Trice Medical

Tenex® 2nd generation System

User Manual

Important

The Tenex 2nd generation system consists of a reusable Console that is to be used with the Tenex 2nd generation single-use MicroTips.

The devices are to be used by appropriately qualified doctors, nurses, and physician assistants for the indicated uses only.

 **CAUTION:** Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. **Rx Only**

This manual describes the recommended procedures for preparing and operating the Tenex 2nd generation Console. It does not describe how any medical procedure is to be performed on a patient with this device.

Read all instructions in this manual carefully before using the Tenex 2nd generation system.

Carefully follow all safety instructions to prevent injury to the user or patient, fire hazards, electrical shock, and damage to the device.

To maintain this device in optimal condition, follow all recommendations in this manual for handling, cleaning, and storage.

Pat. https://tricemedical.com/patents/

Manufacturer:

Manufactured For
Trice Medical, Inc
40 General Warren Blvd, Suite 100
Malvern, PA 19355
U.S.A.
Tel: 1.610.989.8080
Fax. 1.610.644.3073
www.TriceMedical.com

MEDICAL ELECTRICAL EQUIPMENT

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Intertek
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Table of Contents

Introduction

Thank you for your purchase of the Tenex 2nd generation Console. This manual will help you to make the most of the Tenex 2nd generation Console and its components.

The Tenex 2nd generation MicroTip is a sterile, single-use device. It delivers ultrasonic cutting, irrigation, and aspiration as a single handheld, disposable device.

The Tenex 2nd generation Console is a portable device that provides a touchscreen LCD for controlling MicroTip settings. The user can save up to 9999 procedures on the Console. The Console also features a USB-A port to transfer procedure information data via USB drive.

1.1 Indications for Use

The Tenex 2nd generation system is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of both soft and hard (e.g.: bone) tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery, and Plastic and Reconstructive Surgery.

The Tenex 2nd generation system is also indicated for use in debridement of wounds, such as, but not limited to, diabetic ulcers, in applications, in which, in the physician's judgement would require the use of an ultrasonic aspirator with sharp debridement.

1.2 Contraindications

The Tenex 2nd generation system should not be used in any anatomy with an active infection.

The ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

1.3 Adverse Effects

There is a possibility of a delay in the procedure from system issues. Other possible adverse effects include edema at the treatment site, delayed healing, bone degradation, increased morbidity or sub-optimal outcomes, sensitization, and allergic reaction, histological or toxic reaction, infection, irritation, fever, pain, tissue injury, foreign body reaction, electrical shock, and burns.

1.4 Possible Side Effects

Pain, soreness, bleeding, drainage, bruising, swelling, inflammation, infection, and allergic reaction.

1.5 How to Use This Manual

It is recommended that the user studies this manual before attempting to set up, operate, and care for the Console. This document will describe the proper setup, operation, and care of the devices.

1.6 Manual Conventions

The words **WARNING, CAUTION,** and **NOTE** signify special meaning and should be read carefully.

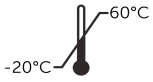
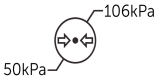
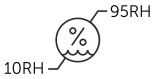
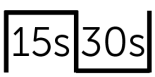
 **WARNING:** This statement contains information concerning the safety and/or health of the patient, user, or a third party who are at risk. Comply with this warning to avoid injury.

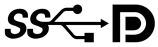
 **CAUTION:** This statement contains information concerning the intended use of the device or accessory, with a low risk of minor or moderate injury if not avoided.

NOTE: Notes usually pertain to a recommended protocol that will help extend the life of your equipment.

1.7 Symbols

1.7.1 Tenex 2nd generation Console Labeling Symbols

Symbol	Meaning
	Manufacturer
	Medical Device
	Date of Manufacture (YYYY-MM-DD)
	Catalog number
	Serial number
	Refer to instruction manual/booklet
	Consult instructions for use
	Waste Electrical and Electronic Equipment (WEEE) regarding recycling of electronic equipment at the end of its useful life.
	Alternating current from power source.
	Temperature Limit: -20°C – 60°C
	Pressure Limit: 50kPa – 106kPa
	Humidity Limit: 10RH – 95RH
Rx Only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician
IP20	Not protected against liquid entering the device. Device protected against particulate matter with diameter greater than 12.5mm from entering the device.
	Duty cycle of 15 seconds on, 30 seconds off.
	Power Button - On/Off (push-push)

Symbol	Meaning
	USB-A Port
	USB-C and Display Port
	Fuse, Time Delay 2.5AL, 250V
	Equipotentiality Connector **(Do not use this connector)**
	Footswitch
	Shock protection afforded by the device is Type B (Applied Part) per EN 60601-1
	Caution

1.5.2 Tenex 2nd generation User Interface Symbols

Symbol	Button Meaning
	Console Power Off
	User Toggle
	Password Backspace
	Settings
	Lock Screen
	Back Arrow
	Check Mark
	Up Arrow

Symbol	Button Meaning
	Down Arrow
	Delete
	Transfer to USB Drive
	Select All
	Select Procedure (Procedure History Screen)
	Add User

NOTE: Button background colors will change based upon state: active, inactive, or pressed.

1.5.3 Tenex 2nd generation User Interface Symbols for the MicroTip

Symbol		Button Meaning
		On/Off toggles for Aspiration, Irrigation, and Cutting

NOTE: Button background colors will change based upon state: active, inactive, or pressed.

1.5.5 Tenex 2nd generation User Interface Symbols

Symbol			Button Meaning
 Wrist/Hand	 Ankle	 Foot	Preset Buttons. Use these buttons to note the anatomy for the procedure and then proceed to set the Frequency, cutting power, irrigation, and power settings
 Elbow	 Knee	 Shoulder	
 Hip/Gluteus	 DFU		

NOTE: Button background colors will change based upon state: active, inactive, or pressed.

Device Features and Specifications

The Console is supplied with the required accessories.

2.1 Contents and Accessories

The following components are included in your Console:

> **Note:** The type of Power Cord (Item No. 2) included is determined by the destination of the Tenex 2nd generation system.

Item No.	REF No.	Description	Qty.
1	3-10-0487	ASM, CONSOLE, MAIN TXA	1
2	2-10-0452	POWER CORD, NEMA5-15P, 10FT	1
	2-10-0453	POWER CORD, JIS8303, 2.5M	
	2-10-0454	POWER CORD, AS NZS 3112, 2.5M	
	2-10-0168	POWER CORD, CEE7-7, EU, 2.5,	
	2-10-0169	POWER CORD, BS1263, UK, 2.5M	
3	3-10-0513	FOOT SWITCH ASSY, SGL, TXE	1
4	3-10-0529	FUSE SET, 2ND GEN	1
5	1-10-0915	MANUAL, USER, TENEX 2nd GENERATION, EN	1

WARNING: Only use the components specified in the user manual. Use of components other than those specified in the user manual and supplied by Trice Medical may result in an unsafe level of electrical isolation, increased electromagnetic emissions, and/or decreased electromagnetic immunity.

The following items are compatible with your Tenex 2nd generation Console:

Tenex 2nd generation MicroTips:

Item No.	REF No.	Device	Description
1.	T600-030	TXL, MICROTIP, 3.0in	Single-use, ultrasonic surgical aspirator with a 3.0” working length
2.	T600-025	TXL+, MICROTIP, 2.5in	Single-use, ultrasonic surgical aspirator with a 2.5” working length
3.	T600-020	TXS, MICROTIP, 2.0in	Single-use, ultrasonic surgical aspirator with a 2.0” working length
4.	T600-013	TXS+, MICROTIP, 1.3in	Single-use, ultrasonic surgical aspirator with a 1.3” working length

Replacement Components/Accessories

Item No.	REF No.	Device	Description
5.	1-10-0066	USB DRIVE, 4GB, TRICE	USB Drive
6.	2-10-0455	CABLE, USBC-HDMI, 10FT	USB C – HMDI Cable to connect to external HDMI TV or Video Monitor. See notes below.
7.	3-10-0529	FUSE SET, 2ND GEN	QUANTITY = 2, Slo-blo (Time Delay) 5mm x 20mm 2.5A 250V Fuse
8.	3-10-0137	KIT, SMARTPHONE ADAPTER, EN	Multiport USB Drive with iPhone USB adapter

The Console has a USB-A Connector on the side of the unit to allow connection to a USB drive, including the Smartphone Adapter listed in the accessories table above. The Smartphone Adapter acts like a USB flash drive that connects directly to the phone. The Smartphone Adapter allows users to export procedure information from Tenex 2nd generation Console and save it to the Smartphone Adapter flash memory. The Smartphone Adapter is then disconnected from the Tenex 2nd generation Console and inserted into a phone for copying of the exported procedures.

Note: The Smartphone Adapter cannot be used to connect a smartphone to the Console.

The Console also has a USB-C Connector on the back of the unit to allow connection to an HDMI TV or Video Monitor via the recommended USB-C to HDMI Cable listed in the compatible accessories table above. The connected External TV or Video Monitor must be medically certified to IEC 60601-1 and have an Earth Ground Terminal on the plug of its power cord (3-pronged plug).

Note: When an External TV or Video Monitor is connected to the Console, the user must ensure the system complies with IEC60601-1.

2.2 Unpacking and Inspecting the Console

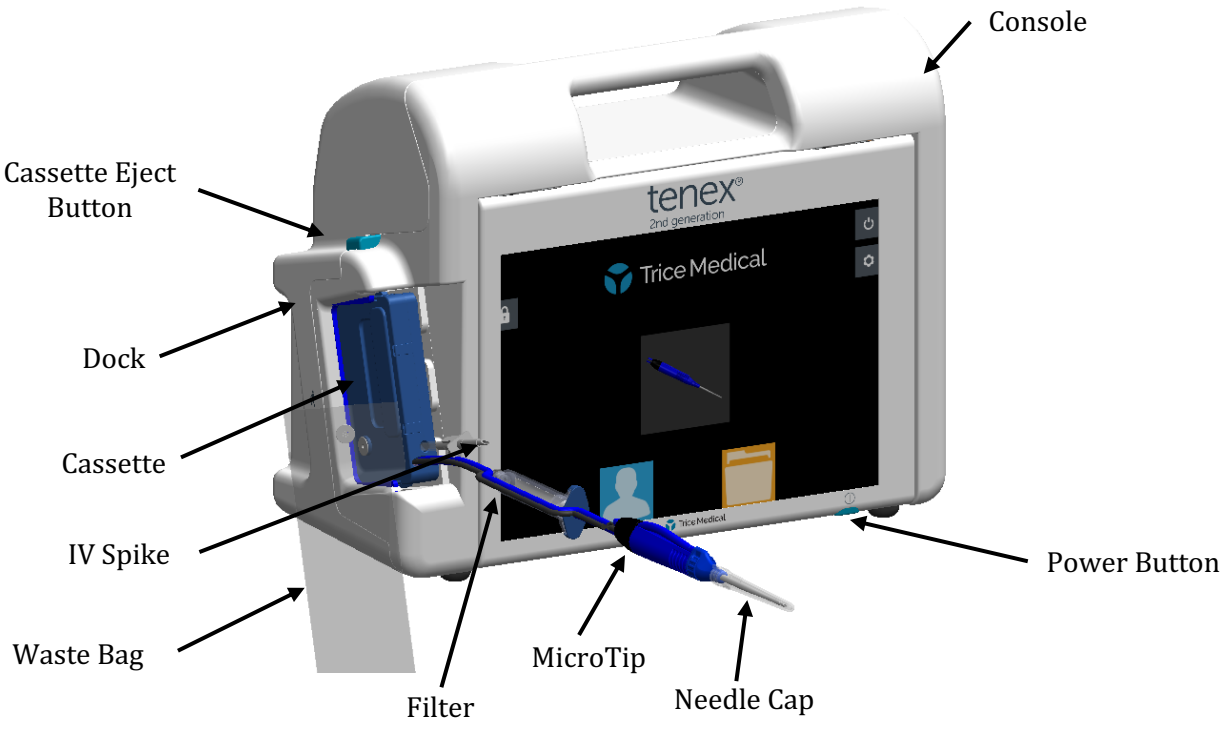
Upon receipt, carefully unpack and check to see that you have all these components before proceeding. If any are missing or damaged, contact Trice Medical immediately using the contact information below:

Trice Medical
40 General Warren Blvd, Suite 100
Malvern, PA 19355
Phone: 1.844.643.9300 or 1.610.989.8080
Fax. 1.610.644.3073
www.TriceMedical.com

Save all packaging materials; they may be needed to verify any claims of damage with the shipper or for returning the Console.

2.3 Features and Controls

2.3.1 Tenex 2nd generation Console



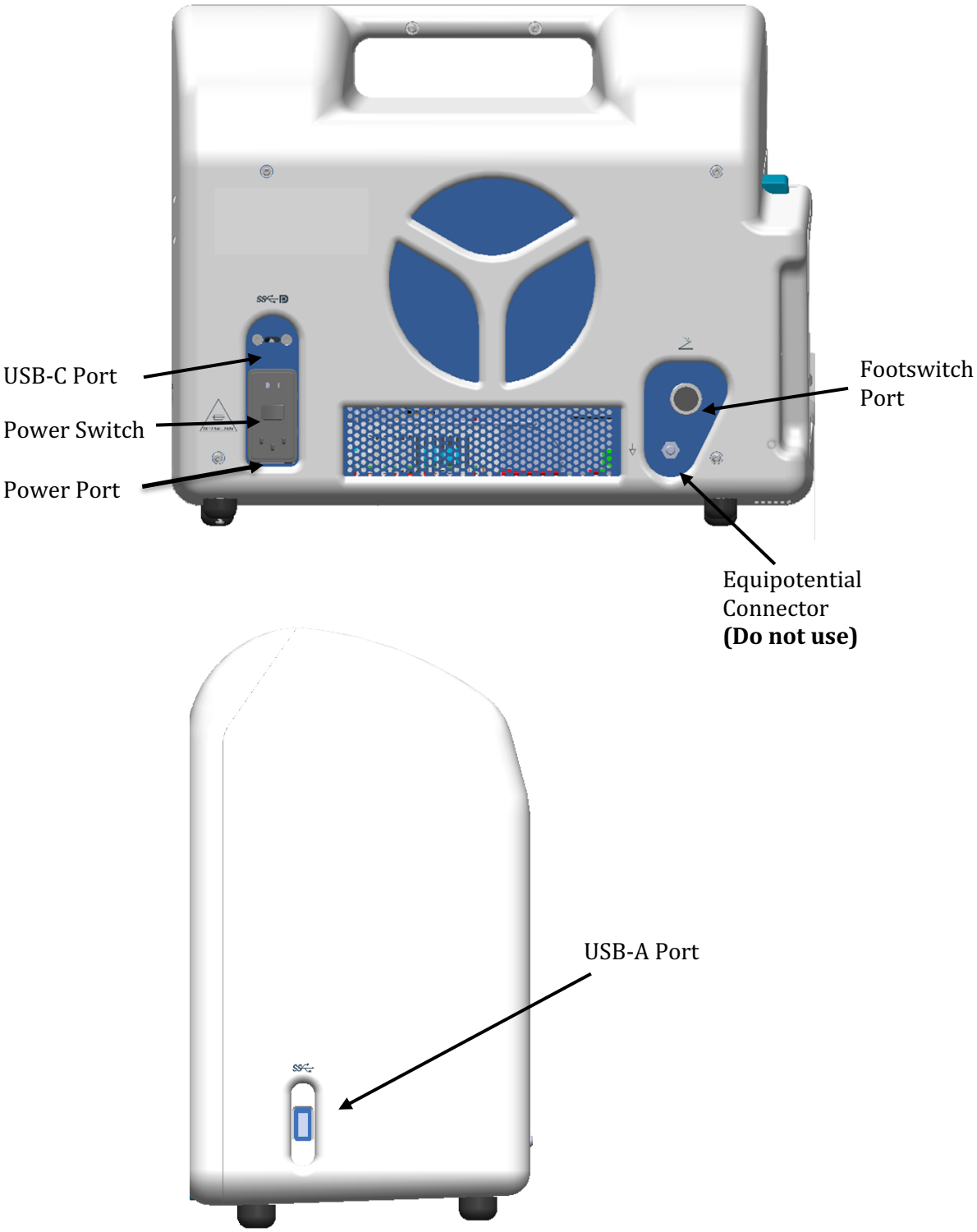


Figure 1: Tenex 2nd generation Console

2.3.2 Tenex 2nd generation MicroTip

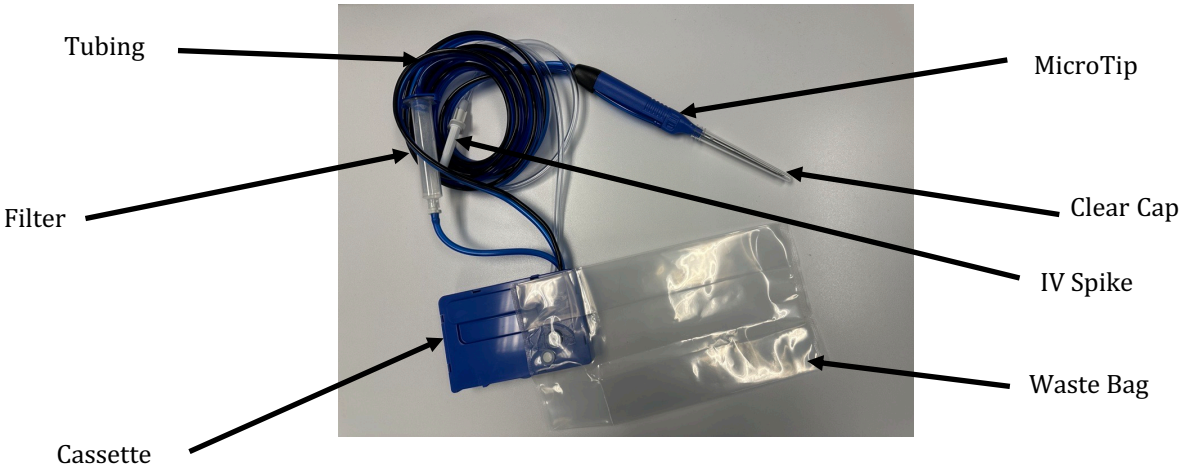


Figure 2: Tenex 2nd generation MicroTip

NOTE: The Tenex 2nd generation MicroTip is a Type B Applied Part

2.4 Specifications – Tenex 2nd generation Console

Electrical	
Power Source	AC/DC Power Supply (External)
Input Voltage	~100-240VAC
Input Current	2.0 A
Input Frequency	50/60 Hz
Classification	I per EN60601-1
Cable Length	
Power Cord	2.5 m (8.2ft) to 3 m (9.8ft.)
Device	
Dimensions (W x D x H)	40 x 18.49 x 32.31 cm (15.75”x7.28”x12.72”)
Weight	6.8 kg (15 lbs.)
Wireless	
Bluetooth	Wireless 5.1 technology (2400 to 2483.5 MHz) Radiated Power:100 mW (max) RX Bandwidth: 83.5MHz
Wi-Fi	Wi-Fi 6E. 802.11ax compatible (5 GHz band) Radiated Power:750 mW (max RX Bandwidth: 80 MHz

Cooling

IV Bag	0.5L or 1.0L

Environmental

Operating Pressure	70 to 106 kPA
Operating Temperature	10°C to 31°C
Operating Humidity	30% to 75% RH, non-condensing
Operating Altitude	≤ 3000 m
Storage/Transport Pressure	50 to 106 kPA
Storage/Transport Temperature	-20°C to 60°C
Storage/Transport Humidity	10 to 95% RH, non-condensing

Video/Display

Display Type	13” (33.0 cm) LCD
Resolution	2880 x 1920 (267 pixels per inch)
Aspect Ratio	3:2

System Media Capture

Storage Media	
Internal Memory	128 GB
Removable Trice USB Drive	4-8 GB

2.5 Specifications – Tenex 2nd generation MicroTips

Cable Length

Tubing/Wire	2.0 m (6 ft 8 in.)

Environmental

Operating Pressure	70 to 106 kPA
Operating Temperature	10°C to 31°C
Operating Humidity	30% to 75% RH, non-condensing
Operating Altitude	≤ 3000 m
Storage/Transport Pressure	50 to 106 kPA
Storage/Transport Temperature	-20°C to 60°C
Storage/Transport Humidity	10 to 95% RH, non-condensing

3.0 Device Setup

The following section describes how to set up the Tenex 2nd generation system for procedures. Proper initial setup is essential to provide you and your staff with the best access to operational and visual performance while conducting procedures.

WARNING: If liquid has entered the Tenex 2nd generation Console, do not use it as the liquid will affect the safety levels of electrical isolation and leakage current.

WARNING: The Tenex 2nd generation system is not intended for use in an oxygen rich environment.

WARNING: The Tenex 2nd generation system is not intended for use with flammable anesthetics or flammable agents.

3.1 Power Up Procedure

To power on the Tenex 2nd generation Console, ensure the power cord is plugged into a wall outlet and the back of the Console. Ensure the power switch on the back of the Console is set to On. Depress the Power Button located on the front bottom right of the Console (See Figure 1). When turned on, the screen will illuminate, and the Windows Logo will appear on the screen. The Console will take approximately forty seconds to boot up.

WARNING: To Avoid risk of electric shock, the Tenex 2nd generation Console must only be connected to a supply main with protective earth.

3.2 Console Sign-In

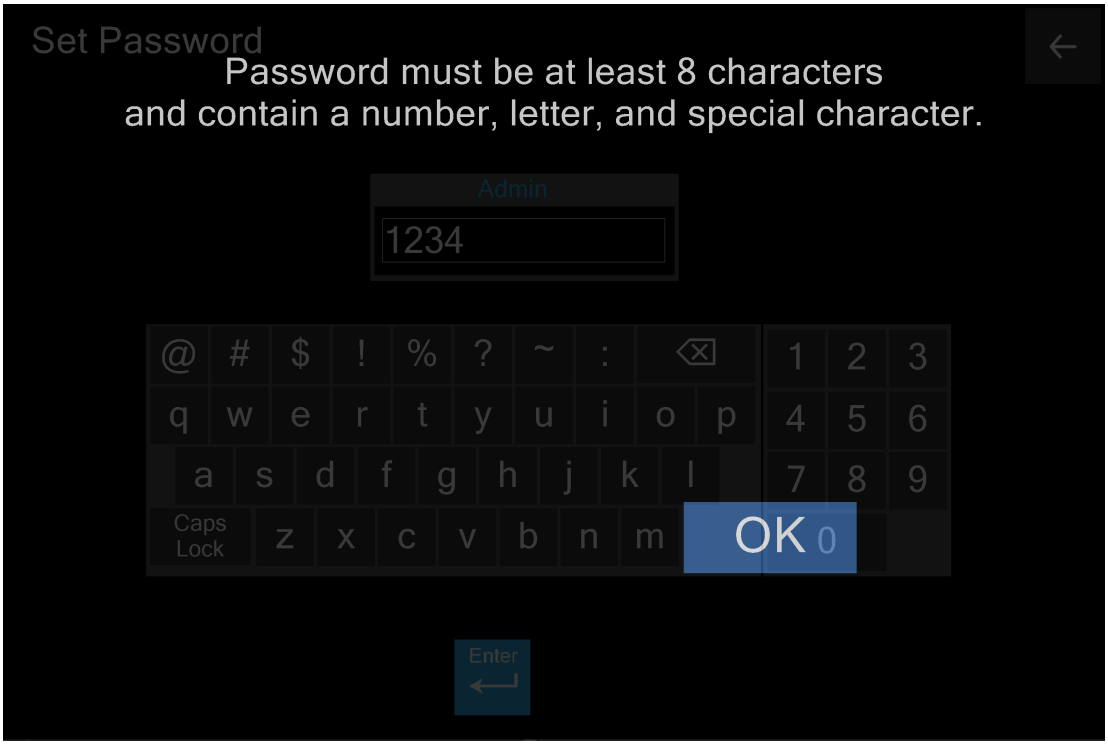
The Console will boot to the Lock Screen. Touch the Lock Screen to access the Login Screen. Touch the (Down arrow) to select the next user and to display the username list. Select the user profile to access from the dropdown menu using the touchscreen or by using the Down Arrow to cycle through the list. Note: Upon delivery the only user profiles are User 1 and Admin. As more users are added they will be displayed to the left of the sign-in when the Down arrow is pressed.

See Section 3.3 Administrator Mode for instructions on adding and deleting Users.

For first sign-in, enter the default password “1234” and select the Enter key. The Console will prompt a password change.

The password must be at least 8 characters and contain a letter, number, and special character. Type in a new password and then press the Enter key to proceed to the Home Screen.

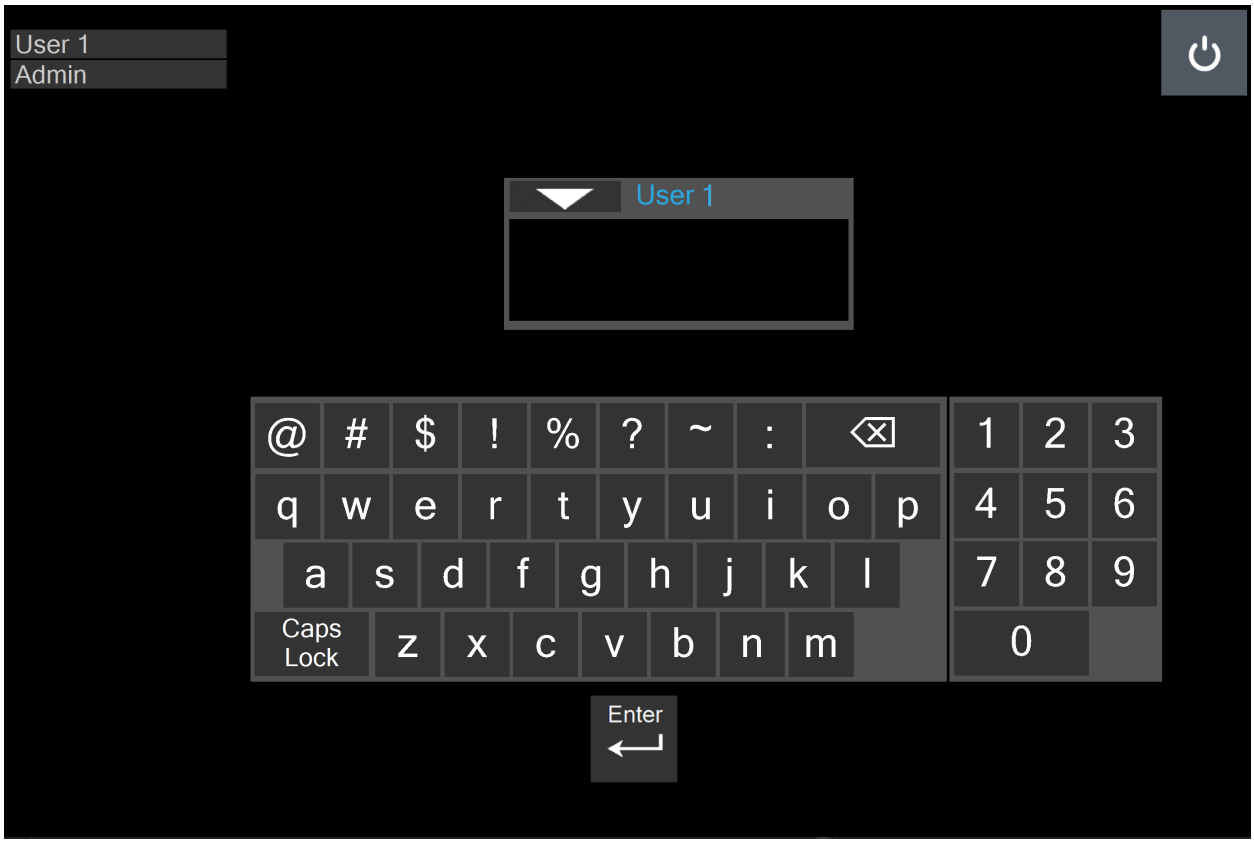
If the password does not meet the requirements, a message will display.



Press the OK button and then enter a password that meets the minimum requirements.

Note: The maximum password length is 10 characters.

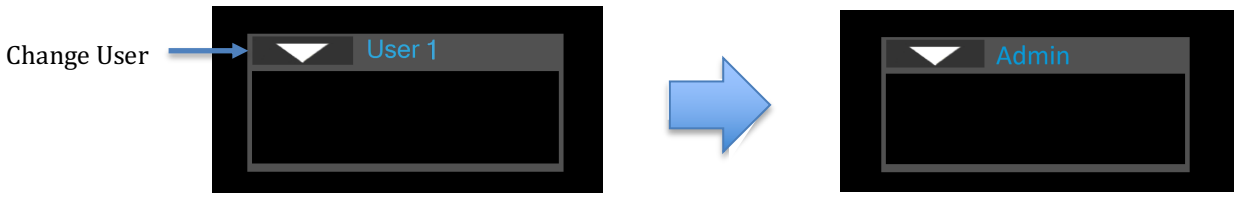
Passwords can be changed once logged into the system.
To change a password, access the Settings Screen by pressing . Select “Passwords” and input the desired password that meets the minimum requirements. Select Enter after inputting a new password. A confirmation chime will be heard, and the entered password will turn blue when password is successfully changed.



Passwords Screen

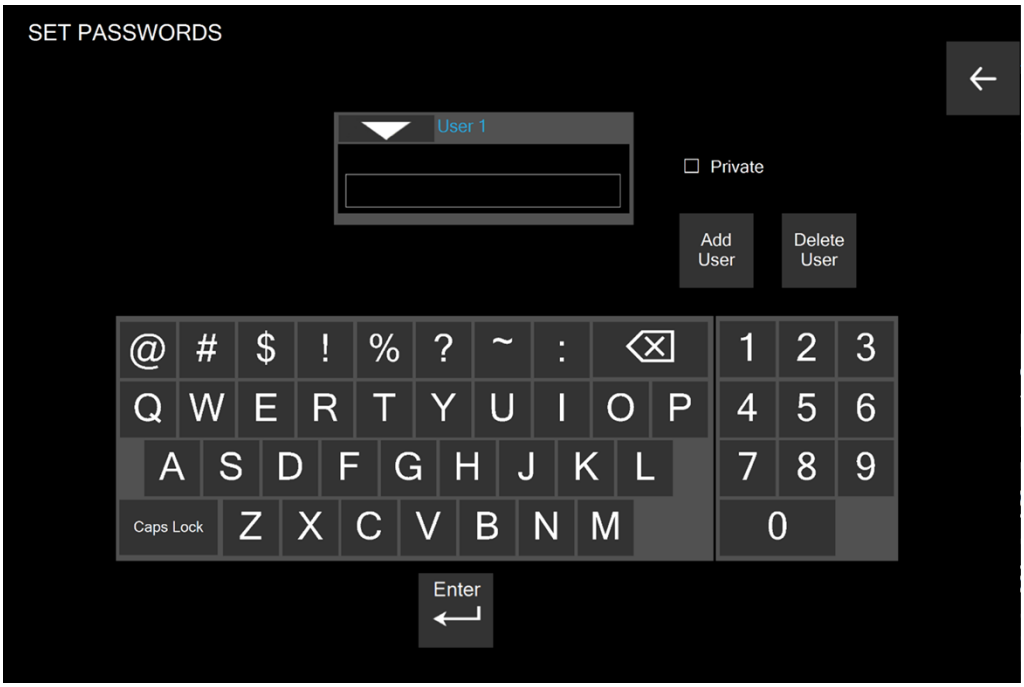
3.3 Administrator Mode

Administrator Mode is accessed by tapping the down arrow on the Sign-In Screen to change the user to “Admin.” For the first sign-in, enter in default administrator password “987654” and press the Enter key. The Console will prompt a password change (see Section 3.2 Console Sign-In).

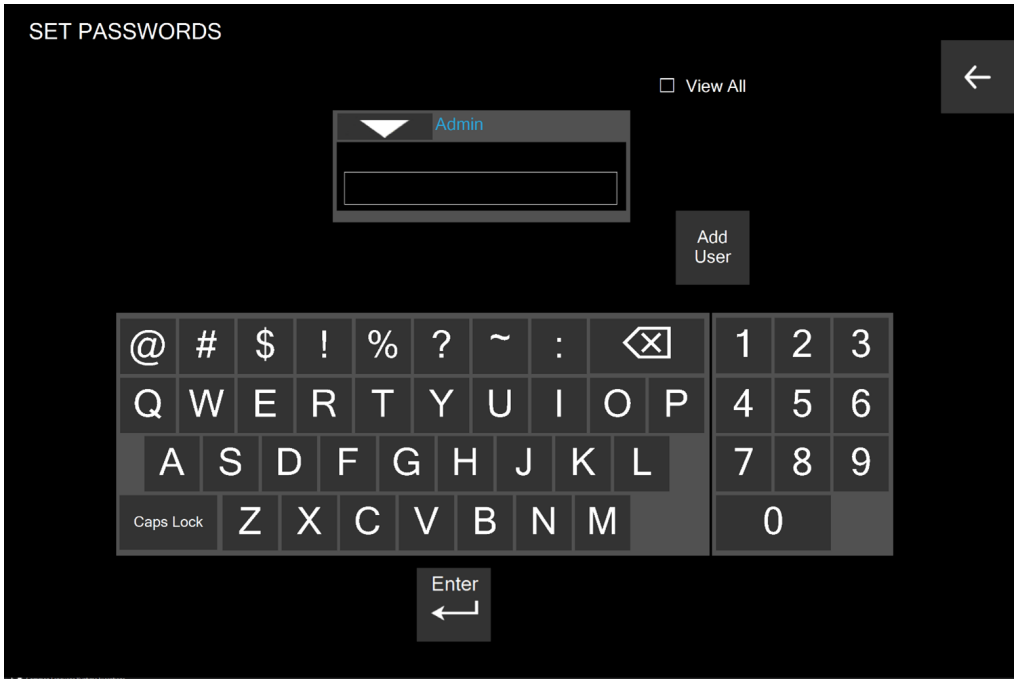


Within Administrator Mode, the Settings Screen will be displayed, and you can manage the following:

- Set Passwords (all users)
  - Private (Individual user Procedure History privacy setting)
    - If checked, this user's procedure history will not be visible to any other users.

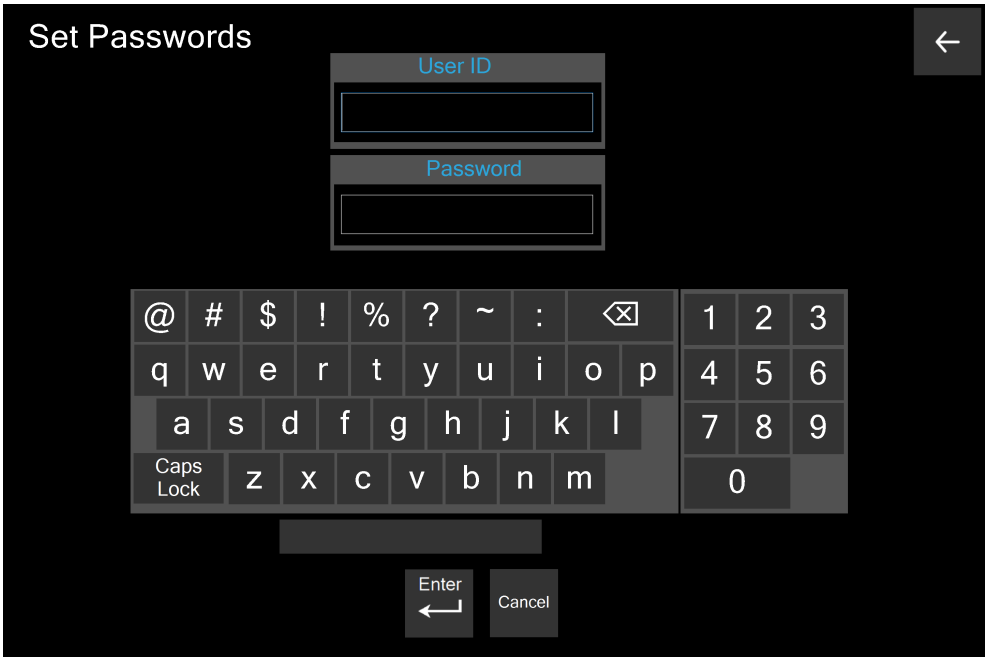


- View All (on = checked or off = not checked)
  - If on, the “View All Users” check box will be visible on the Procedure History Mode (See Section 4.4 Procedure History Mode). This option allows the procedure history of any user whose “Private” option is not checked to be visible to any other user.
  - If off, users can only see their own procedure history.

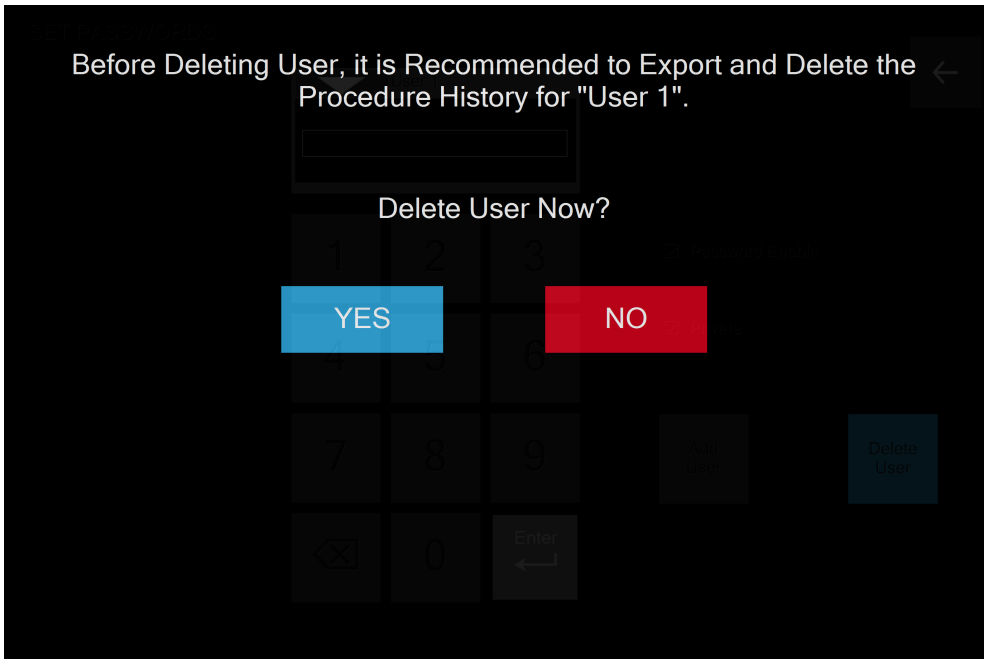


3.4 Add/Delete User Profiles

When adding a new user, the system will prompt the administrator to enter a new user ID and password.



When deleting a user, the system will prompt the administrator to export and then delete the user's procedure history prior to deleting the user. See 4.9 Transfer of Procedure Information Data to USB (PDF).



See Section 3.3 Administrator Mode for instructions on how to change passwords.

3.5 Positioning of Device

Find a suitable flat surface off the floor to set the Console. Ensure there is enough space behind or around the Console so:

- the Foot switch and Power Cord can be connected and disconnected from the rear of the Console.
- the power switch on the back of the Console can be switched on and off.
- the screen power switch on the front bottom right corner can be switched on.
- a saline bag can lay propped up on the flat surface adjacent to the Console.
- the Cassette Waste Bag can fill.

3.6 Connecting the MicroTip to the Console

Inspect the packaging of the MicroTip to ensure product sterility has not been compromised and there are no signs of damage.

⚠ **WARNING:** Do not use the MicroTip if there are signs of damage or if it has been previously opened.

⚠ **WARNING:** Do not use the MicroTip after the expiration date indicated on the package.

⚠ **WARNING:** The MicroTip is a single-use only device. Do not attempt to re-sterilize.

NOTE: The MicroTip is a Type B Applied Part

When ready to begin the procedure, ensure the clear cap on the end of the MicroTip is securely attached to the MicroTip. Remove the Cassette of the MicroTip from the tray and uncoil the tubing.

NOTE: Keep the MicroTip in the tray until ready for use.

Locate the Cassette Dock on the left of the Console and insert the Cassette with the waste bag positioned on the left of the Cassette and the tubing positioned at the bottom. If on the Home Screen a tone will be sounded, and the Priming Screen displays if the Cassette was inserted correctly. The Handpiece Type is displayed at the top of the Priming Screen.

Insert the IV Spike from the Cassette into a 500mL or 1L saline bag. Lay the IV Bag next to the Console. Ensure the IV Bag is propped up or tilted so the air in the IV Bag is above all the fluid. This prevents air from entering the IV Tube during the procedure. The IV Bag provides fluid for irrigation and aspiration.

WARNING: Irrigation with saline and Aspiration are required when using the MicroTip. The waste bag of the MicroTip will fill with biological hazard fluid and tissue from the patient. Surgical waste presents a biological hazard and must be handled and disposed of properly. The MicroTip, including the waste bag filled with biological hazard fluid and tissue, must be disposed of according to local regulations. Please refer to the Tenex 2nd MicroTip's Instructions for Use document (Trice REF 1-10-0842) for disposal instructions for the single-use MicroTip.

CAUTION: To facilitate proper cooling of the MicroTip handle, do not use the MicroTip continuously. Always follow a duty cycle of 15 seconds on, 30 seconds off.

3.7 Connecting the Console to an External TV or Video Monitor

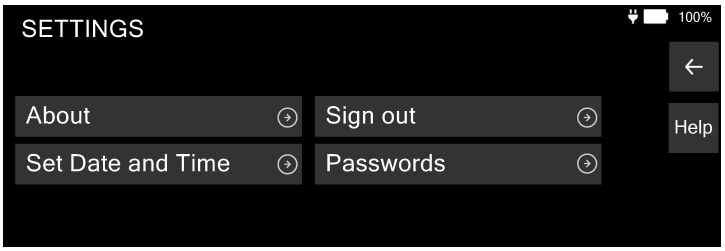
The Console may be connected to an HDMI External TV or Video Monitor that is medically certified to IEC 60601-1 and has an Earth Ground Terminal on the plug of its power cord 3-pronged plug. When an External TV or Video Monitor is connected to the Console, the user must ensure the system complies with IEC60601-1.

To connect an External HDMI TV or Video Monitor, connect the recommended USB-C to HDMI cable to the USB-C connector on the back of the Console and the HDMI connector on the External TV or Video Monitor. Then connect the power cord of the External TV and Video Monitor to the wall outlet and turn it on.

NOTE: The Console screen will momentarily flash when an HDMI External TV or Video Monitor is connected while it is turned on. This is a normal operation. To avoid the momentary flash, connect the External HDMI TV or Video Monitor before turning on the Console.

When connected, the image displayed on the Console touchscreen will be duplicated on the External TV or Video Monitor.

3.10 Settings Screen



The "Settings" Screen provides the capability to see the software version, set date and time, sign out from the system, and change the user passwords. To view the system software version and revision, select "About" from the Settings Screen. The Settings Screen can be accessed from Home Screen by pressing button.

The “Settings” Screen also provides the capability to see that AC Mains Power is connected, if the Console Battery is charging or charged, and the Battery charge percentage. See Section 4.6 Powering the for more information.

3.10.1 Help

For electronic versions of the Tenex 2nd generation system User Manual and Instructions for Use, there is a QR code on the Help Screen that links to electronic copies of these documents.

To access the QR Code, go to Settings Screen by pressing the “Settings”  button on the Home Screen and then press the “Help” button  . Scan the QR code with your phone to be redirected to the electronic documents.

4.0 Basic Usage

The Tenex 2nd generation Console has the following primary modes:

Ready Mode (Home Screen): Allows access to Procedure History Mode.

Priming Mode: Displays the graphical instructions for Cassette insertion to the Console, controls for procedure setup and priming the MicroTip. It is the Default Mode when a MicroTip is connected to the Console.

Procedure Mode (MicroTip): Displays controls for aspiration, irrigation, and cutting. Depressing the footswitch initiates aspiration, irrigation, and cutting in accordance with the configured settings controlled by the user.

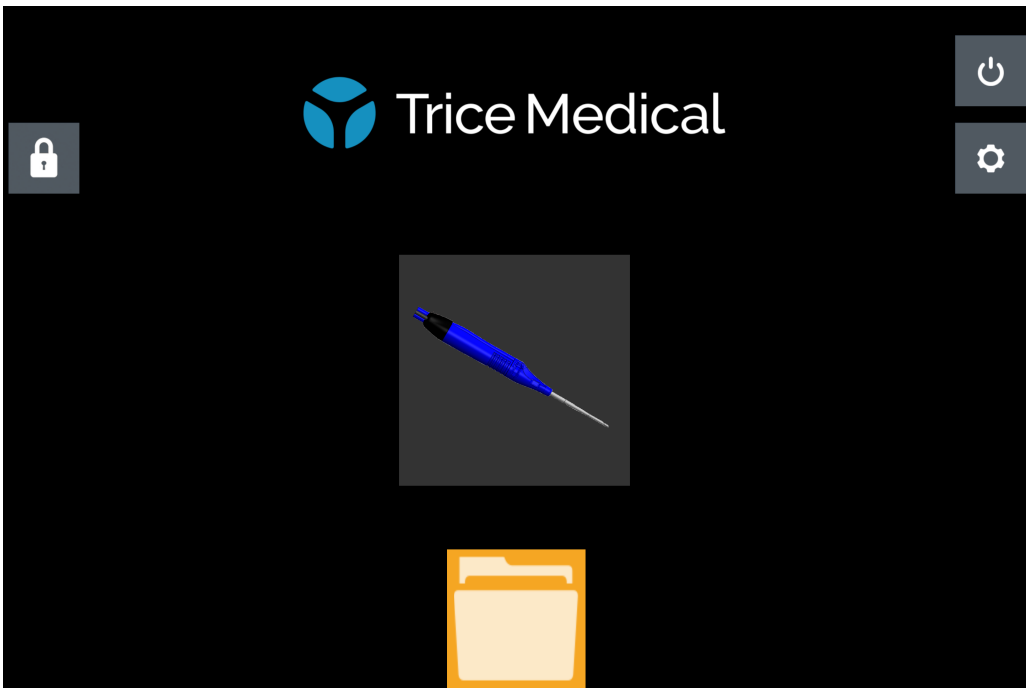
Procedure History Mode: Allows navigation through past procedures. Allows the ability to delete procedure(s) or transfer procedure(s) to a connected USB drive. The Procedure History Mode also provides the capability to view the summary of all the procedures performed using the system.

Screen Saver Mode: Displays a power saving screen after two minutes of inactivity. This mode will only be entered from Ready Mode (Home Screen).

Lock Screen Mode: Displays the Lock Screen after fifteen (15) minutes of inactivity when a procedure is not being performed. Requires a user to log in to return to Ready Mode (Home Screen).

4.1 Ready Mode (Home Screen)

Ready Mode displays the Home Screen and allows access to the Procedure History Mode, Settings Screen, and the Lock Screen. Ready Mode is only accessible through a standard user, not an administrator.



To view Procedure History:

- Touch the "Procedure History" button.

To enter MicroTip Procedure Mode:

- Connect a MicroTip and complete priming.
  OR
- Press the button with the MicroTip image and follow the prompts on the screen, if any, and then complete priming.

To enter Settings Screen:

- Touch the "Settings" button.

To exit the program and Power Off the Console:

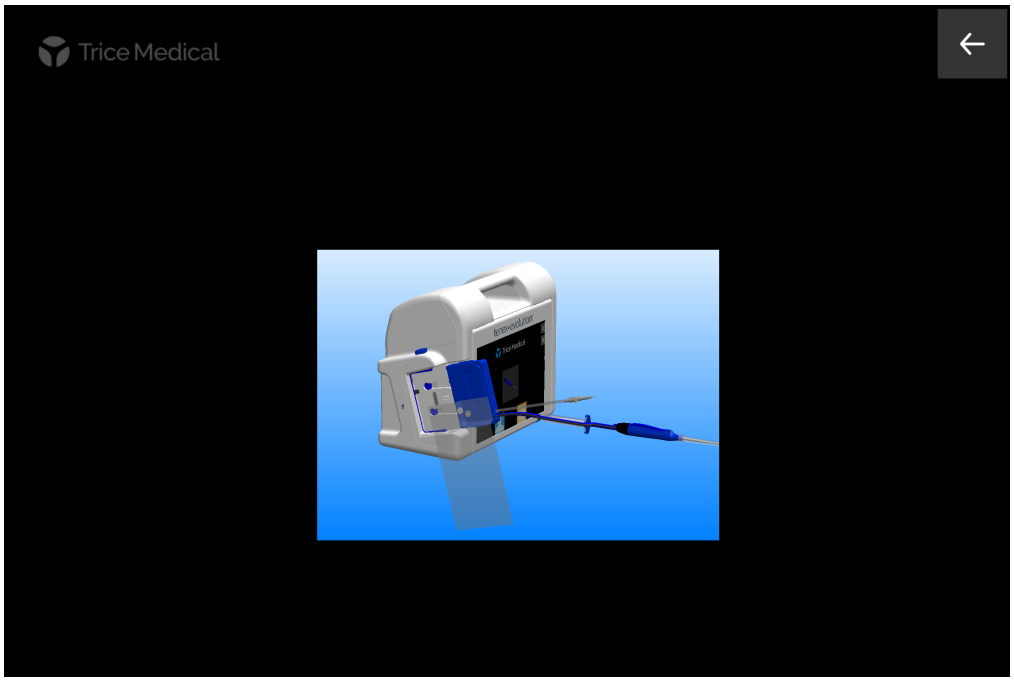
- Touch the "Power Off" button.

To lock the Console screen:

- Touch the "Lock Screen" button.

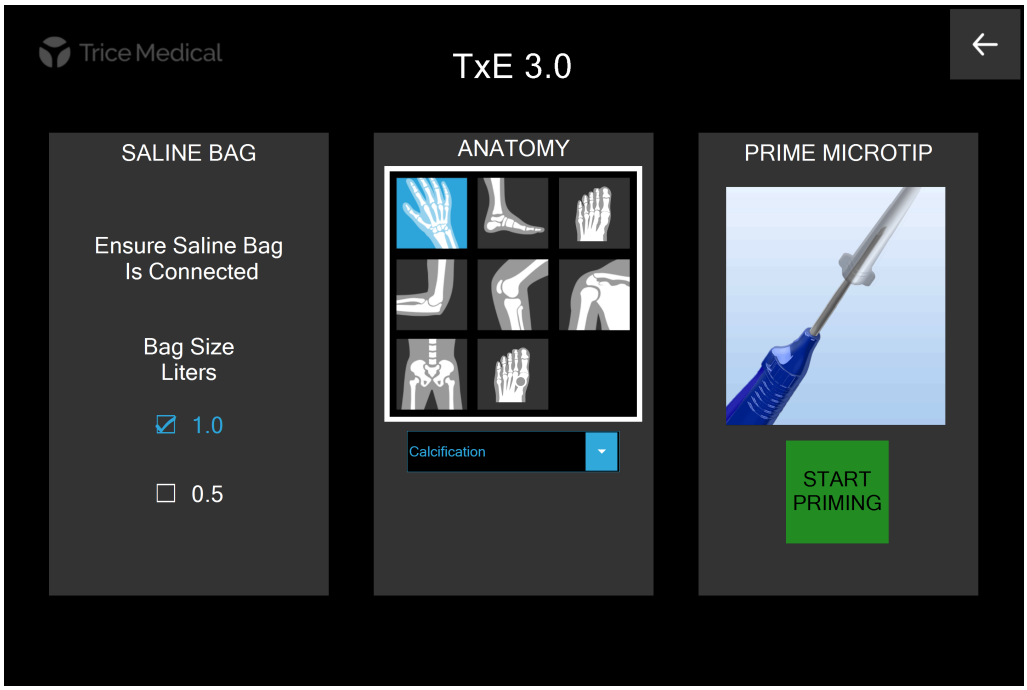
4.2 Priming Setup/Screen/Anatomy/Application Selection

4.2.1 MicroTip Cassette Insertion Screen



MicroTip Cassette Insertion Screen plays animated video on how to properly insert the Cassette to the Console. This screen is displayed when the MicroTip graphic is selected from Home Screen and the MicroTip is not inserted in the Console.

4.2.2 Priming/Anatomy & Procedure Type Selection Screen



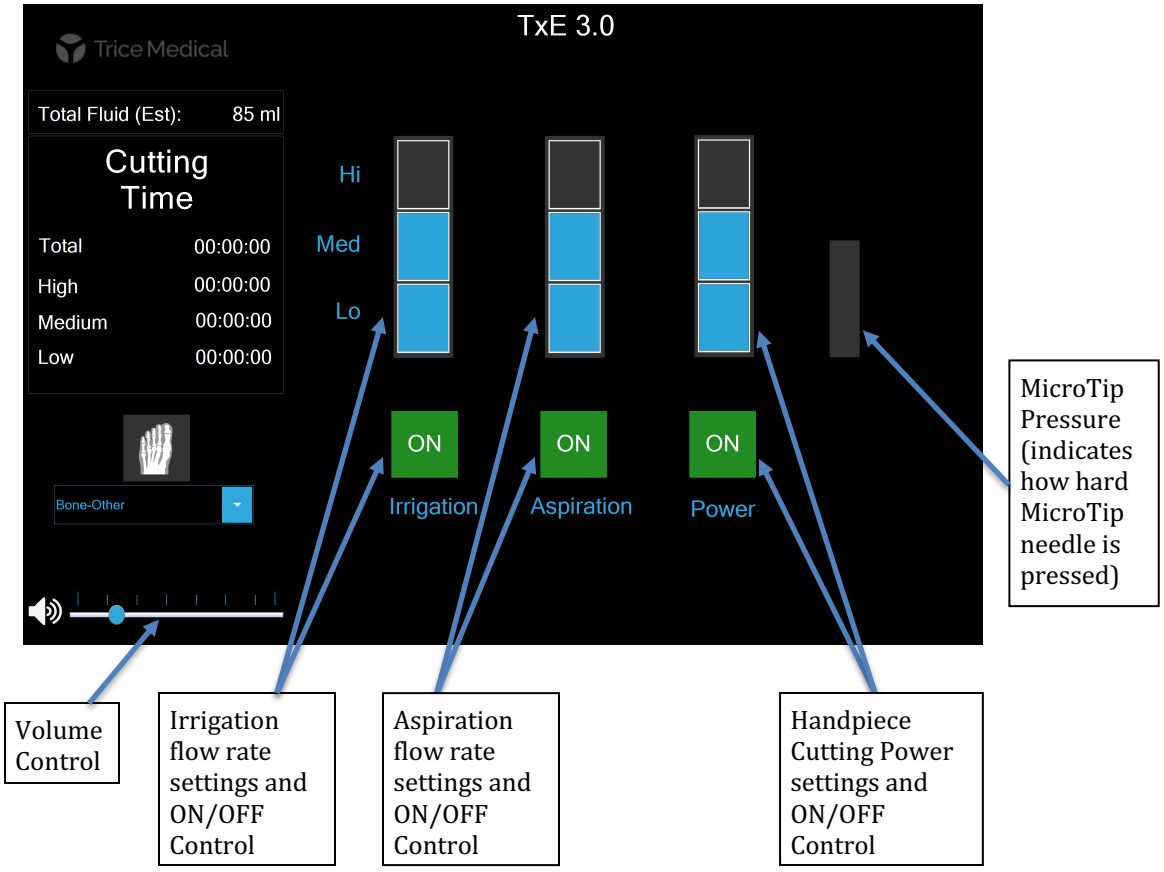
On the Priming Screen, select the size of the Saline Bag, “Anatomy,” and "Sub-type” from the dropdown menu and “Start Priming” to prime the system.

Note: There is a graphical video demonstrating how to secure the clear MicroTip cap before priming the system. Ensure the clear MicroTip cap is firmly secured.

4.3 Procedure Mode

4.3.1 MicroTip Procedure Mode

The MicroTip Procedure Mode allows the user to control irrigation and aspiration flow rates, cutting power, and turn off irrigation/aspiration/cutting. When the foot pedal is pressed, the motors and handpiece operate according to the settings set by the user. The MicroTip Procedure Mode also records and displays cutting time and cutter voltage feedback.



At the beginning of a procedure, Irrigation, Aspiration, and Cutting (Power) are automatically set to ON 

. All three of these functionalities can be toggled ON/OFF by the user. Pressing the "ON" 

button turns the corresponding functionality OFF 

. To turn the functionality back ON, press the "OFF" 

button.

NOTE: If cutting power is turned ON, then Irrigation will automatically turn ON. If Irrigation is turned OFF, then cutting power will automatically turn OFF.

Irrigation and Aspiration Flow Rates and Cutting Power can be changed by pressing a level from the bar  for the corresponding functionality. Each functionality has three levels. The current set level is indicated via the blue bar.

How hard the MicroTip is being pressed is indicated from the MicroTip Pressure bar  . The bar displays green, yellow, or red, with green indicating the MicroTip is being adequately pressed and red indicating the MicroTip is being pressed too hard.

NOTE: If the MicroTip Pressure bar is displaying red, the MicroTip is being pressed too hard. Users should apply less pressure to the MicroTip.

The Procedure ends and the Home Screen displays when the MicroTip (Cassette) is disconnected.

4.4 Procedure History Mode

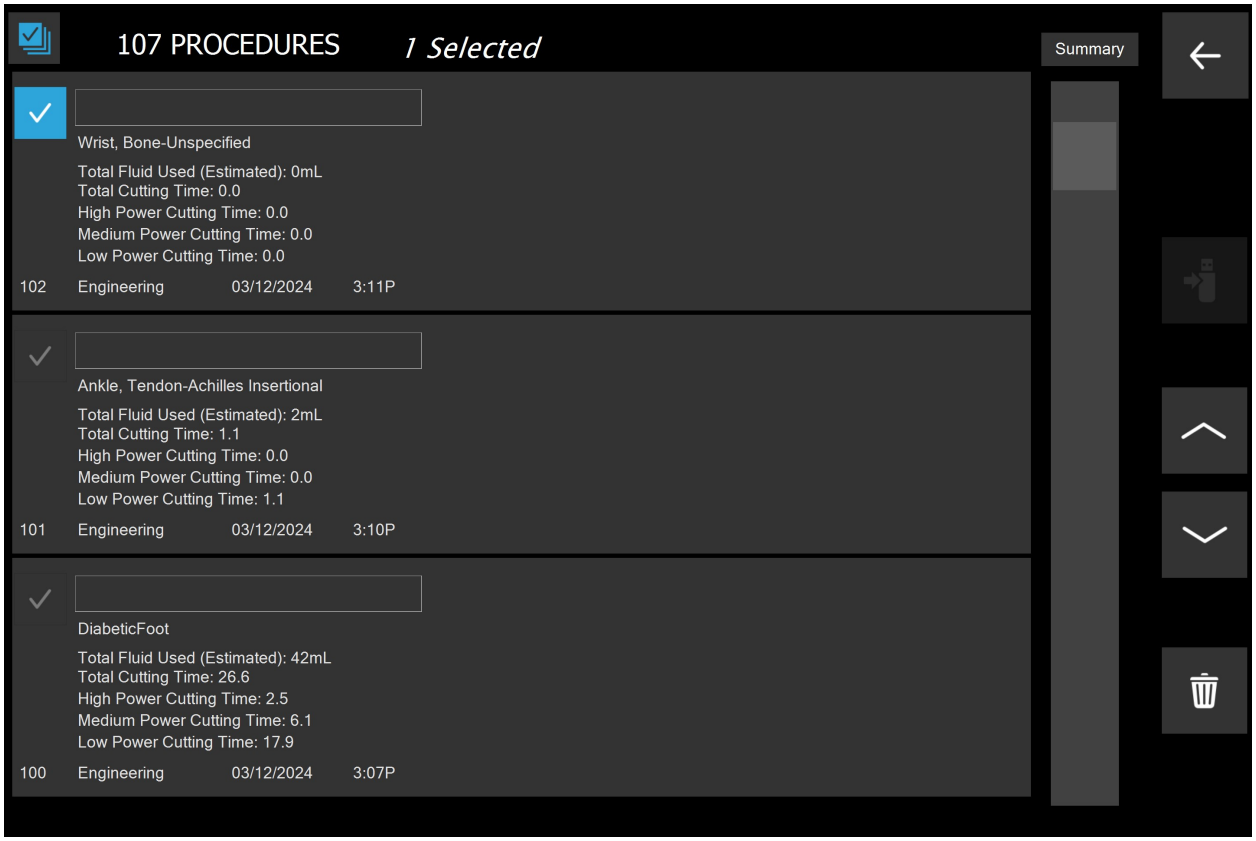
Procedure History Mode allows for the navigation through the saved procedures.

If the Administrator has set the Console to “View All” (See Section 3.3 Administrator Mode), a “View All Users” box will be visible in the header of the Procedure History Screen. If checked procedures from other users, who have not set their Procedure History to “Private,” will be visible. The user associated with the individual procedure history is identified at the bottom of the procedure info.

NOTE: Procedures attributed to other users cannot be selected for exporting, deleted, or edited, but can be viewed in Procedure Review Mode.

Procedure History Mode is only accessible when a MicroTip is not connected or when the exam is ended (End Exam button is pressed).

Touching the “Back Arrow” button will return the user to the previous screen.



The Procedure History Mode Screen displays a list of all visible procedures based on the current user and the View All setting (only three are displayed on the screen at a time with the latest at the top). The “Up Arrow” and “Down Arrow” can be used to scroll through procedures stored on the Console. The images displayed within the procedure will be listed from left to right; latest (highest number) to oldest.

The “Check Mark”  button to the left of a procedure is used for transferring or deleting procedures. The “Check Mark” will only be visible on the current user’s procedures. Selecting a procedure by pressing the “Check Mark”  button will enable the “Transfer to USB Drive”  button (if a USB drive is connected). This allows the user to transfer selected procedures to an external memory device. Procedure information data can be transferred to an Android Smartphone, Apple iPhone, and USB flash drive.

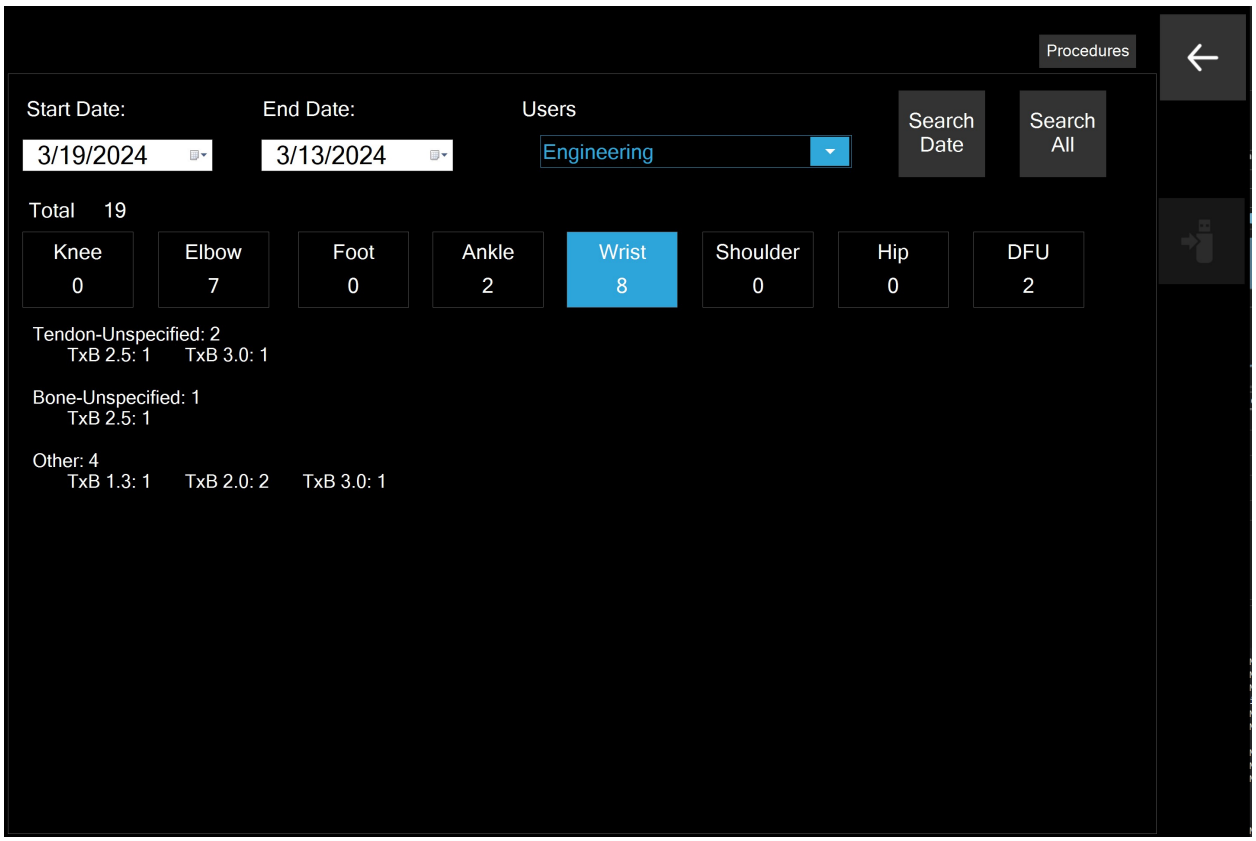
Selecting a procedure will also enable the “Delete Procedure”  icon which will remove the selected procedure/procedures from the procedure history.

The “Select All”  button is used to delete or transfer all of the current user’s procedures currently saved on the Console.

NOTE: When copying procedures to USB, wait until the “Copying Files” message is no longer visible before removing USB drive.

Touching the “Back Arrow”  button will return the user to the previous screen.

4.4.1 Procedure Summary Screen



To view the summary of all the procedures performed on the system, click the “Summary” button at the right upper corner of the Procedure History Screen. The “Summary” Screen lists all the procedures categorized by the specific anatomy selected during the procedure. By selecting the anatomy category, the user will be able to see specific MicroTip used to perform the procedure.

4.5 Screen Saver Mode

After 2 minutes of inactivity on the Home Screen, the Console will enter Screen Saver Mode to save the screen from burn-in. Touch anywhere on the screen to return to the Home Screen or attach a MicroTip to enter Procedure Mode.

4.6 Powering the Console

The Console must always be connected to AC power while using it. If the Console is turned on using the Power Button on the front of the unit and the AC power is not connected, a message will appear informing the user that no AC power is connected, and the unit will shut down. If the device detects that it is not connected to AC power after it is running, it will automatically shut down.

The Console contains a tablet; this tablet contains an internal battery. Because the Console must always be plugged into AC power, the tablet's internal battery is not likely to completely drain. However, if the Console is left unplugged/unused for a long stretch of time, the battery could lose charge. If the battery level reaches ≤4%, and the Console is powered on, the system will automatically shut down upon booting, even if the AC power is connected. In this case, leave the AC power connected, and the Console powered off so that the tablet's internal battery can charge greater than 4%.

The battery percentage, along with an icon, is displayed on the Settings Screen in the upper right corner. See table below for details on what each icon means.

	Tenex 2nd generation connected to power supply.
	Tenex 2nd generation battery charge level is 100%.
	Tenex 2nd generation battery charge level is ≥75%.
	Tenex 2nd generation battery charge level is ≥50%.
	Tenex 2nd generation battery charge level ≥25%.
	Tenex 2nd generation battery level is critically low

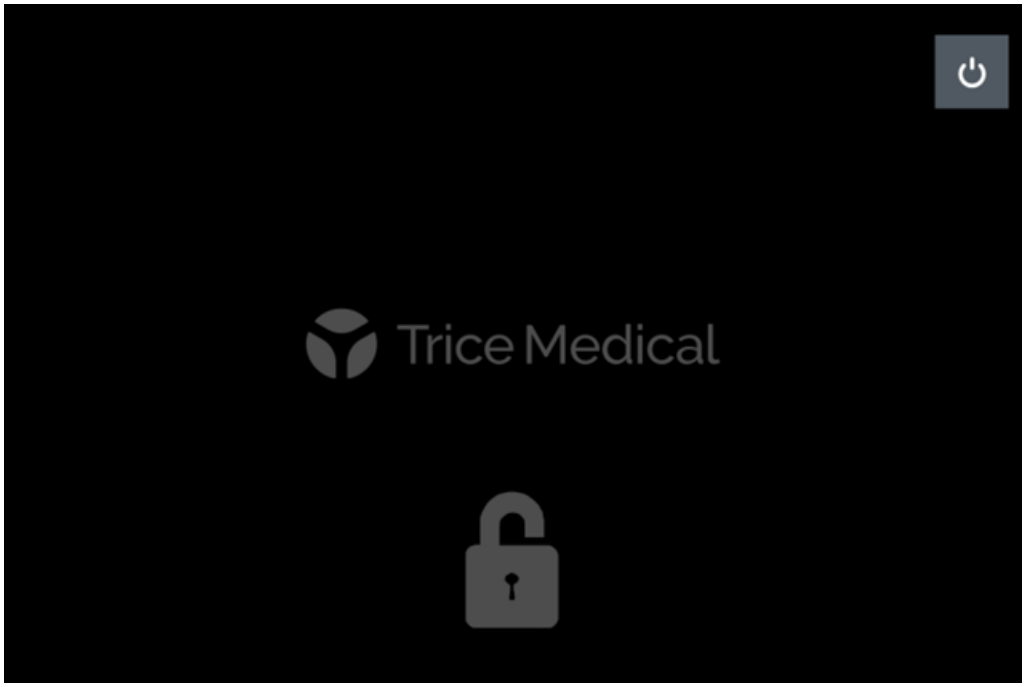
NOTE: As a best practice, turn off the power switch of the back of the Console when not in use

To connect the Console to AC power:

1. Connect the three-prong power cord connector to the Power Port.
2. Connect the AC plug of the Power Cord to the wall outlet.

To isolate the Console from the mains voltage, the power cord needs to be disconnected from the Console.

4.7 Lock Screen



To lock the Console screen when not in use, press the "Lock Screen" button on the Home Screen. To unlock the screen, press anywhere on the screen and re-enter password. See Section 3.2 Console Sign-In for instructions on how to sign in.

NOTE: If a procedure is not being performed, the Lock Screen will display after 15 minutes of inactivity.

4.8 Transfer of Procedure Information Data

NOTE: The procedure information data can only be transferred from the Procedure History Mode Screen. Procedure History Mode is only accessible when there is no active procedure.

The procedures will be exported in PDF format only. See 4.4 Procedure History Mode.

Plug the Trice USB Flash Drive or the USB portion of the Smartphone Adapter into the Console's USB-A port. Select the procedures to be copied. Tap the USB icon.

Allow for files to copy before removing the Smartphone Adapter from the Console. The Copying Files message clears and a tone sounds when complete.

4.9 Transfer of Procedure Information Data to USB (PDF)

NOTE: Procedure information data can only be transferred from the Procedure History Mode. Procedure History Mode is only accessible when there is no active procedure. See 4.4 Procedure History Mode.

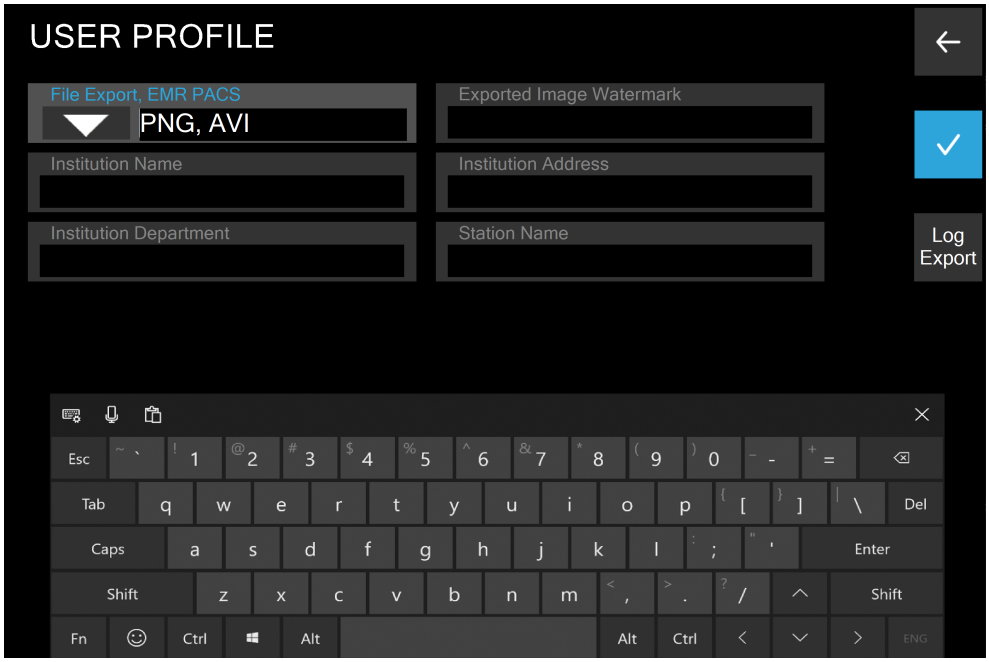
Plug an external memory device (i.e., Trice USB Drive) into the Console's USB-A port. Select the procedures to be copied. Tap the USB icon. Allow for files to copy before removing the USB Drive from the Console. The Copying Files message clears and a tone sounds when complete.

Place the USB Drive in a USB port on a computer and use that computer's operating system to access the USB Drive folder.

4.10 Data Logging

All activity on the Console is logged and can be downloaded in a log file by the Console administrator. To download the data log(s):

1. Log into Administrator profile.
2. Press the  button from the Home Screen.
3. Attach a USB drive to the Console via the USB-A connection.
4. Select the "Log Export"  icon. The icon will turn blue while exporting and once complete, will return to gray.



Once the log(s) is exported to a USB drive, it can be viewed on a PC by attaching the USB drive and navigating to the “Removable Device” folder. The log(s) will be exported as a .txt file(s).

4.11 Power Down Procedure

To turn off the Console, press the “Power Off” button  on the Home Screen. Select “Yes” from the Shutdown Confirmation Screen to power down the Console. Select “No” to return to the Home Screen.

To power off the Console power supply, press the switch on the back of the unit so that it is on the Off position.

5.0 Maintenance

Recommended care and handling of the Console includes proper day-to-day operation, cleaning, and visual inspection.

5.1 Serviceable Life of the Console

As with all active electronic components, the Console has a defined life. In the case of the Tenex 2nd generation Console, the life has been identified as five (5) years.

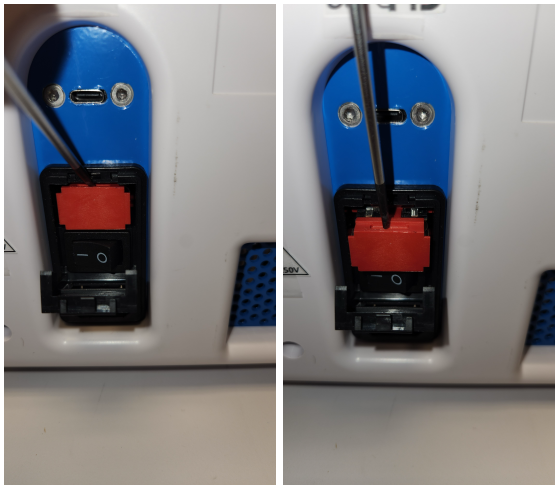
5.2 Service

The Console AC inlet has 2 fuses that can be replaced if they are blown. There are no other serviceable parts. Do not replace the fuses while the Tenex 2nd generation system is being used on a patient.

To replace the blown fuses, turn off the Console and disconnect the Power Cord from the back of the Console to disconnect (isolate) the Console from AC Mains.

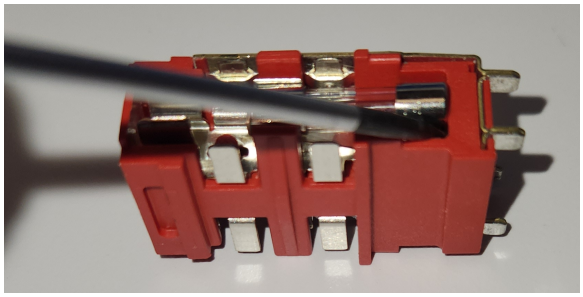
Insert the head of a small flat head screwdriver into one of the slots in the fuse holder door located at the top of the appliance inlet. Gently pry open the fuse holder door.

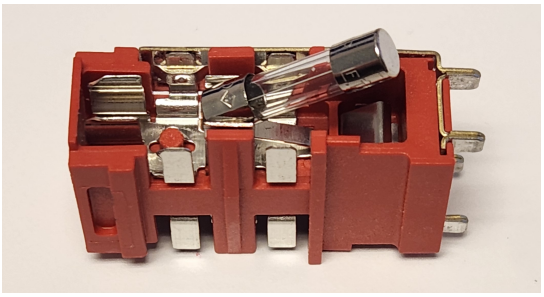
Insert the head of a small flat head screwdriver between the top of the red colored fuse holder and the housing of the appliance inlet. Pry out the fuse holder to slide it out.



Remove the fuse holder noting its orientation.

Insert the head of a small flat head screwdriver under the end of each blown fuse. (Note: there are 2 fuses). Gently lift up the end of the fuse and remove.





Replace the blown fuses with Slo-blo (Time Delay) 5mm x 20mm 2.5A, 250V fuses as specified in the accessories table in Section 2.1 Contents and Accessories.

⚠ **WARNING:** Only use the components specified in the user manual. Use of components other than those specified in the user manual and supplied by Trice Medical may result in an unsafe level of electrical isolation, increased electromagnetic emissions, and/or decreased electromagnetic immunity.

Reinstall the fuse holder (note correct orientation). Ensure it is fully seated within the appliance inlet. Close the fuse holder door.

5.3 Disposal of the single-use MicroTips

Please refer to the Tenex 2nd generation MicroTip's Instructions for Use document for disposal instructions for the single-use MicroTip.

5.4 Periodic Maintenance

The Console and its accessories should be inspected prior to and after each use to ensure they are not damaged or worn.

- Check for exposed wiring, damaged connectors, or other defects and replace cable if any are visible.
- Visually inspect the touchscreen display, molded case, and connectors for damage, and replace the Console if any damage is observed.

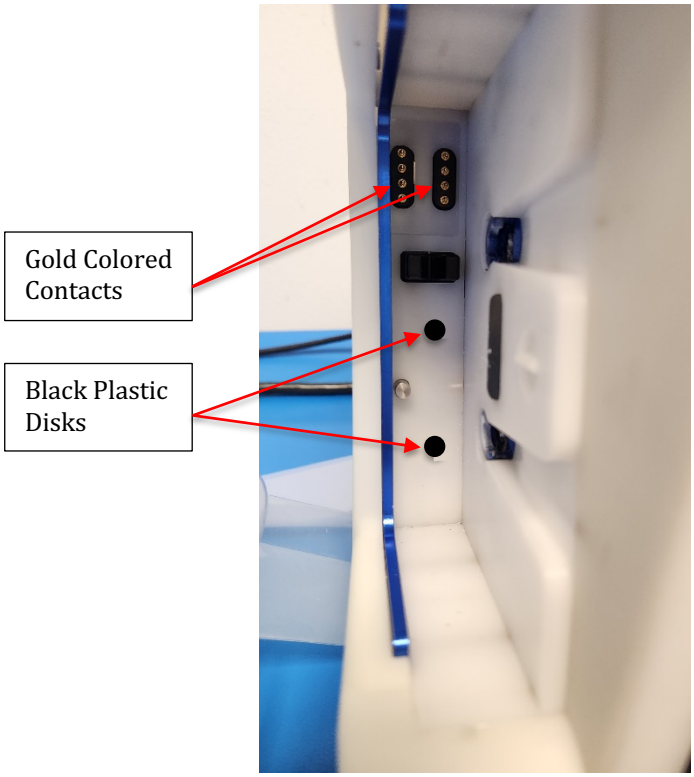
The Cassette Dock (where the Cassette is inserted) should routinely be cleaned of debris and dirt. See Section 2.3.1 Tenex 2nd generation Console and Section 5.5 Cleaning the Console.

If connecting an External TV or Video Monitor to the Console, follow the TV or Video Monitor's Manufacturer's instructions for preventative maintenance.

5.5 Cleaning the Console

Note: Do not clean the Console while the Tenex 2nd generation system is being used on a patient.

1. Turn the Console Off (flip power switch on back of unit to Off)
2. Disconnect the MicroTip, power cord, and USB drive from the Console.
3. Wipe the Console with a clean, soft cloth dampened with a mild pH-balanced detergent. **DO NOT** press down on the black circular disks in the Cassette Dock. **DO NOT** wipe the gold-colored contacts in the Cassette Dock.



4. Wipe the Console again with a clean, soft cloth dampened with tap, distilled or sterile water to remove any detergent residue. **DO NOT** press down on the black circular disks in the Cassette Dock. **DO NOT** wipe the gold-colored contacts in the Cassette Dock.
5. Dry with a clean, soft, lint-free cloth. **DO NOT** press down on the black circular disks in the Cassette Dock. **DO NOT** wipe the gold-colored contacts in the Cassette Dock.

WARNING:

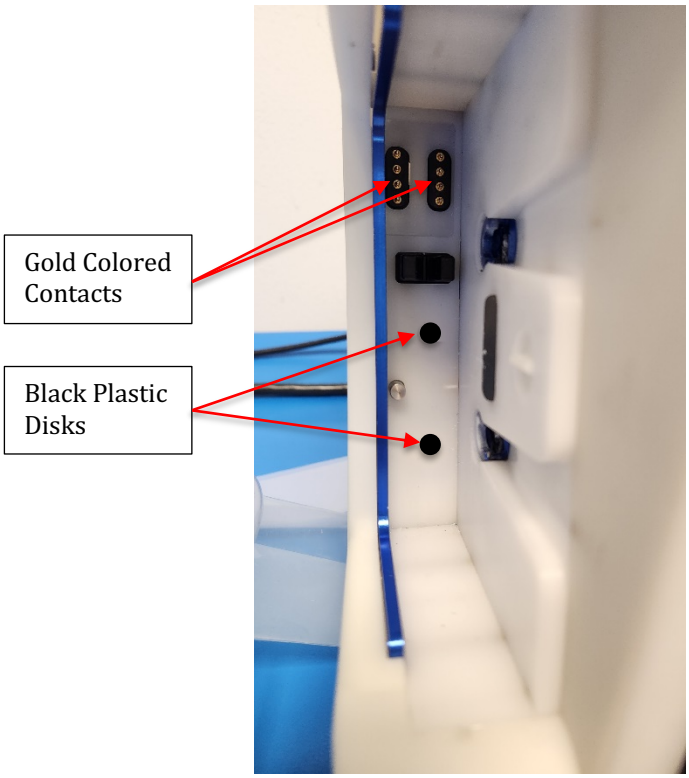
- Do not immerse in liquid or autoclave the Console or its power cable, as this will damage the Console and its accessories, and affect the safety levels of electrical isolation and leakage current.

- Do not use an abrasive or sharp tool when cleaning, as it may damage the Console.
- Do not spray liquid directly onto the Console, as it may damage the Console and affect the safety levels of electrical isolation and leakage current.
- Do not modify this equipment without authorization of the manufacturer.

5.6 Cleaning the Cassette Dock

Note: Do not clean the Cassette Dock while the Tenex 2nd generation system is being used on a patient.

1. Turn the Console Off (flip power switch on back of unit to Off)
2. Disconnect the MicroTip, power cord, and USB drive from the Console.
3. Check the Cassette Dock for dirt and debris. If there is dirt or debris, gently wipe the Cassette Dock with a clean, soft cloth dampened with tap, distilled or sterile water to remove the dirt or debris. **DO NOT** press down on the black circular disks. .**DO NOT** wipe the gold-colored contacts.



4. Dry with a clean, soft, lint-free cloth. **DO NOT** press down on the black circular disks. **DO NOT** wipe the gold-colored contacts.

WARNING:

- Do not immerse in liquid or autoclave the Console or power cable, as it will damage the Console, its accessories and affect the safety levels of electrical isolation and leakage current.
- Do not use an abrasive or sharp tool when cleaning, as it may damage the Console.
- Do not spray liquid directly onto the Console, as it may damage the Console and affect the safety levels of electrical isolation and leakage current.
- Do not modify this equipment without authorization of the manufacturer.

5.7 Errors List and Troubleshooting

Errors display in the upper left corner of the Home Screen, Priming Screen, and Procedure Mode Screen. Below lists each error, the cause of the error, and how the user can correct and/or troubleshoot the error.

Error Code	Cause	User Corrective Action	Notes
E001	Tablet powered on and no AC power detected.	Set AC power on within 30 seconds. After 30 seconds without power, tablet powers off.	Instructional message is displayed.
E002	AC power lost after unit is operational.	Tablet powers off.	
E003	No communication with Hardware.	Power the unit on/off. If issue persists, contact Trice Medical.	Console turns off the motors, solenoids, hand piece.
E004	Hard drive has low space	Delete old procedures	MicroTip still functional.
E005	USB Drive low space	Insert USB with more space	MicroTip still functional
E008	Foot switch not connected	Connect foot switch	
E010	IV bag empty, detected by total fluid flow.	Replace IV bag. Repeat prime.	If the original bag was 0.5L (500mL), then replace the IV bag with another 0.5L bag. If the original IV bag was 1L, then replace MicroTip first.
E011	IV bag empty, detected by bubble sensor.	Replace IV bag and MicroTip.	Console turns off the motors, solenoids, hand piece.
E012	Cassette Waste bag full. As calculated by fluid flow.	Replace MicroTip. Continue with priming.	
E013	IV Bag empty warning by total fluid flow	Check if IV bag is empty. If 500mL IV Bag is empty, replace with another 500mL Bag. Follow prompts on screen to repeat prime. If 1L IV Bag is empty replace handpiece and IV Bag. If IV Bag is not empty, continue with procedure.	Console turns off the motors, solenoids, hand piece.

Error Code	Cause	User Corrective Action	Notes
E014	Waste Bag full warning by total fluid flow	Check if Waste Bag is full. If Waste Bag is full, replace Handpiece and IV Bag. If Waste Bag is not full, continue with procedure.	
E015	Air detected in IV tube of IV Bag before IV Bag should be empty	Check IV Bag. If IV bag still has saline, prop the IV Bag so air is at top of IV Bag and fluid is at IV Spike. Then follow on-screen instructions.	Console turns off the motors, solenoids, hand piece
E016	500mL IV bag empty, detected by bubble sensor.	Replace saline bag with a 500mL saline bag and follow on-screen instructions.	Console turns off the motors, solenoids, hand piece
E019	No IV Fluid during Priming, detected by bubble sensor	Ensure IV Spike is connected to IV Bag. Press Prime again. Press “Start Priming” again and squeeze IV Bag during priming. Once fluid begins to flow in IV Tube, stop squeezing the IV bag.	
E020	Irrigation motor running when stopped.	Power the unit on/off. If issue persists, contact Trice Medical.	
E021	Irrigation motor not running when started.	Power the unit on/off. If issue persists, contact Trice Medical.	
E022	Irrigation motor not running at correct speed. +/-20% exceeded.	Retry with next footswitch press. If issue persists, contact Trice Medical.	
E023	Aspiration motor running when stopped.	Power the unit on/off. If issue persists, contact Trice Medical.	
E024	Aspiration motor not running when started.	Power the unit on/off. If issue persists, contact Trice Medical.	
E025	Aspiration motor not running at correct speed. +/-20% exceeded.	Retry with next footswitch press. If issue persists, contact Trice Medical.	
E030	Lock sensor failed to detect activation of lock solenoid.	Retry with next footswitch press. If issue persists, contact Trice Medical.	
E031	Lock sensor reports lock solenoid active when solenoid is turned off.	Retry with next footswitch press. If issue persists, contact Trice Medical.	
E040	Sweep failed.	Retry with next footswitch press. If issue persists, contact Trice Medical.	Error clears with next footswitch press.
E041	Phaco PCB H Bridge Peak Current too high	Retry with next footswitch press. If issue persists, contact Trice Medical.	Error clears with next footswitch press.

Error Code	Cause	User Corrective Action	Notes
E042	Phaco PCB H Bridge Average Current too high.	Retry with next footswitch press. If issue persists, contact Trice Medical.	Error clears with next footswitch press.
E043	Not Used		
E044	Phaco PCB AGC Bridge Current too high, from Phaco PCB.	Retry with next footswitch press. If issue persists, contact Trice Medical.	Error clears with next footswitch press.
E045	Frequency too low. Low limit reached during sweep or high power mode.	Retry with next footswitch press. If issue persists, contact Trice Medical.	Error clears with next footswitch press.
E046	PF Phase signals or DSP frequency failure.	If issue persists, contact Trice Medical.	Phaco PCB, DSP PCB, or cable failure.
E047	Not used.		
E048	Not Used		
E049	Handpiece Voltage is too high, detected by software	Step off foot pedal; apply less pressure on the MicroTip.	
E050	Irrigation Occlusion (Irrigation pressure too high)	Check for clog from saline bag to irrigation exit at MicroTip.	Console turns off the motors, solenoids, hand piece
E051	Aspiration Occlusion warning, (Aspiration pressure low)	Warning. Check for clog from hand piece to waste bag.	Clog warning sound emits.
E052	Aspiration Occlusion, (Aspiration pressure too low)	Check for clog from hand piece to waste bag.	Console turns off the motors, solenoids, hand piece
E053	Irrigation Pressure too high	Remove Cassette from Console. Reinsert Cassette. Prime again	
E054	Irrigation Line Sensor faulty	Press footswitch or restart priming. If issue still occurs, contact Trice Medical.	Console turns off the motors, solenoids, hand piece
E055	Aspiration Line Sensor faulty	Press footswitch or restart priming. If issue still occurs, contact Trice Medical.	Console turns off the motors, solenoids, hand piece
E060	Could not read Handpiece Type upon Cassette insertion.	Reinsert Cassette. If issue persists, use a different Cassette. If issue still occurs, contact Trice Medical.	Cannot go to Priming Screen while this error is active.
E061	Invalid handpiece ID	Reinsert Cassette. If issue persists, use a different Cassette. If issue still occurs, contact Trice Medical.	Cannot go to Priming screen while this error is active.
E062	Irrigation Line Sensor faulty	Reinsert Cassette. If issue persists, use a different Cassette. If issue still occurs, contact Trice Medical.	Cannot go to Priming Screen while this error is active.

Error Code	Cause	User Corrective Action	Notes
E063	Aspiration Line Sensor faulty	Reinsert Cassette. If issue persists, use a different Cassette. If issue still occurs, contact Trice Medical.	Cannot go to Priming Screen while this error is active.
E070	Cassette ID Failure	Shutdown the Unit and restart. If issue persists, contact Trice Medical.	
E071	Bubble Sensor Failure	Shutdown the Unit and restart. If issue persists, contact Trice Medical.	
E072	Aspiration Pressure Sensor Failure	Shutdown the Unit and restart. If issue persists, contact Trice Medical.	
E073	Irrigation Pressure Sensor Failure	Shutdown the Unit and restart. If issue persists, contact Trice Medical.	
E074	Handpiece Voltage too High, detected by hardware	Shutdown the Unit and restart. If issue persists, contact Trice Medical.	
E075	Handpiece Voltage too High, detected by software	Shutdown the Unit and restart. If issue persists, contact Trice Medical.	
E076	Irrigation motor running when no cassette is inserted	Shutdown the Unit and restart. If issue persists, contact Trice Medical.	
E077	Aspiration motor running when no cassette is inserted	Shutdown the Unit and restart. If issue persists, contact Trice Medical.	
E090	Power Factor value too low	Step off foot pedal. MicroTip pressed too hard.	Error clears with next footswitch press

5.8 Product Warranty

Trice Medical, Inc. ("Trice") warrants to the purchaser of its products that its products are free from defects in material and workmanship at the time of purchase from Trice. Trice's obligations under this Product Warranty shall be limited to repair or replacement, at Trice's option. This Product Warranty is premised on the safe, proper, and legal use of the products.

Trice further warrants its Tenex 2nd generation Console for an initial warranty period of one (1) year from the date of original purchase from Trice to be free from defects in materials and workmanship under normal conditions and use. This Product Warranty does not include preventive maintenance.

The single-use Tenex 2nd generation MicroTip is warranted to be free from defects only at the time of purchase from Trice.

Disclaimer

THIS PRODUCT WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE AND IS IN LIEU OF ALL OTHER OBLIGATIONS OR LIABILITIES OF TRICE. Trice does not assume, and does not authorize any other person to subject Trice to, any other liability for its products. Trice shall in no way be responsible for the improper use of its products or for service thereof performed by unauthorized or untrained persons; such use or service shall void this product warranty. It is understood and agreed that Trice's liability, whether in contract, tort, warranty, negligence or otherwise, shall not exceed the repair or replacement cost of the product. No action, regardless of form, arising out of transactions covered under this product warranty, may be brought by the warrantee more than one (1) year after the cause of action has accrued. UNDER NO CIRCUMSTANCES SHALL TRICE BE LIABLE FOR SPECIAL, INDIRECT, CONSEQUENTIAL, OR INCIDENTAL DAMAGE OR LOSSES.

5.9 Returning the Device

If it becomes necessary to return the device, always use the original packaging. Trice Medical does not take responsibility for damage that has occurred during transportation if the damage was caused by inadequate transport packaging. Please make sure that all required information has been supplied. Call Trice Medical 1-844-643-9300 or 1-610-989-8080 for an RMA Number before returning the device for service.

Owner Name
Owner Address
Owner Daytime Telephone Number
Device Model and Part Number.
Device Serial or Lot Number
Detailed explanation of the damage.

NOTE: It is strongly recommended, before returning a Tenex 2nd generation Console, that the user export important files to their own computer. See Section 4.9 Transfer of Procedure Information Data to USB (PDF).

5.10 End of Life

The Directive [2002/96/EC] on Waste Electrical and Electronic Equipment (WEEE) obliges manufacturers, importers, and/or distributors of electronic equipment to provide for recycling of the electronic equipment at the end of its useful life.

Do not dispose of WEEE in unsorted municipal waste. The WEEE symbol on the product or its packaging indicates that this product must not be disposed of with other waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of Waste Electrical and Electronic Equipment. The separate collection and recycling of your waste equipment at the time of disposal will help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your Tablet at the end of its useful life for recycling, please contact Trice Medical Customer Service Department.

In the US, a list of recyclers in your area can be found at www.eiae.org/.

Appendix 1: Patient Privacy and Confidentiality

The Tenex 2nd generation Console does not receive or save any patient-specific data. The data saved and exportable to USB drive includes technical details on each procedure, pertaining to the settings used for procedure notation, cutting, irrigation, and aspiration, along with the durations for individual functions and the overall procedure.

Note: Trice Medical software does not include electronic signature control and is not meant to substitute for an electronic medical record.

Appendix 2: Cybersecurity Risks and Control Measures

Cybersecurity risk management was followed throughout the Console's design and development. The following controls were implemented to mitigate cybersecurity risk:

- The on-board Wi-Fi/Bluetooth features inside the Console are disabled.
- Windows features not needed for the functioning of the device are disabled.
- System Authentication: Strong passwords are required for Standard and Admin users.
- Passwords File is encrypted.
- The Console is configured to deny connections of rogue USB devices such as keyboard and mouse.
- The Application automatically signs the user out after 15 minutes of no activity.
- Procedure data is encrypted and does not include patient information.

After risk assessment, implementation of controls, and penetration testing, the Tenex 2nd generation Console is categorized as having Low cybersecurity risk.

Despite these measures, cybersecurity risk can never be fully eliminated. The sections below highlight key risk areas and provide recommended actions to further minimize potential risks.

A. Exposed USB Ports

The Console has two exposed USB ports: a USB-C port and a USB-A port. These ports are specifically designed for use with USB drives (to export procedures and logs) and external monitors. The Console will automatically block unsupported USB devices.

To further mitigate risk and maintain security of the system, it is recommended to only connect USB drives from known and trusted sources. It is also recommended to use only medical grade external monitors.

Avoid connecting unknown or unsupported USB devices, as they may pose a security risk despite existing cybersecurity controls.

If an unknown device is connected, immediately disconnect it. Ensure the Console is in a restricted-access facility to prevent unauthorized access.

B. On-Screen Keyboard

The On-Screen Keyboard (OSK) remains active on the Console, which presents a minor security risk as it could be used to interact with the Console in unintended ways. However, this risk is considered low due to existing cybersecurity controls.

To further mitigate this risk, ensure the Console is in a restricted-access facility to prevent unauthorized access.

Appendix 3: Console Electromagnetic Compatibility

The Tenex 2nd generation Console and its specific components (e.g., Foot Switch (included), Power Cord, and MicroTip) have met the requirements of the Electromagnetic Compatibility (EMC), IEC/EN 60601-1-2, which addresses EMC in North America, Europe, and other global communities. This includes immunity to radio frequency electric fields and electrostatic discharge, in addition to the other applicable requirements of the standard. Compliance with EMC standards does not mean a device has total immunity; Electromagnetic Disturbances from certain devices (cellular phones, pagers, etc.) and from A.C. mains networks can interrupt operation if they are used near medical equipment, or the level of disturbances are too high. If interference is noticed, remove the offending device and/or move the Console to another location.

This device is classified as Class I Type B medical electrical equipment and the device complies with specified safety levels for electrical isolation and leakage current. The Console is connected to earth ground.

The essential performance of the Console when used with a MicroTip accessory is to provide percutaneous fragmentation, emulsification, irrigation, and aspiration of both soft and hard tissues. The Console, when used with MicroTip, provides sharp debridement of soft and hard tissues in wounds such as neuropathic ulcers.

The intended environment of the Console is a professional healthcare facility (e.g., physician office, clinic, ambulatory surgery center, hospital [operating room, emergency room, patient room], etc.) directly connected to the public mains network (low voltage electricity power lines other than those to which consumers have access).

> **Note:** The emissions characteristics of the Console meet the requirements of CISPR 11 class B.

 **WARNING:** Use of the Console adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Console should be observed to verify that it is operating normally.

 **WARNING:** Avoid exposure of the Tenex 2nd generation System to electrocautery, MRI, electrosurgical units, and diathermy devices. Injury or device damage may result.

 **WARNING:** Only use the Tenex 2nd generation Console with components specified in the Contents and Accessories section. Use of the Tenex 2nd generation Console with components (e.g., accessories and cables) other than those specified or provided by Trice could result in improper operation due to increased electromagnetic emissions or decreased electromagnetic immunity of the Console.

WARNING: Portable RF communications 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 Console including cables specified by Trice. Otherwise, degradation of the performance of this equipment could result.

Table 1: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance
Radiated RF Emissions CISPR 11	Group 1, Class B
Conducted RF Emissions CISPR 11	Group 1, Class B
Harmonic Distortion IEC/EN 61000-3-2	Compliant
Voltage Fluctuations and Flicker Emissions IEC/EN 61000-3-3	Compliant

Table 2: Guidance and Manufacturer's Declaration - System Cables and Accessories

Cables and Accessories that are likely to affect compliance of the Tenex 2nd generation system

Type	Use	REF	Max Length (m)
AC Input Cord	Supply power to Tenex 2nd generation system	2-10-0168 (EU) 2-10-0169 (GB) 2-10-0452 (EN) 2-10-0453 (JP) 2-10-0454 (AU)	3.05m (10FT) for EN 2.5 m (8.2 ft.) for others
USB Drive	Procedure Information data storage	1-10-0066	N/A
MicroTips	Debridement, fragmentation, emulsification, irrigation, and aspiration of both soft and hard tissues	T600-0XX	2.3 m (7 ft. 7 in.)
USB-C to HDMI Video Cables	Connecting Tenex 2nd generation system to an external video monitor (not supplied)	2-10-0455	3.05 m (10 ft)

Table 3: Recommended separation distances between portable and mobile RF communication equipment and the Tenex 2nd generation system

Immunity Test	IEC/EN 60601 Test Level	Compliance Level
Proximity Fields from RF Wireless Communications Equipment IEC/EN 61000-4-3	Per Table 9 in subclause 8.10 of EN 60601-1-2:2015+A1:2021	0.3 m (1 ft)

Table 4: Guidance and Manufacturer's Declaration – Electromagnetic Immunity		
Immunity Test	**IEC/EN 60601 Test Level**	**Compliance Level**
Electrostatic Discharge (ESD) IEC/EN 61000-4-2	±8 kV Contact ±2 kV, ±4 kV, ±8 kV, ±15 kV Air	±8 kV Contact ±15 kV Air (See Note 1)
Radiated RF EM fields IEC/EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m (See Note 1)
Electrical fast transients/bursts IEC/EN 61000-4-4	±0.5 kV, ±1 kV, ±2 kV for Input AC Power Port ±0.25 kV, ±0.5 kV, ±1 kV, for SIP/SOP Ports 100 kHz repetition frequency	±2 kV for Input AC Power Port ±1 kV for Input SIP/SOP Ports (See Note 1)
Surges IEC/EN 61000-4-5	±0.5 kV, ±1 kV line to line and ±0.5 kV, ±1 kV, 2.0kV line to ground	±1 kV line to line and ±2 kV line to line (See Note 1)
Conducted disturbances induced by RF fields IEC/EN 61000-4-6	3 Vrms 0.15 MHz - 80 MHz and 6 Vrms In ISM bands 0.15 MHz - 80 MHz 80% AM at 1 kHz	3 Vrms and 6 Vrms (See Note 1)
Rated power frequency magnetic fields IEC/EN 61000-4-8	3 A/m 50 or 60 Hz	3 A/m
Voltage dips IEC/EN 61000-4-11	0 % Ut; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % Ut; 1 cycle and 70 % Ut; 25/30 cycles Single phase: at 0°	0 % Ut; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % Ut; 1 cycle and 70 % Ut; 25/30 cycles Single phase: at 0° (See Note 2)
Voltage interruptions IEC/EN 61000-4-11	0 % Ut; 250/300 cycles	0 % Ut; 250/300 cycles (See Note 2)
Proximity magnetic fields BS EN 61000-4-39	65 A/m, 134.2 kHz, 50% Pulse Modulation @ 2.1 kHz 7.5 A/m, 13.56 MHz, 50% Pulse Modulation @ 50 kHz	65 A/m, 134.2 kHz, 50% Pulse Modulation @ 2.1 kHz 7.5 A/m, 13.56 MHz, 50% Pulse Modulation @ 50 kHz

Notes:

1) When the Tenex 2nd generation Console is subjected to these Electromagnetic Disturbances at the compliance levels listed, a short interruption of image display, or resetting to 'standby' or 'safe' mode may be observed. If these issues are observed, remove the offending device, and/or move the Tenex 2nd generation Console to another location.
2) Ut is the A.C. mains voltage prior to application of the test level.