M3T
Safety and performance information

Revision 1

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This manual includes all operating instructions for the M3T system.

℞ Only Caution: federal U.S. Law restricts this device to sale by or on the order of a physician.

Table of Contents

1. Introduction

1.1. About The M3T system

The M3T System is a mini-hysteroscope to evaluate the uterine endometrium condition. The endometrium is the the mucous membrane lining the uterus. The endometrium changes throughout the female periodic cycle and the uterine various conditions.

The M3T system includes a disposable mini-camera and illumination means, located at the distal end of a flexible shaft and perpendicular to its long axis (the “Device”). The camera and illumination elements are surrounded by a transparent mini-balloon that inflates and deflates by air flow coming through the shaft’s lumen.

The thin "device", less than 4mm in diameter, is introduced by the physicians into the uterus without anesthesia or sedation.

The proximal end of the Device engages (and disengages) to a multi-use Handle assembly that controls the basic operation and image capture capabilities, using an Image Process Unit – IPU. The Handle also controls the pressured air supply to the mini-balloon, using a dedicated syringe and a valve (“one-way stopcock”).

The Handle assembly is connected to a medical grade workstation and screen. The workstation runs Fertigo’s dedicated user interface software to display and analyze the captured images and store them in a database.

The M3T system is intended to be used as a viewing and image capture tool for the physician.

2. System Components

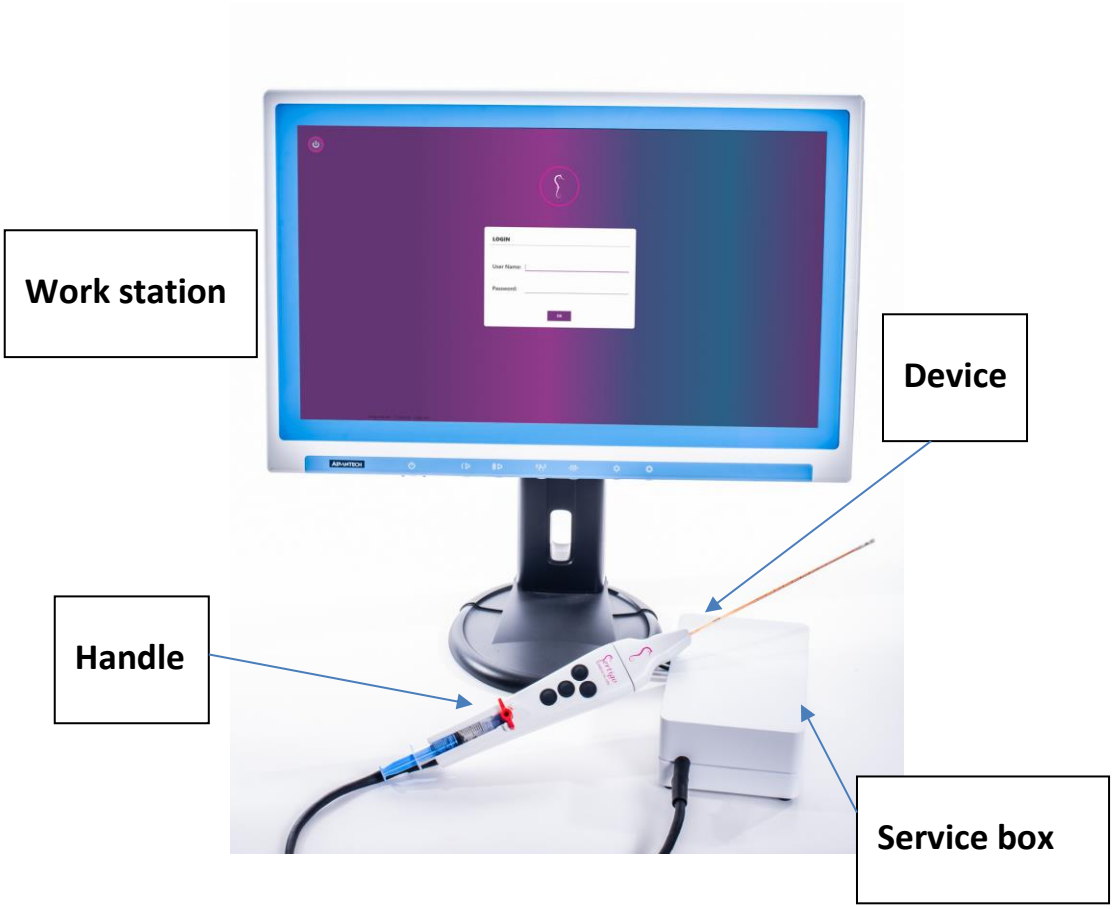
System Description

The M3T system is intended to be used as a mini-hysteroscope to view the structure and morphology of the endometrium tissue.

What Are the Parts of the M3T?

The following table provides the description for the elements of the M3T system.

Part name	Description	Picture
M3T Device	A sterilized, single-use, disposable shaft that encloses a mini-camera and illumination within its inner side. The camera and illumination section of the shaft is surrounded by an inflatable balloon.	
M3T Handle assembly	The handheld **Handle** is a multi-use component that connects to the Device. Through an additional box it connects to the workstation.	
The Workstation - Medical Grade PC	The Medical grade Workstation runs all the user interface and database operations. It optionally includes a medical grade keyboard and mouse.	


Work station
Device
Handle
Service box

3. System Indications

Intended Use

The M3T System is a single-use video hysteroscope for transient use (< 60 minutes), with a disposable mini-camera and illumination means with a distal end, to enable device insertion. It is intended to be used in a clinical setting by physicians with adequate training in hysteroscopy, to visualize and evaluate the endometrium conditions and evolution thereof of adult women who suffer from specific gynecological issues, or who require diagnostic evaluation or treatment of conditions related to the endometrium. Its ability to provide a magnified, real-time view of the endometrium.

Indications for Use

Generally recognized indications for diagnostic hysteroscopy include:

- Endometrium evaluation
- Abnormal bleeding
- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain

3.1. Contraindications

- Acute Pelvic Inflammatory Disease

Hysteroscopy may be contraindicated by the following conditions depending on their severity or extent:

- Inability to distend the uterus
- Cervical stenosis
- Cervical/Vaginal infection
- Uterine bleeding or menses
- Known pregnancy
- Invasive carcinoma of the cervix
- Recent uterine perforation
- Medical contraindication or intolerance to anesthesia

3.2. Precautions

Currently, there are no known precautions for this product

3.3. USER QUALIFICATION – PLEASE READ PRIOR TO USE

- M3T system should only be used by physicians with adequate training in hysteroscopy.

- All external components connected to the M3T system (such as video converters, video splitters, etc.) should be properly certified for use according to local regulations ahead of use.
- Mini-Hysteroscopy System, model M3T is intended for use in professional healthcare facility environment (such as Physician offices, clinics, limited care facilities, freestanding surgical centers, freestanding birthing centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care, surgery rooms except near HF SURGICAL EQUIPMENT, outside the RF shielded room of an ME SYSTEM for magnetic resonance imaging))

4) WARNINGS AND CAUTIONS

- Follow the warnings and cautions given below when handling the M3T system. This information is to be supplemented by the warnings and cautions provided in each chapter.

Warning

- Following use of the system, clean, (or disinfect if necessary) and store the Handle according to the instructions found in the companion "M3T system: Handle cleaning and disinfection instructions". Using M3T Handles that have either been improperly or incompletely cleaned, disinfected or stored may cause cross-contamination or infection.
  Dispose the Device element, treating it as a bio-hazard material.
- Do not hit or drop the M3T Handle or Device. Also, do not bend, pull, or twist the Device's insertion section with excessive force.
- Never withdraw the M3T Device abruptly or with excessive force. Operator injury, cross-contamination or infection may result. Always make sure the device balloon is deflated before you withdraw the Device.
- If it is difficult to insert the M3T Device through natural orifice, do not forcibly insert it; Forcible insertion can injure the patient and damage the Device.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 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 Mini Hysteroscopy System, model M3T, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Mini-Hysteroscopy System, model M3T needs special precautions regarding EMC and needs to be installed and put into service according to the specific instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life provided in Section 10 of this manual.

- No defibrillation protection: The M3T is not defibrillator protected. The Device must be removed from the patient before a defibrillator procedure.
- User provided ancillary equipment and/or accessories are not validated or warranted by Fertigo Medical ltd. The use of such user provided items is the sole responsibility of the party using such items.
- Any serious incident involving the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

Caution

- Do not hit or impact the distal end of the M3T Device, as it contains a delicate camera. Damaged probes should be immediately decommissioned.
- If the quality of the Fertigo Medical system deteriorates during the procedure, tissue or debris might have adhered to the M3T Device distal end. Try extracting the Device and cleaning the tip using the standard procedure for hysteroscopes in the clinic and then re-introduce it.

Electrical safety

- To minimize the potential for electrical shock, the power cable of the Workstation must be plugged into an approved grounded electrical outlet. Do not use an adapter to plug the system into an ungrounded outlet.
- Do not operate the M3T with any damaged element.
- Do not attempt to disassemble any component of the M3T system. Any such attempt would render the warranty void. Only qualified personnel are authorized to maintain and service the system.

Be sure to install the M3T system equipment in the recommended combination for optimal use. If combinations other than those shown throughout this and other M3T manuals are used, optimal operation cannot be assured.

Warning

- Do not place a power strip on the floor.
- Do not connect an additional power strip to the system.
- Do not connect items which are not specified as part of the M3T system. Using incompatible equipment can result in patient or operator injury and/or equipment damage.

CLASSIFICATION:

1) Class I ME EQUIPMENT internal powered.

2) No applied part.

3) Continuous Operation.

4) Not AP or APG category.

Caution

- *The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include: 1.) Use of the accessory in the patient vicinity, and 2.) Evidence that the safety certification of the accessory has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-2 harmonized national standard.*

Electric Interference Safety

This equipment generates and can radiate radio frequency (RF) energy. The equipment may cause RF interference to other medical and non-medical devices as well as to radio communications. To provide reasonable protection against such interference, the system complies with the iec 60601-1-2 standard. If the device is suspected of interfering with other nearby electrical equipment, power down the device to see if the interference is eliminated.

Use of improperly shielded and grounded cables may result in the equipment causing RF interference in violation of local regulations. The manufacturer is not responsible for any interference caused by using cables other than those recommended or by unauthorized changes or modifications to this equipment.

Do not use devices that intentionally transmit RF signals (cellular phones, transceivers, or radio-controlled products) in the vicinity of this equipment as it may cause performance outside the published specifications. Keep the power of these types of devices turned off when located near this equipment. The medical staff in charge of this equipment is required to instruct technicians and other persons who may be around this equipment to fully comply with the above requirement.

Fire and Explosion Safety

- To avoid electric shocks and burns potentially caused by application of the wrong type of fire extinguisher, ensure that the fire extinguisher at the site has been approved for use on electrically induced fires.
- Do not operate the equipment in the presence of flammable or explosive liquids, vapors or gases such as flammable anesthetic, oxygen or nitrous oxide. Do not plug in or turn on the system if hazardous substances are detected in the environment. If flammable substances are detected after the system has been turned on, do not attempt to turn off the system or unplug it. Evacuate and ventilate the area before turning the system off.

Operation Environment

- Do not place any object on top of the M3T hardware. These objects may cause damage to equipment.
- Avoid exposing the system to direct sunlight or other heat sources.

Reprocessing

- The M3T Handle is a multi-use element. Cleaning it or disinfecting should be performed after each use (session). Validated procedures for these processes are provided in the companion "**M3T system: Handle cleaning and disinfection Instructions**".
- The M3T Handle was not disinfected before shipment. Before first time use, disinfect the device according to the instruction provided in the companion "**M3T system: Handle cleaning and disinfection Instructions**".

- After use, clean, disinfect and store according to the "**M3T system: Handle cleaning and disinfection Instructions**".
  Improper and/or incomplete process or storage can create an infection control risk, cause equipment damage, or reduce performance.

4. Maintenance and Troubleshooting

4.1. Maintenance

4.1.1 M3T WORK STATION

Work Station components are off-the-shelf items, maintenance is based on references to the manufacturer instructions. Do not open and reassemble any of the components in the field.
Work Station Maintenance: properly maintain and clean the surfaces, use only the approved products or clean with a dry applicator.

4.1.2 M3T HANDLE

The M3T Handle is a multi-use element. Cleaning it or disinfecting should be performed after each use (session). Validated procedures for these processes are provided in the companion "M3T system: Handle cleaning and disinfection Instructions".

(b) Trouble shooting

Symptom	Cause	Fix
The handle is connected but its signal light next to its icon appears red or blinks red.	USB not securely plugged in	Make sure the USB connector from the service box is plugged into one of the workstation USB ports and well secured.
	USB port is ill-defined	Connect the USB to the previously working port OR re-define the connected USB port by re-configuration of the Fertigo software. This should be done by a certified technician

Symptom	Cause	Fix
The handle is connected and a grin signal appears next to its icon, however red signal appears next to the Device icon or blink red.	Device is not well connected to the handle	Detach and reconnect the device to the handle, make sure it went all the way without leaving a gap between the Device and the Handle shells.
	Damaged electric connector at the Device's end	Replace the Device
	Damaged electric connector at the Handle's end	Verify both charger LEDs are orange and green after 8 hours.
The balloon won't inflate	The handle is not well connected to the Device	Disconnect the Handle, pull out the syringe's piston. Reconnect the Device, assuring the air-nozzles are well matched. Attempt to inflate the balloon.
	The balloon is punctured	Immerse the balloon within sterile saline and attempt to inflate it using the syringe. If bubbles come out of the balloon, discard the Device and use another one.
	The Device air nozzle is damaged	Inspect the air nozzle on the Device's proximal end. If it is malformed, replace the Device.
	The Handle air nozzle is damaged	Inspect the air nozzle on the Handle's distal end. If it is malformed, replace the Handle.

5. Technical Specifications

5.1. Capacities

Dimension					
Element	**Sub-assembly**	**Length * (mm)**	**Width/Diameter* (mm)**	**Height* (mm)**	**Weight (gr)**
Device		294	Shaft: d<4mm		59
Device box		370	115	53	70
Handle Assembly	Handle	187	50	-	311
	Additional (service) box	120	342	60	670 (ex. cables)
Workstation		550	65 (depth)	360	6900 (exc. Leg)

[1]Rounded to the closest integer

*Maximal value

Temperature range	
Operating range	10 °C to 42 °C (14 ° F to + 108° F)
Storage range	-20°C to 70°C (-4 ° F to + 140° F)
Power input and frequencies	100 – 240 vac, 50/60 Hz
Other specifications	
Output connector	
Output cable length	1.5–2 m / 1.83 m (4 ft. 11 in. – 6 ft. 6 in / 6 ft.)
Safety	EN60950-1, EN 60601-1, EN 60335-2-29 / IEC60601-1, ES60601-1
EMC standards	EMC med. EN 60601-1-2 /Emission EN 61000-6-3/ Immunity EN 61000-6-1
Continuous Duration (Working time)	60 minutes
EXPECTED Shelf LIFE of the M3T Device	6 months
EXPECTED LIFE Time of the M3T Work Station & Handle	5 Years
Environmental	
Atmospheric pressure	700 hPa-1060hPa
Humidity	15%-90%

5.2. Electromagnetic IMMUNITY & EMISSIONS

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Mini-Hysteroscopy System, model M3T uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The Mini-Hysteroscopy System, model M3T 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/flicker emissions IEC 61000-3-3	Complies	

NOTE The EMISSIONS characteristics of this equipment 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) this equipment 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 equipment.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Immunity test	IEC 60601 level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD), IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 61000-4-4	2 kV for power supply lines 1 kV for SIP/SOP lines	2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge, IEC 61000-4-5	1 kV line to line 2 kV line to earth	1 kV line to line 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips and interruptions on power supply input lines IEC 61000-4-11	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency 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.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

* In the case of the Electrical Fast Transients (EFT) testing with reference to the specified standards IEC 60601-1-1-2 Tables 4 & 9 and ETSI EN 301 489-1 Section 9.4, it's notable that the EFT testing successfully passed all the prescribed limits mandated by the standard requirements. However, an interesting observation was made during the EFT testing at -2kVolt, which is beyond the standard's requirements.

During this exceptionally high EFT testing at -2kVolt, the system did encounter a temporary failure but intriguingly revived to the same operational state after initiation.

While the system showed a momentary failure under extreme conditions, it is crucial to highlight that this failure was temporary and did not cause any permanent damage or degradation to the essential performance limits as specified by the standards.

In summary, the rationale for not meeting the standard requirement under the extreme EFT testing condition of -2kVolt can be attributed to the system's temporary failure, which was effectively mitigated by the system's recovery, ensuring the continued adherence to essential performance limits post-testing.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY FOR PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT, IEC 60601-1-2 ED.4.1

Immunity test	IEC 60601 level	Compliance level
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz)	[*V*] = 3 Vrms [*V*] = 6 Vrms
IEC 61000-4-3 Radiated RF	3 V/m 80 MHz to 2.7 GHz	[*E*] = 3 V/m
Proximity fields from RF wireless communications equipment	385 MHz	27 V/m
	450 MHz	28 V/m
	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	
	1720 MHz	28 V/m
	1845 MHz	
	1970 MHz	
	2450 MHz	28 V/m
	5240 MHz	9 V/m
	5500 MHz	
	5785 MHz	
IEC 61000-4-39 Immunity to magnetic fields in close proximity	65 A/m 134.2 kHz 7.5 A/m 13.56 MHz	65 A/m 134.2 kHz 7.5 A/m 13.56 MHz

6. Regulations

6.1. USA Regulation

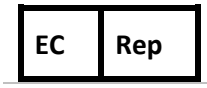
Federal U.S. Law restricts this device to sale by or on the order of a physician.
The System is NOT cleared by the FDA.

6.2. CE Conformity

	EC REP
Fertigo Medical Ltd. 9 Hameginim St.. Zichron Yaakov 3905303, Israel Email: info@Fertigo-medical.com	AR Experts B.V. Address: Amerlandseweg, 7, Breukelen, Netherlands
	CE 2797

The System is NOT cleared by the EU.

Summary of Instrument Symbols

Symbol	Description
	Consult Instructions for Use
	Attention, See Instructions
	Manufactured By
	CE Mark (class IIa)
	European Representative
	Federal US law restricts this device for sale by or on the order of a physician.
	Indicates a medical device that has been sterilized using ethylene oxide

Symbol	Description
Note:	The IFU contains limited information and should be used only as a quick reference. Be sure to refer to the complete User Reference Manual for all additional information.