stella™

Powered by **Tristel**

Automated disinfection made simple

USER GUIDE

CONTENTS

The Operating Instructions in this manual outline general safety guidelines for the correct operation of Stella System (hereinafter referred to as Stella), Stella IQ (hereinafter referred to as IQ), Stella Pulse (hereinafter referred to as Pulse) and Stella Cradle (hereinafter referred to as Cradle).

Carefully read and understand the user instructions before attempting to operate Stella, IQ or Pulse.

Never use Stella, IQ, Pulse or Cradle for any purpose other than the Intended Purpose.

Refer to the Safety Data Sheet of the approved disinfectant product to be used prior to use.

Should the unit(s) appear to malfunction, download the data and observe the LCD graphic messages. This will allow you to take appropriate corrective action or to arrange for repair. All repairs must be carried out by an approved and qualified service technician.

Do not use the Stella, IQ, Pulse or Cradle, including the IQ or Pulse power adaptors, if they have been damaged or have changed in performance.

Ensure the instrument for disinfection is compatible with the Stella System prior to use.

For professional use only.

SECTION ONE
INTRODUCTION

SECTION 1: INTRODUCTION

Stella is an automated system designed specifically for the disinfection of heat-sensitive small and medium-sized, rigid and flexible, non-lumened and single-lumened endoscopes used in Urology, Gynaecology, IVF, Cardiology, ENT, Anesthesiology and Respiratory. Stella combines the simplicity of manual soaking with the sophistication of a fully automated washer disinfector. There are three Stella options available, which are outlined below.

stella™
System

PRODUCT CODE: STELLA A

The **Stella System** provides a five minute turnaround of instruments. It records electronic validation information which can be downloaded to software for traceability.

INTENDED USE

For the high-level disinfection of non-lumened medical devices, such as transoesophageal echocardiographic probes, transvaginal probes, transrectal probes, manometry catheters and laryngoscope blades.

stella™
with Pulse System

PRODUCT CODE: STELLA B

The **Stella with Pulse System** provides all the benefits of the Stella System whilst additionally confirming instrument connection and determining blocked instruments, protecting them from over-pressure.

INTENDED USE

For the high-level disinfection of non-lumened (see Stella System) and single-lumened medical devices, such as hysteroscopes, cystoscopes, nasendoscopes, intubation endoscopes and bronchoscopes.

stella™
with Pulse & Cleaning System

PRODUCT CODE: STELLA C

The **Stella with Pulse & Cleaning System** provides all the benefits of the Stella with Pulse System, plus a cleaning cycle. It has a ten minute turn around of instruments; five minutes for automated cleaning and five minutes for automated high-level disinfection.

INTENDED USE

For the cleaning and high-level disinfection of single-lumened and non-lumened medical devices, such as those listed above.

All Stella systems exclude consumables, which are ordered separately.

TRISTEL FUSE FOR STELLA CHEMISTRY

Tristel Fuse for Stella is a single-use disinfectant solution designed specifically for use in Stella for the high-level disinfection of semi-critical medical devices.

Tristel Fuse for Stella incorporates two separate compartments that contain 50ml Tristel Base solution (citric acid) and 50ml Tristel Activator solution (sodium chlorite). When mixed upon bursting the sachet, Tristel's proprietary chlorine dioxide chemistry is generated for dilution into five litres of water.

The Stella System provides chemistry detection based on conductive measurements of the Tristel Fuse for Stella working solution. Ambient temperature tap water should be used for the working solution. Very hard water and reverse osmosis (RO) water can affect the conductivity function.

COMPONENTS

STELLA PACK CONTAINS:

- Stella IQ pack
- Base
- Lid
- Drainage hose set
- Small Parts Tray and lid
- 2 grommets
- Stella Lube
- Drainage outlet cap
- Instructions for Use
- Stella Jug (packed separately)

STELLA CRADLE PACK CONTAINS:

- Cradle with fill cap and Cradle feet
- Assembly Instructions

STELLA TOOLBOX CONTAINS:

- Stella Manual Emergency Kit
- Pump Hose Replacement Process Kit
- Stella Suite Installation Card
  Also included in the toolbox for Pulse systems only are;
- Surrogate Lumen Kit
- Double Luer Lock Connector Kit
- Pump Head Change Kit

STELLA IQ PACK CONTAINS:

- Stella IQ
- Power adaptor
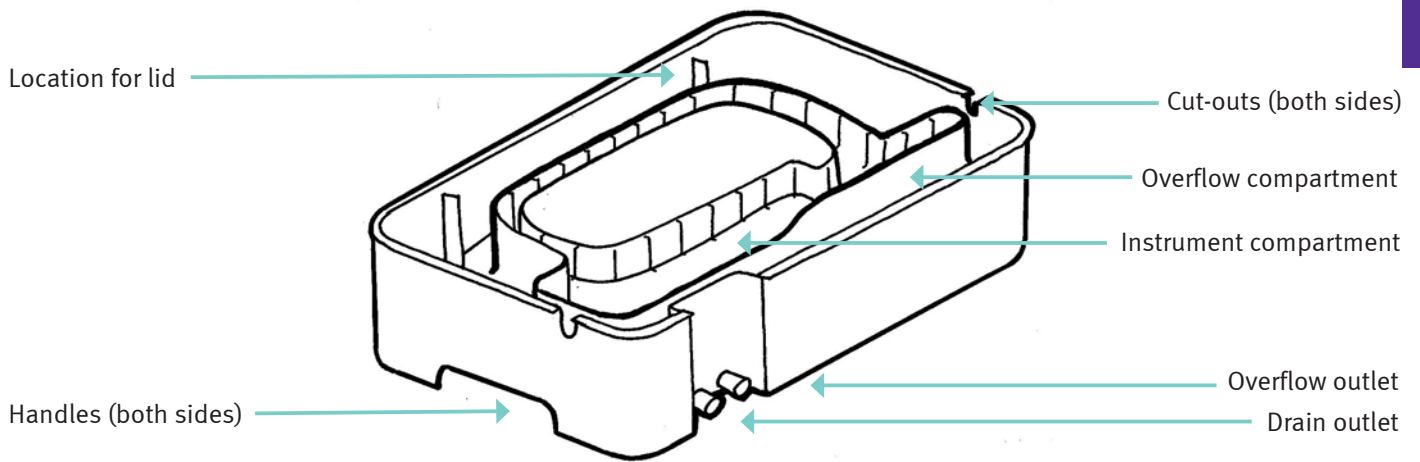- USB Cable

STELLA PULSE PACK CONTAINS:

- Stella Pulse unit
- Stella Pulse tube set
- Power adaptor
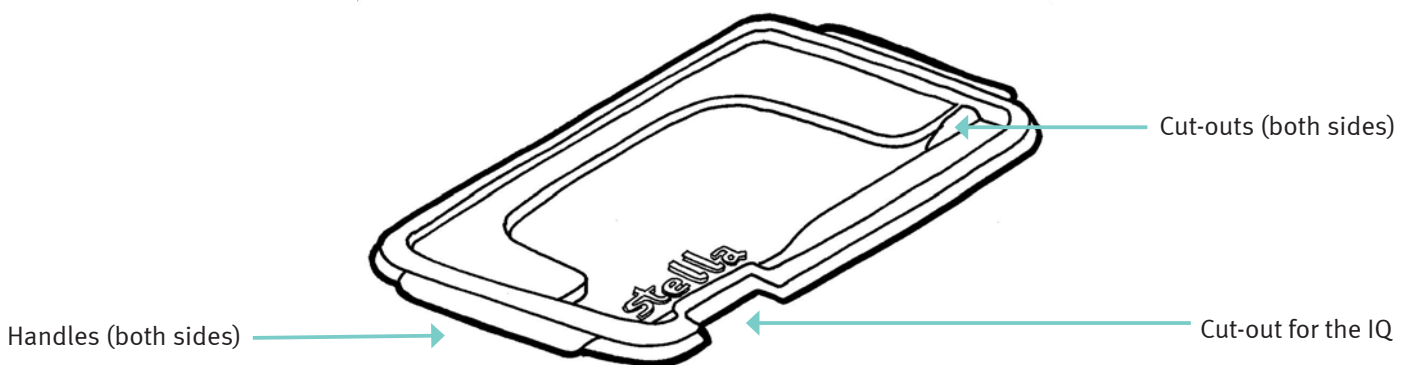- Surrogate lumen

STELLA CRADLE SHELF PACK CONTAINS:

- Cradle Shelf
- Shelf Fixings
- Assembly Instructions

STELLA BASE

Location for lid ———————————

Cut-outs (both sides)

Overflow compartment

Instrument compartment

Overflow outlet

Drain outlet

Handles (both sides) ———————————

STELLA LID

Cut-outs (both sides)

Handles (both sides) ———————————

Cut-out for the IQ
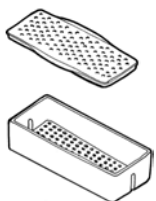
ACCESSORIES

Small Parts Tray and Lid for securing instruments' accessories in the Stella Base.

Drainage Outlet Cap for covering outlets of the Base during transportation. The Cap should not be used on a full tray of disinfectant. It is for containing disinfectant residues only.

Stella Lube should be applied to Stella IQ before first use then every 6 months in order to ensure a firm fit of the IQ to the base.

The grommets close the cut-outs when they are not being used.

STELLA IQ

Display

OFF button

ON / OK button

ON / OK   OFF

USB port and power port behind cover

Drain outlet

IQ Drain inlets (connect to Stella base)

STELLA PULSE

Lid

ON / OFF button

LED light indicators

USB port and power port behind cover

PULSE TUBE SET

Luer lock for connection to lumen

Tube mount

Disinfectant pick-up / filter

Connectors to Pulse unit

Dual luer lock connector (optional) for instruments with non-removable tap
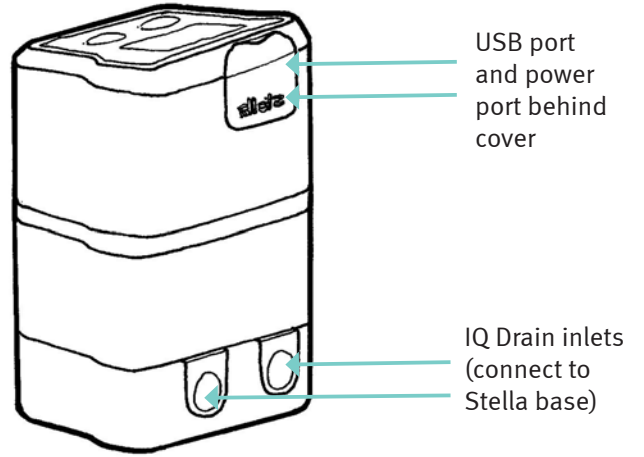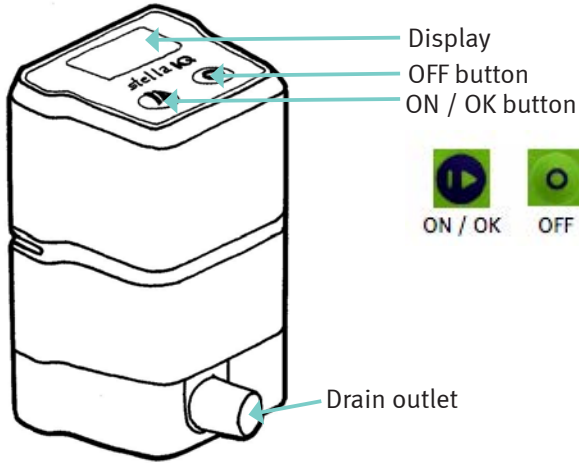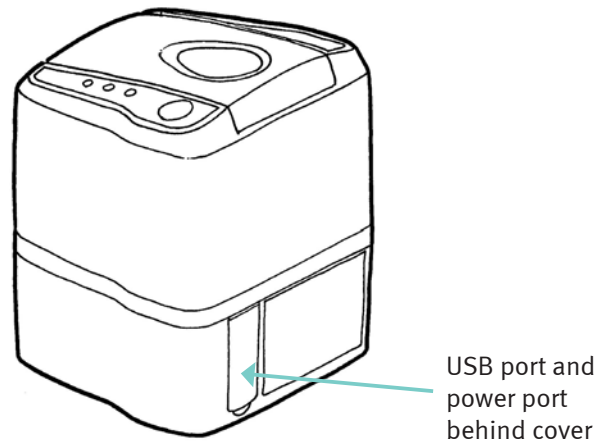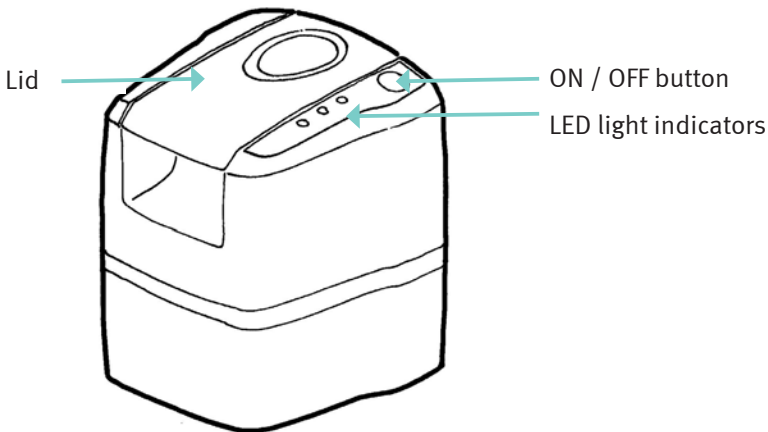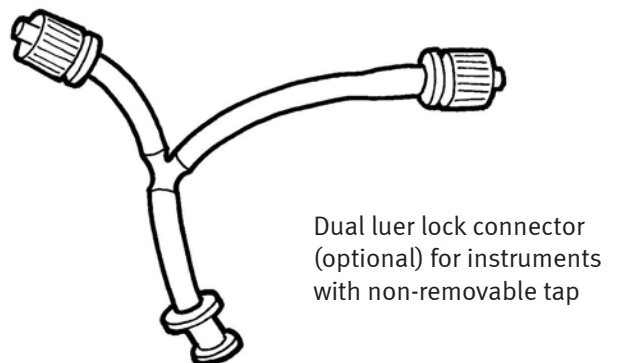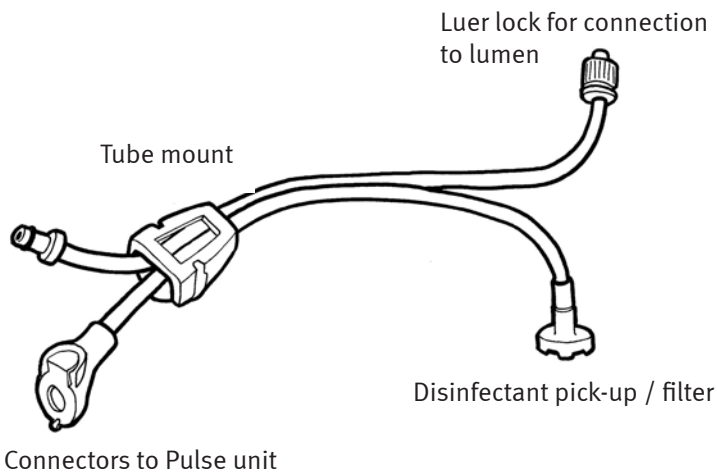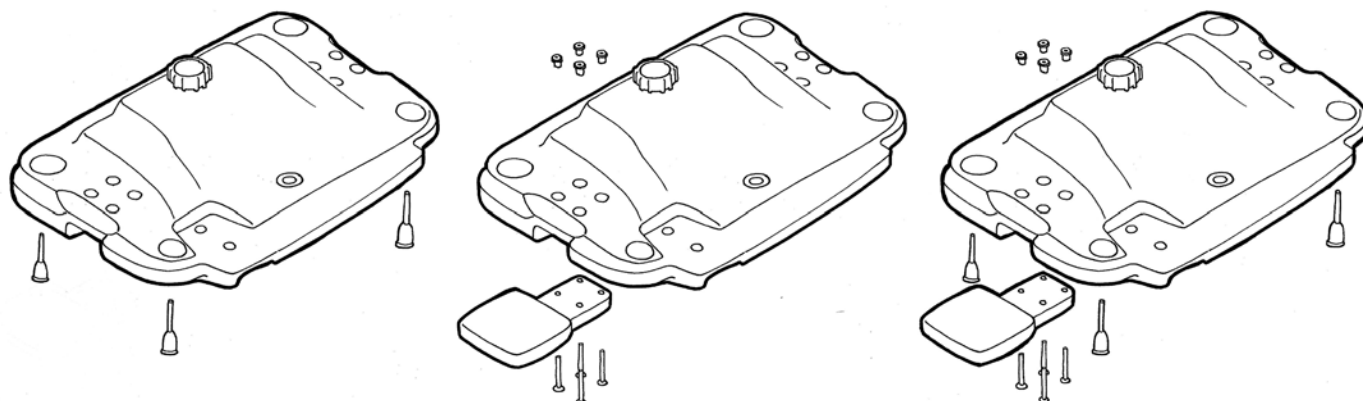
STELLA CRADLE

Once Stella Cradle is positioned for use, adjust the feet using the spirit level. It is important to ensure that the Stella is operated on a stable and level surface. Otherwise, the automatic sensor that triggers the cycle will not operate reliably.

STELLA FOOTPRINT
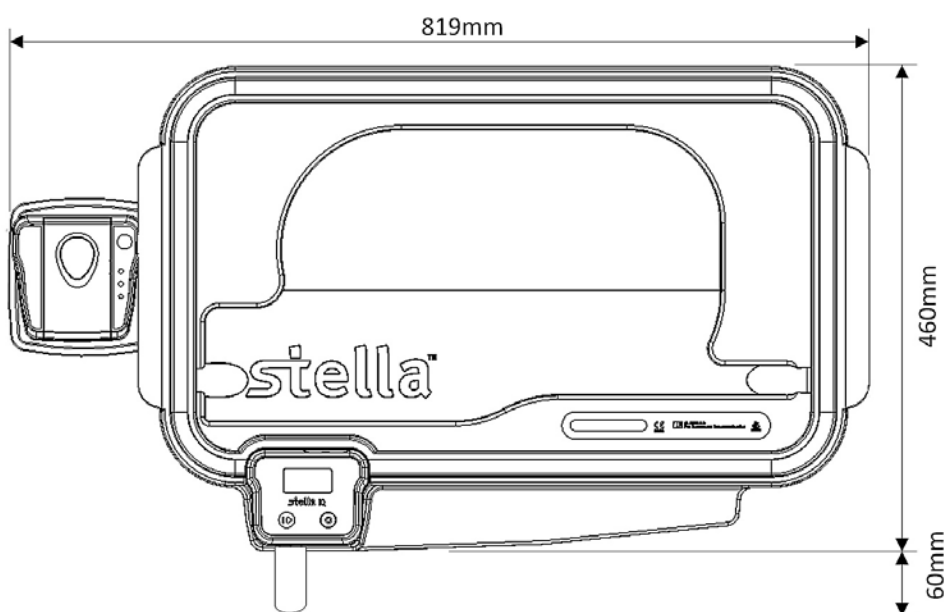
The Stella System measures 70 cm x 46 cm.

The Stella with Pulse System measures 81 cm x 46 cm.

The height of the Stella and Stella with Pulse System is variable depending on the adjustment of Cradle Feet, but on average when holding the Stella Base and lid measures 23 cm.

The Stella Base and Lid can be stacked and easily transported due to their portable size and weight. When empty, the weight is 5.5kg.

DISINFECTANTS AND MEDICAL DEVICES FOR USE WITH STELLA

Tristel Fuse for Stella is a single-use disinfectant solution designed specifically for use in Stella for the high-level disinfection of semi-critical medical devices.

Tristel Fuse for Stella incorporates two separate compartments that contain 50ml Tristel Base solution (citric acid) and 50ml Tristel Activator solution (sodium chlorite). When mixed upon bursting the sachet, Tristel's proprietary chlorine dioxide chemistry is generated for dilution into five litres of water.

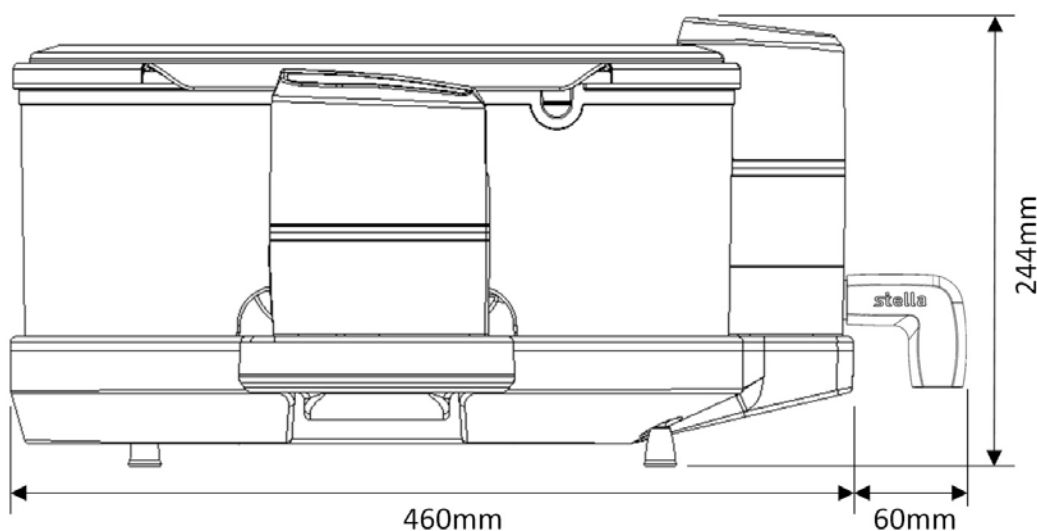The Stella System provides chemistry detection based on conductive measurements of the Tristel Fuse for Stella working solution. Ambient temperature tap water should be used for the working solution. Very hard water and reverse osmosis (RO) water can affect the conductivity function.

The Stella IQ ensures that a medical device is in contact with Tristel Fuse for Stella for 5 minutes only. The disinfectant is then automatically drained to waste. Tristel Fuse for Stella is a single-use disinfectant and must not be re-used. The disinfectant should be disposed of in accordance with the user instructions and Safety Data Sheets provided by the manufacturer.

The Stella System is intended for the decontamination of non- and single-lumened medical devices. Follow the medical device manufacturers' guidance for recommended reprocessing of the device.

PREPARING THE STELLA SYSTEM FOR FIRST USE

- Remove all components from their packaging.
- Inspect components for damage. If damaged, report to your local Stella Service Agent.
- If required, Stella Base, Lid and Small Parts Tray can be autoclaved.
- Use the supplied power adaptors to charge the IQ and Pulse for 12 - 16 hours.
  Refer to the Maintenance section of this manual for charging instructions.
- Apply Stella Lube (silicone lubricant) to Stella IQ drainage inlets before attaching onto the Stella Base using the following instructions:

1 Wearing gloves apply a small amount of Stella Lube to the outside perimeter of each of the drainage inlets (spread the lubricant evenly around the surface of the inlets). DO NOT apply lubricant to the IQ drain outlet onto which the drain hose is attached.

2 Wash your hands carefully after applying the lubricant.
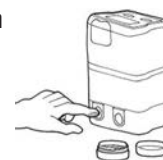
⚠ *From time to time the lubricant may need to be re-applied to the drainage inlets of Stella IQ to ensure the firm fit of IQ to the Base. For video instructions visit the help section on www.stella-performance.com.*

⚠ *Do not autoclave the grommets, drainage outlet cap, drainage hose or any parts of IQ, Pulse and Cradle.*

INSTALLING THE STELLA SUITE SOFTWARE

Stella Suite is the software that allows the user to download important information relating to the Stella IQ and Pulse, and events relating to the disinfection cycle. This information can be downloaded onto compatible equipment such as a PC or laptop for storage and printing. Using a laptop or PC, install the Stella Suite and follow the instructions on screen.

⚠ *Stella software is available via the Stella website www.stella-performance.com. If an update or additional components are purchased, please ensure you install the relevant software for your Stella package. Refer to your local Stella agent if you are unsure.*

SECTION TWO
STELLA OPERATING PROCEDURE

SECTION 2: THE STELLA SYSTEM: OPERATING PROCEDURE

SET-UP PROCEDURE

This section covers the set-up and operating procedures of the Stella System.
For instructions on using Stella Pulse System please refer to Section 3.

Ensure all components of the Stella System are clean and free of debris.

Assemble the Cradle in accordance with the instructions provided and as demonstrated
in the Introduction section. Once level, place the Stella Base onto the Cradle.
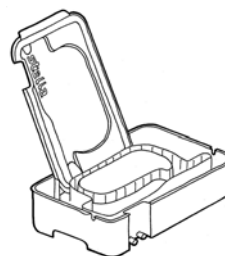
⚠️ *Parts of the instrument may not be effectively immersed in the disinfectant if the Base is not placed level. It is important to ensure that the Stella is operated on a stable and level surface. Otherwise, the automatic sensor that triggers the cycle will not operate reliably.*

⚠️ *Choose a position for Stella where leaks, splashes or spills of disinfectant will not cause damage to surrounding surfaces or materials.*

Stand the Lid in an upright position at the rear of the Base,
in its secure place within the overflow compartment.

Firmly attach the IQ to the Base.
The drain outlets from the Base slide into the drain inlets in the IQ.
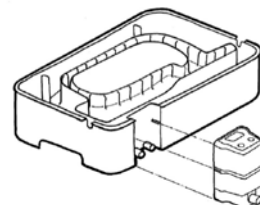
⚠️ *Ensure the IQ is firmly attached to the Base. Failure to ensure correct connection may result in a leak.*

Firmly connect the drain tube to the IQ and ensure the end of the tube is
directed into a sink or waste container. Ensure that the end of the drain
tube is not immersed into the waste solution, i.e. there is an air gap.
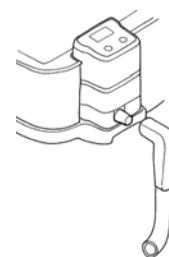
⚠️ *The drain tube must be in a downward position to ensure free water flow.*

Pre-clean all instruments and devices before disinfecting them in Stella.
See section 4 for manual cleaning, leak test the device if applicable.
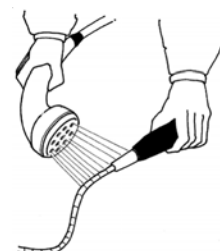
⚠️ *Follow the medical device manufacturers' guidance.*

Push the 'ON' button on the IQ until you hear a sound and follow the instructions shown on the screen.

The IQ performs a short self-check. It then asks to add the pre-cleaned instrument.

Place the pre-cleaned instrument into Stella's instrument compartment.

Position the instrument in a way that best fits the shape of the compartment, making sure all parts fit easily below the top edge of the inner wall.

Instruments that do not fit correctly in the instrument compartment must not be used in Stella.
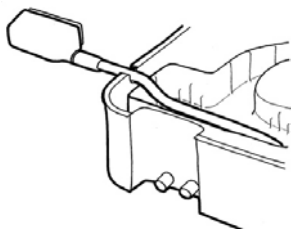
Any cables and parts of the instrument that cannot be immersed, should exit Stella through the designated cut-outs in the side walls.
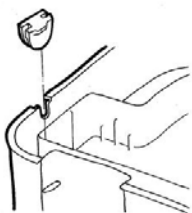
If the instrument is completely submersible, seal the cut-outs with the grommets provided.

Any small removable parts from the instrument requiring disinfection should be placed in the Small Parts Tray and closed with its lid.
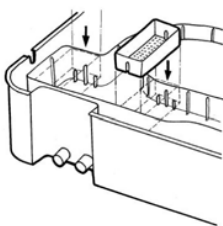
There are two positions in the instrument compartment where the Small Parts Tray and lid are best positioned, one to the left and one to the right of the IQ.

When the instrument is correctly placed into the instrument compartment, make up five litres of Tristel Fuse for Stella disinfectant solution.

Tristel Fuse for Stella should be prepared and used at room temperature.

Follow the Fuse for Stella instructions for use, and refer to the Safety Data Sheet.
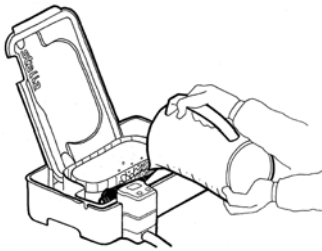
When prompted by the IQ, carefully and steadily pour Tristel Fuse for Stella disinfectant into the inner instrument compartment.

It is recommended to position the jug on the outer wall of the Base, just right of the IQ, and tilt the jug slowly, supporting the base of the jug with one hand.

Fill the instrument compartment of the Base with the full five litres of Tristel Fuse for Stella Disinfectant.

The disinfectant will overflow over the edges of the inner compartment into the overflow compartment of the Base. It will drain out immediately.

ADD TRISTEL FUSE

Pour the disinfectant carefully to avoid or minimise splashes.
Refer to the disinfectant Safety Data Sheet for Spillage Procedures.

Failure to fill the instrument compartment with the full five litres will result in the cycle not commencing.
If the correct level of liquid is not detected within 10 minutes, the Stella IQ will abort the procedure.

Do not move Stella whilst it is filled with liquid.

The correct level of disinfectant automatically triggers the contact time count down. Allow up to 10 seconds for the liquid sensor to detect the liquid in the Base.

An audible beep confirms the start of the disinfection cycle.

DISINFECTING

If Stella is not positioned on a level surface, then the disinfection cycle will not automatically trigger as Stella's liquid sensor will not detect the correct level of disinfectant.

Please check the Stella IQ display for the disinfection symbol. On rare occasions, the cycle may have to be started manually. In this case, Stella IQ will ask you to press the 'ON' button as indicated on the display.

ILLUSTRATION	DESCRIPTION	IQ REFERENCE

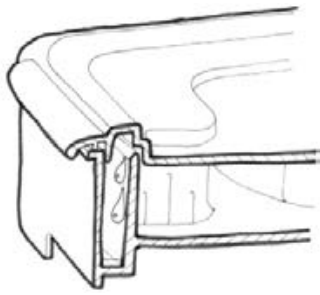Place the Lid onto the Base. Ensure it is closed tightly. Closing the Lid will displace more disinfectant solution into the overflow compartment. The IQ displays the countdown of disinfection time (contact time).

DISINFECTING

DISINFECTING

DISINFECTING

DISINFECTING

⚠ *Do not turn the IQ off during the contact time as this will lead to ineffective disinfection of the instrument and draining of the solution from the Base. A manual interruption of the disinfection cycle will be recorded into the data log report produced in Stella Suite and no validation code will be presented.*
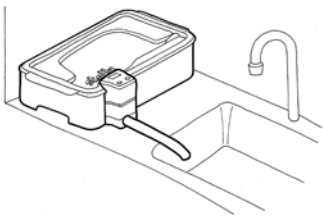
After the completed contact time, Stella drains the disinfectant automatically. The draining process may take up to one minute. Tristel Fuse for Stella does not require rinsing.

STELLA DRAINING

⚠ *Follow medical device manufacturers' guidance for any rinsing, drying and storage.*

When the Base is empty, there is an audible reminder that the cycle is complete.

✓ COMPLETE

To acknowledge the completion of the cycle, press the 'ON' button.

The disinfected instrument can now be removed for immediate use or placed in sterile storage.

CONFIRM REMOVAL OF INSTRUMENT

⚠ Failure to confirm the removal of the instrument will result in the IQ display backlight shutting down after 15 minutes to maintain battery life. The audible beep is also turned off at this stage. If after 30 minutes 'Confirm Removal of Instrument' has not been confirmed, Stella IQ will shut down. When the unit is turned on again, the 'Confirm Removal of Instrument' instruction remains, allowing the user to confirm by pressing the 'OK' button which will retrieve the Validation Code.

ILLUSTRATION	DESCRIPTION	IQ REFERENCE
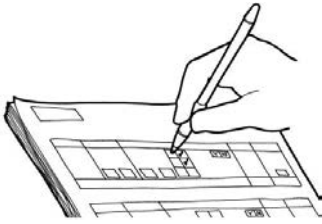
Upon pressing the 'ON' button, a Validation Code is displayed.

This Validation Code should be noted in the Stella Quality Audit Trail Book.

VALIDATION CODE
FMQP–56

SHUTDOWN PROCEDURE

ILLUSTRATION	DESCRIPTION	IQ REFERENCE

A new cycle can immediately be started by pressing the 'OK' button again.

Alternatively, turn off the IQ by pressing the 'OFF' button. There is a sound to indicate that the IQ is switching off. If the IQ is not turned off manually, it will automatically shut down after 15 minutes to save the battery.

After the Stella IQ has been switched off, it can be detached from the Stella Base. The Base can be used as a transportation unit. Fitting the drainage outlet cap prevents small liquid spills.

RESTART CYCLE

⚠️ *Wipe the unit with a paper towel to remove any drops or spills from the drain.*

SECTION THREE
PULSE OPERATING PROCEDURE

SECTION 3: PULSE OPERATING PROCEDURE

SET-UP PROCEDURE

This section covers the set-up and operating procedures of the Stella Pulse System. For instructions on using Stella System please refer to Section 2.

Ensure all components of the Stella Pulse System are clean and free of debris. Assemble the Cradle in accordance with the instructions provided and as demonstrated in the Introduction section. Once level, place the Stella Base onto the Cradle.

⚠️ *Parts of the instrument may not be effectively immersed in the disinfectant if the Base is not placed level. It is important to ensure that the Stella is operated on a stable and level surface. Otherwise, the automatic sensor that triggers the cycle will not operate reliably.*

⚠️ *Choose a position for Stella where leaks, splashes or spillages of disinfectant will not cause damage to surrounding surfaces or materials.*

Stand the Lid in an upright position at the rear of the Base, in its secure place within the overflow compartment.

Firmly attach the IQ to the Base. The drain outlets from the Base slide into the drain inlets in the IQ.

⚠️ *Ensure the IQ is firmly attached to the Base.*
Failure to ensure correct connection may result in a leak.

Firmly connect the drain tube to the IQ and ensure the end of the tube is directed into a sink or waste container. Ensure that the end of the drain tube is not immersed into the waste solution, i.e. there is an air gap.

⚠️ *The drain tube must be in a downward position to ensure free water flow.*

Place Pulse on the Cradle Shelf. Remove the grommet from the left cut-out of the Base.
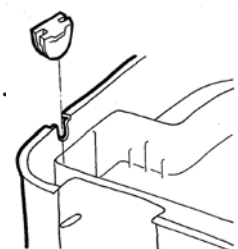
Attach Pulse tube set to Pulse by matching the male and female connectors. Place the green tube mount provided with Pulse tubing firmly onto the cut-out. Ensure that the disinfectant pick-up / filter is sitting in the inner compartment.
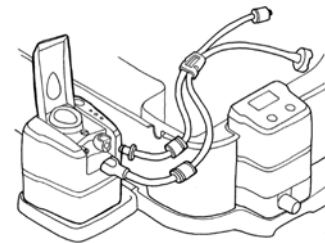
Pre-clean all instruments and devices before disinfecting them in Stella. See section 4 for manual cleaning, leak test the device if applicable.
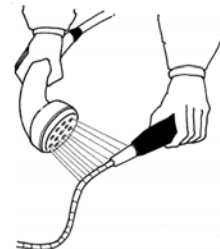
⚠ *Follow the medical device manufacturers' guidance.*

Connect the luer lock connector to the instrument when it is placed in the inner compartment.

⚠ *If the instrument is not equipped with a compatible fitting, please contact the scope manufacturer/distributor to obtain an adaptor.*

⚠ *When using the Stella Pulse System with a non-lumened instrument, please attach the supplied surrogate lumen to Pulse tube set. Ensure the surrogate lumen is placed within the inner compartment next to the instrument.*

⚠ *Every 1000 disinfection cycles, the Stella Pulse Pump must be changed. Cycles are counted in the Stella Suite Report.*

STELLA IQ:

ILLUSTRATION	DESCRIPTION	IQ REFERENCE	DESCRIPTION

STELLA PULSE:

Push the 'ON' button on the IQ until you hear a sound and follow the instructions shown on the screen.

In the background, the IQ performs a short self-check.

IQ automatically connects to Pulse.

The IQ and Pulse are paired. The Bluetooth sign confirms the connection and remains on throughout operation.

The IQ asks to add the pre-cleaned instrument into Stella's instrument compartment.
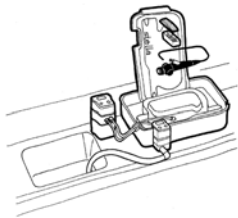
Place the cleaned instrument into Stella's inner instrument compartment. Position the instrument in a way that best fits the shape of the compartment making sure all parts fit easily below the top edge of the instrument compartment's wall.

STELLA PULSE DESCRIPTION:

Push the 'ON' button on Pulse until you hear a sound.

The LED top light will glow solid green to show that it is turned on.

In the background, Pulse performs a short self-check.

The blue LED will flash whilst it is establishing a Bluetooth connection.

When a connection is established the LED will glow solid blue.

The green LED will start flashing to indicate the automatic pump control is on standby.

⚠ *Instruments that do not fit correctly in the instrument compartment must not be used in Stella.*

⚠ *Ensure that the disinfectant pick-up / filter is sitting in the instrument compartment.*

Connect the luer lock connector to the instrument's channel.
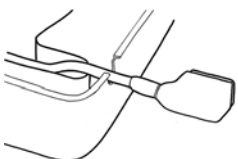
Any cables and parts of the instrument that cannot be submerged should exit Stella through the right cut-out. If the instrument is completely submersible, seal the cut-out with the grommets provided.

Any small removable parts from the instrument that are submersible should be placed in the Small Parts Tray with the lid firmly closed.

There are two positions within the instrument compartment where the Small Parts Tray is best positioned, one to the left and one to the right of the IQ.

When the instrument is properly placed into the instrument compartment and connected to Pulse make up five litres of Tristel Fuse for Stella disinfectant solution.

Tristel Fuse for Stella should be prepared and used at room temperature.

⚠️ *Follow the Fuse for Stella instructions for use and refer to the Safety Data Sheet.*

When prompted by the IQ, add Tristel Fuse for Stella disinfectant into Stella.

ADD
TRISTEL
FUSE

Carefully and steadily pour the disinfectant into the inner instrument compartment.

To avoid having to lift the five litre jug, it is recommended to position it on the outer wall of the base to the right of the IQ and tilt the jug slowly. The liquid pours slowly and steadily into the instrument compartment.

Fill the instrument compartment in the Base with the full 5 litres of Tristel Fuse for Stella disinfectant. The liquid will overflow over into the overflow compartment.

PULSE OPERATING PROCEDURE

⚠️ *Pour the disinfectant carefully to avoid or minimise splashes. Refer to the disinfectant Safety Data Sheet for Spillage Procedures.*

⚠️ *Failure to fill the instrument compartment with the full 5 litres will result in the cycle not commencing. If the correct level of liquid is not detected within 10 minutes, the Stella IQ will abort the procedure.*

⚠️ *Do not move Stella whilst it is filled with liquid.*

⚠️ *Ensure the disinfectant pick-up / filter is fully submerged.*

The level of the disinfectant solution automatically triggers the disinfection cycle and contact time countdown. Allow up to ten seconds for the liquid sensor to detect the liquid in the Base.

A sound confirms the start of the disinfection cycle.

⚠️ *Please check the Stella IQ display for the disinfection symbol. On rare occasions the cycle may have to be started manually. In this case Stella IQ will ask you to press the 'ON' button as indicated on the display.*

⚠️ *Stella Pulse has a fluid detection system that detects the presence of the Fuse for Stella disinfectant. If water is added without disinfectant, a failure code 119 will be displayed on the LCD screen, the cycle will fail and drain the water from Stella. This detection will occur in the first 30 seconds of the cycle.*

⚠️ *If the instrument is not attached to the Stella Pulse tube set, a fail notification graphic and sound alternating with a message reporting 'instrument unhooked' will be displayed. If the instrument is not connected within 30 seconds Stella will drain the disinfectant and report an incomplete cycle.*

STELLA IQ:

ILLUSTRATION
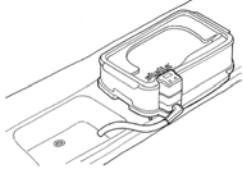
DESCRIPTION

IQ REFERENCE

DESCRIPTION

Fit the Lid onto the Base. The IQ displays the countdown of the remaining disinfection time (contact time).

The animated arrow in the LCD graphic confirms that Pulse is pumping. When the pump stops the animated arrow remains stationary.

 DISINFECTING

 DISINFECTING

 DISINFECTING

 DISINFECTING

At the start of the disinfection cycle, Pulse will start pumping the disinfectant through the channel of the instrument for one minute and then pause to hold the disinfectant within the channel. This is indicated by the solid green LED light.

When Pulse stops, the green LED light flashes momentarily indicating standby.

⚠ *Do not turn the IQ off during the contact time as this will lead to ineffective disinfection of the instrument and draining of the solution from the Base. A manual interruption of the disinfection cycle will be recorded into the data log report produced in Stella Suite and no validation code will be presented.*

After the contact time Stella automatically drains the disinfectant from the Base. The animated arrow in the LCD graphic confirms that Pulse is operating. The draining process may take up to one minute. Tristel Fuse for Stella does not require any rinsing. When the Stella is empty there is an audible reminder that the cycle is complete.

 STELLA DRAINING

After 40 seconds of Stella draining, Pulse pumps air through the instrument's channel to remove residual disinfectant. This may take up to one minute. This is indicated by the solid green LED light.

⚠ *If the instrument becomes detached from the Stella Pulse tube set during the disinfection cycle, a fail notification graphic and sound, alternating with a message reporting 'instrument unhooked' will be displayed at the end of the disinfection cycle. An incomplete cycle will be reported and the disinfection cycle must be repeated.*

⚠ *Follow medical device manufacturers' guidance for any rinsing, drying and storage.*

STELLA IQ:			STELLA PULSE:
ILLUSTRATION	**DESCRIPTION**	**IQ REFERENCE**	**DESCRIPTION**

The IQ display confirms that the disinfection cycle is complete. It asks to confirm that the disinfected instrument will be removed for immediate use or to (sterile) storage. Confirm by pressing the 'OK' button.

✔ COMPLETE

▶ CONFIRM INSTRUMENT CONNECTED

Pulse returns to Standby which is indicated by the flashing green LED light.

Upon pressing the 'OK' button, a validation code is displayed. This validation code should be noted in the traceability book for future reference.

The IQ asks if a new cycle should be started and prompts the user to press the 'OK' button. A new cycle can immediately be started by pressing the 'OK' button again.

VALIDATION CODE
FMQP-56

▶ RESTART CYCLE

If a new cycle is started, Pulse follows the instruction from the Stella IQ. The disinfection cycle starts from the beginning.

⚠ *Failure to confirm removal of the instrument will result in the LCD backlight shutting down after 15 minutes to maintain battery life. The audible beep is also turned off at this stage. If after 30 minutes 'confirm removal of instrument' has not been confirmed, Stella IQ will shut down. When the unit is turned on again, the 'confirm removal of instrument' instruction remains allowing the user to confirm by pressing the 'OK' button, which will retrieve the validation code.*

SHUTDOWN PROCEDURE

Turn off the IQ by pressing the OFF button. There is a sound to indicate that the IQ and Pulse are switching off.

If the IQ is turned off, Pulse will switch off automatically.

SECTION FOUR

MANUAL PRE-CLEANING, STELLA CLEANING & DISINFECTION OPERATING PROCEDURE

SECTION 4: MANUAL PRE-CLEANING, STELLA CLEANING & DISINFECTION OPERATING PROCEDURE

Always follow medical device manufacturers' guidance for correct handling of the device during the decontamination cycle.

MANUAL PRE-CLEANING

1. Remove any visible soil and excess water from the medical device.

2. Prepare 25ml of Tristel Clean for Stella by squeezing the bottle until the marking on the cap is reached. Pour the 25ml concentrate into five litres of cold water.

3. Immerse the instrument in the Tristel Clean for Stella and ensure a five minute contact time.

4. In the case of a lumened instrument, thoroughly brush the channel with the Tristel Clean for Stella, following hospital approved protocols.

5. Remove the instrument from the Tristel Clean for Stella and remove excess liquid.

6. Place the instrument in the Stella System. Follow the instructions on the display.

7. Discard the Tristel Clean for Stella after each use.

⚠️ *Pour the disinfectant carefully to avoid or minimise splashes.*
Refer to the disinfectant Safety Data Sheet for Spillage Procedures.

⚠️ *If a detergent other than Tristel Clean for Stella is used,*
rinse the medical device prior to placement in the Stella System.

AUTOMATED CLEANING IN STELLA

Tristel Clean for Stella must be used. Use of other detergents must be approved by Tristel. Unsolicited use of other detergents may affect the efficacy of the disinfectant.

STELLA IQ:

ILLUSTRATION	DESCRIPTION	IQ REFERENCE	STELLA PULSE: DESCRIPTION
	Push the 'ON' button on the IQ until you hear a sound and follow the instructions shown on the screen. In the background, the IQ performs a short self-check. IQ automatically connects to Pulse.	stella PULSE	Push the 'ON' button on Pulse until you hear a sound. The LED light will glow solid green to show that it is turned on.
		READ INSTRUCTIONS	In the background, Pulse performs a short self-check. The blue LED will flash whilst it is establishing a Bluetooth connection.
	The IQ and Pulse are paired. The Bluetooth sign confirms the connection and remains on throughout operation. The IQ asks to add the 'pre-cleaned instrument' into Stella's instrument compartment.	BLUETOOTH CONNECTED	When a connection is established the LED will glow solid blue. The green LED will start flashing to indicate the automatic pump control is on standby.
		ADD PRECLEANED INSTRUMENT	
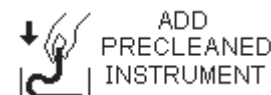
Connect the luer lock connector to the instrument channel.
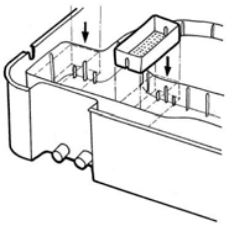
Any small removable parts from the instrument that are submersible should be placed in the Small Parts Tray with the lid firmly closed.

There are two positions within the instrument compartment where the Small Parts Tray is best positioned, one to the left and one to the right of the IQ.

When the instrument is properly placed into the instrument compartment and connected to Pulse make up five litres of Tristel Clean for Stella.

  Follow the Clean for Stella instructions for use, and refer to the Safety Data Sheet.

When prompted by the IQ, add diluted Tristel Clean for Stella.

Carefully and steadily pour 5 litres of Tristel Clean for Stella into the inner compartment. To avoid having to lift the five litre jug, it is recommended to position it on the outer wall of the base to the right of the IQ and tilt the jug slowly. The liquid pours slowly and steadily into the instrument compartment.

Fill the instrument compartment in the Base with the full five litres of Tristel Clean for Stella. The liquid will overflow over into the overflow compartment.

When the full 5 litres of Tristel Clean for Stella is added, the cleaning cycle will automatically start. The following features will be monitored;

• Stella will detect if the instrument is connected at the beginning of the clean cycle and at the end.
• Stella will detect if the instrument has a blockage.
• Stella will detect if cleaning solution vs water is added.

MANUAL PRE-CLEANING, STELLA CLEANING & DISINFECTING OPERATING PROCEDURE

ILLUSTRATION	DESCRIPTION	IQ REFERENCE	DESCRIPTION
	Fit the Lid onto the Base. The IQ displays the countdown of the remaining cleaning cycle (contact time five mins). The animated arrow in the LCD graphic confirms that Pulse is pumping. When the pump stops the animated arrow remains stationary (wheel segments will need to be have time split reallocated).	CLEANING CLEANING CLEANING CLEANING	At the start of the cleaning cycle, Pulse will start pumping the solution through the channel of the instrument for one minute and then pause to hold the solution within the channel. This is indicated by the solid green LED light. When Pulse stops, the green LED light flashes momentarily indicating standby.
	After the Tristel Clean for Stella contact time, Stella automatically drains the solution from the Base. The animated arrow in the LCD graphic confirms that Pulse is operating. The draining process may take up to one minute. When Stella is empty and ready for the disinfection cycle an audible reminder will sound. If the disinfection cycle does not follow within 15 minutes, the backlight on Stella IQ LCD will shut down to maintain battery life. The audible reminder will also be turned off at this stage. If after 30 minutes the disinfection cycle has not been started, Stella IQ and Stella Pulse will shut down. When the IQ and Pulse units are turned on again, the complete cleaning and disinfection cycle must be re-started.	STELLA DRAINING	After 40 seconds of Stella draining, Pulse pumps air through the instrument's channel to remove residual Tristel Clean for Stella. This may take up to one minute. This is indicated by the solid green LED light.

ILLUSTRATION	DESCRIPTION	IQ REFERENCE	DESCRIPTION

The Stella Disinfection Cycle is ready to start. Make up 5 litres of Tristel Fuse for Stella disinfectant. Carefully and steadily pour the disinfectant into the inner instrument compartment.

To avoid having to lift the five litre jug, it is recommended to position it on the outer wall of the base to the right of the IQ and tilt the jug slowly. The liquid pours slowly and steadily into the instrument compartment.

Fill the instrument compartment in the Base with the full five litres of Tristel Fuse for Stella disinfectant. The liquid will overflow over into the overflow compartment.

When the full five litres of Tristel Fuse for Stella disinfectant is added, the disinfection cycle will automatically start.

ADD TRISTEL FUSE

When the full 5 litres of Tristel Fuse for Stella is added, the disinfection cycle will automatically start.

The following features will be monitored;

- Stella will detect if the instrument is connected at the beginning of the disinfection cycle and at the end.
- Stella will detect if the instrument has a blockage.
- Stella will detect if cleaning solution vs water is added.

Follow the Fuse for Stella instructions for use, and refer to the Safety Data Sheet.
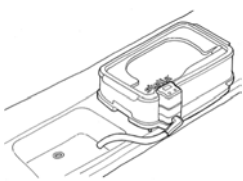
The IQ displays the countdown of the remaining disinfection time (contact time). The animated arrow in the LCD graphic confirms that Pulse is pumping. When the pump stops the animated arrow remains stationary.

DISINFECTING

DISINFECTING

DISINFECTING

DISINFECTING

At the start of the disinfection cycle, Pulse will start pumping the disinfectant through the channel of the instrument for one minute and then pause to hold the disinfectant within the channel.

This is indicated by the solid green LED light. When Pulse stops, the green LED light flashes momentarily indicating standby.

STELLA IQ:		STELLA PULSE:

STELLA IQ:

ILLUSTRATION	DESCRIPTION	IQ REFERENCE	STELLA PULSE: DESCRIPTION
	After the contact time Stella automatically drains the disinfectant from the Base. The animated arrow in the LCD graphic confirms that Pulse is operating. The draining process may take up to one minute. Tristel Fuse for Stella does not require any rinsing. When the Stella is empty there is an audible reminder that the cycle is complete.	STELLA DRAINING	After 40 seconds of Stella draining, Pulse pumps air through the instrument's channel to remove residual disinfectant. This may take up to one minute. This is indicated by the solid green LED light.

⚠️ *If the instrument becomes detached from the Stella Pulse tube set during the disinfection cycle, a fail notification graphic and sound, alternating with a message reporting 'instrument unhooked' will be displayed at the end of the disinfection cycle. An incomplete cycle will be reported and the disinfection cycle must be repeated.*

⚠️ *Follow medical device manufacturers' guidance for any rinsing, drying and storage.*

	The IQ display confirms that the cycle is complete. It asks to confirm that the disinfected instrument will be removed for immediate use or to (sterile) storage. Confirm by pressing the 'OK' button	COMPLETE / CONFIRM INSTRUMENT CONNECTED	Pulse returns to Standby which is indicated by the flashing green LED light.
	Upon pressing the 'OK' button, a validation code is displayed. This validation code should be noted in the traceability book for future reference.	VALIDATION CODE FMQP-56	If a new cycle is started, Pulse follows the instruction from the Stella IQ. The disinfection cycle starts from the beginning.
	The IQ asks if a new cycle should be started and prompts the user to press the 'OK' button. A new cycle can immediately be started by pressing the 'OK' button again.	RESTART CYCLE	
	Turn off the IQ by pressing the OFF button. There is a sound to indicate that the IQ and Pulse are switching off.		If the IQ is turned off, Pulse will switch off automatically
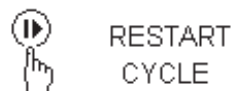
SECTION FIVE
MAINTENANCE

SECTION 5: MAINTENANCE

BLUETOOTH PAIRING PROCESS

Stella IQ and Pulse are supplied paired from the manufacturer.
However, if either unit is replaced, the following Pairing Process must be completed:

1. Switch on Stella Pulse.

2. Switch on Stella IQ and press the 'ON/OK' button two more times and the "Bluetooth Pulse Search" logo will display followed by "Bluetooth". The search commences.

3. Once the Bluetooth link is established, any available Pulse units will display by product serial number.

> › Pulse 100598
>   Pulse 100366

Use the 'ON/OK' button to scroll the arrow to the Pulse unit serial number you wish to pair the IQ too.

4. **Hold down the 'ON/ OK' button for 4 seconds or more** until the IQ 'beeps' and the "Bluetooth Pairing Complete" graphic displays.

5. Stella IQ and Pulse will now return to "read instructions" and are ready to start a disinfection cycle. If a new disinfection cycle is not required, turn Stella IQ off, which will also shut down Stella Pulse.

BARCODE VALIDATION

If utilizing a scanning software package for audit trail, the Stella with Pulse and Cleaning variant can issue a validation barcode when a decontamination cycle has successfully completed.

The barcode used is 128 format. This feature operates with a 2D image scanner, a laser scanner cannot be used.

To enable this feature, complete the following steps;

1. Connect the USB cable to the PC and connect to Stella IQ.

2. Wait until the USB symbol displays on the Stella IQ screen.

3. Press the Stella IQ 'ON' button **three times** to enter the screen for turning the barcode validation on or off.

4. The black box with white text specifies which option is set;

Validation code with barcode	The validation code **with barcode** is set on. If you wish to turn it off, you need to select the 'OFF' Button on Stella IQ.
OFF key = Barcode off	

Validation code without barcode	The validation code **without barcode** is set on. If you wish to turn it off, you need to select the 'OFF' Button on Stella IQ.
OFF key = Barcode on	

5. Remove the USB cable from Stella IQ, and push the 'ON' Button once, then the 'OFF' Button to switch the equipment off.

6. Stella is now ready to with the selected validation code option.

Example of validation barcode;

LUBING STELLA IQ

Every 6 months apply Stella Lube (silicone lubricant) to Stella IQ drainage inlets to ensure a firm fit of the IQ to the base.

1. Wearing gloves apply a small amount of Stella Lube to the outside perimeter of each of the drainage inlets (spread the lubricant evenly around the surface of the inlets). *DO NOT apply lubricant to the IQ drain outlet onto which the drain hose is attached.*

2. Wash your hands carefully after applying the lubricant.

For video instructions visit the help section on www.stella-performance.com. Only use Stella Lube on Stella IQ drainage inlets.

ORDERING REPLACEMENT PUMP HOSE SETS

Each new Stella Pulse unit comes with a fitted Pump Hose, and one spare Pump Hose Set. It is recommended that as soon as a hose is replaced, that a spare part be ordered.
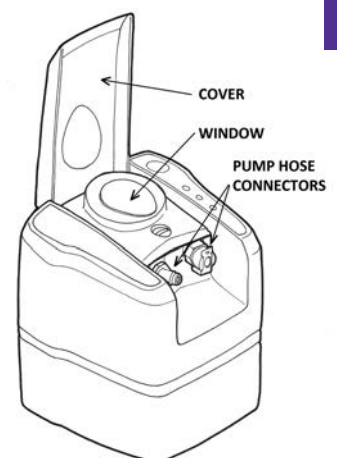
STELLA PUMP HOSE REPLACEMENT PROCESS

You will find a Pump Hose Replacement Instruction card and screwdriver in your Stella Toolbox.
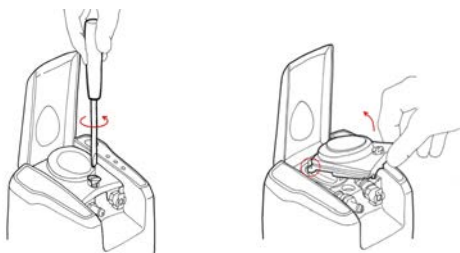
Equipment you will need for pump hose replacement process:-

- Stella Pulse.
- Pump Hose Replacement Set.
- Flat Head Screw Driver located in the Stella Toolbox.

1. Ensure that Stella Pulse is turned off. Lift the green cover on Stella Pulse.

2. Using a flat head screw driver, unscrew the clear window and remove from Stella Pulse.

3. Remove the pump hose by lifting the pump hose connector on one side. Turn the green pump head clockwise to lift the curved hose, and then lift the pump hose connector on the second side.
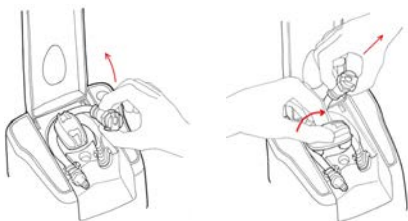
4. Insert the new pump hose into Stella Pulse. Place the left hand pump hose connector in first. This is the smaller connector with the plastic point. The hose then curves around the green pump head which can be turned by hand. Check that the hose is pushed down at the rear of the green pump head. The right hand pump hose connector is then locked into place.
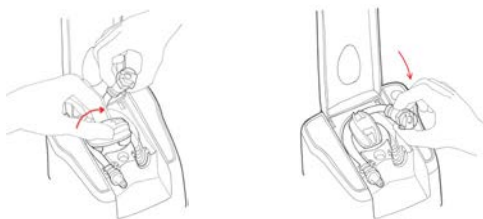
5. Replace the window, ensuring that the back ridge is pushed back correctly into Stella Pulse, and then fix the screw securely, taking care not to over tighten.

For video instructions, go to the help section of the Stella website www.stella-performance.com/help/. Re-order spare Pump Hose parts from your Stella Sales Agents. Follow the re-cycle program instructions from your Sales Agent which reduces the cost of spare parts.

⚠ *The pump hose connectors will not fit if they are not connected to the correct sides of Stella Pulse. Stella Pulse will not operate if the Window is not replaced correctly.*

THE BATTERY

BATTERY LEVEL INDICATOR AND CHARGING PROTOCOL

Stella IQ reports the battery status for both Stella IQ and Stella Pulse. The Stella IQ LCD screen will reference Stella Pulse in the graphic when reporting on that product. There are five levels of charge:

IQ	100%	The battery is 76 - 100% full
PULSE	100%	60 - 80 cycles available
IQ	75%	The battery is 51 - 75% full
PULSE	75%	41 - 59 cycles available
IQ	50%	The battery is 26 - 50% full
PULSE	50%	21 - 40 cycles available
IQ	25%	The battery is 11 - 25% full
PULSE	25%	9 - 39 cycles left
IQ LOW	10%	The battery is 0 - 10% full
PULSE LOW	10%	0 - 8 cycles left

CHARGING

CHARGE IQ	0%	Before switching off, the display will show
CHARGE PULSE	0%	that the battery needs charging.

Pulse

When charging, the battery is full only when the full battery graphic is displayed.

Stella Pulse will indicate charging is complete when the green light is constant.

⚠ *Stella IQ will not allow the start of a disinfection cycle when there is insufficient battery left to support a full cycle.*

⚠ *To prolong battery life, a full battery charge of 12 – 16 hours should be completed at least once a month and when the battery display indicates low battery.*

⚠ *Cycles are indicative. As the product ages the cycle numbers will decrease.*

⚠ *Units should be put on full overnight charge once a week, or if frequently used twice a week.*

The battery life of Stella IQ and Pulse is dependent upon operating conditions and frequency of use.
If Stella IQ or Pulse ceases to perform due to battery failure, contact your Stella Sales Agent.
The battery may only be replaced by an authorised trained technician.

To charge the battery, disconnect Stella IQ or Pulse from the Base. Stella IQ and Pulse will not operate whilst being charged.

⚠️ *Do not charge Stella IQ or Pulse whilst they are attached to the Base or near any forms of liquid.*

⚠️ *Only the supplied power adaptor should be used for charging the Stella IQ and Pulse units. Use of other adaptors may damage the equipment or cause malfunction.*

CHARGING THE BATTERY OF THE IQ AND PULSE

Open the protective cover of the power port on the back of Stella IQ or Pulse.

Plug in the power adaptor supplied and connect to the mains power supply.

The IQ display shows the status of charging the unit. For Pulse indicators, please see the table below.

The symbol for a fully charged battery indicates that the charging process is complete. A full charge takes 12 – 16 hours.

When using the IQ and Pulse for the first time, always charge the battery to 'full'.
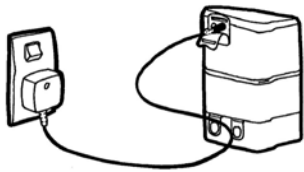
CHARGING

CHARGING

FULL 100%

PULSE BATTERY INDICATORS

PULSE REFERENCE	DESCRIPTION
Green light constant.	Battery Charged.
Green light flashing on and off.	Battery Low. Charge Battery.
Yellow/Orange light flashing on and off.	Charging - when adaptor is plugged in this indicates charging is in progress.

Top Light Power status

DOWNLOADING THE INFORMATION

A record of every part of the disinfection process is stored in the memory of Stella IQ (for both Stella IQ and Pulse). This data should be downloaded regularly and stored in a safe place together with the Stella Audit Record Book, if used, for future reference.

Prior to downloading information from Stella IQ, Stella Suite software must be installed on the computer to which Stella IQ will be downloaded. Please refer to the Stella Suite instructions for use, which can be downloaded from the Stella Suite.

There are two options to download the data from Stella IQ:

1. via USB
2. via Bluetooth

These options are explained within the following pages.

To download the data, disconnect Stella IQ from the Base and place it on a stable surface away from liquids.

⚠️ *Stella IQ cannot perform any disinfection cycles whilst downloading.*

⚠️ *Ensure the Stella Suite software has been installed on the computer prior to plugging the USB cable into the Stella IQ.*

DOWNLOADING VIA USB CABLE

STELLA IQ: STELLA PULSE:

ILLUSTRATION	DESCRIPTION	IQ REFERENCE
stella Stella Suite	On your PC, open the Stella Suite and follow the instructions on screen. Connect the USB cable to your computer. Open the protective cover of the USB port on the back of Stella IQ and connect the USB cable to the IQ. The IQ automatically detects the USB connection to the PC. The IQ display will light up to show the Stella logo. Do not push the 'ON' button. If you do so, turn off Stella IQ, and repeat the steps above. The IQ is now ready for download via USB connection. The USB Download symbol is displayed on the screen. Choose the download icon option on the Stella Suite toolbar. Stella IQ displays the transfer of data. Once the download is complete, disconnect the USB cable. The Stella IQ will automatically switch off.	stella USB DOWNLOAD DOWNLOAD

⚠️ *Remove the USB cable and reseal the cover over the USB port on the IQ.*
Ensure the cover is securely sealed to prevent the ingress of water or disinfectant into Stella IQ.

DOWNLOADING VIA BLUETOOTH

STELLA IQ:
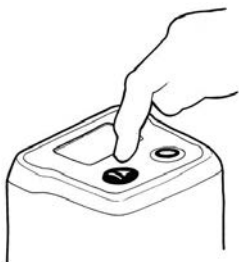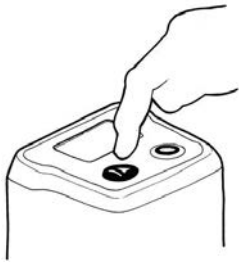
ILLUSTRATION   **DESCRIPTION**

Turn on the Bluetooth connection on your computer and place Stella IQ within a ten metre range of the computer.

Press the 'ON' button on the IQ until you hear a sound.

While the Stella logo is displayed on screen, press the 'ON' button again until the operation mode screen appears. Use the 'ON' button to select the download option.

Stella IQ is now ready for download via Bluetooth and displays the Bluetooth symbol on its screen. On your computer, open the Stella Suite. Follow the instructions on screen and link your computer to Stella IQ via Bluetooth.

(Also refer to the Stella Suite user instructions).

Once the link is established, Stella IQ displays an active signal.

Choose the download icon on the Stella Suite toolbar. Stella IQ displays the transfer of data.

Once the download is completed, shut down Stella IQ by pressing the 'OFF' button.

If Stella IQ is not switched off, it will shut down automatically after 30 minutes.

STELLA PULSE:

IQ REFERENCE

USB DOWNLOAD

BLUETOOTH DOWNLOAD

DOWNLOAD

CLEANING, DISINFECTION AND STERILISATION OF STELLA, IQ AND PULSE

STELLA BASE AND LID CLEANING PROCEDURE

Local guidelines and Hospital protocols should be referred to for equipment cleaning requirements.

Tristel recommend visual debris should be cleaned from Stella Base, Lid and Small Parts tray after use.

Every disinfection cycle completed in Stella provides disinfection to the inner compartment of the base and the inner compartment footprint of the lid.

The following cleaning and disinfectant agents are compatible with Stella Base and Lid components;

TRISTEL PRODUCTS

Tristel Jet for Surfaces is a cleaning and high-level sporicidal disinfectant solution, specifically designed to kill harmful organisms such as *Clostridium difficile*, Norovirus and MRSA on near-patient surfaces in short contact times.

Tristel Jet is available in a gel or liquid spray format, with a unique reusable trigger head that prohibits internal contamination of the bottle.

Tristel Jet can be used for cleaning the Stella Base, Lid, Small Parts Tray and Cradle only.

http://www.tristel.com/tristel-jet-surfaces

DISTEL WIPES

Distel Wipes are impregnated with quaternary ammonium disinfectant. They are suitable for the disinfection of Stella Base, Lid, Small Parts Tray, Cradle, IQ and Pulse units.

http://www.tristel.com/tristel-products/distel-wipes

STERILISATION

Autoclaving of the Base, Lid and Small Parts Tray is permitted if required by local infection control policies. These parts can be autoclaved at 134°C for three minutes.

The Base, Lid and Small Parts Tray are not intended for autoclaving on a regular basis. Cosmetic changes (cracks and fading) to the Base, Lid and Small Tray may present if autoclaved.

⚠️ *DO NOT AUTOCLAVE the Stella IQ, Pulse, Cradle, power adaptors, grommets or any other accessories.*

⚠️ *DO NOT IMMERSE Stella IQ, Pulse, power adaptors or USB cable in water or any other liquid.*

⚠️ *Stella IQ and Pulse Power covers* **must be firmly sealed** *to protect units from ingress of fluid.*

STORAGE AND OPERATING CONDITIONS

Stella IQ and Pulse are suitable for operating and charging in temperatures of 10 to 35°C
with a maximum allowable humidity of 90% (within the prescribed temperature range).

Stella Base with Lid measure 70cm x 48cm x 18cm and weigh 5.5kg when empty.
The Base and Lid can be stacked and easily transported due to their portable size and weight.

Stella Cradle measures 84cm x 48cm. The height is variable depending on the adjustment of Cradle feet,
but on average when holding Stella Base measures 23cm. Refer to page 5 for full Stella footprint measurements.

The drainage outlet cap can be used when transporting Stella Base to contain any small droplets of disinfectant
that may be left in the Base. Do not use the drainage cap to hold solution in the Base.

DISPOSAL CONSIDERATIONS

The Stella Base, Lid, and Small Parts Tray can be recycled once decontaminated.
Autoclaving is recommended prior to disposal.

The IQ and Pulse units contain batteries and electronic components and must be disposed of in
accordance with local regulations, or returned to the local Stella Service Agent for disposal. The units
should be decontaminated using chemical high-level disinfection prior to disposal. For further information
refer to your local Stella Service Agent.

OTHER

In the event of damage to parts within the Stella System, contact the manufacturer or your local Stella
Service Agent to purchase replacement parts.

If you experience a problem with the operation of the Stella System, please refer to the Troubleshooting
section of this manual.

Should you not be able to resolve the operational problem, contact your local Stella Service Agent. Before
calling, please ensure that you have serial numbers of the hardware and revision numbers of the software:

• Hardware serial numbers can be found on the unit product labels.
• Software revision numbers can be found by downloading the data log report using the Stella Suite.

Stella IQ, Pulse and their power adaptors should periodically be tested for electrical safety in accordance
with local health and safety procedures.

SECTION SIX

TROUBLESHOOTING GUIDE & GLOSSARY

SECTION 6: TROUBLESHOOTING GUIDE & GLOSSARY

TROUBLESHOOTING GUIDE AND FREQUENTLY ASKED QUESTIONS

In this section you will find a troubleshooting guide to assist if you have problems with operating the Stella System.

This troubleshooting guide is your first port of call in resolving issues.

This section covers the following troubleshooting topics:

- Damaged Goods
- Battery Reporting
- Stella Pulse LED Light Reporting
- Stella IQ LCD Display and Troubleshooting
- Frequently Asked Questions

If you are unable to resolve an issue after referring to this guide, please contact your local Stella Service Agent. A list of contacts can be found in the Contacts section of this manual.

If for any reason the Stella Equipment needs to be returned, you must first contact the Stella Service Agent you purchased your Stella equipment through to register the return and initiate an investigation process. You will be required to complete a product return form which is contained in the last page of this section.

DAMAGED GOODS

If goods are damaged during delivery, it is the user's responsibility to contact the Sales Service Agent immediately.

If the equipment is dropped during use, the user should run a cycle through Stella to check it is operating correctly and contact the Stella Service Agent if any damage has occurred.

BATTERY MANAGEMENT

BATTERY LEVEL INDICATOR AND CHARGING PROTOCOL

Stella IQ reports the battery status for both Stella IQ and Stella Pulse. The Stella IQ LCD screen will reference Stella Pulse in the graphic when reporting on that product. There are five levels of charge:

IQ	100%	The battery is 76 - 100% full	
PULSE	100%	60 - 80 cycles available	
IQ	75%	The battery is 51 - 75% full	
PULSE	75%	41 - 59 cycles available	
IQ	50%	The battery is 26 - 50% full	
PULSE	50%	21 - 40 cycles left	
IQ	25%	The battery is 11 - 25% full	
PULSE	25%	9 - 20 cycles left	
IQ LOW	10%	The battery is 0 - 10% full	
PULSE LOW	10%	0 - 8 cycles left	

CHARGING

CHARGE IQ / CHARGE PULSE	0% / 0%	Charge warning.	Before switching off, the display will show that the battery needs charging.
CHARGING		Charging commenced.	Charging of IQ battery has commenced. Stella Pulse indicates charging is in progress when the adaptor is plugged in and the Yellow/ Orange LED light is flashing.
IQ / PULSE	100% / 100%	Charging complete.	When charging, the battery is full only when the full battery graphic is displayed. Stella Pulse will indicate charging is complete when the green light is constant.
NO BATTERY		Battery not detected.	The battery or charging system may have developed a fault or have become excessively discharged during long periods of storage. Place the unit on charge for 12 - 16 hours, then disconnect and reconnect the charger. If the problem persists, contact your Stella Service Agent.

REPLACE BATTERY [▭]   Battery needs replacing   The battery or charging system may have developed a fault. Contact your Stella Service Agent.

⚠️ *Stella IQ will not allow the start of a disinfection cycle when there is insufficient battery left to support a full cycle.*

⚠️ *To prolong battery life, a full battery charge of 12 – 16 hours should be completed at least once a month a nd when the battery display indicates low battery.*

⚠️ *Cycles are indicative. As the product ages the cycle numbers will decrease.*

⚠️ *Units should be put on full overnight charge once a week, or if frequently used twice a week.*

PULSE LED LIGHTS

Stella Pulse has a series of three LED lights that reports battery, connection and pump activity.

Power Button

Power Status LED
Bluetooth Status LED
Pump / Fault Status LED

POWER STATUS LED

Green light constant.	Battery Charged.
Green light flashing on and off.	Battery Low.
Yellow/Orange light flashing on and off.	Charge battery.
	Charging - when adaptor is plugged in this indicates charging is in progress.

BLUETOOTH STATUS LED

Blue light flashing on and off.	Bluetooth Search Mode.
Blue light constant.	Bluetooth link established.
No light.	Off – no Bluetooth link.

PUMP STATUS LED

Green light constant.	Pump operating.
Green light flashing on and off.	Pump ready – in standby mode.
Red light flashing.	Pump failure.
Red light constant.	System failure.

STELLA IQ LCD GRAPHICS

In this section you will find a table of failure codes, their descriptions and actions for troubleshooting.

LCD GRAPHIC	WHAT HAS HAPPENED?	TROUBLESHOOTING
START CYCLE	5 Litres of Tristel Fuse for Stella have been added to Stella but the Disinfection cycle does not start. Moisture may be present in the sensor tube prior to starting a cycle. This should clear after the cycle has completed.	Manually activate the start of the disinfection cycle by pressing the 'ON' button. If problem persists there may be a moisture droplet trapped in the sensor tube. Holding the IQ horizontal, press the 'ON' button. This will close the valve. Then flush clean water into the drain inlet, turn over and flush the outlet. Leave the Stella IQ to dry. Once dry, restart Stella IQ.
STELLA IQ XX / STELLA PULSE XX	In the event of a user error, or a problem that may be resolvable on site, a graphic will display.	The graphic will notify whether it is IQ or Pulse related, and the number in the corner alerts us to the table below for how to address.
VALVE NOT CLOSED / STELLA IQ 58	Stella IQ has detected an obstruction and the ball valve will not close.	There is no disinfectant in the Base. Remove Stella IQ from the Base and inspect the IQ drainage outlets for blockages with foreign objects and remove any debris. Refer to the Ball Valve Cleaning Procedure in the Service Manual. Restart the cycle. If the problem persists a blockage may have occurred higher in the Ball Valve area and the unit will need to be returned to the Service Centre to clear.
BLUETOOTH LINK LOST / STELLA PULSE 94	Stella Pulse Bluetooth link has been lost.	The disinfection cycle has not successfully completed and must be repeated. Turn off Stella IQ and Pulse. Start the Bluetooth communication process again by first switching on Stella IQ then Pulse. If this frequently occurs, the Pulse battery may have aged. Contact your Service Centre.

LCD GRAPHIC	WHAT HAS HAPPENDED?	TROUBLESHOOTING
INCOMPATIBLE PULSE SOFTWARE STELLA PULSE 95	Stella Pulse Software is not compatible with Stella IQ Software	Open Stella Suite and connect the IQ via USB cable to the computer. Go to help menu and "check for software updates". When completed repeat the process with Stella Pulse. If Stella Suite is not installed, visit:- www.stella-performance.com/ usingstella/updatestella and install Stella Suite Software
INSTRUMENT BLOCKED STELLA PULSE 110/111/112/114	Stella Pulse has detected a blockage which could be related to the Pump Hose, Tube Set, Pulse Window not replaced correctly, or a blocked instrument, or instrument tap closed.	The disinfection cycle has not completed successfully. Disinfectant in the Base will be drained to waste. Check the instrument for blockages, check the instrument tap is not closed, and visually inspect the Tube Set connected to the instrument for blockage. Open Pulse Window by following the Pump Hose Replacement instructions above. Remove the Pump Hose and check that it is not pinched. If pinched, massage the tube between fingers to return to round shape. Replace the Pump Hose, replace Pulse Window, and restart the cycle
NO SOLUTION CONFIRM INSTRUMENT CONNECTED STELLA PULSE 113	Stella IQ is not detecting solution. The Pulse strainer is either not submerged in the disinfectant or the left hand Tube Set connection is not connected to Pulse unit.	If this occurs prior to the start of the 5 minute disinfection cycle the user will be asked to 'confirm instrument connected'. First ensure that the strainer is fully submerged in the Base inner compartment, that the Tube Set is connected to the instrument and that the Tube Set Connectors are connected to Pulse unit. Stella IQ gives three chances / or a total of 1 minute to make the connection requesting 'confirm instrument connection' by pushing the 'ON' button. If the connection is not made, or this occurs during the disinfection cycle error code 113 will be displayed. The disinfection cycle has not successfully completed and must be repeated.
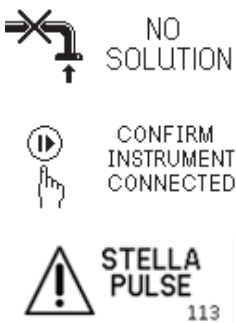
LCD GRAPHIC	WHAT HAS HAPPENDED?	TROUBLESHOOTING
INSTRUMENT UNHOOKED ⚠ STELLA PULSE 115/125	Stella has identified that the instrument has not been connected to Pulse or that it has become disconnected during the disinfection cycle.	If this occurs prior to the start of the disinfection cycle, reconnect Pulse Luer Lock Connector to the instrument within a 30 second time frame and 'Confirm Instrument Connected' by pressing the ON button.

Ensure that gloves and appropriate personal protective equipment are worn when Pulse tubing is being reconnected. If the connection takes longer than 30 seconds, cannot be made, or occurs during the disinfection cycle, disinfectant will drain to waste. In this case the disinfection cycle has not successfully completed and must be repeated. |
| ⊠ NO TRISTEL FUSE ⚠ STELLA PULSE 119 | Tristel Fuse for Stella disinfectant is not detected | The disinfection cycle has not successfully completed and must be repeated.

Stella has not detected Tristel Fuse for Stella. The cycle has failed: water will be automatically drained from Stella. |
| ✕ STELLA IQ xx ✕ STELLA PULSE xx ✕ STELLA xx | In the event of equipment errors that cannot be resolved on site a "X" graphic will display. | The X graphic will notify whether it IQ or Pulse related, and the number in the corner alerts to the problem.

If the issue relates to both IQ and Pulse a Generic X Stella will display.

Please make a note of the graphic details and contact your Stella Service Agent. |

FREQUENTLY ASKED QUESTIONS

POWER

For further information refer to the Electromagnetic Emission tables in the regulatory and warranty section of this manual.

Stella IQ or Pulse will not power up or is operating intermittently.

- Stella IQ will not start a cycle if there is not enough charge in the batteries to finish a full cycle.
- Place Stella IQ and Pulse on charge for 12 - 16 hours.
- For urgent use only: the IQ or Pulse must charge for a minimum of three hours before it can be operated.

Stella IQ or Pulse fails to start or stays switched off.

- Place Stella IQ and Pulse on charge for 12-16 hours.

While charging, Stella IQ or Pulse fails to power up or charges intermittently.

- Check that the green indicator light on the adaptor is lit. If it is not lit, contact your Stella Service Agent.

Stella IQ or Pulse fails to switch on or off.

- Contact your Stella Service Agent.

⚠️ *As Stella IQ and Pulse batteries age, their capacity to store energy decreases.*
If equipment charge levels drop quickly or after full charges, few cycles are completed, contact your Stella Sales

HARDWARE

Water is leaking from the base of Stella.

- Check the Stella IQ is attached firmly to the Stella Base. Ensure that the drain hose is attached and is watertight.
- Applying the Stella Lube (for instructions, see the Introduction section of this manual) will assist a firm fit to the Base. Visit www.stella-performance.com help section for video guides.

Water is leaking from the Valve outlet.

- Note: Excess liquid will exit the outlet when Stella is filled. Even when filling the instrument compartment with five litres, a small amount of liquid will flow into the overflow compartment and out through the drain hose at the start of a cycle.
- If there is a continuous leak throughout the cycle, the Valve may not have closed correctly.
- Flush the System with clean water. Remove any foreign matter from Stella IQ's drain outlets.

Water leaks appearing from the electronics enclosure power cap.

- Discontinue use immediately and contact your Stella Service Agent.

LCD display is hard to read.

- Remove Stella IQ or Pulse from direct heat source or direct sunlight. If the problem persists, contact your Stella Sales Agent.

The LCD display is intermittent.

- Contact your Stella Sales Agent.

COMMUNICATION

For further information refer to the Electromagnetic Emission tables in the regulatory and warranty section of this manual.

USB: Download or Firmware Upgrade is erratic or not possible.

- Check the USB cable is in a good condition with no cable damage, broken or visible wires.
- Check plug connections are in good working order.
- Check the Stella Suite installed on your computer is the latest version. The latest available version of
- Stella Suite software can be found at: www.stella-performance.com (go to Using Stella / Update Stella).
- Refer to the Stella Suite Installation Guide for the correct installation process for your operating system.
- The USB driver may have been installed in the incorrect location.
- Go to the Start menu on your computer and select:

Settings/ Control Panel/ System/ Hardware/ Device Manager

- Plug the USB cable into Stella IQ and then your computer and observe where "USB Tristel" appears in your list. If it appears in the main list and not under Universal Serial Bus controllers, it needs to be shifted.
- To shift select your device manager list and select 'Update Driver'. Follow the wizard. In the wizard select 'Search for the best drivers in these locations' then browse to the following path:

  C:\Program Files\Stella\Stella_Suite

- The driver should now install in the correct location. When complete, unplug the USB from Stella IQ.

Bluetooth: Download erratic or not possible.

- Follow the "Stella Suite Bluetooth Installation User Guide" which can be found in the Help section of the Stella Suite.
- Note: Stella Suite must be installed onto the computer, and the Bluetooth link configured according to the Bluetooth device instructions used on the computer.
- Switch on Stella IQ into Bluetooth mode by pressing the 'ON' button then pressing again during the display of the Stella logo.
- Click the Bluetooth icon at the bottom of your computer screen to identify the com port assigned for IQ.
- Open Stella Suite, in the file tab choose 'Configure', select the Bluetooth window, and then tick 'Use Bluetooth'.
- Select the COM PORT assigned to Stella IQ and click OK. Close the Stella Suite (the serial port pairing code for the com link is "1234").
- Neighbouring electrical equipment and mobile radios may cause electrical interference and affect the performance of the Bluetooth communication link.
- Move Stella IQ and the computer away from strong electromagnetic devices such as radio transmitters and electromagnetic MRI imaging equipment etc.
- Move Stella IQ within a 10 metre radius of the computer.

Stella IQ or Pulse will not power up after a firmware update.

- Plug in the power adapter or USB cable and press the 'ON' button once to check firmware version.
- Check that the correct and latest firmware is installed. Repeat update if necessary.
- During any firmware update, do not remove the USB cable until the update is 100% completed (denoted by two beeps).
- Check USB cable or power adaptor is in good working condition.

Failure alarm occurs after firmware update.

- The Firmware may not have installed correctly.
- Go to Stella Suite Help menu, select "Check for Stella IQ updates" and "Check for Stella Pulse updates".

No Stella log events are displayed after the immediate second download.

- By default the Stella Suite will only download events that took place since the last download. Therefore an immediate second download will not display any detail in the report until further events have taken place using the Stella System.
- To view previous events, click on the EVENT FILTER Icon, choose the date range you would like to view events from then click OK. The events report will now be displayed.
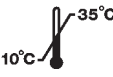
Stella IQ does not automatically activate the disinfection cycle or constantly requires manual activation.

- Check that the Stella System is located on a level and stable surface. If not, Stella Cradle can be used to level your Base.
- If this does not resolve the issue then a blockage may have occurred inside the drain inlet. Restart Stella IQ. Water or air bubbles may be affecting the internal sensor. In this instance the unit will require manual activation. Hold down the 'ON' button to manually activate.

If any issues persist, contact your Stella Service Agent.
The contact details can be found in the 'Contacts' section of this manual.

GLOSSARY OF GRAPHICAL SYMBOLS USED ON THE STELLA SYSTEM

Fragile. Handle with care.

Do not stack pallets.

Material can be recycled.

Read instructions before use.

LOT   Lot number.

SN   Serial number.

USB enabled.

DC supply requirements and polarisation.

Date of manufacture.

35°C / 10°C   Operate within 10°C to 35°C with a maximum allowable humidity of 90% (within the prescribed temperature range). Store and transport within the temperature range of -10°C to 40°C.

FC   Complies to 47 Code of Federal Regulations, part 15 and part 18, of the Federal Communications Commission regulations (relevant to the USA only).

CE 0086   CE marked as a medical device. This device conforms to the European Medical Device Directive 93/42/EEC and the 2007/47/EC amendments thereto.

Recycle in accordance with the WEEE Directive. Under the European Directive 2002/96/EC this electronic device must not be disposed of to normal waste.

Bluetooth enabled.

IP64   Ingress protection: Totally protected against dust; protected against water sprays from all directions: limited ingress may occur.

SECTION SEVEN

REGULATORY & WARRANTY INFORMATION

SECTION 7: REGULATORY & WARRANTY INFORMATION

WARRANTY FOR STELLA IQ AND STELLA PULSE

LIMITED WARRANTY

Tristel Solutions Limited (hereafter referred to as "the Company") warrants that the Stella System, Pulse and associated parts and accessories (hereafter referred to as "the Product") will conform to the Company's written specifications and will be free from defects in material and workmanship under its designated, normal use and service.

Notwithstanding anything herein to the contrary, the warranty period for the Stella System, comprising of Stella IQ, Stella Pulse, Stella Base, Lid and accessories supplied by the Company is twelve (12) months shown from the date of invoice.

Both the Stella IQ and Stella Pulse, if handled appropriately and in accordance with user instructions, have a Warranty Period of twelve (12) months from date of invoice. Stella IQ and Pulse should be registered on the Stella Performance website www.stella-performance.com/register.html for the warranty to be valid and before any warranty claims can be handled.

Warranties shall be made invalid by the misuse of, or unauthorised tampering with, the Product.

The warranty does not cover, and the Company will have no warranty obligation whatsoever with respect to any damage to the Product caused by or associated with: (1) external causes, including without limitation, accident, vandalism, power failure or electrical power surges, (2) abuse, misuse or neglect of the Product by the customer or any other user or through use of unauthorised third party consumables and accessories, (3) usage not in accordance with the product Instructions For Use, (4) the customer's failure to perform required preventive maintenance and care, or (5) servicing or repair not authorised by the Company.

LIMITATION OF REMEDY

The warranty obligation of the Company hereunder is limited to the repair or replacement (at its option) of the defective Product or any parts it deems defective. This will be the customer's exclusive remedy for a covered defect.

In order to recover under the warranty, the customer must notify the Company or its representative in the country of installation of the defect prior to expiration of the warranty period and within thirty (30) days of discovery of the defect. The notification to the Company must include a description of the problem in reasonable detail and the full report downloadable from the IQ using the Stella Suite, showing all details starting seven (7) days before the defect was first noted. Upon receiving the Company's official "return goods authorisation" (RGA), the customer must promptly return the defective part or Product to the Company (or the authorised representative) as indicated on the RGA, freight and insurance prepaid. The Company will not be responsible for any damage during shipment.

WARRANTY DISCLAIMER

The Warranty above is the Company's entire warranty obligation to the purchaser of products. It is in lieu of all other warranties of the Company, express or implied, including, without limitation, warranty of merchantability or fitness for a particular purpose, and the company does not represent or warrant that any product will meet customer's requirements. The Company's responsibility for defects in a product is limited solely to repair and replacement as set forth in this warranty statement.

To the extent permitted by law, the Company shall not, under any circumstances, be liable to the customer for consequential, incidental, indirect or special damages or losses, including without limitation, damages arising out of or in connection with any malfunctions, delays, loss of profit, interruption of service, or loss of business or anticipatory profits, even if the Company has been apprised of the likelihood of such damages occurring.

This Warranty gives the customer specific legal rights, and customers may also have other rights which vary from jurisdiction to jurisdiction.

In no event shall the Company's liability exceed the original purchase price of the covered Product. No representative or agent of the Company has the authority to bind the Company to any other representation or warranty with respect to the Products, and the customer accepts the Products subject to all of the terms above.

REGULATORY INFORMATION

The Stella System is CE marked as a Class IIb medical device as per the Medical Device Directive MDD 93/42/EEC and the 2007/47/EC amendments thereto.

Stella is designed and manufactured to conform to the following standards:

Directive 93/42/EEC	Council Directive 93/42/EEC of June 1993 concerning medical devices, amended by Directive 2007/47/EC.
BS EN ISO 13485:2012	Medical Device -Quality Management Systems – Requirements for Regulatory Purposes.
ISO 13485:2003	Medical Devices - Application of risk management to medical devices.
BS EN ISO 15223-1:2012	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements.
BS EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices.
ISO 7000:2014	Graphical symbols for use on equipment - Registered symbols.
EN 60601-1:2006	Medical electrical equipment. General requirements for basic safety and essential performance.
EN 60601-1-2:2007	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests.
EN 60601-1-6:2007	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
EN 60601-1-8:2007/ AC:2010	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
EN 61000-3-2:2006	Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current ≤ 16 A per phase).
EN 61000-3-3:1995	Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection.
EN 61000-4-2:1995	Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrostatic discharge immunity test.
BS EN 61000-4-3:2006+A2:2010	Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test.
EN 61000-4-4:2004	Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test.
EN 61000-4-5:2006	Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test.
EN 61000-4-6:2007	Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields.

EN 61000-4-8:1994	Electromagnetic compatibility (EMC). Testing and measurement techniques. Power frequency magnetic field immunity test.
BS EN 61000-4-11:2004	Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests.
EN 61010-2-040:2005	Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for sterilizers and washer-disinfectors used to treat medical materials.
BS 5452:1977	Specification for hospital hollow-ware made of plastics material- Clauses 9,10 and 11 (only relating to the lid and base).
Directive 2012/19/EU	Directive of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).
Directive 2011/65/EU	Directive of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
Directive (EU) 2015/863	Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

This includes compliance to relevant sections regarding environmental operating conditions.

ELECTROMAGNETIC EMISSIONS AND IMMUNITY EN60601-1-2:2007

STELLA

For electromagnetic emissions the Stella System has been tested for compliance to IEC 60601-1 CISPR11 Group 1, Class B. Testing has been performed using the following parts which are supplied with the Stella System.

ITEM DESCRIPTION	LENGTH	MANUFACTURER	PART NUMBER
USB Cable Type A to B	1m	Dynamix	C-U2AB-1
GPP10 Medial Power Plug Pack	Not Applicable	FRIWO	1950067

WARNINGS

Use of accessories and cables other than those specified, with the exception of the power pack and cables sold by the manufacturer of the Stella System as replacement, may result in increased emissions or decreased immunity of the Stella System.

ADJACENT EQUIPMENT

The Stella System should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the Stella System should be observed to verify normal operation in the configuration in which it will be used.

OPERATION IN WET AREAS

Keep the Stella IQ and Pulse units clear from wet areas when they are placed on charge or connected to a computer terminal using a USB cable. Do not attempt to use the Stella System for disinfection purposes while charging or downloading. In the case of long-term storage, remove Stella IQ and Pulse from Stella Base and keep it clear from wet areas.

CLOSE POWER CAP

Remove all cables from the Stella IQ and Pulse units and ensure the rear power caps are closed firmly while the Stella IQ or Stella Pulse are in use during disinfection cycles and cleaning.

The Stella System is intended to be used with and connected to other computer equipment within Hospitals and Domestic environments. Refer to Table 1, Table 2, Table 4 and Table 6 as per standard EN60601-1-2:2007 (clause 5.2.2.1) which are detailed below.

EN60601-1-2:2007 (5.2.2.1) TABLE 1

Declaration for compliance: CISPR 11 group 1 Stella System complies with Class B, IEC 61000-3-2 Class A and IEC 61000-3-3.

MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS		
The Stella System is intended for use in the electromagnetic environment specified below. The end-user of the Stella System should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Stella System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any Interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Stella System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

EN60601-1-2:2007 (5.2.2.1) TABLE 2

Declaration for compliance: The Stella System complies with all IEC 60601 Test Levels of this collateral standard for power frequency magnetic field immunity requirement.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Stella System is intended for use in the electromagnetic environment specified below. The end-user of the Stella System should ensure 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 ± 1 kV for input/output lines	± 2kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line to line ± 2 kV line to earth	± 1kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	‹ 5% UR (›95 % dip in Ur) for 0,5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30 % dip in Ur) for 25 cycles ‹5 % Ur (›95 % dip in Ur) for 5 s	‹ 5% UR (›95 % dip in Ur) for 0,5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30 % dip in Ur) for 25 cycles ‹5 % Ur (›95 % dip in Ur) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60Hz) magnetic field IEC 61000-4-6	3 A/m	3 A/m	If disturbance occurs, it may be necessary to position the Stella System further from sources of power frequency magnetic fields or install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

EN60601-1-2:2007 (5.2.2.1) TABLE 4

Declaration of compliance: Stella System which is non-life supporting device that meets IEC 60601 Test Levels of this collateral standard for the radiated and conducted immunity tests.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Stella System is intended for use in the electromagnetic environment specified below. The end-user of the Stella System should ensure 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 Radiate RF IEC 61000-4-3	3 Vrms 150kHz to 80 Mhz 3 V/m 80 MHz to 2,5GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Stella IQ, including cables, than recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 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 (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:
• At 80 MHz and 800 MHz, the higher frequency applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures and people.			
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 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 Stella System is used exceeds the applicable RF compliance level above, the Stella System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientation or relocation of the Stella System. Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V/m.			

EN60601-1-2:2007 (5.2.2.1) TABLE 6

Recommended separation distances between portable and mobile RF communications equipment and the Stella System.

The Stella System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The end user of the Stella System can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the Stella System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter Watts (W)	Separation distance to frequency of transmitter – meters (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$		150 kHz to 80 MHz $d = 1.2 \sqrt{P}$
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 distances 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.

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

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CE
0086   The Stella system is CE marked as a Class IIb medical device as per the
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STL/019/Issue 13

For Tristel patent information please visit: http://www.our-patents.info/tristel

REGULATORY & WARRANTY INFORMATION

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SECTION EIGHT
STELLA SERVICE AGENTS

SECTION 8: STELLA SERVICE AGENTS

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Tristel

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