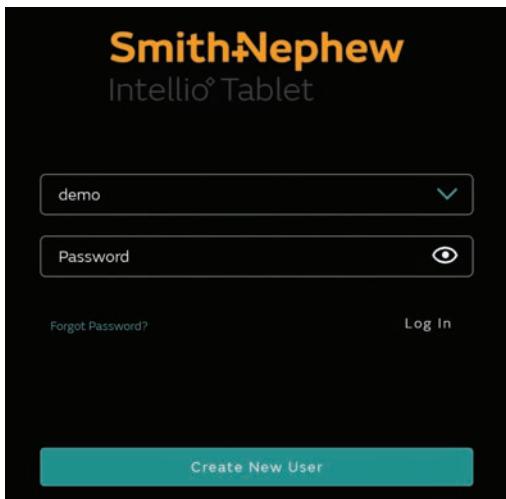
Figure 12. Log in Screen

3. From the Log in screen (Figure 12) tap on the **Create New User** tab. The Create New User screen displays (Figure 13).

Figure 13. Create New User screen

4. Enter your *First Name* and *Last Name*.

5. Enter your *Username*.
   – Once the user account is created your username will display in the drop down list.
   – When you log in, your username will display in the upper left corner of the screen.
6. Enter your *password*.
7. Confirm the password by re-entering your *password*.

   Note: When creating a new user account, select and answer a security question. A warning will appear if the user does not select a security question. The security question and answer are required for a password reset.
8. Tap **Select Security Question** and choose a security question to answer.
9. Enter your *security answer*.
10. Tap and read **Terms & Conditions**.
11. Tap the check box to agree.
12. Tap **Submit** to create your account and return to the Log in screen.

    Note: When the Login screen (Figure 12) appears, you have successfully created a New User Setup.

    It is recommended that you refer to and complete the User Customization – Settings section before moving to the Pre-operative (Offline) – Create a Patient sections in this document.

Configure Integration Broker

Refer to section Integration Broker Set-up Instructions listed in this document, if:

- Installing the INTELLIO◊ Tablet with an existing Integration Broker 3.4, or
- Refer to (Figure 14).

Note: To proceed, your facility must utilize the Smith+Nephew Integration Broker, version 3.4.

CAUTION: If Delete Data is enabled via a Scheduled Push, it will result in permanent loss of all videos from the tablet. For version 3.4 to ensure videos reach PACS and Broker, complete section Configure the Settings for Integration Broker in this document to implement.
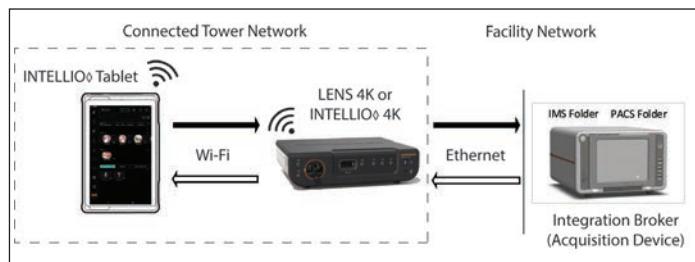
Figure 14. Connection Diagram

Note: INTELLIO◊ 4K CCU (72205707) and LENS 4K (72205059) have a dedicated Ethernet port for Integration Broker accessible via the rear panel.

Integration Broker-One-Time Setup

Integration Broker is an optional software application that converts images and videos provided by LENS 4K or INTELLIO◊ 4K CCU's to a DICOM compatible format for export to the hospital PACS system. In addition, Integration Broker will interface to the hospital PACS and acquire the Patient Query Worklist, at which point, the INTELLIO Tablet system will pull the worklist data for the current day, providing the user with error free patient creation.

Note: To use Integration Broker functionality the product must be installed on the hospital network.

The connection to the Broker server must be configured within the INTELLIO Tablet software to access this functionality.

Prep

Contact your network administrator for the following information.

- The IP Address and Share Name for your facility's Integration Broker, which are required.
- The Username and Password.
- Connection via a CAT 5 connector to the LENS 4K or INTELLIO 4K CCU's.
- Refer to Integration Broker System Admin v3.4 (REF 1061567).

Configure the Settings for Integration Broker

Note: The INTELLIO Tablet is required to be connected to the LENS 4K or INTELLIO 4K CCU to configure Integration Broker. Once connected, continue with the steps below to Configure the Settings for Integration Broker.

1. From the Navigation Bar, tap on the **Settings** ⚙ icon.
2. Tap the **Broker Settings.**
3. Enter the *IP Address* and the *Share Name* for the Integration Broker* (Figure 15).

   Note: The Share Name is strictly the name of the Share folder without the domain notification. Refer to Integration Broker System Admin v3.4 (REF 1061567), section Acquisition Devices: PACS.
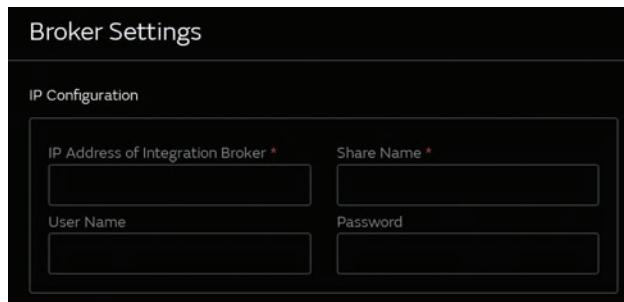
Figure 15. Broker Settings

4. Enter the *Username*, and *Password* for Integration Broker.

Verify the Connection to Integration Broker

1. Turn on the LENS 4K or INTELLIO 4K CCU system.
2. Connect the INTELLIO Tablet to the LENS 4K or INTELLIO 4K CCU. If the Integration Broker settings have been configured, the INTELLIO Tablet will try to establish a connection to Integration Broker.

Note: The system will perform a connection test. If the worklist icon turns **teal**, the connection is good. If the worklist icon turns **red**, please check your information, and retry.

Note: *On Demand Pull requires sufficient time to complete the process. Please allow the process to complete. Failure to do so or repeatedly tapping the Pull icon will cause the Pull icon to turn red.*

Further information regarding an On Demand Pull, Scheduling a Push or Pull; refer to the desired section(s) in this document.

Scheduling for a Pull

A **Pull** refers to the ability of the INTELLIO◊ Tablet to transfer the worklist from the Integration Broker. A success Pull will allow the user to view information from the worklist or facilitate the creation of patients from the data within the worklist. A Pull consists of a Scheduled or On Demand (manual) process.

Note: Ensure the INTELLIO◊ 4K CCU or LENS 4K CCU is powered on and connected to the facility network prior to an On Demand or Scheduled Pull.

A **Scheduled Pull** is conducted by setting the frequency, date, and time.

Frequency is then determined via a popup with the following entries: once, daily, weekly, monthly recurrence entries for selection.

Note: Ensure the Connect status icon is enabled.

1. **Slide** the Pull Schedule button On.
2. Tap Intervals to **select** the frequency, Once, Daily, Weekly, or Monthly (Figure 16).
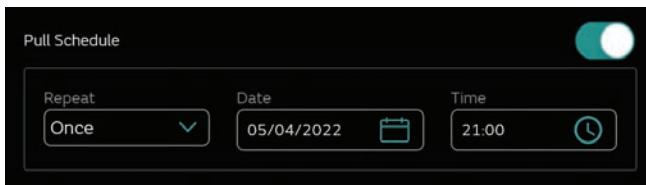
Figure 16. Scheduling for Pull

3. Tap and **select** the appropriate date, then tap **Done**.
4. Tap and **select** the appropriate time to pull the data, then tap Done.

   Note: Do not turn off the INTELLIO◊ Tablet and keep the INTELLIO Tablet Application logged in. Doing so, the connection to the CCU will ensure data is available for a successful scheduled pull.

   Note: Ensure the tablet has adequate memory to support storage. When the INTELLIO Tablet's internal storage reaches 80% capacity, the user receives an alert. A failure by the user to delete old data will result in new data not being pulled until old data is removed. Refer to System Specifications section in this document.

Scheduling a Push

A **Push** refers to the ability of the INTELLIO Tablet to transfer patient data to Integration Broker network location via the CCU for further processing and interfacing with a hospital archive system. The Push process consists of two types of pushes; Scheduled and manual On Demand. Refer to the On Demand Push section in this document.

Note: Ensure the INTELLIO 4K CCU or LENS 4K CCU is powered on and the INTELLIO Tablet is connected to the facility network prior to a On Demand or Scheduled Push.

A **Scheduled Push** is conducted by setting the frequency, date, and time within the Integration Broker settings view.

Frequency is then determined via a popup with the following entries: once, daily, weekly, monthly recurrence entries for selection.

Note: Ensure the Connect status icon is enabled.

1. **Slide** the Push Schedule button On.
2. Tap Intervals to **select** the frequency, Once, Daily, Weekly, or Monthly (Figure 17).
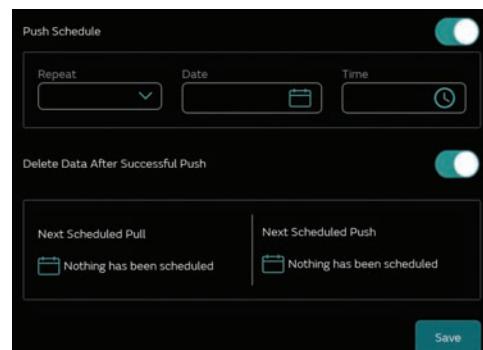
Figure 17. Scheduling for Push

3. Tap and **select** the appropriate date, then tap **Done**.
4. Tap and **select** the appropriate time to push the data, then tap **Done**.
5. **Slide** the Delete Data button On or Off. The default is off.
   – When On the local data will only be delete after a Successful Push.
   – When Off the data remains on the tablet.

Note: The default setting selection is saved for the next push. Do not turn off the CCU to ensure data is available for the scheduled Push.

CAUTION: Selecting the data delete will delete all content from the tablet, after a successful Push is complete. Alternatively, the user may select to manually delete content after a push, refer to the Patient File Management section in this document.

Note: Once the Scheduled Push or Scheduled Pull is complete, it is recommended moving to the User Customization section in this document.

Patient List View

Once you login to the INTELLIO◊ Tablet, the navigation bar, (Figure 18) is on the left side of the screen. The patient list is on the right side of the screen. The patient list provides a list of created patient files the user can view and access.
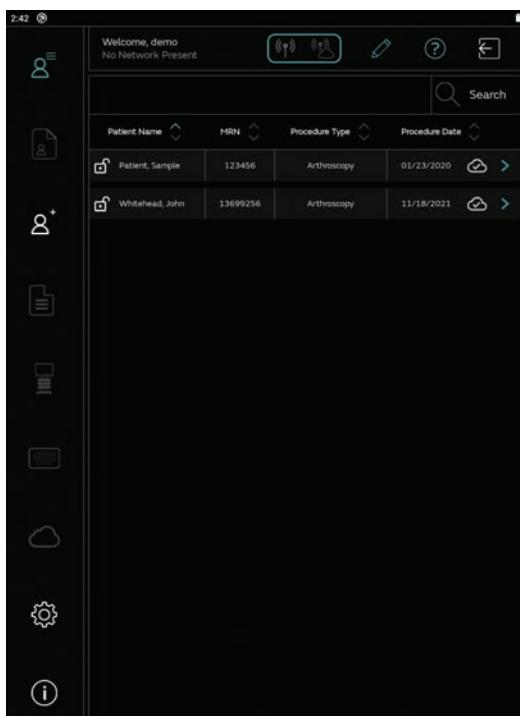
Figure 18. Navigation Bar with patient list

Wireless Network Name Identifier

When you login to the INTELLIO Tablet, the name of the Wireless Network to which you are currently connected will display in the Top Toolbar [Welcome demo TOWER2].

About Page

The About Page, (Figure 19) provides the name, current version of the software, and the remaining storage amount on the INTELLIO Tablet.

Note: When the INTELLIO Tablet is connected to the 4K CCU or the LENS 4K Camera Head, USB and CCU version will display.
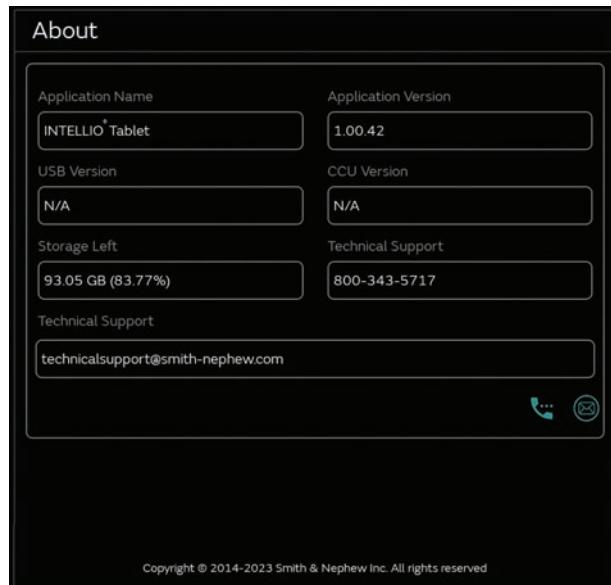
Figure 19. About Page

User Customization – Settings ⚙

The INTELLIO◊ Tablet software provides customization of settings per user account. If no customization exists, the software will use the default settings. An individual user can, if desired, modify the settings offline, Pre-operative.

User Customization – Settings provides eight areas to customize the individual user experience.

Customizing any of the areas can be completed prior to the Operative (Online) scenario and is based on each user's preference.

User Settings

The User Setting screen (Figure 20) allows a user to change four options:

- Change the Existing Password
- Change Security Question and answer
- Camera Setup – assign when creating a patient file. Refer to Camera Setup section in this document.
- Tower Setup – assigned when creating a patient file.
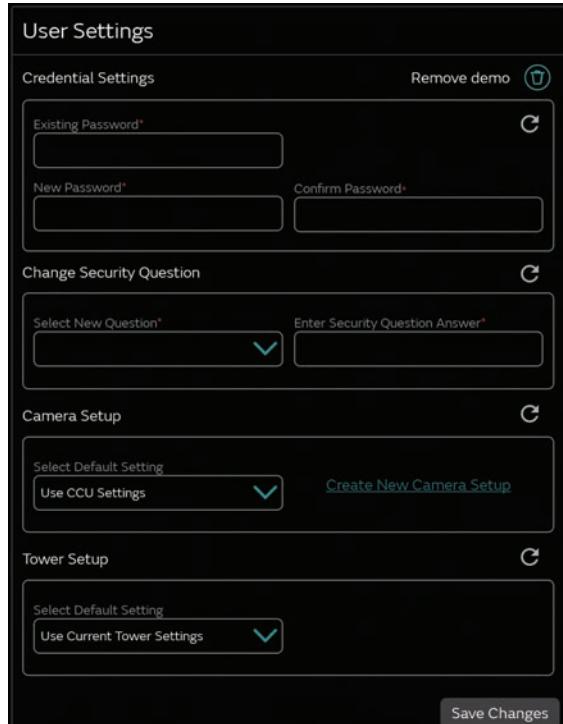
Figure 20. User Settings

Change an Existing Password

Note: The username of the last user to login will appear in the username field.

1. Tap the **Settings** icon on the navigation bar.
2. Tap **User Settings**.
3. Tap the **Existing Password** field and enter your *Existing Password.*
4. Tap the **New Password field** and enter your *New Password*.
5. Tap the **Confirm Password** field and re-enter your *New Password*.
6. Tap **Save Changes** to save the new password.

Change Security Question

1. Tap the **Settings** icon on the navigation bar.
2. Tap **User Settings**.
3. Tap the **Select New Question** field and select a new **Security Question**.
4. Tap the **Enter Security Question Answer** field, and enter your *New Answer*.
5. Tap **Save Changes** to save the new *Security Question Answer.*

Camera Setup

Note: For more in-depth information on Button Mapping, refer to the Button Function and Instructions for Use sections of the IFU, LENS 4K Camera Head (10601349 or 10601459).

The user selects which Camera Setup to assign to a patient and use during the patient's surgery. There are two types of Camera Setup(s):

- Local – created on or offline, located, and accessed via the INTELLIO◊ Tablet per the user account.
- Remote – located and accessed via the control unit when connected to a CCU.

A Camera Setup consists of a group of control unit settings that are easily customized and applied to the INTELLIO◊ 4K CCU. The control unit settings configure the Brightness, Zoom, and Enhancement settings for a specific profile.

Select Default Setting (Camera Setup)

Select a Default Camera Setup Setting to use for a patient's surgery. Refer to section Default Camera Setup section in this document.

1. Tap the **Settings** icon on the navigation bar.
2. Tap **User Settings**.
3. Tap the **Select Default Setting** and then select the new local Camera Setup (Figure 21).
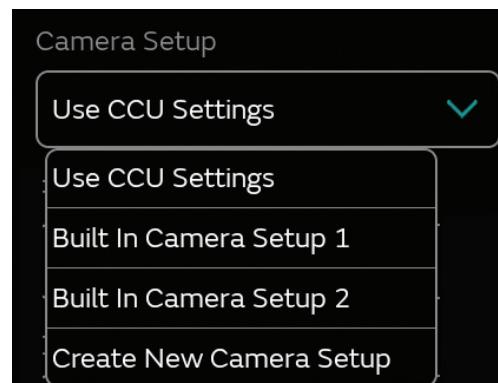
Figure 21. Select Default Camera Setup Setting

4. To create a new Camera Setup, refer to Create New Camera Setup (local - offline) section in this document.
5. Tap **Save Changes**.

Default Camera Setup

A Default Camera Setup refers to a set of defined settings for a particular procedure. The default Camera Setup is assigned to a patient and is used during the patient's surgery.

Note: Ensure a patient(s) are created, refer to section Create a Patient.

The default Camera Setup is applied when connected to the LENS 4K Camera Head or INTELLIO◇ 4K CCU, and the user taps on the patient's name from the Patient List.

The INTELLIO◇ Tablet contains two built-in Camera Setup(s):

- Built-In Camera Setup #1 – cannot be changed
- Built-In Camera Setup #2 – cannot be changed

Note: The user cannot delete the two default camera setups.

The INTELLIO◇ Tablet will provide the user with access to the saved Remote LENS Camera Setups when connected to the INTELLIO 4K or LENS 4K CCU. To access, from the Navigation bar, tap Settings and then Camera Setups. The Remote Camera Setups will display. Refer to the LENS 4K CCU or INTELLIO 4K CCU (Remote Camera Setup(s)) section listed in this document.

Create New Camera Setup (local - offline)

It is a recommendation that the creation of a new local Camera Setup be complete prior to an OR date.

Creating a new Camera Setup, the user selects one of the Built-in Camera Setup(s) 1 or 2. Then applies the defined custom settings of a specific Camera Setup and saves the New Camera Setup.

Note: If the user taps Create New Camera Setup while within the User Settings, the Create New Camera Setup screen displays.

1. To create a new local Camera Setup, tap the teal **Create New Camera Setup** and adjust the control unit settings to the individual user preference.
2. Tap Settings. Refer to section Adjust Control Unit Settings in this document. Adjust the Zoom, Brightness, and or the Enhancement settings to the user's preference.
3. Tap **Button Mapping** and refer to Adjust Button Mapping Functions associated with a Camera Setup (Offline) in this document.
4. Tap **Save As**.
5. *Enter* the name of the New Camera Setup and tap **OK** (Figure 22).
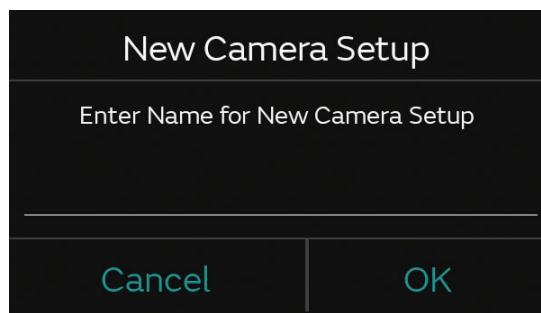
Figure 22. Name of new Camera Setup

History

The History provides each user with access to their operation logs captured by the software. The user needs to login to see the history. Each user can view their logs, create a PDF of the log file(s), and email the PDF for support. Cannot save history to a USB or push to the network.

Note: To assist with HIPAA compliance you can export the History logs for incident tracking.

Camera Setups - (Offline)

Contains a list of the Local Camera Setup(s), when offline, (Figure 23) and contains a list of Remote Camera Setup(s) when connected to a visualization system.
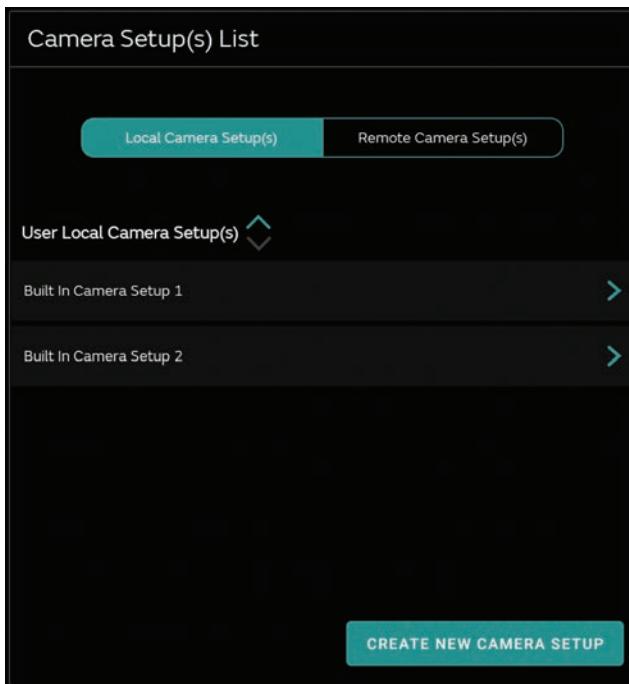
Figure 23. Camera Setup(s) List

Create New Camera Setup

The defined custom settings of a specific profile can be applied to a new Camera Setup.

1. Tap the **Settings** icon on the navigation bar.
2. Tap **Camera Setup(s)**.
3. Tap one of the **Built-In Camera Setup(s)** (Figure 23).
4. Tap on the **Button Mapping** tab and adjust the settings to the individual user preference. Refer to Change Button Mapping Functions Associated with a Camera Setup (Offline) section in this document.
5. Tap **Save**.
6. Adjust the control unit settings (Figure 24) to the individual user preference. Refer to section Adjust Control Unit Settings section in this document
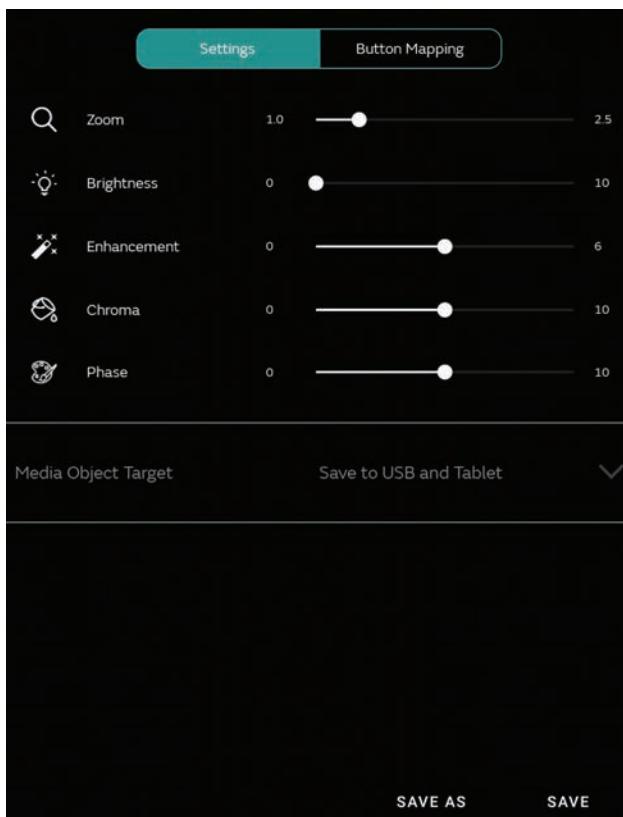
Figure 24. Adjust new Camera Setup settings

7. Tap **Save As**.
8. *Enter* the name of the New Camera Setup refer to (Figure 22) and tap **OK**.

Manage Shortcuts

A shortcut is a predefined text field that can be inserted into any media object's text annotation.

Example: A standard patient note or hyperlink.

Shortcuts reduce text entry for commonly used annotations.

Note: You may create, save, and append shortcut(s) in advance to reduce the amount of manual typing required. Shortcuts can be applied to a patient's file during surgery. There is a limit of 64 shortcuts per each user.

Create Shortcuts

1. Tap the **Settings** icon on the navigation bar.
2. Tap **Manage Shortcuts**.
3. Tap **Add Shortcut** to bring up the Add Shortcut box and keyboard (Figure 25).
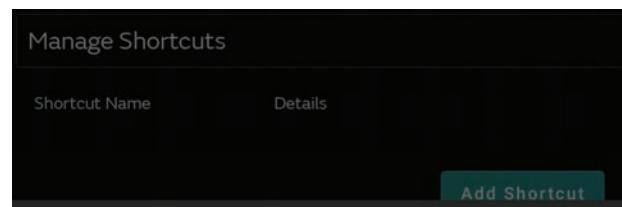
Figure 25. Create a Shortcut

4. Enter a unique *Shortcut Name.*
5. **Tap** inside the box (Figure 26).
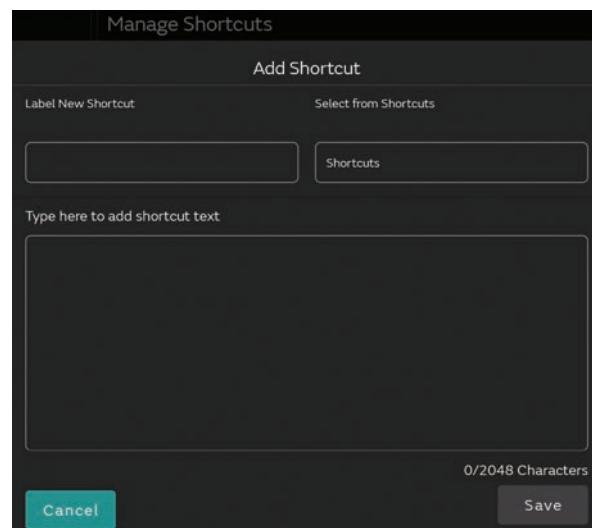
Figure 26. Adding a Shortcut

6. Enter the *Shortcut information*.
7. Tap **Save**.

    Note: As you create shortcuts, the list of Manage Shortcuts will display in the Manage Shortcuts list view.

Once the shortcut is saved, the annotation appears in the patient file.

Change an Existing Shortcut

1. Tap the **Settings** icon on the navigation bar.

2. Tap **Manage Shortcuts**.

3. From the Shortcut list (Figure 27) tap the **Shortcut** to be changed.
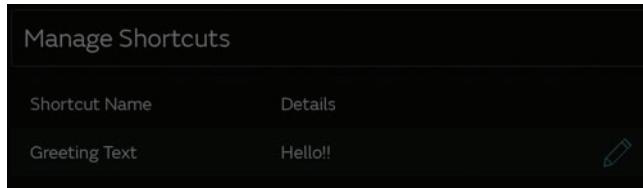
Figure 27. Existing Shortcut list

4. Tap inside the box and make any change(s) to the **Shortcut** and tap **Save**.

5. To save the Shortcut with a different name, enter a unique *Shortcut Name*.

6. Tap **Save** to return to the Shortcut list.

Append an Existing Shortcut

The user can append a different shortcut to an existing shortcut.

1. From the Shortcut list (Figure 27) tap the **Shortcut** to be changed.

2. Tap the down arrow next to Shortcuts and select the Shortcut with the (+) to append (Figure 28) and tap **Save**.
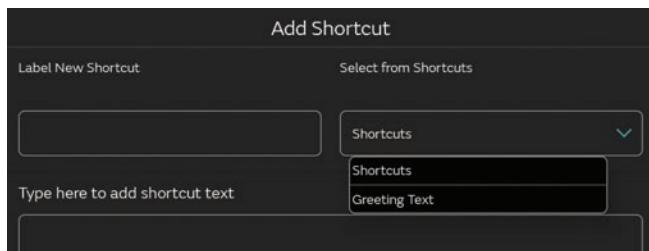
Figure 28. Append Shortcut

3. To save the Shortcut with a different name, enter a unique *Shortcut Name*.

4. Tap **Save** to return to the Manage Shortcut list.

Report Settings

The Report Settings consists of Secure Report and Full Report Settings template(s). The Report Settings is an optional configuration, per user. Each user can customize a report. Tap the Preview button and quickly verify the changes as the user creates the Report, (Secure Name or Full report). A sample of the Full Report Settings template is shown in (Table 2). A description of the label settings and the location of the assets are provided in the table with respect to the final Report.
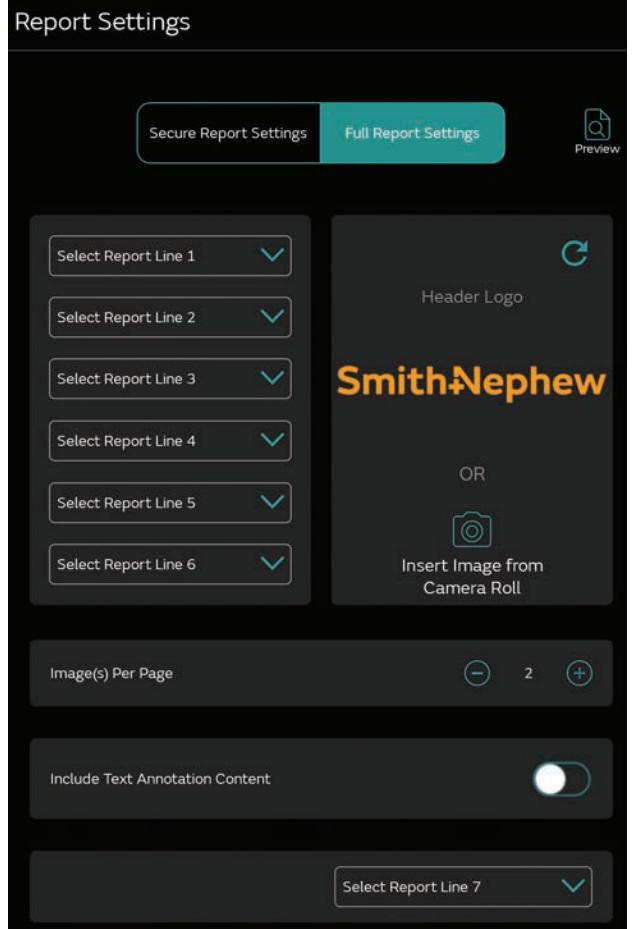
Label	Description	Sample Report (Full)
Secure or Full Report Settings	**Secure Report** – Is anonymous, does not contain patient information. It does contain the logo or image, and number of images per page. **Full Report** – Contains patient's information via one of 7 selectable fields. A logo or image and a few images per page.	
Select Report Line (1-7) Note: Applies to a Full Report	Each report line provides customization of the information contained within the report. The user can select from 10 report elements.	
Header Logo Applies to both Report Types	A graphical logo or symbol representing an organization or individual(s). Ensure the Logo is saved to the tablet prior to being selected from the Camera Roll. The default is the Smith+Nephew logo.	
Image(s) Per Page Applies to both Report Types	The user can select from 1 to 12 different images to appear on the report.	
Include Text Annotation Content	When selected ON, the Full Report will contain text annotations. No text annotations will appear on the Secure Report.	
Preview Applies to both Report Types	Tap Preview to see how the report will look when generated.	

Table 2. Report Settings

Cover Page PDF Settings

The Cover Page PDF is a one-time optional configuration, per user. Each user can customize a greetings Cover Page. A description of the settings and the location of the assets are provided in (Table 3) with respect to how the PDF report will display. Refer to Cover Page Settings and Customizing the Cover Page PDF sections in this document on how to create.

Label	Description	Sample Cover Page PDF
Use this template for Patient Report Generation	Toggles OFF/ON. When ON will generate a customized report that is attached to the PDF sent via email to the patient. The default is OFF.	
Report Logo	A graphical logo or symbol representing an organization or individual(s). Ensure the Logo is saved to the tablet prior to being selected from the Camera Roll. The default is the Smith+Nephew logo.	
Top Section Text	The name of the organization, the address, phone/fax, and website link. The default is text blank.	
Greetings Text and Surgery Information	A general message from the Doctor regarding the discharge summary of the patients' procedure, and any follow-up.	
Bottom Image Header #1	Name of Physician Assistant.	
Image #1	Ensure the picture is saved to the tablet prior to selecting from the Camera Roll.	
Bottom Image Caption #1	Name of Physician.	
Bottom Image Header #2	Name of Physician Assistant.	
Image #2	Picture of Physician Assistant. Ensure the picture is saved to the tablet prior to selecting from the Camera Roll.	
Bottom Image Caption #2	Name of Physician.	

Table 3. Customize Cover Page PDF Settings

General Settings

In this section you may customize how to:

- Sort File By
- Max E-mail Attachment Size
- File Storage Alerts
- Tool tips
- File name under media objects
- Enable Patient Info on OSD
- Printer Settings
  - Configuration of a Silent Printer
  - Auto Printing
  - PDF Settings
  - Paper Orientation
  - Paper Size of a Report
- Close Procedure Settings
  - Push to Broker
  - Complete Auto Printing
  - Generate Report

Sort Files By

The App provides you with four different options for sorting the patient files. The four options include Sorting Files By:

- Patient Name
- MRN#
- Procedure Type
- Procedure Date

All options can be sorted in Ascending or Descending order, as preferred (Figure 29).

Patient Name	MRN	Procedure Type	Procedure Date		
Patient, Sample	123456	Arthroscopy	01/23/2020	☁	›
Whitehead, John	13699256	Arthroscopy	11/18/2021	☑	›

Figure 29. Sort File by Methods – Name – Ascending

1. Tap the **Settings** icon on the navigation bar.
2. Tap **General Settings**.
3. Tap the **drop-down arrow** in the **Sort File By** field to view the list of available sorting methods.

Max E-mail Attachment Size

The user can set the desired maximum e-mail size to between 5MB and 25MB. To set the maximum e-mail attachment size:

1. Tap the **Settings** icon on the navigation bar.
2. Tap **General Settings**.
3. Tap the **drop-down arrow** in the Max E-mail Attachment Size.
4. Tap the maximum **e-mail attachment size (MB)**.

File Storage Alerts

You may customize when you receive alerts that the total remaining storage on the device has dropped the set percentage (%) level.

1. Tap the **Settings** icon on the navigation bar.
2. Tap **General Settings**.
3. To receive File Storage Alerts, **swipe** with your finger to switch On.

Note: Complete step four if File Storage Alerts is switched on.

4. Tap the down arrow to select the **level** 10, 20, 30 percent.

Tool Tips ⓘ

1. Tap the **Settings** icon on the navigation bar.
2. Tap **General Settings**.
3. Swipe with your finger to switch **Off** or On the Tools Tips in the field.

File Name Under Media Objects

File Name under media objects can be switched Off and On. This is useful for quick look up of user-created annotations and images.

1. Tap the **Settings** icon on the navigation bar.
2. Tap **General Settings**.
3. Swipe with your finger to switch **Off** or **On** in File name under media object field.

Note: Switch File Name is helpful when annotating as it displays the File Name under the media objects.

Enable Patient Info on OSD

Note: The Connected Tower settings on the LENS 4K or INTELLIO 4K Camera Control Unit must be enabled.

1. Tap the **Settings** icon on the navigation bar.
2. Tap **General Settings**.
3. Swipe with your finger to switch **Off** or **On** in Enable Patient Info on OSD.

CAUTION: If a secure pdf report is desired, ensure the patient information is not visible on the image or in a secure report.

Printer Settings

Note: The INTELLIO 4K CCU needs to be configured to operate in 2.4 GHz when using Sony printer (Ref 72203944).

There are two Printer modes to choose: Manual Print and Auto Printing.

- Silent Print – connects a compatible Wi-Fi Printer the user selects during the Manual Print Configuration. To change printers, the user must go to the General Settings and reconfigure. To print the user taps manual printing while in the App.
- Auto Printing – the user configures the auto print mode once, per user. This involves selecting the PDF settings, the number of copies (a limit of 4) to auto print per page.

Silent Print Configuration

1. Tap the **Settings** icon on the navigation bar.
2. Tap **General Settings**.
3. Tap the **down arrow** and select the desired Printer compatible printer.

Auto Printing

Involves a number of settings on the tablet to be configured. The settings include:

- **General Settings** – allows the user to configure a default Print printer. Refer to section **Configuring Auto Printing** in this document.
- **PDF Settings** – allows the user to select the Report Settings and configure the number of copies.

The software saves the default auto print settings per user to ensure that the user does not need to configure the desired auto printer each time.

- If an auto printer is not configured, then the app displays a popup for selection of a printer.
- If the auto printer is offline at the time of the print, the app displays a popup and notifies the user that the print failed. Tap **Select Printer** and then choose a printer. Tap Print.

The PDF settings define which PDF setting report to use, as well as the number of images per page. The auto print default is the PDF Settings selected during the configuration of Auto Printing, (Secure Report or Full Report Settings).

Refer to section Configuring Auto Printing in this document.

Configuring Auto Printing

1. Tap the **Settings** icon on the navigation bar.
2. Tap **General Settings**.
3. **Swipe** with your finger to slide the button either **ON** or **OFF** to enable.
4. Tap on the **down arrow** and select the PDF Settings, either Secure Report Settings, or Full Report Settings (Figure 30).

Figure 30. PDF Report Type

Note: Full report, will contain patient information.

5. Select the **number** of copies (from 1-4) per page to display. The maximum is four copies per page (Figure 31).

Figure 31. Copies per Report

Note: The page count of a report when printed will be based on the number of pages, (i.e. 1, 2,3, 4 etc.)

Note: When viewing the report within the App, the page count will be 1 of x, based on the total number of pages.

Paper Orientation

Select the page orientation to display in the PDF view, either portrait or landscape.

- Portrait = vertical – (taller)
- Landscape = horizontal – (wider) The default is Portrait.

Paper Size of a Report

Select the paper size of how the report will print; 8 ½ x 11, or Paper Print A4.

The default is 8 ½ x 11.

Close Procedure Settings

Enabling one, or all three options under Close Procedure will push patient data to the enabled option(s).

1. Tap the **Settings** icon on the navigation bar.
2. Tap **General Settings**.
3. Swipe with your finger to switch **Off** or **On**

   Push To Broker

   Complete auto printing
4. Tap on the **down arrow** for Generate Report and select; None, Full Report, Secure Report or Both.

Refer to Capture Data, Close Procedure section in this document.

MY.INTELLIO◊ Cloud Settings

This feature of the INTELLIO◊ Tablet allows the user to backup various data to MY.INTELLIO storage. The data which may optionally backed up include patient records, intra-operative images and videos, and media annotations. This feature also allows the user to share media, and to sync data across multiple devices.

Each user must register for the MY.INTELLIO cloud account and use their credentials to sign in.

1. Tap the **Settings** icon on the navigation bar.
2. Tap on **Cloud Settings**.

   Note: If no existing user MY.INTELLIO cloud account, the user must Sign up and Register.

Credential Settings

From the Credential Settings (Figure 32), **tap** the appropriate button; Sign In or Sign up for Cloud.
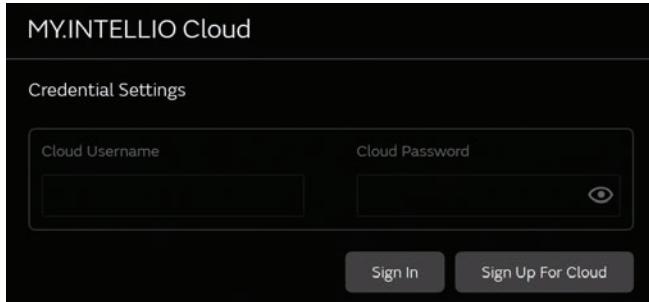
Figure 32. MY.INTELLIO Cloud Settings

Sign up for MY.INTELLIO Cloud

To initiate the Registration, Process the user will need a valid License ID and a Password. Please contact your Hospital IT to obtain the License ID and Password.

Note: Each License ID, Passcode combination can create only one (1) account.

1. Tap on **Sign up for Cloud**.
2. **Enter** the *required* (*) **details** on the Registration Page.
   - *Username*: Is a unique case-sensitive name the user.
   - *Password*: Enter your password for the subscription.
3. **Tap** Submit to trigger the e-mail verification. A code will be sent to the user's e-mail address.

Existing MY.INTELLIO Cloud Account

1. Tap on **Sign In** (Figure 32).
2. Enter the *Username* and *Password* used in the Registration process.
3. Tap on **Log In**.

   Note: Upon successful login, the cloud icon on the navigation bar will be active (turn orange).

Data Upload Settings

Allows the user to enable and determine when to have the local media data uploaded to the MY.INTELLIO Cloud (Figure 33).
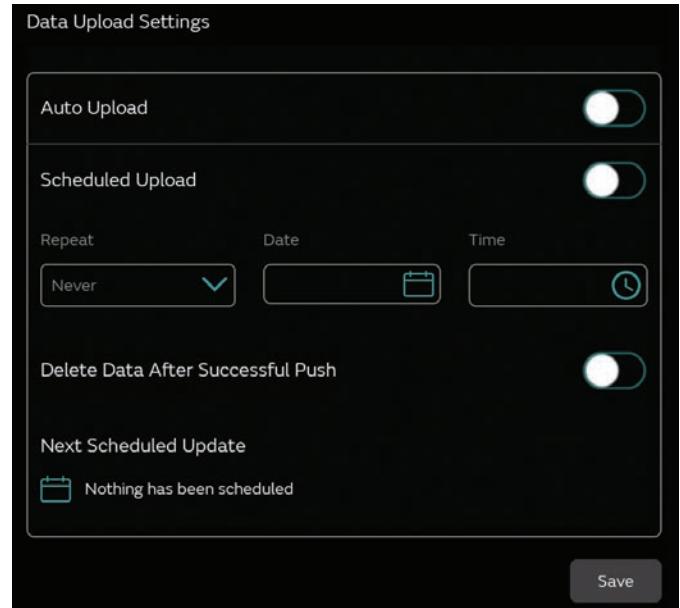
Figure 33. Data Upload Settings

Auto Upload

Auto Upload when enabled, will automatically upload any of the user's saved media objects. **Swipe** with your finger to slide the Auto Upload button to **On**.

Scheduled Upload

A Scheduled Upload is conducted by setting the frequency, date, and time within the MY.INTELLIO◊ cloud Scheduled Upload view.

Frequency is then determined via a popup with the following entries: Never, once, daily, weekly, monthly recurrence interval.

Note: Ensure the Connect status icon is enabled.

1. **Swipe** with your finger to slide the Pull Schedule button to On.
2. Tap Repeat and select the frequency, Never, once, Daily, Weekly, or Monthly.
3. **Tap** and select the appropriate **date**, then tap **Done**.
4. **Tap** and select the appropriate time to upload the **data**, then tap **Done**.

Note: Do not turn off the INTELLIO◊ Tablet and keep the INTELLIO Tablet Application logged in. Doing so, the connection to the CCU will ensure data is available for a successful scheduled pull.

Delete Data after Successful Push

1. **Swipe** with your finger to slide the Delete Data after Successful Push button On.
2. Tap **Save**.

   Note: On the Tablet, please ensure Internet connectivity is enabled.

   Note: Do not turn off the INTELLIO◊ Tablet and keep connected to the internet. Doing so, will ensure data is available for the scheduled push to the MY.INTELLIO Cloud.

CAUTION: Selecting the data delete will delete all content from the tablet, after a successful Push is complete. Alternatively, the user may select to manually delete content after a push, refer to the Patient File Management section in this document.

Note: The patient data remains available on the MY.INTELLIO cloud, and can be downloaded back into the INTELLIO Tablet, if required.

Medical Device Settings

Allows the Admin user to navigate to the web server pages on the connected network to configure a connected medical device(s). Refer to the LINK for DYONICS◊ POWER II Control Unit, WEREWOLF◊ System, and DOUBLEFLO◊ Pump (REF 10601432) for more information.

Snapshot View

A Snapshot allows the user to capture the parameter settings from all connected medical devices, not just a connected tower device. Giving the user the ability to restore to a Snapshot view. The Snapshot list is sorted alphabetically.

The user can Import and/or Export the captured view from the MY.INTELLIO cloud.

Capture Snapshot

1. Tap the **Settings** icon on the navigation bar.
2. Tap **Snapshot View**.
3. Tap on **Capture Snapshot**.

   Note: A confirmation with a check mark will appear.

   If a pop-up message appears indicating a failure. Please re-try capturing the snapshot view.
4. Tap on **Save Snapshot**.
5. Tap on the **Tower Setup**, the user wants to save or rename & save.
6. Tap on **Save**, or.

   Note: Save to capture the Tower Setup data to the selected local tower.
7. Tap on **Rename** & **Save**.

Import Snapshot

User must have a MY.INTELLIO◊ cloud account and log in.

1. Tap the **Settings** icon on the navigation bar.
2. Tap **Snapshot View**.
3. Tap on **Import**.

   Note: The available Snapshot will import from the MY.INTELLIO cloud.
4. Tap the **Snapshot** from the list.
5. Tap on **Import**.

   Note: The MY.INTELLIO cloud will download the tower configuration collections for all the connected medical devices for the selected Snapshot.
6. Tap on the **Tower Setup**.
7. Tap on **Save**.
8. Tap on Rename & Save to import the Tower Setup data to the selected local tower.

Note: To import a snapshot via a supported (POP and IMAP), click on the tower profile attachment. Then, tap on the INTELLIO◊ Tablet logo and follow steps 5-8 to complete.

Export Snapshot

1. Tap the **Settings** icon on the navigation bar.
2. Tap **Snapshot View**.
3. Tap on **Export**.
4. Tap on the **Tower Setup** to export.
   The user has three export options:

   - Email - confirm export using email client

     Note: The user needs to have a MY.INTELLIO cloud account and log in.
   - Export to MY.INTELLIO cloud
   - Rename & Export to MY.INTELLIO cloud

Device Upgrades

A Device Upgrade for the (DYONICS° POWER II Control Unit, WEREWOLF° System, and LENS 4K CCU or INTELLIO° 4K CCU) is completed using a USB connected to the LENS 4K CCU.

Download Device Upgrade(s)

1. **Connect** to a local Internet connection.
2. Tap the **Settings** icon on the navigation bar.
3. Tap **Device Upgrade(s)**.
4. Tap **Download Device Upgrade(s)**.

   Note: The Device upgrade begins downloading when the user taps on the release package list. The downloaded Device upgrade will list on the Device upgrade screen.
5. Insert a USB stick into the LENS 4K CCU or the INTELLIO 4K CCU.
6. Tap on the **USB** icon.

   Note: The Device upgrade will get pushed to the USB stick connected.

Downloaded Upgrade(s)

Insert a **USB** stick into the LENS 4K Camera Control Unit.

1. Tap to select the **Downloaded Upgrade**.
2. Tap on the **USB** icon.

   Note: The Device upgrade will get pushed to the USB stick connected.

Device Upgrade Records

A Device Upgrade Record can be uploaded to the MY.INTELLIO cloud.

1. Tap the **Create Device Upgrade Record**.

   Note: The asterisk indicates a **mandatory** field.

Device Info

2. Tap the **Device Type*** drop down arrow and then select the Device.
3. Tap the **Device Subtype*** drop down arrow to view and then select the Device Type.

Upgrade Info

4. **Tap** in the Account Number and enter the *customer's account number*.
5. **Tap** in the Serial Number* and enter the *serial number* listed on the rear panel of the system.
6. Tap in the From Version and enter the previous software version.
7. Tap in the **To Version*** and enter the *new software version.*
8. Tap **Upgrade Date*** and enter the *date of the software upgrade*.

   Note: Use your finger to scroll up or down to select the Date, (month/ day/year) and then Tap Done.

9. Tap Time and enter the *time of the software upgrade*. Note: Use your finger to scroll up/down to select the Time in hours and minutes, and then Tap Done.
10. Tap **Upgrade By** and enter the *name of the person* who completed the software upgrade.

    Notes:

    Tap **Add Notes** and enter any applicable note.

    Tap **Submit** after the sections are complete.

On Demand Pull

The On Demand Pull contains a **Pull Worklist** ⬇ icon which is utilized from the Worklist View (Figure 34).
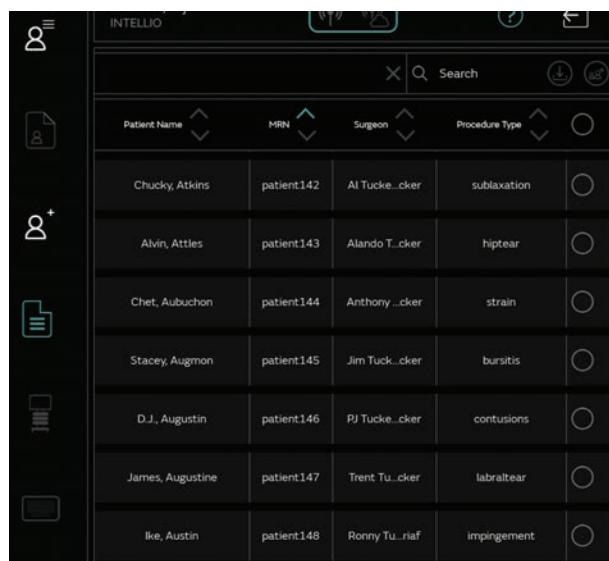
Figure 34. Worklist View

Note: The Worklist icon on the navigation bar will become Teal when connected. Once the worklist pulls the icon will remain Teal even when in offline mode.

Note: *On Demand Pull requires sufficient time to complete the process. Please allow the process to complete. Failure to do so or repeatedly tapping the Pull icon will cause the Pull icon to turn red.*

1. From the Navigation Bar, tap on the **Worklist** 📄 icon.
2. Tap on the **Pull Worklist** icon and the available patients appear in the Worklist view.

   Note: A successful pull (either schedule or on demand) displays the relevant information in the worklist view.
3. From the **Worklist** view the user can select:

   ▪ An individual, tap the circle or swipe left on a patient.

   ▪ Multiple patients, (clicking individually on each circle), or

   ▪ Tap on the circle in the top row to **Select All**.

   Note: The Select All circle toggles from selecting all patients in the Worklist to Deselect All.

Refer to section Create Patient(s) from the Worklist in this document.

Pre-operative (Offline) – Create a Patient

To reduce setup time, it is recommended that a patient file be created before each procedure while offline. This section contains the segments to complete when creating a patient file.

Note: Each user can create up to 64 patient files.

Personal Info

Note: Personal data is only intended to be stored temporarily on the INTELLIO Tablet. While stored it is encrypted with AES-256.

1. From the Log in screen, tap the **drop-down arrow** and select your **username**.

2. Enter your *password* in the Password field.

3. Tap the **Log in** button. The App verifies your information and the Navigation, Patient List screen appears.

4. From the Navigation, Patient List screen, tap the **Create Patient** icon. The Create Patient screen (Figure 35) appears.

Figure 35. Create Patient Screen

5. **Tap** in the First Name field and enter the patient's *First name*.

6. **Tap** in the Last Name field and enter the patient's *Last Name*. Use only alphanumeric characters.

7. **Tap** the (date of birth, recommended) DOB field and select the patient's DOB and then tap **Done**.

   Note: Use your finger to scroll up or down to select the **Date**, (month/ day/year).

8. **Choose** if the patient is Male or Female.

   Note: When creating a patient, the App requires the following field to be completed; MRN #. All other fields are optional.

Procedure Info

1. **Tap** in the **MRN#** field and enter the *patient's MRN number*.

   Note: The MRN# is alphanumeric and is mandatory.

2. To choose a Camera Setup for the patient, tap the **drop down** arrow to view and select an available Camera Setups.

   Note: To change a Camera Setup, go to the Default Camera Setup section of this document.

3. To choose a Tower Setup for the patient, tap the **drop down** arrow to view and select an available Tower Setup.

4. Tap the **Select Default Setting** and then select the Tower Setup.

5. Tap in the Procedure ID and enter the *procedure number* for the patient.

   Note: The Procedure ID is alphanumeric.

6. Tap the **down arrow** and select the Procedure Type.

   Note: The user may create and name a New Procedure Type.

7. If a New Procedure Type is preferred, select **Create New Procedure Type**.

8. Enter the name for the *New Procedure Type* and tap **OK**.

   Note: A Procedure Type name cannot be repeated. If a Procedure Type name exists, the user will receive the message "Procedure type with the same name already exists". The user will need to enter a different name.

9. Tap **Date** and enter the *date* of the patient's surgery.

   Note: Use your finger to scroll up or down to select the **Date** (month/ day/year), and then Tap **Done**.

10. Tap **Time** and enter the *time* of the patient's surgery.

    Note: Use your finger to scroll up/down to select the **Time** in hours and minutes, and then Tap **Done**.

Notes

1. **Tap** in the Notes box to *enter* any notes regarding the patient. Example: Left knee, Right hip, etc.

2. Tap the **Submit** button.

3. Review patient information.

   Note: The user will then preview the patient information. If changes are needed, click on the (<) back arrow and adjust.

4. Once the patient information is complete, tap **Submit**.

   Note: Once **Confirm** is selected, no additional changes can be made.

Create Patient(s) from the Worklist

Once a patient(s) is selected, the user can automatically create the selected patient(s) from the information contained within the worklist. The downloaded patient information from Integration Broker, displays in the Patient List View.

Create Individual or Multiple Patient files

1. Swipe left on a patient and select Create to create an individual patient file (Figure 36).
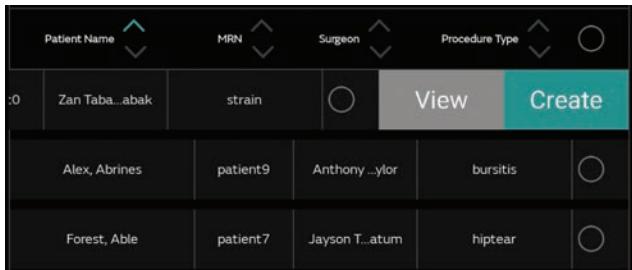
Figure 36. Create patient file(s)

2. To create multiple patient files:
    - Tap the circle on the top row, or
    - Tap each individual circle
3. Tap the **Create Patient** icon.

View Option

The View Option when selected will display a pop-up with the information downloaded from the worklist (Figure 37).
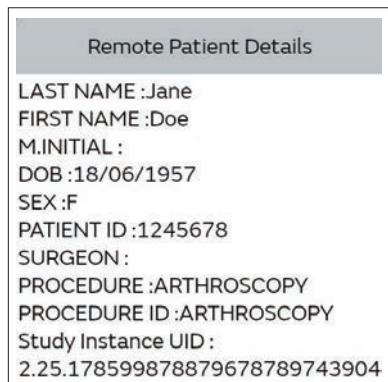
Figure 37. View

Note: Not all entries will be available as the content is a function from the hospital's archiving system specifics.

1. Swipe left on a patient file and select **View**.

- The worklist icon on the navigation bar will reflect either an On Demand or Scheduling Pull failure.
- If a failure occurs the:
    – Worklist icon changes to Red.
    – History log provides the type of On Demand Pull failure.

Note: The error state of the icon will clear on the next attempt of either an On Demand or Scheduled Pull.

Medical Device Adjustments

The INTELLIO◊ Tablet provides the user in the operative state, with remote access to adjust different system functions/settings for each medical device on the INTELLIO◊ Connected Tower.

LENS 4K CCU or INTELLIO◊ 4K CCU (Remote Camera Setup(s))

Remote Camera Setup(s) are those Camera Setup(s) which are stored on the LENS 4K or INTELLIO 4K CCU rather than the Tablet. These Camera Setup(s) are listed as remote Camera Setup(s) on the App when the App is connected to the control unit via Wi-Fi. The titles of the Remote Camera Setup(s) are High Definition, Custom 1 through Custom 8, Moiré 1 and 2. The Camera Setup(s) stored on the App are referred to as Local Camera Setup(s).

When the App is connected to the LENS 4K CCU or INTELLIO 4K CCU and you select Camera Setups, both the Local and Remote Camera Setup(s) display on the App. A remote Camera Setup may be selected, the settings adjusted, and then the Camera Setup saved on the mobile device as a new Local Camera Setup.

Adjust Control Unit Settings

To adjust to the CCU, the user must be connected to the control unit to have access to the camera head icon to perform white balance. The adjustable settings involved in the Camera Setup are:

- **Brightness:** To adjust Brightness, use your finger to drag and release the white circle to adjust the Brightness to the desired level.
- **Zoom**: To adjust **Zoom**, use your finger to drag and release the white circle to adjust the Zoom to the desired level.
- **Enhancement:** To adjust **Enhancement**, use your finger to drag and release the white circle to adjust the Enhancement to the desired level.

Note: Chroma (SAT) and Phase (HUE) apply to LENS 4K and INTELLIO◊4K CCU's.

- **Chroma (SAT)** To adjust, use your finger to drag and release the white circle to adjust the CHROMA to the desired level.
- **PHASE (HUE)** To adjust, use your finger to drag and release the white circle to adjust the PHASE to the desired level.

Adjust Button Mapping Functions Associated with a Camera Setup (Offline)

CAUTION: For more in-depth information on Button Mapping, refer to the Button Function and Instructions for Use sections of the IFU, LENS Camera Head (REF 10601250) and LENS 4K Camera Head (REF 10601349 OUS and REF 10601460 US).

Button Mapping (Figure 38) allows customization of the button functions for the control unit settings. The user may define the Button Mappings for the Camera Head buttons for a particular Camera Setup. The App will associate the changes to the Camera Setup, when connected to the LENS 4K CCU or INTELLIO◊ 4K CCU via Wi-Fi.

Function	Effect
BRIGHTNESS	Control the luminance level of the video output.
ENHANCEMENT	Enhance the sharpness of the displayed video.
ZOOM	Digital zoom of field of view
ALT PAUSE	Pause the video while recording to a device connected to a rear panel port.
PAUSE VIDEO	Pause the video from camera head.
ALT VIDEO	Start or stop video capture from the secondary input source and save to the INTELLIO◊ Tablet
ALT FRAME	Capture a still picture from the secondary input source and save to the INTELLIO Tablet.
FRAME CAPTURE	Capture a still picture from the endoscopic field of view and save to the INTELLIO Tablet.
LIGHT MODE Standby Toggle	Activates and deactivates the illumination device on the control unit.
STRETCH	Switch between an enhanced visualization mode and normal live video.
LAVAGE	To wash out or irrigate.
VIDEO CAPTURE	Start or stop video capture from the endoscopic field of view and save to the INTELLIO Tablet.
LAST IMAGE	Displays the last known frame captures to the INTELLIO Tablet for review.
MENU ACCESS	Access the graphical menu system of the control unit [MAIN MENU].
WHITE BALANCE	Correct for ambient color temperature.
Peripheral Port 1 (Top port)	Triggers the accessory connected to the top port.
Peripheral Port 2 (Bottom port)	Triggers the accessory connected to the bottom port.

Note: The Light Mode function on the CCU is the same as the Standby Toggle label on the INTELLIO Tablet Button.

Note: Lavage is functional only with the INTELLIO 4K CCU.

Mapping, (Figure 38). Only the LENS 4K Camera Head controls the Light Mode, not the INTELLIO Tablet.
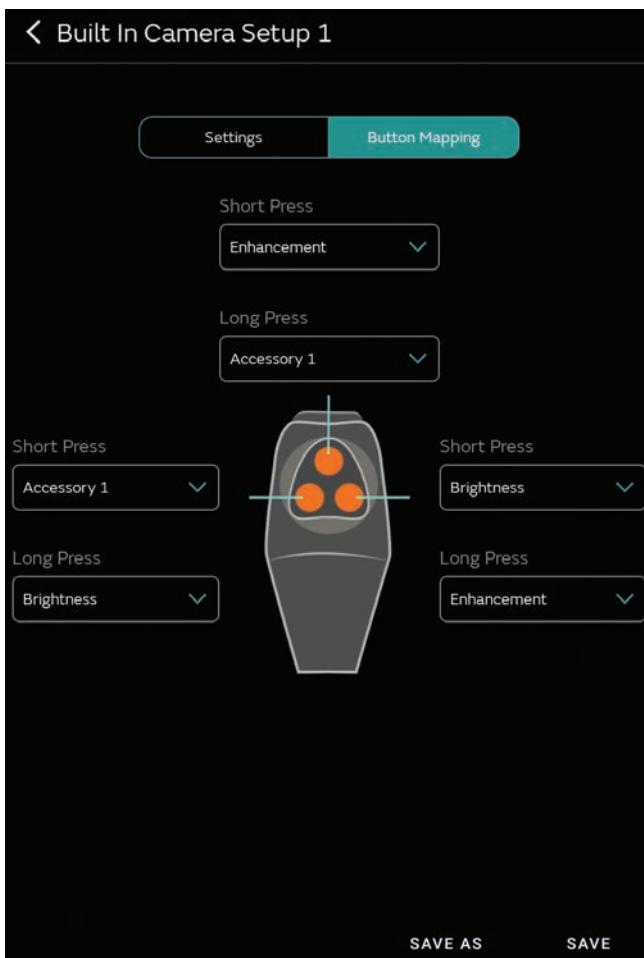
Figure 38. Button Mapping screen

Button Mapping contains both long and short press function mappings with 17 possible selections for each long or short button press.

Button Mapping is accessible from two areas:

- Operatively via the camera head. These changes are temporary.
- Pre-operatively via Settings screen. Select a Camera Setup and make permanent changes.

1. Tap the **Settings** icon on the navigation bar.
2. Tap **Camera Setups**.
3. Select a Camera Setup from the list.
4. Adjust the **control unit settings**.
5. Tap **Button Mapping.**
6. Select which function to associate with each button for each short or long button press (Figure 39).
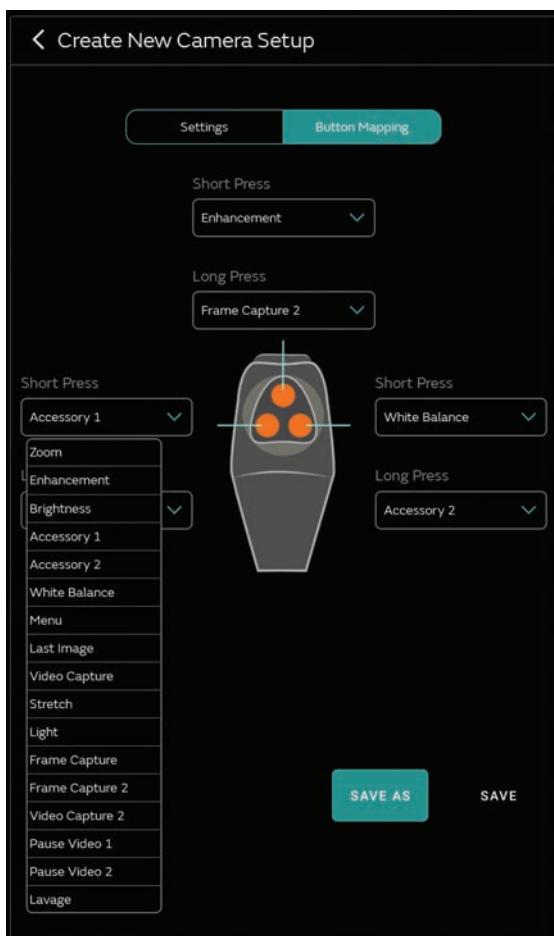
Figure 39. Selecting Button Mapping Functions

Note: Swipe with your finger to scroll up or down on the list.

Note: The Light Mode function on the Camera Control Unit (CCU) is the same as the Standby Toggle label on the INTELLIO◊ Tablet Button Mapping, (Figure 39). Only the Camera Head controls the Light Mode, not the INTELLIO Tablet.

7. Tap **Save**.

8. Enter the *name* of the new Camera Setup.

9. Tap **OK**.

Connecting to the INTELLIO Tower

Tower Setup

The Tower Setup captures different sets of parameters through the Wi-Fi connection to the Connected Tower Network. All connected medical devices, including the LENS 4K CCU or INTELLIO◊ 4K CCU, DYONICS◊ POWER II, WEREWOLF°, and DOUBLEFLO° Pump.

1. Tap the **Settings** icon on the navigation bar.

2. Tap **User Settings**.

3. Tap the **Select Default Setting** and then select the Tower Setup (Figure 40).

Figure 40. Select Tower Setup

4. Tap **Save Changes.**

DYONICS◊ POWER II Functions

Note: The user can use the up and down buttons to adjust the parameter settings a wireless enabled DYONICS POWER II system. Ensure the LINK was installed per the LINK DYONICS POWER II Control Unit, WEREWOLF◊ System, and DOUBLEFLO◊ Pump (10601432) operation/service manual.

The user can view the DYONICS POWER II Ports A & B, increase or decrease the speed. When a handpiece is attached, the user can select the oscillate mode 1 or 2 to adjust. Refer to the DYONICS POWER II Control System (REF 10600181) for more information.

1. Tap the Tower icon on the navigation bar .

Figure 41. DYONICS POWER II - Oscillate Mode 1

2. **Tap** either Port A or Port B to view the handpiece connected for that port.

3. Tap the Mode button to change between Oscillation Modes 1 or 2.

   Note: The directional arrows immediately above the box animates.

4. To select the DII medical device view, tap on the >> arrows at the top (Figure 41).

The medical device view screen will appear (Figure 42).
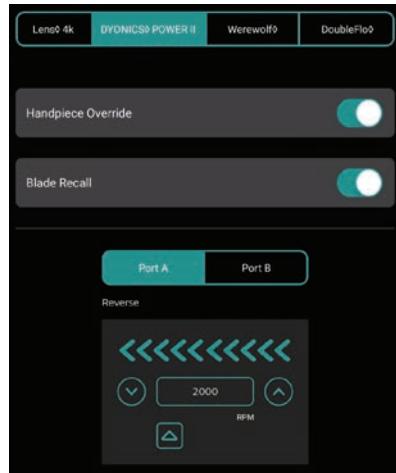
Figure 42. DYONICS POWER II Medical Device View

There are two Mode options for the Handpiece Override.

Note: This option is only applicable when a footswitch is attached.

5. Slide the **Handpiece Override** On to disable the hand control. Or slide the Handpiece Override Off to enable.

Blade Recall is used to reset the factory default settings.

6. Slide the **Blade Recall** to Off to reset the factory default settings. Or slide the Blade Recall On to use the custom defined blade settings.

   Note: The Blade Recall must be **On** to use the custom defined settings from the tablet.

7. **Tap** either the Tower icon or one of the tabs at the top to select another device.

WEREWOLF◊ System Functions

Note: The user can adjust the button functions on a wireless enabled WEREWOLF System. Ensure the Link was installed per the LINK DYONICS◊ POWER II Control Unit, WEREWOLF System, and DOUBLEFLO◊ Pump (10601432) Operation/Service manual.

The user can view the WEREWOLF the Ablate Settings; increase or decrease one (1) of six (6) Ablation Mode settings. The user can enable or disable the FLOW Wand. Refer to the WEREWOLF System (64999.EN) for more information.

1. Tap the **Tower** icon on the navigation bar (Figure 43).

Figure 43. WEREWOLF Ablate Settings

2. Tap the -/+ to adjust the Level in the current Mode.

3. To select the WEREWOLF medical device view, tap on the >> arrows at the top (Figure 43).

   The medical device view screen will appear. (Figure 44).
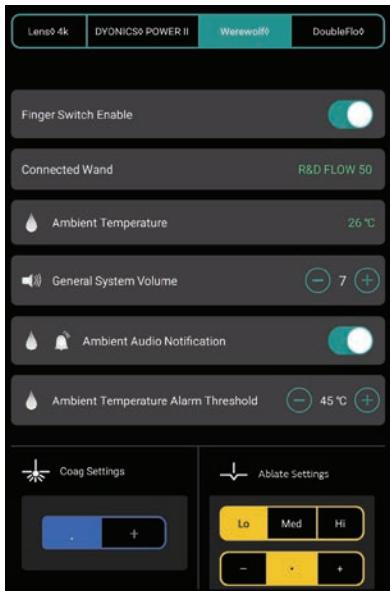
Figure 44. WEREWOLF Medical Device View

4. Slide the **Finger Switch Enable** to toggle the Connected Wand.

5. Tap the Coag dot or the + sign to adjust the Coag settings.

6. **Tap** either the Tower icon or one of the tabs at the top to select another device.

DOUBLEFLO◊ Pump Functions

Note: The user can use the Plus or Minus buttons to adjust the parameter settings on a wireless enabled DOUBLEFLO Pump. Ensure the LINK was installed per the LINK DYONICS◊ POWER II Control Unit, WEREWOLF◊ System, and DOUBLEFLO Pump (10601432) operation/service manual.

The user can view the DOUBLEFLO Pump Settings; increase or decrease the Pump Pressure (mmHg) settings. Refer to the DOUBLEFLO Pump (202078 EN) for more information.

1. Tap the **Tower** icon on the navigation bar .

   Note: The status value is a display only label indicating the current status for the DOUBLEFLO Pump, (Figure 45).
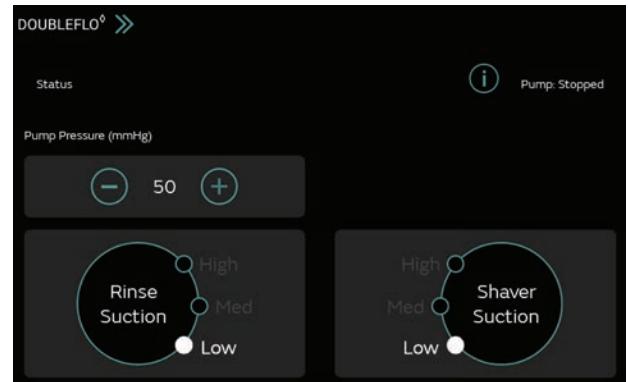
Figure 45. DOUBLEFLO Pump Setting

2. Tap the -/+ to adjust the Pump Pressure (mmHg) setting.

3. Tap the **Rinse Suction** to adjust the value settings, (Low, Med, High).

4. Tap the **Shaver Suction** to adjust the value setting, (Low, Med, High).

Display and Control Functions	Read Only Display labels
Pump setting	Error/Warning
Saline consumption (ml)	Pump Status
Rinse suction	Lavage Status
Shaver suction	Lavage Pressure (mmHg)
	Lavage Time out
	Suction Status

5. To select the DOUBLEFLO medical device view, tap on the >> arrows at the top (Figure 46).

The medical device view screen will appear. (Figure 46).
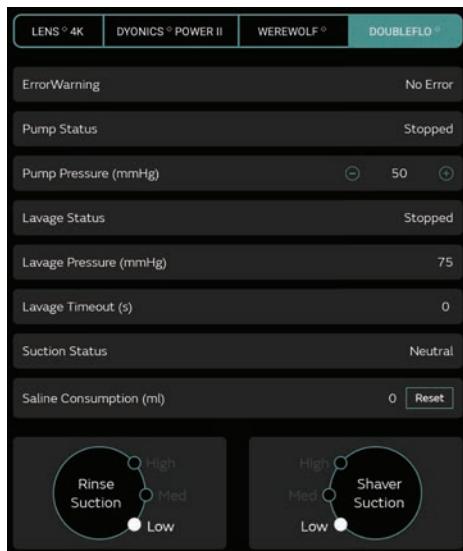
Figure 46. DOUBLEFLO Medical Device View

6. **Tap** either the Tower icon or one of the tabs at the top to select another device.

Going Online (During a Procedure)

Note: During the procedure, the app will need to be on the Connected Tower Network to be functional and receive images/videos.

1. Ensure that the mobile device connected to the local Wi-Fi network. Refer to the INTELLIO Tower Wi-Fi Connectivity section in this document.

2. From the INTELLIO◊ Tablet Home landing page, (Figure 47); locate and tap the INTELLIO Tablet App to open.
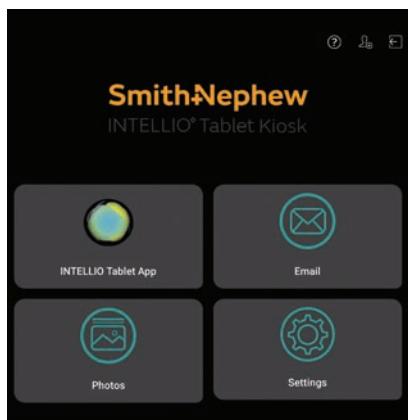
Figure 47. INTELLIO Tablet Home landing page

3. From the Log in screen, tap the **drop-down arrow** and select your **username**.

Note: If you do not remember your username, tap the **drop-down arrow** in the Username field to view the list of available user accounts.

4. Enter your *password* in the Password field.

Note: If you have forgotten your password, refer to the Recover login information – (Forgot Password) section of this document for recovery instructions before proceeding.

5. Tap the **Log in** button. The software verifies your information and the Navigation, Patient List screen (Figure 18) appears.

6. Tap the control unit Connect status icon to connect with the LENS 4K CCU or INTELLIO◊ 4K CCU.

Note: The Wi-Fi icon notifies the user that the INTELLIO Tablet is communicating or not communicating with the control unit. If the Wi-Fi connection between the App and the control unit is lost, the Wi-Fi icon on both the OSD status bar and the INTELLIO Tablet will change from teal to white. The APP will automatically connect when the signal is available again. Should the connection be lost or interrupted during surgery, all control unit control features can be accessed either from the front panel of the control unit or the camera head buttons.

7. From the Navigation, Patient list, tap the desired **patient file** in the displayed patient list.

Note: During surgery, videos and images are captured and the data is reviewed. Refer to the Capture Data section in this document.

You can make annotations to the patient file during surgery. However, it is recommended that you make the annotations postoperatively.

Capture Data

Note: When both the mobile device and a USB CCU storage device are connected, the mobile device patient and the profile information will supersede that of the USB in the Patient Information Box on the On Screen Display (OSD). Ensure that the App is connected to the LENS 4K CCU or INTELLIO◊ 4K CCU. If it is not, the App will not be able to capture data.

1. To begin capturing patient data, tap the **control unit Connect status** to connect with the LENS 4K or INTELLIO 4K CCU.

2. Tap the **patient's** file.

Note: This applies the Camera Setup settings if they are set for that patient.

The patient file displays. At the top of the patient file, (Figure 48) there is information regarding the patient.
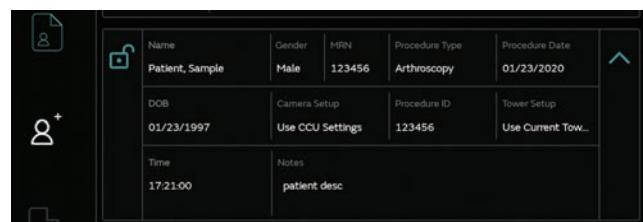
Figure 48. Top of patient file

This is followed by three displays directly below the patient information that pertain to:

 – Annotations
 – Camera Roll
 – Room camera/video

Note: The Room camera/video pertains to the actual camera/video within a facility. The camera/video will be greyed out if there is no valid video source. Refer to the LENS 4K or INTELLIO 4K CCU for more information.

Auto Print

INTELLIO◊ Tablet supports manual printing during or after a case.

If the printer is configured and functional, upon the first successful image capture will print out the greetings template (if enabled) without prompt from the user. Refer to Report Settings, Generate a PDF, and Printer setting sections in this document.

Note: Ensure prior to each patient procedure that the printer is configured and enabled, and the printer is functioning.

While utilizing auto print in the O.R., subsequent successful captures of images shall check against a setting, set by the user from in the General Settings, and pertains to auto print for the number of images per page (1 to 4). Every Nth image (in the same format as PDF formats) will be printed per the setting.

A visible icon flashing in the patient view indicates an uneven number of captures remain, and that there are unprinted images.

Selecting the flashing auto print icon in the patient view signifies the user is done and wants to print out the final page. This will print out the final remaining images.

The auto print icon will indicate:

- A configured auto printer is available or blinks when there are remaining prints to be printed.
- An auto printer is not configured.

Camera 📷

1. Tap and release the **Camera** icon to capture the image. A captured image will appear for viewing.
2. Tap the **Patient** icon to return to the patient file.
3. To choose another patient to view, select the patient from the **patient list** icon.

   Note: When connected to the Smith+Nephew compatible equipment, the captured image appears under Images or Video.

Video 🎥

1. Tap the **Video** icon to start recording a video.

   Note: While recording, a red-light flashes on the video camera.
2. To stop the video, tap the **video camera** again.
3. To review the captured media more in depth, Tap a **thumbnail** to view.

   Note: A progress bar displays when transferring the video.

Close Procedure 🚩

The Close Procedure allows the user to preserving data after a procedure.

1. Tap the **patient** file.
2. Tap the **Close Procedure** icon. Refer to Close Procedure Settings section in this document and ensure the options are enabled.
3. Tap the **Patient** icon to return to the patient file.

- The Close Procedure icon turns **red** when the operation fails. Tap the Close Procedure icon again.

   Note: If one of the operations associated with the Close Procedure; Print, Push to Broker, or Generate Report fails the Close Procedure icon turns red.

- The Close Procedure icon turns **grey** until the operation completes.

Exit a patient file

If you are in a patient file and need to exit, tap on the patient list.

Lock Patient

When all annotations are completed on a patient's file, it is recommended that the patient file be locked. Locking the patient file ensures that all annotations image captures, videos, or PDF file(s) will be prevented from deletion.

CAUTION: *Once a patient file is locked, it cannot be unlocked.*

1. From the Navigation, Patient list view tap the patient file (Figure 49) to lock.

Patient Name	MRN	Procedure Type	Procedure Date		
🔓 Patient, Sample	123456	Arthroscopy	01/23/2020	☁	›
🔓 Whitehead, John	13699256	Arthroscopy	11/18/2021	☁	›

Figure 49. Patient File list

2. At the top of the patient's file, tap the **patient lock**, (Figure 50) icon.

Figure 50. Lock Patient File

CAUTION: *Once the file is locked it cannot be modified. Please ensure that you have completed all annotation prior to locking the file.*

3. Answer the question in the prompt (Figure 51) to ensure that you want to lock patient file.
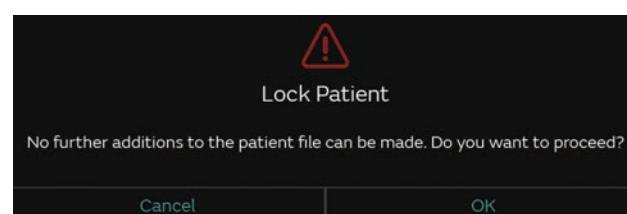
Figure 51. Lock Patient action cannot be undone

Postoperative – (Annotation)

Postoperatively you can create annotations for the captured patient data.

There are three ways to annotate a patient's captured data.

- Create Audio Annotation
- Create Text Annotation
- Create Image Annotation - on captured media

Create Audio Annotation

To add an audio annotation to the patient file or to an individual media object, select the Audio Annotation icon and record your message.

1. From the Navigation, Patient List, tap the **patient's** file.

2. Tap the **Audio Annotation** icon.

   Note: If the user does not select an image, the audio annotation will be added to the patient's file. If the user selects an image or video file, the audio annotation will be added to that file.

3. Tap the **Record** button (Figure 52) to begin the audio annotation.
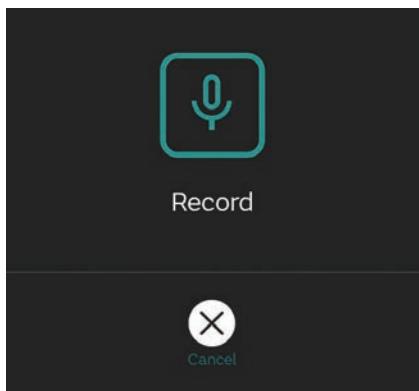
Figure 52. Audio Annotation - Begin recording

4. Tap **Stop** to end the audio annotation (Figure 53).
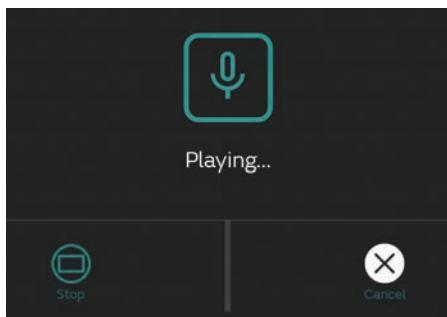
Figure 53. Stop Recording

   Note: You may continue recording, play the recording, cancel, or choose to save the audio annotation.

5. Tap the **Save** button and enter a *name* for the audio annotation. Note: Once saved, the annotation will appear in the patient file under the Patients Notes and Reports.

Create Text Annotation

1. Tap the **patient's** file.

2. Tap the **Text Annotation** icon to add a text, a shortcut or both to the patient file.

   Note: You can create a new shortcut. Refer to the Add New Shortcut section in this document.

Create Image Annotation

Once you have annotated the patient's data you can:

- Lock a patient's file
- Share Patient Data (Media)
- Archive Patient Data

To create a graphical annotation on an image.

1. Tap the **patient's** file.

2. From the patient file, **tap** the (non-video) media object, you want to annotate.

3. Tap the **Image Annotation** icon to bring up the image tool bar.

Image Tool Bar

The image tools allow you to annotate directly on the captured media object.

Note: Prior to identifying an area of an image, select a color for the notation.

Choose a Color		Choose to pick different color as identifiers for text, lines, rectangle, or circles on the selected media object.
Pen tool		Write freehand on the selected media object.
Text		Create a text box and enter your annotation on the selected media object.
Line		Draw a line as an indicator or indicators on the media object.
Eraser		Use the eraser to change a portion of an annotation that you created.
Circle/ Rectangle		Draw a filled or empty circle or rectangle on the selected media object.

Sync to MY.INTELLIO◇ Cloud

Requires a registered user account and the INTELLIO◇ Tablet must be connected to the Internet.

Note: If a user does not a registered an account, refer to MY.INTELLIO◇ Cloud Settings section in this document.

When a user is logged into the MY.INTELLIO cloud, the "Sync to Cloud" symbol is active in the patient view.

1. From the Navigation, Patient List, tap the **patient's** file.
2. From the patient file, tap the **Sync to Cloud** icon (Figure 54) to sync or upload the media objects from MY.INTELLIO cloud storage.

Figure 54. Sync to Cloud from Patient File

Generate a PDF File

You can turn a captured image into a PDF file and export the PDF file to an e-mail address.

Note: A Full report may contain PHI and must not be sent via email. A Secure report does not contain PHI.

Note: An established email address required.

1. Tap the **patient's** file.
2. From the patient file, tap **Edit**.
3. Tap the **media object** you want to generate as a PDF file.
4. Tap the **Share Media** button and select the Report, (Secure or Full) to generate. The PDF file appears in the Patient Notes and Reports section in the patient view.

   Note: To view a PDF file, tap the **captured PDF** located in the Reports to view.

   Note: To exit the PDF file, tap the **back arrow** (<) at the top of the patients' file.

There are two new PDF settings, Secure and Full Report which allow for customization of individual patient data within a report.

- The general greetings page settings can be optionally generated.
- The settings provide for two distinct customization options of the format of the PDF reports, (Secure or Full) which contain patient images.

Cover Page PDF Settings

You can customize the optional Cover Page which will attach a customized greetings page to the PDF file.

1. Tap the **Settings** icon on the navigation bar.
2. Tap Cover Page **PDF Settings**. Begin customizing the report.
3. Tap the template style (1 or 2) for the report generation.
4. To **Enable the Use this template for patient report Generation**, use your finger to slide the button to ON. The default is OFF.

Customizing the Cover Page PDF

The following steps provide the user on how to customize the Cover Page PDF. For Template 1, there are 2 graphical fields, and 6 text fields. Graphical fields: Report Logo, Image 1, and Image 2. Text fields: Top Section Text, Greetings Text and Surgery Information, and Bottom Image Header and Caption (1 & 2).

Template 2 has 1 graphical field (Report Logo), and 2 text fields Top Section Text, Greetings and Surgery Text.

The user has several options for each text field. Populate the text field using a text entry, use the popup to create Add Shortcut, or Add New Shortcut entry from a preexisting shortcut or leave the text field empty. Refer to the **Cover Page PDF Settings** section in this document for an overview of the settings.

Once a new shortcut is defined, the popup will have another option Add From Shortcuts, the user can quickly select the shortcut name rather than entering and creating a custom text or another shortcut.

Report Logo and Top Section Text

This section allows the customization of adding an appropriate business logo or image name of an organization.

Add a logo:

1. To add logo, the user needs to send the logo via the user's email address.
2. Import the logo to the INTELLIO Tablet.

If logo is on camera roll:

1. Tap on **Report Logo** and select the appropriate business logo or insert image from the **Camera Roll**. The default is the Smith+Nephew logo (Table 4).
2. Tap on the **drop-down arrow** and using:
   - Add from Shortcuts
   - Add New Shortcuts
3. Enter in the top section text the name of the *organization*, the full address, including phone, fax, and website link (Table 4).

Smith+Nephew	Facility or Physician Name 150 Main Street Any Town, Any Where www.smith-nephew.com

Table 4. Sample of Report Logo and Top Doctor Text

Greetings Text and Surgery Information

This section allows generic post-operative instructions.

1. Tap the **drop-down arrow** to customize a text entry:
   - Add from Shortcuts
   - Add New Shortcuts
2. Enter the *Surgery Information Text*.

Bottom Image Header and Caption (1 & 2)

This section allows customization of the attending Doctor information (Table 4).

1. Tap the **drop-down arrow** and using:
   - Add from Shortcuts
   - Add New Shortcuts
2. Enter the physician's name in *Header 1* or *Header 2* (Table 5).

Bottom Image Header 1	Bottom Image Header 2
Physician Name	Clinician Name

Table 5. Sample of Image (1 &2), and Bottom Image Caption (1 &2)

3. Tap Image 1 and select the graphic to use. Repeat for Image 2 if necessary.
4. Enter the *caption data* for the bottom images.
5. Tap **Preview** to view and quickly verify the changes as you create Template 1 or 2. The Sample Cover Page PDF in (Table 2) when enabled generates the PDF summary report.

Share a PDF Report From within a Patient File

From the Home screen, tap the desired patient case file.

Edit Button

1. Tap the **Edit** button. The screen will change to allow the user to select multiple individual media objects.
2. Tap the media object(s), a circle with a check mark displays in the lower right corner of an Individual, or multiple images (Figure 55).
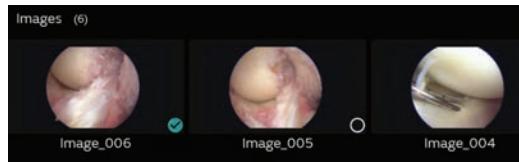
Figure 55. Circle with a Check Mark

3. Tap the **Share Media** button. A menu with the available media types will display (Figure 56).
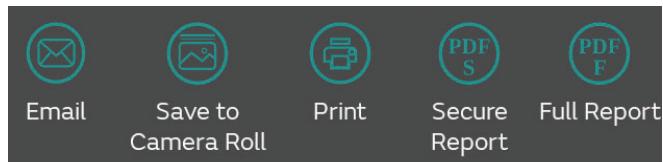
Figure 56. Select PDF Report format

4. Tap the PDF report format to use, either **Secure Report** or **Full Report**.

   Note: A Full report may contain PHI. Email is not considered secure, please contact your Hospital IT to confirm PHI can be shared via email.

Share Patient Data (Media)

The INTELLIO◇ Tablet allows users to share data via various methods from the Patient View.

CAUTION: Not all functions are available and are dependent on the media type.

- Edit, Select All, and then select Shared Media type.
- Save to USB (Archive)

The user can share an entire patient case, an individual media object, or multiple media objects. To share multiple media objects from a patient file, refer to the steps in Archive Patient Data section.

Note: You must follow the policy of the facility when sharing patient information. Ensure patient information remains confidential. By default, media object files do not contain patient names, or MRN's.

1. Tap the **patient's** file.
2. Tap the **Edit** button. The screen will change to allow the user to select multiple individual media objects.
3. To select the captured data to share, tap each media object.

   Note: Use the same process to share individual objects or the entire patient case.
4. Tap on the **Select All** button and select the media type.

   Note: Batch Printing only applies to a single media type.

   Note: To deselect, tap an individual item.
5. Tap on the **Share Media** button and select the delivery method. There are five available delivery methods:

- **E-mail** – Ensure that an e-mail account is registered.
- **Save to Camera Roll** – Captures the data to the mobile device. The captured data is in Photos, Camera Roll.

   Note: When connected to the LENS 4K CCU or INTELLIO◇ 4K CCU, you will have the option of saving to the USB.
- **Print** – Tap Printer.

   Note: The mobile device must be linked to a printer. Refer to the Printer Settings section in this document.
- **PDF Settings** – allows the user to select the Report Settings and configure the number of copies.
- **Save to USB** – Ensure that the USB is installed on the control unit system and that you are connected to the CCU. Tap **Save to USB**.

Archive Patient Data

This section provides the steps to take to archive patient information using the Share Media Data to USB.

Depending on the total size of the captured data in a patient's file, you can either archive the patient's file via e-mail or save it to a USB. To archive a patient's file to a USB, ensure that you are connected to a INTELLIO 4K CCU or LENS 4K CCU and that a USB stick is plugged into to the control unit.

Note: If the total size of the captured data in a patient's file is larger than the Maximum E-mail Attachment Size, refer to the **General Settings** section in this document. E-mailing a patient's file will not be an option if the file size is too large. If you attempt to e-mail a file that is too large, the message "Error! Maximum attachment size exceeded!" will appear.

E-mail:

1. From the Navigation, Patient File screen, tap the **Edit** button.

   Note: A circle displays on the top row and next to each patient's file.
2. Tap the circle next to the **patient's** file to Archive.

   Note: A blue check mark indicates that the patient's file is selected.
3. Tap **E-mail**.
4. Input the desired e-mail address(es) within the e-mail interface.
5. Type in a **message**, if desired, and tap the **Send** button.

   Note: E-mails will queue up until the user switches to a connection with Internet access. The App will automatically detect when a proper Internet connection is available and will send the message(s).

   CAUTION: The e-mail will include a password protected zip file, as well as the password to open the file. Remove the password from the email and provide it to the intended recipient through another communication method.

Save to USB:

Note: All the information will be transferred to the USB. This contains patient information; therefore, the content must be protected from unauthorized access per facility security and privacy policies.

1. From the Navigation, Patient File screen, tap the Edit button.
2. Tap the circle next to the patient's file to Archive.

   Note: A white check mark indicates that the patient's file is selected.

   Note: Ensure that you are connected to the System and that a USB stick is plugged into to the control unit.
3. Tap the **USB** icon.

   Note: As the USB stick is copying the patient's file information, you will see a progress bar (Figure 57) at the top of the mobile device.

Figure 57. Save to USB Progress Status

On Demand Push

The **On Demand Push** is available via the Edit button within the Patient View List (Figure 58).
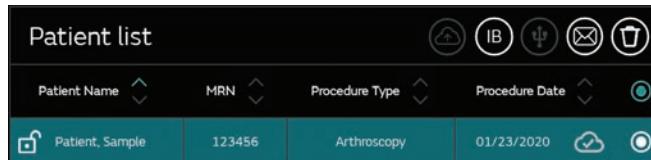
Figure 58. On Demand Push (Integration Broker and MY.INTELLIO◊ cloud)

The On Demand feature provides the user with two options to Push media content based on user's hospital setting. The two options are Integration Broker configuration, or the MY.INTELLIO cloud.

Integration Broker Push

To utilize this feature, ensure the mobile device is configured to Integration Broker. Refer to the Configure Integration Broker section in this document.

1. From the Patient List View, tap the **Edit** button.

   Note: A circle displays on the top row and next to each patient's file.

   Note: The circle on the top row when tapped will select all or deselect all patient file(s).

2. To select an individual, (click individually) on the circle next to the patient's file.

3. To select multiple patients, tap the circle on the top row.

   Note: A blue check mark indicates that the patient's file is selected.

4. Tap the **Integration Broker** icon.

- The worklist icon on the navigation bar will reflect either an On Demand or scheduling Push failure.

- If a failure occurs the:

   – Worklist icon changes to Red.

   – The History log provides the type of On Demand Push failure.

   Note: The error state of the icon will clear on the next attempt of either an on demand or scheduled Push.

   Upon a successful Push, when the auto delete function is enable, local content ONLY will be deleted from the tablet. By default, the auto delete function is set to OFF, see Scheduling a Push section in this document.

MY.INTELLIO Cloud Push

The user must be signed into the MY.INTELLIO cloud, have Internet connectivity, and completed the Data Upload Settings. Refer to the MY.INTELLIO cloud Settings section in this document.

Application Help – Advanced Topics

This section includes information on how to complete advanced topics. The topics are divided into four sections.

- Recover login - (Forgot Password)
- User Management
- Patient File Management
- Tutorials

Recover Login – (Forgot Password)

Forgot Password provides you with the ability to recover your password information if necessary. If you forget your password, use the following information to recover it.

1. From the Log in screen, tap Forgot Password. The Forgot Password screen appears (Figure 59).
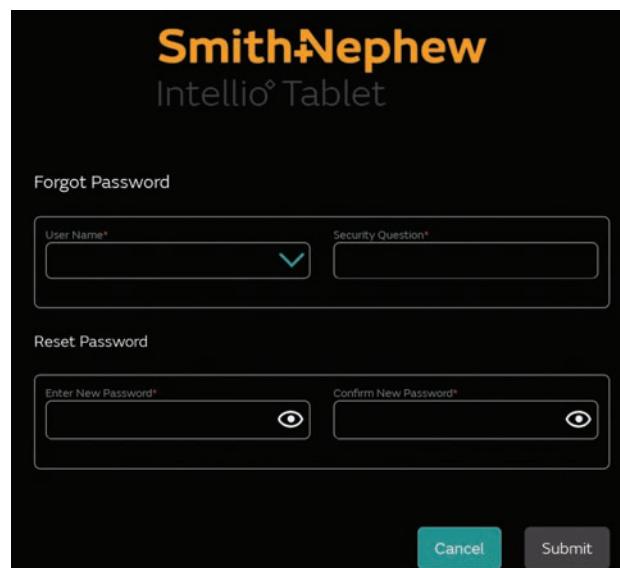
Figure 59. Forgot Password

2. Tap the down arrow and select the **Username**.

3. Answer the prompted **security question**.

4. Enter new *password* and confirm the **password** in the relevant fields.

5. Tap **Submit** to return to the login screen.

User Management

Delete an Existing User

The App supports up to 64 individual users. When the maximum number of users (64) is reached, it is necessary to delete an existing user to add a new user.

Note: Deleting an existing user will permanently delete all media content associated with the user. It is recommended to archive all media content to the USB prior to deleting a user.

1. From the Log in screen, tap the **drop-down arrow** and select your **username**.
2. Enter your *password* in the Password field.
3. Tap the **Log in** button. Enter your user credentials and the Navigation, Patient List screen (Figure 18) appears.
4. Tap the **Settings** icon on the navigation bar.
5. Tap **User Settings**.
6. Tap the **Delete** icon.
7. Confirm the question and tap **OK** to return to the Log in screen.

Delete A Local Camera Setup(s)

Note: Built in Camera Setups 1 or 2 cannot be deleted by the user.

1. Tap the **Settings** icon on the navigation bar.
2. Tap **Camera Setups** and then tap **Edit**.

   Note: A circle displays on the top row and next to each Camera Setup.
3. Tap the **Camera Setup** to delete.
4. Tap the **Delete** icon.
5. You will be prompted to confirm the deletion.

Delete Existing Shortcuts

1. Tap the **Settings** icon on the navigation bar.
2. Tap **Manage Shortcuts**.
3. Tap Edit.

   Note: The blue circle in the header row allows the user to click there to select all shortcuts.
4. Tap the circle next to the **Shortcut** to delete.
5. Tap the **Delete** icon.
6. You will be prompted to confirm the deletion.

Patient File Management

Delete Objects (Media files)

The user has the option of selecting a media object(s) in one of three methods: individual, all objects per category; Images, Videos, Notes/ Reports, and Selecting All objects in all categories. The steps to delete and confirm are the same. The steps below identify the three methods of selecting.

1. From the Navigation Bar, Patient List, tap the **patient's** file.
2. Tap **Edit**.

Individual

3. Tap the individual **media object.**

   Note: The captured data will contain a check mark in the bottom right side.

All Media Objects per Category

4. Per category, tap the words **Select All**.

Select All

5. Tap the words Select All on the top row.

Deselect Media Object(s)

6. To deselect, a media object(s), tap on the media object(s).

To Delete any selected media object(s)

7. Tab on the **Delete** icon and **confirm**.

   Note: This action will delete the selected file(s) on the tablet. Are you sure you want to proceed? Y/N

Confirm the deletion to permanently delete the media object.

Delete Existing Patient File

Once you reach the maximum of 64 patient files, you must delete or archive a patient (and all associated data) before adding a new patient. **Note:** To archive a patient's file, please refer to the Archive Patient Data section in this document.

Note: Once you select to delete the patient all of the patient's data will be deleted.

1. From the Navigation Bar, tap the **Patient List**.
2. Tap **Edit**.

   Note: To delete all patients in list, the user only needs to tap on the blue circle in the headings bar.
3. Tap the circle(s) next to the patient(s) to delete.
4. Tap the **Delete** icon and confirm the deletion.

Tutorials

There are 11 tutorials containing the steps you will need to take to complete the following procedures.

How to Access the Tutorials

You may access the Tutorials by tapping on the **question mark** icon.

The question mark symbol appears on every screen. The question mark symbol also contains access to Frequently Asked Questions (FAQ's), Contacts (App information), and access to the slide show Tutorial.

From Any Screen

1. From any screen, tap the **question mark** icon located to the top right to display the Tutorial.
2. Tap on **Tutorial** to display the Tutorial Center.
3. Once the **Tutorial** Center screen displays, tap the **Tutorial** to display (Figure 60).
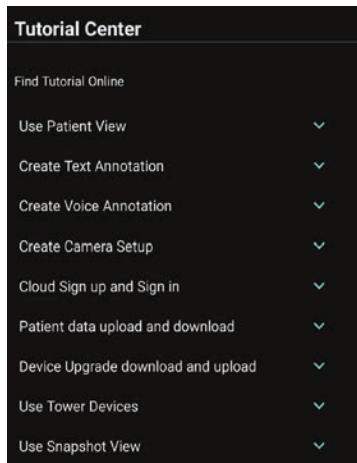
Figure 60. Tutorial Center Menu

4. Tap the **title** of the desired Tutorial.

   Note: Each of the Tutorials lists the steps at the bottom of the screen.
5. To move to each step, use your finger to swipe to or from each frame until you until you reached the desired step or slide.
6. To end the selected Tutorial, tap the (X) in the upper right corner of the tutorial.

Cleaning and Disinfecting

During normal use of the INTELLIO◊ Tablet the device may become dirty and should be regularly cleaned.

To Clean the INTELLIO Tablet

CAUTION: Disconnect the power cord before cleaning the INTELLIO Tablet.

1. Turn off the INTELLIO Tablet and unplug the power cord.
2. Wipe the screen and exterior with a soft, damp cloth moistened only with water. Do not use liquid or aerosol cleaners on the screen, as these will discolor the finish and damage the screen
3. Clean the LCD display only with a soft cloth dampened with 60% above isopropyl alcohol or 60% above ethyl alcohol each time after use.

CAUTION: Do not immerse or rinse the INTELLIO Tablet or its peripherals. If you accidentally spill liquid on the device, disconnect the unit from the power source. Contact your IT support department regarding the continued safety of the unit before placing it back in operation-Do not spray cleaning agent on the chassis.

CAUTION: Do not use disinfectants that contain phenol.

CAUTION: Do not autoclave or clean the INTELLIO Tablet or its peripherals with strong aromatic, chlorinated, ketone, ether, or ether solvents, sharp tools, or abrasives. Never immerse electrical connectors in water or other liquids.

Note: This device is not intended for use within the sterile field. Avoid any contact of this device with contaminated gloves.

Troubleshooting

If a problem persists, contact your authorized Smith+Nephew representative.

Problem	Possible Cause	Solution
Cannot connect to the control unit	Mal-configured network settings	**Check the control unit configurations in the vicinity of the target control unit. Ensure that:** ▪ The target control unit is turned ON ▪ All control units in the vicinity have different Wireless Names ▪ Ensure that the Wireless Channels of any control unit close by are not the same or adjacent channels **Note:** For best performance, the wireless channels need to be as far apart as possible – i.e.: 1, 4, 7, and 11)

		Check Tablet Network Configuration(s)
		▪ Check the Tablet Wi-Fi settings and ensure that the target control unit Wireless SSID Name:
		  – Is available
		  – Is selected
		  – Has a check mark that it is connected
		▪ Check the App Configuration:
		  – Login to the App
		  – Verify that the target control unit Wireless SSID name is present in the upper left corner on the device
		  – Attempt to connect to the control unit
		▪ Move closer to the control unit

		Power Cycle the Devices: ▪ Power down the control unit, then power it up again ▪ Power down the INTELLIO◊ Tablet, then power it up again ▪ Remove and Re-install the App
Constant Disconnection from the target control unit	Interference	**Check the control unit configurations in the vicinity of the target control unit. Ensure that:** ▪ The target control unit is turned ON ▪ All control units in vicinity all have different Wireless Names ▪ Ensure that the wireless channels of any control units close by are not the same or adjacent channels. **Note:** For best performance, the wireless channels need to be as far apart as possible – i.e.: 1, 4, 7, and 11)

		Check INTELLIO Tablet Network Configuration(s):
		▪ Check the Android Tablet Wi-Fi settings, and ensure that the target control unit Wireless SSID Name:
		  – Is available
		  – Is selected
		  – Has a check mark that it is connected
		▪ Check the App configuration:
		  – Login to the App
		  – Verify that the target control unit Wireless SSID name is present in the upper left corner on the device.
		  – Attempt to connect to the control unit
		▪ Check the installation of Integration Broker, if applicable, for proper worklist output.
		▪ Move closer to the control unit

Troubleshooting

Problem	Possible Cause	Solution
		Power Cycle the Devices: ▪ Power down the control unit, then power it up again ▪ Power down the INTELLIO◊ Tablet, then power it up again ▪ Remove and Re-install the App
Transfer of Videos/Images is slow	Interference	Refer to the steps in the solution for "Constant Disconnection from the target control unit"
Cannot Capture Video/Image	Not connected to the control unit	**Ensure that:** ▪ You are connected to the control unit ▪ A valid patient file is open on the Tablet ▪ The Image and Video icons on the Tablet for Camera or Room are active If not active: – Check the available storage on the Tablet To check the storage amount on the INTELLIO Tablet, tap the INTELLIO Tablet settings, tap General, and then tap About. The storage (capacity) amount is displayed. **Note:** Not all functions are available and are dependent on the media type.
		Power Cycle the Devices: ▪ Power down the control unit, then power it up again ▪ Power down the INTELLIO Tablet, then power it up again ▪ Remove and Re-install the App
Cannot Save to Camera Roll	Storage available on the mobile device is insufficient	Archive or delete some information from the device. Refer to the Archive Patient Data section of this document.
User can only export Images and Videos	Text and Audio annotations cannot be exported to the Camera Roll.	None

	The user disabled the App access to the Camera Roll.	▪ The user disabled the App access to the Camera Roll. To correct:
		  – On the mobile device, tap Settings.
		  – Tap Permission Manager
		  – Tap storage
		  – INTELLIO Tablet
		  – Select Allow

Cannot Print	Printer Offline	▪ Check that the Printer is powered on. ▪ Ensure the manual printer is a compatible printer. ▪ Ensure that you are connected to control unit Network. For directions on how to setup the printer to log in to a wireless network (the CCU in this case), please refer to the printer manufacturer's documentation. Prior to setting up, please have both the CCU Wi-Fi Network name and password ready.
	Printer not configured in App	▪ When logging into the tablet, go to the General Settings and ensure the printer is configured. ▪ If the printer is not listed, refer to Printer Offline section in this table.
	Auto Printing, all images did not print.	▪ Before capturing the first image, ensure that the printer is on. ▪ Check the Patient View, and if the printer icon is orange and blinking tap the printer icon once. The remaining images will then print.

Problem	Possible Cause	Solution

Failed to Print an image	Connection to control unit	• Ensure that you are connected to the INTELLIO Tower Network
		• Check the INTELLIO◊ Tablet Network Configuration(s)
		   – Check the INTELLIO Tablet Wi-Fi Settings, and ensure that the target control unit Wireless SSID Name:
		     Is available
		     Is selected
		     Has a check mark that it is connected
		• Check the App Configuration:
		   – Login to the App
		   – Verify that the target control unit Wireless Network name is present in the upper left corner on the device
		   – Attempt to connect to the control unit
		• Move closer to the control unit and ensure the wireless antenna on the CCU is present and seated.
		• Ensure that the printer is properly connected to the control unit Network
		• Check the control unit configurations in the vicinity of the target control unit, ensure that:
		   – Target control unit is Turned ON
		   – All control units in the vicinity all have unique network identifications (SSID/MAC)
		   – Wireless Channels of close control units are not the same or adjacent channels
		Note: For best performance, the wireless channels need to be spaced as far apart as possible – i.e.: 1,4,7, and 11)

		Power Cycle the Devices: • Power down the control unit, then power it up again • Power down the INTELLIO Tablet, then power it up again • Remove and Re-install the App
E-mails are NOT being received	Not connected to the Internet	Be sure to change to a network that has Internet connectivity. **Note:** The e-mail feature requires an Internet connection.
The e-mail form does NOT appear or does not send after completion of sending	The e-mail is too large to send.	Refer to sections General Settings, Max. E-mail Attachment Size in this document.
	No Internet connection	Establish a connection to the server
	E-mail server is Offline	Wait until the e-mail server is online
Failed to Archive to USB Drive Patient and/or individual media objects	The control unit is not connected	Ensure connection to the current control unit
	A USB device is not connected to the control unit	Ensure that a USB stick is inserted in the control unit
	Insufficient storage space	Ensure sufficient storage space is available on the USB stick to which the media files will be saved.
To CCU	USB	Remove and re-insert the USB drive into the CCU front panel. Confirm the USB icon state displayed on the monitor.
Failed to Pull a Scheduled Worklist	Worklist	Perform an On Demand Pull. Refer to the On Demand Pull section listed in this document.
INTELLIO Tablet is non-responsive	User Interface Freezes	In the event the Tablet is nonresponsive. Go into the Home mode and relaunch / power cycle. **Note:** It might be necessary to disconnect the INTELLIO Tablet power supply from AC mains and then remove the battery from the device to accomplish a power cycle.

Problem	Possible Cause	Solution
INTELLIO⁰ Tablet fails to turn on	INTELLIO Tablet does not have power/Battery is discharged.	Please connect the INTELLIO Tablet power adapter to AC mains and try it again.

Expected Life

The design of the Smith+Nephew INTELLIO◇ Tablet is as a reusable device. The functional life of this device depends on various factors, including frequency of use, the method and duration of each use, as well as post- operative methods and handling. Proper maintenance of the equipment is essential to achieve optimal performance over time.

The INTELLIO Tablet should be inspected before each procedural use per the "Service Life Checklist", if any issues occur, perform "Troubleshooting". If the problem persists, contact Smith+Nephew customer service or an authorized Smith+Nephew representative.

Factory Reset:

1. Log into the Tablet as Admin (Owner).

2. Navigate to the INTELLIO Tablet Settings Figure 61).

Figure 61. INTELLIO Tablet Settings

3. Tap on **System**, and then on **Advanced**, (Figure 62).
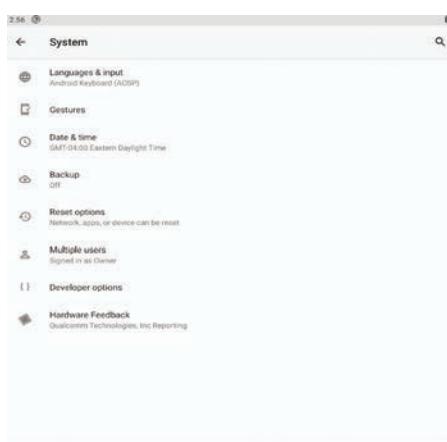
Figure 62. Advanced

4. Tap on **Reset Options**, (Figure 63).

Figure 63. Reset Options

5. Tap on **Erase all data** to perform a factory reset, (Figure 64). Erases all data and returns the INTELLIO Table to a default state.

Figure 64. Erase all data

Service

There are no customer-serviceable components inside the INTELLIO Tablet. Repairs and adjustments are to be performed only by Smith+Nephew authorized service centers.

If service becomes necessary, call an authorized Smith+Nephew Customer Service Representative prior to returning the device and request a Return Authorization (RA) number. A representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully disinfected, repackaged and returned post-paid to Smith+Nephew. A Smith+Nephew Customer Service Representative can provide additional instructions.

Note: Returned product that is found to have been serviced by an unauthorized third-party repair facility and/or sterilized with a sterilization method other than one approved by Smith+Nephew will incur additional costs, regardless of warranty status.

It is not necessary to include accessory items (i.e., power cords, paper trays, footswitches, remote controls, etc.) when returning a device for service.

Do not remove any digital interface boards that may be installed in the unit.

Maintenance

Recommended Annual Performance Checks

Smith+Nephew recommends that dielectric strength, earth leakage current, and protective earth testing be performed annually to assure continued compliance with applicable safety requirements. These tests should be conducted in accordance with specifications IEC 60601-1:2005 + A1:2012 IEC 60601-2-18:2009, IEC 60601-1-2:2014

In the event you encounter a serious incident in relation to this device, please contact the manufacturer and the competent local authority immediately.

CAUTION: Electrical safety testing should be performed by a biomedical engineer or other qualified person.

System Errors

Message	Possible Cause	What to do
Enter valid credentials.	User attempted to login with an invalid password.	**Log in** with the correct password. If you have forgotten your password, refer to the "Recover Login Information - (Forgot Password)" section of this document.
The security question and/or answer is wrong.	User attempted to change the password but answered the wrong security question.	Change the password and answer the correct security question.
This device has not yet registered an e-mail account.	User tried to e-mail a media file but has not registered an e-mail address on the device.	The user can register an existing email address when configuring the INTELLIO◊ Tablet. Once an account has been registered, attempt to e-mail again.
Red Worklist icon (DICOM Connection)	User attempted to Push or Pull Data	▪ Ensure the tablet is the Guided Access mode if the tablet has returned to the locked screen. ▪ Check the IP Address in the Broker Settings for the INTELLIO◊ Tablet matches the IP Address for the Broker. ▪ If appropriate, check the Username, and Password ▪ If appropriate, check the System Name **Note:** Contact your local IT administrator for the correct IP Address, Username, Password, and Share Name. ▪ Ensure the CCU system is On. ▪ Ensure the Tablet and the CCU is connected.
Auto Printing Pop-up sample	User attempted to Print	Pop-up appears; act: – Check the INTELLIO Tablet Network Configuration(s) – Verify the Wi-Fi settings are configured correctly to communicate with printer. – Check the INTELLIO Tablet Wi-Fi Settings, and ensure that the target control unit Wireless SSID Name: » Is available » Is selected » Has a check mark that it is connected – Press OK to continue. ▪ Check that a manual Printer is: – Configured – Is on – Is available
Pop-up Snapshot failed message	User attempted to capture a Snapshot record	Pop-up message appears indicating a failure. Please re-try capturing the snapshot view. Refer to Capture Snapshot section listed in this document.

System Specifications*

Supports	
Operating System	Android™ 10
Storage Configuration	
Internal	128GB in total **Note:** Refer to the Expected Life section regarding Factory restore information.
Power Requirements	
Input Voltage	100-240V~, 2.0-1.0A, 50-60Hz
Battery	10.8V 2300mAh, 24.84Wh Operating time: Up to 5.5 hours
Equipment Classification	Class II; Continuous operation; No applied part
Unit Dimensions	7.1" H x 11" W x 0.7" D 180.1mm H x 280mm W x 18.3mm D
Unit Weight	900 g/2.2 lb.
Display	
Type	10.1" FHD LCD
Resolution	1920 x 1200 WUXGA
Brightness	800 cd/m²
Touch Type	10-point multi touch P CAP touch control
Communication	
WLAN	IEEE 802.11 a/b/g/n/ac
Bluetooth	Bluetooth® v5.0 (Disabled in normal use)
NFC	13.56 MHz, compatible with ISO15693, ISO14443A, ISO 14443B, FeliCa (Disabled in normal use)
Connections	
Standard I/O	USB Type-C 3.0
Extended I/O	1 x AIM extension 14-pin pogo connector: 1 x USB 2.0, 1 x 2-wire UART, 5V/1A power
Docking	1 x AIM docking 15-pin pogo connector, 1 x USB 3.0,12V power
Audio	2 x internal speakers
Camera	
Rear	13-mega pixel auto focus with LED Flash
Ingress Protection	IP65, Tablet device only, does not apply to the power adapter and docking.
Compliance	IEC/UL/EN 60601-1, UL/CB 62368 , FCC, CE, NCC/BSMI, TELEC/VCCI, RCM, IC, CCC/SRRC, EN1789 ANSI/AAMI ES 60601-1 (2005)+ AMD 1 (2012) CAN/CSA-C22.2 No. 60601-1:14
Media Objects Definitions	INTELLIO◊ 4K CCU or LENS 4K CCU Main Camera Input: **Images** Image Size: 1920x1080 jpeg encoded File: ~1MB 16　images is **->**16MB Encoding: JPEG 97 Quality **Videos** Video Size: 1920x1080 H.264/Mp4 encoding (Compliant mp4 files) Capture Rate: ~1.2MB per second **->** thus 100 Second Video file size is ~125MB Encoding: 30 FPS/10 Mbits/sec; Intraframe rate: 5

System Specifications*

Supports		
Room Camera	**Images PAL**	
		Image Size: 720x576 jpeg encoded File Size: ~125KB
		Encoding: JPEG 97 Quality
	Videos PAL	
		Video Size: 720x576 H.264/Mp4 encoding
		Capture Rate: ~720KB per second **->** thus 100 Second Video file size is ~72MB Encoding: 30 FPS/6 Mbits/sec; Intraframe rate: 5
	Images NTSC	
		Image Size: 720x480 jpeg encoded File Size: ~125KB
		Encoding: JPEG 97 Quality
	Videos NTSC	
		Video Size: 720x480 H.264/Mp4 encoding (Compliant mp4 files)
		Capture Rate: ~750KB per second **->** thus 100 Second Video file size is ~75MB Encoding: 30 FPS/6 Mbits/sec; Intraframe rate: 5
Transfer Rates* *Wi-Fi performance is subject to environmental conditions and/or distance from the System.	**Transfer rates to/from Tablet is ~2MB/Second**	
		125MB Video transfer from USB to Tablet : 60 seconds
		300MB Patient Folder from Tablet to USB: 150 seconds
Calculation for Maximum Number of Media Objects	**The following is estimated and will vary based on the system configuration.**	
	Pre-Connect: 4GB Reserved:	
		2GB to keep free
		2GB in application/OS
	Main Video Input / Gigabyte of Storage:	
		800 Seconds Video / Gigabyte Storage 1000 Images / Gigabyte of Storage
	Room Video Input:	
		1300 Seconds Video / Gigabyte Storage 10000 Images / Gigabyte Storage
Auto Printing		
Installation and E-mail	An Internet connection is required.	
Integration Broker	Integration Broker supports 3.4	
	Version 3.4 supports pictures, (jpegs) and videos (H.264).	
	Refer to document (REF 1061567) Integration Broker Administrator's Guide Software Version 3.4 and review sections Save to PACS and DICOM Worklist.	
	In section Save to PACS, select the following in the Optional Settings:	
	• **DICOM Modality**: ES-Endoscopy	
	• **Video Storage Type**: Video Endoscopic Image Storage	
	• **Video Output Type**: MPEG4 AVC/H.264 High Profile/Level 4.1	
	In section DICOM Worklist, select the following in the Optional Setting:	
	• **DICOM Modality**: ES-Endoscopy	

*Specifications subject to change without notice.

^ The battery duration and recharge time can vary depending on different factors, such as screen brightness, applications, features, power management, battery condition, and other configurable settings.

VESA Docking Station Specifications

	Supports Advanced VESA Docking Station
I/O	2 x USB 3.0
	1 x RS-232 COM Port
	1 x Gigabit LAN Port
	1 x DC-in Power Jack
Stand	N/A
Power Requirements	
Input Voltage	19V
Unit Dimensions	8.9 H x 6.3 W x 2.9 D (159.13 mm H x 75.49 W mm x 227 D mm)
Unit Weight	0.33 kg/0.72 lb.

Environmental Conditions

Condition	Transport and/or Storage	Use
Temperature	-4° to 140° F (-20° to 60° C)	50° to 77° F (10° to 25° C)
Humidity	15 - 85% (no condensation)	30 – 75% (no condensation)
Atmospheric Pressure	70–106 kPa	70–106 kPa

Ordering Information

INTELLIO◇ Tablet

Each Smith+Nephew INTELLIO Tablet includes a 1 Tablet, 1 power brick, and 2 USB cables. The International System (REF 72205685) includes a European Continental power cord.

REF	Description
72205455	INTELLIO Tablet
72205608	INTELLIO Tablet Rechargeable Battery (pre-installed)
72205607	INTELLIO Tablet, 4-Battery Charger (optional)
72205611	INTELLIO Tablet Replacement AC/DC adaptor
72205606	INTELLIO Tablet, VESA Mount

Integration Broker Set-up Instructions

To ensure compatibility with INTELLIO◇ Tablet and the Integration Broker, please follow the recommendation for the router base address and the worklist location. Refer to 1061567 Integration Broker IFU.

IP Address

Please ensure the IP of the either the INTELLIO◇ 4K CCU or LENS 4K CCU uses a separate subnet. The INTELLIO 4K CCU or LENS 4K CCU uses the 192.168.1.XXX subnet for Wi-Fi communications. The Ethernet connection to Integration Broker server must not conflict with this network. It is recommended that IP addresses are assigned outside that subnet. (e.g. 192.168.10.XXX) Do not assign the same IP address range for external routers which may be connected to Integration Broker.

Special Considerations

Note: This consideration applies only for the HL7 configuration when Integration Broker is enabled.

The facility can utilize only one directory to transfer all patient information via the Integration Broker and INTELLIO Tablet, use the following steps to change the PACS directory:

1. From the Integration Broker server, open the C:\ Share Name folder in Windows Explorer. The Share Name folder contains 4 folders:
   - Backup
   - Error
   - HIS
   - PACS
2. Open the HIS folder and COPY the serverhome folder.
3. Open the PACS folder and PASTE the serverhome folder.
4. From the Integration Broker Admin Console, select the HL7 Worklist Tab.
5. Select the Share Directory and click on Browse.
6. Locate the C:\Share Name\PACS folder and press Open.
7. Press Save and the Integration Broker Service is Restarted.

Refer to document (REF 1061567) Integration Broker Administrator's Guide Software Version 3.4 for corresponding with PACS.

Guidance and Manufacturer's Declaration

Electromagnetic Emissions		
The Smith+Nephew INTELLIO◊ Tablet is intended for use in the electromagnetic environment specified below. The customer or the user of the INTELLIO Tablet should assure that it is used in such an environment. The Smith+Nephew INTELLIO Tablet was tested to the following:		
IEC/EN 60601-1-2: 2014/2015		
Specification	IEC 60601-1-2 (2014) / 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.	
Test Method	IEC CISPR 11 (2010) / EN 55011 (2010), Industrial, scientific, and medical equipment - Radiofrequency disturbance characteristics - Limits and methods of measurement Radiated	
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group I Environment, Professional Healthcare Facility, and not compatible with a Magnetic Resonance (MR) environment.	The INTELLIO Tablet is suitable for use in a Professional Healthcare environment where utility mains are privately used by the Healthcare Facility.
RF emissions CISPR 11	Class A	**Note:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). Not to be used in a residential environment (for which CISPR 11 class B is normally required) as this equipment might not offer adequate protection to radiofrequency communication services. ⚠️ WARNING: Use of accessories and cables with this equipment, other than those specified or provided by the Smith+Nephew, could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.
Harmonic emissions EN 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	N/A	

Separation Distances

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Smith+Nephew INTELLIO◊ Tablet.

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

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3 \sqrt{P}$
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 power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Electromagnetic Immunity

The Smith+Nephew INTELLIO◊ Tablet is intended for use in the electromagnetic environment specified below. The customer or the user of the INTELLIO Tablet should assure that it is used in such an environment.

Specification	IEC 60601-1-2 (2014) / 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.
Test Method	EN 61000-4-2 (2009) / IEC 61000-4-2 (2008), Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test
	EN 61000-4-3 (2010) / IEC 61000-4-3 +A1+A2 (2010), Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radiofrequency, electromagnetic field immunity test
	EN 61000-4-4 (2012) / IEC 61000-4-4 (2012), Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test
	EN 61000-4-5 (2006) / IEC 61000-4-5 (2005), Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test
	EN 61000-4-6 (2014) / IEC 61000-4-6 (2013), Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radiofrequency fields
	EN 61000-4-8 (2010) / IEC 61000-4-8 (2009), Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test
	EN61000-4-11 (2004) / IEC 61000-4-11 (2004), Electromagnetic compatibility (EMC) – Part 4-11: Testing and measuring techniques – Voltage dips, short interruptions, and voltage variations immunity tests

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 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 +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ 2 kV line to P.E. + 1 kV line to line	+ 2 kV line to P.E. + 1 kV line to line	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% Unom, ½ cycle 40% Unom, 5 cycles 70% Unom, 25 cycles 0% Unom, 250 cycles	0% Unom, ½ cycle 40% Unom, 5 cycles 70% Unom, 25 cycles 0% Unom, 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the INTELLIO Tablet requires continued operation during power mains interruptions, it is recommended that the INTELLIO Tablet be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 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.

Electromagnetic Immunity			
Conducted RF IEC 61000-4-6	3 VRMS 150 kHz to 80 MHz	3 V 3 V/m	⚠ WARNING: Portable and mobile RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the INTELLIO◊ Tablet, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz		
			Field strengths from RF transmitters, such as base stations for radio, (cellular/cordless) telephones, land mobile radios, amateur radios, AM, and FM radio broadcasts, and TV broadcasts cannot be predicted. The Professional Healthcare Facility must assess the electromagnetic environment due to RF transmitters; an electromagnetic site survey should be considered to ensure compatibility with the immunity levels contain in IEC/EN 60601-1-2.
			The INTELLIO Tablet normal operation is for general surgical purposes throughout the duration of orthopedic and arthroscopy applications.
			⚠ WARNING: Abnormal performance, due to Electromagnetic Disturbances, may be manifested by a failure to properly maintain illumination and visualization of the surgical field. If abnormal performance is observed, it may be corrected by one or more of the following measures:
			– Reorient or relocate this equipment, the other equipment, or both.
			– Increase the separation between the pieces of equipment.
			– Connect the pieces of equipment into different outlets or circuits.
			– Consult a biomedical engineer.
			⚠ WARNING: Use of accessories and cables with this equipment, other than those specified or provided by Smith+Nephew, could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.
Note: Unom = Nominal AC input voltage (90, 240VAC/50Hz)			

Special Environment

The INTELLIO◊ Tablet is intended for use in a Special Environment using HF surgical equipment.

⚠️ **WARNING - High Frequency (HF) Interference: This equipment was designed and tested to be used with HF Electrical Surgical Unit (ESU) equipment. If interference occurs with other equipment it may be corrected by one or more of the following measures:**

- Reorient or relocate this equipment, the other equipment, or both.
- Increase the separation between the pieces of equipment.
- Connect the pieces of equipment into different outlets or circuits.
- Consult a biomedical engineer.

For Further Information

If further information, including warranty, on this product is needed, contact Smith+Nephew Customer Service at +1 800 343 5717 in the U.S., or an authorized representative.

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