Genesys HTA®

Endometrial Ablation System

USER'S MANUAL

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℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician. The physician using the system must be trained in diagnostic hysteroscopy.

1 INTRODUCTION

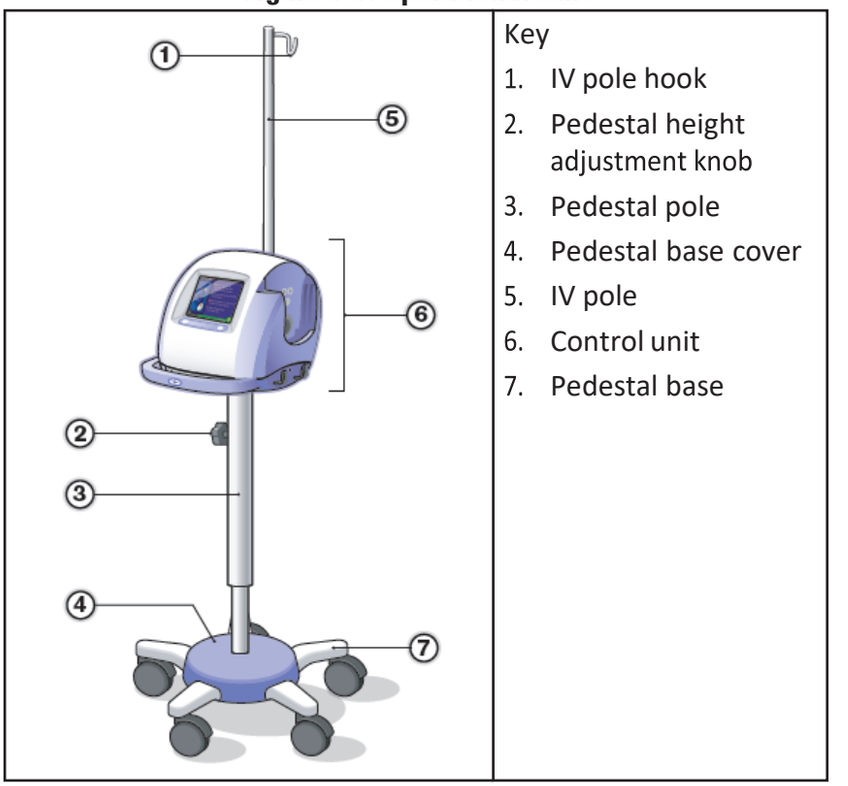
The Genesys HTA® System is a software-controlled hysteroscopic thermal endometrial ablation device that consists of an operational unit (control unit, pedestal and IV pole) and a sterile procedure set. Additionally, an HTA hysteroscope adapter (scope adapter) will be needed.

Figure 1-1 shows the operational unit (Catalog - 58000 series), which is available in 115 VAC and 230 VAC models. The Genesys HTA ProCerva® Procedure Set is disposable and consists of a procedure sheath, a cassette, and a drainage bag. The Genesys HTA ProCerva Procedure Sets are packaged in a box of five.

Additional components and accessories required for use with the Genesys HTA System include: 3 liters (L) 0.9% normal saline bags, a standard ≤ 3 mm diameter hysteroscope, a cervical sealing tenaculum, and a vaginal speculum. Refer to Section 4.4.1, *Components and Accessories*, for a complete list of components and accessories for use with the Genesys HTA System.

The Genesys HTA System is designed to ablate the endometrial lining of the uterus by heating saline to a temperature of 90°C through a heating element located in the disposable cassette. The heated fluid is re-circulated through the uterine cavity for a period of 10 minutes. Sensors in the Genesys HTA System monitor the safe and effective delivery of the treatment therapy.

Figure 1-1: Operational Unit



Key

1. IV pole hook
2. Pedestal height adjustment knob
3. Pedestal pole
4. Pedestal base cover
5. IV pole
6. Control unit
7. Pedestal base

Prior to using the Genesys HTA System, carefully read this entire User's Manual to become familiar with the Genesys HTA System's features and controls. This manual contains information about the proper procedures for inspecting, preparing, and operating the Genesys HTA System.

Failure to thoroughly understand and follow these instructions may result in serious injury to the patient and/or the user; and/or may result in damage to, or malfunction of, this equipment. Follow all instructions, cautions, and warnings provided with all products and equipment to be used in conjunction with the Genesys HTA System to avoid any possible hazard from equipment incompatibility.

Contact Minerva Surgical with any questions about the information contained in this manual or for additional information on the operation and safety of the Genesys HTA System. On-site training is available upon request.

2 BACKGROUND AND CLINICAL INFORMATION

2.1 Intended Use / Indications for Use

The Genesys HTA® System is a hysteroscopic thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.

2.2 Contraindications

The system is contraindicated for use in a patient:

- who is pregnant or wants to be pregnant in the future, as pregnancy after ablation can be dangerous to both mother and fetus;
- who has known or suspected endometrial carcinoma or premalignant change of the endometrium, such as adenomatous hyperplasia;
- who has active pelvic inflammatory disease or pyosalpinx;
- who has hydrosalpinx;
- in whom a tight cervical seal cannot be established and maintained around the procedure sheath;
- who has any anatomical condition (e.g., history of previous classical cesarean section or transmural myomectomy) or pathologic condition (e.g., long term medical therapy) that could lead to weakening of the myometrium;
- who has an intrauterine device in place; or
- who has an active genital or urinary tract infection (e.g., cervicitis, endometritis, vaginitis, cystitis, etc.), at the time of treatment.

2.3 Warnings and Cautions

To ensure that the user is aware of all potential hazards and risks associated with the Genesys HTA System, carefully read all general warnings, technical warnings and cautions listed below.

Leakage of heated fluid can cause serious burn or injury to the tissue contacted, including tissue in or around the cervix, vagina, perineum, etc. failure to follow instructions or to heed any WARNINGS or CAUTIONS could result in serious patient or user injury.

2.3.1 General Warnings

- Although endometrial ablation with the Genesys HTA System significantly decreases the likelihood of pregnancy, it is not a sterilization procedure. The patient should be advised of appropriate birth control methods.
- Endometrial ablation does not eliminate the potential for endometrial hyperplasia or adenocarcinoma of the endometrium and may mask the physician's ability to detect or make a diagnosis of such pathology.
- Patients who undergo endometrial ablation procedures who have previously undergone tubal ligation may be at increased risk of developing post ablation tubal sterilization syndrome which can require hysterectomy. This can occur as late as 10 years post-procedure.
- DO NOT perform same day HTA procedure and hysteroscopic tubal occlusion/sterilization. Ablation may cause intrauterine synechiae which can compromise (i.e. prevent) the 3-month confirmation test (HSG) for the tubal occlusion device. Women who have inadequate 3-month confirmation tests cannot rely on the tubal occlusion device for contraception.
- Bench and clinical studies have been conducted which demonstrate that the HTA procedure can be safely and effectively performed with nickel titanium tubal micro-inserts in place. However, the HTA procedure should only be performed after the 3-month tubal occlusion confirmation test.

2.3.2 Technical Warnings

- The Genesys HTA ProCerva® Procedure Set is provided sterile and is intended for single use only. Do not attempt to resterilize or reuse any component of the procedure set.
- Scope adapters should be reprocessed in accordance with the validated cleaning and sterilization procedure provided in section 4.4.3, *Procedure Sheath Accessories - Sterilization and Assembly*. Do not reuse any scope adapter that has not been cleaned and sterilized accordingly.
- Do not use excessive force when attaching the procedure sheath to the scope adapter as such force may damage device components. Thermal injuries to patients have been reported in association with cracked or damaged procedure sheaths/adapters.
- Care must be taken with advancement and movement of the procedure sheath to avoid uterine perforation.
- The physician must maintain control of the procedure sheath (i.e., not hand off to another individual) for the duration of the treatment to avoid compromising the cervical seal. A compromise of the cervical seal could result in fluid leakage through the cervix, which could result in thermal injury to surrounding tissue.
- Once heating has begun maintain a stable sheath position and do not remove the procedure sheath until the post-treatment cooling cycle has been completed as confirmed by the display screen, as heated fluid may cause thermal injury to the patient. (Refer to Section 5.7, *Patient and System Cooling*.)
- If system cooling is not possible (i.e., power loss), do not remove the procedure sheath from the patient until fluid in the uterus has cooled. It may take up to 10 minutes to ensure that fluid temperature in the uterus is below 45°C. Exercise care when handling the procedure set, because the fluid may still be hot.
- Excessive menstrual clotting at the time of treatment may cause the Genesys HTA ProCerva Procedure Set to become clogged. This condition may trigger an alert. If the condition cannot be resolved, the procedure should be discontinued. To avoid clogging the fluid lines with blood clots, the procedure should not be scheduled during menses. Also, consideration should be given to pretreatment with drugs such as GnRH agonists prior to performing the endometrial ablation to help induce a hypoestrogenic state.
- Do not place the procedure sheath tubing over the patient's leg or in contact with any part of the user's or patient's anatomy, as the tubing carries hot fluid and contact could result in thermal injury. The temperature of the tubing could be up to 55°C.
- Ensure that the temperature of the fluid in the cassette is below 45°C prior to disconnection of the Genesys HTA ProCerva Procedure Set.
- Do not look directly into the control unit's laser aiming beam. Light from the LED may cause retinal damage.
- Do not over-dilate the cervix.

2.3.3 Cautions

- Endometrial ablation procedures using the Genesys HTA® System should be performed only by physicians trained in diagnostic hysteroscopy procedures. Follow all Genesys HTA System instructions to reduce the possibility of compromised safety, malfunction, and/or injury to the patient and/or the user.
- To avoid the risk of electric shock, ensure that the selected electrical supply outlet has a proper ground connection and complies with the information listed on the label located on the rear of the control unit.
- To reduce the risk of explosion, do not operate the Genesys HTA System in the presence of flammable anesthetics or a flammable gas mixture with air, oxygen, or nitrous oxide.
- Never use the Genesys HTA System with equipment that has not been safety tested for excessive leakage current.

- Exercise care when handling liquids around electrical equipment. Do not attempt to operate the Genesys HTA® System if liquid has spilled onto the unit.
- The Genesys HTA System must be used only with the procedure sheath provided in the Genesys HTA ProCerva® Procedure Set. Use of any other hysteroscopic procedure sheath sets will lead to compromised safety for the patient and user.
- Do not hang more than three liters of saline from the hook on the IV pole.
- Confirm that the vaginal speculum is an adequate size (width and length) to assure full separation of vaginal and vulvar tissue away from the procedure sheath, to avoid inadvertent thermal injury, and to provide visibility of the cervix. The temperature of the sheath at this location could be up to 65°C.
- Do not rest the procedure sheath on the vaginal speculum during the procedure.
- Leave the vaginal speculum in place throughout the procedure.
- Confirm that the height of the control unit handle is properly adjusted to the height of the patient's uterus to allow proper fluid flow and pressure, during the procedure. The laser aiming beam can be used as a secondary means to assist with proper height adjustment.
- Ensure that the height of the control unit handle is no higher than the height of the patient's uterus or fluid leakage into the peritoneal cavity and vagina may occur during the procedure.
- Do not grasp the procedure sheath with the tenaculum as doing so may damage the procedure sheath which could result in thermal injury.
- Throughout the procedure, carefully observe the junction of the procedure sheath with the external cervical os to confirm a tight cervical seal and that there is no fluid leakage.
- Be Aware: The fluid loss alarm signals a loss of at least 10mL of fluid. Fluid losses in excess of 10 mL may occur in cases when the alarm is triggered.
- Use caution when handling the fluid in the drainage bag after treatment, as the fluid at this stage may still be hot.
- Follow hospital procedures for handling contaminated fluids and disposables.
- Do not attempt to repair or alter any components/parts of the Genesys HTA System. All repairs and servicing are to be performed only by authorized Minerva Surgical service personnel. See Section 8, *Service and Warranty*.
- Patients who have undergone endometrial ablation, who are later placed on hormone replacement therapy, should have a progestin included in their regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen
  replacement therapy irrespective of whether total amenorrhea has been achieved after ablation.
- Use caution when performing the Genesys HTA System procedure on patients with nickel sensitivity, as the Genesys HTA ProCerva Procedure Set contains nickel.

The safety and effectiveness of the Genesys HTA System has not been evaluated in patients:

- with a large uterine cavity (> 10.5 cm);
- with a small uterine cavity (< 6.0 cm);
- with submucous myomas and/or polyps;
- with intramural fibroids > 4 cm, as documented on ultrasonogram, thought to be contributing to menorrhagia, such as those which distort the uterine cavity;
- with bicornuate or full septate uterus;
- undergoing repeat endometrial ablation procedures (e.g., resection, ablation); or who are post-menopausal.

2.4 Adverse Events

The first generation HTA™ System was evaluated in a randomized, prospective, multi-center clinical trial, comparing the HTA System to Rollerball (RB) as the control arm. Adverse events for both study arms were reported from the time of procedure through the 1-year follow-up study period. Results are presented in tables 2-1, 2-2, and 2-3.

Table 2-1: Adverse Events Within 24 Hours Post-Procedure

Adverse Events	HTA System Group n=184	RB Group n=85
Uterine cramping	51 (28%)	21 (25%)
Nausea	20 (11%)	4 (5%)
Vomiting	20 (11%)	2 (2%)
Abdominal pain	8 (4%)	2 (2%)
Urinary tract infection (UTI)	5 (3%)	2 (2%)
Laceration	2 (1%)	2 (2%)
Endometritis	2 (1%)	1 (1%)

Table 2-2: Adverse Events at 2 Weeks Post-Procedure

Adverse Events	HTA System Group n=184	RB Group n=85
Uterine cramping	37 (20%)	11 (13%)
Transient change in appearance of the cervical epithelium	19 (10%)	0 (0%)
Vomiting	17 (9%)	2 (2%)
Nausea	16 (9%)	4 (5%)
Abdominal pain	6 (3%)	0 (0%)
Urinary tract infection (UTI)	3 (2%)	0 (0%)
Endometritis	1 (1%)	1 (1%)
Thermal injury to extremity	1 (1%)	0 (0%)
Vaginal infection	1 (1%)	0 (0%)
Cervical laceration	1 (1%)	0 (0%)

Table 2-3: Adverse Events at 3, 6 and 12 Months Post-Procedure

Adverse Events	HTA System Group n=184	RB Group n=85
Uterine cramping	25 (14%)	8 (9%)
Vaginal infection	6 (3%)	2 (2%)
Nausea	3 (2%)	0 (0%)
Vomiting	3 (2%)	0 (0%)
Abdominal pain	2 (1%)	1 (1%)
Hematometra	1 (1%)	2 (2%)
Urinary tract infection	1 (1%)	1 (1%)

Note: This table reports individual events. Multiple events may have occurred in the same patient.

Additional information related to some of the adverse events reported during the multi-center clinical trial is provided below.

- Peri-operative uterine cramping typically lasted a few days following ablation. Use of non-steroidal anti-inflammatory drugs (NSAIDs) prior to and following treatment with the HTA System was usually sufficient to manage cramping.
- Nausea and vomiting were generally attributed to certain types of general anesthesia.
- Asymptomatic alterations in cervical tissue ranged from erythema to shallow ulcerations, and were resolved without treatment within 30 days following the ablation procedure.
- Patients with endometritis responded to a course of antibiotics.
- Hematometra was resolved with insertion of a uterine sound.
- Thermal injury to extremity involved a second-degree burn in 1 HTA™ System subject. This burn occurred following prolonged exposure of skin (lower leg) to the heated tubing of the HTA System during treatment. The subject was treated with topical antibiotics and dressing changes. The system was modified after the occurrence of this event to reduce this risk of injury.
- Other events, which occurred in no greater than 3% of subjects treated with the HTA System, included: diarrhea, fever, headaches, abdominal distension, and post-ablation tubal sterilization syndrome.

During the development of the first generation HTA System, prior to the multi-center randomized clinical study described above, a prototype was evaluated in a feasibility study, in which the following adverse events were reported:

- Fluid leakage into the vagina occurred in one subject, when the procedure sheath was withdrawn from the subject during the treatment cycle. This action caused the fluid to spill from the HTA System and onto the perineum.[1] (Refer to Section 2.3, Warnings and Cautions.)
- Fluid leakage through fallopian tubes occurred in two subjects, when the fluid reservoir was elevated to a height greater than 115 cm (45 inches) above the patient's uterus. This action increased the internal system pressure and intrauterine pressure.[2]

2.5 Other Adverse Events

As with all endometrial ablation procedures, serious injury or death can occur. The following adverse events could occur or have been reported in association with the use of the first generation HTA System:

- thermal injury to adjacent tissue, including cervix, vagina, vulva and/or perineum;
- heated saline escaping from the system into the vascular spaces;
- hemorrhage;
- perforation of uterus;
- complications with pregnancy (Note: Pregnancy following any endometrial ablation procedure is dangerous to both the mother and the fetus.);
- risks associated with hysteroscopy;
- post ablation tubal sterilization syndrome;
- infection or sepsis; and
- complications leading to serious injury or death.

[1] During the treatment cycle and during cooling when the fluid is hot, the display screen in the Genesys HTA® System cautions the user not to remove the procedure sheath.

[2] The first generation HTA System was redesigned to address fluid leakage concerns resulting from the height of the fluid reservoir. The Genesys HTA® System control unit is mounted on an adjustable-height pedestal that facilitates aligning the patient's uterus with the height of the control unit handle. A laser aiming beam from the control unit is a secondary means of ensuring proper height of the control unit

2.6 Clinical Trial Summary

Purpose: To evaluate the safety and effectiveness of the first generation HTA™ System in comparison to hysteroscopic Rollerball (RB) technique for endometrial ablation in women with menorrhagia due to benign causes for whom childbearing was complete.

Study Endpoints: The primary effectiveness endpoint was a validated pictorial menstrual blood loss diary scoring system (adapted from *Janssen CAH, Scholten PC, et al. based on " A Simple Visual Assessment Technique to Discriminate Between Menorrhagia and Normal Menstrual Blood Loss". Obstetrics & Gynecology, Vol. 85, No. 6, June 1995*). Treatment success was defined as a reduction in menses from a diary score of > 150 to ≤ 75 at one year. Overall study success was defined as a statistical difference of < 20% in patient success rates between the HTA System and RB. Secondary effectiveness endpoints evaluated were overall percent decreases in diary scores and responses to a quality-of-life questionnaire. Safety endpoints were adverse events associated with each procedure, including system-related complications, time of procedure, and type of anesthesia used.

Study Methods and Patients Studied: A randomized (2:1), prospective, multi-center clinical investigation was conducted at nine sites using investigators experienced with hysteroscopic Rollerball endometrial ablation. Prior to acceptance in the study, subjects underwent a series of screening examinations which primarily documented bleeding status and uterine structure. Subjects were required to meet a set of entry criteria.

Key inclusion criteria for the study were:

- excessive uterine bleeding, as documented by the menstrual diary and calculation worksheet defined by Janssen (with a minimum score of 150);
- endometrial cavity measuring ≤ 10.5 cm but > 6.0 cm;
- age ≥ 30 years; and
- previously failed, not tolerated, or refused medical therapy (i.e., Depo Provera™ Preparation, GnRH analogs, oral contraceptives, progestins, and Danocrine™ Suppressant/Danazol) as reported by the physician.

Key exclusion criteria for the study were:

- age > 50 years;
- active pelvic inflammatory disease;
- clotting defects, bleeding disorders, or anticoagulant treatments;
- abnormal pap smear that showed evidence of dysplasia;
- malignant pathology and/or simple hyperplasia, as documented by endometrial biopsy;
- history of gynecologic malignancy within the past 5 years;
- submucous myomas and/or polyps;
- intramural fibroids > 4 cm, as documented on ultrasonogram, thought to be contributing to menorrhagia, such as those deforming the uterine cavity;
- congenital uterine anatomical anomaly, such as full septate or bicornuate uterus;
- previous endometrial ablation procedure; and
- previous classic cesarean section.

Subjects received one dose of Lupron™ Pharmaceutical 7.5 mg on Cycle Day 21 ± 2 days. Treatment took place on Cycle Day 19 – 27 after injection. After completion of treatment, subjects were followed at 2 weeks, and 3, 6, 12, 24 and 36 months post-treatment.

Description of Patients: Two hundred seventy six subjects were enrolled in the study at a 2-1 ratio of HTA System vs. Rollerball respectively. Baseline demographic and gynecological variables were statistically equivalent between the two groups with regard to age (HTA System 40.7 years, RB 40.6 years), race, body mass index, mean baseline diary score (HTA System 596.6, RB 585.5) and other criteria. Table 2-4 describes the accountability of subjects throughout the study period.

Table 2-4: Subject Accountability

	HTA™ System	RB	TOTAL
Intent to Treat Population	**187**	**89**	**276**
No treatment received	-3	-4	-7
Incomplete treatments	-7	0	-7
Complete Treatments	**177**	**85**	**262**
Subjects not available at 12 month follow-up			
Unrelated death	-2	0	-2
Lost to follow-up	-6	-2	-8
Hysterectomy†	-2	0	-2
Population with 12-Month Data Available	**167**	**83**	**250**
Subjects not available at 24 month follow-up			
Lost to follow-up	-9	-7	-16
Hysterectomy	-10*	-1	-11
Repeat ablations	-1	-2	-3
Subjects Lost to Follow-up at 12 Months, returned at 24 Months	+4	+1	+5
Population with 24-Month Data Available	**151**	**74**	**225**
Subjects not available at 36 month follow-up			
Lost to follow-up	-5	-5	-10
Hysterectomy	-7	-4	-11
Repeat ablations	-3	0	-3
Uterine Artery Embolization	-1	-1	-2
Subjects Lost to Follow-up at 24 months, returned at 36 Months	+1*	+3	+4
Population with 36-Month Data Available	**136**	**67**	**203**

† Subjects were > 40 years old; reasons for hysterectomy were bleeding (1) and pain/myoma (1).

* One subject previously reported as having a hysterectomy, returned at 36 months and had not received a hysterectomy.

Primary Effectiveness Endpoint

Success was based on a reduction in excessive uterine bleeding to normal levels or better. A success at 12 months post-treatment is defined as a reduction in diary score from ≥ 150 pre-treatment to ≤ 75. Success at 24 and 36 months is defined as amenorrhea (no bleeding), hypomenorrhea (light bleeding), or eumenorrhea (normal menstrual bleeding) as reported by subject via questionnaire. Results at 12, 24 and 36 months post-treatment are presented in Table 2-5 for the Intent to Treat (ITT) Population.

Table 2-5: Effectiveness: Bleeding Rates for the Intent to Treat Population

Intent to Treat Population: n = 276	HTA System n = 187			RB n = 89		
Months post treatment	**12[a]**	**24[b]**	**36[b]**	**12[a]**	**24[b]**	**36[b]**
Number of successful subjects	128	139	127	68	68	62
Study success rate	68%	74%	68%	76%	76%	70%
Number of subjects with Amenorrhea	66	70	72	42	34	31
Amenorrhea rate	35%	37%	39%	47%	38%	35%

Note: Intent to Treat (ITT) population represents all subjects enrolled in the study including those considered as failures because they were not available for follow-up, did not receive treatment, and/or received partial treatment. Therefore, the ITT group represents a worst case scenario for effectiveness. See Subject Accountability section for complete accounting of all subjects enrolled in the study.

a Based on diary score.

b Based on questionnaire response.

Secondary Effectiveness Endpoint

Quality of Life (QOL) information was obtained by comparing QOL scores obtained via questionnaire at pre-treatment and at 12, 24, and 36 months post-treatment. These scores were compared and the results are presented in Table 2-6.

Table 2-6: Effectiveness: Quality of Life (QOL)

	HTA™ System	RB
Number of subjects who responded @ 1 year	167	83
QOL score (mean ± SD)†		
@ baseline	54.2 ± 13.5	53.3 ± 13.5
@1 year	13.0 ± 15.0	11.4 ± 15.2
Leisure activities affected		
@ baseline	70.1%	66.3%
@ 1 year	21.6%	28.9%
Work and activities of daily life affected		
@ baseline	90.4%	91.0%
@ 1 year	19.8%	20.0%
Number of subjects who responded @ 2 years	151	74
QOL score at 2 years++	11.0	10.0
Number of subjects who responded @ 3 years	136	67
QOL score at 3 years++	5.0	4.5

† The QOL information was obtained from the Ruta QOL questionnaire, with a scoring scale range of 2.6 - 89.5. A higher score is associated with increased menorrhagia (e.g., mild = 37.6; moderate = 46.7; and severe = 50.7).
++There is no standard deviation noted for 2 years or 3 years.

In addition, 98% of HTA System subjects and 97% of RB subjects reported satisfaction with their treatments at 36 months post treatment.

Safety Endpoint: Adverse event information is described in Section 2.4, *Adverse Events*. Overall mean treatment time was 26.4 ± 12.1 minutes and 32.2 ± 12.2 minutes for the HTA System and RB groups, respectively. Anesthesia was delivered at the discretion of the investigator and attending anesthesiologist. General anesthesia was administered to 55% and 76% of the HTA System and RB subjects, respectively. Paracervical block with IV sedation was administered to 30% and 13% of the HTA System and RB subjects, respectively; and paracervical without IV sedation was administered to 15% and 9% of the HTA System and RB subjects, respectively.

2.7 Patient Selection

Menorrhagia can be caused by a variety of underlying problems, including, but not limited to, endometrial cancer, myomas, polyps, anovulation, drugs, and dysfunctional uterine bleeding. Patients should always be evaluated to determine the cause of their excessive uterine bleeding before any treatment option is initiated.

2.8 Patient Counseling

As with any procedure, the physician needs to discuss with the patient, the risks, benefits, and alternatives to endometrial ablation.

The Genesys HTA® System is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure. Patients of childbearing capacity should be counseled that endometrial ablation is not a sterilization procedure and should be counseled on the use of an appropriate birth control method. Patients with childbearing capacity should be cautioned that serious potential complications may result to both mother and fetus in the event of a pregnancy.

Vaginal discharge is typically experienced during the first few days following ablation and may last as long as a few weeks. Generally, the discharge will be bloody during the first few days, then serosanguinous at one week post-treatment, and watery thereafter.

2.9 Pretreatment Preparation of Patient

- The endometrium should be in a basal state prior to Genesys HTA® System treatment. This can be accomplished by timing the menstrual cycle to the early proliferative phase or administering pretreatment drugs such as GnRH agonists prior to performing the endometrial ablation.
- As with any hysteroscopic procedure, the bladder should be empty.
- The usual vaginal preparation for hysteroscopy should be employed.
- It is recommended that a non-steroidal anti-inflammatory drug (NSAID) be given at least one hour prior to treatment and continued post-operatively as necessary to reduce intra-operative and post-operative uterine cramping.

2.10 Clinical Use Checklist

Prior to the use of the Genesys HTA System on a patient, the physician should complete the following checklist to better ensure safe and effective use of the system. Note that this is not a comprehensive list, but an attempt to cover some of the key issues before a physician uses the Genesys HTA System.

The physician must:

- along with ancillary personnel, thoroughly read and understand all directions for use, Indications and Contraindications supplied with the Genesys HTA System and those for compatible accessories to be used with the Genesys HTA System;
- be trained to perform diagnostic hysteroscopy;
- be able to verify that the uterine cavity is properly prepared for the ablation procedure and be able to identify the cornu;
- be able to observe, confirm, and maintain proper placement of the hysteroscopic tip beyond the internal os and be able to maintain control of the procedure sheath throughout the entire procedure;
- neither advance nor withdraw the procedure sheath into or out of the uterine cavity once heating has begun until the cooling is complete;
- be aware of the appropriate sequence of actions to halt, resolve and/or continue the treatment, in the event the Genesys HTA System detects a fluid loss of 10 mL (Refer to Section 7, Troubleshooting); and
- be aware that, on the day of treatment, previously undetected pathology (e.g., submucous myomas), may be present in the endometrial cavity which may affect treatment results.

3 HOW SUPPLIED

3.1 Parts and Illustrations

The Genesys HTA System operational unit is shipped in two separate packages:

- Pedestal, IV pole and hardware accessories
- Control Unit

Contents of the pedestal package (see Figure 3-1):

- (1) Accessory Bag containing:
  - (1) 5/16” Flat Washer (see Figure 3-2)
  - (1) 5/16” Split Lock Washer (see Figure 3-2)
  - (1) 5/16 - 18 x 1” Bolt (see Figure 3-2)

- (1) 1/2” (13mm) Socket Wrench (not shown)
- (1) Phillips Screwdriver (not shown)

- (1) Pedestal Pole
- (1) IV Pole
- (1) Pedestal Base

Contents of the control unit package (See Figure 3-4):

- (1) User’s Manual
- (1) Power Cord
- (1) Control Unit
- (1) Troubleshooting Guide (not shown)

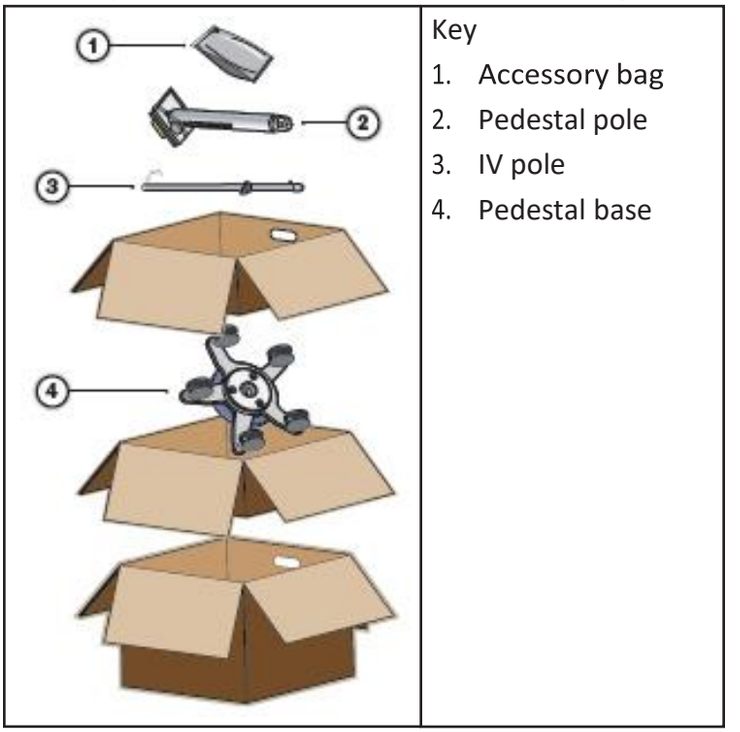
3.2 Genesys HTA® System Operational Unit Assembly

Examine the pedestal and control unit packages for damage. Do not use if package is opened or damaged.

3.2.1 Pedestal Assembly

1. Open the pedestal package and remove all contents.

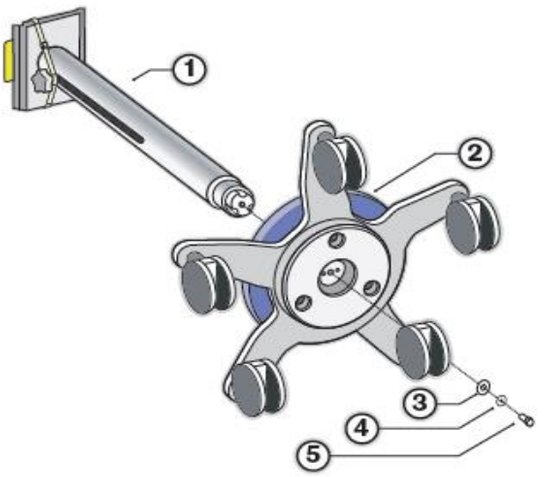
Figure 3-1: Contents of the Pedestal Package



Key
1. Accessory bag
2. Pedestal pole
3. IV pole
4. Pedestal base

2. Remove the hardware items from the accessory bag.
3. Confirm that all components listed in Section 3.1, *Parts and Illustrations*, are included in the packaging, and that the components have no dents, scratches, or abnormalities.
4. Insert the pedestal pole into the pedestal base as illustrated in Figure 3-2.
5. Insert the bolt (5) through the split lock washer (4) and the flat washer (3), and thread the bolt through the bottom of the base into the pedestal pole as illustrated in Figure 3-2.

Figure 3-2: Attaching the Pedestal Base to the Pedestal Pole

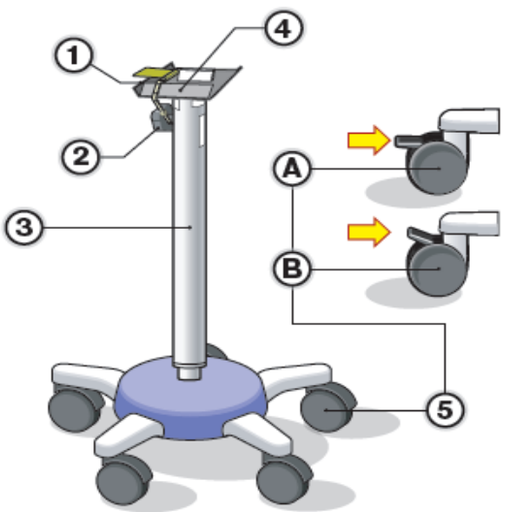


Key

1. Pedestal pole
2. Pedestal base
3. 5/16” Flat washer
4. 5/16” Split lock washer
5. 5/16 - 18 x 1” Bolt

6. Use the provided socket wrench to tighten the bolt.
7. Stand the pedestal upright with the casters on the floor.
8. Confirm that the two caster locks are pressed down to lock as shown in Figure 3-3 to secure the pedestal position.

Figure 3-3: Assembled Pedestal



Key

1. Mounting bracket
2. Height adjustment knob
3. Pedestal pole
4. Angled front lip
5. Casters
   A. Caster locked
   B. Caster unlocked

9. Confirm that the height adjustment knob (see Figure 3-3) is tight by turning clockwise. **Do not over-tighten the height adjustment knob, as damage to the pedestal pole could result.**

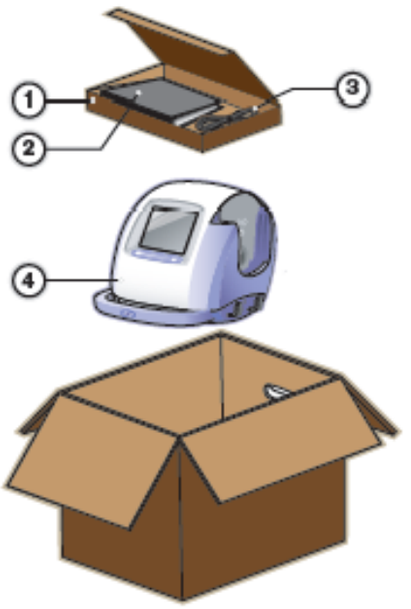
   CAUTION: The pedestal is spring loaded. Place a hand on the mounting bracket when cutting the tie wrap.
10. Cut the tie wrap from the mounting bracket and the height adjustment knob.

3.2.2 Control Unit Assembly

CAUTION: Use two hands when lifting the control unit. Place one hand on the control unit handle and one hand on the power cord wrap on the rear of the control unit (see Figure 3-5). The control unit is heavy, so use proper technique when lifting.

1. Open the control unit package and remove all contents.

Figure 3-4: Contents of the Control Unit Package

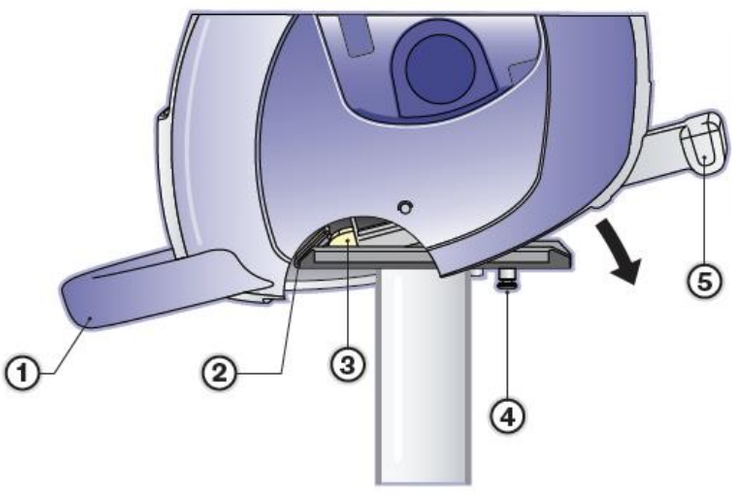


Key

1. Accessory box
2. User's manual
3. Power cord
4. Control unit

2. Inspect the control unit for any visible damage and confirm that there are no dents, scratches, or abnormalities.
3. Attach the control unit to the pedestal as follows, referencing Figure 3-5:
   A. Angling the front of the control unit downward, engage the mounting nose of the control unit such that the mounting nose rests on top of the mounting bracket and under the angled front lip.
   B. Lower the back end of the control unit until it snaps in place on the mounting bracket. An audible click confirms the control unit is properly mounted to the pedestal.
   C. Confirm that the locking pin is pushed in, engaging the locking mechanism.

Figure 3-5: Attaching Control Unit to Pedestal Pole



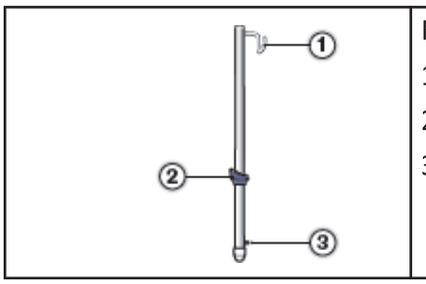
Key

1. Control unit handle
2. Angled front lip
3. Mounting nose
4. Locking pin
5. Power cord wrap

4. Insert the IV pole securely into the top of the control unit as follows:
   A. Align the locator pin (refer to Figure 3-6) towards the rear of the control unit.

Figure 3-6: Positioning IV Pole with Locator Pin

B. Push the IV pole completely into the top of the control unit making sure that the locator pin slides into the slot.

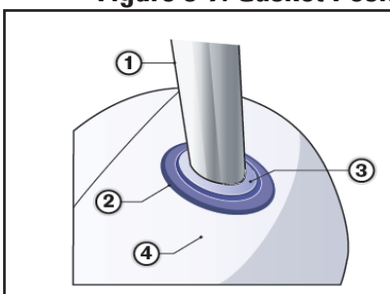


Key
1. IV pole hook
2. IV pole gasket
3. Locator pin

C. Ensure that the IV pole gasket sits on top of the control unit gasket, with no distortion to either gasket as shown in Figure 3-7.

NOTE: Ensure that there are no gaps between the control unit and IV pole gaskets to prevent fluid from inadvertently entering the control unit.

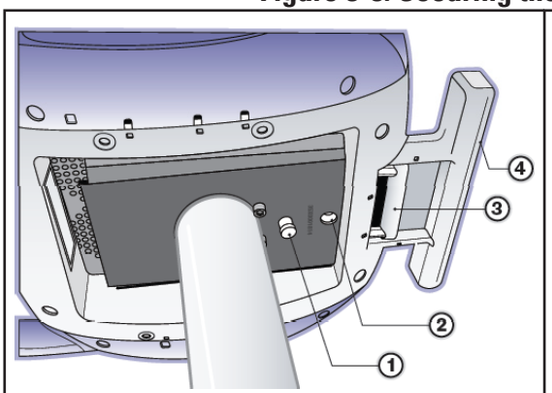
Figure 3-7: Gasket Positioning with IV Pole



Key
1. IV pole
2. Control unit gasket
3. IV pole gasket
4. Control unit

5. Secure the IV pole to the control unit, as shown in Figure 3-8, by inserting the screwdriver into the access hole and tightening the internal screw.

Figure 3-8: Securing the IV Pole



Key
1. Locking pin
2. Access hole
3. Release mechanism
4. Power cord wrap

6. Connect the power cord into the rear of the control unit. Reference Figure 4-3 for the location of the power cord inlet.

3.3 Moving and Storage

The following instructions provide information for proper movement and storage of the Genesys HTA® System.

1. If desired, to facilitate movement and storage, turn the pedestal's height adjustment knob and lower the pedestal pole to its lowest setting.
2. Ensure that the power cord is securely looped around the power cord wrap on the rear of the control unit.

3. Raise the caster locks to unlock and move the Genesys HTA® System to a storage area that is safe from impact or other accidental damage.
4. Confirm that the storage area is within the normal temperature and humidity range as defined in Section 3.4.6, *Environmental and Transport Information*.
5. Confirm that the storage area is free from risk of water leakage or splashes.
6. Push the caster locks down to secure the Genesys HTA System position. This will prevent accidental rolling and potential impact damage.

3.4 Specifications

3.4.1 Electrical

Table 3-1: Electrical Specifications

Input Voltage	115 VAC, 50/60 Hz 230 VAC, 50/60 Hz
Rated Current	6 amps maximum @115 VAC 3 amps maximum @230 VAC
Earth Leakage Current	< 250 microamps @115 VAC < 400 microamps @230 VAC

Table 3-2: fuse Ratings

115 VAC	250 V, 8A, Type T
230 VAC	250 V, 5A, Type T

3.4.2 Physical (nominal)

Table 3-3: Control Unit Specifications

Height	30.5 cm / 12 inches
Width	31.8 cm / 12.5 inches
Depth	43.8 cm / 17.25 inches
Weight (unpackaged)	13.64 kg / 30 lbs

Table 3-4: Pedestal Specifications

Height (minimum) (maximum)	Approximately 83.8 cm / 33 inches Approximately 110.5 cm / 45 inches
Width	53.3 cm / 21 inches
Depth	53.3 cm / 21 inches
IV Pole Height (minimum) (maximum)	48.3 cm / 19 inches (from top of unit) 157.5 cm / 62 inches (from floor) 48.3 cm / 19 inches (from top of unit) 187 cm / 73.5 inches (from floor)
Weight (unpackaged)	14.5 kg / 32 lbs

Table 3-5: Power Cord Specifications

115 VAC – Domestic (US)	Length - 3.05 m Voltage Rating - 125 VAC Current Rating - 10 amps Connector Type - IEC 60320 C13 CE Marking - Yes

230 VAC – International (Outside US)	Length - 2.50 m Voltage Rating - 250 VAC Current Rating - 10 amps Connector Type - IEC 60320 C13 CE Marking - Yes
230 VAC - UK	Length - 2.50 m Voltage Rating - 250 VAC Current Rating -10 amps (cord) Connector Type - IEC 60320 C13 (cord) CE Marking - Yes (cord) Internal Fuse - 13 amps Current Rating - 13 amps (plug) Plug Type - BS 1363 Approvals - VDE, IRAM

3.4.3 Laser Aiming Beam

The control unit handle is the primary means for ensuring the height of the control unit is correct. The control unit also contains a laser aiming beam, which is the secondary means for assisting with the height adjustment of the unit. When activated by the laser aiming beam alignment button on the control unit handle, the laser aiming beam exits from the lower right side of the control unit (see Figure 4-2).

The laser beam is classified as a “Class 1 Laser Product”, and has the specifications identified in Table 3-6. The Class 1 Laser Product is compliant to IEC 60825-1:2007. It also complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, date June 24, 2007.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Table 3-6: Laser Aiming Beam Specifications

Maximum output of laser radiation	516 µW
Emitted wavelength	635 nm

3.4.4 Medical Electrical Classifications

The Genesys HTA® System meets the requirements of the following standards CAN/CSA-C22.2 No. 601.1-M90; IEC 60601-1-4; IEC 60601-1-6; IEC 60601-1-8; IEC 60825-1; UL 60601-1.

Table 3-7: Medical Electrical Classifications

Type of Protection Against Electric Shock	Class 1 equipment
Degree of Protection Against Electric Shock	Type BF Applied Part
Degree of Protection Against Ingress of Liquids	IPX1
Mode of Operation	Continuous Operation
Method of Sterilization (Scope Adapters)	Moist Heat Sterilization (Autoclave)
Suitability for use in oxygen rich environments	Equipment not suitable for use in the presence of flammable mixtures
Installation and Use	Mobile

3.4.5 Software Information

Software revision level is controlled by Minerva Surgical. Current revision level can be obtained by contacting Minerva with the serial number listed on the machine.

3.4.6 Environmental and Transport Information

Table 3-8: Environmental Information

System Transport and Storage	
Ambient temperature	-29°C to 60°C
Relative humidity	30 to 85% RH non-condensing
System Operation	
Ambient temperature	10°C to 32°C
Relative humidity	30 to 85% RH non-condensing

3.5 Description of Symbols

Table 3-9: Description of Symbols

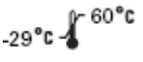
Symbol	Description
REF Catalog No.	Catalog number
CE 0197	CE marking of conformity
	Consult instructions for use
	Contents
EC REP	EU authorized representative
	Legal manufacturer
LOT	Lot
℞ ONLY	Prescriptive statement
UPN Product No.	Product number
	Attention, see instructions for use
	Date of manufacture
	Non sterile
	Fragile
	Keep dry
	This end up
	Fuse
IPX1	Ingress protection from vertically dripping water
	Separate collection
SN	Serial number
	Storage humidity range 30% RH to 85% RH (± 5%)
	Storage temperature 29°C to 60°C
	Type BF applied part

Table 3-9: Description of Symbols (Continued)

Symbol	Description
	Listing Agency Mark (Intertek)
	For single use only, do not reuse
	Open here
	Sterilized using ethylene oxide gas
	Use by
	Recyclable package
	Lock
	Unlock

3.6 Overview of Alarms

The alarms listed in the Table 3-10 are not grouped into physiological alarm conditions, technical alarm conditions, or other groupings. For additional information on these alarms, reference Section 7.1, *System Generated Alarms*.

When executing the procedure, position the control unit such that the user can observe the screen, hear the audible tones, and press the control panel buttons.

Table 3-10: Overview of Alarms

Description	Priority	Sound Pressure Range	Algorithm
Temperature Error (Target Temperature Exceeded)	Medium	63 dBA 1 meter away from control unit	Triggered when measured cassette temperature exceeds 40°C during the Heater Test or greater than or equal to 95°C during Heating or Ablation.
Fluid Loss Detected	Medium	63 dBA 1 meter away from control unit	Triggered in the Seal Integrity Check, Heating or Ablation when a fluid loss of 10 mL is detected.
Third Fluid Loss Detected	Medium	63 dBA 1 meter away from control unit	Triggered in Heating or Ablation when a third fluid loss of 10 mL is detected after the temperature has reached 50°C.
Cooling and Flushing (Insufficient Patient Cooling)	Medium	63 dBA 1 meter away from control unit	Triggered at the end of the Cooling & Flushing cycle when measured cassette temperature is 45°C or greater.

4 GENESYS HTA® SYSTEM

4.1 System Overview

The Genesys HTA System is designed to deliver 90°C saline to the uterine cavity under hysteroscopic visualization for the treatment of abnormal uterine bleeding.

The Genesys HTA System consists of an operational unit and a disposable procedure set. The operational unit includes a control unit, an adjustable-height pedestal, and a fixed-length IV pole. The disposable procedure set includes a cassette, a procedure sheath, and a drainage bag.

The control unit drives system operation. Information on the display screen guides the user through each step. In addition, the control unit alerts the user with audible tones. The user interfaces with the control unit by pressing one of two control panel buttons in response to prompts on the display screen.

The pressure in the uterine cavity is approximately 50 mmHg during system operation. This pressure and the corresponding distention of the uterus are achieved by a combination of system pump speed and the height of the control unit. The height of the control unit is aligned with the patient's uterus using the control unit handle as the primary means. A laser aiming beam is provided as a secondary means for assisting with the height adjustment.

The cassette interfaces with the control unit to facilitate heating, cooling, and distribution of saline throughout the procedure. The procedure sheath serves as the fluid conduit between the cassette and the uterine cavity. Effluent is collected in the drainage bag.

The system guides the user through setup, diagnostic hysteroscopy, the seal integrity check, heating, ablation, cooling, post ablation hysteroscopy, and system shutdown. When the system is paused, or in the event of any system generated alarm or alert, the system will go into a safe state with the heater off and the patient valve closed.

4.2 Principles of Operation

4.2.1 Fluid (Saline) Circulation

Circulation of fluid is accomplished with an impeller pump. An impeller in the cassette is magnetically coupled to a motor in the control unit. The motor speed is preset and not adjustable by the user.

Fluid circulates at a flow rate of approximately 300 mL/min. and a pressure of approximately 50 mmHg. Flow and pressure are controlled through pump efficiency, motor speed control, and control unit height adjustment.

Flow is directed by a series of motor-driven valves in the control unit. The valves protrude from the side of the control unit into openings in the back of the cassette. When a valve is engaged, it pinches the tubing within the cassette and closes a specific fluid path. Figure 4-1 illustrates fluid flow and key fluid system elements.

During diagnostic hysteroscopy, cooling, and post ablation hysteroscopy, fluid circulates in an open- loop system. Saline from the supply bag enters the cassette. Saline exits the cassette through the procedure sheath and into the patient's uterine cavity. The fluid returns from the uterine cavity to the cassette through a second lumen in the procedure sheath, flows through the cassette, and proceeds to the drainage bag. The fill, patient, and drain valves are open. The middle valve is closed.

During the seal integrity check, heating and ablation, fluid circulates in a closed-loop system. The fill and drain valves are closed, while the patient and middle valves are open. In the cassette, fluid from the reservoir enters the pump and continues through the heater. When the heater is activated, heated fluid then exits the cassette through the procedure sheath and into the uterine cavity. The fluid returns to the cassette through a second lumen in the procedure sheath, flows through the debris handling chamber, and returns to the reservoir to repeat the loop.

Excessive bleeding during treatment may lead to occlusion of the system with uterine debris. Occlusion can affect fluid flow and pressure and may prevent treatment completion through the activation of safety systems within the Genesys HTA® System. A sieve on the tip of the procedure sheath and the debris handling chamber in the cassette are designed to minimize the occurrence of occlusion due to uterine debris.

4.2.2 Fluid Measurement

Closed-loop fluid circulation during the seal integrity check, heating and ablation facilitate measurement of fluid loss. In the cassette, a level sensor detects the fluid height in the reservoir. Fluid loss may be caused by leakage in the procedure sheath, cassette, or in connections between

the procedure sheath and cassette.

Decreases in fluid level are shown in real-time, on the display screen, during the seal integrity check, heating and ablation. If the system detects a fluid loss of 10mL, the patient valve is closed and the system notifies the user. A fluid loss of greater than 10mL can occur prior to patient valve closure, especially in the event of a rapid leak.

After a fluid loss alarm, the user may elect to continue the procedure if deemed safe to proceed. However, if there are three fluid loss alarms after fluid temperature has reached 50°C, the system will not allow the user to proceed. In this case, the system will guide the user to automatic shutdown.

Fluid level gains may be caused by tissue obstruction in the system, uterine contraction, excessive bleeding, or kinked tubing. Significant increases in fluid level will result in an excessive fluid level alert.

4.2.3 Fluid Heating and Cooling

Fluid heating is achieved with a microprocessor-based controller in the control unit and a heater with redundant temperature sensors in the cassette. Fluid temperature in the cassette is shown on the display screen during heating, ablation, and cooling.

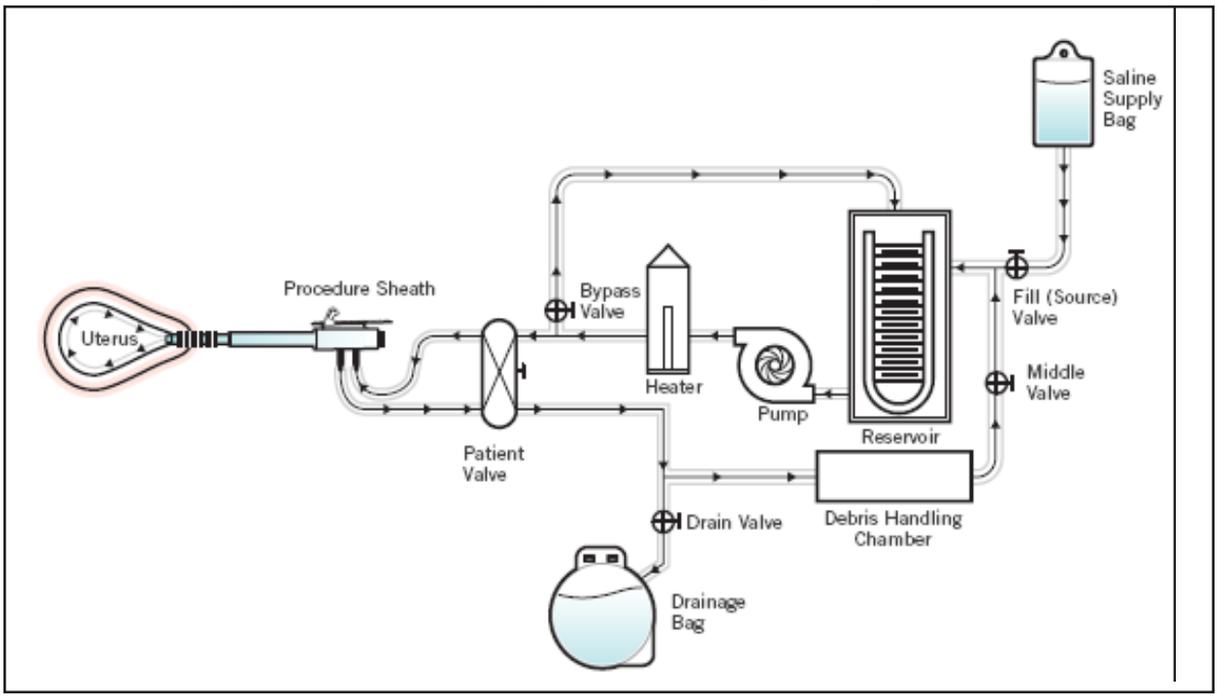
Fluid heating begins gradually. Approximately one minute is required for fluid to reach 45°C in the uterine cavity. Approximately two more minutes are required for fluid temperature to increase from 45°C to 80°C in the uterine cavity.

The ten-minute ablation period begins automatically when the temperature reaches 80°C; however, the temperature continues to rise to a target temperature of 90°C. Heated fluid is circulated within the uterine cavity via the procedure sheath.

Once heating has begun, the user must maintain a stable sheath position and not remove the procedure sheath until cooling has been completed and confirmed by the display screen, as heated fluid may cause thermal injury to the patient.

Immediately following ablation, the Genesys HTA® System begins cooling by circulating fresh room-temperature saline through the uterine cavity. Sufficient cooling is achieved if the fluid temperature is below 45°C after 90 seconds of cooling. Following cooling, the user has the option of proceeding directly to system shutdown or conducting a post ablation hysteroscopy prior to system shutdown.

Figure 4-1: Schematic Diagram of the Genesys HTA System flow



4.3 System Description

4.3.1 Control Unit

4.3.1.1 Display Screen and User Interface

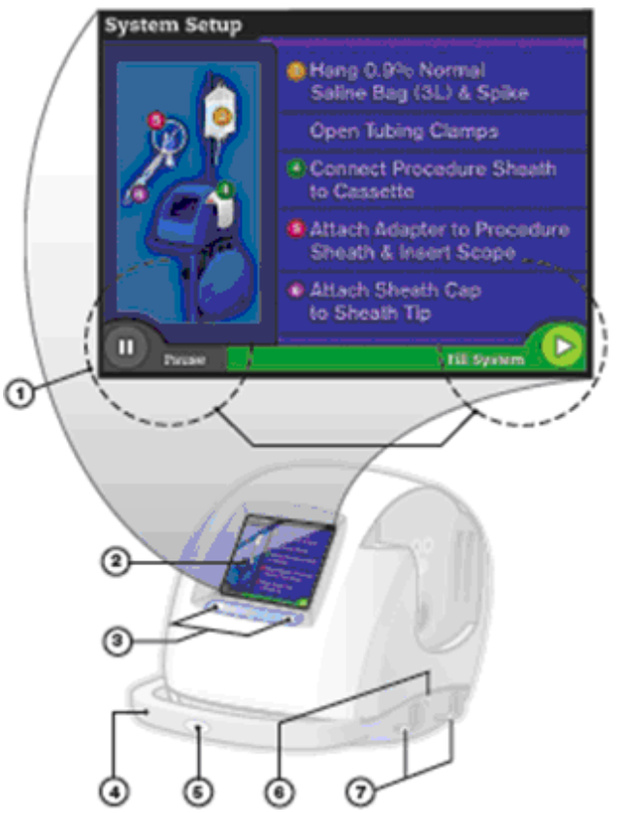
The front of the control unit, as shown in Figure 4-2, has a color liquid crystal display (LCD) screen that provides graphical and textual instructions to guide the user through the procedure. The display screen also indicates warnings and instructions for subsequent corrective actions if necessary.

NOTE: In the event of a problem that cannot be resolved with the onscreen instructions, refer to Section 7, *Troubleshooting* for additional information.

Some display screens allow or require user interaction (e.g., pausing the system, continuing to the next step of the procedure), as indicated by prompts on the lower left and/or right of the display screen. The user responds to the prompts by depressing the control unit's left or right control panel button located directly under the message on the display screen. The prompts on the display screen are not touch-activated.

Throughout this manual, control panel buttons are named by the function they perform as shown in the instructional text above the button. For example, when the Fill System icon is visible in the right bottom corner of the display screen, the right control panel button is described as the Fill System button (see Figure 4-2).

Figure 4-2: front View of the Control Unit



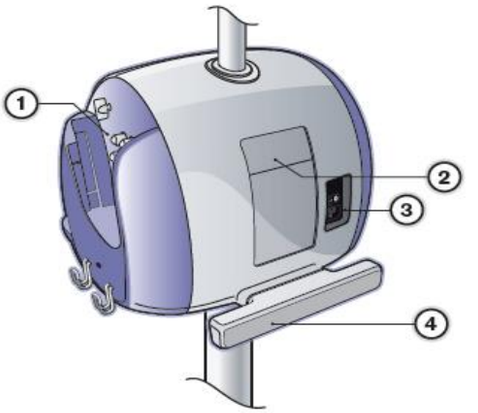
Key

1. Display icons and prompts for control panel buttons
2. Graphical User Interface (GUI) display screen
3. Control panel buttons
4. Handle
5. Laser aiming beam alignment button
6. Laser aiming beam exit
7. Drainage bag hooks

4.3.1.2 Rear Panel

The rear panel of the control unit contains a label, an on/off switch, a power cord inlet, and a power cord wrap, as depicted in Figure 4-3.

Figure 4-3: Rear View of the Control Unit



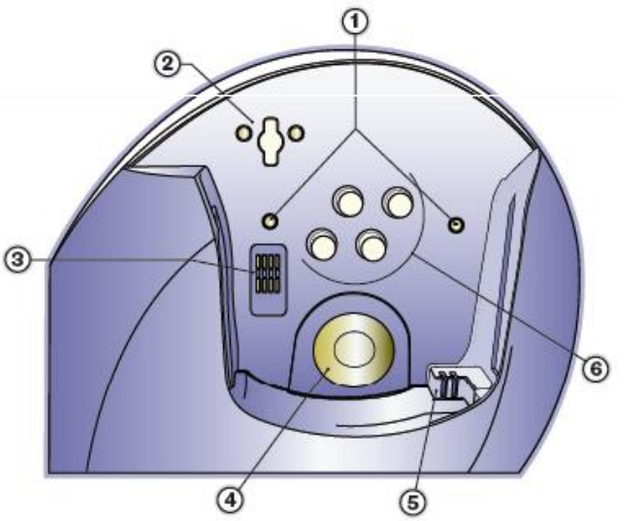
Key

1. Right side
2. Label location
3. On/Off switch and power cord inlet
4. Power cord wrap

4.3.1.3 Right Side

The right side of the control unit contains elements necessary to interface with the cassette. It includes the valves, electrical and heater contacts, and the blue LED indicators that show cassette engagement. The pump motor drive components are located behind the pump motor plate.

Figure 4-4: Right View of Control Unit



Key

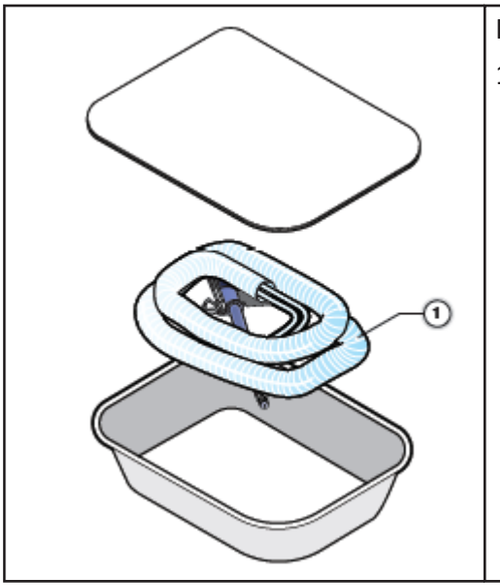
1. Blue LED indicators
2. Patient valve
3. Control unit contacts
4. Pump motor plate
5. Heater contacts
6. Middle, drain, bypass and supply valves

4.3.2 The Genesys HTA ProCerva® Procedure Set

The Genesys HTA ProCerva Procedure Set contains two packages within each shipper box. Figure 4-5 depicts one package, which includes a disposable procedure sheath and sheath cap. The second package contains the cassette and drainage bag as shown in Figure 4-6.

See product labeling for expiration date. Do not use product beyond its expiration date.

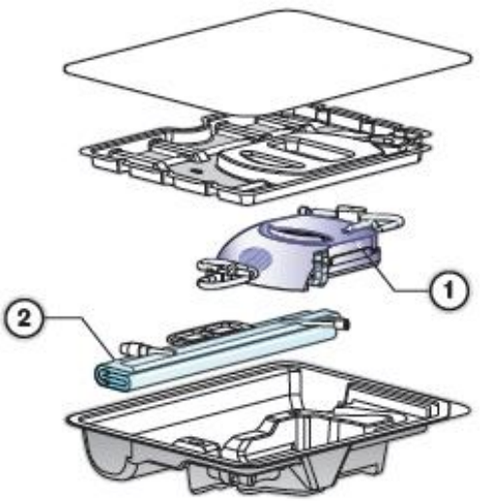
Figure 4-5: Contents of the Procedure Sheath Package



Key

1. Procedure Sheath and tubing

Figure 4-6: Contents of the Cassette and Drainage Bag Package



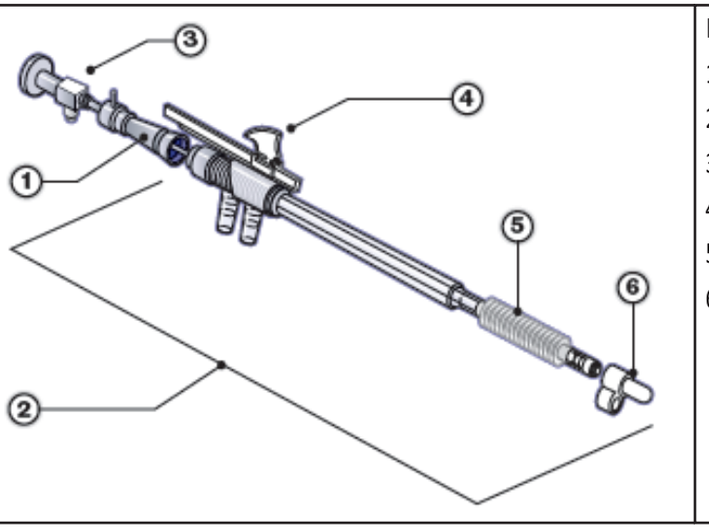
Key

1. Cassette
2. Drainage bag

4.3.2.1 Genesys HTA ProCerva® Procedure Sheath

Figure 4-7 shows the single use Genesys HTA ProCerva Procedure Sheath, which circulates the saline to and from the uterus during operation. The procedure sheath contains 2 lumens (one for fluid delivery and one for fluid return), a cervical seal assist feature that aids the user in gaining and maintaining a cervical seal, and tubing that attaches it to the cassette. A sieve tip on the end of the procedure sheath is intended to minimize the occurrence of occlusion due to uterine debris. The procedure sheath also includes a tenaculum stabilizer that when engaged, allows the physician to hold the procedure sheath and tenaculum with one hand. A hysteroscope (not supplied) is inserted into the procedure sheath to provide visualization during the procedure. Various scope adapters (sold separately) are available to ensure proper connection between the hysteroscope and procedure sheath. A sheath cap is included for priming the system.

Figure 4-7: Procedure Sheath Assembly

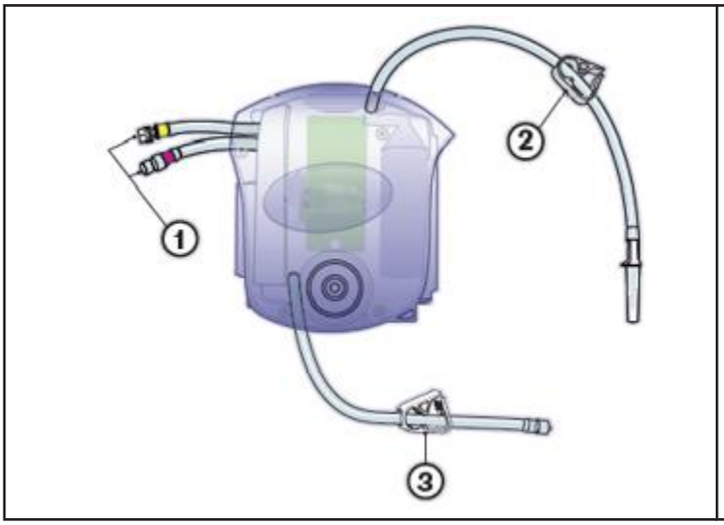


Key
1. Scope adapter
2. Procedure sheath
3. ≤ 3mm hysteroscope
4. Tenaculum stabilizer
5. Cervical seal assist
6. Sheath cap

4.3.2.2 Cassette

The cassette contains the heater, fluid level sensor (contained in the reservoir), impeller, debris handling chamber, and ancillary component connections used to provide circulation and direction of fluid during the procedure. An internal fluid level sensor is used for fluid measurement during the procedure. Figure 4-8 shows areas of user interface on the cassette.

Figure 4-8: front View of the Cassette

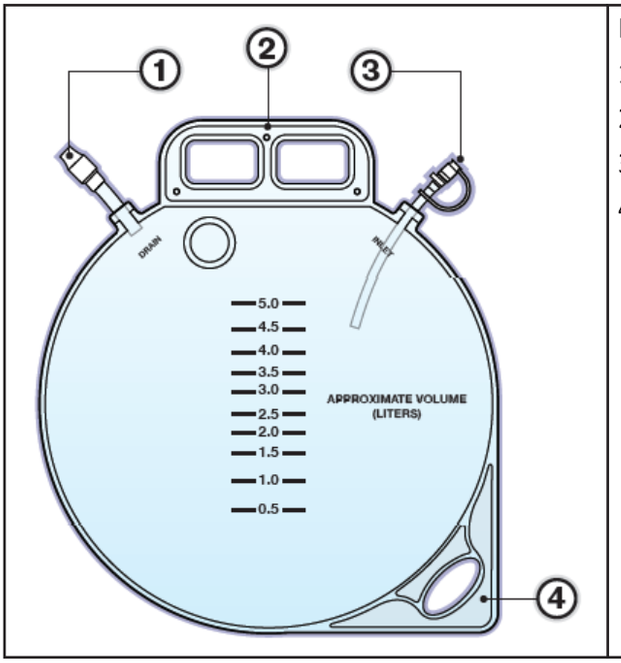


Key
1. Sheath connections
2. Supply line and clamp
3. Drain line and clamp

4.3.2.3 Drainage Bag

The drainage bag, as shown in Figure 4-9, connects to the cassette's drain line via the inlet tubing to collect the effluent from the procedure. It has a capacity of approximately 5L. The drain valve provides an exit port for emptying the collected drainage fluid. Openings in the rigid handle fit over drainage bag hooks on the control unit when attaching the bag. The inlet tubing contains a tethered luer cap that allows the inlet line to be capped during transport and prior to draining. A finger loop at the bottom of the bag assists the user in emptying the drainage bag.

Figure 4-9: Drainage Bag



Key

1. Drain valve
2. Rigid handle
3. Inlet tubing
4. Finger loop

4.4 Preparation for Use

Ensure that the user has read this entire manual, and understands and applies all instructions relating to the Genesys HTA® System, including all safety warnings and cautions listed in this manual.

4.4.1 Components and Accessories

Collect the following Genesys HTA System components and accessories for use:

Applied Parts Provided by Minerva Surgical

- Genesys HTA ProCerva® Procedure Set containing the sterile procedure sheath, cassette, and the drainage bag - (sold separately)
- Scope adapter - (sold separately)

Provided by User

- Vaginal speculum
- 3L bag(s) of 0.9% Normal Saline (Sodium Chloride)
- Hysteroscopic telescope, ≤ 3 mm diameter (refer to section 4.4.2, Selecting a Hysteroscope)
- Fiber optic cable
- Camera controller and video camera head with cable (or camera drape)
- Endoscopic light source
- Video monitor
- Standard hysteroscopy instrument set (including cervical dilators, 9 - 10 inch single-toothed tenacula and/or 9 - 10 inch cervical sealing tenacula (i.e., Richard Wolf 8371.10 by Richard Gimpelson, M.D.)

4.4.2 Selecting a Hysteroscope

Users of hysteroscopes with 30°direction of view must consider that proper alignment of the procedure sheath medial to the axis of the uterine cavity will result in a hysteroscopic view oriented towards the cavity side wall. A centralized view of the uterine cavity with a 30° hysteroscope may result in the procedure sheath being directed towards the cavity wall and a possible restriction of fluid flow.

Users of hysteroscopes with a 0° - 15° angle of view may find proper alignment of the procedure sheath medial to the axis of the uterus easier to accomplish while maintaining a centralized view of the uterine cavity and proper fluid flow.

Table 4-1 lists hysteroscopes compatible with the Genesys HTA ProCerva® Procedure Set. Use only these hysteroscopes with a compatible scope adapter. Do not use a non-listed hysteroscope. Refer to the catalog for a complete list of scope adapter order numbers.

NOTE: Contact Minerva Surgical if your specific hysteroscope model number is not listed or your hysteroscope manufacturer is not listed.

Table 4-1: Compatible Hysteroscopes

Hysteroscope Supplier	Supplier Model Number	Outside Diameter	Angle of View	Securement to Scope Adapter
Karl Storz	26020BA 26120FA	2.9 mm 2.9 mm	30° 12°	Rotating Lock Ring
Richard Wolf	8974.401	2.7 mm	25°	Rotating Lock Ring
Circon / ACMI	G27L30WA G27L-12A	2.7 mm 2.7 mm	30° 12°	Snap Fit
Olympus	A4674A A4673A A4672A	3.0 mm 3.0 mm 3.0 mm	30° 12° 0°	Snap Fit

4.4.3 Procedure Sheath Accessories – Sterilization and Assembly

Prior to assembly for use, clean and sterilize the fiber optic cable, ≤ 3 mm hysteroscope, video camera head (or camera drape), and standard hysteroscopy instrument set in accordance with each manufacturer's instructions.

The scope adapter must also be cleaned and sterilized prior to use. Following is a recommended minimum cycle for steam sterilization that has been validated by Minerva Surgical under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters listed below.

Scope Adapter – Cleaning and Sterilization

1. Device can be reused up to 40 times.
2. After use, wipe down scope adapter with a damp cloth to remove any residuals.
3. Soak fully immersed in Enzol™ Solution for 5 minutes.
4. Brush with a soft bristle brush to remove soil, use a pipe cleaner to brush the lumen three times from both ends. Using a syringe, flush the lumen and crevices three times with Enzol Solution.
5. Rinse under lukewarm running tap water for one minute. Using a syringe, flush the inside lumen three times and the crevices one time.
6. Fully immerse and sonicate for 10 minutes in Enzol Solution.
7. Rinse in RO/DI water for one minute, use a syringe to flush the lumen three times and the crevices one time.
8. Dry with a soft clean cloth, then wrap device.
9. Sterilize as instructed below:
   - Sterilizer type: Pre-vacuum
   - Preconditioning pulses: 3
   - Minimum temperature: 132°C
   - Full cycle time: 6 minutes

- Minimum dry time: 20 minutes
- Sample configuration: wrapped device

NOTE: Do not handle hot.

Assemble the hysteroscopy instrument set according to the manufacturer's recommended instructions.

4.4.4 Control Unit Preparation

1. Unlock the pedestal's casters by pushing the caster locks up.
2. Move the Genesys HTA® System operational unit to the desired location.
3. Lock the casters by pushing the two caster locks down until secure.
4. Prior to system usage, ensure that the control unit contacts are clean.

5 SYSTEM OPERATION

5.1 System Startup

1. Ensure that the power switch is in the OFF (O) position. The switch is located above the power cord on the rear side of the control unit.
2. Unwrap the power cord from the power cord wrap on the rear of the Genesys HTA System control unit.
3. The power cord is the means of isolating the Genesys HTA System from the mains supply.
4. Connect the power cord to a proper electrical supply outlet in an easily accessible location that is not blocked by other equipment when the Genesys HTA System is in use.

   CAUTION: Ensure that the selected electrical supply outlet has a proper ground connection and complies with the information listed on the label located on the rear of the unit. Never use a three (3) prong plug in a two (2) prong adapter.
5. Push the power switch to the ON (I) position.

Figure 5-1 shows the *System Startup* screen that is displayed for up to two minutes while the system completes self-diagnostic checks, and confirms that a disposable cassette is not yet inserted in the control unit. Do not attempt to insert the cassette until prompted by the system.

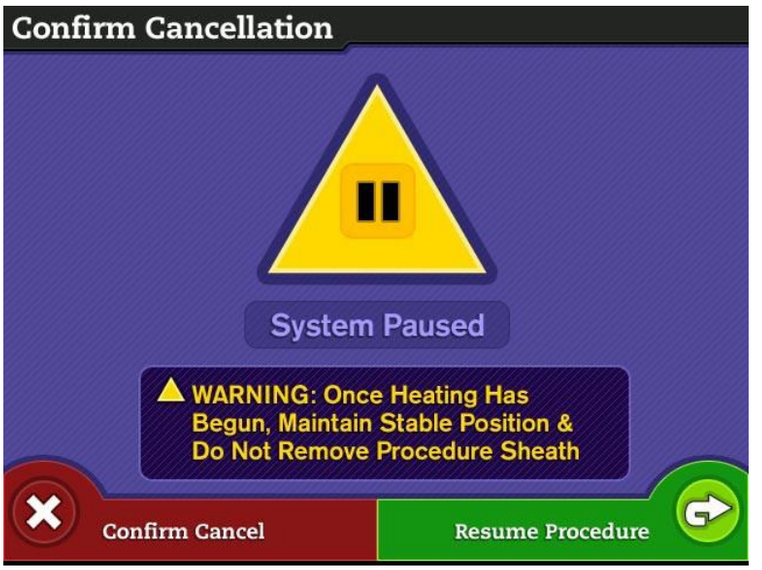
Figure 5-1: System Startup

When finished, the *System Setup* screen illustrated in Figure 5-3 is displayed, and a chime sounds.

5.2 Pausing or Cancelling a Procedure

Whenever the *Pause* button is visible on the lower left portion of the display screen, such as in Figure 5-3, the user can press the left control panel button to temporarily halt the procedure. The *Confirm Cancellation/System Paused* screen, shown in Figure 5-2, is displayed until the user determines whether to cancel or resume the procedure.

Figure 5-2: Confirm Cancellation/System Paused



The following steps provide instructions on ending or resuming the procedure.

1. Press the *Confirm Cancel* button to end the procedure. The system will proceed directly to system shutdown if the fluid temperature is ≤ 45°C; otherwise, it will proceed to cooling and then to shutdown.

WARNING: If cancelling the procedure from ablation, the fluid in the tubing and uterus is still HOT. **Maintain stable sheath position and DO NOT remove the procedure sheath until prompted by the Genesys HTA® System.** The system prompt indicates that patient and system cooling is complete, and it is safe to remove the procedure sheath.

2. When the *Resume Procedure* button is pressed during Ablation, the system first returns to Heating to ensure correct temperature prior to continuing the ten-minute ablation countdown. In all other instances, pressing the *Resume Procedure* button returns the system to where ithad been before the system was paused.

5.3 System Setup

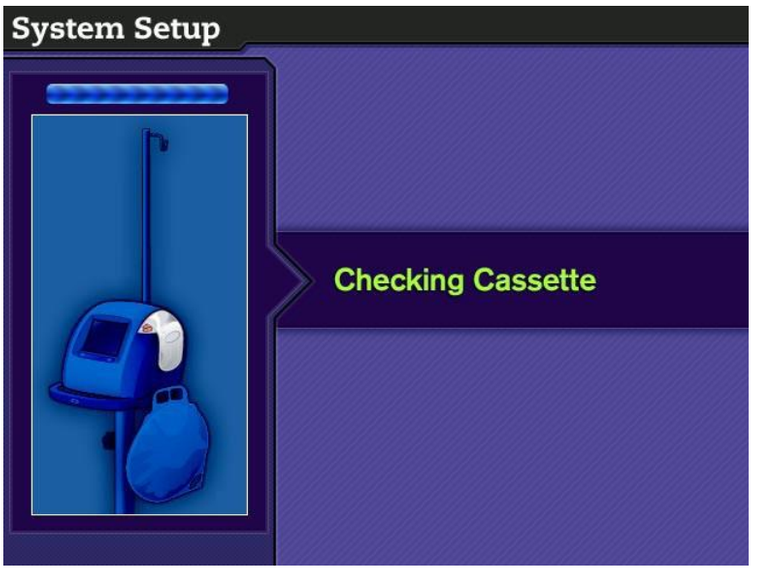
The following three System Setup display screens provide the instructions necessary to set up the system, prompting the user to complete each step. Figure 5-3 instructs the user on the first two setup steps to take.

Figure 5-3: System Setup: Steps 1 and 2

1. Examine the procedure set and insert the cassette into the control unit as follows:
   A. Examine the Genesys HTA ProCerva® Procedure Set package for damage. Do not use if the package is opened or damaged.
   B. Open the procedure set package and remove the contents.
   C. Inspect each tray for damage. Do not use if the procedure sheath or cassette trays are open or damaged.
   D. Peel open the cassette tray and remove the cassette and drainage bag from the tray and inspect. Do not use if the contents are damaged.
   E. Facing the cassette slot, position the cassette above the cassette slot with the Minerva Surgical logo facing away from the control unit.
   F. Slide the cassette down until it is fully seated in the control unit. The top of the cassette should be flush with the top of the control unit, and the two blue LED indicators behind the cassette should illuminate, indicating that the cassette is properly inserted.
2. Hang the drainage bag, attach and engage the cassette as follows:
   A. Attach the drainage bag to the right side of the control unit by placing the rigid handle of the drainage bag onto both of the drainage bag hooks.
   B. Connect the drain line luer fitting from the cassette to the drainage bag.
   C. After the drainage bag is connected, press the *Engage Cassette* button to engage the cassette to the control unit.

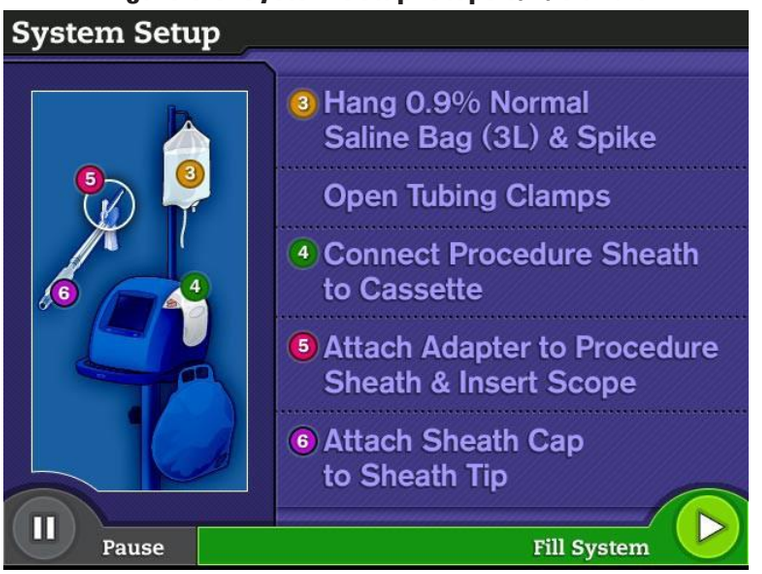
Figure 5-4 is displayed while the system verifies that the cassette was inserted correctly and is functioning properly.

Figure 5-4: System Setup: Checking the Cassette



After verification of the cassette, screen content as shown in Figure 5-5 is displayed, prompting the user to complete the remaining setup steps.

Figure 5-5: System Setup: Steps 3, 4, 5 and 6



3. Setup the saline supply bag and confirm tubing clamps are open as follows:
   A. Hang a 3L bag of 0.9% Normal Saline from the IV pole hook.
   B. Spike the saline bag.

      NOTE: Ensure that the saline bag ports are pulled away from the bag and into a vertical position, and that the saline spike has sufficiently penetrated the bag port to facilitate flow.

   C. Confirm that the cassette's supply and drain lines are unclamped.
4. Peel open the procedure sheath tray. Place its contents onto the sterile field and inspect for damage. Do not use if the contents are damaged. Observing sterile technique, connect the procedure sheath inflow and outflow tubing connectors to the matching color-coded sheath connections on the cassette (male and female luer style, Purple – Purple and Yellow – Yellow).

   NOTE: Prior to attaching the luer fittings from the procedure sheath to the cassette, twist the procedure sheath tubing ¼ turn counterclockwise. This may decrease the likelihood of kinked tubing.

5. Attach the scope adapter to the procedure sheath and insert the scope as follows:
   A. Attach the sterilized scope adapter to the proximal end of the procedure sheath.

      NOTE: Seat the scope adapter fully onto the procedure sheath. There will be resistance due to an O-ring on the procedure sheath.

   B. Turn the knurled knob on the scope adapter approximately 2 ¼ turns to secure the scope adapter to the procedure sheath.

      NOTE: Do not over-tighten the scope adapter, as doing so may cause damage to the procedure sheath.

   C. Carefully guide the distal end of the hysteroscope through the procedure sheath until it stops in the scope adapter and secure according to the securement means listed in Table 4-1.
6. Attach the sheath cap to the tip of the procedure sheath. To prevent leakage, ensure that the sheath cap fully covers the sieve tip area and openings of the distal tip.
7. Press the *Fill System* button to advance to System Preparation.

5.4 System Preparation

System Preparation initializes the system, filling it with saline and then briefly warming the saline to 35°C to confirm the heater is functional (Heater Test). While this is in progress, the physician can adjust the system height and prepare the patient for the diagnostic hysteroscopy as instructed in Sections 5.4.2 and 5.4.3.

At any time during System Preparation, the Pause button may be pressed if the user wishes to temporarily halt or cancel the procedure. If the procedure is cancelled, the system will proceed directly to system shutdown (refer to Section 5.9, *Shutting Down the System*). If the procedure is resumed, the system will return to the screen that was displayed when the Pause button was pressed.

5.4.1 System Initializing and filling

Figure 5-6 is displayed as the Genesys HTA® System initializes and fills with fluid. The system is filled to flush out air, and to initialize the pump. Filling is complete after approximately two minutes.

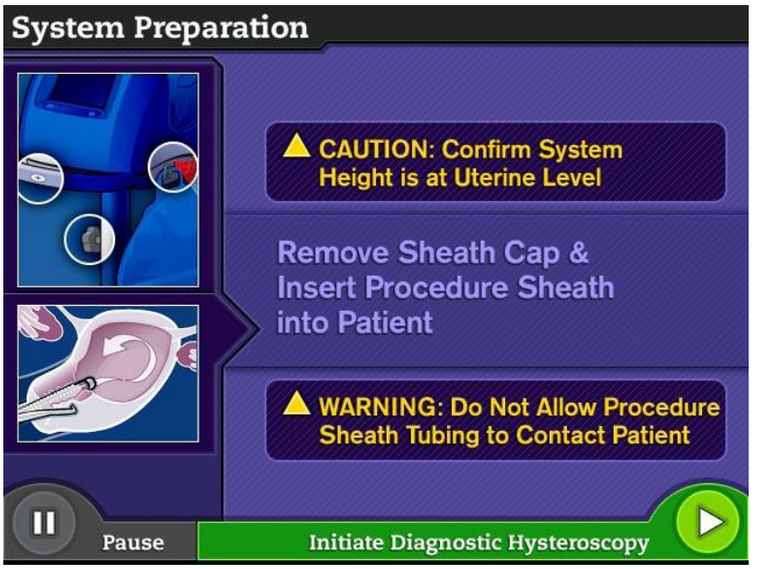
NOTE: Inspect the supply line tubing and confirm there are no kinks. Inspect the procedure set attachment points to confirm that they are fully connected and that there is no leakage.

Figure 5-6: System Preparation: Initializing and filling

Upon completion of filling, a checkmark is displayed next to the System Initializing & Filling step on the screen and the heater functionality is checked.

A chime sounds when the initialization process is complete, and Figure 5-7 is displayed while the physician finishes setting the system height and preparing the patient.

Figure 5-7: System Preparation: System Height and Procedure Sheath



5.4.2 Setting the System Height to Uterine Level

WARNING: Do not look directly into the control unit's laser aiming beam. Light from the LED may cause retinal damage.

The primary means for setting system height is by aligning the control unit handle with the patient's uterus on the procedure table. As a secondary means, the laser aiming beam emitted from the right side of the control unit assists the user with setting the height. Height can be adjusted with the following steps:

1. Unlock the pedestal's casters by pushing the caster locks up.
2. Move the Genesys HTA® System so that the aiming beam exit on the right side of the control unit is directed toward the patient's uterus on the procedure table.
3. Lock the pedestal's casters by pushing the caster locks down.
4. Grasp the control unit handle and push the laser aiming beam alignment button using one hand.
5. With the other hand, turn the height adjustment knob counter-clockwise to loosen the pedestal pole. Adjust the height of the pole until the control unit handle and laser aiming beam from the control unit are aligned with the patient's uterus.

   CAUTION: Ensure that the height of the control unit handle is no higher than the height of the patient's uterus or fluid leakage into the peritoneal cavity and vagina may occur during the procedure.
6. Turn the height adjustment knob clockwise to tighten the pedestal pole.
7. If the height of the patient table is raised or lowered during the procedure, reposition the height of the pedestal pole to ensure that the laser aiming beam remains aligned with the patient's uterus.

5.4.3 Preparing the Patient

CAUTION: Confirm that the vaginal speculum is an adequate size (width and length) to assure full separation of vaginal and vulvar tissue away from the procedure sheath, to avoid inadvertent tissue damage, and to provide 360° visibility of the cervix.

1. Expose the cervix using a vaginal speculum.
2. Attach the tenaculum.

3. Sound the uterus.
4. Carefully dilate the cervix to approximately 8 mm (24Fr.).

   WARNING: Do not over-dilate the cervix.

   CAUTION: Leave the vaginal speculum in place throughout the procedure.
5. Remove the sheath cap and gently insert the procedure sheath into the patient's cervical canal. Gently position the procedure sheath tip beyond the internal cervical os to ensure proper fluid flow.

   NOTE: The sheath cap should be retained for disposal of the procedure sheath.

   NOTE: The flushing hysteroscopy cycle may be started prior to insertion, to allow introduction of the procedure sheath under direction visualization.

   CAUTION: Care must be taken with advancement and movement of the procedure sheath to avoid uterine perforation.
6. Press the *Initiate Diagnostic Hysteroscopy* button as displayed in Figure 5-7.

5.5 Diagnostic Hysteroscopy

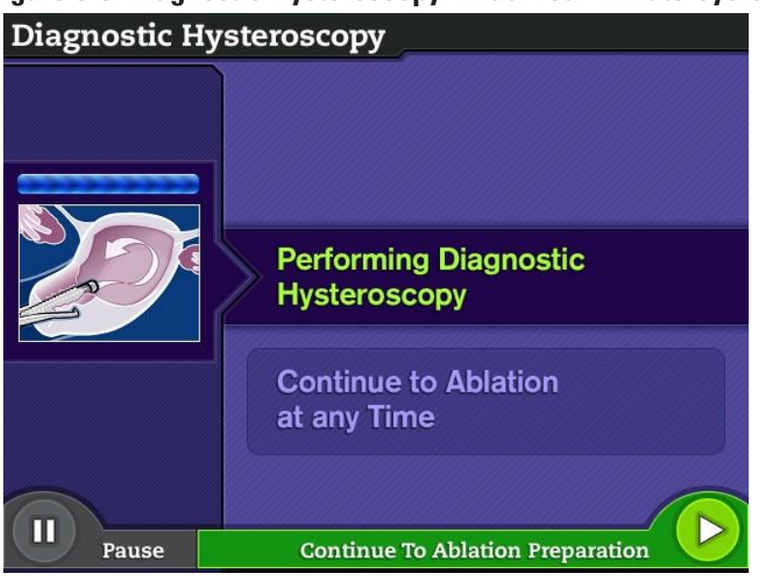
During the diagnostic hysteroscopy, the patient's uterus is flushed with room temperature saline to allow visualization for the diagnostic examination. If the *Continue To Ablation Preparation* button is not pressed during the diagnostic hysteroscopy, the system will prompt for additional time.

If the Pause button is pressed during the diagnostic hysteroscopy, the saline flush temporarily stops, and the *Confirm Cancellation/System Paused* screen, shown in Figure 5-2, is displayed. The user has the option of cancelling the procedure by pressing the *Confirm Cancel* button, or continuing the diagnostic hysteroscopy, by pressing the *Resume Procedure* button.

The following steps provide instructions for performing a diagnostic hysteroscopy.

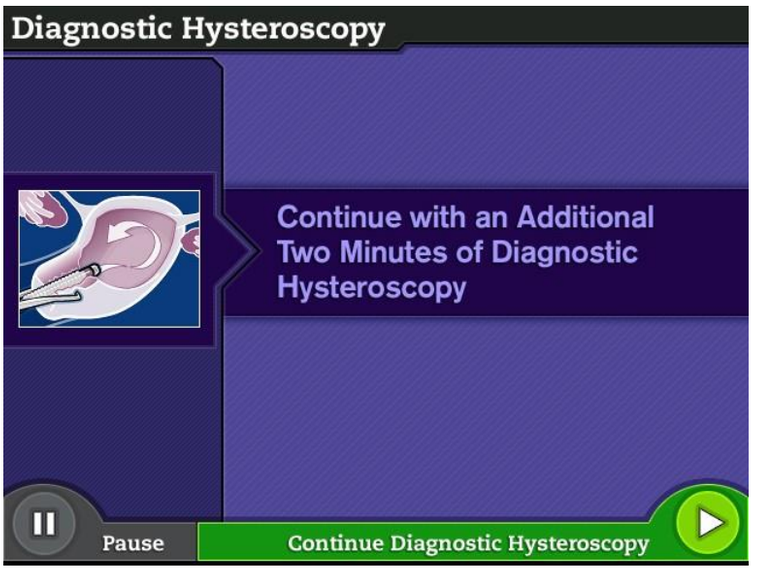
1. Room temperature saline is flushed for four minutes. Observe the uterine cavity to identify any anatomic landmarks, and confirm that no contraindicated pathology exists before proceeding. Refer to Section 2.2, *Contraindications*, for additional information.
2. To proceed to ablation at any time during the diagnostic hysteroscopy, press the *Continue To Ablation Preparation* button, shown in Figure 5-8, and continue with Section 5.6, *Ablation*.

Figure 5-8: Diagnostic Hysteroscopy: Initial four Minute Cycle



3. After four minutes of diagnostic hysteroscopy, if the *Continue To Ablation Preparation* button is not pressed, the screen in Figure 5-9 is displayed. A chime alerts the user that a button press is required to resume the diagnostic hysteroscopy.

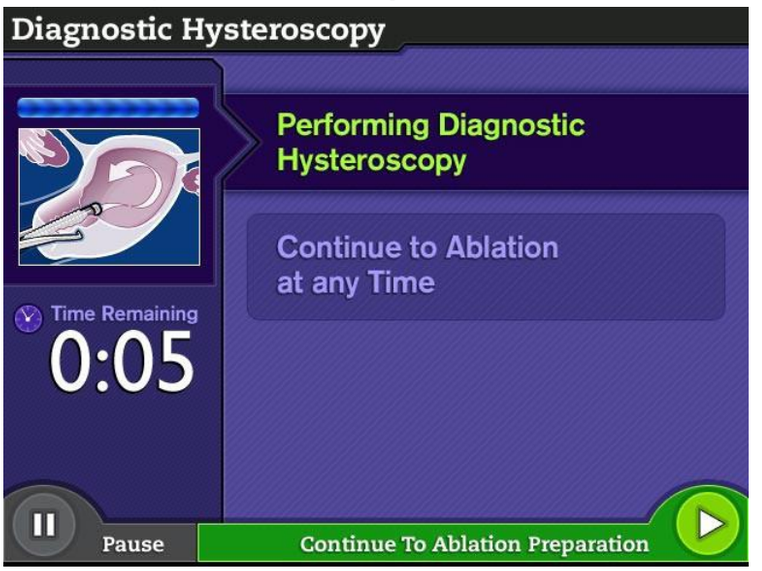
Figure 5-9: Diagnostic Hysteroscopy: Prompt for Additional Time



4. If additional diagnostic hysteroscopy time is desired, or to continue to ablation, press the *Continue Diagnostic Hysteroscopy* button. Figure 5-10 will be displayed as a chime sounds. A two-minute timer counts down the remaining time in this cycle.

   NOTE: The user may perform as many additional two-minute diagnostic hysteroscopy cycles as needed, prior to ablation.

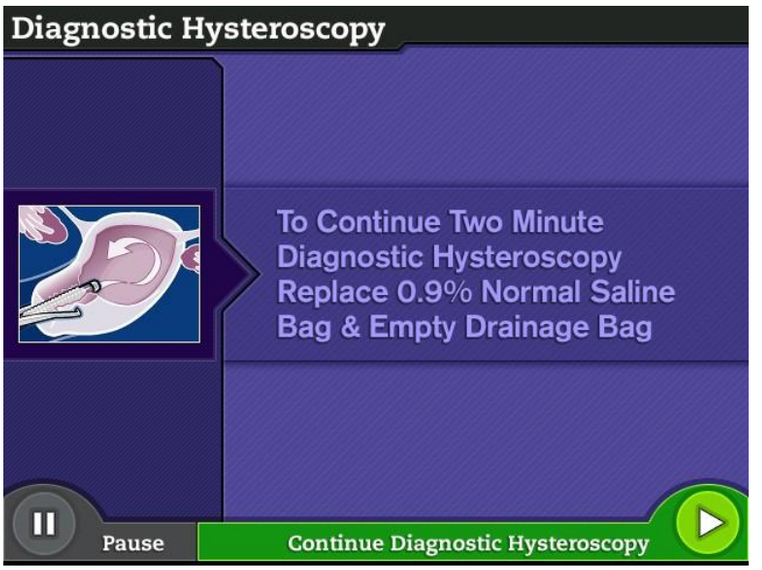
Figure 5-10: Diagnostic Hysteroscopy: Additional Two Minute Cycle



5. To move onto ablation, at any time press the *Continue To Ablation Preparation* button, and continue with Section 5.6, *Ablation*.
6. If the additional two-minute diagnostic hysteroscopy cycle completes and the *Continue To Ablation Preparation* button was not pressed, the user will be prompted to:
   A. Begin another diagnostic hysteroscopy cycle, as described in Figure 5-9 and step 4 above; or to
   B. Replace the saline bag and empty the drainage bag, as described in Figure 5-11 and steps 7 and 8 below.

      NOTE: To assure sufficient fluid for cooling, the system will prompt the user to replace the saline bag and empty the drainage bag after the first six minutes of diagnostic hysteroscopy, and then after every eight minutes. An audible tone alerts the user that action is required.

Figure 5-11: Diagnostic Hysteroscopy: Replace Saline Bag, Empty Drainage Bag



7. Replace the Saline Bag, as follows:
   A. Pinch the tubing clamp on the supply line.
   B. Detach the saline bag from the cassette's supply line tubing.
   C. Remove the used saline bag and dispose in accordance with hospital procedures.
   D. Hang a new 3L bag of 0.9% Normal Saline from the IV pole hook.
   E. Spike the saline bag.
   F. Release the tubing clamp.
8. Empty the Drainage Bag, as follows:
   A. Pinch the tubing clamp connected to the cassette's drain line.
   B. Disconnect the luer fitting from the inlet tubing.
   C. Connect the tethered luer cap to the inlet tubing on the drainage bag and close to prevent contents from spilling.

      NOTE: If hazardous fluids are spilled during removal, clean up in accordance with hospital procedures.
   D. Open the drain valve on the drainage bag and discard the contents in accordance with hospital procedures.
   E. Attach the drainage bag to the right side of the control unit by placing the rigid handle of the drainage bag onto both of the drainage bag hooks.
   F. Connect the drain line luer fitting from the cassette to the drainage bag.
   G. Release the tubing clamp.
9. Press the *Continue Diagnostic Hysteroscopy* button, as shown in Figure 5-11, to return to the screen shown in Figure 5-9 and step 4.

5.6 Ablation

WARNING: Do not place the procedure sheath tubing over the patient's leg or in contact with any part of the user's or patient's anatomy, as the tubing carries hot fluid and contact could result in thermal injury. The temperature of the tubing could be up to 55°C.

CAUTION: Prior to ablation and throughout the procedure, carefully observe the junction of the procedure sheath with the external cervical os to confirm a tight cervical seal and that there is no fluid leakage.

If heated fluid leaks onto the patient, flush the area with cool saline. It is important to assess the area in order to determine if a burn is present. If a burn is present, determine the severity and an appropriate treatment should be made per the standard of care of your facility. It is also recommended that the area be assessed again at follow-up.

5.6.1 Pausing or Stopping the Procedure

The procedure can be interrupted or terminated by the user at anytime during ablation preparation, system heating, or the ablation procedure.

If the ablation preparation screen was reached in error, or if the user wants to cancel the procedure before beginning ablation, press the *Additional Hysteroscopy* button to return to the 2-minute diagnostic hysteroscopy screen, as shown in Figure 5-9. From this screen additional cycles may be performed, or the procedure may be temporarily halted or cancelled by pressing the *Pause* button.

The *Pause* button may also be pressed during heating as shown in Figure 5-14, or ablation (Figure 5-15), to advance to the *Confirm Cancellation/System Paused* screen shown in Figure 5-2.

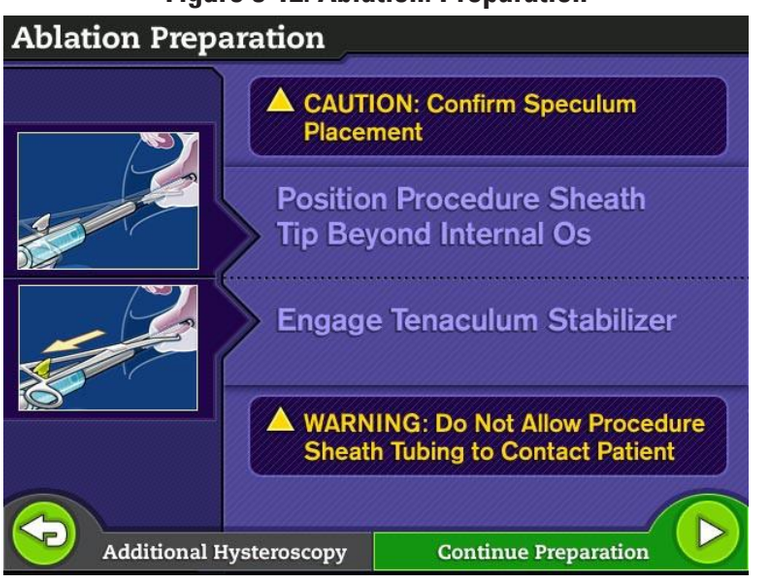
If the procedure is paused during heating or ablation, the flow of heated saline to the patient is stopped; however, heated saline continues to flow through the closed loop system. The ablation timer is also paused until the user resumes the procedure.

WARNING: Once heating has begun maintain a stable sheath position and do not remove the procedure sheath until the post-treatment cooling cycle has been completed as confirmed by the display screen, as heated fluid may cause thermal injury to the patient.

5.6.2 Ablation Preparation

When the user enters ablation preparation from diagnostic hysteroscopy, the screen in Figure 5-12 is displayed.

Figure 5-12: Ablation: Preparation



1. If not already done, gently position the procedure sheath tip beyond the internal cervical os to ensure proper fluid flow.

NOTE: To reduce air released into the uterus, position the procedure sheath so that the insulated tubing is hanging straight down.

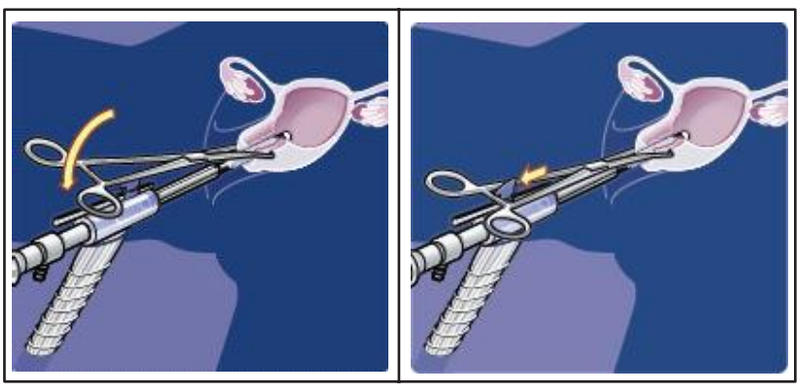
CAUTION: Care must be taken with advancement and movement of the procedure sheath to avoid uterine perforation.

2. If not previously applied, apply a tenaculum to the cervix. This will serve the dual purpose of helping maintain the correct positioning of the procedure sheath within the cervix, and providing additional sealing of the cervix around the procedure sheath.
3. Engage the tenaculum stabilizer by performing the following steps, as shown in Figure 5-13.
   A. Place a tenaculum onto the procedure sheath's tenaculum stabilizer.
   B. Slide the tab backward until it touches the "T" (ratchet) of the tenaculum. Do not push the procedure sheath forward, or engage the tab too tightly.

   NOTE: If the procedure sheath is inadvertently advanced too far beyond the internal os, release the tenaculum stabilizer and reposition the sheath. Press down and slide the tab forward to release the tenaculum. Re-engage the tenaculum in the proper position at the "T" and slide tab back to the "T".
4. Observe the junction of the procedure sheath and cervical os to confirm a tight cervical seal and no fluid leakage.

   CAUTION: Do not grasp the procedure sheath with the tenaculum as doing so may damage the procedure sheath which could result in thermal injury.

Figure 5-13: Place and Engage the Tenaculum onto the Tenaculum Stabilizer



5. Press the *Continue Preparation* button to continue to the cervical seal integrity check while the screen in Figure 5-14 is displayed.

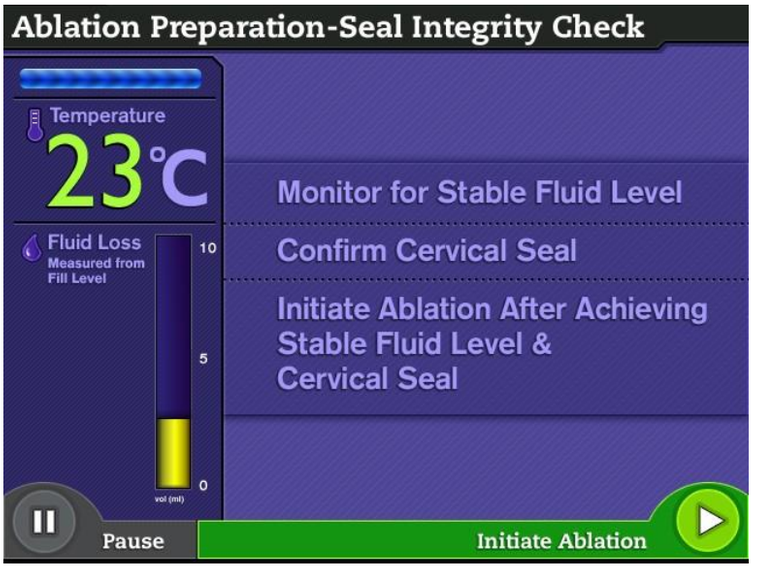
5.6.3 Seal Integrity Check

Figure 5-14 is displayed while the Genesys HTA® System circulates room temperature saline in a closed loop, initiating the integrity check of the uterine cavity and cervical seal by the user.

1. Monitor the fluid level on the screen to assure it is stable.

   CAUTION: Throughout the procedure, carefully observe the junction of the procedure sheath with the external cervical os to confirm a tight cervical seal and that there is no fluid leakage.
2. Confirm there is no fluid leakage from the cervix.
3. Press the *Initiate Ablation* button once a stable fluid level is achieved to begin heating the fluid.

Figure 5-14: Seal Integrity Check



5.6.4 Heating and Ablation

Figure 5-15 is displayed while the Genesys HTA® System heats the fluid to 80ºC. The fluid temperature and fluid loss are updated on the screen.

WARNING: Once heating has begun maintain a stable sheath position and do not remove the procedure sheath until the post-treatment cooling cycle has been completed as confirmed by the display screen, as heated fluid may cause thermal injury to the patient.

Figure 5-15: Ablation: Heating the System to Ablation Temperature

CAUTION: Throughout the procedure, carefully observe the junction of the procedure sheath with the external cervical os to confirm a tight cervical seal and that there is no fluid leakage.

When the fluid reaches 80ºC, the Genesys HTA System transitions to the screen in Figure 5-16 and chimes to indicate the start of ablation.

Figure 5-16: Ablation: Procedure

The ablation time begins at 10 minutes and the time remaining is displayed above the temperature and fluid loss readings. During ablation, the saline temperature continues to rise until 90°C is reached, and the user must continuously:

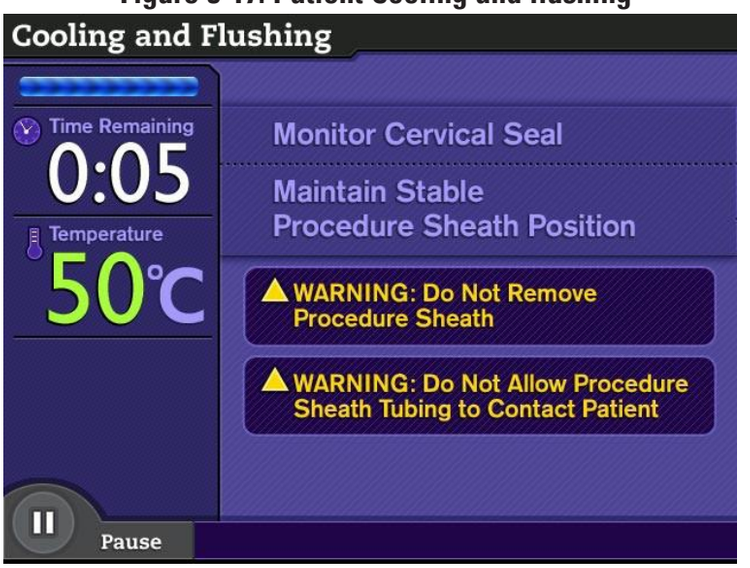
- Monitor the cervical seal for fluid loss and to confirm a tight cervical seal.
- Maintain a stable procedure sheath position throughout the procedure.
- Monitor the screen for fluid loss level.

5.7 Patient and System Cooling

When ablation is complete, the Genesys HTA® System automatically begins flushing the uterus with cool, fresh saline, and displays the screen in Figure 5-17. A 90-second countdown timer displays the time remaining in the cooling and flushing cycle and the fluid temperature in the cassette is updated. The timer stops if the procedure is paused, and continues counting down if the cycle is resumed.

WARNING: Once heating has begun DO NOT remove the procedure sheath until the post-treatment cooling cycle has been completed, as heated fluid may cause thermal injury to the patient.

Figure 5-17: Patient Cooling and flushing

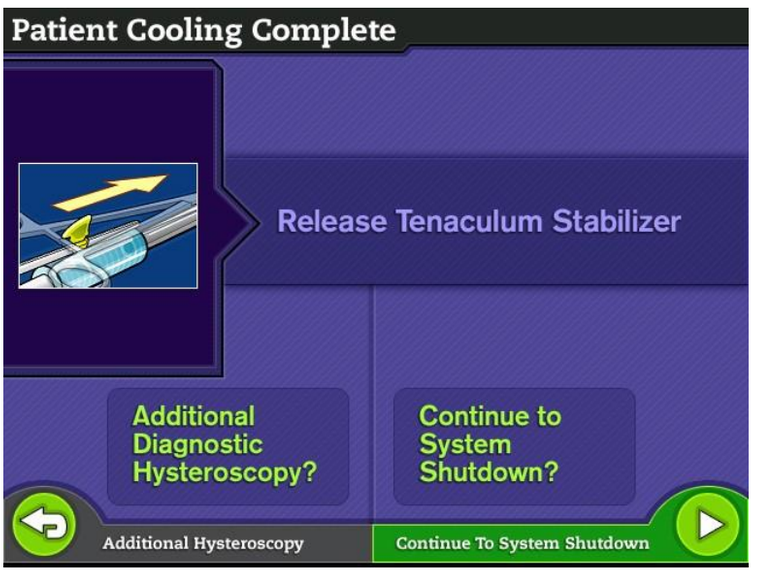


If the procedure is cancelled or if the 90-second cycle ends and the temperature is > 45°C, the system will require additional cooling before it begins to shutdown. A post ablation hysteroscopy is not allowed.

- Monitor the cervical seal for fluid loss and to confirm a tight cervical seal
- Maintain a stable procedure sheath position throughout the procedure

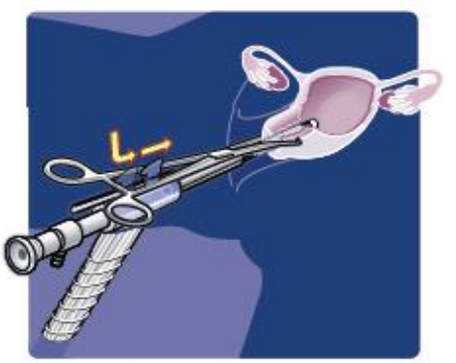
If fluid temperature is ≤ 45°C when cooling and flushing ends, a chime sounds and the screen in Figure 5-18 is displayed, providing the user with the option of performing a post ablation hysteroscopy before proceeding to shutdown.

Figure 5-18: Patient Cooling Complete



1. Release the tenaculum by pressing the tab down and sliding the tenaculum stabilizer forward to release, as illustrated in Figure 5-19.

Figure 5-19: Releasing the Tenaculum Stabilizer



2. If a post ablation hysteroscopy is desired, press the *Additional Hysteroscopy* button and continue with Section 5.8, *Post Ablation Hysteroscopy*.
3. If a post ablation hysteroscopy will not be performed, press the Continue To System Shutdown button and continue with Section 5.9, *Shutting Down the System*.

5.8 Post Ablation Hysteroscopy

If patient cooling is completed within 90 seconds, a post ablation hysteroscopy of up to 10 minutes may be selected by pressing the *Additional Hysteroscopy* button as shown in Figure 5-18, to observe the results of the ablation.

The post ablation hysteroscopy screen shown in Figure 5-20 is displayed while the 10-minute timer counts down the remaining time. If the system is paused during the post ablation hysteroscopy, the *Confirm Cancellation/System Paused* screen in Figure 5-2 is displayed and the timer on the clock stops. If the post ablation hysteroscopy is resumed, the timer continues from where it left off.

Figure 5-20: Post Ablation Hysteroscopy

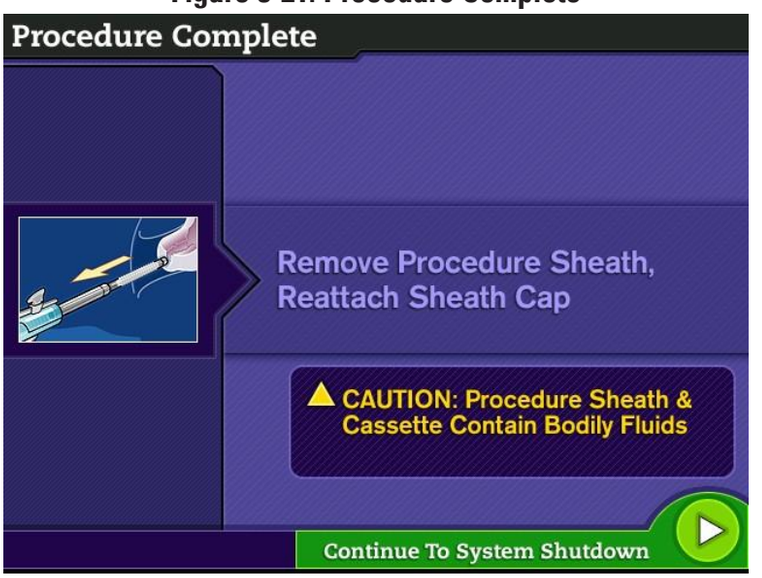
Press the *Continue To System Shutdown* button at any time to end the post ablation hysteroscopy, and continue with Section 5.9, *Shutting Down the System*.

NOTE: If the *Continue To System* Shutdown button is not selected before the ten minute diagnostic hysteroscopy completes, the system automatically ends the procedure and begins the system shutdown process.

5.9 Shutting Down the System

When the user presses the *Continue To System Shutdown* button after the ablation procedure or during the post ablation hysteroscopy, the screen in Figure 5-21 is displayed indicating that the procedure is complete.

Figure 5-21: Procedure Complete



With the completion of the procedure, the user is prompted to remove the procedure sheath and reattach the sheath cap.

1. Withdraw the procedure sheath from the cervical canal.

2. Reattach the sheath cap to the distal tip of the procedure sheath to prevent fluid from spilling.

   NOTE: If the sheath cap has inadvertently been discarded, pinch the supply line tubing clamp and the drain line tubing clamp to help contain the fluid.

3. Press the *Continue To System Shutdown* button to resume the shutdown process. The system displays the screen in Figure 5-22.

5.9.1 Disconnecting the Saline and Drainage Bags

CAUTION: Use caution when handling the fluid in the drainage bag after treatment, as the fluid at this stage may still be hot.

Figure 5-22: System Shutdown: Disconnecting the Bags

1. Clamp & remove the saline bag as follows:
   A. Pinch the tubing clamp on the supply line.
   B. Detach the saline bag from the cassette's supply line tubing.
   C. Remove the saline bag and dispose in accordance with hospital procedures.
2. Clamp, disconnect, & cap the drainage bag as follows:
   A. Pinch the tubing clamp connected to the cassette's drain line.
   B. Disconnect the luer fitting from the inlet tubing.
   C. Connect the tethered luer cap to the inlet tubing on the drainage bag and close to prevent contents from spilling.

      NOTE: If hazardous fluids are spilled during removal, clean up in accordance with hospital procedures.

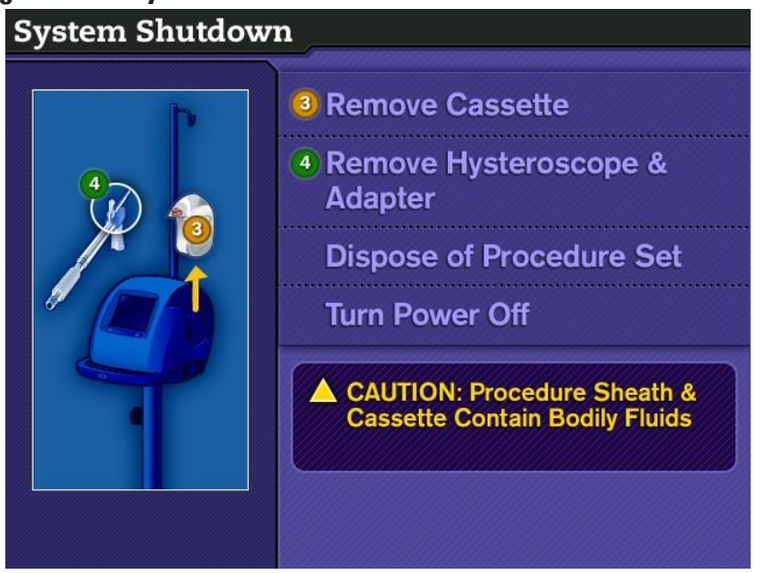
   D. Open the drain valve on the drainage bag and discard the contents in accordance with hospital procedures.
   E. Safely dispose of the drainage bag and contents in accordance with hospital procedures.
   F. Press the *Release Cassette* button, and the system will continue with the final system shutdown screen.

5.9.2 Removing the Cassette

After the *Release Cassette* button is pressed, the control unit valves retract and the screen in Figure 5-23 is displayed.

NOTE: At the end of the procedure, the disposable procedure set components may contain approximately 270 mL of fluid.

Figure 5-23: System Shutdown: Cassette Removal and Power Off



Remove the cassette from the control unit, and remove and dispose of the procedure set as instructed below:

1. Pull the cassette straight up to remove it. Ensure that the cassette is held upright and handle carefully to prevent contamination from residual fluids.
2. Remove the hysteroscope and scope adapter from the procedure sheath and route both for sterilization according to hospital procedures.
3. Dispose of the cassette and the procedure sheath according to hospital safe disposal procedures.
4. Place the power switch on the rear of the control unit to the OFF (O) position.

5.9.3 Power Disconnection

1. Confirm that the power switch is in the OFF (O) position.
2. Disconnect the Genesys HTA® System's power cord from the outlet.
3. Loop the power cord around the power cord wrap (refer to Figure 4-3) on the rear of the control unit, and ensure that it is securely in place.
4. Clean the Genesys HTA System as recommended in Section 6, *Cleaning and Maintenance*.

6 CLEANING AND MAINTENANCE

Following proper cleaning and maintenance instructions contributes to the most reliable performance of the Genesys HTA System. Instructions for proper care are provided in the sections below.

6.1 Cleaning

Clean the Genesys HTA System operational unit after each procedure to reduce the risk of cross-contamination and to optimize the system's performance.

CAUTION: Follow hospital procedures for handling contaminated fluids and disposables. Place all disposables in appropriate containers.

CAUTION: Prior to cleaning, ensure that the cassette, procedure sheath, saline bag, drainage bag, and all tubing are removed from the System, and that the power is disconnected.

1. Lightly wipe the exterior surfaces of the Genesys HTA System operational unit using a soft cloth moistened with a hospital-grade disinfectant solution.

   NOTE: Avoid using harsh or abrasive disinfectant materials.

   NOTE: Avoid using a cloth saturated with solution around electrical equipment. The soft cloth should only be slightly damp when cleaning.

2. Wipe the control unit contacts and ensure they are clean.
3. Safely dispose of all cleaning and personal protective materials in accordance with hospital procedures.

6.2 Maintenance

The Genesys HTA® System does not require any preventive maintenance or calibration; however, that does not preclude the user from performing testing per hospital procedures (i.e., electrical tests for chassis ground integrity and leakage).

The Genesys HTA System performs self-diagnostic tests when the system is turned on. In the event of a problem that cannot be resolved with onscreen instructions, refer to Section 7, Troubleshooting, for additional information.

6.3 Serviceable and Replacement Parts

The control unit contains no user serviceable parts. Contact Minerva Surgical for service. Replacement parts are available for the following:

- Pedestal
- IV pole
- Casters
- Power cord

6.3.1 Pedestal Replacement Procedure

1. Ensure that the casters on the pedestal are in the locked position, as shown in Figure 3-3.
2. Detach the control unit from the pedestal as follows:
   A. With one hand, pull the locking pin (see Figure 3-8) down.
   B. With the other hand, pull the release mechanism toward the power cord wrap (see Figure 3-8).
   C. Remove the control unit by first lifting the rear (power cord end) of the control unit from the pedestal and then disengaging the mounting nose of the control unit from the angled front lip of the pedestal mounting plate (see Figures 3-3 and 3-5).
3. Assemble the replacement pedestal per Section 3.2.1, *Pedestal Assembly*.
4. Attach the control unit to the replacement pedestal per step 3 in Section 3.2.2, Control Unit *Assembly*.

6.3.2 IV Pole Replacement Procedure

1. Ensure that the casters on the pedestal are in the locked position as shown in Figure 3-3.
2. Loosen the internal screw in the IV pole access hole underneath the control unit. Refer to Figure 3-8 for the location of the access hole.
3. Gently pull out the IV pole and replace according to steps 4 and 5 in Section 3.2.2, *Control UnitAssembly*. Reference Figures 3-7 and 3-8.

6.3.3 Caster Replacement Procedure

No tools are required to replace the casters. All replacement casters are locking. To replace:

1. Detach the control unit from the pedestal as follows:
   A. With one hand, pull the locking pin (see Figure 3-8) down.
   B. With the other hand, pull the release mechanism toward the power cord wrap (see Figure 3-8).
   C. Remove the control unit by first lifting the rear (power cord end) of the control unit from the pedestal and then disengaging the mounting nose of the control unit from the angled front lip of the pedestal mounting plate (see Figures 3-3 and 3-5).

2. Lay the pedestal on its side.
3. Pull the caster out of the base.
4. Insert a new caster into the base.
5. Stand the pedestal upright with the casters on the floor.
6. Confirm that all caster locks are pressed down to lock, as shown in Figure 3-3.
7. Reattach the control unit to the pedestal per step 3 in Section 3.2.2, *Control Unit Assembly*.

6.3.4 Power Cord Replacement Procedure

1. Unwrap the existing power cord from the power cord wrap and remove from the power cord inlet.
2. Connect the Genesys HTA® System replacement power cord to the power cord inlet (see Figure 4-3) on the rear of the Genesys HTA System control unit.
3. If the system will not be used immediately, loop the power cord around the power cord wrap until ready for use.

7 TROUBLESHOOTING

This section provides an overview of alarms, alerts and other potential system problems. Steps to facilitate problem correction are described.

7.1 System Generated Alarms

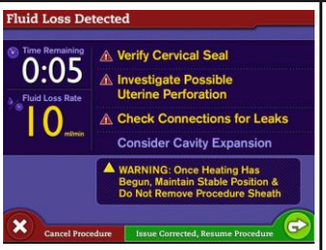
If any of the faults in Table 7-1 are detected, an alarm sounds, and a message is displayed on the screen indicating how the system is responding to the error, or what corrective actions the user may consider taking.

Table 7-1: Troubleshooting Table for System Generated Alarms

Screen Display	Description	System/User Actions
	The temperature exceeded 40°C during the Heater Test or was greater than or equal to 95°C while in Heating or Ablation. Possible Causes: • Control unit problem • Defective cassette	• This alarm screen is displayed for approximately 15 seconds as the system begins cooling. Maintain a stable sheath position, and do not remove the procedure sheath until instructed to do so by the system after cooling is complete. • Follow instructions on the display screen to shut down the system. • If appropriate, restart using a new procedure set. • If the error persists contact Minerva Surgical.

Table 7-1: Troubleshooting Table for System Generated Alarms (continued)

Screen Display	Description	System/User Actions

	A 10 mL fluid loss occurred during seal integrity check, heating or ablation. If the temperature is ≥ 50°C, the system will shut down if a third fluid loss is detected.
	Possible Causes:
	• Cervical leakage
	• Uterine perforation, internal fluid absorption, or leakage
	• Cavity expansion
	• Procedure set leakage
	• Air in the system
		• If there is cervical leakage, consider adding a second tenaculum. If cervical leakage cannot be stopped, cancel the procedure.
		• If the physician is certain that there is no perforation, internal fluid absorption, or internal leakage, then consider resuming the procedure. If a second alarm occurs, then consider cancelling the procedure.
		• In the event of:
		  • If cavity expansion – consider proceeding
		  • If procedure set leakage – correct if possible; if corrected, continue the procedure
		  • If air in the system – consider proceeding
		• To continue, press the Issue *Corrected, Resume Procedure* button.
		• To shut down the system, press the *Cancel Procedure* button and follow instructions on the display screen. Once heating has begun, maintain a stable sheath position and do not remove the procedure sheath until instructed to do so by the system after cooling is complete.

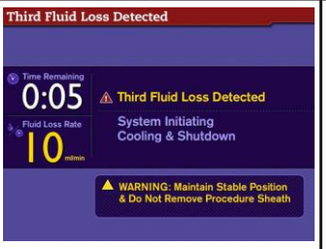
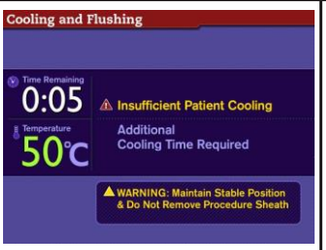
	A fluid loss has occurred for the third time after the temperature reached 50°C. For safety reasons the system will automatically shut down.	• This alarm screen is displayed for approximately 15 seconds as the system begins cooling. Maintain a stable sheath position and do not remove the procedure sheath until instructed to do so by the system after cooling is complete. • Follow instructions on the display screen to shut down the system.

Table 7-1: Troubleshooting Table for System Generated Alarms (continued)

Screen Display	Description	System/User Actions
	Additional time is required to complete cooling. For safety reasons the system will not offer a post ablation hysteroscopy. Possible Causes: • Kinked tubing • Tissue obstruction in sheath or tubing • Insufficient saline	• Adhere to the warnings on the display screen while the system is cooling. Maintain a stable sheath position, and do not remove the procedure sheath until instructed to do so by the system after cooling is complete. • When the countdown timer reaches 0:00, follow instructions on the display screen to shut down the system.

7.2 System Generated Alerts

If any of the faults in Table 7-2 are detected, an alert sounds, and a message is displayed on the screen indicating how the system is responding to the error, or what corrective actions the user may consider taking.

Table 7-2: Troubleshooting Table for System Generated Alerts

Screen Display	Description	System/User Actions
	A cassette containing hot fluid was detected during system setup. For safety reasons the system is designed to prevent the use of a fluid-filled cassette. Possible Causes: • Power failure • Accidental cancellation • Used cassette	• Press the Continue *To System Cooldown* button. Maintain a stable sheath position, and do not remove the procedure sheath until instructed to do so by the system after cooling is complete. • Follow instructions on the display screen to shut down the system. • If appropriate, restart using a new procedure set.
	A cassette containing cool fluid was detected during system setup. For safety reasons the system is designed to prevent the use of a fluid-filled cassette. Possible Causes: • Saline bag spiked during system power-up • Used cassette	• Press the *Release Cassette* button. • Follow the instructions on the display screen to shut down the system. • If appropriate, restart using a new procedure set. • When rerunning the procedure make sure not to spike the saline bag until prompted by the system after the cassette is engaged.

Table 7-2: Troubleshooting Table for System Generated Alerts (continued)

Screen Display	Description	System/User Actions
	A cassette was not detected. Possible Causes: • Cassette not pushed in completely • Control unit contacts may not be clean • Cassette defective	Follow the steps below: • Confirm that the two blue LED indicator lights are on, showing the cassette is pushed down all the way. • Press the *Issue Corrected, Resume Procedure* button. • If the error persists, remove the cassette, and confirm that there are no debris/abnormalities on the cassette connection. Reinsert the cassette and press the *Issue Corrected, Resume Procedure* button. • If the error persists, power off and restart with a new procedure set. • If the error is not resolved, press the *Cancel Procedure* button and contact Minerva Surgical.
	Fluid was not detected when the system was trying to fill. Possible Causes: • Saline bag clamp is closed • Saline bag not spiked properly • Kinked tubing	• Ensure that the saline bag clamp is open and that there is no kink in the tubing. • Ensure that the saline bag ports are pulled away from the bag and into a vertical position. • Ensure that the saline spike has sufficiently penetrated the bag port to facilitate flow. • To continue, press the *Issue Corrected, Resume Procedure* button. • If the error is not resolved, press the *Cancel Procedure* button and follow the instructions on the display screen to shut down the system. • Contact Minerva Surgical.

Table 7-2: Troubleshooting Table for System Generated Alerts (continued)

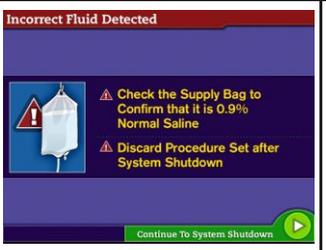
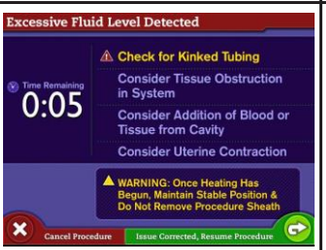
Screen Display	Description	System/User Actions
	The system detected a fluid other than 0.9% normal saline. For safety reasons the system must be shutdown and restarted with a new procedure set.	• Press the *Continue To System Shutdown* button and follow the instructions on the display screen to shut down the system. • After the system has been shut down, dispose of the procedure set, including the used supply bag. • Restart the System using a new procedure set. Confirm that the new supply bag is 0.9% normal saline.
	Fluid is not detected or is below the expected level. Possible Causes: • Kinked tubing • Fluid bag tubing clamp is closed • Saline bag is empty • Drainage bag is full	• Follow the checklist on the display screen and press the *Issue Corrected, Resume Procedure* button to continue with the procedure. • If the error persists, press the *Cancel Procedure* button and follow the instructions on the display screen to shut down the system.
	Fluid level exceeded the limit. Possible Causes: • Kinked tubing • Tissue obstruction • Addition of blood or tissue from the cavity • Uterine contraction • Foam in reservoir	• Follow the checklist on the display screen and press the *Issue Corrected, Resume Procedure* button to continue with the procedure. • The system will continue if it can adjust the fluid level. If it cannot adjust the level the *Unexpected Fluid Level* screen may also be displayed. • If the error persists, press the *Cancel Procedure* button and follow the instructions on the display screen to shut down the system. Once heating has begun, maintain a stable sheath position and do not remove the procedure sheath until instructed to do so by the system after cooling is complete.

Table 7-2: Troubleshooting Table for System Generated Alerts (continued)

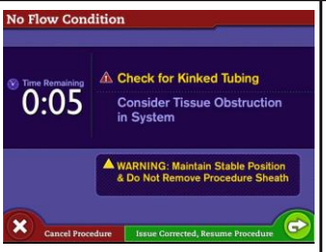
Screen Display	Description	System/User Actions
	The system detects low or no fluid flow. Possible Causes: • Kinked tubing • Tissue obstruction in sheath or tubing	• Follow the checklist on the display screen and press the *Issue Corrected, Resume Procedure* button to continue with the procedure. • If the error persists, press the *Cancel Procedure* button and follow the instructions on the display screen to shut down the system. Maintain a stable sheath position and do not remove the procedure sheath until instructed to do so by the system after cooling is complete.
	The temperature did not increase fast enough during heating, or it dropped below 70°C during ablation. Possible Causes: • Control unit problem • Defective cassette	• This alert screen is displayed for approximately 15 seconds as the system begins cooling. Once heating has begun, maintain a stable sheath position, and do not remove the procedure sheath until instructed to do so by the system after cooling is complete. • Follow instructions on the display screen to shut down the system. • If appropriate, restart using a new procedure set. • If the error persists, contact Minerva Surgical.
	A faulty cassette has been detected. For safety reasons, the system must be shut down. Possible Cause: • Invalid sensor reading, defective cassette	• Press the *Continue To System Shutdown* button, and follow the instructions on the display screen to shut down the system. The system will automatically cool the fluid if needed. Once heating has begun, maintain a stable sheath position, and do not remove the procedure sheath until instructed to do so by the system after cooling is complete. • If appropriate, restart using a new procedure set. • If the error persists, contact Minerva Surgical.

Table 7-2: Troubleshooting Table for System Generated Alerts (continued)

Screen Display	Description	System/User Actions
	A system error was detected.	• Make a note of the error code indicated on the screen. • Press the *Continue To System Shutdown* button and follow instructions on the display screen to shut down the system. Once heating has begun, maintain a stable sheath position, and do not remove the procedure sheath until instructed to do so by the system after cooling is complete. • If appropriate, restart using a new procedure set. • If the error persists, contact Minerva Surgical.

7.3 Other Potential Problems

Other Problems	Description and System/User Actions
Blank Screen	If the display screen is blank when the system is powered on or during the procedure, power off the unit and contact Minerva Surgical. Note: if this occurs during heating, ablation or cooling do not remove the procedure sheath from the patient until fluid in the uterus has cooled. It may take up to 10 minutes to ensure that fluid temperature in the uterus is below 45°C. Exercise care when handling the procedure set, because the fluid may still be hot.
Blue LED Indicators Flashing	Internal system error. Contact Minerva Surgical.
Cassette cannot be Removed	For safety reasons, a cassette can only be removed from the system during certain phases. When it is safe, the system allows the user to cancel the procedure and remove the cassette. Press the *Pause* button, then press the *Confirm Cancel* button and follow the instructions on the display screen. If the cassette cannot be removed when prompted by the system, contact Minerva Surgical.
Cassette cannot be Inserted	Ensure that cassette insertion follows prompts on the display screen. Confirm that the alignment and orientation of the cassette are correct by facing the cassette slot and positioning the cassette with the Genesys HTA logo facing away from the control unit. If the cassette cannot be inserted after multiple attempts, retry with a new procedure set. If the cassette cannot beinserted due to faulty valve position, contact Minerva Surgical.
Control Panel Button not Working	If the screen prompts the user to press a button and nothing happens, make sure that the control panel button below the display screen is being pressed, not the screen itself. If nothing happens when a control panel button is pressed, contact Minerva Surgical.
Language Error	If the display screens are in the wrong language, contact Minerva Surgical.

Other Problems	Description and System/User Actions
Laser Aiming Beam Problem	If the laser aiming beam does not produce a line when the laser aiming beam alignment button on the control unit handle is fully depressed, then use only the handle height to determine the appropriate height for the control unit. The control unit handle is the primary means for ensuring the height of the control unit is correct. The laser aiming beam is intended as a secondary method for assisting with height adjustment. Contact Minerva Surgical.
No Audible Sounds	If an audible sound is not heard at the end of system setup, or when an alarm or alert screen is displayed, contact Minerva Surgical.
Noisy Pump	An occasional pump noise is normal due to air bubbles in the cassette. In the event of severe pump noise over multiple procedures, contact Minerva Surgical.
System Cooling not Possible	If system cooling is not possible (i.e., power loss), do not remove the procedure sheath from the patient until fluid in the uterus has cooled. It may take up to 10 minutes to ensure that fluid temperature in the uterus is below 45°C. Exercise care when handling the procedure set, because the fluid may still be hot.
System does not Turn On	If the power switch is in the On position, and the system does not turn on, verify that the power cord is plugged into the control unit and the appropriate wall outlet. If the system remains off, then contact Minerva Surgical.

8 SERVICE AND WARRANTY

Limited Warranty

Minerva Surgical, Inc. warrants that reasonable care has been used in the design and manufacture of the Genesys HTA® System Operational Unit. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of lawor otherwise, including, but not limited to, any implied warranties of merchantability or fitness fora particular purpose.** Handling and storage of the Genesys HTA Operational Unit as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Minerva Surgical's control may directly affect the Genesys HTA Operational Unit and results obtained from it. Minerva Surgical shall repair or replace, at its option, any part of the Genesys HTA Operational Unit that Minerva Surgical determines is caused by defects in material and workmanship if notice thereof is received within one year plus a 7-day grace period from the date of shipment. Minerva Surgical shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of the Genesys HTA Operational Unit. Minerva Surgical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the Genesys HTA Operational Unit. Buyer shall be responsible for the ongoing support and maintenance of the Genesys HTA Operational Unit not covered by this original one-year manufacturing warranty and after the one-year warranty period has expired. Buyer may, at its sole cost and expense, purchase an extended warranty (CORECare Warranty Agreement) from Minerva Surgical to extended term of this warranty.

Minerva Surgical warrants that reasonable care has been used in the design and manufacture of the Genesys HTA ProCerva® Procedure Set. **This warranty is in lieu of and excludesall other of warranties not expressly set forth herein, whether express or implied by operationof law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling and storage of the procedure set as well as other factorsrelating

to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Minerva Surgical's control directly affect the instrument and the results obtained from its use. Minerva Surgical's obligation under this warranty is limited to the repair or replacement of this instrument and Minerva Surgical shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. Minerva Surgical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Minerva Surgical assumes no liability with respect to procedure sets reused, reprocessed or resterilized and makes no warranties whether express or implied by operation of law or otherwise, including, but not limitedto, any implied warranties of merchantability or fitness for a particular purpose, with respect to such instruments.**

Obtaining warranty service from Minerva Surgical

Contact the Customer Service Department at Minerva Surgical at 855-646-7874 to report any problem with the Genesys HTA® System Operational Unit and obtain a Return Authorization Number, if required. Minerva Surgical will ship a replacement unit using ground shipping. Customer may elect to pay for expedited shipping.

The Genesys HTA System Operational Unit must be returned to Minerva Surgical within 30-days from the date of receipt of the replacement unit or Customer will be invoiced for the prevailing standard replacement cost of the Genesys HTA System Operational Unit. The replacement unit will be covered by the remaining portion of the original term of this warranty which is one year plus a 7-day grace period from the date of shipment of the original unit. If Minerva Surgical determines that the damage to the original unit was not due to a manufacturing defect then customer will be invoiced for the repair of the unit which shall not exceed the prevailing standard replacement charge. All shipments to Minerva Surgical must be safely and securely packaged, preferably in the original shipping carton, and should include the pre-paid shipping label provided with the replacement unit, and a letter explaining the problem and making reference to the Return Authorization Number.

9 APPENDIX: ELECTROMAGNETIC COMPATIBILITY (EMC) REQUIREMENTS

Table 9-1: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration-electromagnetic emissions</th></tr>
<tr><td colspan="3">The Genesys HTA® System is intended for use in the electromagnetic environment specified below. The customer or the user of the Genesys HTA System should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPER 11</td><td>Group 1</td><td>The Genesys HTA System uses Radio Frequency (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.</td></tr>
<tr><td>RF emissions
CISPER 11</td><td>Class B</td><td rowspan="3">The Genesys HTA System is suitable for use in all establishments, including domestic establishmentsand those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Table 9-2: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and manufacturer's declaration-electromagnetic immunity			
The Genesys HTA® System is intended for use in the electromagnetic environment specified below. The customer or the user of the Genesys HTA 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	± 6 kV contact ± 8 k/V air	± 6 kV contact ± 8 k/V air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	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 (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5 % U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user ofthe Genesys HTA System requires continued operation during power mains interruptions, it is recommended that the GenesysHTA System be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical locationin a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Table 9-3: Guidance and Manufacturer's Declaration - Electromagnetic Immunity, cont.

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration-electromagnetic immunity</td></tr>
<tr><td colspan="4">The Genesys HTA® System is intended for use in the electromagnetic environment specified below. The customer or the user of the Genesys HTA System should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment-guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 Vrms</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the Genesys HTA System, including cables, than the recommendedseparation distance calculated from theequation applicable to the frequency ofthe transmitter.
Recommended separation distance
$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturerand d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters,as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</td></tr>
<tr><td colspan="4">NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">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 Genesys HTA System is used exceedsthe applicable RF compliance level above, the Genesys HTA System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Genesys HTA System.
b) Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.</td></tr>
</table>

Table 9-4: Recommended separation distances between portable and mobile Rf communications equipment and the Genesys HTA® System

Recommended separation distances between portable and mobile RF communications equipment and the Genesys HTA System			
The Genesys HTA® System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Genesys HTA System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Genesys HTA 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 $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.7	11.7	23.3
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 of the transmitter in watts (W) according to the manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Legal Manufacturer

Manufactured for:
Minerva Surgical, Inc.
4255 Burton Drive,
Santa Clara, CA 95054 USA
Customer Service 855-646-7874

Recyclable Package

Do not use if package is damaged.

L0131 Rev. A