Adtec SteriPlas

SteriPlas (and SteriPlas Sensor Module) User Manual

DB0016-21

Contents

1 Preface

1.1 About this Manual

This manual provides important instructions about the installation and safe operation of the SteriPlas and SteriPlas Sensor Module medical devices manufactured by Adtec Europe Limited. The user should carefully read this manual until it is understood. In order to operate the SteriPlas with SteriPlas Sensor Module safely, be sure to pay attention to the safety cautions and warnings. The manufacturer cannot be responsible for damages caused because of use contrary to these cautions/warnings and the warranty will be invalid in such a case.

1.2 Mode of Action & Clinical Effects

Initial research was conducted to determine the mechanism of action of an argon microwave plasma device on bacteria and its general safety, which led to the first clinical trials of gas plasma on wounds worldwide. The SteriPlas treatment head contains a patented ionization chamber that bombards argon gas with electrons emitted from multiple hot electric filaments.

Neutral argon plasma is a consistent and controllable energized gas, with predictable constituent agents that include heat, OH radicals, ions, electrons, photons, and UV light, which ensures reproducible physical and physicochemical effects.

1.3 Intended Use

The SteriPlas is a non-thermal gas plasma-generating device used for the treatment and management of infections on the external surface of the body. The plasma is directed at a patient's wound, ulcer or lesion, where it has an antibacterial effect. The plasma destroys bacteria in the wound, ulcer or lesion and is used to manage infections by reducing the bacterial load, allowing the wounds to heal.

1.4 Users and Training

The SteriPlas may only be *prescribed* by healthcare professionals - those professionals who maintain health in humans through the application of the principles and procedures of evidence-based medicine and caring - in line with hospital policy and national laws. The SteriPlas may be *used* by any person who has been approved to treat the patient by a healthcare professional responsible for the care of the patient ***and*** who has received the training specified below.

Training on the operation of the SteriPlas is provided by the manufacturer or a trained distributor using the form FM-P06-02TrainingPack. The trainer(s) shall guide the trainee(s) through all documentation relevant to the device's use (as detailed in the Training Pack), ensuring that the trainee(s) fully understand every aspect of the device's use. Close attention is paid to the indications, contraindications, warnings, cautions, and any special instructions for the user and/or patient. Before signing the Training Pack to confirm receipt of their training, the trainee(s) must be able to fully control the medical device to the satisfaction of the trainer(s). The trainer(s) shall ensure that the trainee(s) are capable of doing so and that the trainee(s) understand all operating principles of the device. Only once the trainee(s) can show the trainer(s) complete understanding of the training materials, they shall sign the Training Pack to confirm their full understanding.

Distributors are trained in how to administer training in the operation of the SteriPlas using form FM-P02-01DistributorsTraining by fully trained Adtec employees. Distributor training covers all aspects of training also covered in FM-P06-02TrainingPack. Only once the trainee(s) can show the trainer(s)

complete understanding of the training materials, they shall sign the Distributors Training Pack to confirm their full understanding.

The use of the SteriPlas does not require any specialist or pre-requisite training outside of the requirement to have received training provided by Adtec or its trained distributors, and to have received approval to treat the patient by a healthcare professional responsible for the care of the patient. All necessary information on the application of the SteriPlas can be found in these instructions for use.

1.5 Treatment Times and Use

The SteriPlas should be operated using Section 6 of this user manual. Instructions for the use of the SteriPlas Sensor Module are also included in this user manual. When the device is ready to use, manoeuvre the torch head so that it is directly over the patients wound, making sure to leave a small gap so that the sensor module does not touch the patient.

Treatment times are suggested to be 2-5 minutes, repeated 1-2 times a week until the infection is managed.

The treatment area of the SteriPlas is 12 cm^2. If the wound area is larger than the treatment area of the SteriPlas, the treatment head should be carefully relocated to the next untreated area and the plasma treatment restarted. This procedure is repeated until the entire wound has been treated. The user should pay attention to creating a slight overlap between the areas covered by the SteriPlas plasma torch head aperture when relocating the treatment head.

1.6 Side Effects

There are no known or recorded side effects or complications associated with treatment using the SteriPlas.

1.7 Contraindications

Minors (patients younger than 18 years old) and pregnant or breastfeeding women are not intended to receive treatment from the SteriPlas. The decision to exclude these vulnerable populations is based on a lack of evidence proving that the treatment is successful rather than evidence of an unsuccessful treatment.

1.8 Treatment Warnings

The general definitions of the safety symbols used in this instruction manual:

WARNING	Procedures that you must follow to prevent possible serious injury or death
CAUTION	Procedures that you must follow to prevent damage to the equipment

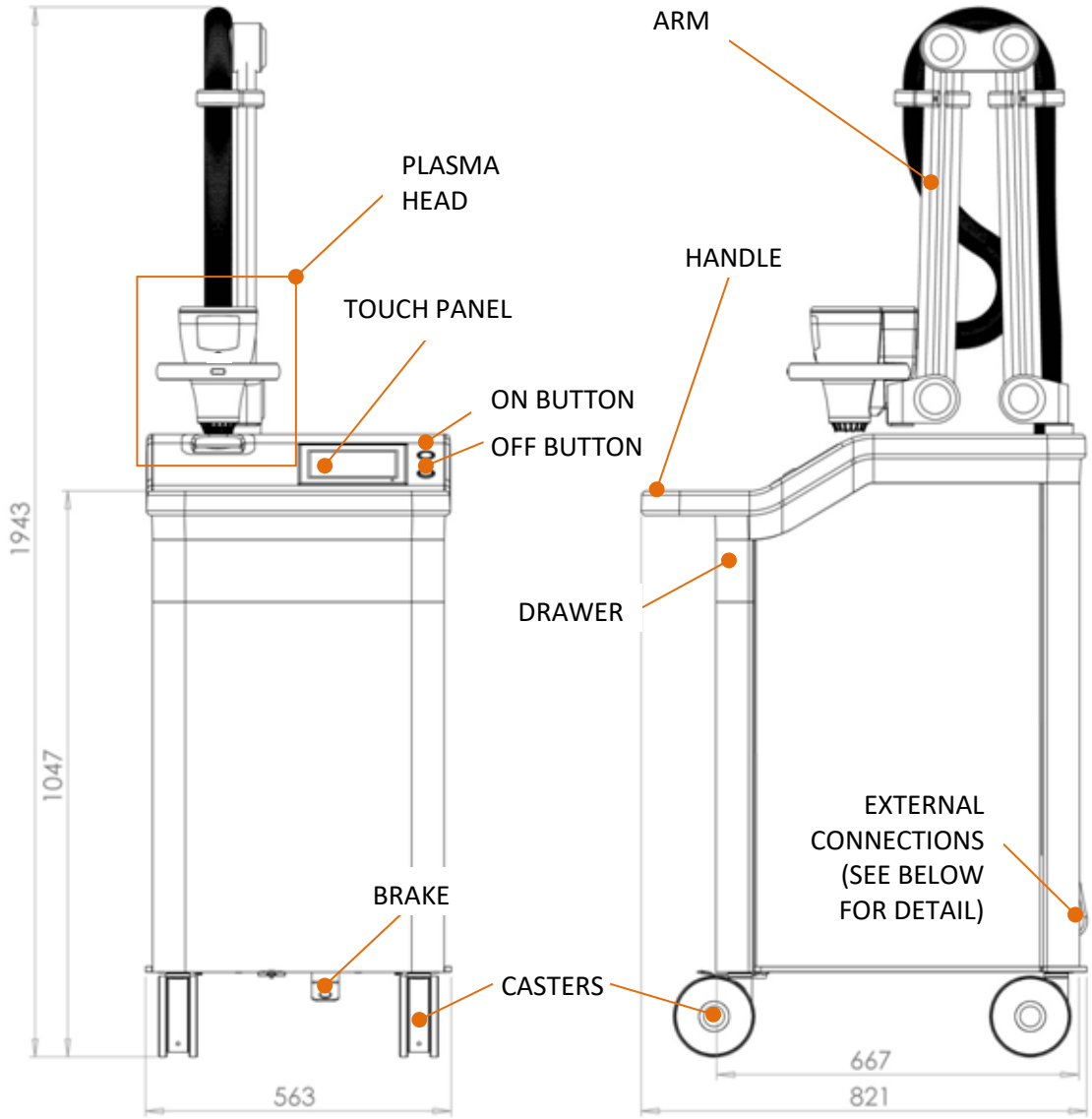
WARNING	The SteriPlas treatment mesh can reach temperatures of up to 300°C (572°F), and the internal metal ring may heat up to 80°C (176°F), which can cause burns. DO NOT push small body objects through the SteriPlas Sensor Module.
WARNING	SteriPlas Sensor Module temperature may reach up to 48 °C (118.4 °F) which could burn skin if contacted for extended periods of time. Please do not touch SteriPlas Sensor Module while the device is operating.
WARNING	Do not treat the same area for more than 5 min per treatment.
WARNING	The SteriPlas produces ozone (O_3) and nitrogen oxides (NO_x) from reactions of the plasma with the environment and may be harmful if inhaled. Do not treat within 2.5 cm of the mouth or nostrils.
WARNING	Traces of hazardous gases such as ozone and NO_X may form from reactions in the air. Only operate in a well-ventilated room.
WARNING	Ozone and NO_x at concentrations of 0.06 ppm and 0.012 ppm are present at 2.5 cm below the SteriPlas Sensor Module. NIOSH and HSE state an 8-hour continuous exposure limit of 0.1 ppm for inhalation of ozone. NIOSH and HSE state a 1 ppm and a 0.5 ppm 8-hour continuous exposure limit for NO_2 and a 25 ppm and 2 ppm for NO with regards to inhalation. Assuming the SteriPlas is the only ozone and NO_x source applicable, the user and patient's exposure is below the exposure limits provided by these government agencies at 2.5 cm from the SteriPlas Sensor Module. Nevertheless, the user is advised to consider other sources of ozone and NO_x and ensure that they do not exceed these limits.
WARNING	Do not directly look at the plasma. Low levels of UV radiation are emitted from the plasma.

WARNING	There are no completely safe levels of UV since UV radiation is a carcinogen. The SteriPlas emits UV radiation at a maximum of 0.36 µW/cm^2 directly below the SteriPlas Sensor Module. The International Commission on Non-Ionizing Radiation Protection (ICNIRP) states that for the most sensitive, non-pathologic, skin photo-types, ultraviolet radiant exposure in the spectral region of 180 to 400 nm upon the unprotected skin should not exceed 30 J/m^2 (or 3000 µW/cm^2 if the exposure time is set to 1 s in a given 24 h period). In order to calculate the user's maximum exposure time in a 24-hour period, 3000 µW/cm^2 should be divided by the effective irradiance experienced by the user from all possible UV radiation sources. Assuming the SteriPlas is the only UV source applicable, the maximum plasma on exposure time in a 24 hour period is 2 h, 18 min, 53 s.
WARNING	If treating an area near the face, ensure the patient is wearing eye protection. Eye protection must take the form of CE marked goggles that are compliant with EN 170.
WARNING	If patients have known allergies to UV, ozone and/or NO_x gases, then do not treat them.

2 General Information

2.1 SteriPlas Outline

2.1.1 SteriPlas Parts and Dimensions



*Images display two medical devices. SteriPlas with SteriPlas Sensor Module applied part.

2.1.2 Plasma Head

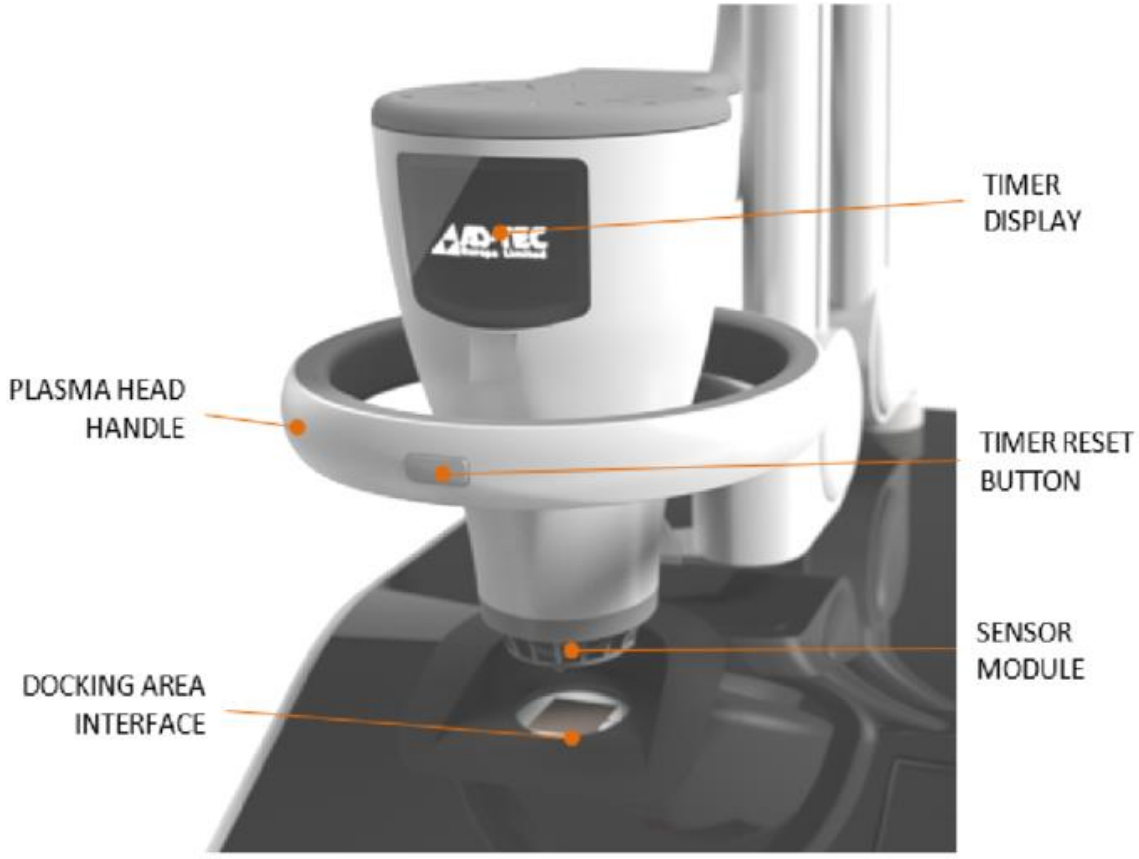
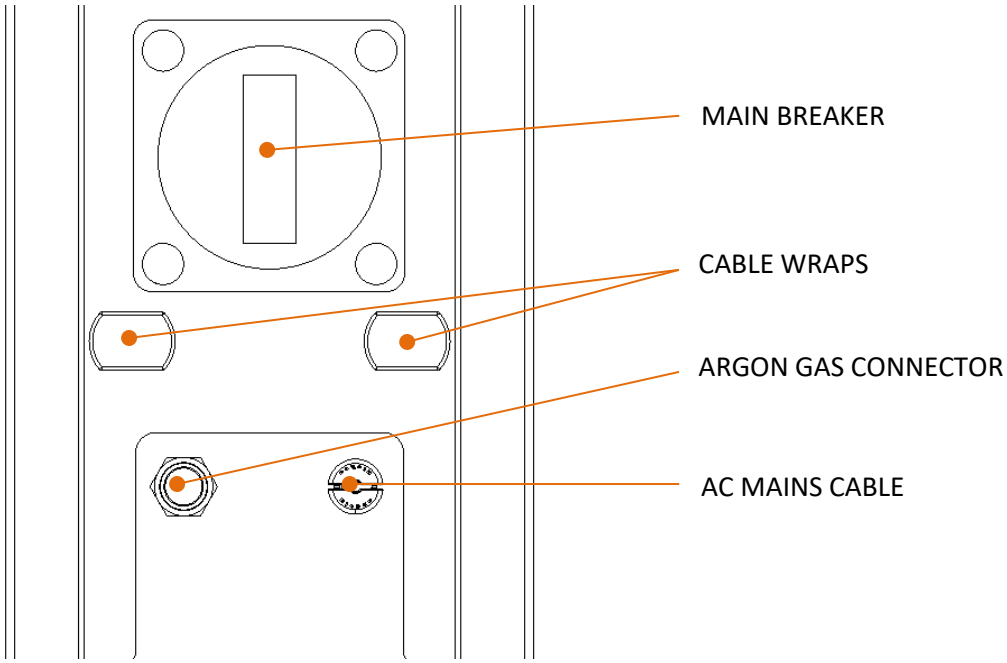
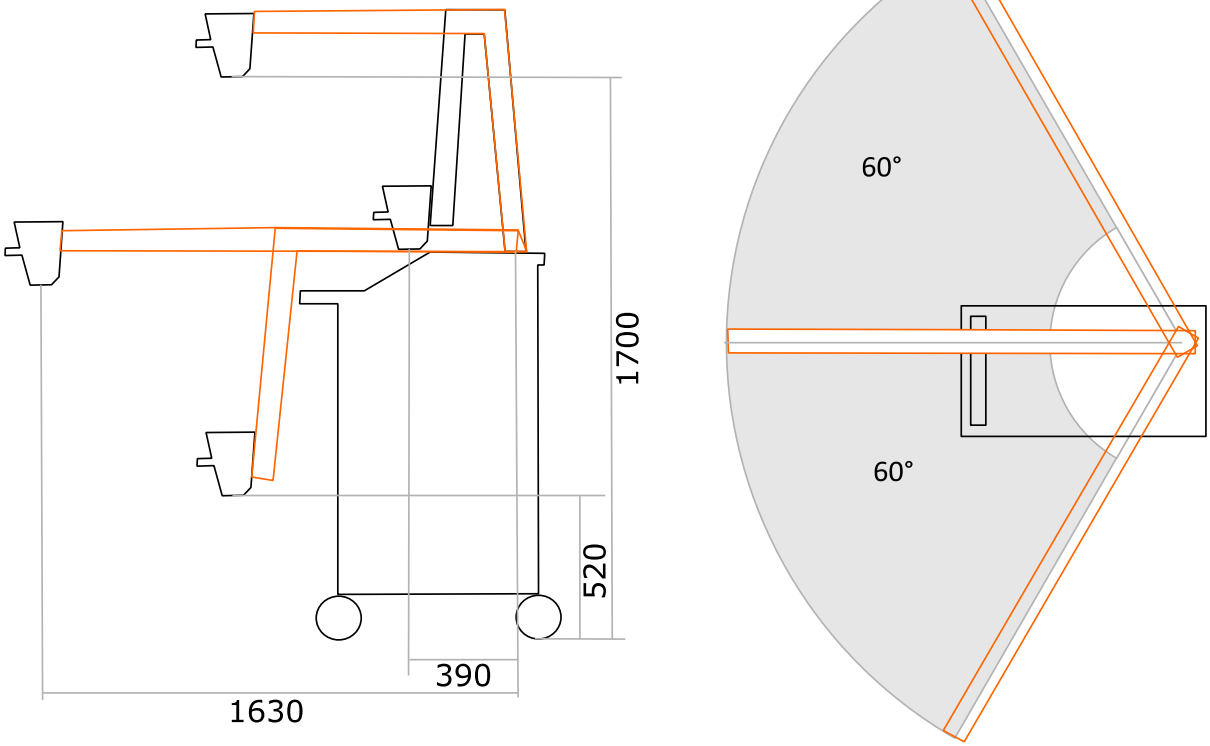


*Image displays two medical devices. SteriPlas with SteriPlas Sensor Module applied part.

2.1.3 External Connections Panel



2.1.4 Treatment Range



2.2 Device Identification

The label on the device identifies the device by:

- Product name.
- Serial number.
- Model number.
- Voltage required to operate.
- Power consumption and electrical classification.
- Gas required to operate and specification.
- Operation parameters.
- Total product mass.
- EU MDR medical device classification.
- Manufacturer contact information.
- Date of manufacture.
- CE mark and relevant other markings.

3 Safety Information

3.1 General Safety

The SteriPlas is classified as a Class IIb medical device.
The SteriPlas Sensor Module is classified as a Class I, Type B applied part, IPX0 – medical accessory.

 ***WARNING***	Lethal voltages exist inside this device. Do not remove any covers. To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
 ***WARNING***	Do not expose the equipment to water or other liquids. It may cause injury or damage to the equipment.
 ***WARNING***	Heat is emitted from the SteriPlas plasma head.
 ***CAUTION***	Low levels of microwaves (average: 0.01 W/m^2, unstable plasma: 0.315 W/m^2) are emitted from the medical device. It is the user's responsibility to consider other microwave-emitting devices in their vicinity, to calculate their exposure, and to work within occupational exposure limits.
 ***CAUTION***	Do not attempt to operate the device without fully understanding device operation procedures. Incorrect operation may cause device failure. Read the instruction manual carefully before using the device.
 ***CAUTION***	Operate only with rated voltage supply. Do not attempt to operate from a power supply with which you are not familiar. Confirm that the appropriate AC power supply frequency, voltage and current are being used.
 ***CAUTION***	Low Levels of UV radiation (<0.36µW/cm²) are emitted from the medical device.

3.2 Electromagnetic disturbances

 ***WARNING***	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.
 ***WARNING***	Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
 ***WARNING***	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SteriPlas, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION

Potential interference with other devices. It is possible that this device may cause electromagnetic interference with sensitive devices. Do not install in the same room as life support systems. If interference of any kind is noted, discontinue use, and contact the manufacturer or an authorized agent.

The SteriPlas and SteriPlas Sensor Module are intended to be used in a professional healthcare environment.

Applicable Test Standards

Basic Test Standard	Classification	Pass Criteria
EN60601-1-2: 2015	Class A	Below standards
EN61000-4-2:2009 – Electrostatic Discharge	Criterion A	Air discharge: 15kV Contact Discharge: 8kV
EN61000-4-3:2006 +A2:2010 – Radiated Immunity	Criterion A	3 V/m 80 MHz up to 2.7 GHz 80 % AM at 1 kHz
EN61000-4-4:2012 – Electrical Fast Transients	Criterion A	± 2 kV 100 kHz repetition frequency
EN61000-4-5:2006 – Voltage Surge	Criterion A	± 0,5 kV, ± 1 kV
EN61000-4-6:2009 – Conducted Radio Frequency Immunity	Criterion A	6 Vrms 0.15 MHz to 80 MHz
EN61000-4-8:2010 – Power Frequency Magnetic Field	Criterion A	30 A/m 50 Hz or 60 Hz
EN61000-4-11:2004 – Voltage Dips and Short Interruptions	Criterion A	
EN55011:2009 +A1:2010 – Radiated Electromagnetic Emissions	CISPR 11 Class A – Group 2	10m: 30 MHz to 230 MHz: Maximum of 40 dBµV/m 230 MHz to 1 GHz: Maximum of 47 dBµV/m 3m: 30 MHz to 230 MHz: Maximum of 30 dBµV/m. 230 MHz to 1 GHz: Maximum of 37 dBµV/m
EN55011:2009 +A1:2010 – Conducted Electromagnetic Emissions	CISPR 11 Class A – Group 2	Frequency Range: 150 kHz to 500 kHz: Limit: 79 dBµV (Average) and 66 dBµV (Peak) for the Phase and Neutral lines. Frequency Range: 500 kHz to 30 MHz: Limit: 73 dBµV (Average) and 60 dBµV (Peak) for the Phase and Neutral lines.
EN61000-3-2:2006 +A1/A2:2014 – Mains Harmonics	Class A	3rd harmonic: 2.30 A 5th harmonic: 1.14 A 7th harmonic: 0.77 A 9th harmonic: 0.40 A
EN61000-3-3:2013 – Voltage Fluctuations and Flicker	Class A	Plt limit: 0.65 Pst limit: 1

Deviations from test specifications: Due to the EUT's size, the generated magnetic field was increased to encompass it with a maximum of 30 A/m. This resulted in over testing in the centre of the field, to almost double the required level.

3.3 Symbols

This symbol signifies “No access”. Personnel may not access these parts unless specifically advised by the manufacturer. Disregarding the caution may result in injury or void product warranty.

This symbol represents the instruction manual. It is a reminder to consult the manual before attempting to operate the equipment. Injury, malfunction, or damage to the equipment may result if this is disregarded.

This symbol signifies “Do not operate in a poorly ventilated environment”. Argon is an asphyxiant and other harmful gases may be produced during operation. Operate only in well-ventilated areas.

This symbol signifies "High voltage". This symbol is displayed where there is a possibility of electric shock. Disregarding the caution may result in serious injury.

This symbol signifies "Hot surface". This symbol is displayed where a high temperature may exist. Disregarding the caution may result in injury.

This symbol signifies “Crush hazard”. Keep your body away from moving parts to prevent physical injury.

This symbol signifies “UV radiation”. This symbol is displayed where there is a possibility of UV radiation exposure. Appropriate handling and precautionary measures should be taken. Disregarding this caution may result in injury.

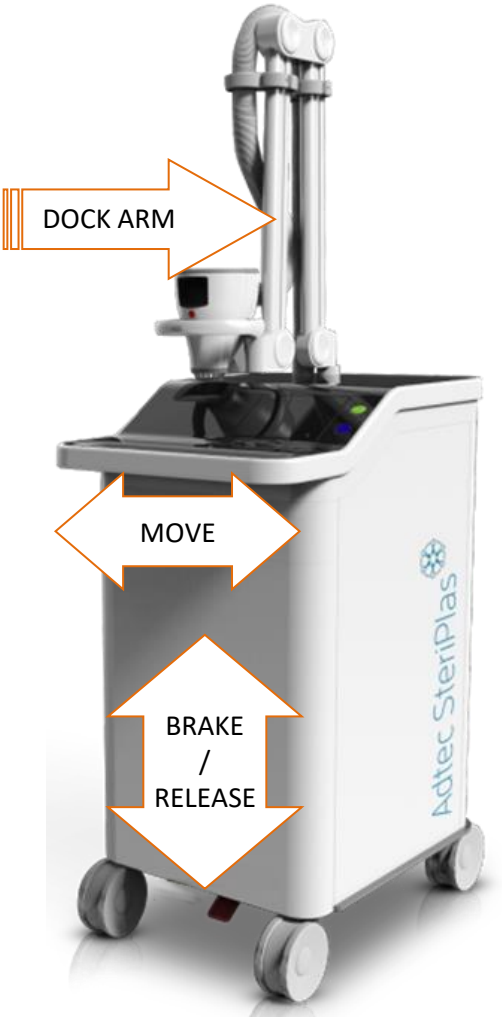
This symbol signifies “Tipping Hazard”. Do not move the device over an inclined surface over 5° with the arm/head extended.

	This symbol signifies “Waste Electrical Electronic Equipment”. Do not dispose of with regular waste. Contact the manufacturer for disposal instructions.
	This symbol signifies “Single use only”. To prevent the spread of infection, use a new part and follow the instructions in the user manual.
	This symbol signifies “Keep away from sunlight”. The SteriPlas Sensor Module should be stored out of sunlight before use.
	This symbol signifies the “Manufacturer”.
	This symbol signifies the “Manufacture date”.
 0297	This symbol is the CE marking. Where compliance with the applicable requirements (2017/745/EU) has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity, and affix the CE marking of conformity. The CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures. 0297 is the identification number of the notified body.
	This symbol signifies “Authorised Representative”.
	This symbol signifies that the product is a medical device.

	This symbol signifies “Model number”.
	This symbol signifies “Serial number”.
	This symbol signifies “Type B Applied Part”. Its location on the torch head signifies where the applied part (SteriPlas Sensor Module) should be attached the device.
	This symbol signifies “Importer”.
	This symbol indicates “Consult User Manual” before using. It is present on the SteriPlas Sensor Module packaging label and indicates this User Manual.

4 SteriPlas Movement

WARNING	Before and while moving the arm, keep the operator's and patient's fingers clear of the arm joints. Fingers could get pinched, and it may cause injury.
WARNING	Before moving the torch to the start point after plasma treatment, ensure that there are no obstructions.
WARNING	After finishing the treatment, move the plasma torch to the start point.
WARNING	Before moving the SteriPlas, ensure that the arm/head is docked in the start point. Disregarding the warning may result in the SteriPlas tipping over when moved across an inclined surface.



CHECKLIST:

- AC cable is unplugged and wrapped.
- Gas is off and disconnected.

MOVE:

1. Dock the arm/head securely.
2. Push up on the brake pedal to release the brake.
3. Move using the handlebar.

PARK:

1. Move into position.
2. Step on the brake pedal to engage the brake.

5 Installation

Read the following cautions carefully before attempting to install the equipment.

 ***WARNING***	Traces of hazardous gases such as ozone and NO_X may form from reactions in the air. Ensure that enough ventilation is provided (greater than 5 litres per minute).
 ***WARNING***	To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
 ***WARNING***	Only trained engineers should handle and install gas equipment.
 ***WARNING***	Argon gas plasma generated. Do not install in an oxygen rich environment (a closed environment where oxygen is added).
 ***CAUTION***	Operate only with rated voltage supply. Do not attempt to operate from a power supply with which you are not familiar. Confirm that the appropriate AC power supply frequency, voltage and current are being used.
 ***CAUTION***	Avoid exposing the equipment to excessive shock or vibration as it may damage the equipment. This equipment contains precision apparatus.
 ***CAUTION***	Do not expose the equipment to a naked flame or install the SteriPlas near a naked flame. It may cause damage to the equipment.

5.1 Installation Environment Requirements

In some cases of failure or breakage of this equipment, it may emit smoke, catch fire, or cause electric shock.

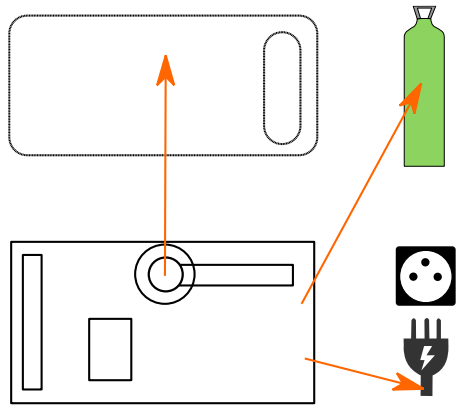
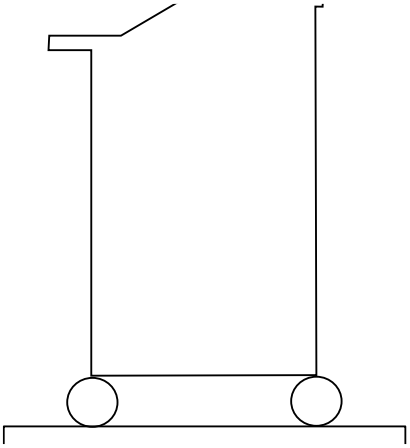
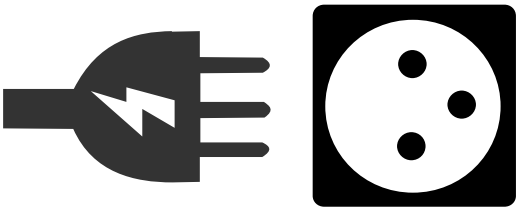
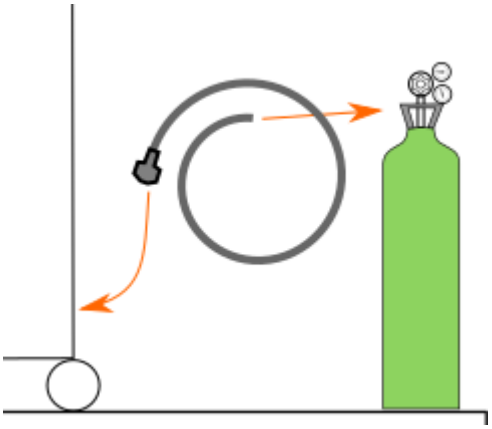
Check the following points regarding the installation environment of the SteriPlas:

- Install the equipment in a sufficiently ventilated environment out of direct sunlight, and free from high humidity, dust, salt, or sulphur etc.
- Install the SteriPlas in a stable position on a level surface where it will not be exposed to vibration, shock etc.
- Ensure that the equipment is being installed where there is sufficient space.
- Do not store or install in proximity to corrosive, explosive or flammable chemicals.
- Do not install the SteriPlas where there may be flammable gas.
- Do not install the SteriPlas near a high temperature environment.
- Do not install in an oxygen rich environment (a closed environment where oxygen is added).

5.2 Installation Instructions

Be sure to read and understand the following notes before attempting to install the equipment:

- Confirm that the appropriate AC power supply frequency, voltage and current are being used. Do not attempt to operate from a power supply with which you are not familiar.
- A power cord of 3 m is attached to this equipment. Wall socket needs to be within 3 m.
- Ensure that the power cord does not become a tripping hazard. Ensure wall socket is easily reachable in order to turn off and unplug device.
- The equipment uses argon gas and connects to a gas cylinder via a regulator outside the equipment. Ensure the gas tubing is adequate and does not become a tripping hazard.

1. Locate equipment within reach of treatment area, gas supply and AC outlet with sufficient space for arm movement. 	2. Position on a stable and flat floor and engage the brakes. 
3. Connect the AC cable. 	4. Connect the gas regulator to the equipment using the supplied tube. 

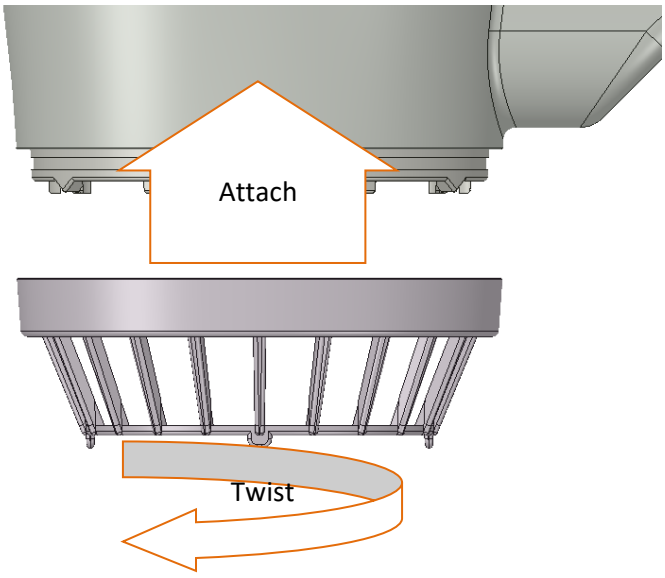
6 Operation

Read the following cautions carefully before attempting to use the equipment.

WARNING	When in use, the equipment and patient must be supervised by a competent operator at all times, and it must be ensured that no abnormalities arise.
WARNING	Do not open or remove parts from the equipment during operation. High voltages and temperatures exist inside the equipment and may cause electric shock or burns.
WARNING	Do not use the plasma treatment on parts other than the affected part of the patient.

6.1 SteriPlas Sensor Module Installation

WARNING	Each SteriPlas Sensor Module is for single use application only. Use a new SteriPlas Sensor Module for each patient. Reusing SteriPlas Sensor Module may cause contamination between patients.

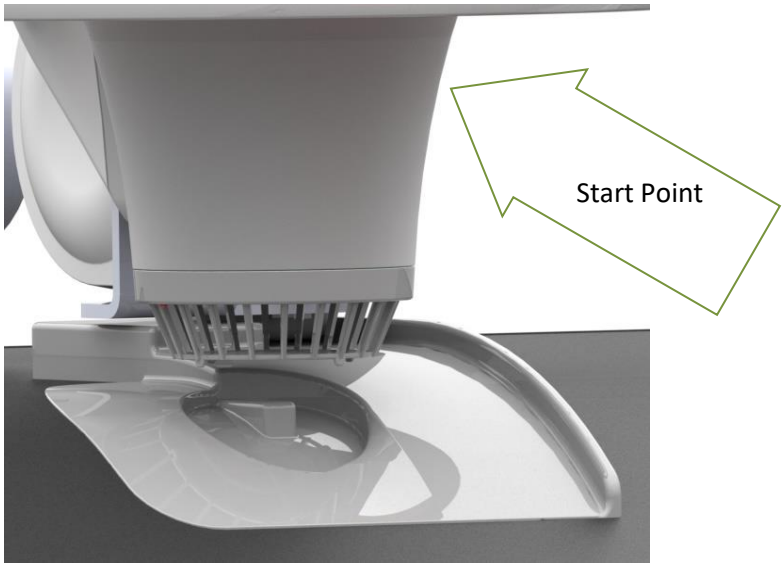


1. Remove Sensor Module from its package.
2. Twist clockwise to attach the SteriPlas Sensor Module to the plasma head.

6.2 Cleaning

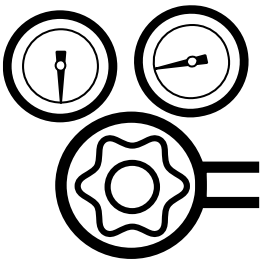
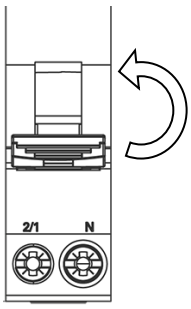
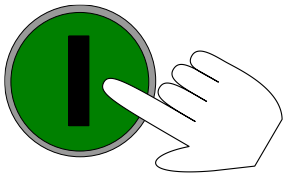
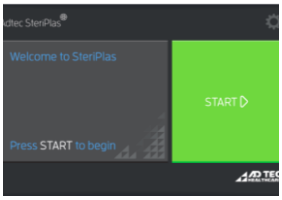
The installed single use sensor module, treatment head and areas of possible cross contamination contact, should be cleaned using local hospital cleaning procedures. Recommended cleaning materials include disinfectant wipes or an IPA 70% solution on a lint free cloth.

6.3 Start Point Docking

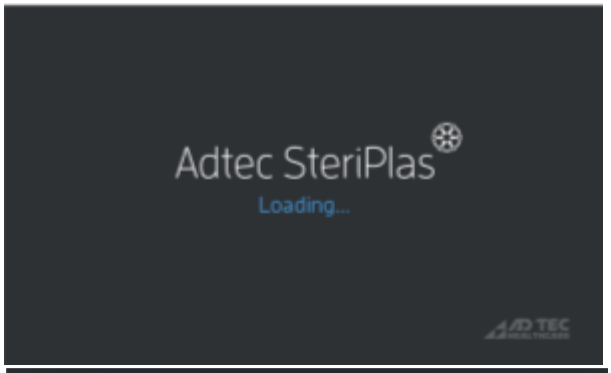


1. Push the plasma head using the handle into the start point docking interface area.
2. It will stop once it reaches the start point docking interface area.

6.4 Turning On

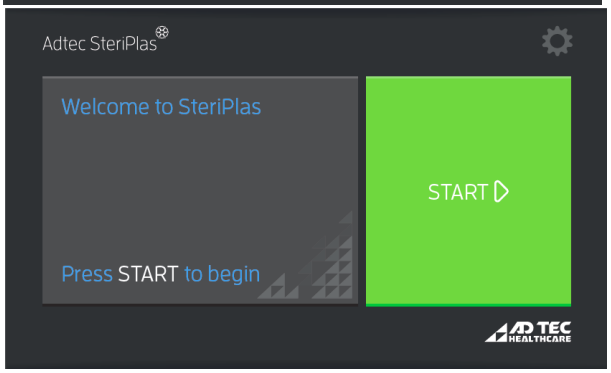
			
1. Open gas, set regulator pressure to 0.2 MPa / 2 bar	2. Breaker ON	3. Turn on - ON button	4. Follow on-screen instructions

6.5 Screens and their operation



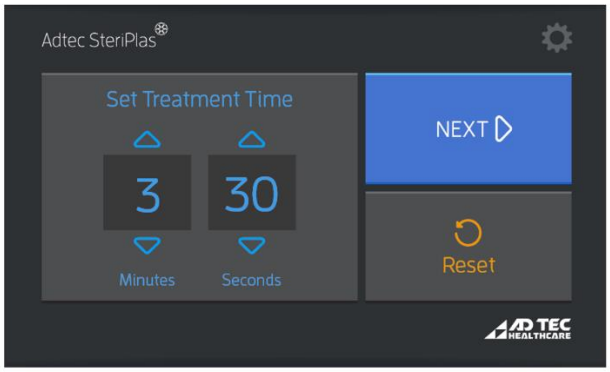
Loading screen

- Please wait for the unit to initialize.



Welcome screen

- The unit is ready to set up.
- To begin press START.

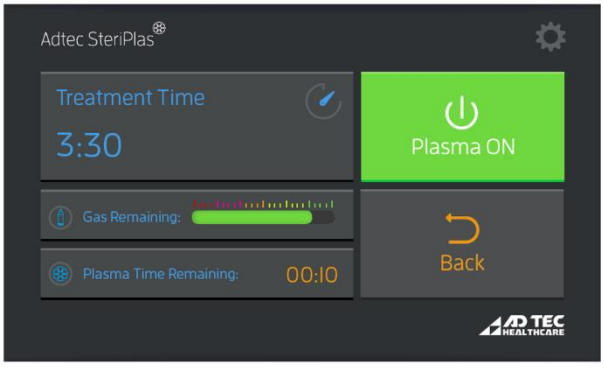


Set Timer screen

- Set single treatment time (in Minutes and Seconds) between 1min and 5min by pressing or .

Note:
Recommended treatment time – 2min
Treatment time per treated area should not exceed 5 min!

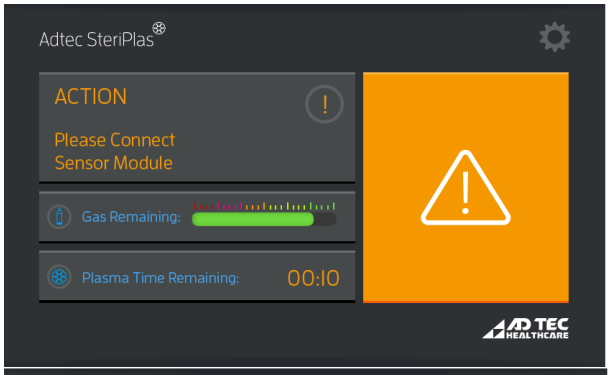
- Confirm with NEXT.
- The values can also be reset to the original settings by pressing Reset.
- If no treatment time has been set, the previous time will be set.



Ready to Start / Timer Confirmation screen

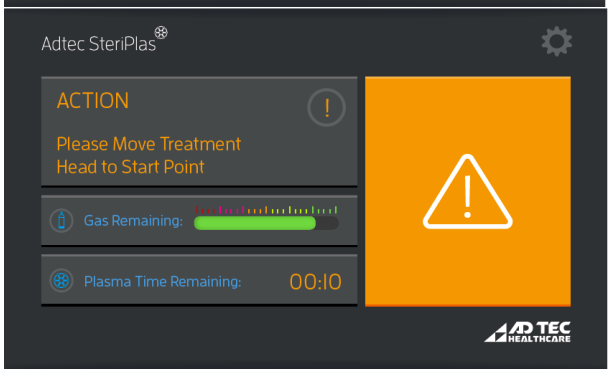
- The unit is now ready to begin treatment.
- The screen displays the following:
  - Treatment Time (Recommended Treatment Time: 2min)
  - Gas Remaining
  - Plasma Time Remaining (Maximum Plasma On Time: 9min 30sec)
- Press Plasma ON to start treatment.

- To review settings press Back.



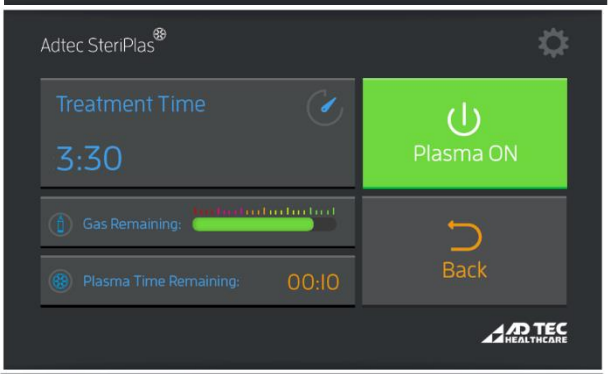
Action screen:
"Please Connect Sensor Module"

- Connect Sensor Module to the treatment head to enable treatment.



Action screen:
"Please Move Treatment Head to Start Point"

- Move the treatment head slowly to the start point to enable treatment.

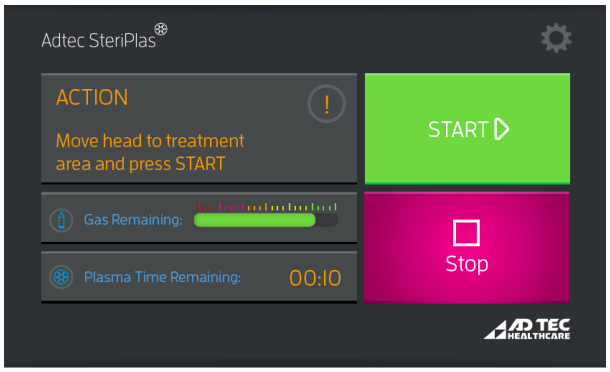


Ready screen

- The unit is ready to start treatment.
- Press Plasma ON to start treatment.
- To review settings press Back.

Plasma ON screen

- A Plasma ON sequence is started to activate the plasma.
- Wait until the timer beep and next instruction.

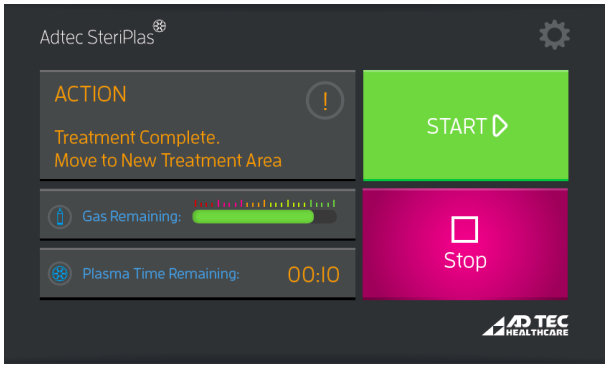


Action screen:
"Move head to treatment area and press START"

- Move the treatment head slowly away from the unit towards the patient area to be treated.
- Position the Sensor Module as close as possible to the area to be treated without touching it.
- Press START to start the timer or alternatively press the timer reset button on the treatment head handle.
- At any time during treatment Stop can be pressed to stop the plasma if needed.

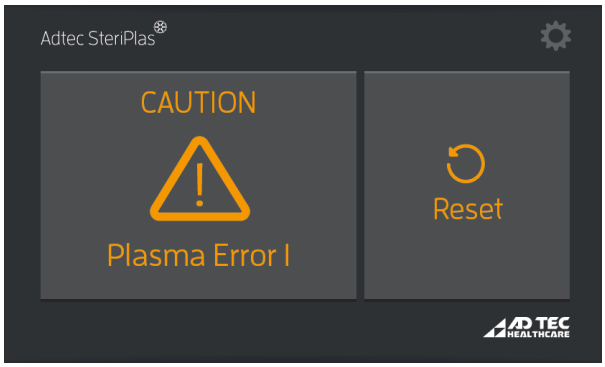
During Treatment screen

- If needed to re-start the timer, press Reset or alternatively press the timer reset button on the treatment head handle.
- At any time during treatment Stop can be pressed to stop the plasma if needed.



Action screen:
"Treatment Complete. Move to New Treatment Area"

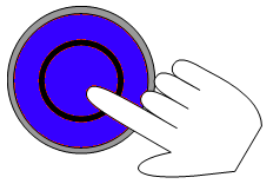
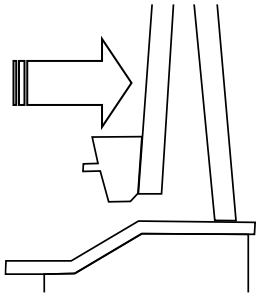
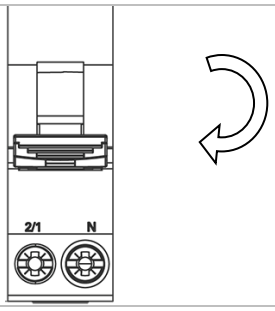
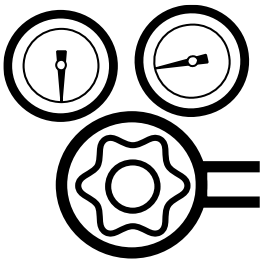
- Move the treatment head slowly to the next area to be treated.
- Press START to start the timer or alternatively press the timer reset button on the treatment head handle.
- At any time during treatment Stop can be pressed to stop the plasma if needed.



Caution screen

- It is possible for this unit to stop functioning from certain conditions.
- Please refer to the Caution Messages in the Troubleshooting section.

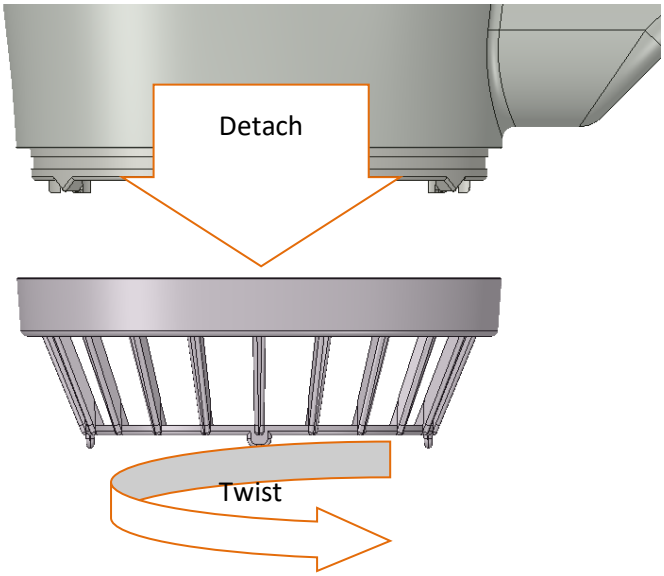
6.6 Turning Off

			
1. Turn off - OFF button	2. Dock Arm	3. Breaker OFF	4. Close gas

6.7 After Treatment Cleaning

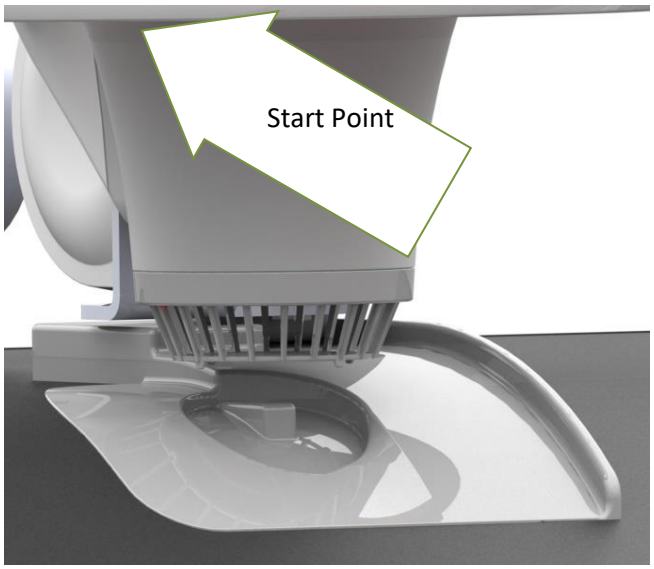
The treatment head, handles and areas of possible cross contamination contact should be cleaned using local hospital cleaning procedures. Recommended cleaning materials include disinfectant wipes or an IPA 70% solution on a lint free cloth.

6.8 Sensor Module Removal



1. Wait 1 minute after use before changing the SteriPlas Sensor Module, to allow it to cool down.
2. Twist counterclockwise to detach the SteriPlas Sensor Module.
3. Dispose of the SteriPlas Sensor Module in the medical waste bin.

6.9 Start Point Docking



1. Push the plasma head using the handle into the start point docking interface area .
2. It will stop once it reaches the Start Point Docking Interface Area.

6.10 Troubleshooting

In the event of equipment failure, please take note of any messages displayed on the device. If the on-screen messages are listed in the section, follow the advice provided.

If the device shuts down and cannot be operated, contact the manufacturer or the distributor for further instructions. Follow the below cautions and warnings:

WARNING	If equipment failure occurs, do not attempt repair. Report the fault to appropriate technical support.
WARNING	Do not substitute parts or modify the equipment in any way. It may cause injury.
CAUTION	If the equipment cannot be operated, cease attempting to use the equipment and report the failure to appropriate technical support (manufacturer/agent).

In the event of adverse conditions, please follow the below notes and warnings:

WARNING	If the patient complains or if any abnormal reaction occurs, cease use immediately and report to appropriate authority and the manufacturer.
WARNING	In the occurrence of a serious incident, cease use immediately and inform the appropriate authority, the manufacturer, and the authorised representative.
CAUTION	Any change in environmental conditions causing the device to operate outside of its required specifications, cease use, and switch off device and gas supply.

6.10.1 Caution Messages

Message on screen	Action
Plasma Error	Reset caution and repeat Plasma ON sequence.
Temperature Over	Wait until cooled down. Reset caution and repeat Plasma ON sequence.
Power Error	Reset caution and repeat Plasma ON sequence.
Fan Failure	See steps to contact representative.
Gas Flow Error	Check gas connections, gas cylinder pressure, gas cylinder valve open. If all is correct, reset caution and repeat Plasma ON sequence.
Process Interrupted by User	Arm moved from start point during Plasma ON sequence. Reset caution and repeat Plasma ON sequence.
Maintenance Required	SteriPlas Service Overdue. See steps to contact representative.

If any of the above Cautions are repeatedly encountered, please contact your representative.

7 Storage and Maintenance

Adhere to the following points after use of the SteriPlas.

 ***WARNING***	Shut-down the equipment according to the procedure and turn the breaker OFF. Disconnect the power supply at the wall socket.
 ***WARNING***	Always keep the equipment clean. There is a possibility of secondary infection.
 ***WARNING***	Do not expose SteriPlas Sensor Module to direct sunlight. It may degrade the material and result in injury.
 ***WARNING***	Only use national/regional qualified gas cylinders
 ***CAUTION***	Do not use excessive force or pull the plug out by gripping the cable.
 ***CAUTION***	If the equipment is not in use for extended periods, close the main valve of the gas cylinder.
 ***CAUTION***	Ensure that the power cord to the equipment is placed and fixed so as not to be an obstruction.

7.1 Storage

 ***CAUTION***	Do not expose equipment to direct sunlight.
 ***CAUTION***	Do not expose equipment to water or other liquids.
 ***CAUTION***	Do not store in proximity to corrosive, explosive or flammable chemicals.

Store equipment in a secure indoor area. Avoid long periods of storage between uses.

7.2 Maintenance

The lifetime of the device is 7 years. To ensure the performance of the SteriPlas over the 7 years, it is recommended that maintenance is performed on the equipment every 6-9 months.

7.2.1 Maintenance - Users

Gas cylinder

Compressed gas: Contains gas under pressure; may explode if heated.

If the gas cylinder that feeds into the SteriPlas becomes low on gas, it must be replaced by a fresh cylinder before further use. The residual quantity of the gas inside the cylinder can be seen in the LCD panel. The gas cylinder should be exchanged before becoming completely empty.

Wall socket plug

Please be sure to check the wall socket plug before use.

Please make sure that the wall socket plug does not get wet or become dirty.

7.2.2 Maintenance - Technical Staff

WARNING Technical maintenance must be performed by Adtec qualified personnel.

WARNING Use of accessories, transducers, and cables, other than those specified or provided by the manufacturer of this equipment, could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, and result in improper operation.

Plasma Chamber

To ensure that the plasma functions as intended, the chamber should be disassembled, cleaned, and reassembled during maintenance. All the RF equipment should be checked to ensure no electromagnetic disturbances.

8 Distributor

Representative contact details will be supplied with the SteriPlas maintenance contract.
For more information, contact the manufacturer Adtec Europe Limited.

9 Manufacturer

Adtec Europe Limited
Unit 8, Heathlands Industrial Estate
Heathlands Close
Twickenham
TW1 4BP
United Kingdom

For any maintenance, servicing, or support, please contact Adtec Europe Limited.

Website: www.adtechealthcare.com
Email: info@adtecplasma.com
Telephone: +44 (0) 208 737 5500

10 Authorised Representative

(For regulatory affairs only)

Name: MedEnvoy Global B.V.
Address: Prinses Margrietplantsoen 33, Suite 123, 2595 AM, The Hague, The Netherlands

Website: www.medenvoyglobal.com
Email: vigilance@medenvoyglobal.com
Telephone: +31 70 326 2148

11 Device Specifications

11.1 SteriPlas

To be used with the SteriPlas Sensor Module only. The SteriPlas and SteriPlas Sensor Module are two separate medical devices and must be purchased individually.

Name	SteriPlas	
Model	ARPP-SP2-01	
Medical device classification	Class IIb	
Marking + Notified Body No.	CE0297	
Plasma gas temperature	≤ 48 °C (118.4 °F) at a distance of 20 mm from the plasma torch grid	
Maximum plasma on time	9 min 30 sec	
Treatment time	2 min - 5 min	
Gas specification	Argon, minimum purity 99.998% (N3.5)	
Gas Input pressure	0.4 MPa / 4 bar	
Gas Input connector	SMC KK4P-06E, S type sleeve lock coupling size 4 bulkhead plug side to 6 mm tube. Mating part: KK4S-06H	
Duty cycle	After plasma off, wait 1 minute before changing the SteriPlas Sensor Module ARPP-SP-02	
Power input	200-240 V, 50 / 60 Hz (Class I)	
Power consumption	1.5 kVA	
Operating temp range	10 °C – 30 °C (50 °F – 86 °F)	
Operating humidity range	10% - 80% RH	
Operating atmosphere	Altitude < 2000 m (6500 ft)	
Storage environment	–10 °C – 55 °C (14 °F – 131 °F) RH < 80%	
Isolation from supply mains	Siemens SENTRON 5SV1316 13 A RCBO 2 P 6 kA Trip Sensitivity 30 mA Type A	
Outside dimensions	Main body	W 563 × D 821 × H 1943 mm
	Arm operation range	L 1635 × H 650 mm × ±60 °
Weight	150 kg (330 lbs)	

11.2 SteriPlas Sensor Module (applied part) specifications

To be used with the SteriPlas only. The SteriPlas and SteriPlas Sensor Module are two separate medical devices and must be purchased individually.

Name	SteriPlas Sensor Module (SSM)
Model	ARPP-SP-02
Classification	Class I
Marking	CE
Notified Body No.	N/A
Type of Applied Part	Type B
Usage	Single use
Material	Nylon (Polyamide)
Maximum Temperature	SteriPlas Sensor Module temperature may reach up to 48 °C (118.4 °F)

11.3 Medical Device Accessories

Model	Description
ARPP-SP-02	SteriPlas Sensor Module (SSM)

11.4 Parts Supplied with the Device

Model	Description
KK4S-06H	SMC Push in Gas connector

Appendix I

1 Transportation

WARNING	Do not attempt to pick up the SteriPlas or use ramps for loading. This device is heavy and may crush persons handling it incorrectly.
CAUTION	Avoid exposing the equipment to excessive shock or vibration as it may damage the equipment. This equipment contains precision apparatus.

Use only vehicles with tail lifts and load carefully.
Tie down inside of vehicle to stop movement.

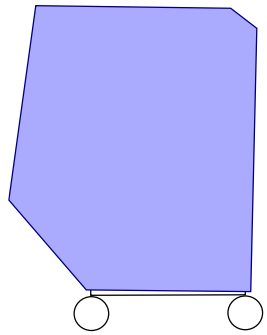
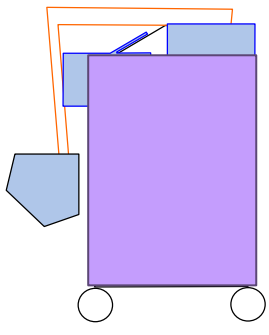
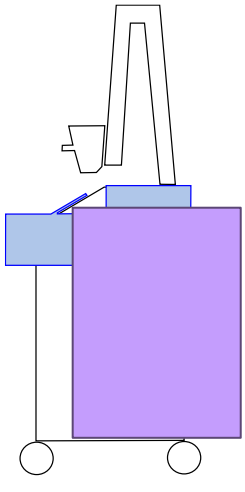
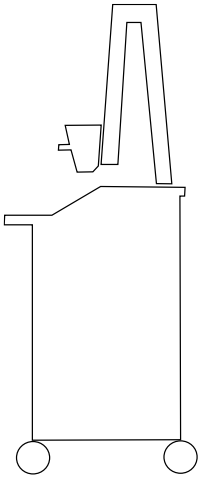
Packaged dimensions (approximate mm)	W600 × D1200 × H1300
Packaged weight (approximate kg)	150

2 Unpacking

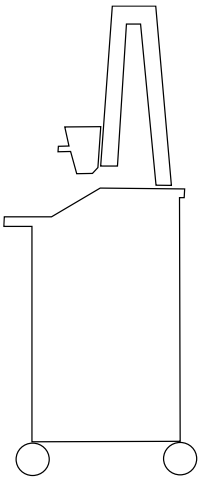
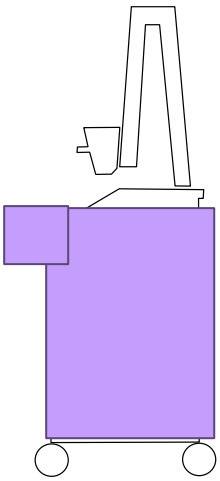
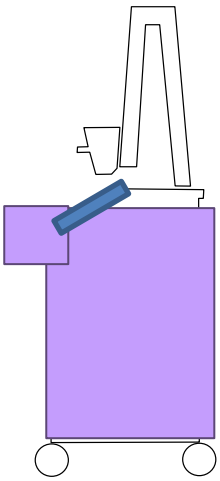
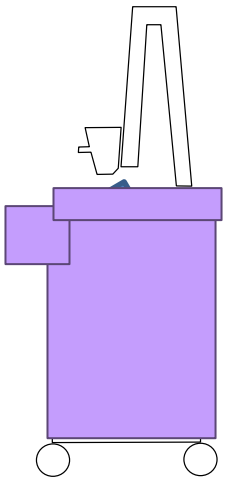
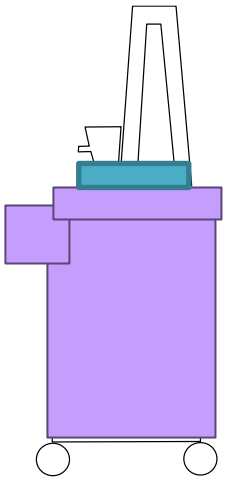
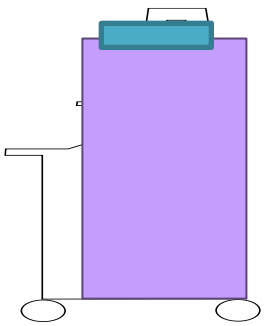
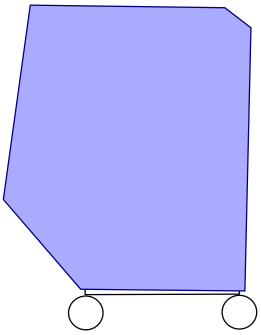
CAUTION	Carefully remove packaging to avoid damaging the equipment.

Move the unit to its final position before unpacking. Dispose of the cling film and bubble wrap as plastic.

Unfold and keep the protective cardboard covers for future use.

1. Unwrap carefully	2. Remove wrapping from head	3. Move arm upright to docking position	4. Remove protective cardboard covers and remaining plastic wrap
			

3 Packing

1. Move arm upright to docking position	2. Wrap bubble wrap and plastic wrap around body of SteriPlas	3. Add foam sheet over display screen	4. Wrap bubble wrap and plastic wrap over top of SteriPlas body (keep foam sheet over display screen).
			
5. Add foam wedges onto body, under arm	6. Lower arm and wrap head in bubble-wrap	7. Completely wrap unit in plastic wrap.	
			

4 Storage

 ***CAUTION***	Do not expose equipment to direct sunlight.
 ***CAUTION***	Do not expose equipment to water or other liquids.
 ***CAUTION***	Do not store in proximity to corrosive, explosive or flammable chemicals.

Store equipment in a secure indoor area. Avoid long periods of storage between uses.

SteriPlas

Revision History

Rev	Changes	Date
13	Authorised representative changed from Emergo to MedEnvoy Global. Intended use reworded for clarification. Warnings relocated to section 1.8. Contraindications corrected.	07/02/2023
14	Change of classification for SSM	28/03/2023
15	Intended Use wording clarified	03/04/2023
16	Microwave leakage value updated, UV warning clarified	26/04/2023
17	Company name updated to Adtec Healthcare Limited. Additional symbols added. Treatment time and use section updated with directions on how to treat patients.	23/05/2023
18	Updated Warnings/Cautions and safety symbols	07/09/2023
19	Front page: include reference to sensor module. Front page: Table has been removed. Section 1.1: Include reference to SteriPlas and SSM. Throughout: removal of word 'system' Throughout: Units and values amended in line with ISO standards. Throughout: Adtec Europe reinstated. Section 11: Notified body and marking sections added	27/11/2023
20	Include the lifetime of the device under section 7.2 Maintenance.	17/05/2024
21	CE mark and NB number placed together. CE marking updated to match EU MDR. Update to Section 3.2 to include a table on the test standards.	12/12/2024

Adtec SteriPlas

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