Trice Medical

TENEX HEALTH | Tenex Health is now a part of Trice Medical

TX System Console

Operator's Manual

for Software Version 2.0.0

TX™ TENEX HEALTH SYSTEM

Preface

This is your written guide to the Tenex Health TX System. Please read the entire manual carefully. DO NOT attempt to use the system without having an adequate understanding of all of its functions, controls, and limitations.

No information on surgical procedures is given in this manual. Tenex Health claims no responsibility or liability resulting from any technique practiced.

Pay close attention to warnings and cautions in this manual. Warnings are intended to protect individuals from serious bodily harm. Cautions are intended to protect the individuals from potential harm and the TX System from damage.

If you have any questions or require additional information, please contact Tenex Health Customer Service at:

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Chapter 1 Indications for Use

TENEX HEALTH TX SYSTEM WITH TX1 / TX2 MICROTIP

The Tenex Health TX System with the TX1 / TX2 MicroTip is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.

TENEX HEALTH TX SYSTEM WITH TXB MICROTIP

The Tenex Health TX System with TXB MicroTip 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 Health TX System with TXB MicroTip is also indicated for use in the 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.

Chapter 2 Information for Safety

CONTRAINDICATIONS:

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

The Tenex Health TX System with the TXB MicroTip is also contraindicated for:

Active Infections

Weakness of the posterior muscle group with a calcaneal gait disorder

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, infection, irritation, fever, pain, tissue injury, foreign body reaction, electrical shock, and burns.

POSSIBLE SIDE EFFECTS:

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

WARNINGS AND PRECAUTIONS:

Warnings and Cautions related to the MicroTip apply to the TX1, TX2, and TXB MicroTips unless otherwise indicated.

WARNING: The MicroTip is single use. DO NOT resterilize/reuse. Reusing the device could result in compromised device performance, cross-infection, and other safety hazards.

WARNING: DO NOT recap the tip of the MicroTip.

WARNING: Electrical shock hazard exists. No user serviceable parts within console. Call manufacturer for service.

WARNING: No modification of this equipment is allowed.

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

WARNING: DO NOT check function of MicroTip by placing hand or finger against tip or unintended damage to healthy tissue may result.

WARNING: Use of a cutting handpiece other than the MicroTip may result in patient injury or damage to the TX Console.

WARNING: Surgical waste presents a biological hazard and must be handled and disposed of properly. The MicroTip must be disposed of according to local regulations.

WARNING: DO NOT use the MicroTip after the expiration date indicated on the package.

WARNING: The MicroTip is sterile if package is unopened and undamaged. DO NOT use if the sterile package has been compromised.

WARNING: Monitor the location of the MicroTip during use. Failure to monitor the location of the tip of the device may present a hazard to the user, result in damage to unintended tissue or limit the ability to detect device malfunction or damage to the MicroTip related to use.

WARNING: To prevent cross-infection, DO NOT use the device on multiple treatment sites.

WARNING: DO NOT hold MicroTip static. Keep the MicroTip moving using axial motion when targeting and emulsifying tissue to prevent damage to the MicroTip and/or occlusion of the tip. Due to friction related to ultrasonic vibration, appropriate technique is necessary for thermal management at the treatment site and will minimize the potential for tissue burns.

WARNING: Verify integrity of the MicroTip needle and irrigation sheath upon completion of treatment. Failure to do so may result in device remnants left in the patient in the event of device damage.

CAUTION: Minimal edema associated with the TX system occurs only occasionally and is considered a routine response to treatment.

CAUTION: Utilize Universal Precautions and Sterile Technique at all times. Failure to do so can lead to increased risk of infection or aggravation of a recent infection.

CAUTION: Use caution when removing potentially malignant or harmful tissues, to isolate contamination from surrounding tissue.

CAUTION: For TX1 and TX2 MicroTips, only use 500cc saline irrigation bag and cuff. Use of an alternate volume irrigation bag in the inflation cuff may result in possible contamination of the surgical environment, lack of irrigation flow during use, or electrical hazard.

CAUTION: For TXB MicroTips, only use 1000cc saline irrigation bag and cuff. Use of an alternate volume irrigation bag in the inflation cuff may result in possible contamination of the surgical environment, lack of irrigation flow during use, or electrical hazard.

CAUTION: Always check the saline irrigation bag for leaks prior to surgical procedures.

CAUTION: DO NOT use the device if the tip of the MicroTip is received bent or is bent during use.

CAUTION: The TX Console contains electrical circuit boards and must be returned to Tenex Health for disposal.

CAUTION: The foot pedal must be disposed of according to local regulations at the end of its useful life.

CAUTION: Pinch point hazard exists. Keep hands and fingers clear when lowering the display.

CAUTION: The console can only be disconnected from the supply mains by means of the power cord. Position equipment so that power cord is easily accessible.

CAUTION: Ensure successful priming cycle and presence of acoustic signal prior to incising the patient.

CAUTION: DO NOT activate the MicroTip with the tip in air as immediate damage may result.

CAUTION: DO NOT rest the saline irrigation bag on the TX Console enclosure or touchscreen.

CAUTION: Failure to align the Red Dot on the MicroTip connector with the Red Dot on the console receptacle may damage the connector pins.

CAUTION: Maximum tip temperature can approach 47 degrees C. This does not present a hazard to the patient if the TX System is used according to the recommended duty cycle: 15 seconds on, 45 seconds off on HIGH cutting power.

CAUTION: DO NOT use abrasive cleansers or solvents on the TX console, particularly the touchscreen.

CAUTION: DO NOT spray liquids directly onto the TX console or submerge the TX console or foot pedal into liquids.

CAUTION: Individual TX Supply Kit components (if present) are sterile if the package is unopened and undamaged.

CAUTION: DO NOT laterally load the MicroTip during use. Failure to follow appropriate technique could result in potential hazard to adjacent tissue due to excessive heating or damage to the MicroTip such as a broken needle and/or damage to irrigation sheath.

CAUTION: For use on hard tissue, use multiple cortical penetrations using axial motion to facilitate entry into bone. Attempting to breach cortical shell through a single insertion point will not provide for adequate tip cooling and maneuverability of the tip and may result in damage to the sheath of the device or tissue burns.

CAUTION: DO NOT use the TXB Microtip for a total cutting time exceeding 10-minutes on hard tissue or 15-minutes cumulative (hard and soft tissue). Failure to limit use beyond the maximum cutting time could result in device damage or failure.

CAUTION: DO NOT use the TX1 or TX2 Microtip for a total cutting time exceeding 10-minutes. Failure to limit use beyond the maximum cutting time could result in device damage or failure.

CAUTION: The TX1 and TX2 MicroTips should not be used on hard tissue such as bone.

CAUTION: The Tenex Health TX System should not be used on bone cement.

Chapter 3 Warranty Information

LIMITED WARRANTY

Tenex Health warrants that each component of the Tenex Health TX System will, upon delivery, conform to the manufacturer's then current version of the published specifications as such. The Tenex Health TX System in all material aspects shall be free from defects in material and workmanship from a period of one (1) year from the date of ownership when properly installed, maintained, and used for the intended purpose. Disposable TX Procedure Packs are not covered by this warranty.

The exclusive remedy for any breach of this warranty shall be, at Tenex Health's sole option, the repair or replacement of the nonconforming Tenex Health TX System or component thereof, which is returned to Tenex Health during the warranty period. Any claim based upon this warranty must be submitted to Tenex Health during the applicable warranty period. All replacement components provided during the warranty period shall be deemed to have been delivered on the original delivery date of the Tenex Health TX System.

This warranty is nontransferable without Tenex Health's prior consent.

Any Tenex Health TX System or component thereof returned for any reason must be accompanied by a Return Merchandise Authorization (RMA) number, obtained by calling Tenex Health at +1 949.454.7500. Any shipping charges incurred shall be paid by the purchaser/user of the equipment.

This warranty does not apply to abnormal use or to defects, malfunctions, or failures that result from abuse, neglect, improper setup, or maintenance, tampering, alteration, modification, accident, or misuse of the Tenex Health TX System or its components. Failure to maintain the Tenex Health TX System and its components in accordance with manufacturer recommendations shall void the warranty.

THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. TENEX HEALTH SHALL NOT BE RESPONSIBLE FOR ANY LOST PROFITS OR OTHER DIRECT, INCIDENTAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES SUFFERED BY ANY PARTY, EVEN IF IT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

In no event shall Tenex Health's liability for any claim, whether in contract or tort, exceed the amount paid to Tenex Health for the TX System. The warranty set forth herein may not be extended, enlarged, or otherwise modified by any Tenex Health agent or employee, and Tenex Health does not assume any liability or make any warranty except as stated herein.

For information regarding an extended Equipment Service Contract, please contact Tenex Health Customer Service Department at +1 949.454.7500. For warranty information outside the United States, please contact your local distributor.

Chapter 4 General Information

a. SYSTEM DESCRIPTION

The Tenex Health TX System is an ultrasonic surgical aspirator that cuts and removes soft and hard tissue. The TX System includes the TX MicroTip, a sterile, single-use, disposable ultrasonic handpiece with integrated tube set, and the TX Console, an ultrasonic and fluidics driver.

The TX MicroTip (the Applied Part) is supplied in a Procedure Pack, which includes the Microtip, and a convenience kit with individually sterile items for use during the procedure. The MicroTip has three models with varying needle lengths and diameters which are to be selected based upon the target tissue type and depth from the surface of the skin. The TX-Bone (TXB) MicroTip is indicated for both soft and hard tissue applications. ***TX1 and TX2 MicroTips are indicated for use in soft tissue applications only.***

MicroTip Model No. and Desc.	Procedure Pack Model No.	Needle Length	Needle Diameter	Tissue Application
557-1002-001, TX-Bone (TXB) MicroTip	554-3003-001, 554-3003-002, 554-4003-002	1.3″	.074″ (non-standard gauge)	Soft and Hard Tissue
554-2002-001, TX2 MicroTip	554-2003-001, 554-2003-002	1.7″	.050″ (18 gauge)	Soft Tissue Only
554-1002-001, TX1 MicroTip	554-1003-001, 554-1003-002	1.0″	.042″ (19 gauge)	Soft Tissue Only

The TX Console provides control over the three modes of operation including irrigation, aspiration, and cutting. The console has a large, color LCD and employs a touchscreen for selection of required settings. The console provides audible tones for confirmation of selections. The console houses irrigation and aspiration pumps, thereby eliminating the need for a dedicated service cart or suction/waste source. Irrigation fluid is delivered to the target site under pressure by operation of an air pump housed in the console. The regulated output of the air pump pressurizes a cuff that is fitted around an irrigating fluid bag, thus providing irrigation at a fixed pressure regardless of the height of the fluid bag. Connections for the TX MicroTip and irrigation cuff are located on one side of the console. On the back of the console are an equipotential grounding stud, the power inlet module to connect the console to a power source using the cord provided, and a foot pedal connection. The supplied foot pedal is used by the clinician to control each of the three user functions. Simple in design, it offers on/off functionality. It is splash-proof for protection against liquids.

The pathology for treatment with the TX System is to be identified by ultrasound imaging, direct visualization and/or palpation as appropriate. When ultrasound is used, the ultrasound probe is placed directly over the TX MicroTip with the MicroTip at the edge and midline of the transducer to provide for visualization of the target tissue. The ultrasound imaging device is not manufactured or provided by Tenex Health, Inc.

b. UNPACKING

Your Tenex Health TX System was thoroughly inspected and tested prior to shipment. Carefully unpack and visually inspect all items for any apparent damage that may have occurred during shipment. If any physical damage is found or if the system is not within specification when received, immediately notify the shipping company and Tenex Health Customer Service. All claims for damage should be filed promptly.

NOTE: All packing material should be saved for reuse in case the system is returned for service.

The contents of the case should always be checked against the packing slip to ensure all items have been shipped. If the system is incomplete, notify Tenex Health Customer Service immediately.

QTY	ITEM
1	Console
1	Foot Pedal
1	Power Cord**
2	Inflation Cuff, 500cc*
2	Inflation Cuff, 1000cc*
1	Extra Fuse Set
1	Operator's Manual
1	Travel Case

**POWER CORD BY COUNTRY/REGION

Country/Region	*Description*	*Ref No.*
European Union, Continental	Europe Power Cord, 220V	430-4024-001
United Kingdom	UK Power Cord, 230V	430-4026-001
Ireland	UK Power Cord, 230V	430-4026-001
United States	USA Power Cord, 120V	430-4023-001
All other countries	As appropriate for local power	-

*1000cc Inflation Cuffs are to be used with TXB. 500cc Inflation Cuffs are to be used with TX1 and TX2.

c. SYSTEM OVERVIEW

Figures 1, 2, and 3 refer to all controls, indicators, and connectors on the TX Console. The associated Table 1 describes these in detail.

Console Overview

Table 1. Controls, Indicators, and Connections

NUMBER	NAME	DESCRIPTION
1	REAR PANEL LABEL	Displays system ratings, serial number, warnings and cautions
2	ON/OFF SWITCH	"I" is ON and "O" is OFF
3	EQUIPOTENTIAL GROUND STUD	Provides a means of securely linking the earth grounds of the Console to other grounded equipment
4	FUSE HOLDER	Holds system fuses
5	FOOT PEDAL CONNECTOR	Connection for system foot pedal
6	AC POWER INPUT	Provides power connection and overload protection to the system
7	NRTL Certification	Certification Mark and Device Listing: Electrical Safety Testing for Medical Electrical Equipment and Devices
8	SERIAL NUMBER	Unique code assigned for identification of the unit
9	CARTRIDGE LOCK	Locking mechanism for tube set cartridge
10	VACUUM SENSOR	Sensor for measuring vacuum
11	CARTRIDGE RELEASE BUTTON	Releases the tube set cartridge when pressed
12	CUT CONNECTOR	Provides power to TX MicroTip
13	AIR CONNECTOR	Provides pressurized air to irrigation cuff
14	IRRIGATION VALVE	Controls flow of irrigation fluid
15	VENT VALVE	Controls aspiration line venting
16	PERISTALTIC PUMP HEAD	Provides system aspiration
17	TOUCHSCREEN DISPLAY	Provides access to user interface
18	SPEAKERS	Provide audible feedback

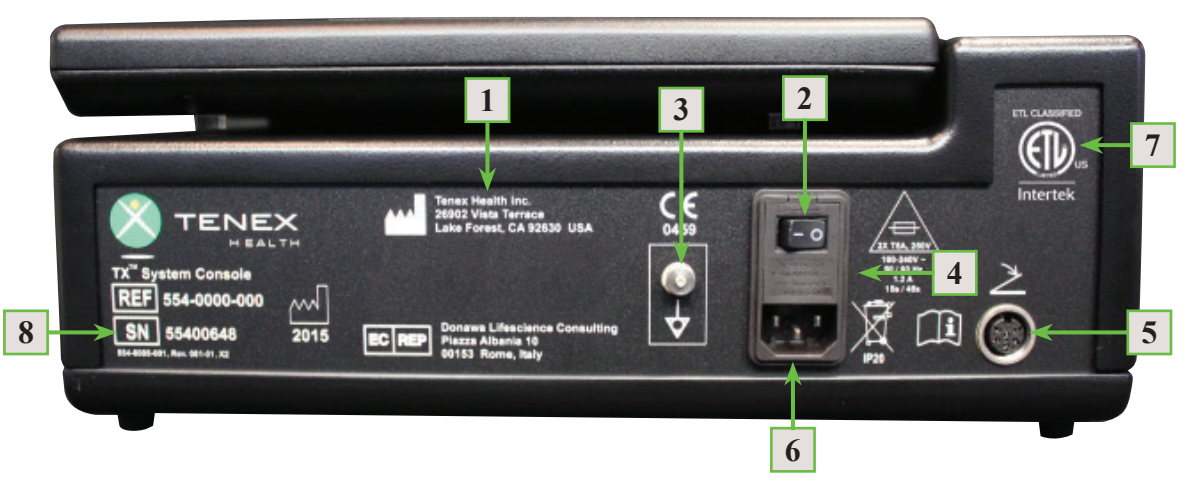


Figure 1 – Rear View

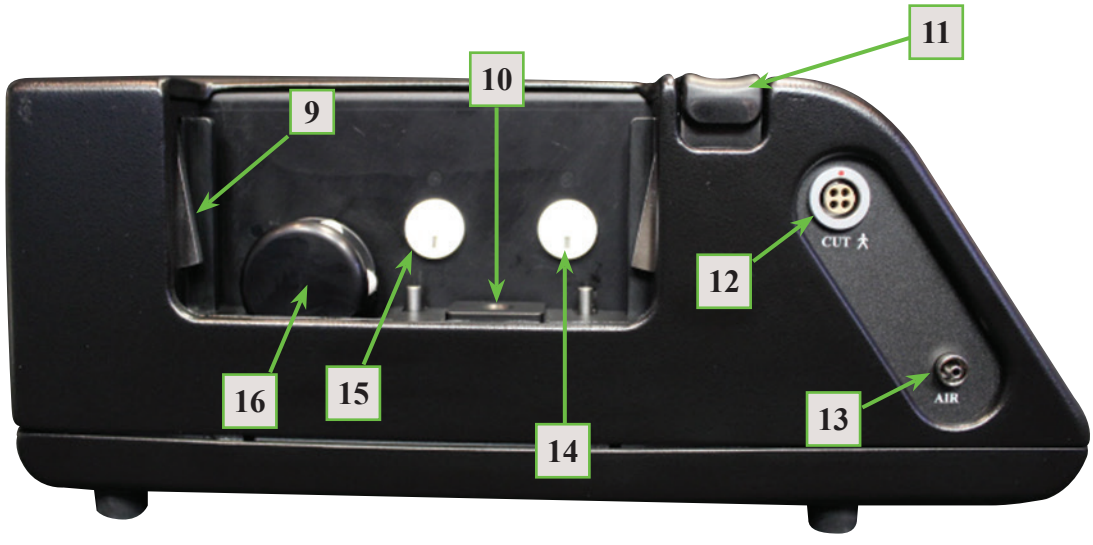


Figure 2 – Side View

Figure 3 – Front View

CAUTION: Pinch point hazard exists. Keep hands and fingers clear when lowering the display.

d. TECHNICAL SPECIFICATIONS

Manufacturer	**TENEX HEALTH**
Model	**TX**
Classification (IEC 60601)	**CLASS I**

PARAMETER	SPECIFICATION
Electrical	
INPUT VOLTAGE	100 to 240 VAC @ 50/60 Hz
MAXIMUM CURRENT	1.2 Amps
LINE FUSES	5A T (Slow-blow)
MAX. OUTPUT VOLTAGE (CUTTING)	250 Volts
MAX. OUTPUT VOLTAGE (FOOT PEDAL)	5 Volts
Irrigation	
FLUID DELIVERY	Pressure fed: regulated compressor
OPERATING PRESSURE	4 PSI nominal
VALVE TYPE	Solenoid-actuated Pinch Valve
CONTROL	Foot Pedal
Cutting	
TX MicroTip TYPE	Sterile, Disposable Ultrasonic
OPERATING FREQUENCY	25–28 kHz
CONTROL	Foot Pedal
SYSTEM PRIMING	Automated Prime Cycle
Available Power Delivery	
LOW	100% delivered at 50 ms ON and 50 ms OFF
MEDIUM	100% delivered at 75 ms ON and 25 ms OFF
HIGH	100% delivered Continuously
DUTY CYCLE (USER-CONTROLLED)	15s/45s (15 seconds ON, 45 seconds OFF at maximum power)
Aspiration	
ASPIRATION PUMP	Peristaltic, Low Pulsation
AVAILABLE MAX. VACUUM LEVEL	User selectable: Low/Medium/High (100/300/500 mmHg)
AVAILABLE FLOW RATE	User selectable: Low/Medium/High (10/20/30 cc/min)
CONTROL	Foot Pedal
Dimensions (Console)	
HEIGHT	6.5 inches / 16.5 centimeters
WIDTH	14.5 inches / 36.8 centimeters
DEPTH	13.5 inches / 34.3 centimeters
WEIGHT	21 lbs.
LCD TOUCH PANEL DISPLAY	12.1 inches diagonal / 280(H) × 218(V) millimeters 800 x 600 pixels, color

e. ENVIRONMENTAL REQUIREMENTS

The TX System Console should be used in a clean environment that is suitable for surgery. Environmental requirements are as follows:

Operating Environment

Temperature	Humidity	Altitude
10°C to 35°C	30% to 85% RH	≤2,000 meters (6,561 feet)

Storage/Transport Environment

Temperature	Humidity	Altitude
+5°C to +60°C	30% to 85% RH	≤4,267 meters (14,000 feet)

f. SYMBOL DESCRIPTIONS

The Table below provides the symbols that are found on the TX Console and their definitions. These symbols are used to provide quick information or instruction in a limited space.

It is important to become familiar with these symbols and their definitions before setting up and operating the TX Console.

Table 2. Symbols found on the TX Console and Packaging

No.	Symbol	Definition	No.	Symbol	Definition
1		Date of Manufacture	12		Foot pedal
2		Waste Electrical and Electronic Equipment	13		Caution
3		Serial Number	14		Pressure Range
4		Consult accompanying documents	15		Temperature Range
5		Equipotential Ground Stud	16		Manufacturer
6		ON (power: connection to the mains)	17	**Rx Only**	**Caution:** Federal (US) law restricts this device to sale by or on the order of a physician.
7		Humidity Range	18		Medical Electrical Equipment and Devices - Device Listing Number: 5001321
8		OFF (power: disconnection from the mains)	19	**REF**	Catalog Number
9	IP20	Degree of protection against access to hazardous parts and against solid foreign object, as well as degree of protection from ingress of water	20	**EC REP**	European Authorized Representative
10		Type B equipment	21	CE	CE Mark (European Conformity)
11		Fuse Replacement	22	**MD**	Medical Device

Chapter 5 System Setup

Warnings and Cautions related to the MicroTip apply to the TX1, TX2, and TXB MicroTips unless otherwise indicated.

a. INTRODUCTION

This section contains instructions necessary for the setup of the Tenex Health TX System prior to use. It assumes that you have all necessary accessories for surgery, including a saline irrigation bag and the disposable purchase components (TX MicroTip, and TX Supply Kit if applicable, which come with their own Instructions for Use).

WARNING: Use of a cutting handpiece other than the TX MicroTip may result in patient injury or damage to the TX Console.

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

WARNING: The console can only be disconnected from the supply mains by means of the power cord. Position equipment so that power cord is easily accessible.

b. SETUP

1. Insert power cord and foot pedal cable into back of console.
2. Turn ON console by pressing the power switch on the back panel to the ON position. Wait for the Main Mode screen to appear.
3. Insert saline irrigation bag into inflation cuff.

CAUTION: For TX1 and TX2 MicroTips, only use 500cc saline irrigation bag and cuff. Use of an alternate volume irrigation bag in the inflation cuff may result in possible contamination of the surgical environment, lack of irrigation flow during use, or electrical hazard.

CAUTION: For TXB MicroTips, only use 1000cc saline irrigation bag and cuff. Use of an alternate volume irrigation bag in the inflation cuff may result in possible contamination of the surgical environment, lack of irrigation flow during use, or electrical hazard.

CAUTION: Always check the saline irrigation bag for leaks prior to surgical procedures.

4. Insert air tube fitting on inflation cuff into AIR receptacle on side panel by twisting clockwise until snug.
5. Rest cuff with saline bag on flat surface near console or hang from side of cart, if available.

CAUTION: DO NOT rest the saline irrigation bag on the TX Console or touchscreen.

NOTE: Gown and/or prepare the necessary instrumentation for STERILE procedures according to your institution's requirements.

6. Peel back the Tyvek seal of the MicroTip beginning with the easy access tab on the bottom right of the tray.

WARNING: DO NOT use the MicroTip after the expiration date indicated on the package.

WARNING: The MicroTip is sterile if package is unopened and undamaged. DO NOT use if the sterile package has been compromised.

7. Wear sterile glove and lift the internal tray lid off of the tray and discard.
8. Using the sterile gloved hand, remove the MicroTip from the thermoform tray.

9. Ensure that the aspiration tube is properly centered on the bottom side of the cartridge and then insert cartridge into side of console, pressing straight down firmly until locked in place. NOTE: The TX Console is not sterile.

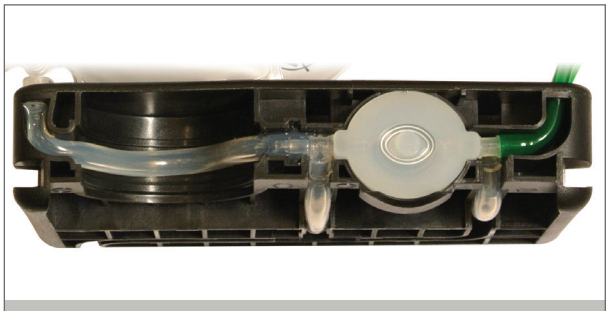


Figure 4. CORRECT Aspiration Tube Alignment

Figure 5. CORRECT Insertion

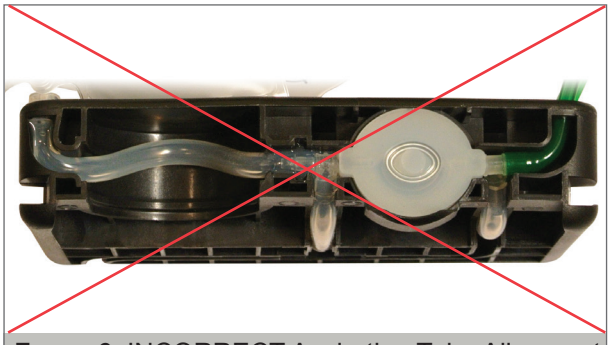


Figure 6. INCORRECT Aspiration Tube Alignment

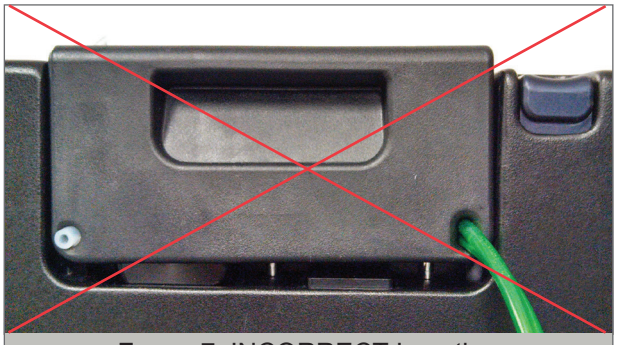


Figure 7. INCORRECT Insertion

10. Align the Red Dot on the MicroTip electrical connector with the Red Dot on the console side panel CUT receptacle, and then insert straight into the receptacle.

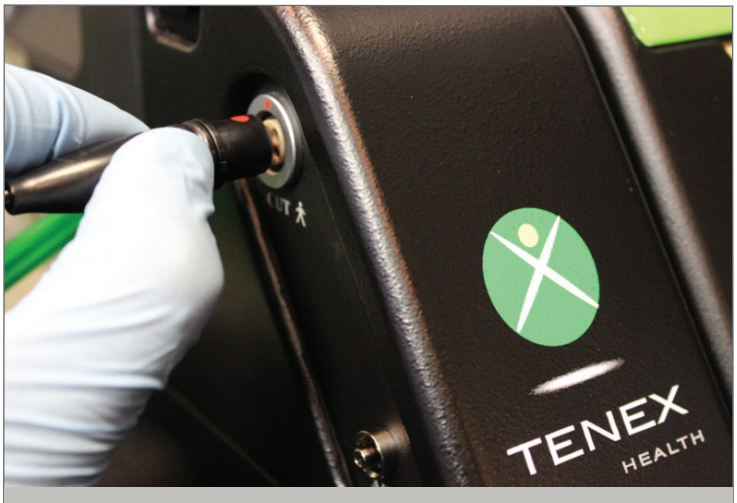


Figure 8. Electrical Connector Orientation

CAUTION: Failure to align the Red Dot on the MicroTip connector with the Red Dot on the console receptacle may damage the connector pins.

11. Spike saline irrigation bag.
12. With the tip cap on, hold the MicroTip handpiece in a vertical position (needle pointing upward) and press the PRIME key on the TX Console.
13. After successful priming, leave the tip cap on. Select IRRIGATION to ON, ASPIRATION to MEDIUM or HIGH, and CUTTING POWER to MEDIUM or HIGH, then depress foot pedal to test for acoustic signal.

CAUTION: Ensure successful priming cycle and presence of acoustic signal prior to incising the patient.

WARNING: DO NOT check function of the MicroTip by placing hand or finger against the tip or unintended damage to healthy tissue may result.

NOTE: For a description of setup related error messages, consult the Troubleshooting and Factory Default Settings sections of the TX Console Operatorís Manual.

14. Prepare the patient for procedure using the (if present) TX Supply Kit and/or other appropriate clinical supplies.

CAUTION: Individual TX Supply Kit components are sterile if the individual package is unopened and undamaged.

15. Select desired settings for IRRIGATION, ASPIRATION, and CUTTING POWER.

NOTE: See Operations section of the TX Console Operator's Manual for detailed information regarding each function.

16. Remove the tip cap from the handpiece.
17. The Tenex Health TX System is now ready to use.

WARNING: Monitor the location of the MicroTip during use. Failure to monitor the location of the tip of the device may present a hazard to the user, result in damage to unintended tissue or limit the ability to detect device malfunction or damage to the MicroTip related to use.

NOTE: Identify the target pathology via ultrasound imaging, direct visualization and/or by palpation, as appropriate.

CAUTION: The TX1 and TX2 MicroTips should not be used on hard tissue such as bone.

CAUTION: The MicroTip should not be used on bone cement.

CAUTION: Use caution when removing potentially malignant or harmful tissues, to isolate contamination from surrounding tissue.

CAUTION: DO NOT activate the MicroTip with the tip in air as immediate damage may result.

CAUTION: DO NOT use the device if the tip of the MicroTip is received bent or is bent during use.

CAUTION: Maximum tip temperature can approach 47 degrees C. This does not present a hazard to the patient if the TX System is used according to the recommended duty cycle: 15 seconds on, 45 seconds off on HIGH cutting power.

CAUTION: DO NOT hold MicroTip static. Keep the MicroTip moving using axial motion when targeting and emulsifying tissue to prevent damage to the MicroTip and/or occlusion of the tip. Due to friction related to ultrasonic vibration, appropriate technique is necessary for thermal management at the treatment site and will minimize the potential for tissue burns.

CAUTION: DO NOT use the TX1 or TX2 Microtip for a total cutting time exceeding 10-minutes. Failure to limit use beyond the maximum cutting time could result in device damage or failure.

CAUTION: DO NOT use the TXB Microtip for a total cutting time exceeding 10-minutes on hard tissue or 15-minutes cumulative (hard and soft tissue).Failure to limit use beyond the maximum cutting time could result in device damage or failure.

CAUTION: For use on hard tissue, use multiple cortical penetrations using axial motion to facilitate entry into bone. Attempting to breach cortical shell through a single insertion point will not provide for adequate tip cooling and maneuverability of the tip and may result in damage to the sheath of the device or tissue burns.

CAUTION: DO NOT laterally load the MicroTip during use. Failure to follow appropriate technique could result in potential hazard to adjacent tissue due to excessive heating or damage to the MicroTip such as a broken needle and/or damage to irrigation sheath.

NOTE: When using the cutting function, there will be a 1 second delay between activation of the foot pedal and delivery of ultrasonic cutting power. This is to allow for sufficient supply of irrigation fluid at the ultrasonic tip.

NOTE: Keep the MicroTip moving to prevent occlusion. A triple beeping sound will be generated by the console to indicate occlusion during use. Release and depress foot pedal to remove occlusion.

NOTE: A user-controlled duty cycle of 15 seconds ON, 45 seconds OFF (15s/45s) is to be followed when using HIGH CUTTING POWER. This is equal to a ratio of 1:3 of FOOT PEDAL ON time to FOOT PEDAL OFF time with a maximum of 15 seconds of continuous FOOT PEDAL ON time.

WARNING: Verify integrity of the MicroTip needle and irrigation sheath upon completion of treatment. Failure to do so may result in device remnants left in the patient in the event of device damage.

18. Upon completion of the procedure, prepare the patient using the TX Supply Kit and/or other appropriate clinical supplies.

CAUTION: Minimal edema associated with the TX system occurs only occasionally and is considered a routine response to treatment.

c. SHUT DOWN

WARNING: DO NOT recap the tip of the MicroTip.

WARNING: The MicroTip is single use. DO NOT resterilize/reuse. Reusing the device could result in compromised device performance, cross-infection, and other safety hazards.

WARNING: Surgical waste presents a biological hazard and must be handled and disposed of properly. The MicroTip must be disposed of according to local regulations.

1. Select OFF for IRRIGATION, ASPIRATION, and CUTTING POWER.
2. Deflate the inflation cuff by disconnecting the air tube fitting from the AIR receptacle on the console side panel OR by turning off the console by pressing the power switch on the back panel to the OFF position.
3. Remove the saline irrigation bag from the inflation cuff. DO NOT discard the inflation cuff.
4. Remove the spike and discard the saline irrigation bag.
5. Disconnect the MicroTip electrical connector from the CUT receptacle on the console side panel.
6. Depress the cartridge release button and remove the cartridge from side of console.
7. Dispose of the MicroTip in a receptacle designated for sharps/biohazard according to your facility requirements.

Chapter 6 Operation

a. INTRODUCTION

This chapter contains information that identifies the modes, functions, parameter settings, and commands necessary to operate the TX Console. The following information should be read and thoroughly understood in detail before operating the system.

b. PRIME

The PRIME command will only be available after startup if the foot switch, cassette and hand piece connector are properly installed. The PRIME command will initiate the priming cycle when the command soft key is pressed, which fills the tube set with liquid, tests the valves, and tests the peristaltic pump. The priming cycle will be indicated by the PRIME soft key turning RED, and the message "*Priming …Please Wait!*" will be displayed on the screen. The aspiration pump will run for approximately 60 seconds. The prime cycle may be stopped at any time by depressing the PRIME soft key.

A successful priming cycle will be indicated by the message "*Priming successful!*" and an audible tone, followed by the IRRIGATION panel being highlighted, indicating that the system is ready for parameter settings. The PRIME button will then be disabled.

A failed priming cycle will be indicated by the message "*Fluid path blocked! Prime again!*" or "*Vacuum test failed! Manually Prime!*" and an audible TONE. Refer to the troubleshooting section for instructions.

NOTE: Removing the cassette at any time will force the user to re-prime the cassette!!

c. MAIN MODE

The Main Mode displays three (3) panels, which provide access to the parameter settings for the available system functions. Each function is activated by simply pressing a soft key in the panel labeled with the name of that function. This will be indicated by the function being highlighted. When the TX Console is first powered ON, the initialization screen will momentarily display the Tenex Health logo, followed by the Main Mode screen. The three (3) panels will remain dark until the system is primed.

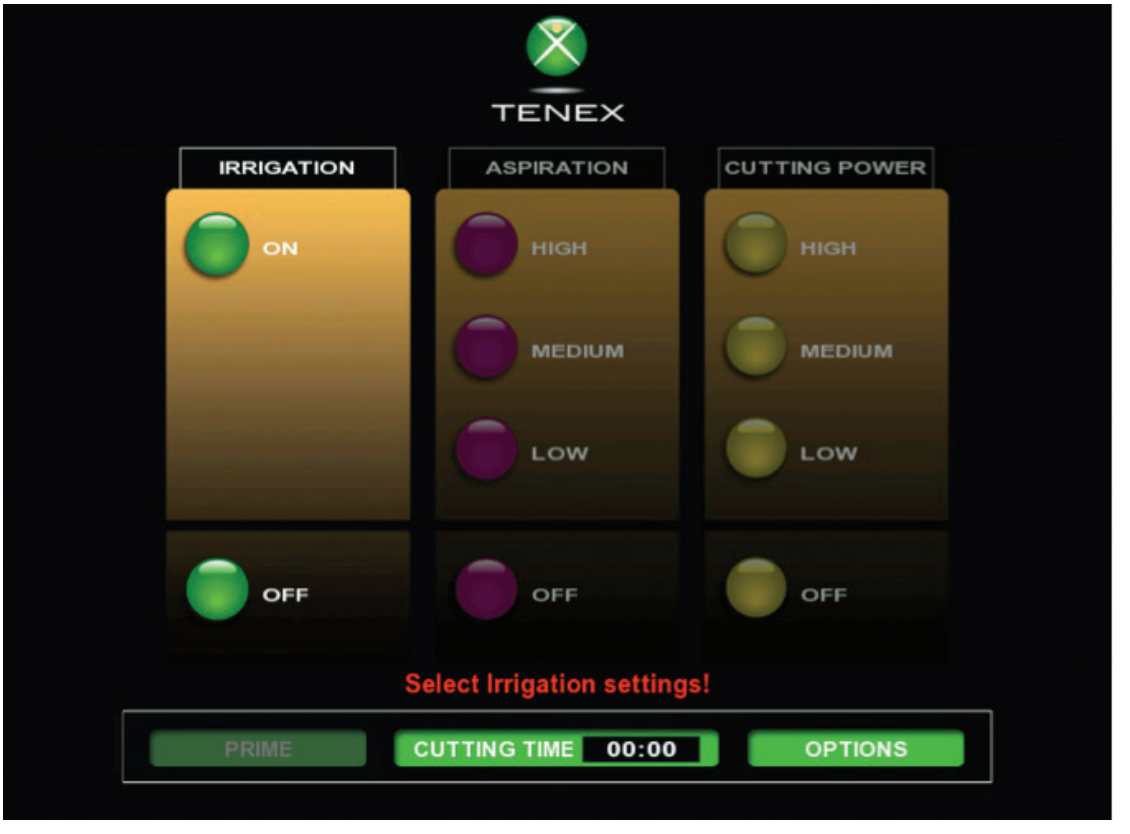
The three (3) user functions are **Irrigation, Aspiration, and Cutting Power**. The parameter settings for each function are only available sequentially from left to right after prime. The system is not ready for use until parameter settings are made for all three (3) functions.

The Main Mode also contains the **Prime, Cutting Time, and Options** commands. The PRIME command soft key will initiate the priming cycle when pressed, which fills the tube set with liquid, tests the valves, and tests the peristaltic pump. After the priming cycle is completed successfully the Prime button will be disabled. The CUTTING TIME command soft key resets the cutting timer when pressed. The OPTIONS command soft key will access the Options Mode when pressed, providing access to the **Sound, Brightness**, and **Software Upgrade** functions. NOTE: The software upgrade function is for factory use only.

d. IRRIGATION FUNCTION

The IRRIGATION Panel provides access to the parameter settings for the Irrigation function. Controlled by depressing the Foot Pedal, irrigation is intended to deliver fluid to the target site. When IRRIGATION is selected ON, the irrigation pinch valve will open when the Foot Pedal is depressed allowing fluid to flow. When the Foot Pedal is released, the pinch valve will close and the fluid will stop flowing. If IRRIGATION is selected to OFF, the Foot Pedal will have no effect on irrigation flow and the cuff pressure will be disabled. If IRRIGATION is selected to OFF and CUTTING is ON, CUTTING will automatically be selected to OFF.

IRRIGATION may be used independently, or together with ASPIRATION or CUTTING. IRRIGATION will automatically be selected ON when CUTTING POWER is enabled.

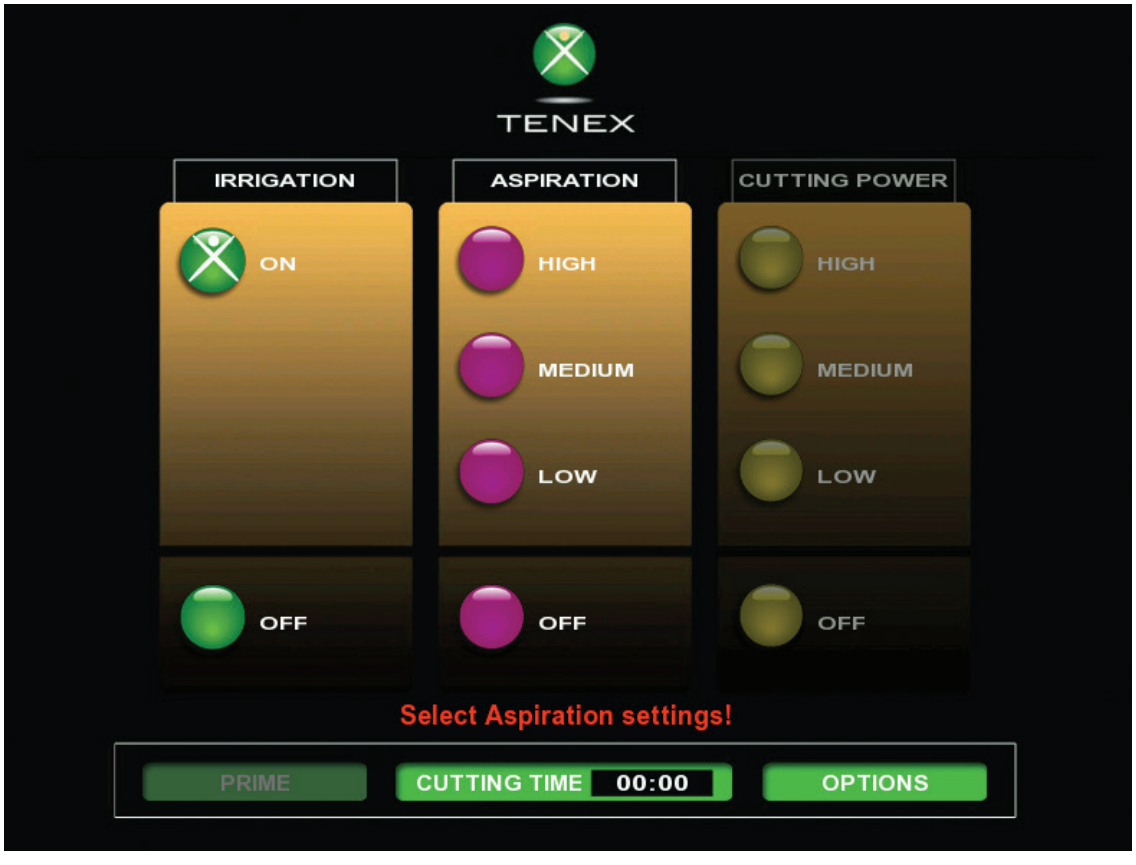


e. ASPIRATION FUNCTION

The ASPIRATION Panel provides access to the parameter settings for the Aspiration function. Controlled by depressing the Foot Pedal, aspiration is intended to remove cut tissue and fluid from the target site. When ASPIRATION is selected to LOW, MEDIUM, or HIGH, the peristaltic pump will start when the Foot Pedal is depressed, and continue until the vacuum limit is reached. When vacuum drops below the limit, the pump will restart.

When LOW is selected, the vacuum limit is 100 mmHg. When MEDIUM is selected, the vacuum limit is 300 mmHg. When HIGH is selected, the vacuum limit is 500 mmHg.

ASPIRATION may be used independently, or together with IRRIGATION or CUTTING POWER. When used together with IRRIGATION, fluid will flow at 10 cc/min when ASPIRATION is selected to LOW, 20 cc/min when selected at MEDIUM, and 30 cc/min when selected at HIGH.



f. CUTTING FUNCTION

The CUTTING POWER Panel provides access to the parameter settings for the Cutting function. Controlled by depressing the Foot Pedal, CUTTING POWER sends an ultrasonic power signal to the TX MicroTip, which converts it into mechanical vibration, thereby emulsifying tissue at the target site. When CUTTING POWER is selected to LOW, MEDIUM, or HIGH, IRRIGATION will automatically be selected ON. Depressing the Foot Pedal will open the irrigation pinch valve to allow fluid to flow, and turn ON the TX MicroTip at 100% Power. When the Foot Pedal is released, the TX MicroTip will turn OFF and fluid will stop flowing.

For LOW and MEDIUM CUTTING POWER settings, the console provides power delivery according to a software-controlled duty cycle. When LOW is selected, the CUTTING POWER is delivered in cycles at 50 milliseconds ON and 50 milliseconds OFF. When MEDIUM is selected, the CUTTING POWER is delivered at 75 milliseconds ON and 25 milliseconds OFF. For the HIGH CUTTING POWER setting, cutting power is delivered continuously; therefore a user-controlled duty cycle is required to ensure adequate cooling of the TX MicroTip. A user-controlled duty cycle of 15 seconds ON, 45 seconds OFF (15s/45s) is to be followed when using HIGH CUTTING POWER. This is equal to a ratio of 1:3 of FOOT PEDAL ON time to FOOT PEDAL OFF time with a maximum of 15 seconds of continuous FOOT PEDAL ON time.

CAUTION: Maximum tip temperature can approach 47 degree C. This does not present a hazard to the patient if the TX System is used according to the recommended duty cycle: 15 seconds on, 45 seconds off on HIGH cutting power.

The CUTTING POWER function can never be used independently, only together with IRRIGATION, or with IRRIGATION and ASPIRATION.

While using the cutting function, occlusion may occur. Occlusion is when the Aspiration flow channel of the TX MicroTip become blocked by tissue or debris. In this case, the system responds with an audible indicator (Tone), which is a series of (3) repeating "beeps" and a message "MicroTip Occlusion" will be displayed.
NOTE: Keep the TX MicroTip moving to prevent occlusion. Release and depress foot pedal to remove occlusion.

g. MAIN MODE COMMANDS

1. CUTTING TIME

The CUTTING TIME command indicates the total time in minutes and seconds that the cutting function is active. Whenever the Foot Pedal is depressed in CUTTING POWER, the clock will run. Pressing the CUTTING TIME Soft key at any time will reset the clock to zero. At 10:00 of cutting time, an alert will be displayed reading “Monitor Saline bag. Monitor Collection bag” to help ensure sufficient saline irrigation is present and that the collection bag is not overfilled during extended use.

2. OPTIONS

The OPTIONS command will access the Options Mode and display the three Option functions when the OPTIONS command Soft key is pressed.

h. OPTIONS MODE FUNCTIONS

1. SOUND

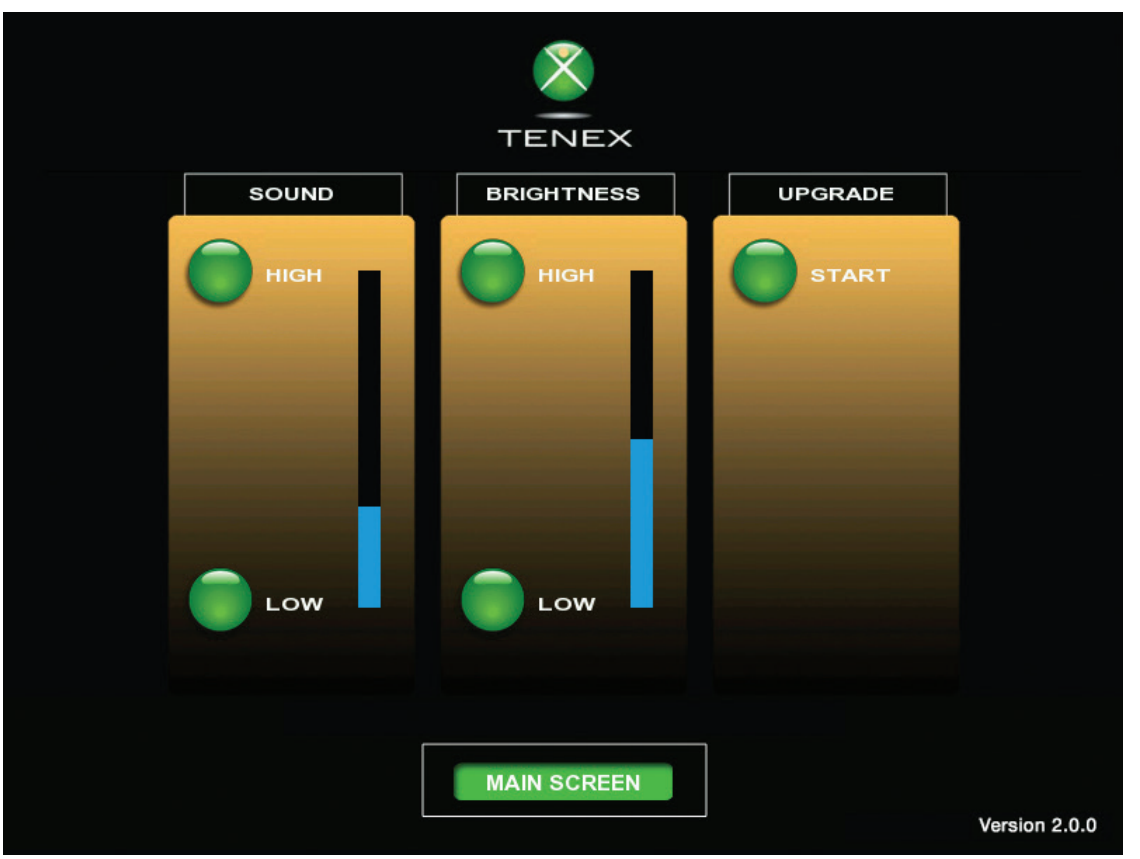
The SOUND function allows the volume for Audible Indicators to be adjusted by depressing the HIGH Soft key to raise the volume or depressing the LOW Soft key to lower the volume. The volume will adjust incrementally with each press of a Soft key, or if a Soft key is pressed and held. The volume can also be adjusted by dragging your finger along the volume indicator bar or pressing anywhere on the bar.

2. BRIGHTNESS

The BRIGHTNESS function allows the brightness of the screen to be adjusted by depressing the HIGH Soft key to raise the brightness or depressing the LOW Soft key to lower the brightness. The brightness will adjust incrementally with each press of a Soft key, or if a Soft key is pressed and held. The brightness can also be adjusted by dragging your finger along the brightness indicator bar or pressing anywhere on the bar.

3. UPGRADE

The UPGRADE function is used by factory personnel to perform upgrades to the system software, should they become available.



Chapter 7 Troubleshooting Guide

Problem	Suggested Action
AC POWER	
Unit will not turn "ON"	* Check AC power cord is properly connected. * Check for adequate supply voltage from mains. * Check fuses in AC power input module, replace if blown. * Cycle the power switch OFF for 10 seconds and then back ON.
SYSTEM SETUP	
TX MicroTip will not Prime	* Check that tip protector is securely fastened during priming. * Check TX MicroTip and tubing for fluid leaks and proper connection. * Verify cartridge is properly installed and securely locked into place. * Make sure pressure cuff maintains pressure. * If the prime cycle fails with the "Vacuum Test Failed" message, perform manual priming as follows: 1. Select irrigation ON, aspiration HIGH, and cutting power OFF. 2. Depress the foot pedal until the Inflation Cuff is tight around the irrigation bag and the needle cap is filled with irrigation fluid. 3. Select cutting power LOW, MEDIUM or HIGH and depress the Foot pedal to test ultrasonic power.
IRRIGATION SYSTEM	
No Irrigation	* Check Irrigation parameter setting is selected ON. * Depress foot pedal and listen for irrigation pinch valve operation (click). * Check tubing is properly connected. * Check the Inflation Cuff Air Tubing is properly connected to the Console receptacle. * Check tubing is not kinked or damaged. * Depress foot pedal and listen for air pump operation. * Depress foot Pedal and check that air is coming out of Console.
ASPIRATION SYSTEM	
No or Poor Aspiration (*Vacuum*)	* Check Aspiration parameter setting is LOW, MEDIUM or HIGH. * Parameter setting is too low. Increase to higher aspiration setting. * Check cartridge is properly installed. * Check tubing is not kinked or damaged. * Check for blocks in TX MicroTip, or tubing.
CUTTING	
No or Poor Cutting Power	* Check the TX MicroTip connection. Ensure that the electrical connector is properly inserted into the Console CUT receptacle. * Parameter setting is too low. Increase to higher cutting power setting. * Check for damaged TX MicroTip. * Faulty TX MicroTip. Replace TX MicroTip.
TOUCHSCREEN	
Malfunctioning or Unresponsive	* Close the screen to the horizontal position. Reopen. Turn the system ON. * Verify there is no visible moisture or debris on the touchscreen. If needed, clean the touchscreen with a very small amount of 70% Isopropyl Alcohol applied to a soft cloth.

Chapter 8 Run-Time Messages

a. USER FUNCTION PARAMETER SETTINGS

The TX Console comes with fixed values for select User function parameter settings. These values cannot be changed.

Mode		Setting		
		LOW	MEDIUM	HIGH
IRRIGATION		ON / OFF		
CUTTING POWER (delivery cycle at 100% power)		50ms ON, 50ms OFF	75ms ON, 25ms OFF	Continuous
ASPIRATION	FLOW (cc/min)	10	20	30
	VACUUM (mmHg)	100	300	500

b. MESSAGES

START-UP MESSAGES	DESCRIPTION
Install Foot Pedal!	The foot switch is not connected to the console. Displayed after the system is powered on in Main Mode.
Install Cassette!	The Cassette is not installed, or completely inserted into the console, the footswitch is detected. Displayed after the system is powered on in Main Mode.
Install Handpiece Connector!	The handpiece electrical connector is not installed, or completely inserted into the console connector; the footswitch and the cassette are detected. Displayed after the system is powered on in Main Mode. If installed: check to see that the Red dot on the handpiece connector is aligned with the red dot on the console.
Please Press Prime!	After all connections are made this message will be displayed and the prime button will be enabled.
PRIMING MESSAGES	**DESCRIPTION**
Priming ... Please Wait!	Prime button pressed: will clear when priming cycle is complete.
Fluid Path Blocked! Prime Again!	Vacuum too high during prime cycle: check tubing setup. Check that fluid is flowing; check tube set is not pinched or blocked.
Check: Irrigation Spike, Pressure Cuff, Tubing and Cassette	These messages will be displayed in sequence with a delay between each message until Prime is pressed again. If the cassette is removed the messages will clear, *"Install Cassette!"* will be displayed until the cassette is reinstalled. User will be forced to Press prime. **Check Tubing Setup:** Verify no visible kinks in microtip tubing. Deflate inflation cuff by disconnecting air fitting. Depress the cartridge release button and remove the cartridge. Verify proper alignment of the peristaltic tubing on the bottom edge of the cartridge. Reinstall the cartridge and inflation cuff. Press Prime.

PRIMING MESSAGES	DESCRIPTION
"Vacuum test failed!"	Cannot build sufficient vacuum during priming cycle: check the tube set for open connections or leaks. Verify the tip cap is installed and secure.
"Check MicroTip Cap, Check Cassette"	The Irrigation panel will become available. These messages will be displayed in sequence with a delay between each message until the irrigation is selected. After the aspiration and cutting power is selected a manual prime can be done.
"Select Irrigation and Manually Prime"	Manual Prime: 1. Select Irrigation: ON, Aspiration: HIGH, Cutting: OFF. 2. Depress the foot pedal until the Inflation Cuff is tight around the irrigation bag and the needle cap is filled with irrigation fluid. 3. Select the cutting power LOW, MEDIUM or HIGH and depress the foot pedal to test ultrasonic power. If the cassette is removed and reinstalled the user will be forced to Press prime again.
Check Cuff Connection! Press prime again	Pressure Cuff not connected to console or leaking air. Check connection and re-prime.
RUN TIME MESSAGES	
Select Irrigation Settings!	System is ready for input of IRRIGATION parameter setting.
Select Aspiration Settings!	System is ready for input of ASPIRATION parameter setting.
Select Cutting Power Settings!	System is ready for input of CUTTING POWER parameter setting.
Check Handpiece!	TX MicroTip not plugged in or TX MicroTip failure. Ensure electrical connector is properly installed. Remove and reinstall. Check for faulty or damaged microtip.
Cassette Removed! Please Install and Prime again!	Cassette has been removed after a successful prime: Prime must be run again. Cassette not seated all the way down: should click into place when seated correctly.
MicroTip Occlusion!	When occlusion occurs. Will continue until occlusion clears. Occlusion or blockage of aspiration line in microtip. Adjust aspiration setting to provide more fluid. To help dislodge the blockage depress foot pedal for 3-5 seconds and release the foot pedal.
Monitor Saline bag. Monitor Collection bag.	The total on the *Cutting Time* timer has reached the 10 minute mark. Check the remaining fluid levels.

c. AUDIBLE INDICATORS

TONE	DESCRIPTION
Single beep	When any soft key is depressed.
Two beeps	Occurs when an on-screen text notification message is displayed.
Three beeps - Pause	When occlusion occurs. Will continue until occlusion clears. Occlusion or blockage of aspiration line in microtip. Adjust aspiration setting to provide more fluid. To help dislodge the blockage depress foot pedal for 3-5 seconds and release the foot pedal.

Chapter 9 Cleaning

a. INTRODUCTION

This section contains information on cleaning the Tenex Health TX System.

b. CONSOLE

When cleaning any external surface on the Console, use only isopropyl alcohol (70%) or a mild soap and water solution. Use of any other type of cleaning solutions or solvents can damage the surface of the Console and void your warranty.

CAUTION: DO NOT spray liquids directly onto the TX console or submerge the TX console or foot pedal into liquids - see Cleaning Chapter.

CAUTION: DO NOT use abrasive cleansers or solvents on the TX console, particularly the touchscreen.

Before cleaning the Console, be sure the AC input power has been disconnected. Use a soft cloth moistened with cleaning solution and gently wipe the surface of the Console. Use only a very small amount of cleaning solution around the electrical and pneumatic connectors and front panel display. Thoroughly wipe the unit with a lint-free cloth and do not leave any cleaning solution residue or water spots on the surface. Never spray cleaning solution directly on any part of the Console. Never submerge the Console into any cleaning solution.

c. FOOT PEDAL

Even though the Foot Pedal is waterproof, always wipe away any fluids that come into contact with the Foot Pedal during the course of surgery. Never submerge the Foot Pedal into any cleaning solution. Use only isopropyl alcohol (70%) or a mild soap and water solution. A germicidal solution may be used, but it must be compatible with plastic parts. Also, gently clean the connecting cable at the end of each day, using only approved solutions. Be sure to examine the Foot Pedal Cord for nicks or tears.

d. TOUCH SCREEN

Use a soft cloth moistened with a small amount of 70% IPA and gently remove the soil from the Touch Screen. DO NOT use any cleaning solutions to remove soil from the Touch Screen. Cleaning solutions can fade and/or discolor the Touch Screen material. Use a soft dry cloth to remove any remaining moisture left on the Touch Screen.

e. INFLATION CUFF

Use a soft cloth moistened with warm water and gently wipe the surfaces of the Inflation Cuff, including the tubing. Be sure to examine the inflation cuff for nicks or tears prior to subsequent use or storage. If damage or deterioration of the inflation cuff is observed, contact Tenex Health Customer Service for a replacement.

Chapter 10 Maintenance and Service

a. INTRODUCTION

The Tenex Health TX System requires no maintenance other than cleaning as described in Chapter 9 of this manual. With appropriate care, the TX System has an expected use life of 7-years from the date of manufacture listed on the device.

WARNING: No modification of this equipment is allowed.

The following section contains instructions for fuse replacement, should it be necessary, and information for Service and Technical Support issues.

b. FUSE REPLACEMENT

Should an over voltage condition occur, the fuses in the AC Power Input Module that protect the console from excessive loads and line fluctuations may need to be changed as dscribed below.

Only replace with 5 x 20 250 V T 5.0A fuses which are included with your System Accessories. Additional fuse sets are available as a set of 2, Part No. 430-2215-002 by contacting Tenex Health Customer Service.

To replace the fuses, perform the following steps:

1. Remove the AC power cord from the unit.
2. Use a small slotted screwdriver to pull out on the notch on the fuse cover tab above the switch and pull the cover down. The fuse holders can then be removed.
3. Push the fuse holders the opposite way of the arrow on the top of the holders and pull them up.
4. Remove the old fuses and replace with Part No. 430-2215-002 (fuse type 5 x 20 250 V T 5.0A).
5. Push the fuse holders back into place toward the arrow on the holders.
6. Push the fuse holder cover closed until it snaps closed.
7. Connect the AC Power Cord.

c. SERVICE

WARNING: Electrical shock hazard exists. No user serviceable parts within console. Call manufacturer for service.

CAUTION: The TX Console contains electrical and electronic components. For safe disposal, do not discard in the general waste stream. Please contact your dealer or supplier for further information, or contact the manufacturer at returns.tenex@tricemedical.com or +1 (949) 454-7500

CAUTION: The foot pedal must be disposed of according to local regulations at the end of its useful life.

No component of the Tenex Health TX System is serviceable by the user. Should service or repair be required, contact customer service or technical support at the contact information provided below. Before returning any system conponent, a Return Merchandise Authorization (RMA) must first be obtained.

For information regarding an extended Equipment Service Contract, please contact Tenex Health Customer Service Department at +1 949.454.7500. For all console returns, use the packing material that was provided with your system, with transportation and shipping prepaid to the following address:

Tenex Health
26902 Vista Terrace
Lake Forest, CA 92630
USA

d. CONTACTING CUSTOMER SERVICE AND TECHNICAL SUPPORT

For customer service or technical support call:

Tel.	**+1 949.454.7500**	
Toll-free	**+1 855.2TENDON** **+1 855.283.6366**	**In USA only**
Fax	**+1 949.580.1270**	
E-mail	**orders.tenex@tricemedical.com**	
Website	**www.tenexhealth.com**	

Appendix 1

EMC Requirements for TX Console

The TX Console meets all applicable requirements of IEC/EN 60601-1-2 for electromagnetic compatibility. The TX Console needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Appendix.

Portable and mobile RF communications equipment can affect the operation of the TX Console.

The following is a list of cables that are used with the TX Console that comply with applicable sections of the EMC Standard:

- Power Cord
- TX MicroTip
- Foot Pedal

Use of cables or accessories other than those specified, with the exception of cables and accessories sold by the manufacturer of the Tenex Health TX System as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Tenex Health TX System.

TABLE 5. Guidance and Manufacturer's Declaration, Electromagnetic Emissions, for the Tenex Health TX System.

The Tenex Health TX System is intended for use in the electromagnetic environment specified below. The customer or the user of the Tenex Health TX System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment: guidance**
RF emissions CISPR 11	Group 1	The Tenex Health TX System uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic environment.
RF emissions CISPR 11	Class A	The Tenex Health TX System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 6. Guidance and Manufacturer's Declaration, Electromagnetic Immunity, for the Tenex Health TX System.

The Tenex Health TX System is intended for use in the electromagnetic environment specified below. The customer or the user of the Tenex Health TX System should assure that it is used in such an environment.

Immunity test	EN 60601 test level	Compliance level	Electromagnetic Environment: guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic materials, 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 ground 1 kV line to line	2 kV line to ground 1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (< 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (< 95% dip in UT) for 5 sec	< 5% UT (< 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (< 95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Tenex Health TX System requires continued operation during power mains interruptions, it is recommended that the Tenex Health TX System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A (rms)/m	3A (rms)/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the AC mains voltage prior to application of the test level.

Table 7. Guidance and Manufacturer's Declaration, Electromagnetic Immunity, for the Tenex Health TX System.

The Tenex Health TX System is intended for use in the electromagnetic environment specified below. The customer or the user of the Tenex Health TX System should assure that it is used in such an environment.

Immunity test	EN 60601 test level	Compliance level	Electromagnetic Environment: guidance
			Portable and mobile RF Communications equipment should be used no closer to any part of the Tenex Health TX System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2 √ P
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 mHz	3 Vrms	
Radiated RF IEC 61000-4-3	3 V(rms)/m 80 mHz to 2.5 gHz	3 V(rms)/m	d = 1.2 √ P 80 mHz to 800 mHz d = 1.2 √ P 800 mHz to 2.5 gHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from the fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 mHz and 800 mHz, 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.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless), telephones, and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Tenex Health TX System is used exceeds the applicable RF Compliance level above, the Tenex Health TX System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorientating or relocating the Tenex Health TX System.

b. Over the frequency range 150 kHz to 80 mHz, field strengths should be less than 3 V(rms)/m.

Table 8. Recommended Separation Distances between Portable and Mobile RF Communications and the Tenex Health TX System.

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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
W	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 $d = 1.2 \sqrt{P}$
0.01	0.12	0.12	0.12
0.1	0.38	0.38	0.38
1	1.2	1.2	1.2
10	3.8	3.8	3.8
100	12	12	12

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 to 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.

Notes:

Notes:


TX
TENEX HEALTH
SYSTEM

Trice Medical

TENEX HEALTH | Tenex Health is now a part of Trice Medical

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