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IntelliBlate Microwave Ablation System

Model Number	Description
IB-CON	IntelliBlate Microwave Ablation System Console

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Legal Information

Publication ID

P1061031-001-C

Publication Title

IntelliBlate Microwave Ablation System
Instructions for Use

Abstract

This document provides reference information and procedures for using the IntelliBlate Microwave Ablation System.

This publication is the English-language original.

Notice

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For customer support and to report incidents, contact us at vis.support@varian.com or call +1 (877) 457-2009 or contact your local representative.

Any serious incident that has occurred while using the device should be reported to the manufacturer and the competent authority of the Member State in which the user or patient is established.

Medical Device

MD

CAUTION: US Federal law restricts this device to sale by or on the order of a physician.

Basic Unique Device Identification

UDI-DI	Model Number	Description
00810563022278	IB-CON	IntelliBlate Microwave Ablation System Console

FDA 21 CFR 820 Quality System Regulations (cGMPs)

Varian Medical Systems products are designed and manufactured in accordance with the requirements specified within this federal regulation.

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Varian Medical Systems products are designed and manufactured in accordance with the requirements specified within the ISO 13485 quality standard.

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The link to the current EU REACH SVHC disclosure statement can be found at http://www.varian.com/us/corporate/legal/reach.html

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Introduction

About this Publication

This publication contains instructions and supporting information for using the IntelliBlate Microwave Ablation System.

Visual Cues

This publication uses the following visual cues to help you find information:

WARNING: A warning describes actions or conditions that can result in serious injury or death.

CAUTION: A caution describes hazardous actions or conditions that can result in minor or moderate injury.

NOTICE: A notice describes actions or conditions that can result in damage to equipment or loss of data.

Note: A note describes information that may pertain to only some conditions, readers, or sites.

Tip: A tip describes useful but optional information such as a shortcut, reminder, or suggestion, to help get optimal performance from the equipment or software.

Safety

Warnings

The IntelliBlate Microwave Ablation System and accessories should only be used by clinicians who are properly trained users of ablation technology and image guidance technology such as ultrasound or computed tomography (CT) for the placement of probes. The users must be familiar with the precautions and the potential hazards involved.

Note: Ensure that users authorized to use the ablation system are appropriately trained before using the system.

Users should read and understand the Instructions for Use before operating the system.

Users should read all warnings, precautions and instructions provided with the Varian ablation systems that are compatible with the IntelliBlate Microwave Ablation System.

All users responsible for operating and maintaining the IntelliBlate Microwave Ablation System should be provided with the *IntelliBlate Microwave Ablation System Instructions for Use*.

Users should read all warnings, precautions, and instructions provided with the Varian microwave accessories.

For general instructions on the microwave ablation system, see *IntelliBlate Microwave Ablation System Instructions for Use*.

For specific instructions on the Ximitry Probe Assembly (XPA), see *IntelliBlate Ximitry Probe Assembly Instructions for Use*.

For specific instructions on the Temperature Sensor Probe (TSP), see *Temperature Sensor Probe Instructions for Use*.

Provide these Instructions for Use to all personnel responsible for operating and/or maintaining the IntelliBlate Microwave Ablation System and accessories.

The IntelliBlate Microwave Ablation Console is designed to support its own weight and that of the IntelliBlate accessories. Using the console to support any other equipment could lead to enclosure fracture and electrical shock hazard.

While the equipment is designed to provide robust mechanical strength, the IntelliBlate Microwave Ablation Console display is constructed of glass and may be broken or cracked if bumped on a hard surface or dropped.

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 IntelliBlate

Microwave Ablation System, including cables specified by the manufacturer. Otherwise, degradation of the performance of the IntelliBlate Microwave Ablation System could result.

Insert the cassette of the Ximitry Probe Assembly into the pump receptacle of the console only. Otherwise, pinch, crush, or entrapment hazards may occur.

Use caution when adjusting the moveable display to avoid pinching of hands or fingers.

When the IntelliBlate Microwave Ablation System is used simultaneously with physiological monitoring equipment, any monitoring electrodes should be placed as far as possible from the ablation treatment area.

Only fuses on the rear panel of the console are user serviceable. See the *System Care and Maintenance* section of this document.

Do not operate the IntelliBlate Microwave Ablation System near equipment that is sensitive to microwave energy in the range of 2.45 GHz ± 50 MHz.

Only use accessories that are compatible with the IntelliBlate Microwave Ablation System. These accessories include the Mobile Cart, the Ximitry Probe Assemblies, and the Temperature Sensor Probes. Non-compatible accessories may fail to operate and may cause user and/or patient injury.

Use of non-compatible accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the IntelliBlate Microwave Ablation System. This may cause improper operation.

Remove hearing aids and all metal jewelry from the patient prior to a microwave ablation procedure. Ensure that there are no metallic buttons, snaps, or other metallic items in direct contact with the patient.

Microwave ablation procedures are not recommended for patients with cardiac pacemakers or other implanted electronic devices. Potential risks have not been evaluated.

Microwave ablation procedures are not recommended for pregnant patients. Potential risks to the patient and fetus have not been evaluated.

If the console continues to provide microwave energy after you have turned off the system, press and hold the power button to deactivate power and all user interfaces. Afterwards, disconnect the power cord from the console immediately. Do not use the console. Contact Varian customer service.

Do not obstruct the vents in the handle area of the console. The vents are used for proper ventilation of the console.

Keep liquids and foreign objects away from the microwave system. Never operate the console if any liquid or foreign object has entered the system. There is a risk of electrical shock, causing fire or shock hazards in addition to damage to the console.

Always use the IntelliBlate Microwave Ablation System as specified. If the IntelliBlate Microwave Ablation System is not used as specified, the protection provided by the system could be

impaired causing patient and/or user injury, illness, or death. Use the IntelliBlate Microwave Ablation System only if all means for protection are intact.

Excessive patient movement during the procedure may affect the accuracy of the IntelliBlate Microwave Ablation System, potentially resulting in tissue irritation or injury.

The accessories of the IntelliBlate Microwave Ablation System are contained in sterile packages. Do not use the accessories if the package is damaged. Potential infection may occur.

Disposable products have been validated and warranted for single use only. Any reuse, reprocessing, or resterilization may result in the devise failure causing patient and/or user injury, illness, or death.

Reuse, reprocessing, or resterilization could cause contamination of the device, which may result in patient infection.

Do not remove the cover or any other access plates of the console. Contact Varian customer service.

Always disconnect the console from mains power before cleaning.

Reliable grounding can only be achieved when the IntelliBlate Microwave Ablation System is plugged into a properly grounded receptacle. Any interruption of the protective earth conductor will result in a potential shock hazard, putting the patient and operator at risk of injury or death.

Connect the console to a mains supply with protective earth.

Only use the power cord provided with the IntelliBlate Microwave Ablation System to prevent damage to other equipment and/or harm to the patient and user. The power cord and plug must be intact and undamaged.

Connecting the IntelliBlate Microwave Ablation System to a multiple-socket outlet, such as a power strip, may result in a reduced level of safety.

Do not use power plug adapters.

Ensure that the electrical connectors are dry before using the console.

Console internal circuits can be disconnected from supply mains by removal of the power cord from the rear of the console, which should be positioned such that it is always accessible. Disconnect the power cord from the console before replacing fuses.

Ensure microwave energy is deactivated before connecting or disconnecting the accessories.

If the console has any visible damage, stop using the device and contact Varian customer service.

Do not direct microwave output (probe) towards eyes or testes when energized as this may result in burns or other injuries to the patient or operator.

Do not test or maintain the IntelliBlate Microwave Ablation System while it is being used on a patient.

A failure of the IntelliBlate Microwave Ablation System may cause an unintended increase of output power. If you read parameters that do not correspond to the preset values, stop the

procedure immediately by pressing and holding the power button on the front panel. Do not operate the IntelliBlate Microwave Ablation System again until the source of the problem has been identified and fixed.

If the power cord or plug is cracked, frayed, broken, or damaged, replace it immediately.

Shut down the console and unplug the power cord before cleaning or service. Only perform the following servicing of the IntelliBlate Microwave Ablation System:

- Cleaning of the console and cart.
- Replacing fuses on the console.

Do not remove, open, or operate any parts of the IntelliBlate Microwave Ablation System Console while internal components are exposed. This can cause injury or death.

Do not allow fluids to enter the ventilation holes or sockets.

Do not touch any exposed wiring or conductive surface while the IntelliBlate Microwave Ablation System is energized. The high power can cause injury or death.

Do not use sanitizing agent or wipes to clean the console touch screen.

Use non-flammable agents for cleaning and disinfection wherever possible.

Do not use abrasive agents or solvents to clean the system components.

Do not activate the output of the console until the probe is properly positioned in the patient. Regularly inspect the accessories of the console.

If mechanical damage has occurred to the IntelliBlate Microwave Ablation System, return the IntelliBlate Microwave Ablation System to the supplier for inspection. Always test the IntelliBlate Microwave Ablation System before any further use and contact Varian customer service for inspection.

The mains input socket is factory-set and should not be changed by the user. The serial number label shows the correct mains input voltage for the device and the rating of the fuses to be used in the mains input unit fuse holder. An incorrect voltage setting may result in console malfunction and potential damage to the console and injury to the patient..

Place the coolant fluid bag (usually saline) for the IntelliBlate Microwave Ablation System cooling on the supplied coolant fluid mount on the console.

Ensure that cleaning cloths are free from excess chemical agent before cleaning.

The IntelliBlate Microwave Ablation System has the following additional risks:

- Ignition hazards
- Risk of electric shock
- Risk of thermal burns to patient
- Interference with other devices
- Risk of patient injury
- Risk of corrosive or contaminating materials
- Non-biocompatible materials

- Non-recommended use of patient category

Tip: During operation, one operator should always stand next to the power button of the console. If the system behaves in an unpredictable or unexpected way, press and hold the power button for at least three seconds to power down the system.

MRI Safety Information

- The Ximitry Probe Assembly and the Temperature Sensor Probe are Magnetic Resonance (MR) unsafe and pose a projectile hazard.
- Keep the Ximitry Probe Assembly and the Temperature Sensor Probe away from the magnetic influence of MR machines.

Electromagnetic Interference (EMI)

Electromagnetic interference (EMI) produced by the IntelliBlate Microwave Ablation System may adversely affect performance of other equipment during normal operation. Take all necessary precautions to always ensure the safety of all patients. To minimize the risk of EMI, the following protocols should be applied:

- Do not activate microwave power until hardware setup is complete and the radiating section of the probe is fully inserted into tissue.
- Ensure adequate space between the Microwave Ablation System and the other electronic medical devices.
- Plug devices into separate branch circuit outlets.
- Contact Varian customer service for assistance if required.

To limit exposure to electromagnetic interference from nearby equipment, which can degrade system performance, operate the system under conditions that minimize power supply transients, mechanical interactions, vibration, and thermal, optical, and ionizing radiation.

Fire Hazard

The IntelliBlate Microwave Ablation System is not suitable for operation in the presence of a flammable anesthetic mixture with air or with oxygen, or nitrous oxide.

Heating associated with microwave energy may be an ignition source. Keep all probes away from flammable materials and oxygen-enriched environments. Keep gauze and sponges wet.

Avoid the accumulation of naturally occurring flammable gases that may accumulate in body cavities such as the bowel.

Prevent pooling of flammable liquids and the accumulation of flammable and/or oxidizing gases or vapors under drapes or near the site of the ablation procedure.

Ensure the flammable agents for cleaning, disinfecting, or as solvents of adhesives are completely evaporated before any microwave procedure.

Explosion Hazard

Do not activate microwave energy in potentially explosive environments, such as in the presence of flammable anesthetics.

Essential Performance

The IntelliBlate Microwave Ablation System is designed to deliver the set amount of microwave power over the set time duration to heat tissue for coagulation (ablation). The IntelliBlate Microwave Ablation System is designed to provide accurate reflected energy and temperature values at specified locations on the IntelliBlate Ximitry Probe Assembly (XPA) and Temperature Sensor Probe for the user to monitor the delivery of the microwave power. The IntelliBlate Microwave Ablation System ensures that microwave power is not being inadvertently delivered when the user expects the system to be in a paused, stopped, or off condition. The IntelliBlate Microwave Ablation System employs measurement systems to detect and turn off microwave output for conditions adverse to safe administration of power delivery. These include measurements of reflected microwave energy and temperatures of the transmission line and coolant fluid.

The IntelliBlate Microwave Ablation System

About the IntelliBlate Microwave Ablation System

System Overview

1	IntelliBlate Microwave Ablation System Console
2	IntelliBlate Microwave Ablation System Mobile Cart
3	Ximitry Probe Assembly (XPA) (Shown in Channel 1)
4	Temperature Sensor Probe (Shown in Connection A)
5	DPA Cassette (Shown in Channel 1)
6	Coolant Fluid Mount (with user supplied coolant bag shown)

Note: The IntelliBlate Microwave Ablation System and its components and accessories are not made with natural rubber latex.

WARNING: The Ximitry Probe Assembly and the Temperature Sensor Probe are not Magnetic Resonance (MR) safe and pose a projectile hazard. This may cause puncture injuries to the user, people in the area, or patient. Keep the Ximitry Probe Assembly and the Temperature Sensor Probe away from MR magnetic fields.

System Components

This IFU contains information and instructions on the IntelliBlate Microwave Ablation System including the following accessories that are compatible with the IntelliBlate Microwave Ablation System:

- IntelliBlate Ximitry Probe Assembly (XPA)
- Temperature Sensor Probe (TSP) (optional)
- IntelliBlate Microwave Ablation System Mobile Cart (optional)

Accessories

Model Number	Description	Image
IB-XPA-1315 (Qty 1) IB- XPA-1320 (Qty 1) IB- XPA-1327 (Qty 1) IB- XPA-1315-K3 (Qty 3) IB- XPA-1320-K3 (Qty 3) IB- XPA-1327-K3 (Qty 3) IB- XPA-1315-K12 (Qty 12)	IntelliBlate Ximitry Probe Assembly Available sizes: 15 cm, 20 cm, 27 cm	
ABL-TP-1820 (Qty 1) ABL- TP-1820-K5 (Qty 5)	Temperature Sensor Probe	
IB-CART	IntelliBlate Microwave Ablation System Mobile Cart	

Intended Use / Indications for Use

The IntelliBlate Microwave Ablation System is intended for coagulation (ablation) of soft tissue.

The IntelliBlate Microwave Ablation System is not intended for use in cardiac procedures.

Intended Users

The IntelliBlate Microwave Ablation System is intended to be used by clinicians performing microwave ablations.

Target Patient Group

The IntelliBlate Microwave Ablation System is intended for patients requiring microwave ablation therapy for those treatments within the scope of the indications for use (above).

The IntelliBlate Microwave Ablation System is contraindicated in pediatric population as performance and safety of the IntelliBlate system has not been evaluated in pediatric population.

Residual Risks

There are residual risks associated with the use of the microwave ablation system to achieve the clinical benefit. These residual risks are communicated within the instructions for use and may contribute to the undesirable side effects disclosed. Varian has determined that the clinical benefit outweighs the residual risks for the indicated use of the microwave ablation system. An adequately trained user and/or patient should make an informed decision that weighs the residual risks against the benefits of using the medical device for specific treatment scenarios.

Contraindications for Use

The IntelliBlate Microwave Ablation System is contraindicated for use in cardiac procedures and in patients with pacemakers or other active electronic device implants.

The IntelliBlate Microwave Ablation System is contraindicated in pregnant women as potential risks to the patient and fetus have not been evaluated.

The IntelliBlate Microwave Ablation System is contraindicated in pediatric population as performance and safety of the IntelliBlate system has not been evaluated in pediatric population.

Clinical Benefits

The intended clinical benefit is ultimately the treatment of tumors or other tissues designated for microwave ablation (MWA) therapy, while minimizing unwanted side effects. The goal is the destruction of the target (tumor/tissue), or a reduction or cessation of growth of the target tissue, or reduction of patient discomfort (palliation). Typically, target tissues are malignant neoplasms that would otherwise continue growing and ultimately have a negative impact on the patient's health, including death.

The IntelliBlate Microwave Ablation System provides clinical benefit by delivering microwave energy for coagulation (ablation) of soft tissue (target tissue). Microwaves are used to destroy or ablate diseased soft tissue (tumors) by heating the tissue to a temperature that causes coagulation and cell death.

Undesirable Side Effects

The following is an expansive list of potential undesirable side effects that may be associated with the use of the IntelliBlate Microwave Ablation System and the microwave ablation treatment. These side effects vary depending on the target tissue being treated as well as other clinical and technical factors.			
Allergic reaction	Anaphylaxis	Bacteremia	Bone infection
Bruising/skin discoloration	Bullous dermatitis	Dysesthesia (abnormal sensation such as painful burning, prickling or aching feeling)	Device-related infection
Edema	Fever	Fluid accumulation	Hematoma
Hemorrhage	Infection of organ or vital structure	Injury to skin	Neurological injury
Organ failure	Organ or vital structure injury such as stenosis, fistula, perforation, anastomotic leak, obstruction	Pain	Pneumothorax
Skin deformity	Skin infection	Skin ulceration	Skin/tissue atrophy
Soft tissue infection	Soft tissue injury	Tissue necrosis	Tumor lysis syndrome
Tumor seeding	Urinary retention	Vessel injury	Wound dehiscence
Wound infection	Dyspnea	Fatigue	

Features & Performance

Features Summary

Pumps	Two (2) fully integrated peristaltic pumps
Touchscreen Monitor	15.6-inch foldable touchscreen Swivels 180-degrees CW/CCW Operable with gloved fingers Operable with sterile drape
Input / Output	One (1) USB port and one (1) Ethernet port
Tract Ablation	Cauterizes needle tract
Needle Lock	Probe migration solution
Coolant	1000mL or greater Sterile water or 0.9% saline (user provided)

Performance Characteristics

MWA Generator Frequency	2.45 GHz ± 50 MHz
Applied Part Type	Type BF – Dual probe support and independent channel controls. Type BF – Two remote temperature probe support.
Output power (tip referenced):	Single Channel: 0-90W Two (2) Channel: 0-80W (each) 0-160W (linked)
Microwave Output Power Accuracy	Within 10 seconds of activation of output energy on the touchscreen: Power (tip referenced) <25W: ± 20% Power (tip referenced) ≥ 25W: ±5W or ±8%, whichever is greater
Ximitry Probe Antenna Temperature Measurement	10-60°C (±3°C accuracy) 60-85°C (±6°C accuracy) 85-150°C (±10°C accuracy)
Temperature Probe Measurement	10-60°C (±2°C accuracy) 60-85°C (±5°C accuracy) 85-150°C (±10°C accuracy)
Weight (without Cart)	38 lbs. (17.2 kg)
Weight (with Cart)	95 lbs. (43 kg)
Dimensions (without Cart)	17.5 in. x 14.8 in. x 8.2 in. (445mm x 375 mm x 208mm)
Dimensions (with Cart)	W – 24 in. (609.6 mm) D – 22 in. (558.8 mm) H – 43.3 in. (1100 mm) Touchscreen closed H – 52.75 in. (1340 mm) Touchscreen open (max)
Electrical Power Connection	$100V_{AC}$-$240V_{AC}$ 50Hz/60Hz 900 VA
Power Cord Length	25 ft. (7.62 m)

Cybersecurity Information

Cybersecurity was a fundamental consideration in the design of the console and provides security features such as:

- Digital signature verification for software updates.
- Integrity checks of operating system files.

It is essential to follow cybersecurity best practices when storing, setting up, and using the console. These recommendations include:

- Restricting physical access to network devices to prevent tampering.
- Ensuring the software is kept up to date with the latest security patches.

Refer to the *IntelliBlate 1.0 Security White Paper and MDS*[2] for detailed cybersecurity information and recommendations.

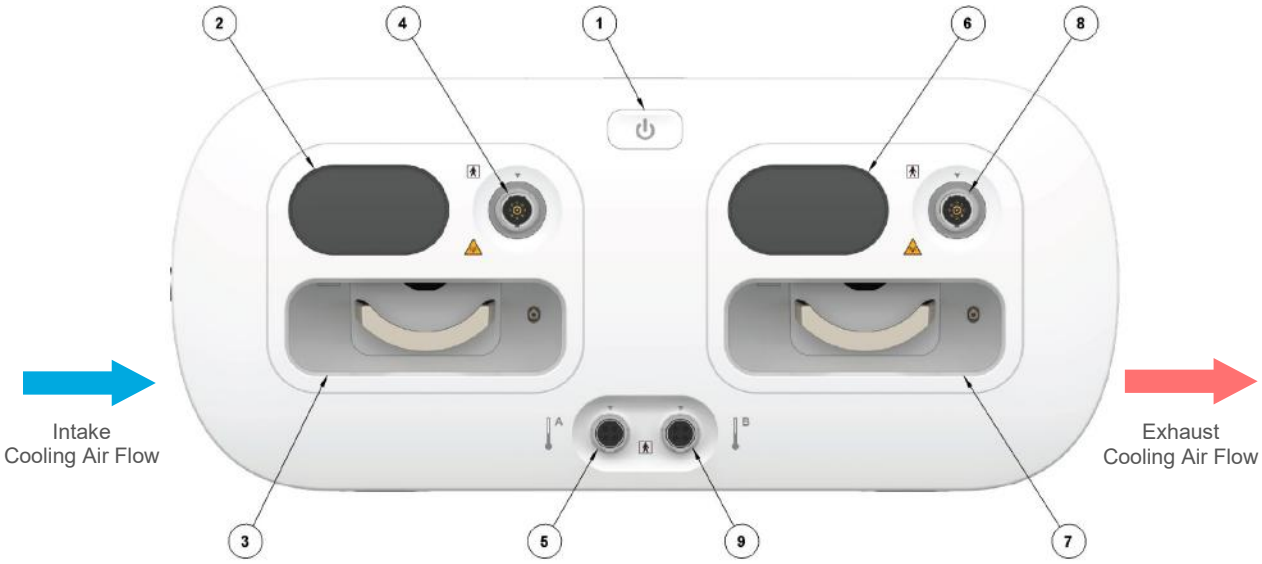
IntelliBlate Console

Overview

The IntelliBlate Microwave Ablation System Console (console) is the core of the IntelliBlate Microwave Ablation System. It provides the microwave generator along with connections for the Ximitry Probe Assemblies, Temperature Sensor Probes, coolant fluid cassette mounting, and coolant fluid mounting. It also includes the operating software.

IntelliBlate Microwave Ablation System Console without accessories connected

1	Touchscreen	• Flips up/down similar to a laptop screen • When flipped up, can rotate left / right 180° to allow visibility from any operating position • To close the touchscreen, rotate back to its original center position (as shown in image). There will be a tactile detent, then flip down to close
2	Coolant Fluid Mount	• The coolant fluid mount may be installed on either the left or the right side of the console. A thumbscrew secures the mount to the console.



IntelliBlate Console Front Panel

1	Power button	Switches mains power supply to the system on/off
2	Channel 1 Status	Color screen shows the status of Channel 1 operations
3	Channel 1 Cassette Cavity	For connection of the cassette for Channel 1 for fluid flow control
4	Channel 1 Ximitry Probe Assembly Connector	This connector is only intended for connection of the Ximitry Probe Assembly on Channel 1. This port enables power delivery to the needle and digital signal transmission to and from the needle.
5	Temperature Sensor Probe A Connector	This connector is only intended for connection of the Temperature Sensor Probe. This port enables digital signal transmission to and from the needle. Temperature Sensor Probe is independent of channel number.
6	Channel 2 Status	Color screen shows the status of Channel 2 operations
7	Channel 2 Cassette Cavity	For connection of the cassette for Channel 2 for fluid flow control
8	Channel 2 Ximitry Probe Assembly Connector	This connector is only intended for connection of the Ximitry Probe Assembly on Channel 2. This port enables power delivery to the needle and digital signal transmission to and from the needle.
9	Temperature Sensor Probe B Connector	This connector is only intended for connection of the Temperature Sensor Probe. This port enables digital signal transmission to and from the needle. Temperature Sensor Probe is independent of channel number.

IntelliBlate Console Rear Panel

1	Mains Power Input & Fuse Holder	For connection of mains power cord and fuse maintenance
2	Potential Equalization Connection	For connection of a Potential Equalization conductor. Connected Potential Equalization Conductors shall conform with the requirements of IEC 60601-1
3	USB Connection	For connection of USB flash memory devices only for software updates and export of research log data
4	Ethernet Connection	Ethernet port is disabled. Device has no network connectivity.
5	Device Label	Displays model number, serial number, and other relevant information

Note: The console power supply operates using input voltage range of 100-240 V_{AC} at either 50 Hz or 60 Hz.

WARNING: Only connect the system to a mains supply with protective earth. Otherwise, electric shock may occur.

WARNING: Only use the Varian supplied power cables. Otherwise, damage to the IntelliBlate Microwave Ablation System and/or harm to the user may occur.

WARNING: Do not connect the IntelliBlate Microwave Ablation System to a multiple-socket outlet, such as a power strip. This may reduce the overall level of safety.

IntelliBlate Console Side Panel
(Both sides have the same features)

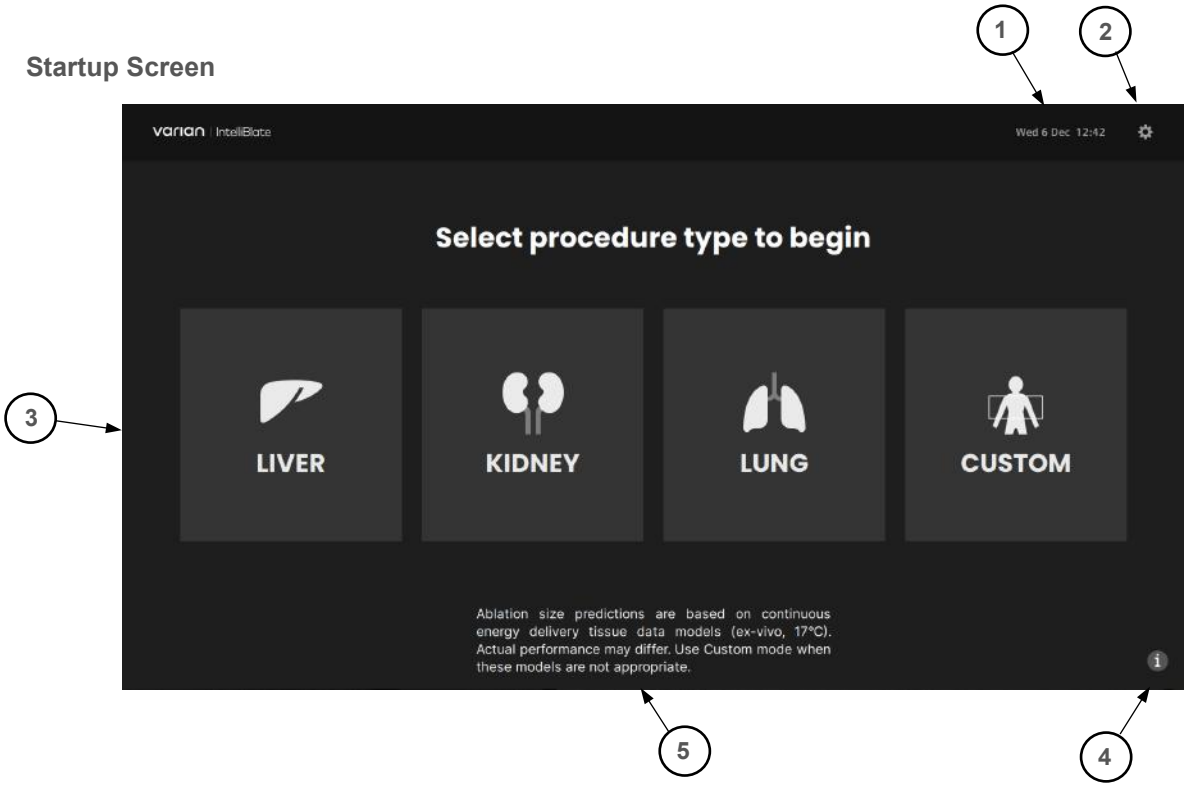
1	Coolant Fluid Mount	For hanging coolant fluid bottle/bag
2	Carrying Handle and Ventilation	For carrying the console. Looking at the front, ventilation flow is left (intake) to right (exhaust). (*See Console Front Panel image on page 21*)

NOTICE: Do not obstruct the ventilation flow.

Console User Interface

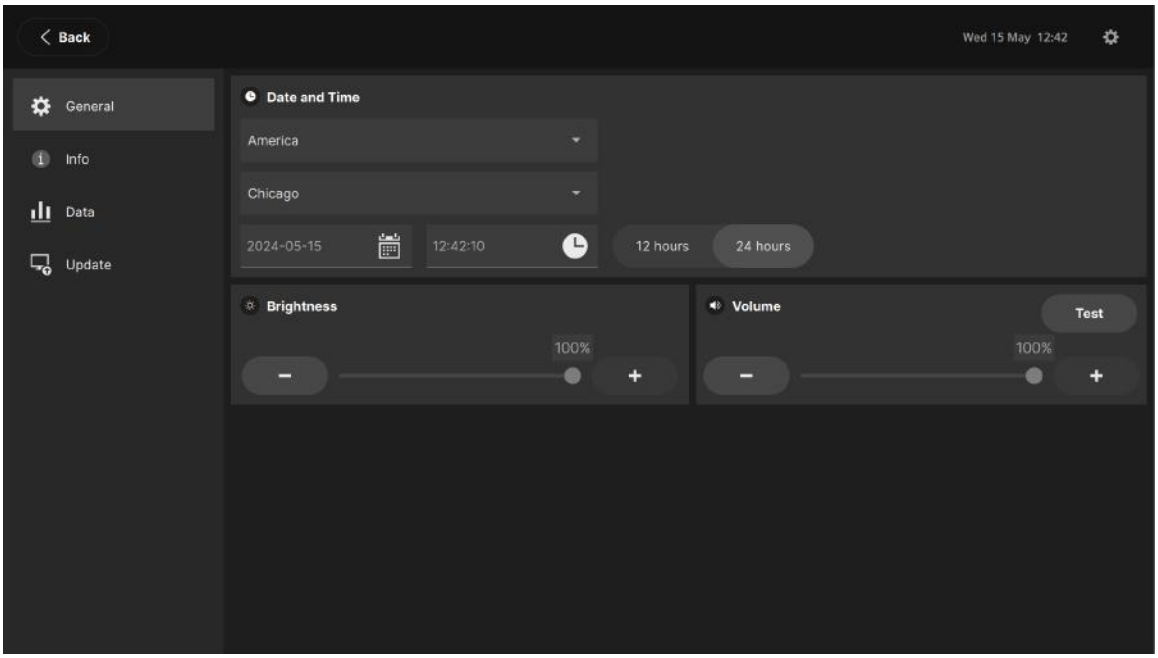
The console touchscreen powers on when the console powers on and will initialize to the startup screen.

Startup Screen



1	Date and time information
2	Gear icon (Settings)
3	Procedure buttons
4	Info icon
5	Info display (toggled on/off with info icon

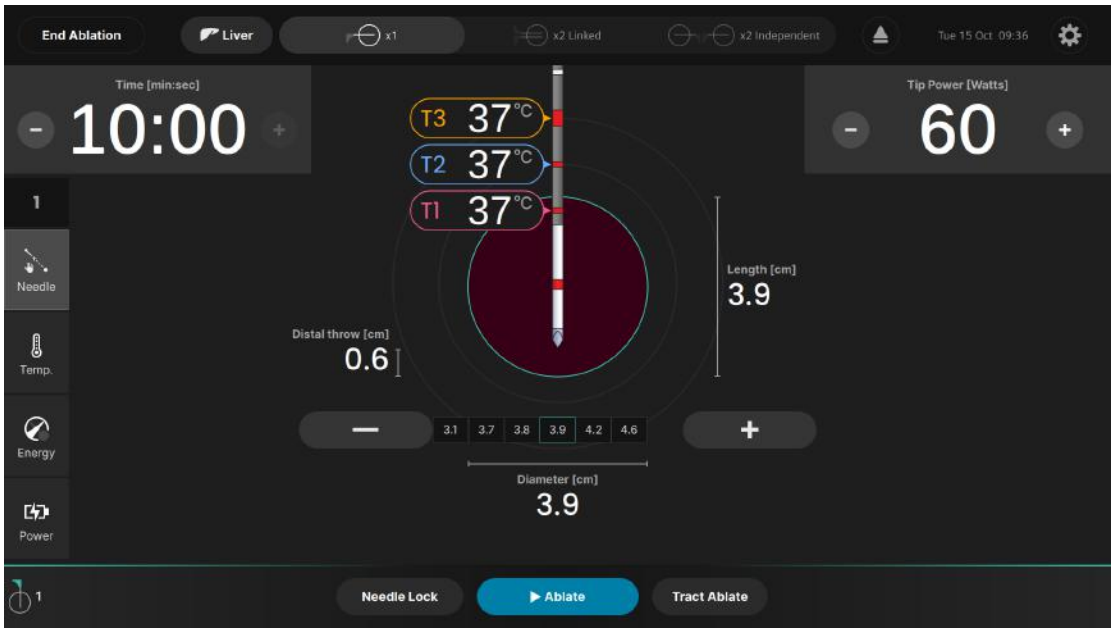
Settings



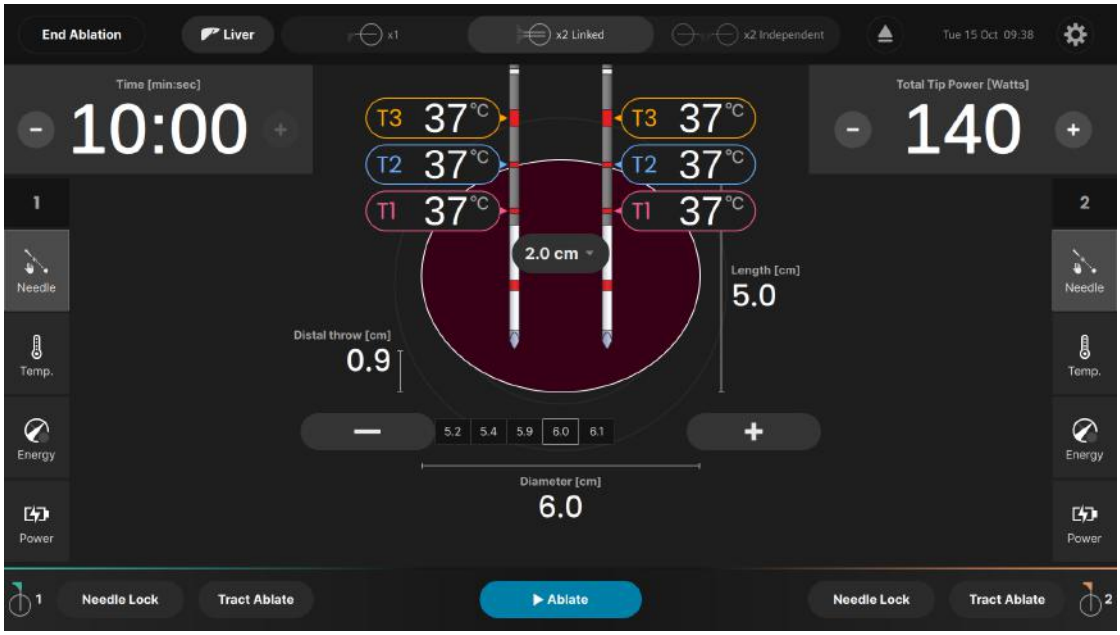
All available settings, system information, and maintenance procedures are accessed by selecting the gear icon.
The following menus are available:

General	Select this section to see all basic settings. You can edit these settings as desired.
Info	Select this section to see all main system information.
Data	Select this section to see and export all data. A USB storage is required to use this section.
Update	Select this section to update the software. A USB storage is required to use this section.

Touchscreen main view with single Ximitry Probe Assembly



Touchscreen main view with dual Ximitry Probe Assemblies linked



The following menus are available from the left side of the main screen:

Needle	This is the main view as shown above.
Temp.	Depicts the recorded temperatures at locations on the probe shaft during the ablation procedure.
Energy	Depicts the total energy emitted by the probe during the ablation procedure.
Power	Depicts the reflected power measured during the ablation procedure.

Reusable Accessory (Optional)

The optional IntelliBlate Microwave Ablation System Mobile Cart is available to support and transport the console within the clinical setting.

See *IntelliBlate Microwave Ablation System Mobile Cart Instructions for Use*

System Setup and Use for Ablation

WARNING: Electrical Shock Hazard: Connect the console mains power cord to a properly grounded receptacle. Do not use power plug adapters or power strips.

CAUTION: Failure to understand and follow the instructions provided may result in system malfunction and may cause injury to the patient and/or user.

CAUTION: Accessories compatible with the IntelliBlate Microwave Ablation System Console are designed for single use.

NOTICE: Connect the system power cord to a wall outlet having the correct voltage to prevent damage to the system.

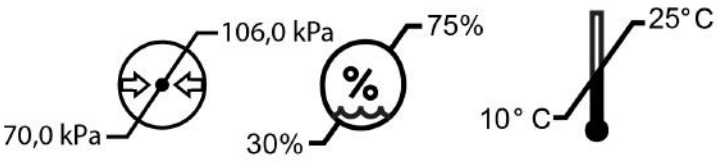
NOTICE: To prevent system damage, do not use three-prong to two-prong adapters with the system power cords. Periodically inspect the power cord assembly for damage to the insulation or connectors. Never use damaged cords.

NOTICE: Ensure that the mounting surface for where the console is placed has adequate clearance for the system accessories to be plugged into the console front, rear, and side connections. Failure to provide proper clearance may damage the console and/or accessories or may prevent the use of the system.

Note: Do not attempt to use the IntelliBlate Microwave Ablation System prior to reading and understanding the system setup instructions.

Environmental Conditions for Console Use

NOTICE: Use the console within the following environmental conditions:



Atmospheric pressure | Humidity | Temperature

CAUTION: If the console is stored at a temperature outside the specified operating temperature range, allow the console to acclimate in the operating environment temperature for one hour prior to use.

System Setup

Prepare the IntelliBlate Microwave Ablation System Console

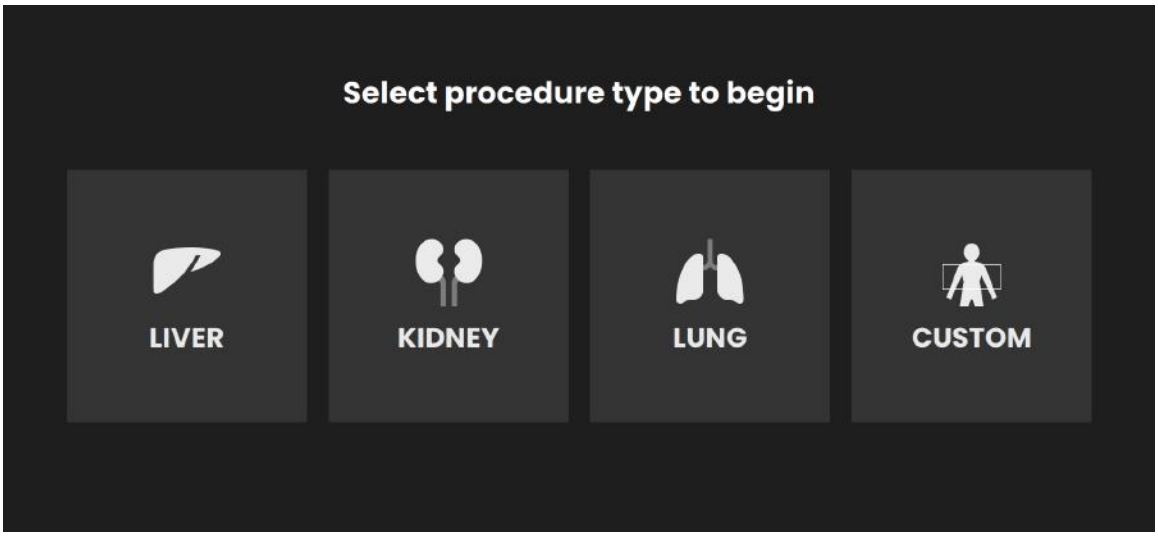
1. Remove the console from its packaging (if applicable)
2. Place the console onto the IntelliBlate Microwave Ablation System Mobile Cart.
3. Secure the console using the thumbscrew.

Note: If you do not have the IntelliBlate Microwave Ablation System Mobile Cart, place the console on a stable, hard, and flat surface that can support the console weight.

4. Adjust the monitor to a comfortable angle for viewing and operating.
5. Connect the socket-end of the power cord into the rear of the console and the plug-end of the power cord to a hospital-grade power outlet with protective earth.
6. Press the power button to power on the console.

Select the Procedure Type

1. Determine the appropriate probe length (15 cm, 20 cm, 27 cm).
2. Select the appropriate procedure type on the console touchscreen.



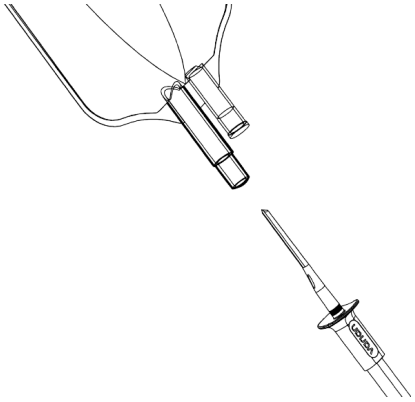
3. Select between a single-channel ablation (default), dual-channel linked ablation, or dual-channel independent ablation.

Install and Configure the Ximitry Probe Assembly

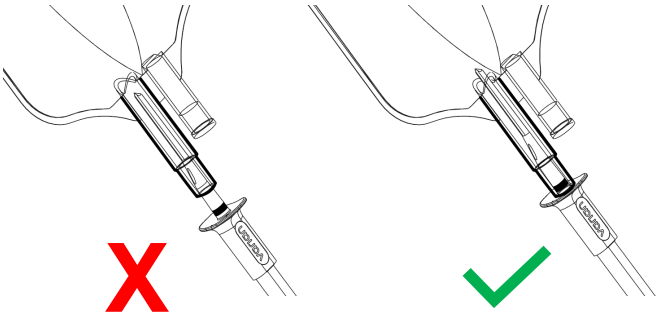
1. Remove the coolant fluid spike sharps cover by sliding off axially.

> CAUTION: The coolant fluid spike tip is very sharp and may cause puncture damage. Handle carefully as a sharps object.

2. Insert the coolant fluid spike into the coolant fluid bag using a twisting motion. Make sure to insert at least to the insertion mark on the spike. Twist as needed to ease insertion and verify there are no leaks.



Before Spike Insertion



After Spike Insertion

3. Hang the coolant fluid bag (1000 mL) onto the coolant fluid mount on the console.
4. Visually inspect all components for damage prior to connecting to the console.
5. Insert the cassette into the channel 1 cassette cavity and wait for recognition and locking (approximately 5 seconds).

6. Connect the probe connector to the console connector of the same channel as the cassette.

NOTICE: Ensure that the arrows on the XPA connector are in line with the arrow on the console XPA connector.

7. Prime the coolant pump following the on-screen instructions. The display indicates when priming is completed.

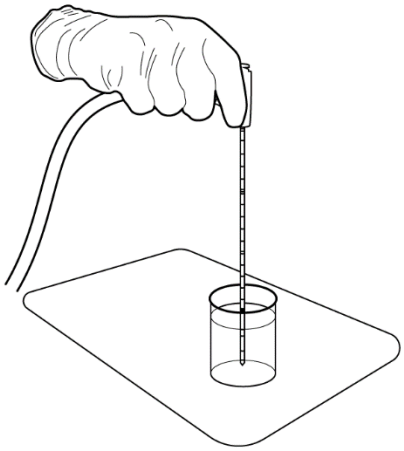
NOTICE: The coolant fluid bag needs to meet the operating temperature requirements of the system (room temperature) (10°C to 25°C) and must be sterile water or sterile saline.

8. If necessary, prepare a second Ximitry Probe Assembly per steps 1 to 7 above.

Perform the Pre-Test Procedure (Optional)

Ximitry Probe Assembly (XPA) pre-test is recommended for every XPA following these steps:

1. Remove the probe protective sheath.
2. Place a clear container of sterile coolant onto a flat surface.
3. Insert the probe tip at least 3 cm (2nd red marker band) into sterile coolant fluid in the clear container.



WARNING: Do not hold the container in your hand. Microwave energy emanating from the probe tip may cause serious injury when too close to the hand.

4. Select **Needle Lock** on the display to activate the probe pre-test. The **Needle Lock** button turns green after a successful pre-test.

Tip: The Needle Lock feature could be used when the probe is inserted into the target tissue by selecting the **Needle Lock** button again.

5. In the event of an unsuccessful pre-test, refer to the *Troubleshooting* section to address.

Insert the Probe

1. Remove the probe protective sheath if it hasn't already been removed during pre-test.
2. Insert the probe into the target tissue to be ablated.
3. Secure the probe in the desired location. If desired, use the optional Needle Lock function when securing.
4. If appropriate, use proper imaging modalities to guide and confirm probe placement.

WARNING: Incorrect placement or repositioning of probe may lead to patient injury. Evaluate for potential obstructions within the procedural field that may lead to patient injury.

Use the Needle Lock Function (Optional)

The Needle Lock function delivers microwave energy to secure the radiating section of the probe to tissue at the intended placement location. This feature may be used to stabilize the probe while using direct imaging to place an additional probe. Only use the Needle Lock function on one probe at a time. Energy output activation is indicated on the Ximitry Probe Assembly LED that is emitting energy.

Selecting **Needle Lock** ablation sets the console to a specific power level for the duration needed to secure the probe in position.

1. Press **Needle Lock**
    a. Engage Needle Lock when the probe is placed at the desired location.
    b. Ensure the entire radiating section of the probe is always inserted in tissue when microwave energy is activated.
2. Prior to Needle Lock, either manually hold the probe or affix the probe in the desired position.
    a. If needed, affix the clips provided on the Ximitry Probe Assembly cable to a stationary object. This prevents the probe from moving unnecessarily.
3. Needle Lock microwave energy is delivered as indicated by the timer, progression bar, audible tone, and Ximitry Probe Assembly LED indicator.

Use inter-procedural imaging to monitor placement. If repositioning of a probe is required after Needle Lock, discontinue Needle Lock function. Gently rotate the shaft to ensure the probe can move freely before repositioning.

Use the Temperature Sensor Probe (Optional)

1. Insert the temperature probe connector into connector A or B on the console front panel.

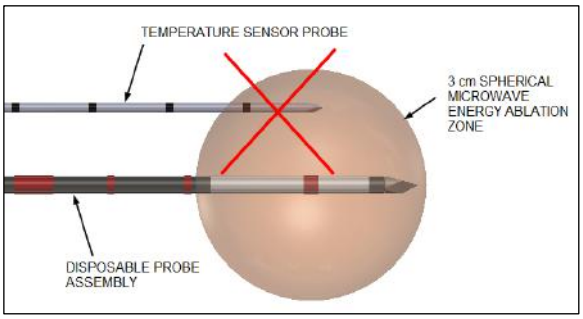
Note: Ensure that the arrow on the TSP connector is in line with the arrow on the console temperature connector.

Tip: Console temperature connectors are independent from Channels 1 and 2.

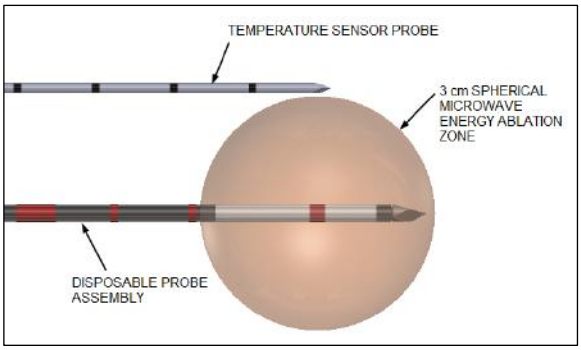
2. Insert the temperature probe into the target tissue where temperature observation is desired.

CAUTION: For microwave ablation, keep the TSP probe outside of the ablation energy zone.

INCORRECT



CORRECT



See *Temperature Sensor Probe Instructions for Use*.

3. Secure the temperature probe in the desired location.
4. If required, prepare a second temperature probe following the same steps.

Set the Ablation Parameters

Ablation parameters can be set either by interacting with the needle diagram in the center of the screen or by manually adjusting the **Time** and **Tip Power** settings.

Set ablation parameters using the needle diagram:

1. Use the **+** or **–** buttons to set the desired ablation diameter. Alternatively, the slider can be moved left or right to the appropriate size selection.
2. The **Time** and **Tip Power** settings will update automatically.

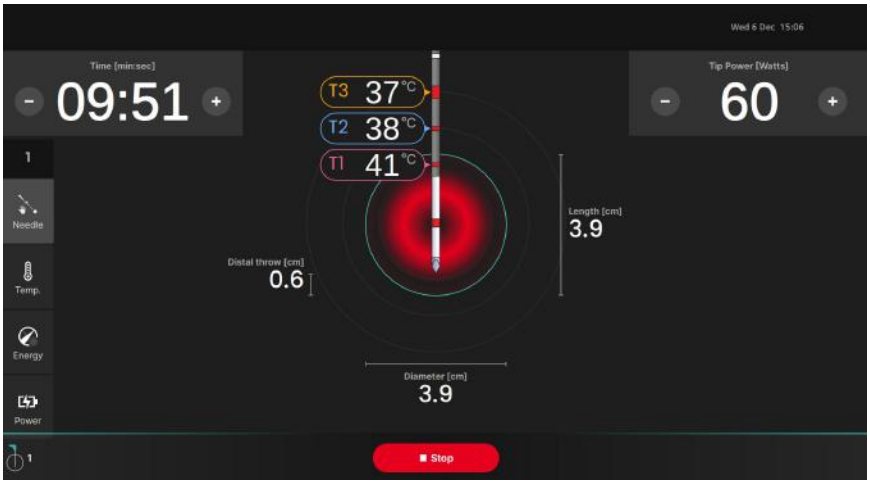
Set ablation parameters manually:

1. Use the **+** or **–** buttons at the left of the screen to set the desired **Time** for the ablation in 30-second increments.
2. Use the **+** or **–** buttons at the right of the screen to set the desired **Tip Power** for the ablation in 5-Watt increments.

Treat the Patient

1. Select the **Ablate** button to begin the ablation. When the ablation is started, there will be an audible tone every 4 seconds for the duration of the ablation. Additionally, the LED pattern of the active probe handle will change to indicate output of microwave energy.

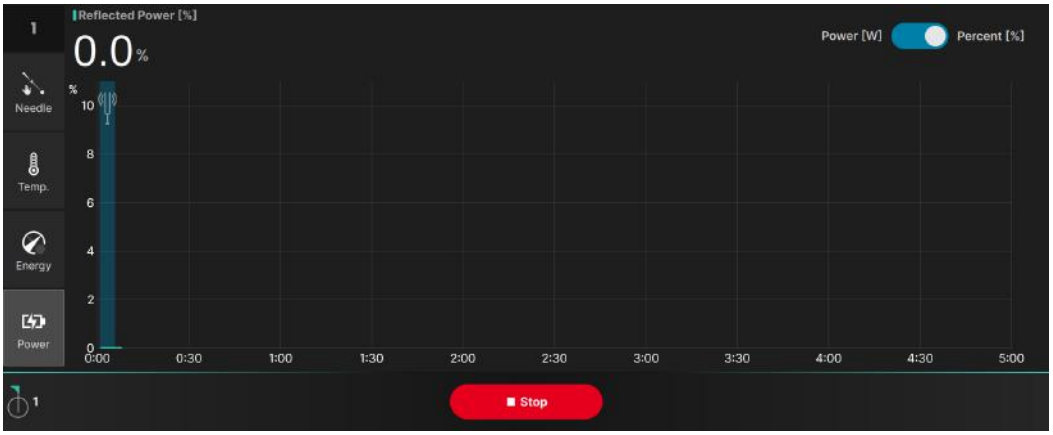
Note: Selecting the **Stop** button on the touchscreen on the ablation procedure screen will stop the procedure and deactivate the microwave energy output. Selecting the **Ablate** button will restart the procedure and activation of microwave energy output.



Note: Press and hold the power button on the console for at least 3 seconds to shut down the system and stop microwave energy output at any time.

Note: On the left side of the touchscreen, **Temp.**, **Energy**, and **Power** can be observed during and after an ablation procedure. These are informational screens and have no user-defined settings.

Note: During lung ablations, a blue overlay will be displayed in the **Temp**. and **Power** graphs when an ablation is started, indicating when the **Smart Adjust** feature is being used to optimize performance.



2. While the ablation is being performed, the timer at the upper left of the touchscreen will count down. When it reaches zero, there will be an audible tone indicating the ablation procedure for the prescribed treatment parameters has been completed and the microwave power will be turned off.

Ending an Ablation Procedure

When the ablation is complete, safely remove the XPA probe(s) and TSP probe(s), if applicable, from the patient. If desired, select the optional Tract Ablate function for ablation of the probe pathway during removal.

Use Tract Ablation (Optional)

WARNING: To avoid injury to the patient, when using tract ablate in lung tissue, use proper technique to protect the pleural surface.

Tract Ablation is available to ablate the tissue along the insertion tract of the probe when removing the probe from the patient. This feature is used to ablate the insertion tract only and should not be used to ablate or cauterize target tissue. Only one probe can be used in tract ablation mode at a time. Energy output activation is indicated on the Ximitry Probe Assembly LED that is emitting energy.

Selecting Tract Ablate sets the console to output a specific power level designed to ablate approximately 4 – 10 mm of tissue surrounding the insertion tract when used appropriately.

Thermal effects of tract ablation are dependent on probe removal rate and temperature. Performing tract ablation faster or slower than the specified removal rate may result in different thermal effects along the tract.

During tract ablation, the duration timer counts upward. Stop the tract ablation energy when the appropriate tract length ablation has been achieved. Ensure the entire radiating section of the probe is always inserted in tissue when microwave energy is activated. Perform tract ablation as follows:

1. Gently rotate the shaft to ensure the probe can move freely.
2. Press Tract Ablate.
    a. Ensure the entire radiating section of the probe is always inserted in tissue when microwave energy is activated.
3. Begin retracting the probe at a steady rate of 0.5cm per second.
    a. Console will output audible tone each 1 second interval to assist in achieving a uniform retraction rate.
    b. Stop removing the probe and deactivate microwave energy before entirely removing the probe from the target tissue and patient.
4. Press Stop Tract Ablate when the appropriate tract length ablation has been achieved. A single red marker band at 5 cm will indicate the recommended position to stop tract ablation.
5. Fully remove the probe from the patient.

End the Procedure

1. Select the **Next** button at the bottom-center of the touchscreen when the ablation is completed, then choose between the following:
    a. **End procedure** – Select this to release the cassettes and go back to the Startup Screen.
    b. **Start a new ablation** – Select this to continue the procedure with the same Ximitry Probe Assembly(ies).

Disconnect System Accessories

1. Following the removal of the Ximitry Probe Assembly(ies) from the patient, unplug the connector(s).
2. Remove the coolant fluid bag from the console.
3. If applicable, following the removal of the temperature probe(s) from the patient, unplug the connector(s).
4. Dispose of the Ximitry Probe Assembly, Temperature Sensor Probe, and cooling fluid in accordance with sharps and biohazard handling procedures of your facility.
5. Press and hold the power button on the console to turn it off
6. Use appropriate image guidance techniques of the patient target tissue to confirm ablation.

System Care and Maintenance

Regular Maintenance

The IntelliBlate Microwave Ablation System will last longer and perform better when it is properly maintained.

Follow the guidelines below to ensure longevity and proper operation of the system.

Console

The fuses on the rear panel of the console are the only user serviceable parts of the IntelliBlate Microwave Ablation System. Do not open the service panels or the pump covers to repair the fuses.

WARNING: Avoid electric shock. Turn off the console and unplug the power cord from the mains power before changing the fuses.

WARNING: Do not remove the console cover or any service access plates. For any service on console internals, contact Varian Customer Support.

Except for fuses, maintenance and service on other system parts must be performed by Varian personnel only. For all service issues contact Varian Customer Support. See *Contact Varian Customer Support / Report Incidents* on page 2.

The expected service life of the console is six years from the product release date. Before returning the IntelliBlate Microwave Ablation System to Varian, see *Contact Varian Customer Support / Report Incidents* on page 2.

If an issue exists, see the Troubleshooting section of this document. If the issue persists, contact Varian Customer Support.

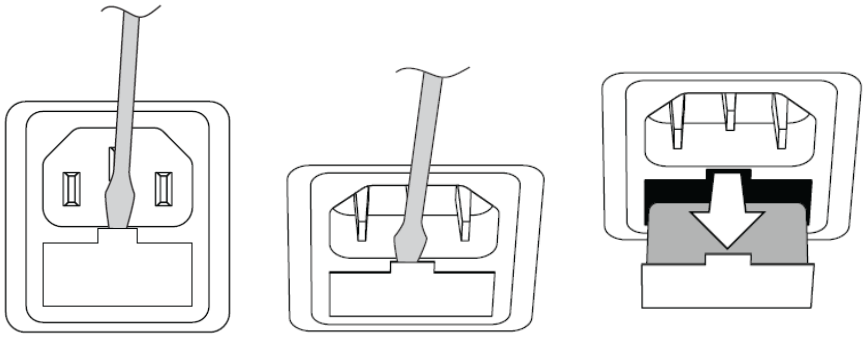
Replacing the Fuses

Note: Two fuses are fitted within the power inlet receptacle on the console rear panel. The specifications are:

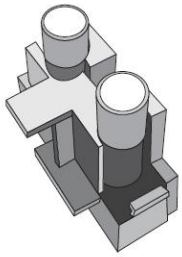
a. Mains voltage: 100-240 VAC

b. Type: T10A, 250V, HBC 5mm x 20mm.

1. To remove the fuse holder, place a flathead screwdriver blade in the area shown and gently pry out.



2. There is a fuse on the live and the neutral. Check and replace both as required.



3. Push the fuse holder back into the power inlet receptacle until it is flush with the housing. There will be an audible click when properly installed.

Visual Inspection

Visually inspect all connectors and cables for insulator and/or connector damage before connecting them to the console. Use compressed air to loosen particles and use a lint-free cloth to wipe away any loose particles still on the cable/connector.

WARNING: Always wear protective eyewear when using compressed air.

CAUTION: Damaged cables or connectors may affect the microwave performance of the device. Clearly mark any damaged items and either dispose of or return to Varian for repair or replacement.

Connectors

WARNING: Verify that connectors are dry prior to use. Use compressed air to dry the connectors if necessary.

WARNING: Always wear protective eyewear when using compressed air.

NOTICE: Do not use chemical agents to clean the connectors, the Disposable Probe Assembly, the Temperature Sensor Probe, or the console. Fluids may damage the products.

Clean the Console or Mobile Cart

WARNING: Always turn off and disconnect the console from mains power before cleaning. Electrical shock hazard may occur.

WARNING: Do not pour or spray chemicals or other liquids onto the console.

NOTICE: The console cannot be sterilized. Sterilization will destroy the electronic components within the console.

NOTICE: Do not permit liquids to enter the console.

NOTICE: Do not use compressed air to remove dust and debris from the console or its vents.

The following chemicals have been tested and are compatible for cleaning the console:

- Soap and water
- 70% Isopropyl alcohol

Clean the console, except the touchscreen, as follows:

1. Turn the console off.
2. Disconnect the power cord from the console.
3. Apply the desired cleaning chemical to a lint-free cloth.
4. Clean the console or the mobile cart.
5. Wait for the console to be completely dry before connecting it to the power cord.

Clean the Console Touchscreen

Materials required:

- Micro-fiber cloth or any medical approved non-abrasive wipe.
- Isopropyl alcohol (≤ 70%) in a spray bottle.

Touchscreen cleaning steps:

1. Turn the console off.
2. Disconnect the power cord from the console.
3. Spray and lightly dampen a dry, soft micro-fiber cloth with the isopropyl alcohol.
4. Wipe all areas of the touchscreen glass, especially the active touch areas.
5. Wait for the console touchscreen to be completely dry before connecting the console to the power cord.

NOTICE: Avoid using paper towels, tissue paper or any similarly abrasive materials to wipe the touchscreen. These non-ultrasoft materials can potentially scratch the screen.

NOTICE: Never spray liquid directly on the touch screen or it could run inside the monitor and cause damage.

Mobile Cart

Brakes

Verify that the brakes on the casters engage and disengage properly.

NOTICE: Faulty brakes may cause damage to the IntelliBlate Microwave Ablation System. If brakes are faulty, contact Varian Customer Support.

Thumbscrew

Verify that the thumbscrew threads are in good condition. The thumbscrew is located under the mobile cart platform near the center and protrudes above the top of the mobile cart platform.

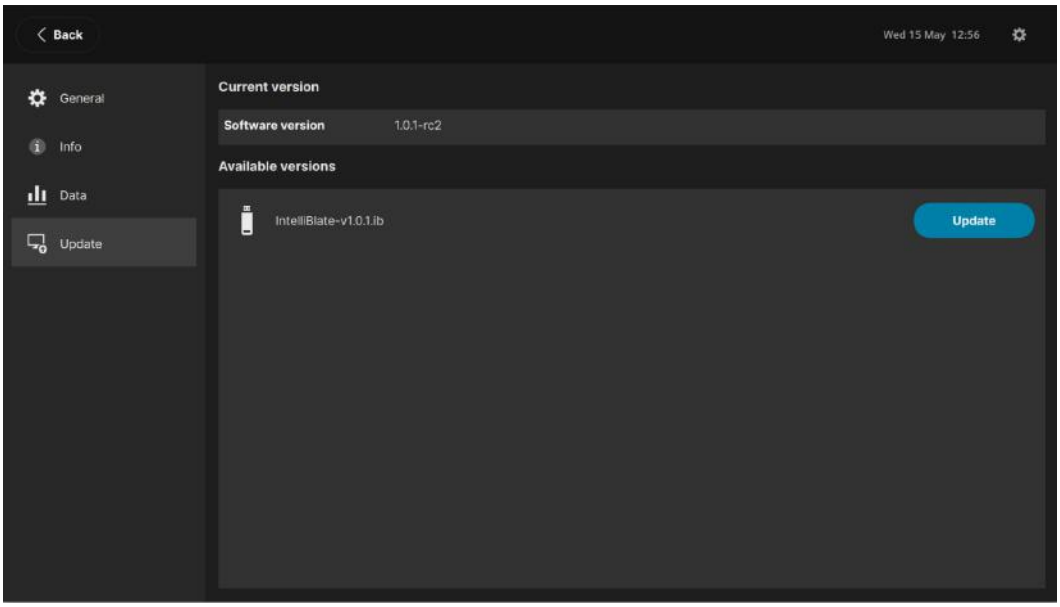
NOTICE: Poor thumbscrew threads may damage the mating threads in the console. This may affect the ability to secure properly the console to the mobile cart.

Software Updates

The console software can be updated from a USB flash drive.

Update Software from a USB Flash Drive

1. Download the software update from your Varian approved service center.
2. Copy the software update file to a USB flash drive.
   Note: For file name, use the format IntelliBlate-vX.Y.Z.ib where X.Y.Z is the new software version. Put the file at the top level of the flash drive, not in any folders.
   Note: Do not store multiple update files as the console detects only one of them.
3. Insert the USB flash drive into the USB port on the rear side of the console.
4. Select the gear icon on the Startup screen of the console touchscreen.
5. Select **Update**. The following window appears:



The console detects within a few seconds the software update file on the USB flash drive.

6. Select **Update** next to the desired software version and wait until the update has completed.
   Note: The update may take up to ten minutes.
7. Turn the console off.
8. Turn the console on to run the new software version.

Confirm the New Software Version

1. Select the gear icon on the Startup screen of the console touchscreen.
2. Select **Update**.
3. Verify that the reported **Software version** matches the new software version.

Export Ablation Data and System Logs

The console allows the export of the following two data types:

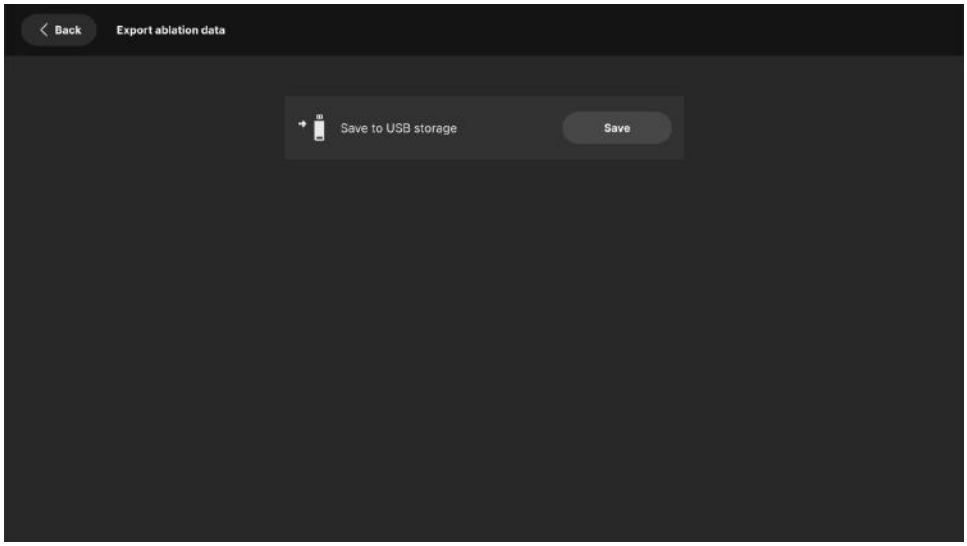
- Ablation data, for reports and scientific use
- System logs, for service and maintenance use

This data does not contain any Protected Health Information (PHI). The console does not store or export any PHI.

The data can be exported to a USB flash drive.

Export Ablation Data

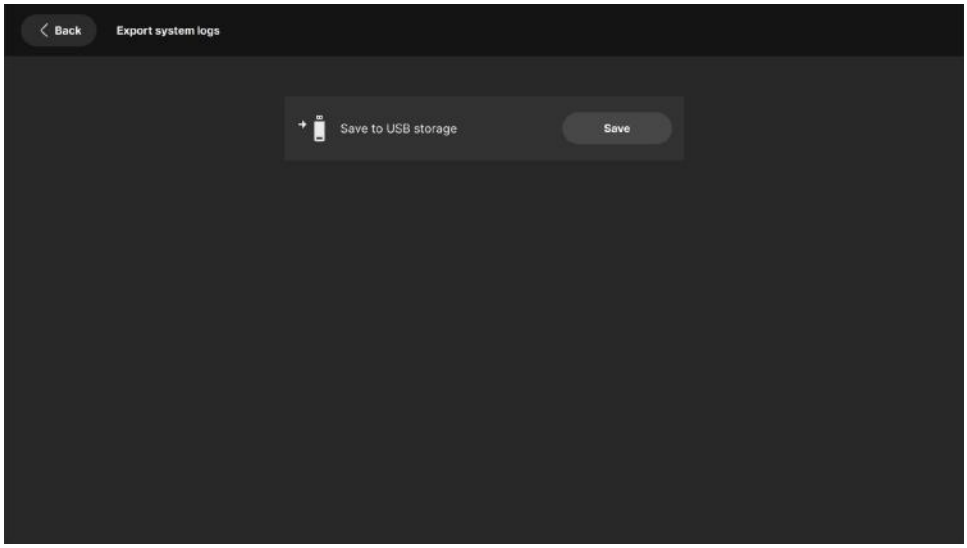
1. Select the gear icon on the Startup screen.
2. Select **Data**.
3. Select **Export**.
   The following window appears:



4. Save the exported data to a USB flash drive. See Save Exported Data to a USB Flash Drive.

Export System Logs

1. Select the gear icon on the Startup screen.
2. Select **Info**.
3. Select System Logs.
   The following window appears:



4. Save the exported data to a USB flash drive. See Save Exported Data to a USB Flash Drive.

Save Exported Data to a USB Flash Drive

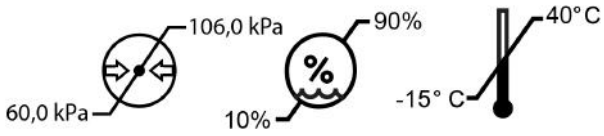
1. Insert a USB flash drive into the USB port on the rear side of the console.
2. The console detects within a few seconds the connected USB flash drive.
3. Select **Save**.

Storing the System

Console and Mobile Cart

NOTICE: Store the console and mobile cart within the following environmental conditions:

Keep away from rain / water



Atmospheric pressure | Humidity | Temperature

Disposable Accessories

For storage information of the disposable accessories, refer to:

- *IntelliBlate Ximitry Probe Assembly Instructions for Use*
- *Temperature Sensor Probe Instructions for Use*

Transporting the System within the Hospital Environment

Transport the System with the Mobile Cart

1. Disconnect the power cord (if connected).
2. Close the touchscreen display into the down/closed position.

3. Put the touchscreen in the closed position.
4. Unlock the mobile cart wheels.
5. Grab the Mobile Cart handle with two hands and move the System carefully to the desired location.
6. Lock the mobile cart wheels.

Transport the System without the Mobile Cart Using the Original Shipping Box

1. Disconnect the power cord (if connected).
2. Remove any obstructions, so that the mobile cart can be moved freely.
3. Put the touchscreen in the closed position.
4. Remove the coolant mount by loosening the thumbscrew.
5. Loosen the thumbscrew below the mobile cart table until you are able to lift the console.
6. Open the original shipping box and check that the foam padding is still there. If foam padding is missing, contact your Varian representative.
7. Remove the upper foam piece.
8. Lift the console carefully from the mobile cart and place it on the lower foam piece into the shipping box.

CAUTION: The lifting of the console may require two people as it weighs approx. 17 kg (38 lbs)

9. Check that the console is seated properly into the shipping box.
10. Install the upper foam piece on the console and check that the shipping box can close properly.
11. Close and seal the shipping box with shipping tape.
12. Move the loaded shipping box to the desired location by using a dolly or cart that is suitable for moving heavy, bulky items.

Note: Be sure all accessories (power cord, IFU, etc.) are moved together with the System.

Transporting the System Outside the Hospital Environment

Transport the System Console and Mobile Cart

Note: The console and the mobile cart are transported / shipped in separate shipping boxes.

Console

1. Disconnect the power cord (if connected).
2. Remove any obstructions, so that the mobile cart can be moved freely.
3. Put the touchscreen in the closed position.
4. Remove the coolant mount by loosening the thumbscrew.
5. Loosen the thumbscrew below the mobile cart table until you are able to lift the console.
6. Open the original shipping box and check that the foam padding is still there. If foam padding is missing, contact your Varian representative.
7. Remove the upper foam piece.
8. Lift the console carefully from the mobile cart and place it on the lower foam piece into the shipping box.

CAUTION: The lifting of the console may require two people as it weighs approx. 17 kg (38 lbs)

9. Check that the console is seated properly into the shipping box.
10. Install the upper foam piece on the console and check that the shipping box can close properly.
11. Place all accessories in the accessory box and place accessory box in the main shipping box.
12. Close and seal the shipping box with shipping tape.
13. Move the loaded shipping box to the desired location by using a dolly or cart that is suitable for moving heavy, bulky items.

Note: Be sure all accessories (power cord, IFU, etc.) are moved together with the System.

Mobile Cart

1. To transport the mobile cart, pack it in the original shipping box or in a box that is suitable for safe movement of the cart.
2. Move all shipping boxes to the desired location by using a dolly or cart that is suitable for moving heavy, bulky items.

Returning the Console or Mobile Cart for Service

Before returning the console or the mobile cart for service, contact your Varian representative or approved agent for assistance. If you are instructed to send the console or the mobile cart to Varian, be sure to obtain the Return Merchandise Authorization (RMA) number before packaging the device.

Obtain an RMA Number

1. Contact your Varian approved service center.
2. Provide the following information:
   - Hospital/Clinic Name/Customer Number
   - Your telephone number
   - Department/address, city, state, and zip code
   - Model number of the device
   - Serial number or lot number of the device
   - Description of the issue
   - Needed type of repair (if known)
3. Request a shipping container, if needed.
4. Obtain the RMA number to be used for shipping.

Ship the Console or Mobile Cart

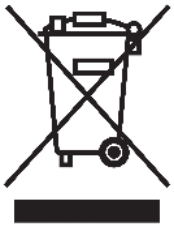
1. Clean the console or mobile cart. See *Clean the Console or Mobile Cart* on page 44.
2. Attach a tag to the console or mobile cart with all necessary information. See *Obtain an RMA Number* in the section above.
3. Pack the console or the mobile cart. See *Transporting the System Outside the Hospital Environment* on page 55.
4. Pack disposable accessories in a shipping box for safe shipping.
5. Ship, prepaid, to your Varian approved service center.

Service Centers

For a complete list of Varian approved service centers and contact information, please go to www.varian.com or see *Contact Varian Customer Support / Report Incidents* on page 2.

Safe Disposal

Disposal of Electronic Equipment



Important

Do not dispose of electrical appliances as unsorted municipal waste. Use separate collection facilities.

Electrical appliances that are incorrectly disposed of in dumps or landfills can leach dangerous substances into the ground causing contamination of soil and groundwater. This can cause environmental damage.

Contact your local government or point of sale for information regarding the waste collection of electronic appliances.

Disposal of Consumables

IntelliBlate Disposable Probe Assemblies and the Temperature Sensor Probes are single-use devices. After use, disconnect them from the console and dispose of all parts in accordance with sharps and biohazard handling procedures of your facility.

WARNING: The Ximitry Probe Assembly (XPA) and the Temperature Sensor Probe (TSP) tips are very sharp and may cause puncture damage. Handle carefully as a sharps object.

Disposal of the Console

The console contains electrical and electronic equipment that falls under the WEEE directive.

The console has been designated as Waste of Electrical and Electronic Equipment (WEEE), which means it cannot be disposed of as unsorted municipal waste at the end of its life.

WEEE contains substances that may present hazards to human health and to the environment. It must be recovered, reused, recycled, or otherwise treated, and properly disposed of.

For advice on how to dispose of the product, contact Varian Customer Support.

Troubleshooting

Software

The following table lists common problems and recommended resolutions. If any issues persist, contact Varian Customer Support.

Error and Resolution Message	Description	Suggested Resolution
Probe overheated **Improve cooling or replace probe assembly**	Indicates that the probe temperature is outside of the normal operating range. Microwave energy activation is disabled.	If this issue occurs, the microwave energy output is deactivated. The ablation procedure can be resumed as soon as the temperature returns to a normal operating range. Replace the coolant bag to expedite the process. Verify that there are no obstructions in the coolant tubing and that the spike has been fully inserted in the coolant bag. If the issue persists, replace the probe and resume.
High reflected power **Replace probe assembly to resume**	Indicates that the reflected microwave power has exceeded the allowable limit.	If this issue occurs, the microwave energy output is deactivated. Verify that there are no obstructions in the coolant tubing and that the spike has been fully inserted in the coolant bag. If the issue persists, replace the probe and resume.
Coolant is too hot **Replace coolant with room temperature coolant then resume**	Indicates that the coolant temperature is too hot.	If this issue occurs, the microwave energy output is deactivated. The ablation procedure can be resumed as soon as the temperature returns to a normal operating range. Replace the coolant bag to expedite the process. Verify that there are no obstructions in the coolant tubing and that the spike has been fully inserted in the coolant bag. If the issue persists, replace the probe and resume.

Probe assembly disconnected **Reconnect the probe assembly**	Indicates that the Ximitry Probe Assembly has been disconnected from the console.	If this issue occurs, the microwave energy output is deactivated. Verify that the probe connector has been fully inserted into the console receptacle. If the issue persists, replace the probe and resume.
Defective probe assembly **Replace probe assembly to resume**	Indicates that the connected Ximitry Probe Assembly potentially has an error condition that renders it unusable.	Verify that the probe connector has been fully inserted into the console receptacle. Verify that there are no obstructions in the coolant tubing and that the spike has been fully inserted in the coolant bag. If the issue persists, replace the probe and resume.
Generator overheated **Check console ventilation then resume**	Indicates that the internal generator of the console has overheated.	If this issue occurs, the microwave energy output is deactivated. The ablation procedure can be resumed once the temperature returns to a normal operating range. Verify that the console ventilation inlet and outlet allow unobstructed airflow.
Probe is not heating **Replace probe assembly to resume**	After 3 minutes of emitting energy the probe temperature has not risen. Indicates either a problem with the safety temperature measurement or the RF capabilities of the probe.	If this issue occurs, the microwave energy output is deactivated.
Probe test failed **Replace probe assembly to resume**	This indicates a problem with the probe connector.	This error might happen either during the “out of box” test during disposable setup, or at the beginning of the activation of microwave energy output. Verify that the connector is firmly seated and try again. If the problem persists, replace the probe and resume.
Defective Temperature probe **Replace temperature probe to resume**	This indicates a problem with the EEPROM in a temperature probe	Unplug the temperature probe and plug it back in again. If the problem persists, replace the temperature probe.

Probe assembly has expired **Replace probe assembly to resume**	Either the probe was manufactured too long ago, or it has been too long since that probe's initial use.	This indication happens immediately after the probe is connected to the console, and indicates the probe is past its recommended lifetime. Replace the probe to continue.
Temperature Probe has expired **Replace probe assembly to resume**	Either the temperature probe was manufactured too long ago, or it has been too long since that temperature probe's initial use.	This indication happens immediately after the temperature probe is connected to the console and indicates the temperature probe is past it recommended lifetime. Replace the temperature probe to continue.
Needle Test Inconclusive **Unplug probe assembly and try again**	Indicates the results of the initial tests of the probe were inconclusive.	Several tests are performed on the probe at startup. One or more of these tests did not produce a definitive result. By unplugging the probe and plugging it back in again the tests will be reperformed and a definitive result should be achieved. If this error persists, replace the probe.

Hardware

The following table lists common problems and recommended resolutions. If any issues persist, contact Varian Customer Support.

Problem	Recommendation
Console will not power on	• Check that the power cord has been fully plugged into the rear panel of the console. • Check that the power cord has been fully plugged into a hospital-grade outlet. • Check that the fuse is in the power receptacle on the rear panel of the console. If the fuse is blown, replace it with a 250V fuse. (See Replacing the Fuses on page 40)
Ximitry Probe Assembly is leaking	• Check that the coolant fluid spike has been fully inserted into the coolant fluid bag. • Check for leaks along the Ximitry Probe Assembly. If leaks are found elsewhere along the assembly, replace the assembly.
Ximitry Probe Assembly has visible air gaps along the fluid line	• Check that the coolant fluid spike has been fully inserted into coolant fluid bag. • Check for kinks along the visible fluid lines on the DPA and remove kinks as necessary. • If visible air gaps are still present, replace the assembly.
Ximitry Probe Assembly is not recognized by the console	• Check that the connector has been fully seated into the front panel of the console. • Unplug and reinsert the connector. • If the issue persists, check if the Ximitry Probe Assembly can be set up on the other console channel. • If the issue persists, replace the assembly.
Ximitry Probe Assembly fails pre-test	• Confirm the fluid spike is properly connected to the coolant fluid bag. • Confirm the coolant tubing is free of obstruction. • Repeat the pre-test. Make sure the probe tip is in sterile coolant. • If the pre-test is still unsuccessful, replace the Ximitry Probe Assembly with a new unit.

Temperature Sensor Probe is not recognized by the console	• Check that the connector has been fully seated into the front panel of the console. • Unplug and reinsert the connector. • If the issue persists, check if the Temperature Sensor Probe can be set up on the other console channel. • If the issue persists, replace the probe.
Coolant fluid mount cannot attach to the console	• Ensure that the coolant fluid mount has been fully pressed into the console before threading the thumbscrew. • Check that the coolant fluid mount has been inserted straight into the console. • Do not use tools as they may damage the thumbscrew and break the coolant fluid mount
Console cannot attach to the mobile cart	• Check that the console is properly aligned within the indentations on the top surface of the mobile cart. • Check that the thumbscrew has been correctly threaded into the console. If not, unscrew and rethread the thumbscrew. • If the issue persists, carefully remove the console from the mobile cart and look for damaged threading on the thumbscrew and the console.
Brakes will not engage or disengage on the mobile cart	• Toggle the brake to its disengaged position (up) and attempt to re-engage the brake (down). • Inspect the brakes for any debris blocking them from engaging or disengaging.
Wheels fail to spin or rotate on the mobile cart	• Ensure brakes are not engaged. • If the issue persists, inspect the wheels for any debris blocking them from spinning and remove if present.

Warranty

Varian Medical Systems, Inc. (Varian) warrants each IntelliBlate Microwave Ablation System to be free from defects in material and workmanship under normal use and service periods as indicated in the table below. Repair and/or replacement will be made according to the warranties listed below. Varian incurs no responsibility for service performed by non-Varian personnel or its authorized agents. Repairs and alterations to the IntelliBlate Microwave Ablation System made by any individual other than Varian certified service personnel will void all warranties of the system.

Part	Warranty
IntelliBlate Microwave Ablation System Console	One year parts and service or replacement of the console at the sole discretion of Varian. Refurbished parts may be substituted to ensure rapid repair.
IntelliBlate Microwave Ablation System Mobile Cart	One year parts and service or replacement of the mobile cart at the sole discretion of Varian. Refurbished parts may be substituted to ensure rapid repair.
IntelliBlate Ximitry Probe Assembly	Until expiration. Expiration date is displayed on the Shelf Carton Label and on the procedure tray label.
Temperature Sensor Probe	Until expiration. Expiration date is displayed on the Shelf Carton Label and on the pouch label.

This warranty is in lieu of all other warranties, express or implied, including without limitation, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of Varian Medical Systems, Inc. neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any products used with the Varian Microwave Ablation System.

Varian Medical Systems, Inc. reserves the right to make changes to the equipment built and sold by them at any time without incurring any obligation to make the same or similar changes on equipment previously built or sold by them. These changes are also applicable to the software system of the Varian Microwave Ablation System which may be revised and updated at any time.

Appendix

Symbol Glossary

See the separate document, P1065783-001, *Microwave Ablation System Symbol Definition Sheet*.

Electromagnetic Compatibility

The IntelliBlate Microwave Ablation System has been tested and found to comply with the limits for medical devices in IEC 60601-1-2 (Edition 4.1): 2014+AMD1:2020. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

It is important to install and use the IntelliBlate Microwave Ablation System in accordance with the instructions, to prevent harmful interference to other devices in the vicinity. See **Table 13.4.2.1** and **Table 13.4.3.1** below.

If the IntelliBlate Microwave Ablation System does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Re-orient or relocate the other device(s).
- Increase the separation between the IntelliBlate Microwave Ablation System and other devices.
- Connect the IntelliBlate console into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the Varian field service representative for help.

CAUTION: Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the IntelliBlate Microwave Ablation System.

CAUTION: Medical electrical equipment requires special precautions regarding EMC and must be installed and operated (put into service) according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources could result in performance disruption of the system. Evidence of disruption may include image degradation or distortion, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site of disruption, and perform recommended actions to eliminate the source(s).

Declaration of Emissions

IntelliBlate Microwave Ablation System is suitable for use in the following environment. The user must assure that it is used only in the electromagnetic environment as specified.

Table 13.4.2.1

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The IntelliBlate Microwave Ablation System is intended for use in the electromagnetic environment specified below. The customer or the user of the IntelliBlate Microwave Ablation System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 2	The IntelliBlate Microwave Ablation System uses radio-frequency energy in the form of electromagnetic radiation or transfer of electromagnetic energy as microwave therapy equipment.
RF emissions CISPR 11	Class A	The IntelliBlate Microwave Ablation System is suitable for use in all establishments other than domestic 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 IEC 61000-3-3	Complies	

CAUTION: The IntelliBlate Microwave Ablation System should not be used adjacent to or stacked with other equipment. The IntelliBlate Microwave Ablation System Monitor should be observed to verify normal operation in the configuration in which it will be used. Care must be taken when operating the IntelliBlate Microwave Ablation System around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or to the other equipment.

Declaration of Immunity

IntelliBlate Microwave Ablation System is suitable for use in the following environment. The user must assure that it is used only in the electromagnetic environment listed.

Table 13.4.3.1

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The IntelliBlate Microwave Ablation System is intended for use in the electromagnetic environment specified below. The customer or the user of the IntelliBlate Microwave Ablation System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV & ±8 kV for Contact Discharge ±2 kV, ±4 kV, ±8 kV and ±15 kV for Air Discharge	±2 kV, ±4 kV & ±8 kV for Contact Discharge ±2 kV, ±4 kV, ±8 kV and ±15 kV for Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	AC Mains Line to Ground ±0.5 kV, ±1 kV and ±2 kV AC Mains Line to Line ±0.5 kV and ±1 kV	AC Mains Line to Ground ±0.5 kV, ±1 kV and ±2 kV AC Mains Line to Line ±0.5 kV and ±1 kV	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% U_T (100% dip in U_T) for 0.5 cycles 0% U_T (100% dip in UT) for 1 cycle 70% U_T (30% dip in UT) for 25/ 30 cycles <5% U_T (100% dip in U_T) for 250/ 300 cycles	<5% UT (100% dip in UT) for 0.5 cycles 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (100% dip in UT) for 250/ 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the IntelliBlate Microwave Ablation System requires continued operation during power mains interruptions, it is recommended that the IntelliBlate Microwave Ablation System be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity Magnetic Fields Immunity Test IEC/EN 61000-4-39	134.2 kHz (Pulse Modulation[a] 2.1 kHz) 13.56 MHz (Pulse Modulation[a] 50 kHz) .	65 A/m [b] 7.5 A/m [b]	This system maintains immunity to magnetic field strengths of a typical hospital environment where RFID readers could be present. Magnetic fields should be at levels characteristic of a typical hospital environment.

NOTE: U_T is the AC Mains voltage prior to application of the test level.

[a] Carrier modulated using 50% duty cycle square wave.

[b] RMS before modulation is applied.

Table 13.4.3.2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The IntelliBlate Microwave Ablation System is intended for use in the electromagnetic environment specified below. The customer or the user of the IntelliBlate Microwave Ablation System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	AC Mains 3 V with 6 V ISM 80% AM at 1 kHz 150 kHz – 80 MHz	AC Mains 3 V with 6 V ISM 80% AM at 1 kHz 150 kHz – 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 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 fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Radiated RF IEC 61000-4-3	3 V/m, 80% AM at 1 kHz 80 MHz – 2700 MHz Test levels for proximity fields from wireless communication equipment are in table 13.4.3.3 below	(E1) = 3 V/m Compliance levels for proximity fields from wireless communication equipment are in table 13.4.3.3 below.	
NOTE: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE:** 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 IntelliBlate Microwave Ablation System is used exceeds the applicable RF compliance level above, the IntelliBlate Microwave Ablation System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the IntelliBlate Microwave Ablation System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 13.4.3.3

Guidance and Manufacturer's Declaration – Proximity Fields for Wireless Communication Equipment						
Test Frequency MHz	**Band [a] MHz**	**Service [a]**	**Modulation**	**Maximum Power W**	**Distance Meters**	**Immunity Test Level (V/m)**
385	380 to 390	TETRA 400	Pulse Modulation [b] 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 469, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse Modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation [b] 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse Modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50% duty cycle square wave signal.

[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst case.

Table 13.4.3.4

Guidance and Manufacturer's Declaration – Guidance for Separation Distances			
Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and the IntelliBlate Microwave Ablation System			
The IntelliBlate Microwave Ablation System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IntelliBlate Microwave Ablation System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IntelliBlate Microwave Ablation System as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 kHz to 80 MHz $d = \left(\frac{3.5}{V_1}\right)\sqrt{P}$	**80 MHz to 800 MHz** $d = \left(\frac{3.5}{E_1}\right)\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left(\frac{7}{E_1}\right)\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

The IntelliBlate Microwave Ablation System is designed to be used in clinical environments including hospital or clinics. The IntelliBlate Microwave Ablation System is not designed to be used near active High Frequency (HF) surgical equipment or in proximity to magnetic resonance (MR) imaging systems, where the intensity of EM disturbances may be high.

Note: The emissions characteristics of the IntelliBlate Microwave Ablation System make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) the IntelliBlate Microwave Ablation System might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the IntelliBlate Microwave Ablation System.

Common Electromagnetic Emitter (Wi-Fi)

This system has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the system is operated in a commercial environment.
This system generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with the applicable user manual, it might cause harmful interference to radio communications.

The system includes an IEEE 802.11 RF transmitter that operates on the following frequencies with a maximum radiated power of 100mW:

802.11a: 5GHz band, up to 54Mbps
802.11b: 2.4 GHz band, up to 11 Mbps
802.11g: 2.4 GHz band, up to 54Mbps
802.11n: 5 GHz or 2.4 GHz band, up to 300Mbps
And on the following frequencies with a maximum radiated power of 1000mW:
802.11ac: 5 GHz band, up to 866.7Mbps

The RF transmitter registration numbers are identified below:

USA (FCC) - FCC Identifier: UAY-W8997-M1216
EEA (CE): No public identifier (self-declaration)
Canada (IC) - Hardware Version Identification Number: W8997-M1216
Japan (TELEC) - Certified number: 020-170034
India (WPC) - Registration number: ETA-SD-20191005525

Note: “Harmful interference” is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

The authority to operate this system is conditioned by the requirement that no modifications are made to the system unless the changes or modifications are expressly approved by Varian.

END OF DOCUMENT