User's Manual
LuViva® Advanced Cervical Scan
Model Number 13500

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1. Introduction

1.1 About this Manual

This instruction manual has been prepared by Guided Therapeutics, Inc. for operators of the LuViva® Advanced Cervical Scan. This manual provides basic instructions for use and troubleshooting procedures. To ensure safe operation of this product, the operator must read the entire instruction manual before operating the device. This manual is available in the help menu. A copy is also available online at www.guidedinc.com.

1.2 LuViva® Advanced Cervical Scan Description

LuViva is a point-of-care device that uses a combination of fluorescence and reflectance spectroscopy to scan the entire ecto-cervix. LuViva is intended for use prior to colposcopy, or indicated follow-up or recall procedure, by a trained healthcare professional, (e.g. physician, nurse practitioner, physician's assistant, nurse, or others who are trained to place a speculum in a patient) to triage the disease state of women with abnormal Pap results or other risk factors associated with cervical disease, such as positive HPV results or previous dysplasia to detect moderate to high-grade dysplasia (i.e. CIN2 or worse). A positive result from LuViva indicates that further evaluation is warranted as indicated by the current standard of care. A negative result from LuViva indicates that a further evaluation is not warranted and the woman may return to routine screening as indicated by the current standard of care.

LuViva consists of two major components—a Hand Held Unit (HHU) and a Base Unit (BU). The HHU is attached to the BU with a cable that contains power, computer data and fiber optic cables. The cable is considered to be a part of the HHU. During the procedure the HHU is used by the operator in combination with a single-use Cervical Guide (CG). The CG serves as the patient interface, provides a patient/instrument barrier, sets the optical distance and helps exclude room light from interfering with the measurement. The CG also includes a removable reference target that is used to calibrate LuViva before each measurement.

2. Device Description

LuViva consists of two subsystems or units. A Hand Held Unit (HHU) and a Base Unit (BU). The HHU has an umbilical cable that connects to the BU, provides power, data and fiber optic elements. This umbilical is considered to be a part of the HHU. The HHU is used by the clinician in combination with a single use Cervical Guide (CG) during a patient examination. The CG serves as a patient instrument barrier, sets the optical distance and helps exclude room light from entering the measurement. The CG also includes a removable reference target that is used to normalize the device output prior to each measurement.

2.1 Components of the LuViva Advanced Cervical Scan System

LuViva Advanced Cervical Scan System (LuViva) arrives in a single container. Some assembly is required prior to use. The LuViva includes the following components:

1. LuViva Cart with locking wheels
2. Hand-Held Unit (attached to base unit with cable – enclosed in protective packaging)
3. Monitor Arm (separate box)
4. Monitor (separate box)
5. LuViva® Cervical Guides (separate box)
6. Installation and Product documentation
    a. Unpacking and Assembly instructions
    b. USB Thumb drive
7. Service Kit (separate box)
8. Power cord (not included, supplied by distributor)

2.2 Components

2.2.1 Cart

2.2.1.1 Wheels

The LuViva has four (4) wheels. All wheels are lockable.

2.2.1.2 Handle

The handle that surrounds the Base Unit allows for LuViva to be moved from room to room, or positioned as needed in the examination room.

2.2.2 Docking Station

The Docking Station is the storage station for the HHU.

2.2.3 Base Unit

The Base Unit is the under the Base Unit Cover. It contains the majority of the electrical equipment. It contains a computer system with LuViva software, the light source and most of the electronics and the hardware necessary to conduct a diagnostic test.

2.2.4 Main Power Switch on Base Unit

The Main Power Switch is used to enable the power to be turned on using the Stand-by Power Switch above on LuViva. LuViva cannot be turned on with the Stand-by Power Switch if the Main Power Switch is not also turned on.

2.2.5 Monitor

The touchscreen allows the operator to progress through a LuViva diagnostic test, to display the result, to access the Help system, and to turn off LuViva after use.

2.2.6 Hand Held Unit

The Hand Held contains the camera, lenses and hardware needed to capture images of the cervix for the LuViva diagnostic test. It has a single activation button in the handle that can be used to advance through the test. It has a touchpad for screen navigation.

2.2.7 LuViva Stand-by Power Switch on HHU

Turn On

The Stand-by Power Switch is used to turn on LuViva. Press and release the Stand-by Power Switch to turn on LuViva.

Turn Off

Typically, the LuViva software is used to turn off LuViva; however, the main power switch may also be used to turn off the LuViva in an emergency. Press and hold the main power switch for ten seconds to turn off LuViva.

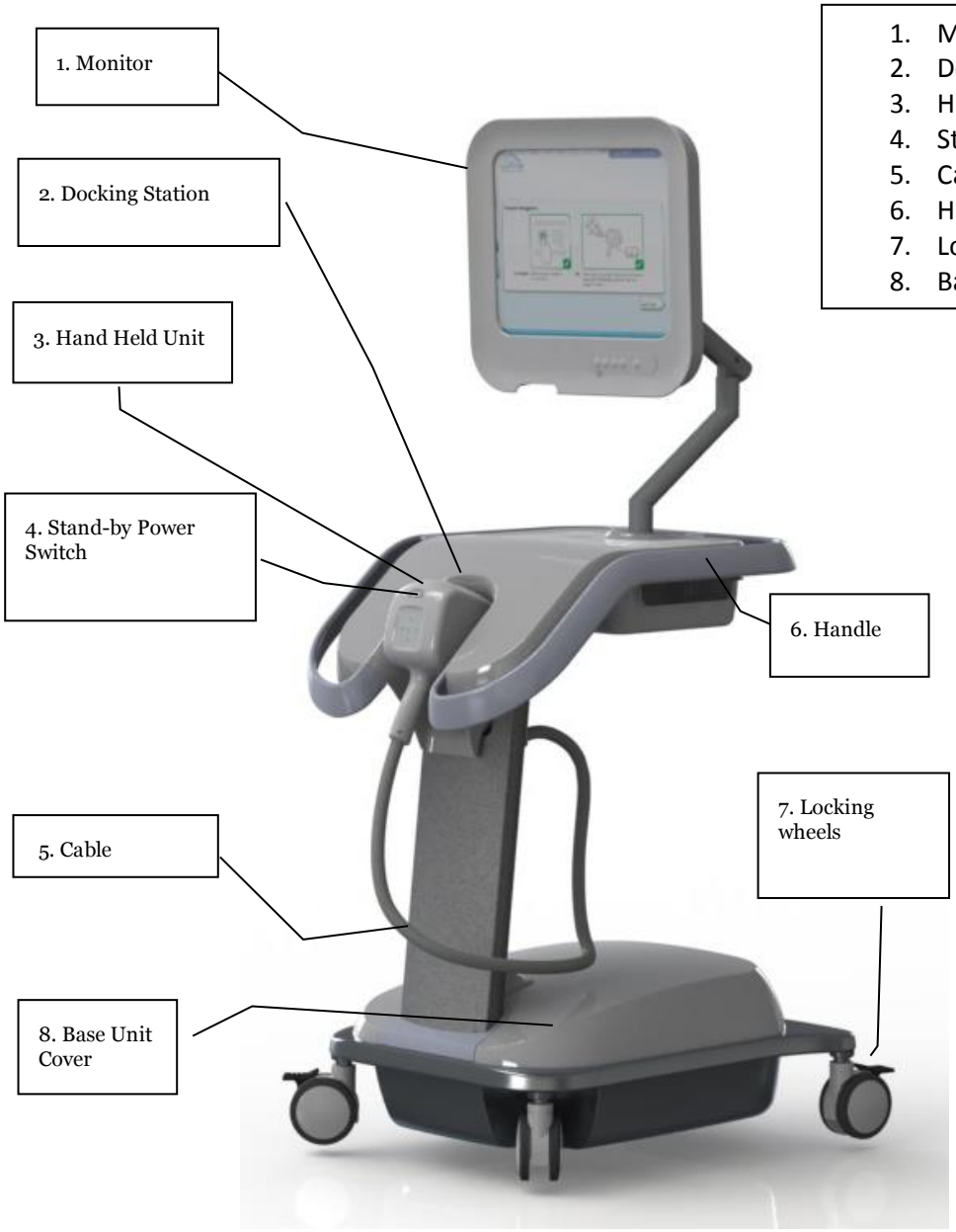
2.2.8 Cable

The cable connects the Hand Held Unit to the Base Unit, and provides the pathways for light and electrical communications between the electronics in both the units. It is tethered to the front column of the Cart.

2.3 Accessory: CG (Cervical Guide)

The CG is attached to the front of the Hand Held Unit in order to conduct a diagnostic test. It is a non-sterile Type B Applied Part accessory to the LuViva device. It is a single-use disposable that is immediately discarded after use. The Calibration Cap provides an internal target used to provide a reference measurement to LuViva. The Cap is removed as part of the test sequence.

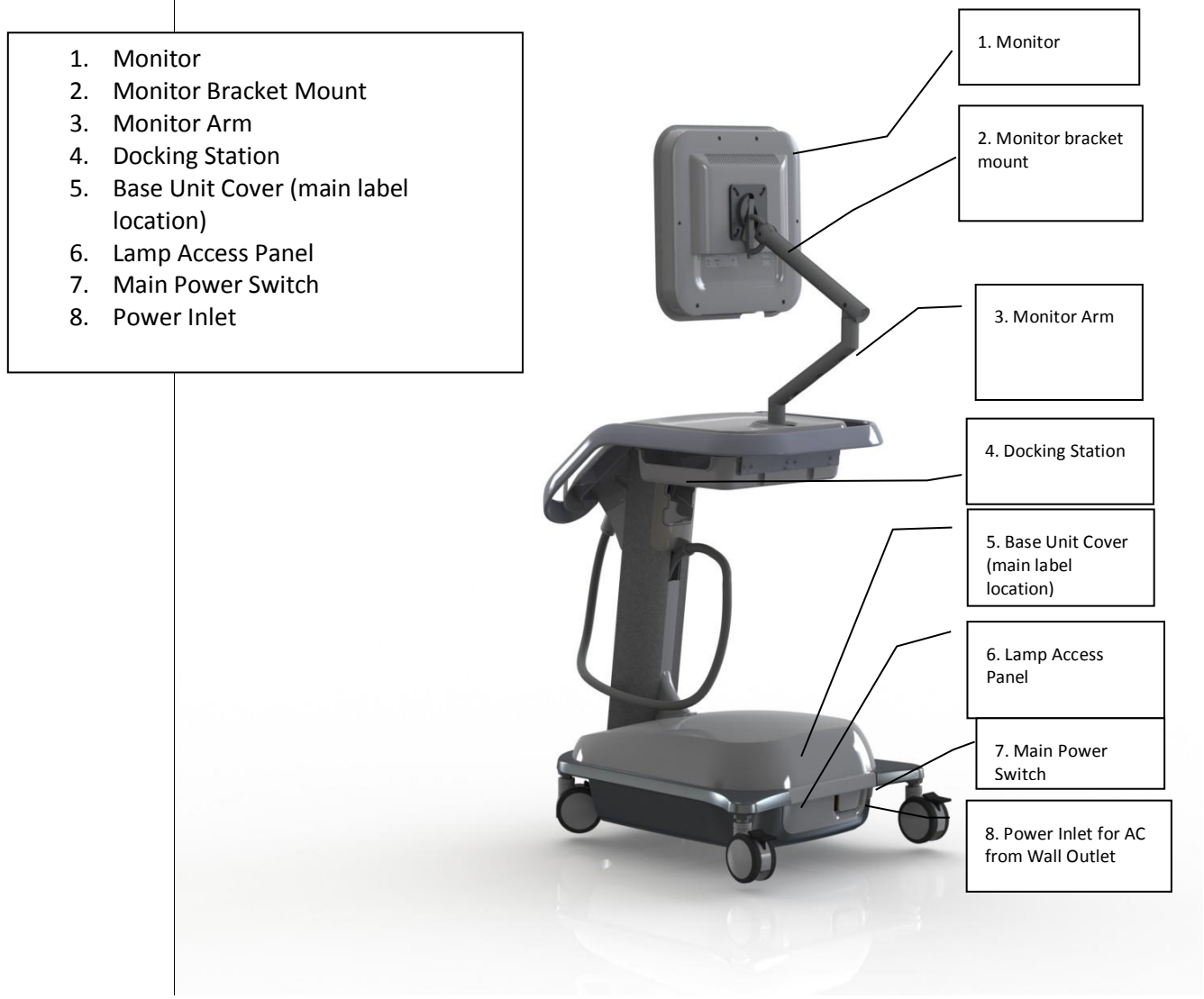
2.4 Side View of LuViva



1. Monitor
2. Docking Station
3. Hand Held Unit
4. Stand-by Power Switch
5. Cable
6. Handle
7. Locking Wheels
8. Base Unit Cover

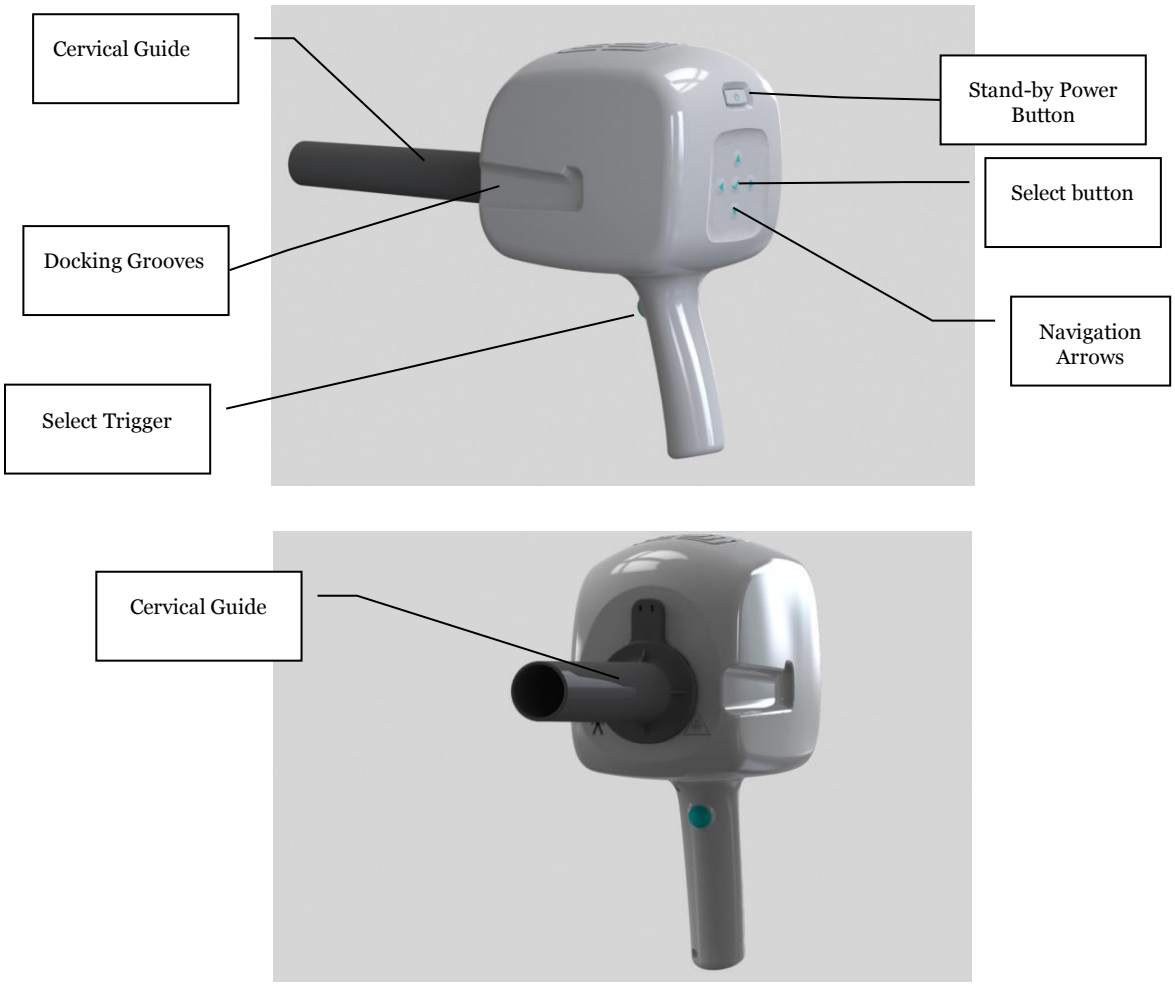
2.5 Back View of LuViva

1. Monitor
2. Monitor Bracket Mount
3. Monitor Arm
4. Docking Station
5. Base Unit Cover (main label location)
6. Lamp Access Panel
7. Main Power Switch
8. Power Inlet



2.6 Accessory: CG (Cervical Guide)

The CG is attached to the front of the Hand Held Unit in order to conduct a diagnostic test. See below.



3. Safety Information-Warnings, Cautions and Symbols

This section contains information regarding Warnings, Cautions and Safety Symbols for LuViva. Review these warnings carefully so that both you and your patients will be safe when using LuViva.

3.1 Notations

Throughout this manual there are texts in differing formats. These texts are warnings, cautions, notes and technique tips and they are used as follows:

> ⚠ **WARNING: A WARNING describes serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.**

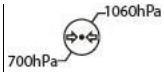
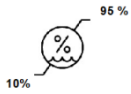
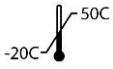
CAUTION: A CAUTION is information regarding any special care to be exercised by the operator and/or patient for the safe and effective use of the device. It indicates possibility for damage to the device.

NOTE: A NOTE provides important general information that will help you make better use of your LuViva.

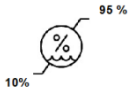
TECHNIQUE TIP: A TECHNIQUE TIP indicates important specific information that will help you make better use of your LuViva.

3.2 Explanation of Safety Symbols found on LuViva

Symbol	Description	Symbol	Description
	Caution, Consult Documentation		Type B Applied Part
	Dangerous Voltage		Ultraviolet Radiation
	Hot Surface		Non-Ionizing Radiation
	Catalogue Number		Explosion Hazard
	Manufacturer		Protective earth terminal
	Filter Changing		Electronic Waste
	Consult Accompanying Documents		Do Not Reuse

Symbol	Description	Symbol	Description
	Stand-by		Lot Number
	Date of Manufacture		Use By (Expiration Date)
	Serial Number		Fragile; handle with care
	This Way Up		Atmospheric Pressure Limitation
	Humidity Limitation		Temperature Limitation
	On/Off Power		European Representative
	Recycle CB		Always Wear Eye Protection
	Keep Dry	 LDPE	Recycle LDPE
	Do not Stack		Do Not Clamp
	SGS Certification Mark		Recycle other
	CE Mark		Federal Communications Commission

3.3 Explanation of CG Safety Information found on Cervical Guide (CG) Packaging

Symbol/Caution	Explanation
Investigational device	Limited by Federal (or United States) law to investigational use.
Use with other devices	This device is intended for use with a speculum and LuViva during a gynecological exam.
	CAUTION: Read LuViva User's Manual and Instructions for Use
	Do Not Reuse—Single -use only ***RISK OF CROSS-CONTAMINATION***
	Type B Applied Part
	Reference Number
	Lot Number
	Use By Date—CG has a shelf life. Do Not Use if CG is beyond its expiration date.
	Date of Manufacture
	Manufacturer
	Humidity limitation
	Temperature limitation
	Recycle ABS
	Controlled Temperature limitation
 **Only**	For Prescription Only
 **0473**	CE Mark

3.4 Explanation of Indicators

The HHU Stand-by button incorporates light emitting diodes (LEDs).

The LEDs indicate the following:

Green - system ready

Green flashing- on but not ready

Yellow - view display for message

Yellow flashing - system error; restart required or in process

3.5 Warnings, Cautions and Notes

3.5.1 LuViva Diagnostic Use Warnings

WARNING: LuViva is not intended to replace primary screening tests such as the Pap smear/test.

WARNING: The LuViva device should not be used in patients with Pap results with high risk for severe dysplasia/dyskaryosis.

WARNING: LuViva should only be operated by healthcare professionals.

WARNING: LuViva is not intended for use as a colposcope.

WARNING: Do not pinch vaginal or cervical tissue between the edges of the speculum blades and the cervical guide. Patient injury may occur.

WARNING: Support the HHU in accordance with instructions. Motion during use may cause misdiagnosis of and injury to the patient.

3.5.2 Frequency of Use—Number of Tests per Day

WARNING: LuViva should not be used on a single patient for more than three LuViva scans per 24 hour period.

3.5.3 Operator Use Cautions

WARNING: LuViva is not intended for use in areas where gaseous anesthesia, oxygen or nitrous oxide is used. Due to the nature of the light source, an explosion may result.

CAUTION: Lock the wheels after positioning in the exam room, prior to use on a patient.

CAUTION: LuViva results depend upon the os of the cervix remaining in the field of view during the test. Movement by the patient may cause misdiagnosis. If patient moves, test should be repeated.

CAUTION: Instruct the patient to be as still as possible to minimize potential injury during the test.

CAUTION: Use handle of HHU to place HHU into Docking Station to avoid pinching or crushing fingers between the HHU and the cradle.

CAUTION: Always wear gloves and use sterile field methods when using LuViva to protect the operator and patient from potential cross-contamination.

NOTE: Ensure the Calibration Cap is fully seated on Cervical Guide before beginning calibration. Do not remove or discard the Calibration Cap until calibration has completed.

NOTE: The results for the patient are NOT saved on LuViva. To save results, use "Save Report" feature.

3.5.5 Cervical Guide Cautions

CAUTION: To prevent contamination, handle the CG with gloves to maintain cleanliness. Do not touch non-disinfected surfaces with CG.

CAUTION: The CG is a single-use disposable. The CG is non-sterile and cannot be sterilized by the operator. Do not clean and reuse. Reuse carries a high risk of cross-contamination and cross-infection of patients.

CAUTION: Dispose of the CG as medical waste. Improper disposal could result in exposure of an unprotected person to bio-contamination.

CAUTION: The CG has an expiration date. Check the CG packaging to ensure the CG has not expired prior to use.

CAUTION: The CG must not be used if the packaging has been damaged.

NOTE: Confirm the compatibility of specula before using with LuViva Cervical Guides.

3.5.6 Lamp Warnings

WARNING: INTENSE LIGHT HAZARD. Do not operate LuViva without the Base Unit Cover in place.

WARNING: The light source for LuViva is a Xenon Arc Lamp that creates Visible and UV Radiation. Improper use of LuViva may result in inadvertent exposure to UV light. Always use LuViva with a LuViva Cervical Guide (CG). Do not look into the CG while operating.

WARNING: Always wear eye protection when handling lamp.

WARNING: The lamp remains at high temperatures during and after operation. Do not let any part of the heated lamp come in contact with your skin. The heated lamp will cause burns. Allow the lamp to cool for one hour before replacing it.

WARNING: The maintenance functions of replacing the lamp or replacing the filter should not be performed while a patient is in the room. The operator shall not touch an accessible part and a patient simultaneously.

CAUTION: Wear long sleeves, gloves and face shield while installing the lamp in LuViva.

CAUTION: Contents of the lamp are under pressure and may explode if dropped, jarred, scratched or exposed to excessive force. Injury may result if the lamp is broken.

CAUTION: Do not touch the lamp with bare hands. Dust, oils and grime will be transmitted to the lamp, and during use may cause the lamp to explode.

CAUTION: Lamp must be replaced after 1000 hours of use.

NOTE: See Performance Characteristics Section for description of optical radiation emitted.

3.5.7 Cleaning and Disinfection

CAUTION: LuViva requires cleaning and disinfection between patients, as specified in this manual, to prevent operator-to-patient, and patient-to-patient contamination and cross-contamination.

CAUTION: During cleaning and disinfection, wear personal protective equipment such as eye wear, moisture resistant clothing and chemical resistant gloves so that you are not exposed to chemical disinfectants and potentially infectious patient debris. Wear appropriate personal protective equipment. Always dispose of contaminated personal protective equipment as medical waste.

CAUTION: Do not spray cleaning and disinfectant solutions directly into the rear and sides of the monitor, where the vent holes are located.

CAUTION: Use of cleaners other than those specified in Section 11 will void the warranty.

CAUTION: Guided Therapeutics has performed cleaning validation and disinfection validation only for the class of cleaning agents and disinfectants listed in the procedure.

CAUTION: If the HHU Window is not cleaned thoroughly and completely (with no debris or streaking), LuViva will not be able to accurately determine the disease state of the patient.

3.5.8 Electrical Safety

WARNING: No modification of this equipment is allowed. Modifications of the unit will void the warranty and may expose operators and patients to serious injury.

CAUTION: To avoid the risk of electrical shock, this equipment must only be connected to a Supply Mains with protective earth (grounded wall outlet).Improperly powering LuViva may result in damage to LuViva and substantial risks of electric shock to the operator or patient.

CAUTION: Risk of Electrical shock. Disconnect main power before replacing the lamp assembly or air filter.

CAUTION: Risk of Electrical Shock. No user-serviceable parts inside. Only components listed as "Replacement Parts" are replaceable by operator or service personnel. Refer servicing to qualified personnel.

CAUTION: Position LuViva so it may be unplugged.

CAUTION: Equipment not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.

CAUTION: Do not load non-LuViva software onto the computer as it could interfere with the proper operation of the system and will void the warranty.

CAUTION: LuViva is not to be used as a personal computer.

CAUTION: Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. (See Section 16: EMC Information: Guidance and Manufacturer's Declarations)

CAUTION: Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

CAUTION: LuViva must not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, LuViva should be observed to verify normal operation in the configuration in which it will be used.

CAUTION: Use of accessories and cables other than those specified, with exception of parts sold by Guided Therapeutics, Inc. or their approved distributors as replacements for internal components, may result in increased emissions or decreased immunity of LuViva.

CAUTION: LuViva may be interfered with by other equipment, even if that other equipment complies with Comité International Spécial des Perturbations Radioélectriques (CISPR) emission requirements.

CAUTION: Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "HOSPITAL ONLY" or "HOSPITAL GRADE."

3.5.4 Mechanical and Ingress

CAUTION: The LuViva handle is designed to roll and push LuViva. The handle may be used to lift LuViva out of the shipping container and to move over thresholds.

CAUTION: LuViva has not been sealed against fluid intrusion. LuViva may be permanently damaged if it is directly sprayed with cleaning solutions. If there is fluid intrusion of any kind, do not use LuViva; call for service. This includes all components of LuViva. Electrical burns or injuries may occur to the Operator. Intrusion of water or cleaning solutions is not allowed for any part of LuViva and will void warranty.

CAUTION: Do not insert fingers or objects into any part of LuViva. Injury may result.

CAUTION: The monitor for LuViva is designed for routine medical use. Damage to the monitor from excessive force may occur, and will impair the ability of LuViva to perform diagnostic tests correctly.

CAUTION: Dropping the HHU onto the floor may result in permanent damage to LuViva and void the warranty. If dropped, discard CG and clean HHU and umbilical cable. Restart LuViva and check for error messages before reuse.

CAUTION: Dropping or tipping LuViva may result in permanent damage and void the warranty. If damage occurs, contact Customer Service for further instructions (770) 242-8723.

4. Intended Use and Indications for Use

4.1 Intended User

LuViva is to be operated by a qualified healthcare professional, (e.g. physician, nurse practitioner, physician's assistant, nurse, or others who are trained to place a speculum in a patient) at the direction of a physician or when indicated by the current standard of care.

4.2 Intended Use

The intended use population consists of women aged 16 and above who are referred to follow-up because of abnormal Pap results, positive HPV results or other risk factors associated with cervical cancer, such as previous dysplasia.

4.3 Indications for Use

LuViva is indicated for use as a triage test for women at risk for cervical cancer based on current cervical cancer screening guidelines, in order to provide the physician with additional information regarding the likelihood of CIN2+ disease. The LuViva device is not indicated for use as a primary screening test for cervical cancer or precancer.

4.3.1 Cytology

For a LuViva result to be valid, a cytology result must be available from cells collected no greater than 120 days prior to the LuViva scan.

"Test Results Not Available" is utilized when the patients' referral cytology result is not immediately available or Pap test is being performed on the same day as the LuViva Advanced Cervical Scan. This selection shown on the Referral Criteria input screen will provide the healthcare professional with a LuViva Advanced Cervical Scan result for all available cytology inputs, so that the LuViva Advanced Cervical Scan result may be compared with the same day Pap test result.

4.4 Contraindications

Contraindications consist of, but are not limited to:

- Pregnancy
- Menstruating on the day of the LuViva test
- Radiation therapy to the patient's genitourinary system within 1 year
- Prior hysterectomy
- Congenital anatomical cervical variant (e.g., double cervix)
- Friable cervix at the time of the exam (i.e., a cervix that bleeds easily upon minimal contact or trauma)
- Post-coital or other significant bleeding at the time of the exam
- Excessive cervical mucus or discharge that cannot be removed and is significant enough, in the opinion of the operator, to interfere with a Pap test or colposcopy, resulting from inflammatory, bacterial or other sources
- History of any photosensitizing disease or other disease affected by ultra-violet radiation, (e.g., porphyria, Lupus Erythematosus).
- Undergoing phototherapy
- Recent use of photosensitizing agents, such as fluoroquinolones or retinoids.
- Referral test results that indicate risk of severe dysplasia, such as an HSIL cytology result

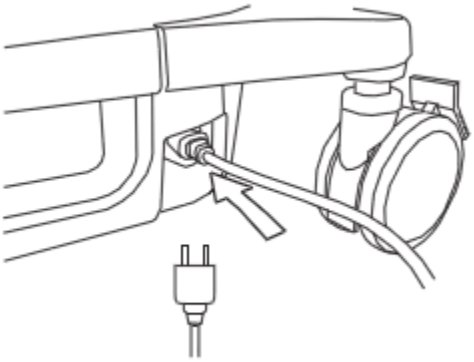
⚠ **WARNING: If the patient has any of these contraindications do not use LuViva. Use of LuViva may cause injury to the patient.**

4.5 Side Effects

LuViva has no known Side Effects.

5. Start-Up and Configuring LuViva

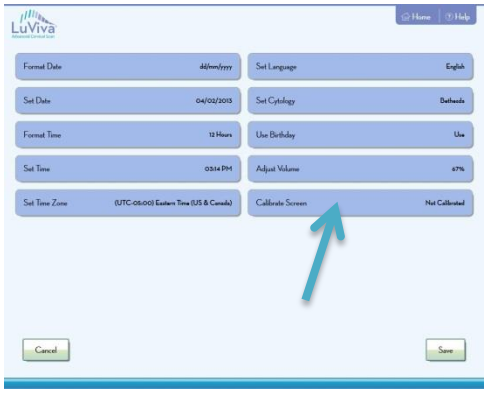
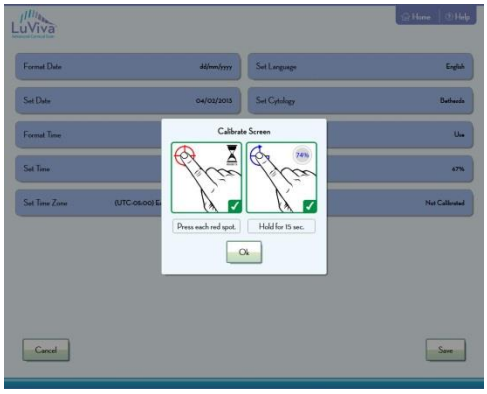
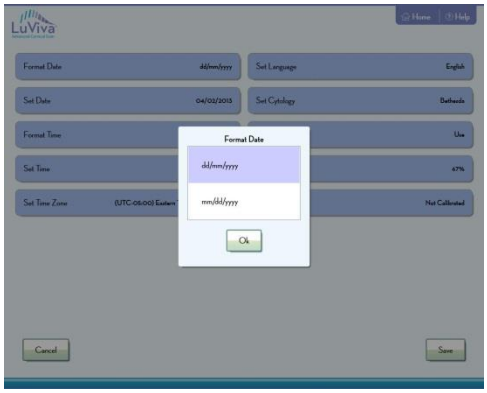
5.1.1 Start up

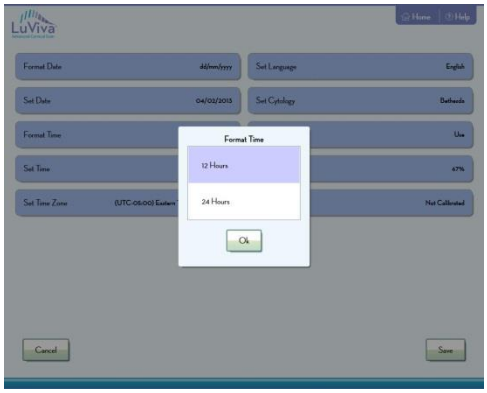
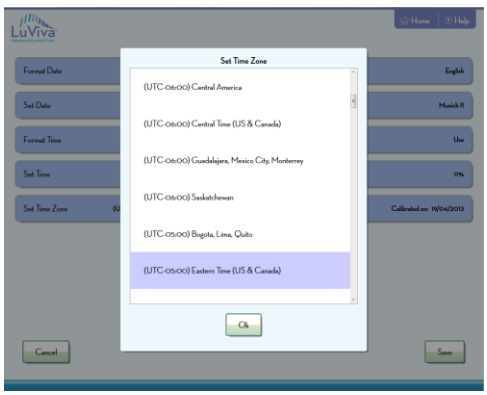
	Plug power cord into LuViva, then into a grounded wall outlet.
	Turn on system using Standby Power Switch.

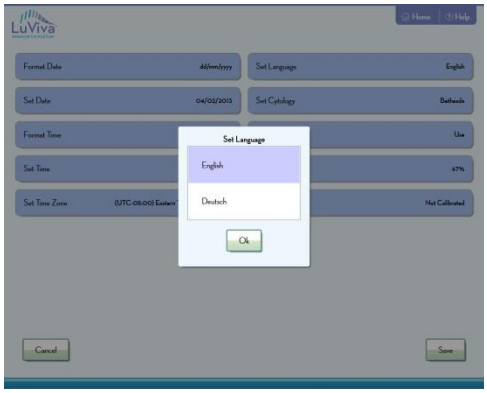
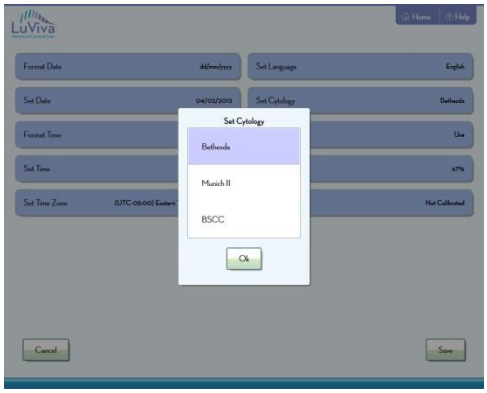
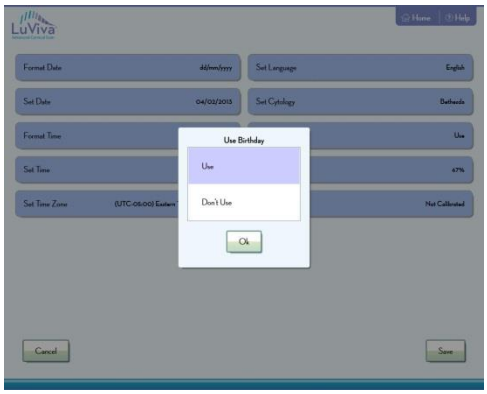
5.1.2 Set-up

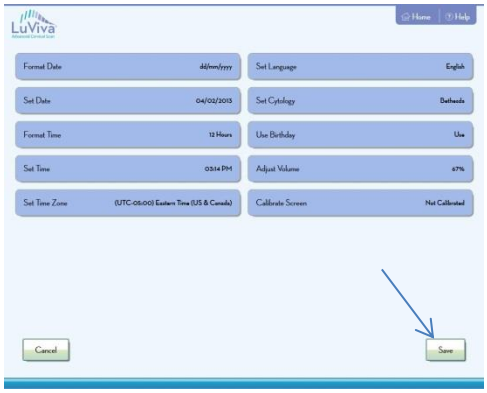
Use touchscreen or HHU Keypad to navigate through set-up screens.

	Start Screen. Select *Set-Up* to configure the system.

	Use touchscreen to navigate set-up menu.
	Run screen calibration to calibrate touchscreen.
	Select screen Calibration button. Follow the instructions, pressing and holding the corners for 15 seconds. They will turn from red to blue to indicate progress and increase to 100%. Touch all 4 corners as indicated. If screen tracking appears slow or uneven, recalibrate touchscreen. Recalibration may be needed throughout the year, or between users.
	Set Date Format dd/mm/yyyy Or mm/dd/yyyy

	Set Date Choose today's Month, Day and Year
	Set Time Format Choose 12 Hours or 24 Hours format 12 Hours: 8:00AM / 8:00PM 24 Hours: 08:00:00 / 20:00:00
	Set Time Use buttons to increment hours and seconds with up and down arrows
	Set Time Zone

	Select Language Choose preferred language
	Select Cytology Current choices: • Bethesda • Munich II • BSCC
	Set Use of Birthday as patient descriptor/ID You may want to use the patient's birth date as a patient ID for the final printed report. Choosing this mode will require you to enter the patient's birth date prior to the diagnostic test. The birthday will be used in the file name as an identifier. If you do not use the Birthday ID, only the date and time of the diagnostic test will be used as a pseudo-patient identifier on the final printed report.
	Set System Volume

	Touch *Save* to save your Set-Up selections. Set-Up is complete. Any of these settings can be changed at a later date by accessing the Set-up Screen through the System Ready screen available at Start-Up and at the beginning of every diagnostic test.

6. Operating Environment

6.1 Operating Environment

The best environment for safe and comfortable operation of LuViva is in an air-conditioned, clinical setting with gynecologic examination equipment present and available and medical waste disposal capabilities.

WARNING: LuViva is not intended for use in areas where gaseous anesthesia, oxygen or nitrous oxide is used. Due to the nature of the light source, an explosion may result.

6.1.1 Room Temperature Requirements

LuViva operates best in a room with air-conditioning, at or below 77°F (25°C). LuViva can be stored in rooms with less controlled temperatures. Please see Environment Specifications for more information.

6.1.2 Visibility Conditions

LuViva does not require specific lighting conditions; light levels needed for a gynecological exam are sufficient to operate the device and its accessories.

TECHNIQUE TIP: A lower lighting level may be helpful during the diagnostic test in order to avoid an Ambient Light Error.

6.1.3 Minimize Noise Level and Distractions during Test

LuViva incorporates both visible and audible cues throughout the test sequence. Maintaining an environment that is free of loud ambient noise or any activities that may cause distractions is recommended.

7. Performing a Test

To perform a LuViva test, you must use the touchscreen to start and navigate through the screens. Some screens will include instructions for you to follow in order to proceed to the next step of the test. Please follow all instructions shown. Additional Warnings, Notes and Technique Tips are given in the next sections of the manual to assist you in completing each test accurately. Each test should take approximately 5 minutes from start to finish.

7.1 Accessories

7.1.1 Cervical Guides

In order to use LuViva, you will need a cervical guide for every patient. The disposables are provided in cases of 20, and may be ordered by contacting a Guided Therapeutics, Inc. authorized distributor or customer service at Guided Therapeutics, Inc. Each case contains instructions for use for the disposable.

LuViva Cervical Guides are non-sterile, single-use devices intended for use with a speculum and LuViva Advanced Cervical Scan during a gynecological exam.

7.1.2 Specula

NOTE: Confirm the compatibility of specula before using with LuViva.

7.1.3 USB Drive

NOTE: The results for the patient are NOT saved on LuViva. Ending the test closes the program and deletes results. The operator shall be given an option to save the results output in PDF format on a USB thumb drive. A USB 2.0 thumb drive is supplied by Guided Therapeutics, Inc. See Specifications Section.

7.2 Patient and Operator Positioning

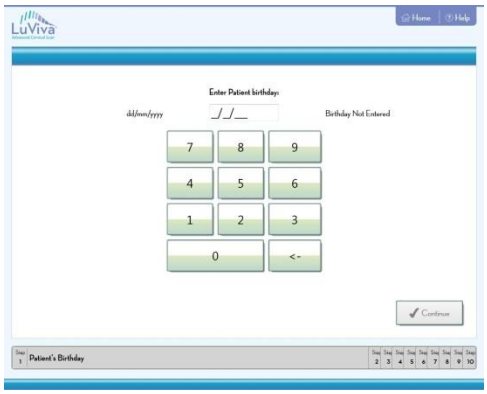
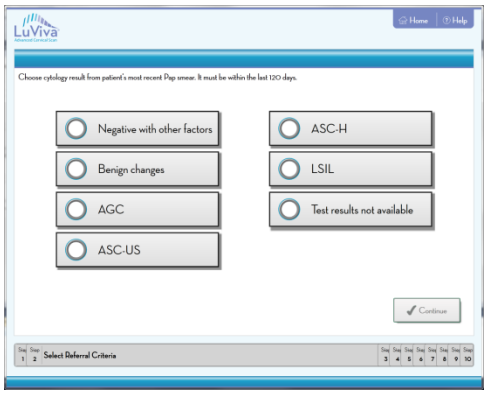
LuViva is accessible by the operator in the standing or seated position. The patient shall be in a position for a gynecological exam, positioned so that the operator can easily manipulate the HHU into the speculum while accessing the touchscreen.

The umbilical cable is 59” (1.5 meters) from the umbilical support ring on the Cart to the bottom of the HHU. Setting up LuViva within 36” (0.9 meters) from both the patient and the monitor will provide the most comfortable usage. Position LuViva at the end of the exam table for best accessibility.

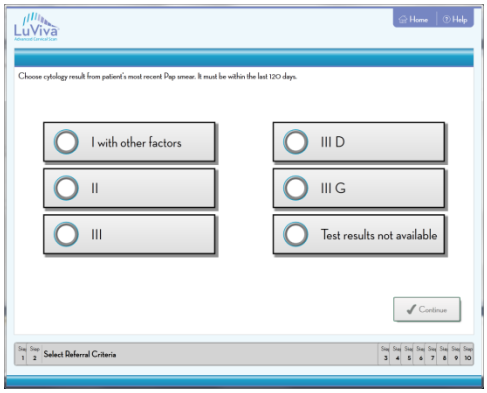
CAUTION: Lock the wheels after positioning in the exam room, prior to use on a patient.

7.3 LuViva Start-Up and Patient ID

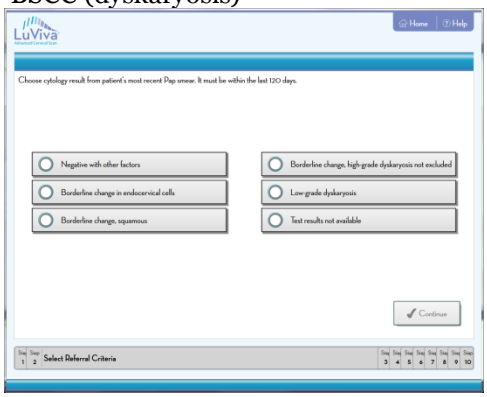
If not already on, turn on system using Standby Power Switch.

	Start-up Screen. Select *Begin Test*
	Enter Patient’s Birth Date Use of birthdate is optional, select configuration under Set-Up.
Bethesda 	Select Referral Criteria Note, this screen will display the cytology system selected during set-up. “Test Results Not Available” is utilized when the patients’ referral cytology result is not immediately available or Pap test is being performed on the same day as the LuViva Advanced Cervical Scan. This selection shown on the Referral Criteria input screen will provide the healthcare professional with a LuViva Advanced Cervical Scan result for all available cytology inputs, so that the LuViva Advanced Cervical Scan result may be compared with the same day Pap test result.

Munich II



BSCC (dyskaryosis)



7.4 Insert Speculum and Attach Cervical Guide

Patient and Test Preparation: Prepare patient per standard of care for a colposcopic exam.

Inspect LuViva for damage, cracks, scratches on the HHU Window, debris on HHU window.	**Visually inspect all components for physical damage. If damage is noted, please contact your local dealer/distributor or Guided Therapeutics, Inc.** ***CAUTION: If the HHU Window is not cleaned thoroughly and completely (with no debris or streaking), LuViva will not be able to accurately determine the disease state of the patient.***
Prepare for the exam using good clinical practices and put on gloves.	***CAUTION: Always wear gloves and use sterile field methods when using LuViva to protect the operator and patient from potential cross-contamination.***
Prepare the patient for the exam (i.e. have patient move into an exam position, prepare speculum and insert)	**NOTE:** Confirm the compatibility of specula before using with LuViva Cervical Guides.
Open CG package.	

CAUTION: The CG must not be used if the packaging has been damaged.

CAUTION: To prevent contamination, handle the CG with gloves to maintain cleanliness. Do not touch non-disinfected surfaces with CG.

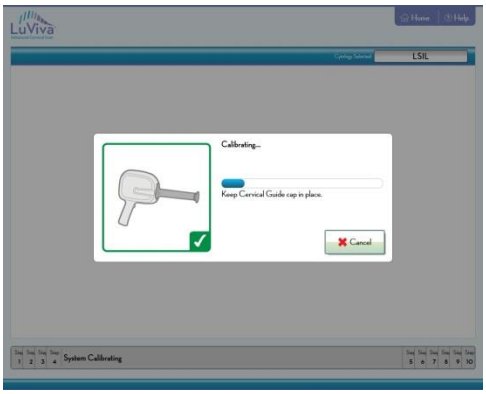
CAUTION: The CG has an expiration date. Please check the packaging to make sure your product has not expired prior to use.

> ⚠ **WARNING: The CG is a single-use disposable. The CG is non-sterile and cannot be sterilized by the operator. Do not clean and reuse. Reuse carries a high risk of cross-contamination and cross-infection of patients.**

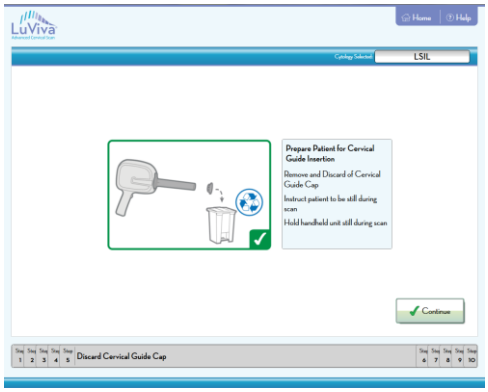
	Inspect the HHU for damage. Inspect the window for cleanliness. Attach the CG to the front of the HHU. Align tab of Cervical Guide to the tab on the face of the HHU. Turn clockwise until tab is pointing to the top of the HHU (12 o'clock). **NOTE: The CG should snap securely into position with a click.**
Use the touchscreen buttons in the lower right corner of the screen or press the button on the HHU handle to proceed.	Start Calibration. You can use the button on the touchscreen or the button on the HHU handle

	to proceed. Calibration of LuViva will begin.

7.5 Calibration

	NOTE: Do not remove or discard the Calibration Cap until calibration has completed.

7.6 Dispose of Calibration Cap

NOTE: Do not remove or discard the Calibration Cap until calibration has completed.	
	Once calibration is complete, discard Cervical Guide Cap. (Recyclable ABS)

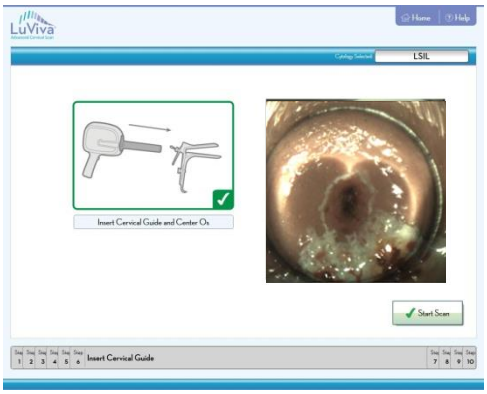
7.7 Clean Cervix and Insert CG

Clean the patient's cervix with a swab to remove any excess mucus or blood.

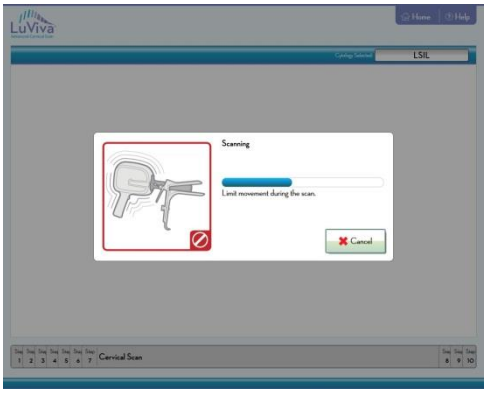
⚠ **WARNING: Do not pinch vaginal or cervical tissue between the edges of the speculum blades and the CG. Patient injury and pain may occur.**

CAUTION: Prepare the patient for CG insertion and instruct the patient to be as still as possible to minimize potential injury during the test. Unintended motion by the patient may cause an error, and the test will need to be repeated.

CAUTION: LuViva results depend upon the os of the cervix remaining in the center and the cervix remaining in the same orientation during the test sequence. Movement by the patient may cause an error and the test will need to be repeated.

	Gently insert the CG into the speculum until it touches the cervix. The screen will show a live video image to help guide the CG against the cervix and to center the os in the image. Maintaining os in field of view; make contact with cervix. Once the os is centered, hold the HHU steady. LuViva evaluation takes approximately 2 minutes. To proceed, use the select button on the HHU keypad (or touchscreen button on the right side of the screen).

7.8 LuViva Evaluation

	A screen will inform the Operator of the testing progress. An audible prompt will occur at the end of the test. The test lasts approximately 2 minutes.

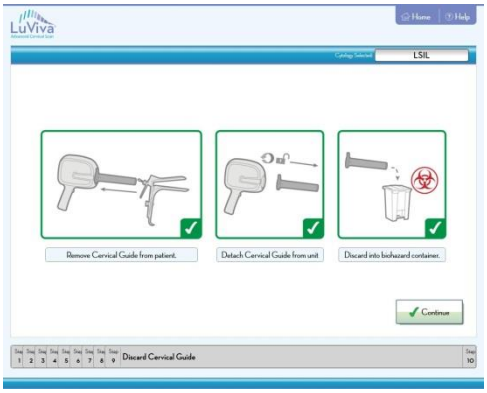
7.9 Evaluate Image

	Motion Evaluation The test includes taking a digital image of the cervix before and after the scan. These "before" and "after" images are compared to minimize errors in diagnosis due to excessive movement. The comparison is based on the presence of the os in each photo. If the os is still visible, the test may continue. Selecting *Yes* will allow the test to be completed. If the os is no longer visible, then the test should be repeated. Selecting *No* will take the operator back to the beginning of the diagnostic test. Perform test again, and repeat the Motion Evaluation.

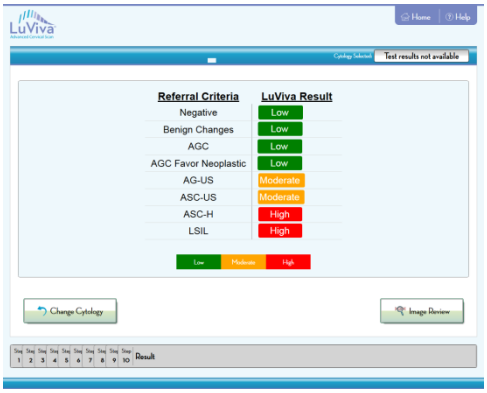
7.9.1 Limitations in Number of Diagnostic Tests

⚠ **WARNING: LuViva should not be used on a single patient for more than three (3) LuViva scans per 24-hour period.**

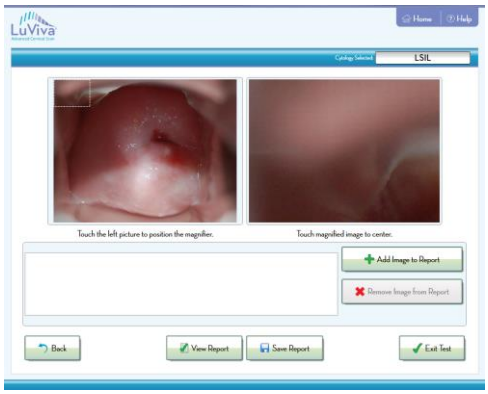
7.10 Remove and Discard of CG

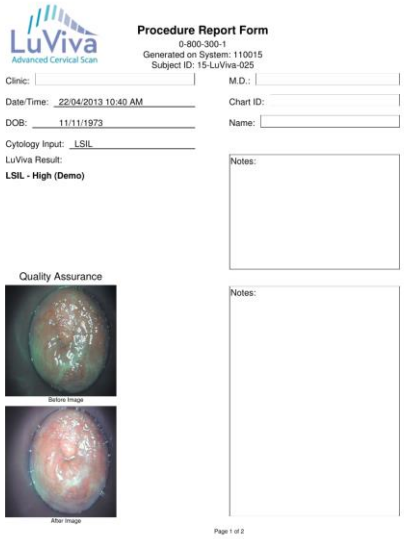
	Remove the CG from the patient. Remove the CG from the HHU and discard as medical waste. Continue to the Results Display.

7.11 Results Display

	LuViva Result (LOW/HIGH)
	LuViva Result (LOW/ MODERATE / HIGH)
	LuViva Result for all available Referral Criteria

7.12 Report Display



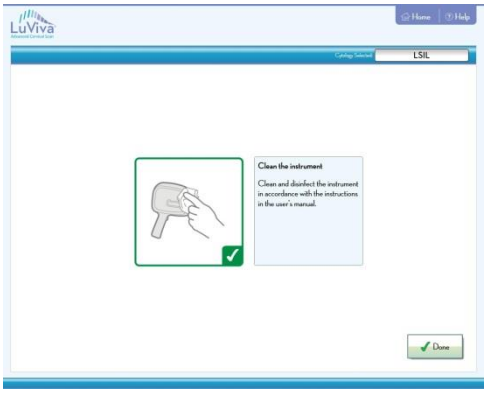


When prompted, select images for report.

To save report, insert USB drive into port on monitor and save report. Alternately, manually record data onto patient chart.

At the conclusion of the diagnostic test, operator is reminded to download the final report, since proceeding will cause the current patient's data to be deleted, in preparation for the next patient.

7.13 Clean Unit Prompt

	Clean and disinfect the unit.

CAUTION: LuViva requires cleaning and disinfection between patients, as specified in this manual, to prevent operator-to-patient, and patient-to-patient contamination and cross-contamination.

CAUTION: Dispose of the CG as medical waste. Improper disposal could result in exposure of an unprotected person to bio-contamination.

7.14 Help Screen

This User Manual will load from the help screen.

The software version is shown on the start-up screen.

7.15 Shut Down Sequence

Power off LuViva through the touchscreen power button or HHU on-standby button by pressing and holding for 10 seconds. To completely power down, disable the Main Power Switch on the Base Unit, and unplug LuViva from the wall.

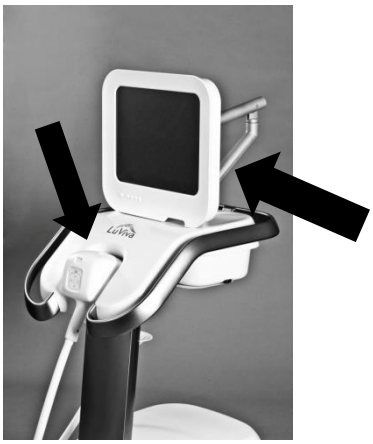
8. Moving and Transporting LuViva

LuViva has wheels to allow for the device to be easily moved within the clinic area, and from room to room within a facility that has elevators and smooth or carpeted floors.

Transporting LuViva up and down stairs and over rough or uneven surfaces requires disassembly; see further instructions below.

8.1 Moving LuViva

To move LuViva, use the touchscreen to turn off LuViva, or the Main Power Switch on the HHU. Unplug LuViva from the wall outlet and secure the power cord. Make sure the HHU is securely docked in the Docking Station and secure the umbilical cable so that it does not drag on the floor. Unlock the wheels, grasp the handle and roll LuViva into another room and place into desired position. Lock the wheels before use on patient. Plug LuViva into the properly grounded wall outlet and turn on LuViva by turning on both the Main Power Switch and the On-Standby Button to verify operation.

Moving Position (room-to-room)	
	Dock the HHU and move the monitor to a low position.
	DO NOT roll LuViva with Monitor Arm in fully extended position.
	DO NOT roll LuViva with HHU undocked. Do not rest HHU on table top.

8.2 Transporting LuViva

LuViva weighs approximately 125 lbs. (57kgs). The preferred method for moving LuViva up or down stairs or over rough terrain is with it disassembled and in its original packaging.

CAUTION: The LuViva handle is designed to roll and push LuViva. The handle may be used to lift the LuViva out of the shipping container and to move over thresholds.

Disassembly

Turn off LuViva and unplug LuViva from the wall outlet. Disconnect the cables from the monitor. Remove the touchscreen from the top of the Base Unit. Remove the monitor arm. Open the Base Unit Cover, open the lamp access panel and remove the lamp assembly. Close the Back Access Panel. Place the Base Unit, Touchscreen, Lamp Assembly, and Base Unit Cover back into their original packaging. Move the packages to the new location. Reassemble LuViva in the new location following the assembly instructions provided in the "Using LuViva for the First Time" section in this manual.

8.3 Transporting LuViva for Service

If service is required, contact distributor for a reusable service case for product return.

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9. Troubleshooting Guide

9.1 Common Errors

<table>
<tr><th>Problem/Indication</th><th>Possible Causes</th><th>Operator Action(s)</th></tr>
<tr><td rowspan="5">LuViva will not turn on.</td><td>LuViva is not plugged into an appropriately rated wall outlet.</td><td>LuViva needs 100-240V/50-60Hz AC current in order to operate.</td></tr>
<tr><td>Main Power Switch of the Base Unit is turned off.</td><td>Remove Base Unit Cover, flip Bottom Switch on at the back of LuViva Base Unit, and replace cover.</td></tr>
<tr><td>Bulb Access door is open.</td><td>Remove Base Unit Cover. Close the bulb access door. If the Access door is opened during operation, LuViva will turn off.</td></tr>
<tr><td>Power Up Sequence not performed in designated order.</td><td>Unplug LuViva and turn all switches to the off position. Follow the Set-Up Assembly steps to activate LuViva.</td></tr>
<tr><td colspan="2">If after performing all of the above troubleshooting actions LuViva will still not turn on, please contact Customer Service for further instructions.</td></tr>
<tr><td>Touchscreen will not turn on.
Indicated by dark touchscreen.</td><td>Touchscreen installed without attaching Power Cables</td><td rowspan="2">Pivot monitor to examine the rear cable connections. Check that the USB, video, audio and power cables from the Base Unit are plugged into the touchscreen.
Remove Base Unit cover and confirm cable connections are made at the front left corner of the base unit.</td></tr>
<tr><td>Touchscreen is on, but LuViva screen is not displayed</td><td>Touchscreen installed without attaching USB Cable</td></tr>
<tr><td>Power Up Screen is Windows desktop.</td><td>Software error during booting.</td><td>Contact Customer Service for further instructions.</td></tr>
</table>

Power Up Screen is MS DOS boot-up error message.	Software error during booting.	Contact Customer Service for further instructions.
LuViva will not move easily.	Wheels are locked (wheel locks are flipped down).	Unlock wheels by flipping wheel locks up. LuViva should move easily.
Error message – low lamp power, on first test and retries.	Lamp installed incorrectly.	Remove lamp assembly and reinstall following Assembly Instructions. If error message continues, contact Customer Service.
All other error messages	Various software and hardware causes	See Sections below.

9.2 Operating Errors and Warning Messages

Warning Screen/Error Message	Possible Reasons	Operator Action(s)
Ambient Light Error	If there is too much ambient light entering the HHU during calibration, then an Error message will appear. Calibration will need to be repeated. Common Causes for the Ambient Light error: removal of the Cap prior to calibration, extremely bright room lighting, or a Cap that is not securely seated on the end of the CG.	Remove and reinstall Cap on the CG Disposable. Press firmly to mount the cap flush with the end of the tube. Touch *OK* to restart calibration. If you receive the same error again, remove and reinstall the CG Disposable onto the HHU. The CG should 'click' into position on the HHU bracket. Touch *OK* to restart calibration. If you receive the same error again, attach a new CG and repeat test. If you receive same error again, contact Customer Service.
Code 247: Cervical Guide not detected.Check Cervical Guide attachment or install a new one.	Cervical Guide installed incorrectly	Check attachment, reinstall.
Code 247: Cervical Guide not detected. Check Cervical Guide attachment or install a new one.	Used Cervical Guide installed	Install new Cervical Guide.
Code 224: Cervical Guide not found. Check Cervical attachment or replace.	Cervical Guide installed incorrectly	Check attachment, reinstall.
Code 239: There is a problem with the attached Cervical Guide. Replace with a new one and retry.		Install new Cervical Guide.
Code 78: System severely overheated. Shutting down. If this problem persists, contact Guided Therapeutics, Inc.	System Error	Shut down and retest.
Code 209: Test limit will be exceeded in 2 min.		Complete test within time window.

Warning Screen/Error Message	Possible Reasons	Operator Action(s)
Code 210: Test time limit exceeded. Recalibration required.	Timing Errors will cause warnings to appear. Continued use will cancel the current test. Timing errors include the Calibration Time being Exceeded, the Measurement Time Exceeded, and System Operating Time Exceeded.	
Test Cancelation was requested. You will lose acquired data. Do you wish to proceed?	LuViva allows for ending a test prior to full test execution. A confirmation message will appear confirming that you want to end the test.	Touch *OK* to end the test Touch *Cancel* to continue the test.
Code 203: Patient Exposure limit is reached. Reschedule a test. Code 95: Retest limit has been exceeed.	LuViva can only be used for 3 scans per patient within one 24-hour period	Rerun test in 24 hours.
Hand Held Unit Overheated. Wait for system to cool or shutdown.	System Error	Wait for system to cool or shutdown.
Code 245: Too many spots were rejected. Retry tissue imaging.	If there is blood or mucus covering more than 25% of the cervix during the Diagnostic Test, this error message will appear. For LuViva to operate successfully, the cervix needs to be swabbed to remove excess blood and mucus.	Remove HHU/CG from patient and keep it from touching any other surface. Swab cervix gently to remove any blood or mucus on the patient's cervix. Touch *OK* and follow the test procedure again. If there is no blood or mucus on the patient's cervix, contact Customer Service.
Code 212 There was a general hardware failure. If this problem presists, Contact Guided Therapeutics, Inc.	General system error message.	
Code 248, 249, 250, and 252 Storage media error	Error message associated with incorrect storage media.	Use larger capacity USB drive. Unplug drive, plug in again and repeat action.

9.3 Other Errors

Other software or hardware errors may occur with regular use of LuViva. See the troubleshooting listing below for information regarding the following errors.

	LuViva Action	Operator Action
System Errors		
	Error Message will appear with Error Code	Make note of error code, click on *OK*, and shut down LuViva. Restart in 10 minutes. If error message reappears – contact Customer Service and inform them of the error code. Service may be needed.
Maintenance Errors		
	Error Message will appear with Error Code – the Lamp Assembly needs to be replaced.	If this error occurs after installation,the Lamp Assembly may be installed incorrectly and needs to be reinstalled. If this error occurs after the first 6 months to 1 year after purchase, contact Customer Service for a Service Kit in order to replace the bulb.
Temperature Errors		
	LuViva will cancel the current test, and an Error Message will appear with Error Code.	LuViva will go into sleep mode to allow the system to cool and will monitor internal temperatures. Place HHU on Docking Station when directed. When LuViva has reached recommended operating temperatures, it will return to the System Ready screen. It will be ready to resume testing.
Operation Errors		
	Error Message will appear with Error Code – System has timed out, and will need to cool.	LuViva will return to the System Ready screen when it is ready to resume testing.

9.4 Additional Errors

Any errors that are received continually (even with troubleshooting efforts) indicate the need for service. Please contact Customer Service for further instructions should any error be repeated three or more times.

CAUTION: Do not load non-LuViva software onto the computer as it could interfere with the proper operation of the system and will void the warranty.

10. Cleaning and Disinfection Procedures

10.1 Cleaning and Disinfection Cautions

- LuViva requires regular cleaning with the cleaners and disinfectants specified in this manual to prevent operator-to -patient, and patient-to-patient contamination and cross-contamination.
- The operator is instructed to handle the device in ways to reduce likelihood of contamination; for example, immediately remove and dispose of soiled CG. Do not place soiled HHU into Table Top Docking Station.

- Failure to properly clean and disinfect LuViva equipment after each examination can compromise patient safety. To minimize the risk of transmitting diseases from one patient to another, after each examination the HHU and HHU dock must undergo thorough manual cleaning followed by intermediate level disinfection.
- If the HHU and Dock are not immediately pre-cleaned, residual organic debris will begin to solidify and it may be difficult to clean.
- If the HHU and HHU dock are not cleaned meticulously, effective disinfection may not be possible. Clean the HHU and dock before disinfection to remove microorganisms or organic material that could reduce the efficacy of the disinfection.
- Patient debris and intermediate level disinfectants are hazardous. Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material. During cleaning and disinfection, wear appropriate personal protective equipment, such as eye wear, moisture resistant clothing and chemical resistant gloves so that your skin is not exposed. Always remove contaminated personal protective equipment and dispose of as medical waste after cleaning and disinfection.
- Thoroughly wipe the surfaces with potable water to remove any cleaning agent residue.
- Do not spray cleaning solutions or disinfectant solutions directly into the rear and sides of the monitor where the vent holes are located.
- Follow the cleaning agents and disinfectant manufacturer's directions.
- Do not use cleaners and disinfectants beyond their expiration date.
- Components to be disinfected MUST be dry before disinfection. Residual rinse water from the cleaning process dilutes the disinfectant, which negatively affects the disinfecting power. Disinfectant claims are not supported when parts are not pre-cleaned and dried thoroughly prior to use.
- Guided Therapeutics, Inc. has performed cleaning validation and disinfection validation only for the class of cleaning agents and disinfectants listed in the procedure.

10.2 Cleaning Procedure

10.2.1 Cleaning Solution Compatibility Summary and Frequency

Component	**Cleaning-Detergent Solution** **dual enzymatic aqueous detergent**	**Cleaning** **Isopropyl Alcohol (IPA)**	**Frequency**
HHU-Window	Yes, do not spray directly, wipe with moistened wipe	Yes, wipe with moistened wipe	After each patient
HHU – Casing	Yes, do not spray directly, wipe with moistened wipe	No	After each patient
Umbilical Cable	Yes, do not spray directly, wipe with moistened wipe	No	After each patient
HHU Dock	Yes, do not spray directly, wipe with moistened wipe	No	After each patient
Touchscreen	Yes, do not spray directly, wipe with moistened wipe	No	After each patient
Base Unit (bottom of cart)	Yes	No	Weekly as required

10.2.2 Equipment and Supplies Needed

Prepare the following equipment:

- Personal protective equipment (eye glasses, face mask, moisture resistant gown and chemical resistant gloves)
- Cleaning area with access to clean water, such as a scrub sink and countertop.
- Disposable Task Wipes (such as lint-free wipes, paper towels or heavy-duty task wipes)
    - Examples: Kim-Wipes Disposable Task Wipes (lint free wipes),
    - Examples: regular paper towels(such as Bounty, Brawny, etc.) or
    - Examples: heavy-duty task wipes, such as dry wipes Wypall L10 Utility Wipes or disposable washcloths, such as CliniGuard Dry Disposable Washcloths

- Cleaning containers or clean disposable task wipes to rest HHU while cleaning it.
- Detergent solution: medical grade, low foaming, neutral pH, *Subtilisin* protease enzymatic aqueous detergent
    - Examples: MetriZyme Dual Enzymatic Detergent and MetriSponge
- Clean, potable water for diluting the detergent solution
- Clean, potable water for rinsing
- Disposable Task Wipes for drying
- Pre-moistened 70% Isopropyl Alcohol wipes or 70% IPA cotton swab applicator
- **CAUTION: The HHU and Base Unit are IP20. The units are not designed for submersion or excessive fluid ingress. Clean, rinse and disinfect via wiping with task wipes moistened with cleaning solution, rinse water or disinfectant.**

10.2.3 Cleaning Instructions

Use a medical grade, low foaming, neutral pH enzymatic detergent and follow the manufacturer's dilution and temperature recommendations.

Prepare detergent solution following manufacturer's directions on the labeling.

Use fresh detergent solution for each cleaning session. Discard solution according to manufacturer's recommendations.

Manual cleaning: Add 1oz (4 pumps yields one ounce) of concentrate to one gallon of warm water (68° F -104° F) /(20° C – 40° C)

HHU	1. Place dirty HHU on a clean disposable task wipe or disinfected cleaning container, such as a metal surgical tray. 2. Keep the HHU handle pointing toward the table to avoid cleaning fluid from penetrating the umbilical-handle interface 3. Wet a disposable task wipe with the detergent solution. Using disposable task wipes, remove all gross visible soil from the contaminated device. Discard each wipe as it becomes dirty. It is best to wipe and discard, using a new disposable task wipe for each removal. Wipe away from the HHU window, towards the handle. 4. Once gross visible soil is removed, thoroughly spray detergent solution onto a disposable task wipe. Apply wipe directly onto the areas to be cleaned. Allow device to be saturated with solution to dissolve any remaining organic soil, loosen attachment of bioburden and thoroughly wet the device surface. Wet surface with soaked wipes at least 2 minutes to ensure that soil is hydrated for easier removal. If matter has dried on, continue to soak surface with new wet wipes until visibly clean. Pay attention to mating surfaces, the HHU-nut interface, and the HHU umbilical cable interface. 5. Using detergent solution and disposable task wipes or pre-soaked detergent sponge, manually scrub the instrument until visible soil is removed—at least 2 minutes. Dispose of wipes as needed. Rinse device by wiping with wipes moistened with warm tap water at (68° F -104° F) /(20° C – 40° C) 6. If the radiator area of the device is heavily soiled, such that soil has dripped below the surface of the radiator cover onto the radiator, remove the radiator cover using small flathead screwdriver to pop it out. Manually scrub the radiator cover if needed until visible soil is removed. Using detergent solution and disposable task wipes or pre-soaked detergent sponge, gently scrub the radiator until visible soil is removed. Rinse radiator and radiator cover by wiping with wipes moistened with warm tap water at (68° F -104° F) /(20° C – 40° C). Replace radiator cover, by aligning the cover and pushing into place. 7. Under normal office lighting, visually inspect the device to ensure soil has been removed. If visible soil remains, clean the device again as directed above.

	8. After device is visibly clean, dry completely with a clean task wipe. 9. Place cleaned HHU on disposable task wipe.
HHU Window	1. Visually inspect the HHU Window for visible soil or streaks. 2. If the window is streaked, wipe the HHU window with disposable task wipes moistened with detergent solution. 3. Discard wipes as they become contaminated. 4. Visually inspect the HHU Window for soil. 5. Repeat wiping until window is not soiled. 6. Wipe window with pre-moistened 70% IPA wipe or 70% IPA cotton swab applicator. 7. Visually inspect the HHU Window for streaks. Repeat IPA wiping until the window is dry without streaks. Allow to air dry at ambient temperature (68° F) /(20° C)
Umbilical	1. Place HHU on a clean disposable task wipe or disinfected cleaning container, such as a metal surgical tray. 2. Keep the HHU handle pointing toward the table/floor to avoid cleaning fluid penetrating the umbilical-handle interface. 3. Wet a disposable task wipe with the detergent solution. Using disposable task wipes, remove all gross visible soil from the umbilical cable. Discard each wipe as it becomes dirty. It is best to wipe and discard, using a new disposable task wipe for each removal. Wipe away from the HHU, toward the handle. 4. Once gross visible soil is removed, thoroughly spray detergent solution onto a disposable task wipe. Apply wipe directly onto the areas to be cleaned. Allow device to be saturated with solution to dissolve any remaining organic soil, loosen attachment of bioburden and thoroughly wet the device surface. Wet surface with soaked wipes at least 2 minutes to ensure that soil is hydrated for easier removal. If matter has dried on, continue to soak surface with new wet wipes until visibly clean. Pay attention to the HHU umbilical cable interface. 5. Using detergent solution and disposable task wipes or a pre-saturated detergent sponge, manually scrub the umbilical cable at least 2 minutes. Dispose of wipe/sponges as needed. Rinse device by wiping with wipes moistened with tap water at (65° F) /(18° C)Under normal office lighting, visually inspect the cable to ensure soil has been removed. If visible soil remains, clean the cable again as directed above. 6. After cable is visibly clean, dry completely with a clean, dry disposable task wipe
BU-Dock	1. Wet a disposable task wipe with the detergent solution. Using disposable task wipes, remove all gross visible soil from the contaminated area (docking station). Discard each wipe as it becomes dirty. It is best to wipe and discard, using a new disposable task wipe for each removal. 2. Once gross visible soil is removed, thoroughly spray detergent solution onto a disposable task wipe. Apply wipe directly onto the areas to be cleaned. Allow device to be saturated with solution to dissolve any remaining organic soil, loosen attachment of bioburden and thoroughly wet the device surface. Wet surface with soaked wipes at least 2 minutes to ensure that soil is hydrated for easier removal. If matter has dried on, continue to soak surface with new wet wipes until visibly clean. 3. Using detergent solution and disposable task wipes or pre-soaked detergent sponge, manually scrub the device until visible soil is removed— at least 2 minutes. Dispose of wipes/sponge as needed. Rinse device by wiping with wipes moistened with warm tap water at (68° F -104° F) /(20° C – 40° C) 4. Under normal office lighting, visually inspect the device to ensure soil has been removed. If visible soil remains, clean the device again as directed above. 5. After device is visibly clean, dry completely with a clean task wipe.
Touchscreen	1. Caution: DO NOT spray detergent solution directly onto monitor. Rear of monitor is not protected against fluid intrusion. Monitor should be cleaned by spraying detergent onto wipes, then using moist wipe to clean the surfaces. 2. Wet a disposable task wipe with the detergent solution. Using disposable task wipes, remove all gross visible soil from the contaminated touchscreen. Discard each wipe as it becomes dirty. It is best to wipe and discard, using a new disposable task wipe for each removal. 3. Once gross visible soil is removed, thoroughly spray detergent solution onto a disposable task wipe. Apply wipe directly onto the areas to be cleaned. Allow device to be saturated with solution to dissolve any remaining organic soil; loosen attachment of bioburden and thoroughly wet the device surface. Wet surface with soaked wipes at least 2 minutes to ensure that soil is hydrated for easier removal. If matter has dried on, continue to soak surface with new wet wipes until visibly clean. Pay attention to monitor touchscreen–bezel interface. 4. Using detergent solution and disposable task wipes, manually scrub the device until visible soil is removed, at least 2 minutes. Dispose of wipes as needed. Rinse device by wiping with wipes moistened with warm tap water at (68° F -104° F) /(20° C – 40° C)Under normal office lighting, visually inspect the device to ensure soil has been removed. If visible soil remains, clean the device again as directed above. 5. After device is visibly clean, dry completely with a clean task wipe.
BU-Touchscreen bezel	1. Caution: DO NOT spray detergent solution directly onto monitor. Rear of monitor is not protected against fluid intrusion. Monitor should be cleaned by spraying detergent onto wipes, then using moist wipe to clean the surfaces. 2. Wet a disposable task wipe with the detergent solution. Using disposable task wipes, remove all gross visible soil from the contaminated monitor bezel. Discard each wipe as it becomes dirty. It is best to wipe and discard, using a

	new disposable task wipe for each removal. 3. Once gross visible soil is removed, thoroughly spray detergent solution onto a disposable task wipe. Apply wipe directly onto the areas to be cleaned. Allow device to be saturated with solution to dissolve any remaining organic soil; loosen attachment of bioburden and thoroughly wet the device surface. Wet surface with soaked wipes at least 2 minutes to ensure that soil is hydrated for easier removal. If matter has dried on, continue to soak surface with new wet wipes until visibly clean. Pay attention to power button grooves and the monitor–bezel interface. 4. Using detergent solution and disposable task wipes, manually scrub the device until visible soil is removed—at least 2 minutes. Dispose of wipes as needed. Rinse device by wiping with wipes moistened with warm tap water at (68° F - 104° F) /(20° C – 40° C)Under normal office lighting, visually inspect the device to ensure soil has been removed. If visible soil remains, clean the device again as directed above. 5. After device is visibly clean, dry completely with a clean task wipe.

10.3 Intermediate-Level Disinfection (ILD) Procedure

This Disinfection procedure is to be conducted immediately after the Cleaning procedure outlined in the section above. If the device is not cleaned meticulously, effective disinfection may not be possible. Clean the device before disinfection to remove microorganisms or organic material that could reduce the efficacy of the disinfection.

10.3.1 ILD Solution Compatibility Summary and Frequency

Component	ILD 70% isopropyl alcohol wipes or 70% IPA cotton swab applicator	ILD quaternary ammonium compounds and 10-20 % isopropyl alcohol in aqueous solution both in solution and in pre-moistened wipes	Frequency
HHU—Window	Yes (disinfect by wiping with IPA pre-moistened wipe)	Yes, do not spray directly, wipe with moistened wipe	After each patient
HHU—Casing	No	Yes, do not spray directly, wipe with moistened wipe	After each patient
Umbilical Cable	No	Yes, do not spray directly, wipe with moistened wipe	After each patient
HHU Dock	No	Yes, do not spray directly, wipe with moistened wipe	After each patient
Base Unit—Touchscreen	No	Yes, do not spray directly, wipe with moistened wipe	After each patient
Base Unit—Base	No	Yes, do not spray directly, wipe with moistened wipe	Weekly as required

10.3.2 Equipment Needed

Prepare the following equipment:

- Personal protective equipment (eye glasses, face mask, moisture resistant gown and chemical resistant gloves)
- Disposable Task Wipes (such as paper towels or heavy-duty task wipers)
- Soft scrubbing implement such as a cotton cervical swab
    - Large Round Tip Swab (cotton swab, cervical swab, or equivalent)
    - Soft brush (nylon instrument brush, disposable toothbrush or equivalent)

- Intermediate Level Disinfectant (ILD) solution
    - Quaternary ammonium compounds and isopropyl alcohol in aqueous solution
    - Example: CaviCide
    - Nominally 0.25% n-Alkyl dimethyl benzyl ammonium chlorides and 10-20% isopropyl alcohol in aqueous solution
- Intermediate Level Disinfectant Wipes
    - Quaternary ammonium compounds and isopropyl alcohol in pre-saturated wipes
    - Example: CaviWipes, Sani-Wipes
    - Nominally 0.25% n-Alkyl dimethyl benzyl ammonium chlorides and 10-20% isopropyl alcohol in aqueous solution
- Pre-moistened 70% IPA wipes or 70% IPA cotton swab applicator.

10.3.3 Disinfection Instructions

- **CAUTION: The HHU and Base Unit are IP20. The units are not designed for submersion or excessive fluid ingress. Clean, rinse and disinfect via wiping with task wipes moistened with cleaning solution, rinse water or disinfectant.**

Base Unit, HHU, Umbilical Cable and Dock	1. Determine that the HHU and Umbilical Cable are dry. If they have not dried completely, use disposable task wipes to wipe down the areas until dry. 2. Inspect surface for cleanliness. If not visibly clean, use one pre-saturated disinfectant wipe to completely preclean the surface of all gross debris. Discard wipe. 3. Spray a new pre-saturated disinfectant wipe with additional disinfectant solution so that it is visibly saturated. Wipe the surface of the HHU with disinfectant wipe so that the entire HHU surface remains visibly wet for at least 1 minute. 4. Saturate a large disposable swab, such as a cervical swab, and a soft brush, with disinfectant solution. Use a cervical swab and brush to lightly scrub the HHU seams, button perimeters, HHU nut-housing interface, and cable-housing mating surface to ensure disinfectant contacts the crevices. Scrub for at least one minute with the swab and brush. 5. After scrubbing seams, spray a new pre-saturated disinfectant wipe with additional disinfectant solution so that it is visibly saturated and use this wipe to vigorously rub the surface to ensure disinfectant contact for one minute. Discard wipe. 6. Using a new pre-saturated disinfectant wipe, rub the surface of the device so that it remains visibly wet for 3 minutes. Repeated use of pre-saturated disinfectant wipes and disinfectant spray may be required to ensure the surface remains visibly wet for 3 minutes at room temperature (65F/18C). 7. Discard used wipes.
HHU Window	1. Visually inspect the HHU window for visible soil or streaks. 2. If the window is streaked, wipe the HHU window with pre-saturated disinfectant wipe. 3. Discard wipes as they become contaminated. 4. Visually inspect the HHU window for soil. 5. Repeat wiping until window is not soiled. 6. Disinfect window with pre-saturated disinfectant wipe. Allow the window to remain wet for 3 minutes, and then air dry at ambient temperature (60-80F). 7. Wipe window with pre-moistened 70% IPA wipe or pre-moistened 70% IPA cotton swab applicator. Allow to air dry at ambient temperature (68F/20C) 8. Visually inspect the HHU window for streaks. Repeat IPA wiping until the window is dry without streaks. Allow to air dry at ambient temperature (68F/20C).
Touchscreen and Bezel	1. Caution: DO NOT spray detergent solution directly onto monitor. Rear of monitor is not protected against fluid intrusion. Monitor should be disinfected with pre-saturated disinfectant wipes.

	2. Determine that the Touchscreen Monitor is dry. If it has not dried completely, use disposable task wipes to wipe down the areas until dry. Discard wipe. 3. Inspect surface for cleanliness. Use one pre-saturated disinfectant wipe to completely pre-clean the surface of all gross debris. Discard wipe. 4. Spray a new pre-saturated disinfectant wipe with additional disinfectant solution so that it is visibly saturated. Wipe the surface of the monitor and bezel and the monitor-bezel interface with disinfectant wipe so that the entire surface remains visibly wet for at least 1 minute. Discard wipe. 5. Use a new pre-saturated disinfectant wipes to thoroughly wet the surface. Firmly rub the monitor and bezel, and monitor-bezel interface with the wipe to ensure disinfectant contact for one minute. Discard wipe. 6. Using a new pre-saturated disinfectant wipe, rub the surface of the device so that it remains visibly wet for 3 minutes. Repeated use of pre-saturated disinfectant wipes and disinfectant spray may be required to ensure the surface remains visibly wet for 3 minutes at room temperature (65° F) /(18° C) 7. Discard used wipes.

11. Maintenance Instructions and Schedule

"Maintenance, inspection, and replacement of parts for LuViva should be performed at specified intervals. Routine cleaning and disinfection procedures should be followed as described in the Cleaning and Disinfection section of this manual.

11.1 Required Inspection

LuViva is an electrical medical device and should be treated with care. The safety of patient and operator depend upon the device maintaining its integrity. The operator should inspect the device for general damage each time the device is used. If the device becomes damaged, contact Guided Therapeutics, Inc.

11.2 Replacement Parts

LuViva will require replacement of some components throughout its lifetime. Replace the bulb after 1000 hours of use. Replace the air filter at the same time.

These replacement parts are replaceable by the operator.

All replacement parts may be ordered by calling Customer Service at (770) 242-8723.

Part	Cat. No.
Cervical Guides	14100
Service Kit	14250
Monitor Assembly	13900
Power Cord	Call Distributor

(Use cable such as: Interpower, 125V, 10A, Hospital Grade, NEMA 5-15 plug, EN60320 connector, 18 AWG, 3m)

Use country –specific equivalent cable, supplied by distributor)

For replacement of any other part, contact distributor or Customer Service at (770) 242-8723.

The Service Kit contains a replacement lamp assembly with tool, air filter and, if needed, USB drive with software update. The lamp will need replacement after 1000 hours of use. An error message will appear on LuViva when this limit is reached. LuViva must be turned off for one (1) hour prior to attempting to replace the lamp.

⚠ **WARNING: The maintenance functions of replacing the lamp or air filter should not be performed while a patient is in the room. The operator shall not touch an accessible part and a patient simultaneously.**

11.3 Replacing the Lamp and Air Filter

⚠ **WARNING: The lamp remains at high temperatures during and after operation. Never let any part of the heated lamp come in contact with your hands or skin. The heated lamp will cause burns.**

CAUTION: Wear long sleeves and face shield while replacing the lamp in LuViva.

Install air filter and new lamp assembly using the tool provided with it in the service kit, following the installation instructions.

- LuViva must be turned off for one (1) hour prior replacing the lamp in order to sufficiently cool.
- Unplug LuViva from wall.
- Remove Base Unit cover. Remove Lamp Access Panel.
- Turn power switch to the off position.

- Using supplied tool, unscrew the lamp access door screw ¼ turn to reveal the lamp assembly. Using retained lamp placement tool from initial install, mount the tool on the alignment pins and remove lamp assembly. Remove the tool with the lamp assembly inside it. Do not touch the bulb or lamp assembly. Either discard the lamp assembly as required by federal and state regulations in your area for high pressure xenon gas bulbs or return the lamp assembly to Guided Therapeutics, Inc. for disposal and recycling. The placement tool should be retained for future use for lamp removal.
- NOTE: The lamp assembly can still be removed without the lamp placement tool. However, this increases the risk of breaking the bulb, which is to be avoided.

To Reactivate LuViva

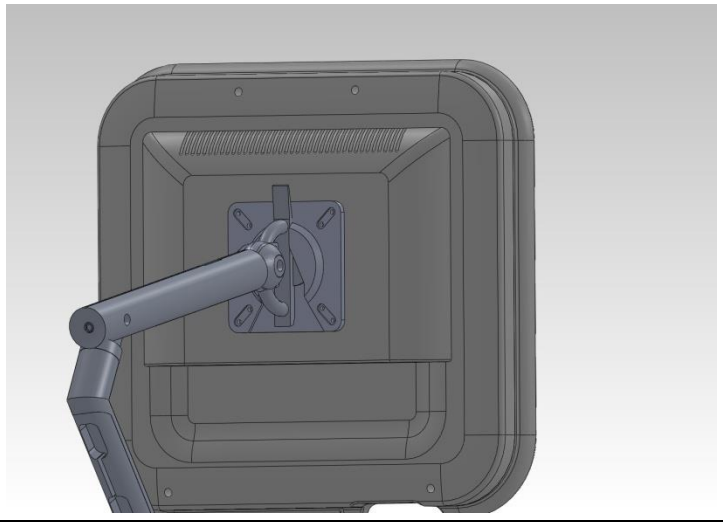
- Once all the Service Kit items have been replaced, enable LuViva by turning on the Main Power Button on the Base Unit.
- Replace the lamp access panel and the base unit cover.
- Plug LuViva back in to properly grounded wall outlet.
- Turn on the unit with the HHU On/Stand-By button.
- Verify operation.

11.4 Replacing Power Cord

Unplug old power cord from wall. Obtain new power cord as specified above. Plug new power cord into Base Unit.

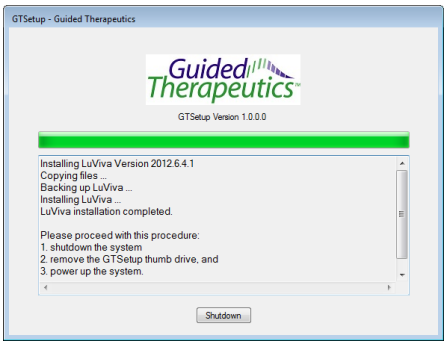
11.5 Replacing Monitor Assembly

Remove the monitor as indicated in the installation instructions, detaching all cables prior to removing from the Monitor Arm bracket. The existing monitor may need to be returned to Guided Therapeutics, Inc. Please see the Warranty and Return Information section in this manual for instructions on returning the Touchscreen.

	To remove the Monitor, press the monitor clamp and slide the monitor upwards.

11.6 Software Upgrade

If software upgrades are needed, the upgrade software will be made available via USB drive. Install as per set-up instructions.

1. Obtain the software upgrade USB drive. 2. Insert the software upgrade USB drive into the USB port of the monitor.	
3. Power up the system using Standby button on the HHU. 4. After system startup, the GT Setup software will install LuViva software. 5. The GT Setup screen will appear and display progress. 6. At the end of the installation, shut down the system. 7. Remove the setup USB. The system is ready for use.	

12. Service

The lamp assembly and air filter are the only operator serviceable components. These can be accessed from the lamp access door with supplied tool.

There are no other operator serviceable parts. Do not attempt to open any other part of LuViva. Doing so could damage LuViva, expose the operator to risk of electric shock and invalidate the manufacturer's warranty.

⚠ **WARNING: To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth (grounded wall outlet). Improperly powering LuViva may result in damage to LuViva and substantial risks of electric shock to the operator or patient.**

CAUTION: Risk of Electrical shock. Disconnect main power before replacing the lamp assembly or air filter.

CAUTION: Risk of Electrical Shock. No user-serviceable parts inside. Only components listed as "Replacement Parts" are replaceable by operator or service personnel. Refer servicing to qualified personnel.

13. Disassembly and Packing Instructions (for Service)

The Instrumentation package, which includes the Base Unit enclosure, umbilical cable and HHU can be completely removed from the cart and returned to Guided Therapeutics, Inc. for service and/or repair as needed. A reusable service case and additional packing instructions will be sent to transport the Instrumentation package.

If new packaging is needed to ship the device locally, please contact distributor and/or Guided Therapeutics, Inc. for return packaging and packing instructions.

14. Specifications

This section provides all the information needed for safe operation of LuViva.

14.1 Technical Description

Technical Description Information	Sections where Information can be found
Safe Operation	Operating Environment, Performing a Test, Safety Information
Safe Transport	Moving and Transporting LuViva
Safe Storage	Environmental Specifications
Safe Installation and Safe Preparation for Use	Set-Up – Assembly, Set-Up – Software Configuration, Operating Environment, Performing a Test
Labels & Marking Explanations	Safety Information
Environmental Conditions of Use	Environmental Specifications
Special Installation Requirements	Set-Up – Assembly, Set-Up – Software Configuration
Means of Isolating LuViva from Supply Mains	System Specifications
Unauthorized Modification of LuViva	Safety Information
Power Cord	Replacement Parts
Mechanical Drawings for Maintenance Procedures	Maintenance Instructions and Schedule
Functional Description	Device Description
Displayed Values—Range, Accuracy and Precision	Performance Characteristics

14.2 Environmental Specifications

Operating Conditions	LuViva	CG
Temperature	10°C - 40°C (50°F – 104°F)	10°C - 40°C (50°F – 104°F)
Humidity	30% to 75% non-condensing	30% to 75% non-condensing
Altitude	700 hPa to 1060 hPa	700 hPa to 1060 hPa
Transport Conditions – Within Same Facility	**LuViva**	**CG**
Temperature	10°C - 40°C (50°F – 104°F)	10°C - 40°C (50°F – 104°F)
Humidity	10% to 95% non-condensing	10% to 95% non-condensing
Altitude	700 hPa to 1060 hPa	700 hPa to 1060 hPa
Transport Conditions – Between Different Facilities	**LuViva**	**CG**
Temperature	-20°C to 50°C (-4°F – 140°F)	-20°C to 50°C (-4°F – 140°F) Do not expose cervical guides to temperatures above 50C (122F). Guided Therapeutics, Inc. cannot guarantee the performance of the cervical guide when stored at temperatures outside of the recommended range.
Humidity	10% to 95% non-condensing	10% to 95% non-condensing
Special Instruction	Transport in packaged configuration	CG-20 packaged configuration
Storage Conditions	**LuViva**	**CG**
Temperature	-20°C to 50°C (-4°F to 140°F)	The cervical guides are best when stored at -20°C to 30°C (-4°F to 86°F)
Humidity	10% to 95% non-condensing	10% to 95% non-condensing

14.3 Physical and System Specifications

Physical Specifications	LuViva	CG
Life Span	5 years	Expiration Date
Total Weight	125 lbs. (57kg)	0.2 pounds, 90 grams
HHU Weight	4.5 lbs. (2kg)	
Instrumentation package (Base Unit- HHU) combined weight	33 lbs. (15 kg)	
Total Dimensions	23 W x 26D x 60"H (58 cmW x 66cmD x 152cmH)	5" x 13" (0.13m x 0.33m) packaged
Display Dimensions	17" diag. (43cm)	
Light Source	Replaceable Xenon Arc Lamp	
Life Span of Light Source	Replace after 1000 hours	
Shelf Life of CG		Expiration Date
Result Format	Discreet Level: Low /High likelihood of neoplasia **or** Low/Moderate/High likelihood of neoplasia	
AC Power Input	100-240V AC, 10.0 Amps 50-60Hz	
Means of Separation from Supply Mains	Double insulation and metal (aluminum) enclosure. Applied parts are not patient connections	
Device Classification	Class I ME Equipment	
Mode of Operation	Continuous	
Classification-Degree of Protection Against Electrical Shock		Type B Applied Part
Degree of Protection Against Electrical Shock	Not suitable for oxygen rich environment.	
IP Rating—Degree of Protection Against Ingress of Water	IP20	

14.4 Standards Compliance

The device is designed to conform to the following Standards:

- ANSI/AAMI ES60601-1:2005: Medical electrical equipment, Part 1: General requirements for basic safety and essential performance

- Medical electrical equipment Part 1: General requirements for safety (IEC 60601-1 1988 A1:1991 +A2: 1995).

- ANSI/AAMI/IEC 60601-1-2:2007: Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance. - Collateral standard: Electromagnetic compatibility - Requirements and tests.

- BS EN 60601-1-2:2007
  Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.

- CAN/CSA C22.2 NO. 60601-1-2-08 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Adopted IEC 60601-1-2:2007, third edition, 2007-03)
  01-Dec-2008.

- IEC 60601-2-57 Ed. 1.0 b:2011 / CAN/CSA C22.2 NO. 60601-2-57:11
  Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

- Medical equipment with respect to electric shock, fire, and mechanical hazards only in accordance with AAMI/IEC/EN 60601-1.

- Intentional emitter
  - US/ FCC part 15, Subpart C
  - FCC ID: 2AAAW-13500
  - Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

- This device complies with Part 15 of the FCC rules. Operation is subject to the following conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interferences received, including interference that may cause undesired operation.

- Canada/RSS-210 Annex 2 Low-power License-exempt Radiocommunication Devices (All Frequency Bands): Category I Equipment

  - MODEL: 13500
  - IC: 11125A-13500

- EU/EN 300 330-2 Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD);Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Part 2: Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive

- EU/EN 301 489-1 Electromagnet compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility standard for radio equipment

14.4.1 Emitted Radiation Characteristics

LuViva emits low levels of UV and visible light. It also emits RF.

UV/visible light from 300 to 800 nm is delivered to the patient. Per analysis to IEC 60601-2-57 ed 1.0 (01-2011) IEC 60601-2-57 Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use, LuViva is in the category of exempt.

- IEC 60601-2-57 Ed. 1.0 b:2011 / CAN/CSA C22.2 NO. 60601-2-57:11
  Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

60601-2-57 RESULTS SUMMARY (ANNEX BB: TABLE BB.1)

Hazard	Wavelength Range (nm)	Symbol	Measurements Included (duration in seconds listed in parenthesis)	Emission Limits for Exempt Group (60601-2-57)	GTI Results (% of Limits in parenthesis)	Units
Actinic UV	180-400	E_s	F1, Reflectance & Illumination	30	0.826 (2.75%)	J/m2
Near UV	315-400	E_{UVA}	All	10000	290 (2.90%)	J/m2
Blue Light	300-700	L_B	All	10^6	$1.87x10^4$ (1.87%)	J/m^2sr^1
Retinal Thermal	380-1400	L_R	F3 (2)	$3.66x10^5$	$9.92x10^3$ (2.36%)	W/ m^2sr^1
			Reflectance (0.5)	$5.95x10^5$	$1.25x10^3$ (0.21%)	W/ m^2sr^1
			Illumination (180)	$2.81x10^5$	$1.70x10^3$ (0.60%)	W/ m^2sr^1
Retinal Thermal, weak visual stimulus	780-1400	L_{IR}	Reflectance & Illumination	6000/α	N/A	
Corneal / Lens IR	780-3000	E_{IR}	Reflectance (0.5)	$3.03x10^4$	2.43 (0.01%)	W/m^2
			Illumination (180)	$3.66x10^2$	0.729 (0.20%)	W/m^2

14.5 Human Blood Derivatives

LuViva Advanced Cervical Scan and Cervical Guides contain no human blood derivatives.

14.6 Lifetime Declaration

LuViva has an expected lifetime of 5 years.

14.7 Disposal and Return Instructions

Dispose of device in accordance with local regulations. See specific guidance below.

14.7.1 Disposal of LuViva (excluding monitor)

Dispose of LuViva as electronic waste following the federal and state laws, regulations and requirements in your area. The lamp assembly contains a xenon gas lamp at high pressure. It is to be disposed of as industrial waste following the federal and state laws, regulations and requirements in your area. The air filter can be disposed of through municipal waste. Contact Guided Therapeutics, Inc. for additional information.

14.7.2 Disposal of LuViva Monitor

The monitor contains mercury. Dispose and/or recycle monitor in accordance with mercury-containing waste following the federal and state laws, regulations and requirements in your area.

14.7.3 Disposal of CG

After use, the CG should be disposed of as medical waste following the federal and state laws, regulations and requirements in your area.

14.7.4 Disposal of Lamp

Either discard the lamp assembly as required by federal and state regulations in your area for high pressure xenon gas bulbs or return the lamp assembly to Guided Therapeutics, Inc. for disposal and recycling

14.7.5 WEEE/RoHS Recycling Directives

If you are subject to the WEEE/RoHS recycling directives, call customer service for assistance.

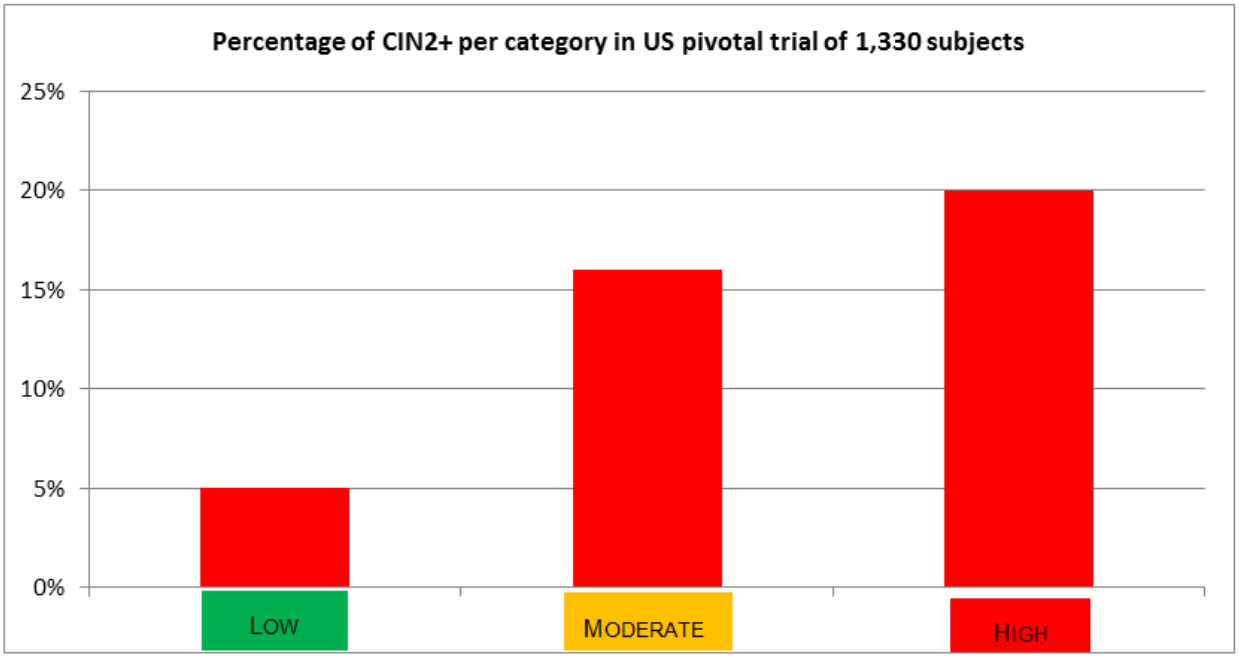
15. Performance Characteristics

LuViva® Advanced Cervical Scan indicates the likelihood of Cervical Intraepithelial Neoplasia Grade II and higher (CIN2+) in a referred population (See Indications for Use) at the time the scan is given to the patient. The likelihood of CIN2+ is presented on a three-point scale: Low (Green), Moderate (Yellow) and High (Red).

LuViva generates the scale by using proven spectroscopy technology to capture spectral data from multiple points on the cervix and the distal endocervix. The data are integrated into LuViva's algorithm to produce the index indicating the likelihood of CIN2+.

LuViva's pivotal clinical trial of 1,330 patients, referred for additional testing after screening, prospectively demonstrated that as the index increased in magnitude, so did the likelihood of CIN2+, as documented by quality-controlled, multi-reader histopathology results.

According to the pivotal clinical trial results, a patient with CIN2+ is approximately four times more likely to be in the High (Red) category than the Low (Green) category and a patient with CIN3+ (including cancer) is approximately seven times more likely to be in the High (Red) category than the Low (Green) category. A patient in either the Low (Green) or Moderate (Yellow) category is least likely to harbor a CIN2+ lesion. (Chart 1)



The Low (Green) category contains the most normal and CIN1 cases (95%) and fewest CIN2+ (5%). The High (Red) category contains the most CIN2+ cases (20%) and fewest normal (36%) and CIN1 (44%) cases. The Moderate (Yellow) category is most likely to contain a mix of normal and CIN1 (84%) cases with some CIN2+ cases. (Table 1)

Table 1: LuViva three level scale with percentages of normal, CIN1, CIN2 and CIN3 (n = 1,330)

LuViva Color Alert Code	Risk of High Grade Dysplasia	Number of Patients	%Normal	% CIN1	% CIN2	% CIN3+
GREEN	LOW	428	52	43	4	1
YELLOW	MODERATE	372	41	43	13	3
RED	HIGH	530	36	44	13	7

Note: CIN3+ includes cancer

Alternative or complimentary table

LuViva Color Alert Code	Risk of High Grade Dysplasia	Number of Patients	%Normal/CIN1	% CIN2+
GREEN	LOW	428	95	5
YELLOW	MODERATE	372	84	16
RED	HIGH	530	80	20

Note: CIN2+ includes cancer

Table 2. Distribution of cervical disease in US pivotal trial (n = 1,330)

Disease State by Histopathology	Number of Patients
No disease (Normal)	562
CIN1	577
CIN2	137
CIN3+	54
Total	**1,330**

Using the diagnostic performance characteristics of sensitivity, specificity and negative predictive value, results at the two thresholds of the scale, or cut-off points, are presented.

Sensitivity, Specificity and Negative Predictive Value of LuViva at the Low/Moderate (Green/Yellow) Threshold

At the threshold where a Low (Green) result transitions to the Moderate (Yellow) result:

- Sensitivity or the ability of LuViva to correctly identify CIN2+ patients was 87% (167/191) and for CIN3+ patients it was 89% (48/54)
- Specificity or the ability of LuViva to correctly identify normal or benign patients was 40% (222/562) and for CIN1 patients it was 32% (182/577)
- Adding the normal/benign patients with the CIN1 patients resulted in a specificity of 35% (404/1139)

- Perhaps most importantly, LuViva's Negative Predictive Value of 99% indicates that a patient with a negative (Green) LuViva result has only a 1% chance of a CIN3+ lesion.

Table 3: Sensitivity/Specificity and Negative Predictive Values (CIN2 and CIN3+)

	Sensitivity CIN3+	Sensitivity CIN2+	Specificity Normal	Specificity CIN1	Specificity Normal/CIN1	NPV CIN2	NPV CIN3+
Low/Moderate Threshold	89%	87%	40%	32%	35%	96%	99%

Note: CIN3+ includes cancer

Sensitivity, Specificity and Negative Predictive Value of LuViva at the Moderate/High (Yellow/Red) Threshold

At the threshold where a Moderate (Yellow) result transitions to the High (Red) result:

- Sensitivity or the ability of LuViva to correctly identify CIN2+ patients was 56% (107/191) and for CIN3+ patients it was 67% (36/54).
- Specificity or the ability of LuViva to correctly identify normal or benign patients was 66% (373/562) and for CIN1 patients it was 56% (343/577).
- This level of sensitivity and specificity indicates that patients with a LuViva result in the Moderate or (Yellow) zone are transitional, many with CIN1 and some with CIN2 lesions, but not as many normal patients or patients with CIN3+ lesions.
- Adding the normal/benign patients with the CIN1 patients resulted in a specificity of 63% (716/1139).
- Perhaps most importantly, LuViva's Negative Predictive Value of 98% indicates that a patient with a negative (Green or Yellow) LuViva result has only a 2% chance of a CIN3+ lesion.

Table 4: Sensitivity/Specificity and Negative Predictive Values (Cin2 and CIN3+)

	Sensitivity CIN3+	Sensitivity CIN2+	Specificity Normal	Specificity CIN1	Specificity Normal/ CIN1	NPV CIN2	NPV CIN3+
Moderate/High Threshold	67%	56%	66%	59%	63%	92%	98%

Note: CIN3+ includes cancer

16. EMC Information: Guidance and Manufacturer's Declarations

The following tables contain the manufacturer's declarations for the LuViva Advanced Cervical Scan's electromagnetic emissions, electromagnetic immunity and recommended separation distances between LuViva and portable and mobile RF communications equipment, as well as a list of compliant cables.

CAUTION: Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

CAUTION: Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

CAUTION: LuViva must not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, LuViva should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
LuViva Advanced Cervical Scan is intended for use in the electromagnetic environment specified below. The customer or the user of LuViva Advanced Cervical Scan should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	LuViva Advanced Cervical Scan must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	LuViva Advanced Cervical Scan is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment /system is intended for use by healthcare professionals only. The equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocation LuViva Advanced Cervical Scan or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
LuViva Advanced Cervical Scan is intended for use in the electromagnetic environment specified below. The customer or the user of LuViva Advanced Cervical Scan 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 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2kV for power supply lines +/- 1kV for input/output lines	+/- 2kV for power supply lines +/- 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1kV line(s) to line(s) +/- 2kV line(s) to earth	+/- 1kV line(s) to line(s) +/- 2kV line(s) to earth	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 IEC61000-4-11	<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 s	<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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of LuViva Advanced Cervical Scan requires continued operation during power mains interruptions, it is recommended that LuViva Advanced Cervical Scan be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be a levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
LuViva Advanced Cervical Scan is intended for use in the electromagnetic environment specified below. The customer or the user of LuViva Advanced Cervical Scan should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of LuViva Advanced Cervical Scan, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less that the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which LuViva Advanced Cervical Scan is used exceeds the applicable RF compliance level above, LuViva Advanced Cervical Scan should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating LuViva Advanced Cervical Scan. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communication equipment and LuViva Advanced Cervical Scan			
LuViva Advanced Cervical Scan is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of LuViva Advanced Cervical Scan can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and LuViva Advanced Cervical Scan 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 $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 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.			

Compliant Cables

Cable or Accessory	**Maximum Length**
86610610 or equivalent For example (Interpower, 125V, 10A, Hospital Grade, NEMA 5-15 plug, EN60320 connector, 18 AWG, 3m) Use equivalent cable compatible with local mains supply.	3m

CAUTION: Use of accessories and cables other than those specified, with exception of parts sold by Guided Therapeutics, Inc. as replacements for internal components, may result in increased emissions or decreased immunity of LuViva Advanced Cervical Scan.

RF Frequency Band
LuViva Advanced Cervical Scan incorporates an RF transmitter and RF receiver that operate within a frequency band of 13.56 MHz +/- 7 kHz.

CAUTION: LuViva Advanced Cervical Scan may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

17. Warranty and Return Policy Information

Guided Therapeutics, Inc. warrants that LuViva® Advanced Cervical Scan will be free from defect in materials and workmanship for one (1) year from the date of purchase. If, during this one year period, LuViva does not work properly because of a defect in materials or workmanship, Guided Therapeutics, Inc. will repair LuViva or replace it free of charge. The warranty of the repaired or replacement LuViva will expire on the date of the original warranty expiration.

This warranty applies to the original purchaser of LuViva.

This warranty does not cover damage due to external causes, including accident, abuse, misuse, problems with electrical power, servicing not authorized by Guided Therapeutics, Inc., usage not in accordance with product instructions and problems caused by use of parts and components not supplied or recommended by Guided Therapeutics, Inc.

Guided Therapeutics, Inc. will repair or replace products covered under this limited warranty that are returned to Guided Therapeutics, Inc.'s facility. To request warranty service, you must contact Guided Therapeutics, Inc. within the warranty period at (770) 242-8723 or your local distributor. You must ship the products back to Guided Therapeutics, Inc. in their original or equivalent packaging, prepay shipping charges and insure the shipment or accept the risk of loss or damage during shipment. Guided Therapeutics, Inc. will ship the repaired or replacement products to you freight prepaid. Guided Therapeutics, Inc. makes no express warranties beyond those stated in this warranty statement. Guided Therapeutics, Inc. disclaims all other warranties, express or implied.

18. Patent Information

The Cervical Guide and LuViva Advanced Cervical Scan device shall be labeled to inform the operator and possible manufacturers with an indication that the Cervical Guide and LuViva Advanced Cervical Scan are manufactured under patent protection.

The product labeling shall include the statements:

LuViva® Advanced Cervical Scan and LuViva® Cervical Guide are covered by one or more of the following patents and patents pending in the United States of America and other countries:

5,203,328
5,582,168
5,792,049
5,860,421
5,924,981
6,002,482
6,045,502
6,055,451
6,192,734
6,226,541
6,400,875
6,577,391
6,590,651
6,792,982
6,870,620
6,975,899
7,006,220
7,301,629

For an updated list of applicable patents, go to www.guidedinc.com/patents.htm

19. References

Colposcopy and Programme Management, Guidelines for the NHS Cervical Screening Programme, Second Edition. NHSCSP Publication No. 20 May 2010.

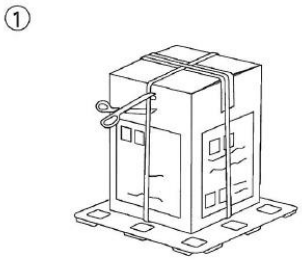
20. Set-Up - Assembly

LuViva has been supplied to you in one box with multiple internal packages. Each package contains a critical component to the device.

1. LuViva Base Unit Cart with locking wheels
2. Hand-Held Unit (attached to Base Unit with umbilical cable)
3. Monitor Arm (in box)
4. Display Monitor (in box)
5. Base Unit Outer Cover (installed)
6. Installation USB thumb drive in documentation packet
7. Unpacking and Assembly instructions
8. User Manual (also found online)
9. Service Kit with filter and replaceable lamp assembly
10. CG-20 (Box of Cervical Guides (Single Use Disposables))
11. Power cord (supplied by distributor; may be in separate box or attached to main shipper)

20.1 Visual Overview of Unpacking and Assembly steps:


LuViva
Advanced Cervical Scan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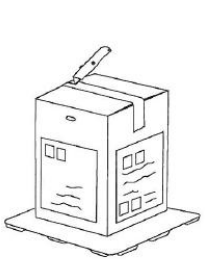
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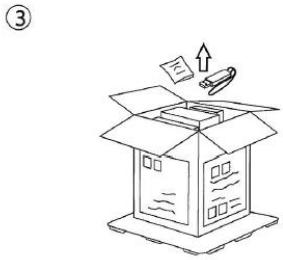
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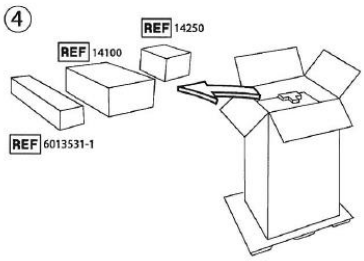
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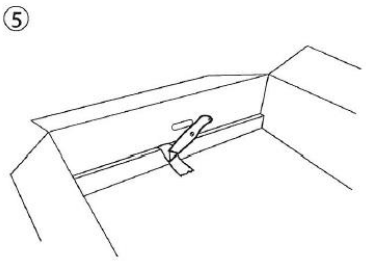
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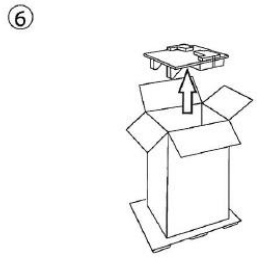
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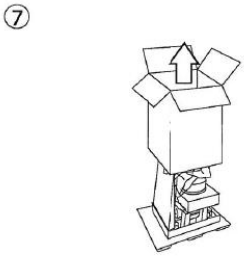
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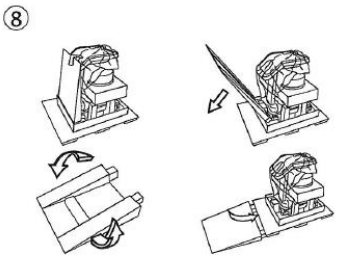
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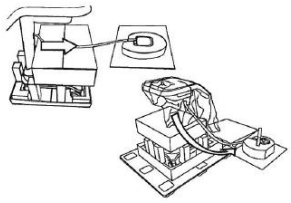

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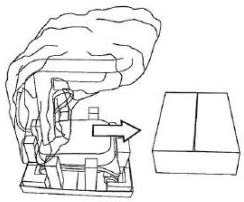

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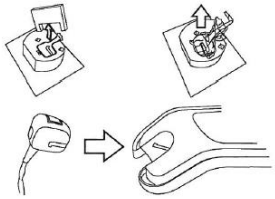

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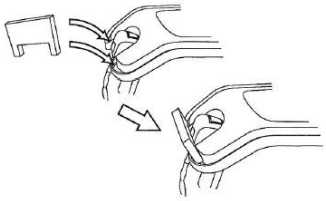

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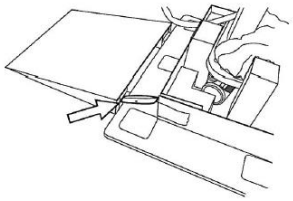

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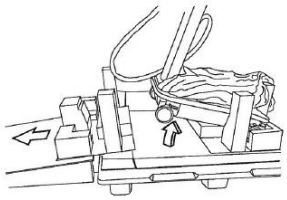

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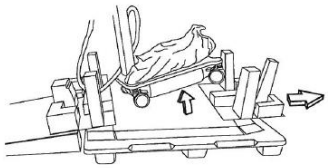

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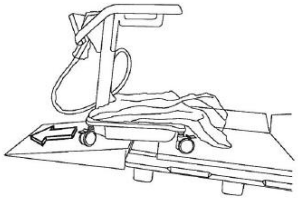

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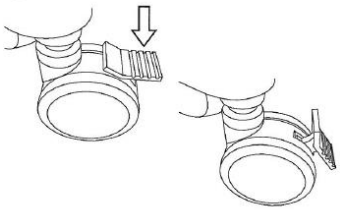

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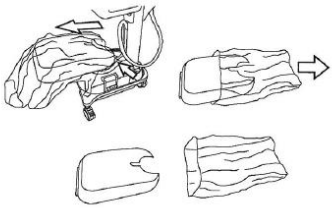

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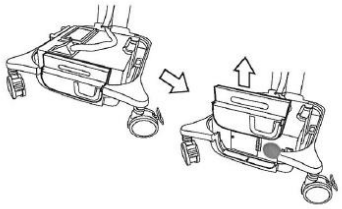

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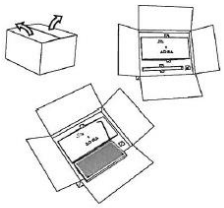

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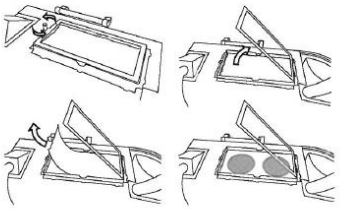

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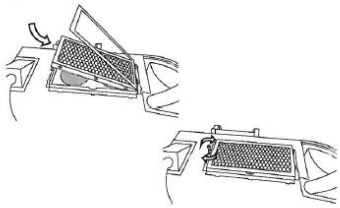

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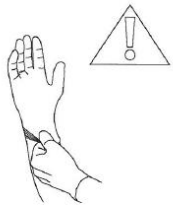

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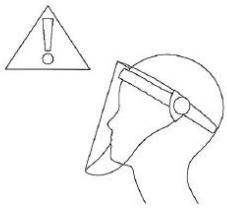

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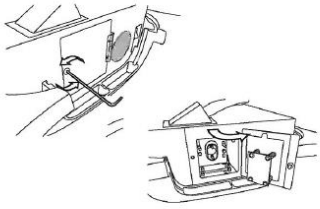

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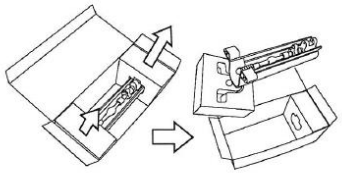

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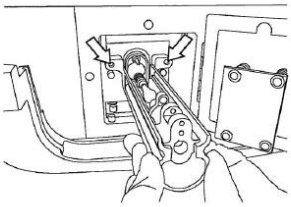

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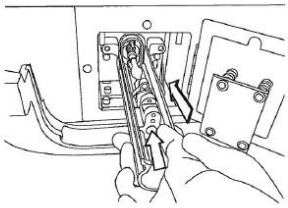

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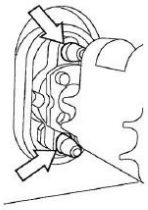

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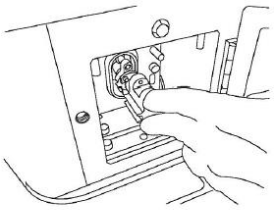

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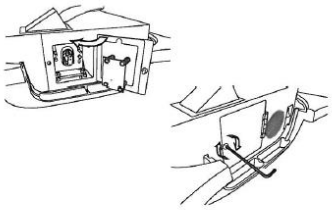

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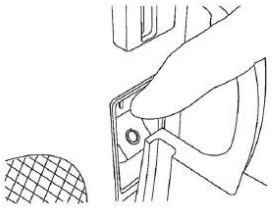

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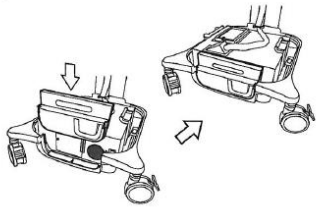

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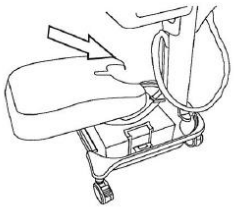

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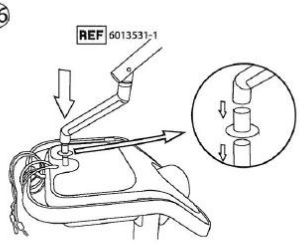

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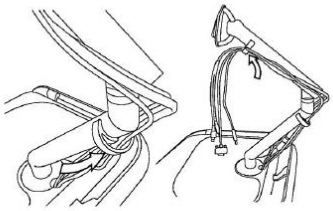

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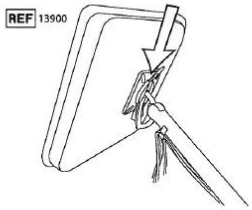

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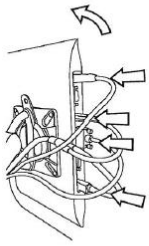

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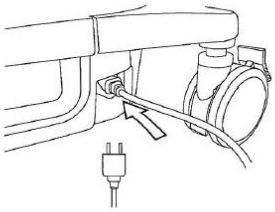

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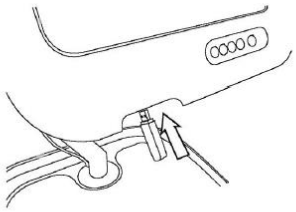

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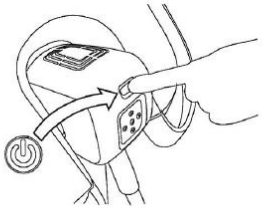


20.2 Remove LuViva from Shipping Container

Visually inspect all components for physical damage. If damage is noted, please contact your local dealer/distributor.

Overview of unpacking steps:

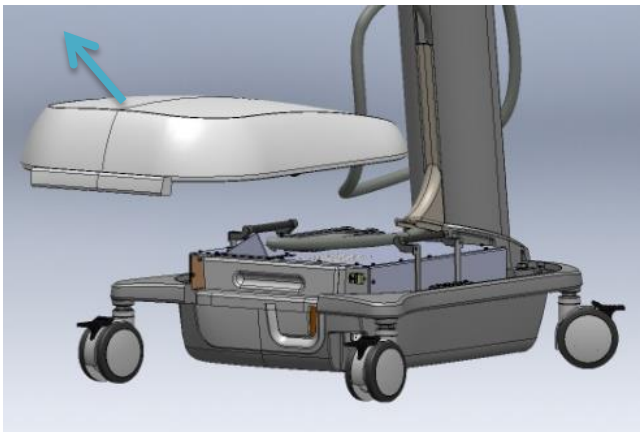
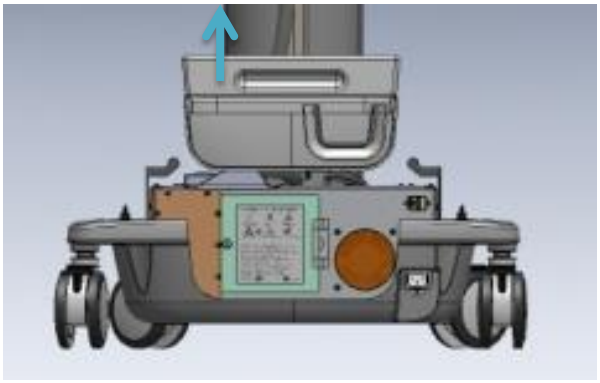
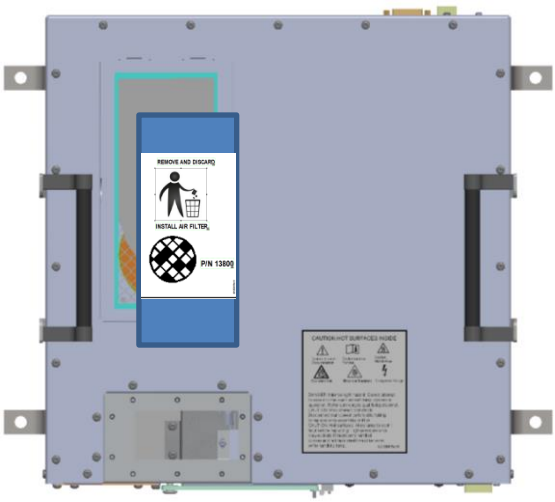
- LuViva is supplied in a single crate with packing materials and boxed items contained within.
- LuViva is supplied fully assembled with the exceptions of: the monitor arm, monitor, Service Kit contents (air filter and lamp assembly) and power cord. These items must be installed.
- The power cord will be supplied separately by the distributor, and not included in the crate.
- Ensure pallet is on flat surface, with a minimum of 10 feet of open space in front of the pallet.
- Cut banding straps on pallet.
- Open the top of the box and remove Unpacking and Assembly Instructions and review.
- Remove documentation packaging (including installation thumb drive), Cervical Guide shipping box, monitor arm box and service kit.
- Remove foam.
- Insert ramp under the pallet, wedging foam between pallet and floor.
- Remove the monitor box and HHU support section and place the HHU, still in protective foam, on the ground next to the pallet. Ensure that the HHU is not in front of the ramp.
- Dock HHU; use restraint foam to secure HHU in dock.
- Remove the rear foam, rocking the unit gently forward to ease removal. Then rock the unit back to remove front foam.
- Orient and unlock wheels.
- Without rolling over umbilical cord, roll the instrument out down the ramp.
- If needed, move the unassembled LuViva and its accessory items to a location appropriate for assembly.
- Lock the front wheels for stability during final assembly. Push the wheel locks down to lock wheels into place.

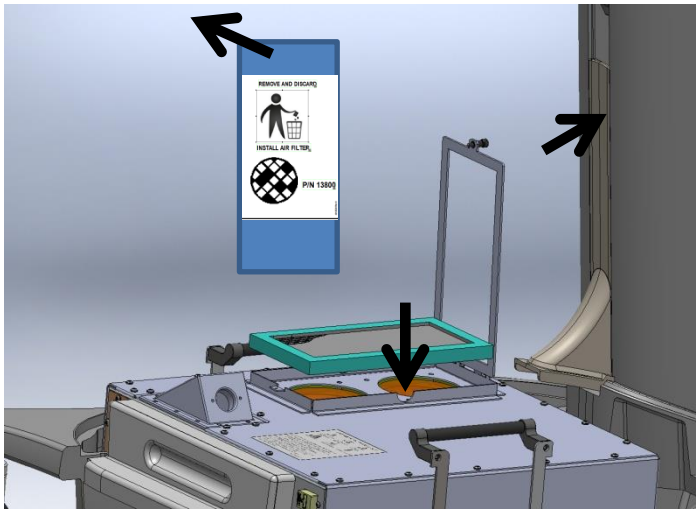
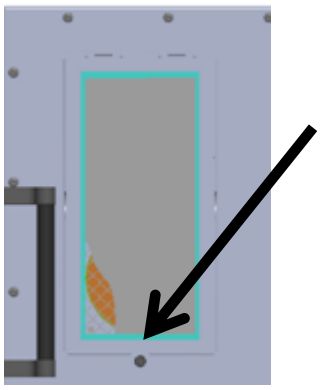
Unlocked

Locked

20.3 Base Unit - Air Filter and Lamp Assembly Installation

20.3.1 Install Air Filter

	Lock wheels for additional stability. Remove base unit cover to access base unit. Remove protective plastic coverings.
	Remove lamp access panel to access base unit.
Top View of Base Unit 	Remove any protective covering from the top of the base unit.

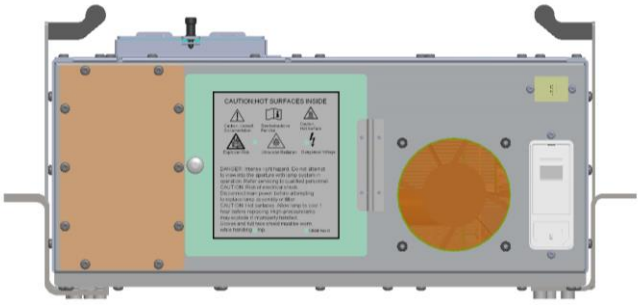
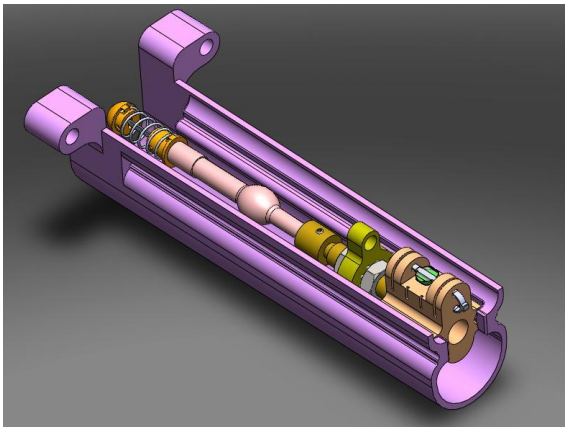
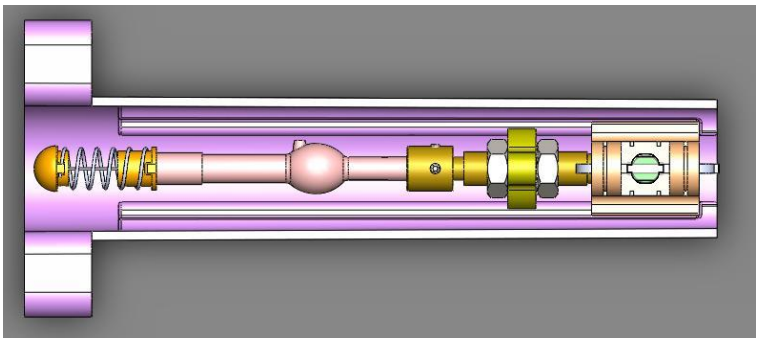
	An air filter holder is mounted to the top of the base unit. Open the holder by unscrewing the screw and lifting the retaining frame. Remove protective covering from air filter. Install air filter from the Service Kit.
	Close the filter retaining frame and tighten screw by hand.

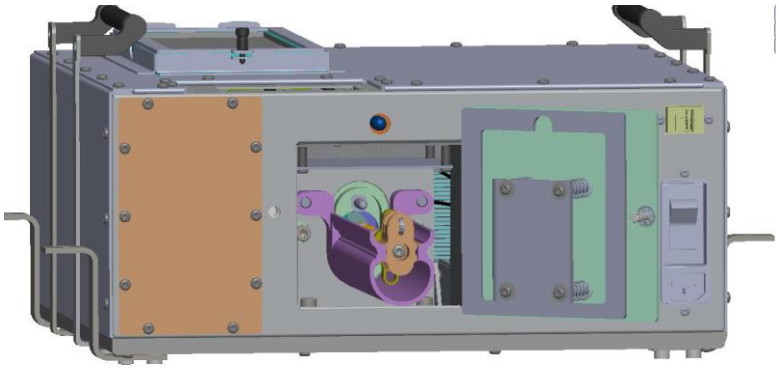
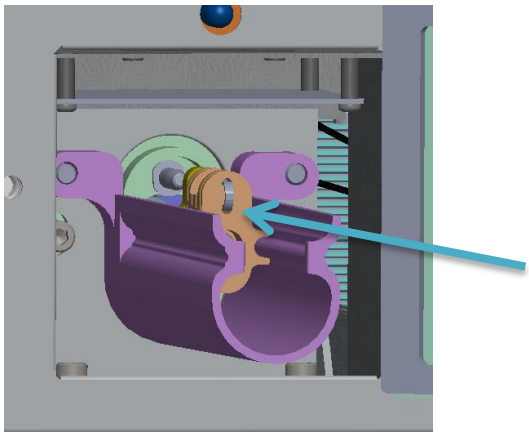
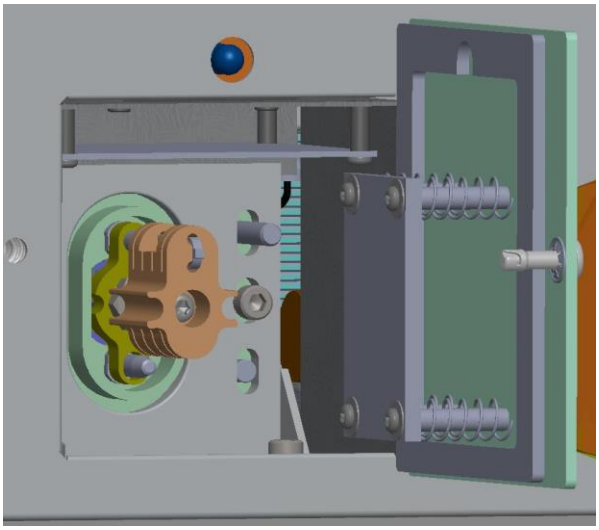
20.3.2 Install the Lamp Assembly

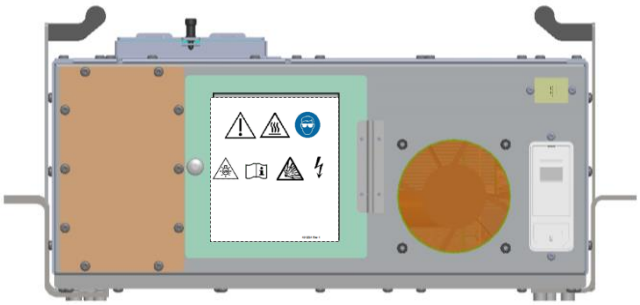
CAUTION: Wear long sleeves, gloves and face shield while installing the lamp in LuViva.

CAUTION: Do not drop the lamp, subject it to impacts, apply excessive force or scratch it: the pressure inside the glass lamp is very high and might cause it to rupture. Injury may result if the lamp is broken.

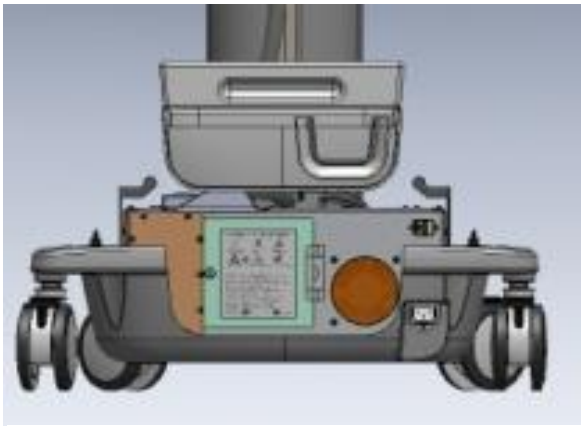
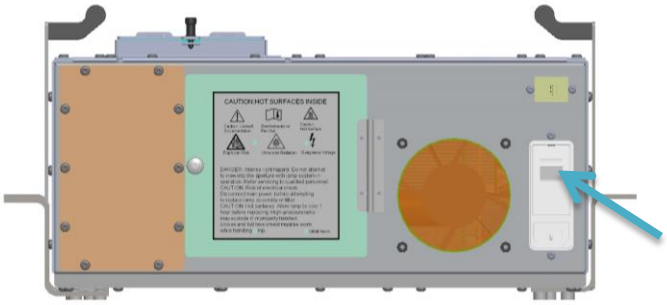
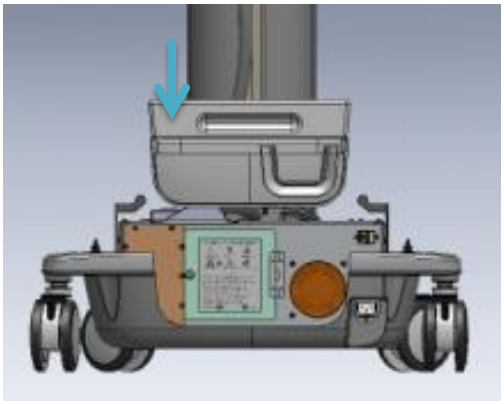
CAUTION: Never touch the lamp with bare hands. Dust, oils and grime will be transmitted to the lamp, and during use may cause the lamp to explode.

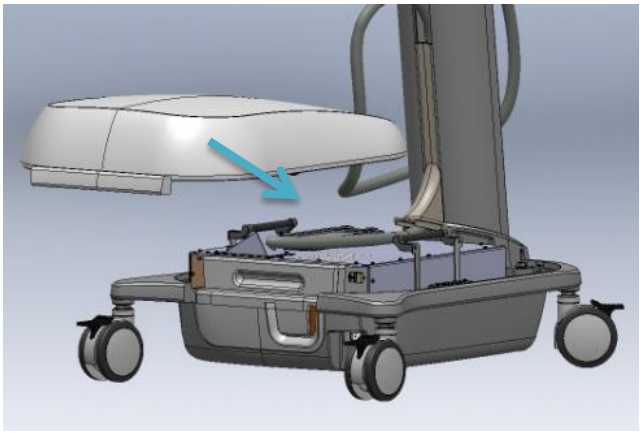
	Open the Bulb Access Door of the Base Unit by unscrewing the locking screw with supplied 5/32 Allen Key, and opening the hinged door.
	Open the Service kit and remove the Lamp Assembly. Lamp Assembly enclosed in Placement Tool: Side View
	Lamp Assembly enclosed in Placement Tool: Top View

	Open the Lamp Access Door. Align the placement tool onto the mounting pins.
	Pushing on the rear of the lamp assembly, gently push the lamp assembly into position.
	Holding lamp in place, remove placement tool. Close door. The door will apply pressure to the lamp assembly and keep it in place.

	Close the Bulb Access Door and replace screws. Save packaging; lamp assemblies require replacement after 1000 hours of use. Return used lamp assemblies to Guided Therapeutics, Inc. for recycling and disposal.

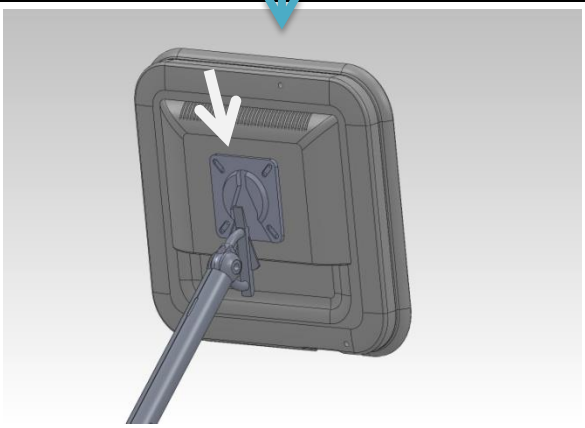
20.4 Install the Base Shell

 	Turn on the Main Power Switch located on the left side of the Base Unit by moving the power switch to the on position. This enables the instrument to be powered on.
	Install lamp access panel.

	Install Base Unit Cart Cover.
PLUG IN POWER CORD	Install country specific power cord, supplied by distributor. Thread through cart base; plug into Base Unit power socket.

20.5 Install the Monitor Arm and Display

The monitor arm and display are supplied in separate packaging. The display is installed on the monitor arm, which is installed on the table top.

	Install the monitor arm into the mounting hole in the table top.
	The touchscreen monitor has a Monitor Mount Retainer bracket installed on its rear side. Slide the holding clamp of the Monitor Arm into the matching slot on the bracket to install the Monitor. It will snap into place when installed correctly.
Connect USB, Video, audio and power to monitor. 	Thread the cables through the cable holders on the monitor arm. Connect the cables to the inputs marked on the monitor.

20.6 Place the HHU on the Docking Station

Remove the protective packaging from the HHU and umbilical cable and place on the Docking Station, as shown below.

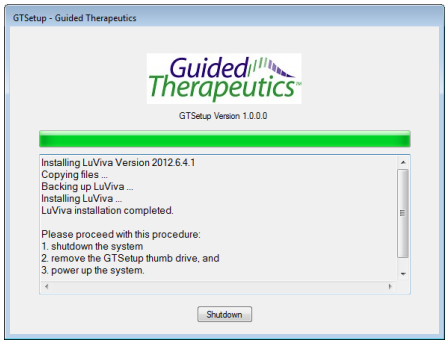
	Docked HHU

21. Set-Up—Software Configuration

21.1 Initial Installation

Once all of the assembly steps are completed, follow the sequence below to activate LuViva:

- Plug LuViva into grounded wall outlet.
- ***CAUTION: To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth (grounded wall outlet). Improperly powering LuViva may result in damage to LuViva and substantial risks of electric shock to the operator or patient.***

1. Remove the set-up USB drive from the documentation package. 2. Insert the setup USB drive into the USB port of the monitor.	
3. Power up the system using Standby button on the HHU.	
4. After system startup, the GTSetup software will install LuViva software. 5. The GTSetup screen will appear and display progress.	
6. Follow screen prompts until installation is completed. 7. Remove the set-up USB. 8. The system is ready for use.	

22. Monitor Arm Instructions for Use

http://www.hmergonomics.nl/wp-content/uploads/2010/11/DYN-013-001-INST-A.pdf

23. Touchscreen Monitor Instructions for Use

http://www.planar.com/media/94079/mn-la17-020_0320_02a.pdf