en

Instructions for Use

ASTODIA®

Diaphanoscope

DIA100
DIA120
DIA130
DIA140

Part no. 0811.7200.12 Rev. 10 11/2024

STIHLERELECTRONIC
A GENTHERM Company

STIHLER ELECTRONIC GmbH • 70771 Leinfelden - Echterdingen • Germany

To be completed by the user: _____

Serial number _____

Registration number _____

Equipment location _____

Start-up date _____

Manufacturer: **STIHLER ELECTRONIC GmbH**
Gaussstrasse 4
70771 Leinfelden - Echterdingen
GERMANY
Tel. +49 (0) 711-720670
Fax +49 (0) 711-7206757
www.gentherm.com/medical
E-Mail: info.ste@gentherm.com

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STIHLER ELECTRONIC GmbH, Leinfelden - Echterdingen, declares in sole responsibility that this product conforms to the regulation (EU) 2017/745 on medical devices (MDR).

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1 Introduction

1.1 Information on these instructions

It is imperative that you read these instructions for use before using this product. Failure to follow the instructions for use can result in damage to the product or to other property and/or personal injury.

These instructions contain important information on the safe use of ASTODIA.

Fully read the instructions for use, including the warning and caution information, before you use ASTODIA. Failure to follow the warnings, cautions, and information on use can result in death or severe injury to the patient.

ASTODIA consists of a control unit DIA120, a hand piece DIA130 and a charger DIA140.

These instructions for use are directed towards trained healthcare personnel and persons in medical professions.

1.2 Intended use

The Diaphanoscope ASTODIA serves for searching blood vessels and helps identify structures filled with air or fluid deep under the skin surface.

1.2.1 Intended medical indications

It serves for the transillumination of the biological tissue, to visualize its structures; e.g. in the overextented, neonatal wrist joint of the dorsopalmar, to punctuate the radial and ulnar arteries while they are visible and for the quick identification of a pneumothorax or a hydrocele in the field of paediatrics/neonatology.

1.2.2 Contraindications

Contraindications for the transillumination of tissue using visible light are not known for the intended use.

1.2.3 Possible adverse effects

In normal use, no adverse effects arising from ASTODIA are to be expected.

1.2.4 Intended patient group

Paediatrics and preferably for premature babies and neonates.

1.2.5 Intended body part

Contact with intact skin, torso and extremities on all sides.

1.2.6 Intended user profile

Medical staff (e.g., doctor, nurse, nurse, service personnel, medical technician).

1.2.7 Intended environment of use / operation

- ASTODIA may only be used in professional healthcare facilities (e.g. hospital, emergency care, dialysis, etc.).
- ASTODIA is not intended for home healthcare environment and for veterinary medicine.
- ASTODIA is reusable, but requires cleaning / disinfection between the applications.
- Appropriate medical hygienic factors must be applied for the use of ASTODIA.
- ASTODIA must not be used in an environment at risk of explosion or in the present of flammable anesthetics.

1.3 Important safety information

These instructions for use define and refer to the following safety information.

DANGER
Describes a maximum risk from a situation which, when not avoided, can lead directly to severe or fatal injuries.

WARNING
Describes a dangerous situation which, when not avoided, can lead to severe or fatal injuries.

CAUTION
Describes a dangerous situation which, when not avoided, can lead to mild to moderate injuries.

NOTICE
Indicates information considered important, but that does not relate to risks (e.g. reference to property damage).

1.3.1 Dangers

DANGER

Explosion hazard!
Do not use the ASTODIA diaphanoscope in an explosion-hazard environment or in the presence of flammable anaesthetics.

1.3.2 Warnings

WARNING

Risk of injury!

- Read and observe all instructions, stickers, and accompanying documentation that came with the medical device. Failure to observe the instructions, including warnings and safety information, can result in incorrect handling, patient injury, user injury, medical personnel injury, damage to the device, or material damage.
- Operate and service this equipment only in accordance with the procedures described in these instructions and with the applicable standards, rules, and guidelines. The manufacturer shall not be responsible for the safety of users or patients if any actions/procedures other than those published are carried out during operation, servicing, or repeated inspections.
- Operating and servicing personnel must be appropriately trained and medically qualified.
- ASTODIA does not contain any parts the user can repair. Therefore, do not attempt to repair ASTODIA yourself. Contact your local sales point.
- Do not use ASTODIA until the following error conditions have been remedied through appropriate corrective action:
  - Damaged or worn cables, plugs, or device box.
  - Damaged casing, damaged or loose control panel.
  - A system that has been exposed to mechanical impact or liquid ingress into internal electronic system components
- Only persons authorised and qualified by the manufacturer may perform repairs to the equipment.
- To prevent the risk of an electric shock, strictly use a charger approved by the manufacturer.
- Modifications to ASTODIA are not permitted.

WARNING

Risk of infection!
Clean and disinfect the equipment after every use and before you return the equipment for repairs.

WARNING

Risk of electric shock!

- All electrical installations must conform to the applicable electrical standards and the specifications defined by the manufacturer.
- During charging, the device shall not be in the patient environment.

WARNING

Risk of radio interference!

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used at a distance less than 30 cm (12 inches) to any part, including cables of the device specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

1.3.3 Caution information

CAUTION

Risk of injury!

- The use of the ASTODIA diaphanoscope must be carried out under the responsibility of a physician.
- In case ASTODIA starts directly after switch on in the highest light level and a change of the highest level is not possible - then do not use ASTODIA!
- Due to its high light intensity this device may not be used in close vicinity to the patient's eyes.
- If the ASTODIA control unit is being charged, a safety distance of at least 1.5 m has to be kept.
- In case of continuous use at maximum intensity to a fixed point on the surface of the skin, temperatures of up to 48 ºC can be reached within a period ≤ 2 minutes even when device is being used in the intended use.
  Due to the small surface area and short amount of time, this should not be classed as a critical issue (see IEC/EN 60601-1).
  The slight redness that can be seen after use is quickly reversible and does not cause tissue lesions.
- ASTODIA may not be used several times on a fixed point on the surface of the skin.
- Once ASTODIA has been switched on, the red and yellow LEDs of the hand piece each flash three times (functional testing). ASTODIA may only be used after the LEDs have flashed. If the LEDs do not flash as described, ASTODIA must be serviced before being used again.

CAUTION

Risk of radio interference!

- According to Standard IEC/EN 60601-1-2, medical electrical equipment requires special precautionary measures in regard to electromagnetic compatibility (EMC). Install and operate medical equipment according to the EMC information listed in the accompanying documentation. Portable and mobile RF communication equipment may have an impact on medical electrical equipment.
- This equipment/system can produce radio interference and can interfere with the operation of equipment in close proximity. It may be necessary to take appropriate corrective action, such as a new direction, a new configuration of ASTODIA, or shielding.
- The essential performance can be lost or degraded due to EM disturbances.

1.3.4 Notices

NOTICE

- Actions to avoid damaging the diaphanoscope:
  - Do not immerse the control unit and/or the connector for the connection cable in liquid.
  - Do not disinfect the system using steam (e.g., in autoclaves), hot air, or thermo-chemical cleaning solutions.
- The customer is responsible for the proper packaging and labelling of returns.
- The operator should not use any cleaning or decontamination methods other than those recommended by the manufacturer.

1.4 Symbols

Symbols and indications on the control panel	
	Switch key for LED-colours - press shortly OFF button - press and hold (ca. 1 s)
	ON button Reduce the light intensity
	ON button Increase the light intensity

Where applicable, these symbols appear at the appropriate location on the patient warming system, on the packaging, on the identification plate, or in the accompanying documentation.	
	This symbol states that this device is a Type BF applied part to standards IEC/EN 60601-1 and VDE 0750 Part 1.
IPX 0	This symbol indicates following IEC/EN 60529 that this device does not have specific protection against humidity.
	Observe the instructions for use.
	General warning/danger symbol
	Reference (part) number
	Lot number
	Serial number
	Year of manufacture
	Manufacturer
	Distributor
	This symbol on the control unit indicates that this device complies with the requirements of the regulation (EU) 2017/745 on medical devices (MDR).
	Warning of optical radiation. Do not aim LED directly at the eyes!
	Electrical devices are recoverable waste and should not be disposed of in domestic waste at the end of their service life.

	Batteries and rechargeable batteries are recoverable waste and should not be disposed of in domestic waste at the end of their service life.
	General recycling symbol
	Additional information
	Symbol for the permitted temperature range for storage and transport
	Symbol for the permitted moisture range for storage and transport
	Symbol for the permitted atmospheric pressure range for storage and transport
	Transport with the arrows pointing up
	Keep dry
	Fragile, protect against impacts
MD	Medical Device

1.5 Conformity with international standards

Standard	Title
IEC/EN 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC/EN 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

1.6 Guarantee conditions

The guarantee period is 12 months. During this guarantee period the manufacturer will repair or replace free of charge all defects caused as a result of material or manufacturing errors.

Other damage is not subject to this guarantee. The guarantee does not include cases of misuse or incorrect handling, use of force, or damage caused by normal wear and tear. This applies also to changes undertaken by persons who are not authorised by the manufacturer and to modifications to the original condition.

If the equipment is damaged during the guarantee period, send the cleaned equipment to the nearest sales point or directly to STIHLER ELECTRONIC GmbH. The sender is responsible for any transport and packaging costs.

1.7 Liability

The manufacturer shall be liable for the safety, reliability, and performance of the equipment only when all operating, servicing, and calibration procedures have been carried out by trained and qualified persons according to the procedures published by the manufacturer; when only original spare parts have been used to replace components as needed; when the assembly and completion of repairs have been carried out only by authorised persons or an authorised service centre; when the electrical installations satisfy the locally applicable regulations and the IEC/EN requirements; and when the equipment is used for its intended purpose and at a suitable location in accordance with the instructions for use.

On request, STIHLER ELECTRONIC GmbH will provide service instructions that will allow properly trained and qualified persons to repair the parts of the equipment that the manufacturer has designated as reparable.

The provision of technical documents or spare parts is not an authorisation from the manufacturer to open or repair the equipment.

1.8 Disposal of the equipment

Electrical devices are recoverable waste and should not be disposed of in domestic waste at the end of their service life. Please follow the local rules for the disposal of used products, or send the cleaned and disinfected equipment with a corresponding note to STIHLER ELECTRONIC GmbH or your closest sales point. This will ensure the most cost efficient and proper disposal of your old equipment.

	Follow the national regulations on the disposal of medical products.

1.9 Information on battery disposal

Batteries must not be disposed of in domestic waste. The user is obliged to ensure proper disposal. Returns can be made to public communal collection points or wherever the batteries are sold.
The battery can be removed by loosening the 4 screws on the underside and opening the housing.

1.10 Return of a used product

A report must be sent together with the equipment, detailing the precise reasons, circumstances, and, if known, the cause of the return. To prevent transportation damage, the equipment should be shipped either in the original packaging or in other, well-protected packaging.

⚠ WARNING

Risk of infection!
Clean and disinfect the equipment after every use and before you return the equipment for repairs.

NOTICE

The customer is responsible for the proper packaging and labelling of returns.

1.11 Service information

For service or technical support, please contact your local sales point or the following:

STIHLER ELECTRONIC GmbH
Gaussstrasse 4
70771 Leinfelden - Echterdingen
GERMANY

Tel. +49 (0) 711-720670
Fax +49 (0) 711-7206757
www.gentherm.com/medical
E-Mail: info.ste@gentherm.com

1.12 Incident reporting

All serious incidents relating to the product should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

2 Product description

2.1 Introduction

The method of transillumination or Diaphanoscopy has been used in the field of paediatrics and especially of neonatology for decades. It is used to identify a pneumothorax or a hydrocele quickly and to visualize vessels in limbs during a puncture. Until now, cold light sources with fibre-optical light cables have been used for this purpose. Nowadays, however, the light emitting diodes (LED) are more often applied. Because of its design, the ASTODIA is particularly suitable for the patient-specific application on small premature babies.

2.2 Technical Description

ASTODIA consists of a control unit, a hand piece and a charger.

Its light in the visible spectrum (yellow/red) is used for the transillumination of thin limbs (e.g. wrist joint) and for the quick identification of a pneumothorax or a hydrocele in the field of paediatrics/neonatology.

Two high-performance light-emitting diodes of different wave length (yellow and red) are used for a wide range of applications. The thermal load for the transilluminated tissue is minimized and regulated by an electronic control unit.

The extremely bright light of the used high-performance diodes is adjustable in 9 steps or infinitely variable. The special yellow coloured light visualizes the vessel structures particularly well, as it is required for venipuncture. The red light ensures a continuous, extensive and deep transillumination, which is required for visualizing the pneumothorax or for diagnosing the hydroceles.

The common interface on the control unit is designed for charging the integrated batteries as well as for the electrical connection of the hand piece cable.

This avoids using and charging of the device at the same time. This way, the charger, when it is charging the device, cannot be seen as a medical device provided the distance to the patient (min. 1.5 m) is kept.

2.3 Components of ASTODIA

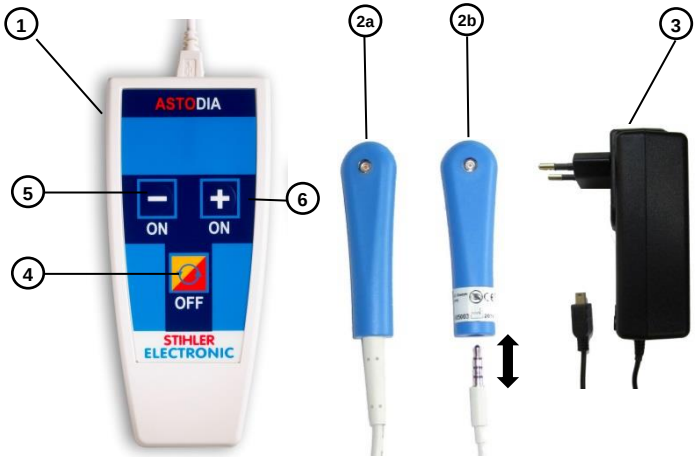

Fig. 1 Components of ASTODIA

No.	Designation	Description
1	Control unit	It includes the complete electronic circuitry and the power supply of the unit. The interface, which is used for the charger and the hand piece ensures that the patient is only treated without galvanic connection to the power mains.
2a	Hand Piece (SN < DH05000)	Two high-performance diodes of different wave lengths (yellow and red) provide for a wide field of application. The round and edge-free design allows the transillumination also on positions which are difficult to access.
2b	Hand Piece (SN ≥ DH05000)	
3	Charger	The intelligent charging management ensures that the integrated batteries work for a long time.
4	Switch key / "OFF"	Switch key for LED-colours - press shortly
		OFF button - press and hold (ca. 1 s)
5	Key "-" / "ON"	Reduce the light intensity
		Switching on the device
6	Key "+" / "ON"	Increase the light intensity
		Switching on the device

3 Installation

3.1 Initial start-up

Before you put the device into operation, charge the integrated batteries. To do this, use the belonging charger which is to plug into the interface of the control unit.

WARNING

Risk of injury!
To prevent the risk of an electric shock, strictly use a charger approved by the manufacturer.

Charging is complete when the LED on the charger lights up green or alternately with a short flash of the yellow LED and the green LED.

Prior to first use, perform the following inspections:
Visual inspection *(see **Section 6.2.1** Visual inspection Visual Inspection)*

4 Start-up

Read each section before you use ASTODIA.

4.1 Preparation for use

To apply the ASTODIA connect the hand piece with the interface of the control unit.

Make sure that the plug of the connection cable for the ASTODIA hand-piece is fully plugged in. If the plug is not completely plugged in, the function of the handpiece is limited; e.g. only the yellow LED lights up.

4.2 Starting

CAUTION

Risk of injury!
- In case ASTODIA starts directly after switch on in the highest light level and a change of the highest level is not possible - then do not use ASTODIA!
- Due to its high light intensity this device may not be used in close vicinity to the patient's eyes.
- ASTODIA may not be used several times on a fixed point on the surface of the skin.
- Once ASTODIA has been switched on, the red and yellow LEDs of the hand piece each flash three times (functional testing). ASTODIA may only be used after the LEDs have flashed. If the LEDs do not flash as described, ASTODIA must be serviced before being used again.

1 Start the device directly with the key  on the lowest light level or with the key  on the second lowest light level.

The device is, after of the LEDs flashed, preset to start with the red LED colour as standard.

Infinitely variable light intensity is set by pressing and holding (for at least 0.5 s) the  /  key.

If you press the button for a short time, you can change the light intensity.

The colour changes from RED to YELLOW and vice versa by pressing this key  .

	The transillumination effect can significantly be improved if you dim the surrounding light.

2 If the device is constantly operated with the highest light level, it will automatically switch over to the next lower level after 2 minutes.

3 If the unit is switched on for about 5 minutes and no key is actuated during this time, it will automatically switch off to save the battery power.

4 If the battery power is low, the LED which is working at that time will start flashing. This warning can be suppressed for 5 minutes by shortly pressing any button. This can be repeated until the battery voltage reaches a critical value and the device automatically switches off.

4.3 End operation

Switch the device off by pressing and holding the key  (for about 1 s).

4.4 Charging the batteries

To charge the integrated batteries only use the charger provided with the basic equipment and follow exactly the instructions of the charger.

WARNING
Risk of electric shock! During charging, the device shall not be in the patient environment.

4.5 Cleaning and disinfecting

NOTICE
Actions to avoid damaging the diaphanoscope: - Do not immerse the control unit and/or the connector for the connection cable in liquid. - Do not disinfect the system using steam (e.g., in autoclaves), hot air, or thermo-chemical cleaning solutions.

Clean and disinfect the control unit and the hand piece, if necessary, or when it is polluted as follows:

1. Clean all surfaces using a soft cloth/cotton swab and a mild soap solution.
2. Disinfect the control unit and the hand piece using a recommended disinfectant.
3. To ensure the durability of the products, we recommend disinfecting the control unit and handpiece only with an alcohol-based disinfectant or one of the recommended disinfectants.

   Other disinfectants may work, but have not been tested by the manufacturer and may affect the lifetime/service life of the product

List of approved, ready-to-use disinfectants:

Disinfectant	**Manufacturer**
Aniosurf ND Premium	Laboratoires ANIOS
Bacillol Plus	BODE Chemie GmbH
BIGUAMED PERFEKT N	Desomed-Dr.Trippen GmbH
Incidin Plus®	Ecolab Healthcare
Incidin Rapid	Ecolab Healthcare
Meliseptol Foam pure	B. Braun Melsungen AG
Meliseptol Wipes sensitive	B. Braun Melsungen AG
Mikrobac forte	Paul Hartmann AG
Mikrozid AF liquid	Schülke & Mayr GmbH
Super Sani-Cloth®	PDI Healthcare
Terralin protect	Schülke & Mayr

Follow the specific instructions for use.

5 Troubleshooting

Device cannot be started	
Device response	Device cannot be started
Possible reasons ►Required action(s)	Battery charge too low. Hand piece is not connected. Control unit or hand piece defect.
Required action(s) for resetting	1. Charge battery 2. Connect the hand piece. 3. Send the control unit and the hand piece to the local dealer.

Batteries cannot be charged	
Device response	Batteries cannot be charged
Possible reasons ►Required action(s)	Charger defect. Batteries defect.
Required action(s) for resetting	1. Replace charger 2. Return the charger and get it repaired 3. Replace batteries

6 Servicing

6.1 Preventative servicing

ASTODIA does not require any preventative servicing.

	No service or maintenance shall be carried out while in use with a patient.

6.2 Periodic Safety Inspection

At least every 24 months - and/or in accordance with the applicable regional and national regulations – it is necessary to check the ASTODIA Diaphanoscope for safety reasons and to document it. The check consists of the following tests:

- Visual inspection
- Check the function of the yellow and the red LED
- Check the functioning of the reduction of the maximum light intensity and the automatic switching off.
- Regionally and nationally required examinations of medical equipment (e.g. electrical safety of the ASTODIA charger)

All tests of the periodic safety inspection have to be passed!
If one of the tests does not pass, the ASTODIA has to be sent to the local dealer or to STIHLER ELECTRONIC GmbH for repair *(see Chapter 1.10 Return of a used product)*.

6.2.1 Visual inspection

Check the following components for completeness and visible damages before each application.

- Charger
- Housing of the control unit
- Control panel
- Hand piece (Especially the plug of the cable)

6.2.2 Check the function of the yellow and the red LED

- Switch on the ASTODIA on the control unit with the key "**-**". The red and yellow LEDs each has to flash three times. The red LED must light up at its lowest level.
- Actuate the shift-key for the LED-colours. The yellow LED must light up at its lowest level.
- Check, if it is possible to change the light intensity by actuating the keys, see *Chapter 4.2 Starting.*
- Check, if the covering glasses of the LEDs are still clear and light-transmitting.

6.2.3 Check the functioning of the reduction of the maximum light intensity and the automatic switching off

- Switch on the ASTODIA on the control unit and set the maximum light intensity - *see Chapter 4.2 Starting*.
- Watch the LED and measure

I. the time, until the ASTODIA automatically reduces the maximum light intensity by one level.
This time must be 2 minutes +/- 10 s.

II. the time, until the ASTODIA automatically switches off completely.
This time must be 5 minutes +/- 30 s.

6.2.4 Electrical Test

The charger has to be checked once a year according to the applicable national safety regulations.

7 Technical data

	DIA120 Control Unit	**DIA130** Hand piece	**DIA140** Charger
Electrical connection	-	-	100-240VAC ±10% 50-60Hz
Nominal voltage	4.8 V	-	-
Classification (IEC/EN 60529)	IPX0		IP4X
Protection class	-	-	Isolation class II ⧈
Classification (EU) 2017/745	Class I		-
Code UMDNS	14-130		-
Code GMDN	36761		-
Dimensions approx. Height approx. Width approx. Depth	 141 mm 63 mm 33 mm	 70 mm 20 mm 10 mm	 100 mm 45 mm 75 mm
Weight	0.2 kg	0.03 kg	0.2 kg
Operating mode	Continuous operation		
Battery type	Battery pack (4x AA, Ni-MH, 4.8 V, min. 1900 mAh)		
Battery capacity	Approx. 5 hours at the highest level		
Charging time	Approx. 3 hours		
Essential performance according to IEC/EN 60601-1	Control of the brightness of the LEDs of the handpiece in different stages.		
Automatically switch over	If the device is constantly operated with the highest light level, it will automatically switch over to the next lower level after 2 minutes.		
Colour LED	Red: 620 – 640 nm	Yellow: 584 – 597 nm	
Illumination intensity	At least 19 lumens (at the highest level)		
Permissible ambient conditions	Humidity	Temperature	Atmospheric pressure
In operation	20% to 85% non-condensing	+10 °C to +40 °C	700 hPa to 1060 hPa
During storage/transport	20% to 90% non-condensing	-20 °C to +60 °C	500 hPa to 1060 hPa
Expected operating life	The expected operating life is 7 years from the date of first use, providing the product is subject to misuse, negligence, damage or inappropriate use and the equipment is used and serviced properly and as intended.		

8 Ordering information

Item	Part no.:
1 ASTODIA **completely packaged consisting of:** 1 piece control unit DIA120 1 piece hand piece DIA130 1 piece charger DIA140 1 pieces cable for DIA130 hand piece Instructions for Use	**DIA100**

Separate order		
1	piece control unit	DIA120
1	piece hand piece (with exchangeable cable)	DIA130
1	piece cable for DIA 130 hand piece (hand piece SN ≥ DH05000 with exchangeable cable)	1607.0001
1	piece charger	DIA140

We reserve the right to modify design and technical data without notice.

9 Guidelines and manufacturer's declaration

Guidance and manufacturer's declaration - electromagnetic emissions		
ASTODIA is intended for use in the electromagnetic environment specified below. The customer or user of the ASTODIA should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11/EN 55011	Group 1	ASTODIA uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11/EN 55011	Class A	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC/EN 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The ASTODIA is intended for use in the electromagnetic environment specified below. The customer or user of the ASTODIA should assure that it is used in such an environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	in compliance	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/bursts IEC/EN 61000-4-4	± 2 kV 100 kHz repetition frequency	in compliance	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	± 0.5 kV, ± 1 kV Line-to-line ± 0.5 kV, ± 1 kV, ± 2 kV Line- to-ground	in compliance	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips-IEC/EN 61000-4-11	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	in compliance	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ASTODIA requires continued operation during power mains interruptions, it is recommended that the ASTODIA be powered from an uninterruptible power supply or a battery.
Voltage interruptions IEC/EN 61000-4-11	0 % U_T; 250/300 cycle	in compliance	
Rated power frequency magnetic fields IEC/EN 61000-4-8	30 A/m 50 Hz or 60 Hz	in compliance	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	Test level	Compliance level	Electromagnetic environment – guidance Recommended separation distance
Conducted disturbances induced by RF fields IEC/EN 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	in compliance	$d = 1.2\sqrt{P}$
Radiated RF EM fields IEC/EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	in compliance	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz

Portable and mobile RF communications equipment should be used no closer to any part of the ASTODIA, including cables, than the recommended separation distance calculated from the equation applicable to frequency of the transmitter.

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b].
Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE1. At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ASTODIA is used exceeds the applicable RF compliance level above, the ASTODIA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ASTODIA.
[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Recommended separation distances between Portable and mobile RF communications equipment and the ASTODIA

The ASTODIA is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the ASODIA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ASTODIA 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 2.7 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 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: The compliance level between 80 MHz and 2.7 GHz is intended to decrease the likelihood that mobile/portable communication equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in this frequency range.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.