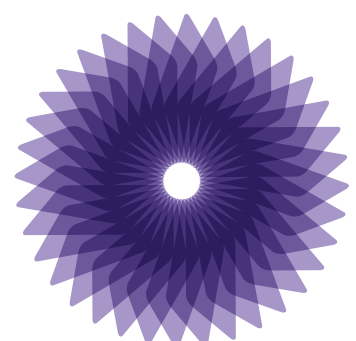
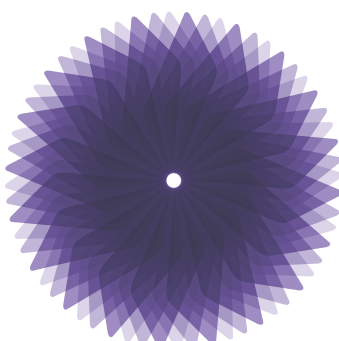
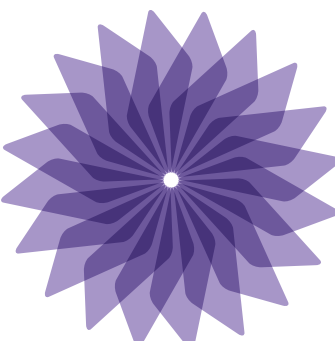
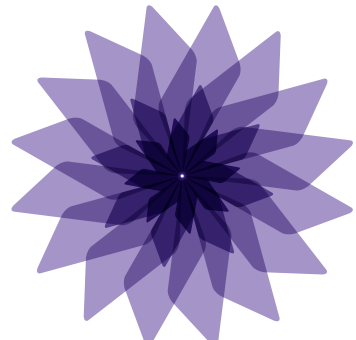
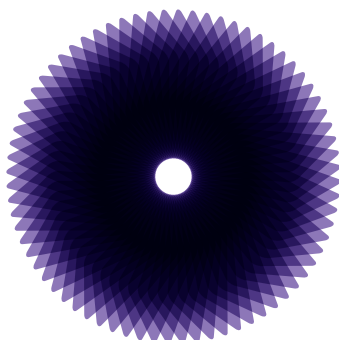
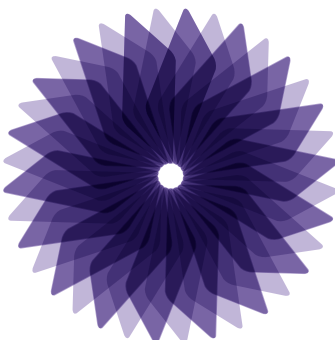
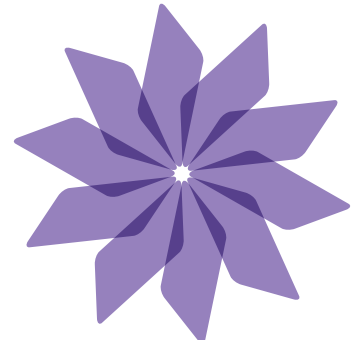
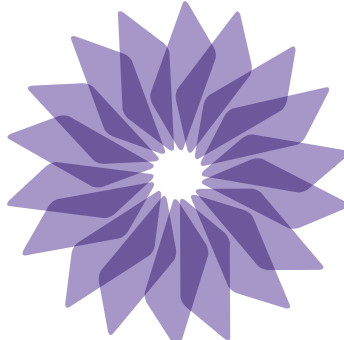
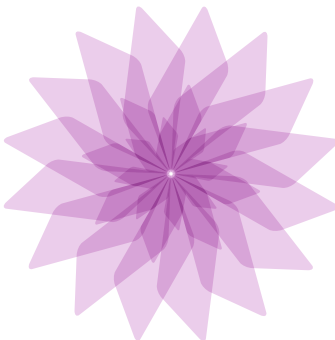
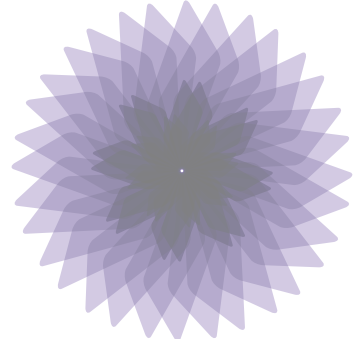
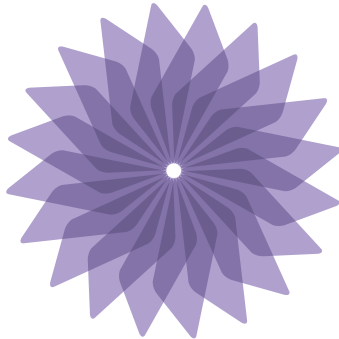
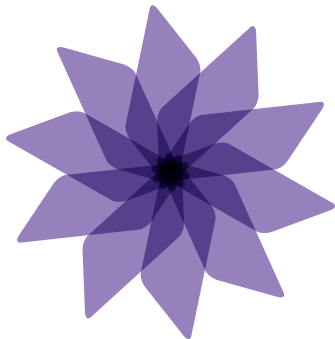


stella

Instructions for Use





Stella with Fuse for Instruments Quality Audit Trail: Record Book Copy

Patient label		Device being decontaminated	
Affix hospital patient label here, if not available, please write the patient's details in this space		Item	
Pre-clinical method		Serial number	
Detergent used			
Lot number			
date			
Disinfection procedure			
Audit trail			
Affix audit trail label here			

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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 Material 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.

1 Introduction

Intended Purpose and Performance

The Stella System is intended for the decontamination of non- and single-lumened medical devices, including bronchoscopes, cystoscopes, hysteroscopes, nasendoscopes, manometry catheters, transoesophageal probes, transrectal and transvaginal probes.

The Stella System is a semi-automated decontamination device that reduces the risk of cross-patient contamination. The System offers the following unique features:

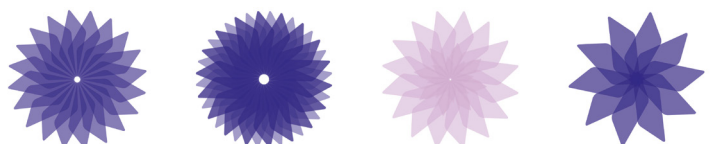
- Controlled cycle time and disinfection process.
- Traceability through downloadable reports and a Stella Quality Audit Trail Book.
- Disinfectant contained within an enclosed compartment.
- Controlled environment for short-term storage and transportation of the instrument after disinfection.
- Improved instrument compatibility with disinfectant through the controlled contact time.
- Easy-to-install mobile device.

Stella Pulse

Stella Pulse is the lumen irrigation device used for the disinfection of single-lumened endoscopic devices. Pulse adds the following features to the Stella System:

- Irrigation of a single lumen (working channel).
- Identification of the presence of Fuse for Instruments chemistry.
- Blocked lumen detection.
- Instrument 'unhooked' detection.
- Self-check for blockage in pump prior to start of disinfection cycle.
- Continuous monitoring of performance and alert to maintenance requirements.

The Stella Pulse works in conjunction with the Stella IQ. The units are connected via Bluetooth. The IQ controls the operation of Pulse. At the start of the cycle, Pulse will irrigate the lumen and ensure that it is filled with disinfectant. At the end of the disinfection cycle, Pulse removes the disinfectant from the lumen.



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

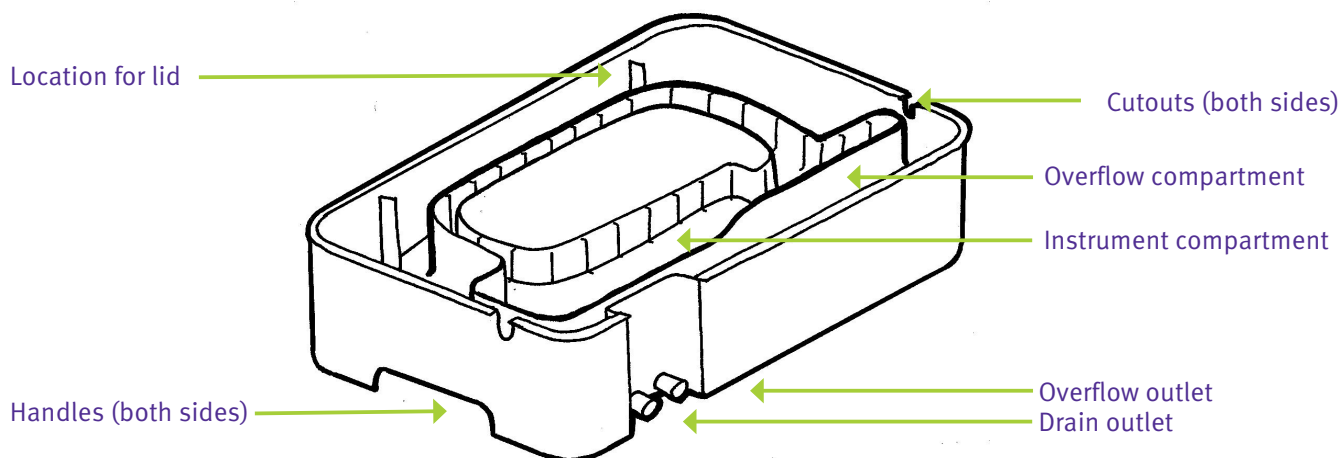
Stella Cradle Shelf pack contains:

- Cradle Shelf
- Shelf Fixings
- Assembly Instructions

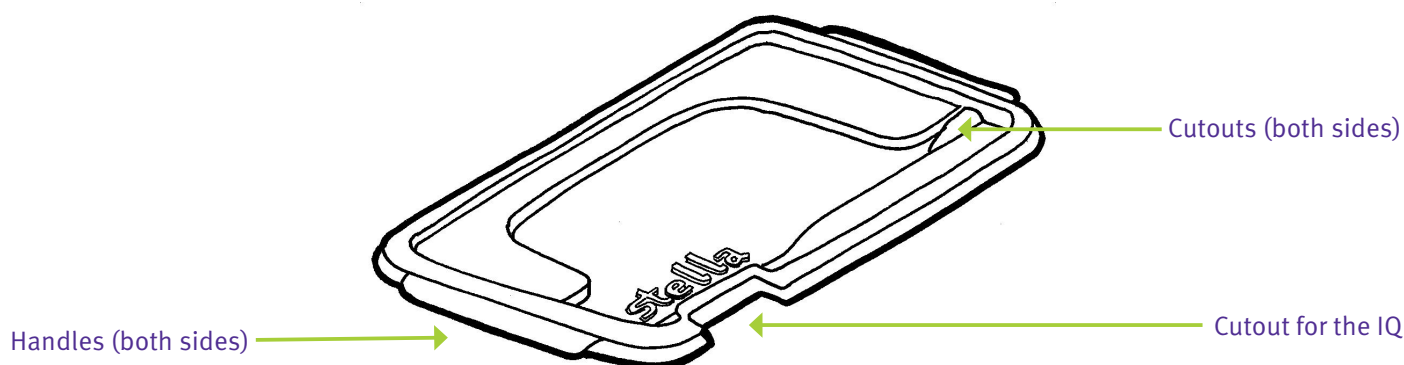


Components

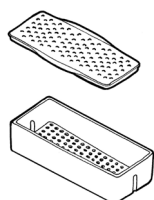
Stella Base



Stella Lid



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.

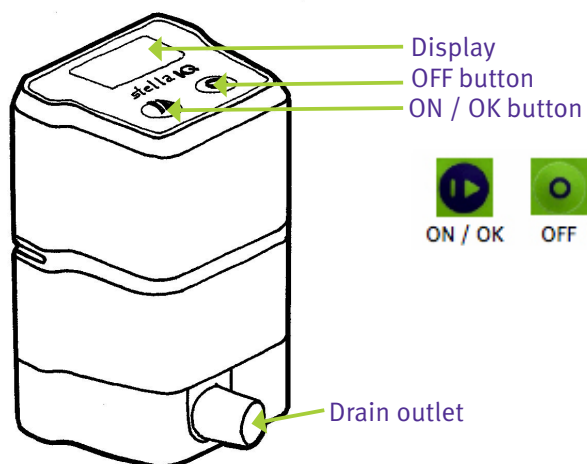


Stella Lube should be applied to Stella IQ before first use then every 6 months in order to ensure a firm fit of the IQ to the base.

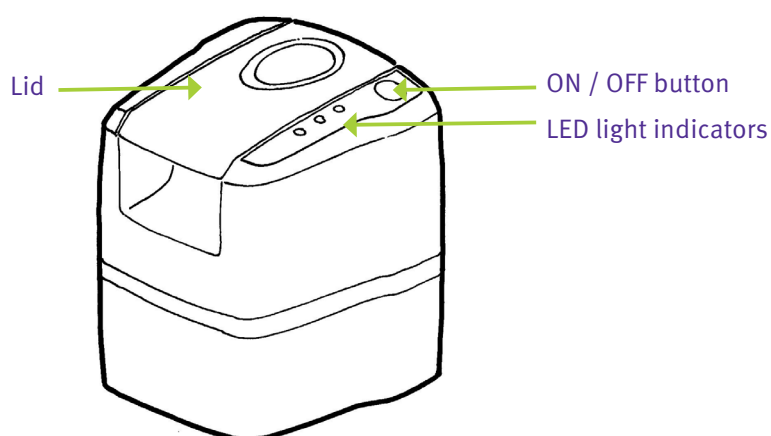


The grommets close the cut-outs when they are not being used.

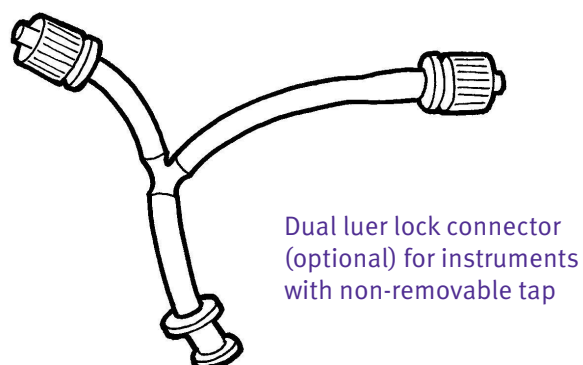
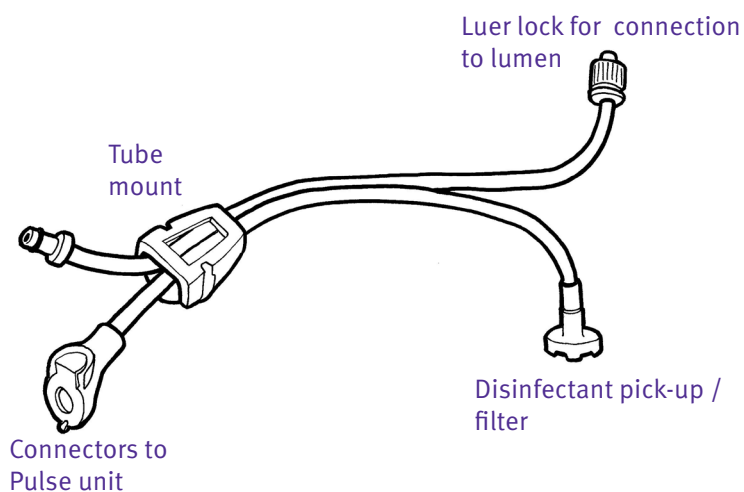
Stella IQ



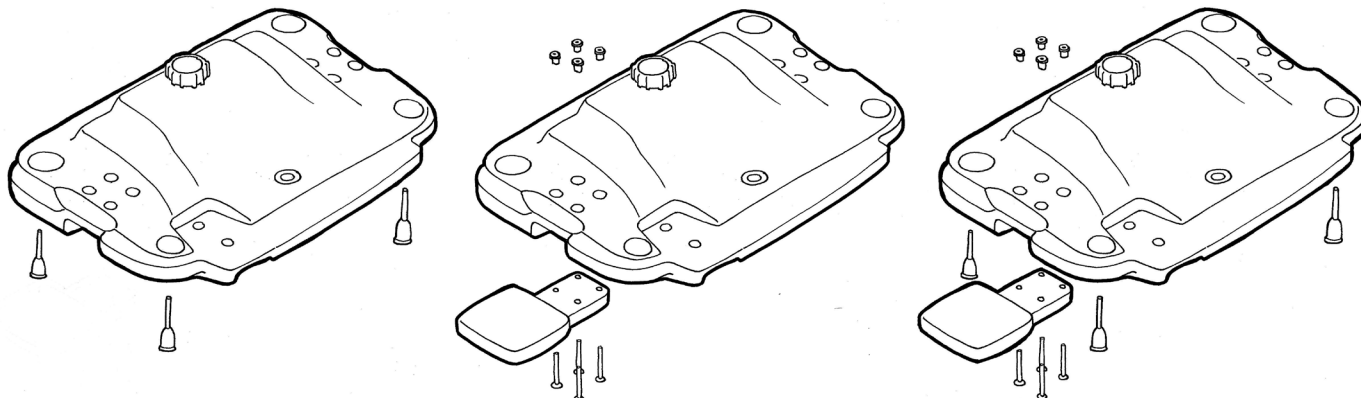
Stella Pulse



Pulse tube set

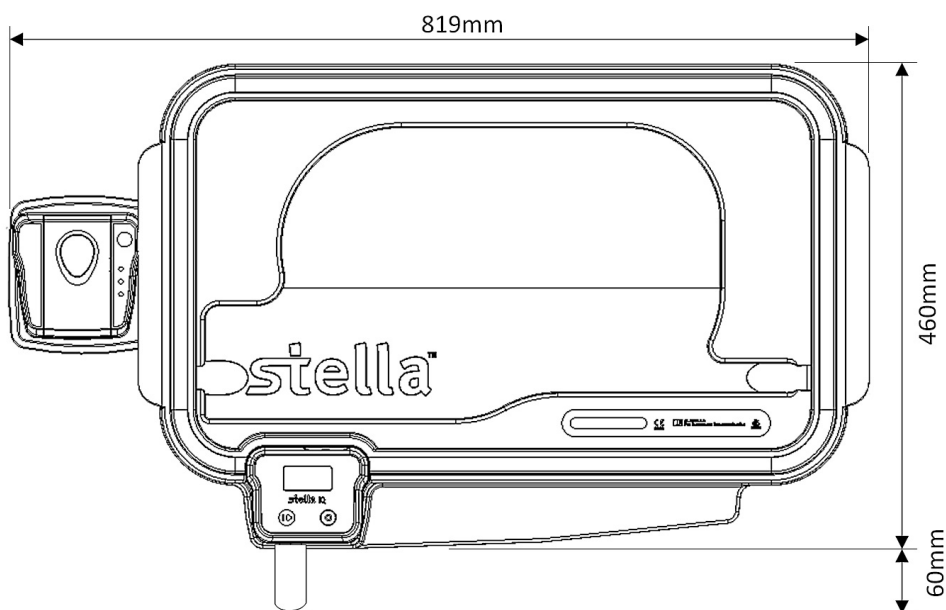


Stella Cradle



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.

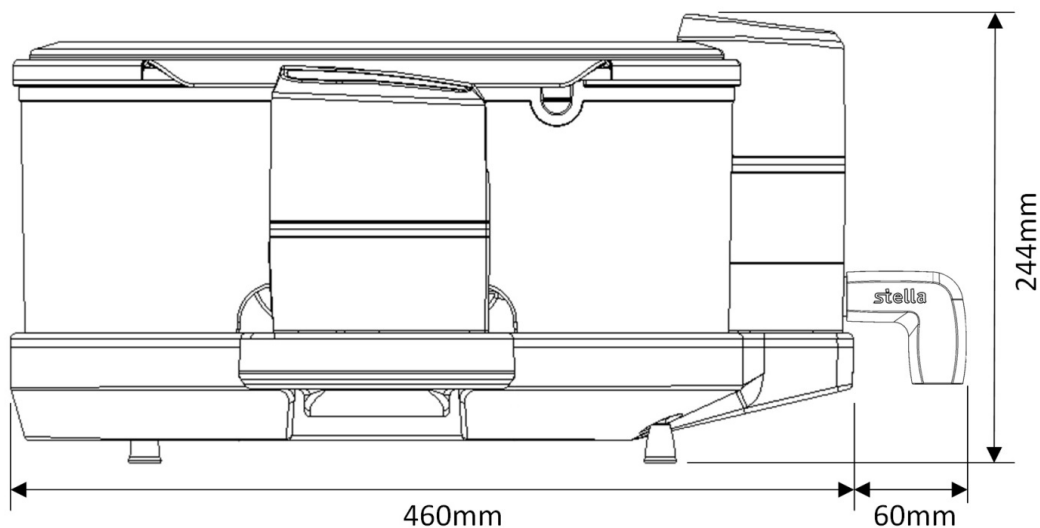
Stella Footprint



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.

The Stella System measures 81cm x 46 cm.

The height is variable depending on the adjustment of Cradle feet, but on average when holding Stella Base measures 23cm.



Disinfectants and Medical Devices for Use with Stella

The Stella System is designed to work with Tristel's chlorine dioxide disinfectant Fuse for Instruments.

The Stella IQ ensures that a medical device is in contact with Tristel Fuse for Instruments for 5 minutes only. The disinfectant is then automatically drained to waste.

Tristel Fuse for Instruments is a single-use disinfectant and must not be re-used. The disinfectant should be disposed of in accordance with the user instructions and Material 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.

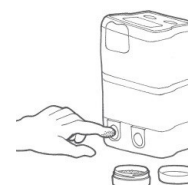


Preparing the Stella System for First Use

- 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 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 Wear gloves. 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.



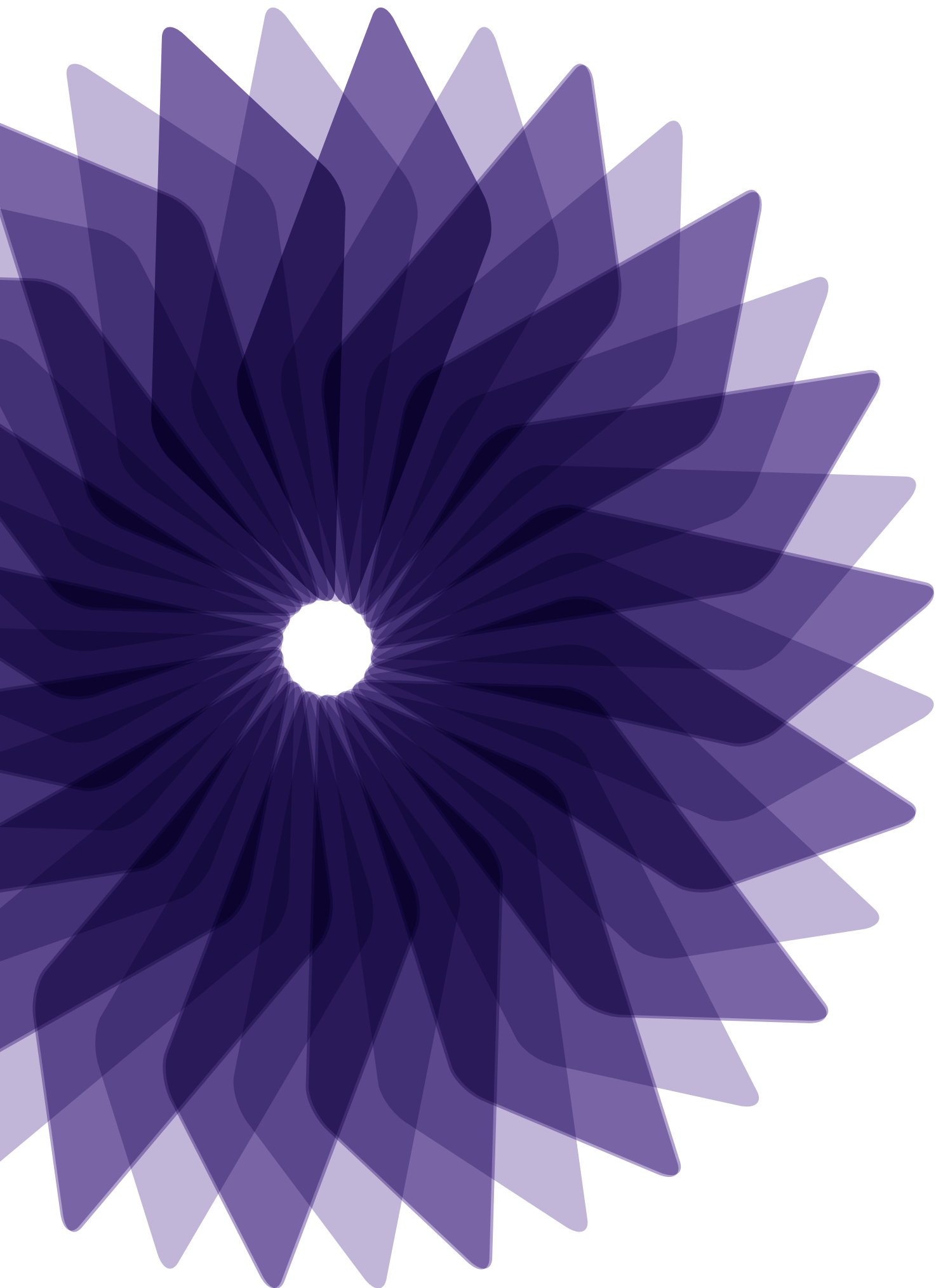
Do not autoclave the grommets, drainage outlet cap, drainage hose or any parts of IQ, Pulse and Cradle.

Installing the Stella Suite Download 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.



2 The Stella System: Operating Instructions

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.

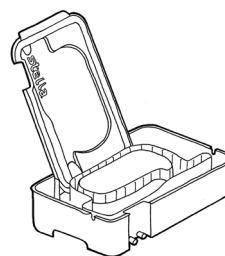


Parts of the instrument may not be effectively immersed in the disinfectant if the Base is not placed level. It is important to ensure that the Stella is operated on a stable and level surface. Otherwise, the automatic sensor that triggers the cycle will not operate reliably.



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

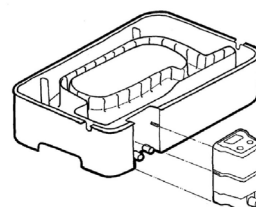
Stand the Lid in an upright position at the rear of the Base, in its secure place within the overflow compartment.



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



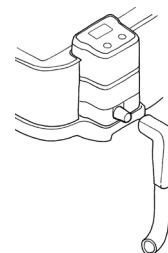
Ensure the IQ is firmly attached to the Base. Failure to ensure correct connection may result in a leak.



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.



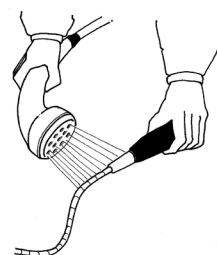
The drain tube must be in a downward position to ensure free water flow.



Pre-clean all instruments and devices before disinfecting them in Stella.



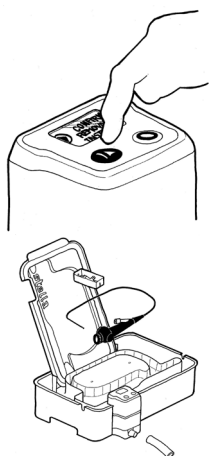
Follow the medical device manufacturers' guidance.



Illustration

Description

IQ Reference



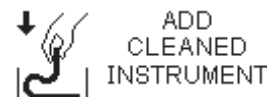
Push the 'ON' button on the IQ until you hear a sound and follow the instructions shown on the screen.

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

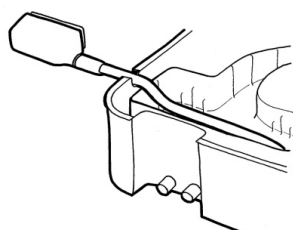
Place the pre-cleaned instrument into Stella's instrument compartment.

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.

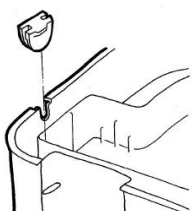
stella



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

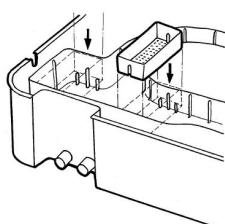


Any cables and parts of the instrument that cannot be immersed, should exit Stella through the designated cut-outs in the side walls.



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 5 litres of Tristel Fuse for Instruments disinfectant solution.

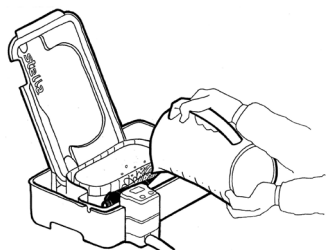


Follow the Fuse for Instruments instructions for use, and refer to the Material Safety Data Sheet.

Illustration

Description

IQ Reference



When prompted by the IQ, carefully and steadily pour Tristel Fuse for Instrument 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 5 litres of Tristel Fuse for Instrument Disinfectant.

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



Pour the disinfectant carefully to avoid or minimise splashes. Refer to the disinfectant Material 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.

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.

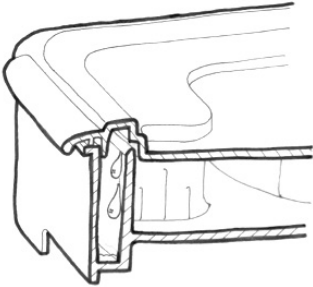





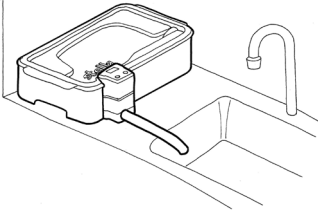



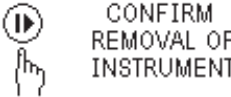



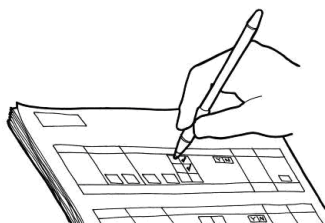
If Stella is not positioned on a level surface, then the disinfection cycle will not automatically trigger as Stella's liquid sensor will not detect the correct level of disinfectant.



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
	<p>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).</p>	 DISINFECTING
		 DISINFECTING
		 DISINFECTING
		 DISINFECTING
	<p><i>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.</i></p>	
	<p>After the completed contact time, Stella drains the disinfectant automatically.</p> <p>The draining process may take up to one minute. Tristel Fuse for Instruments does not require rinsing.</p>	
	<p>When the Base is empty, there is an audible reminder that the cycle is complete.</p>	
	<p>To acknowledge the completion of the cycle, press the 'ON' button.</p> <p>The disinfected instrument can now be removed for immediate use or placed in sterile storage.</p>	
	<p><i>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.</i></p>	

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.

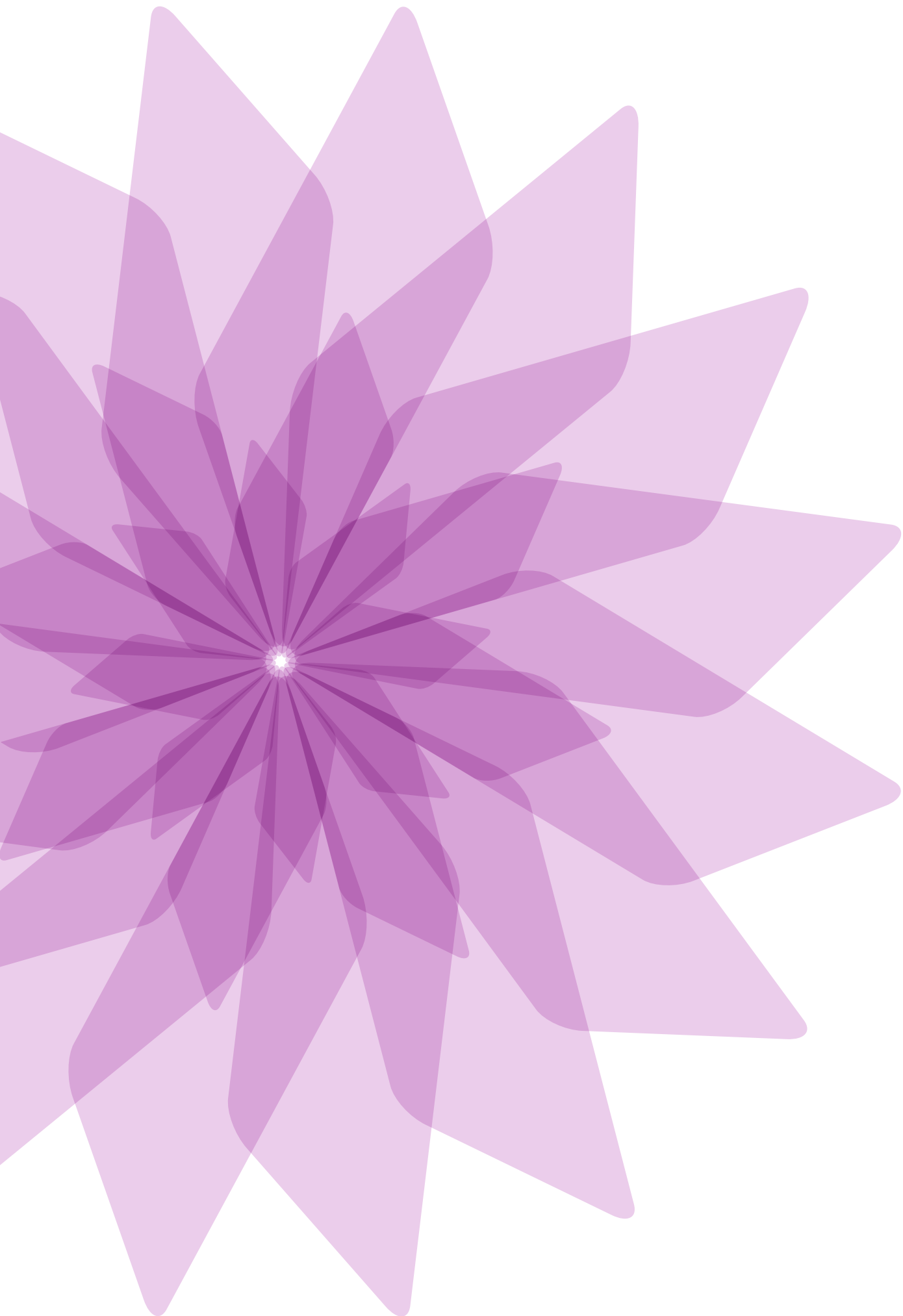
After the Stella IQ has been switched off, it can be detached from the Stella Base. The Base can be used as a transportation unit. Fitting the drainage outlet cap prevents small liquid spills.



RESTART
CYCLE



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



3 The Stella Pulse System: Operating Instructions

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.

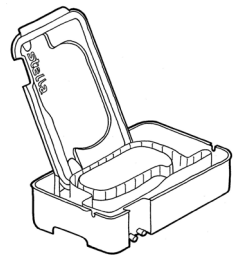


Parts of the instrument may not be effectively immersed in the disinfectant if the Base is not placed level. It is important to ensure that the Stella is operated on a stable and level surface. Otherwise, the automatic sensor that triggers the cycle will not operate reliably.

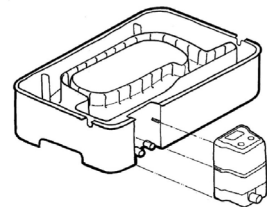


Choose a position for Stella where leaks, splashes or spillages of disinfectant will not cause damage to surrounding surfaces or materials.

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

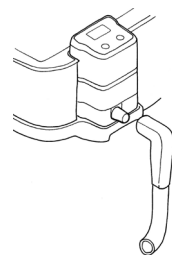


Firmly attach the IQ to the Base. The drain outlets from the Base slide into the drain inlets in the IQ.



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

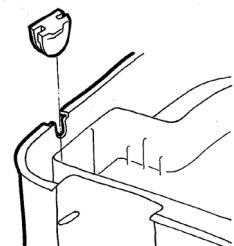
Firmly connect the drain tube to the IQ and ensure the end of the tube is directed into a sink or waste container. Ensure that the end of the drain tube is not immersed into the waste solution, i.e. there is an air gap.



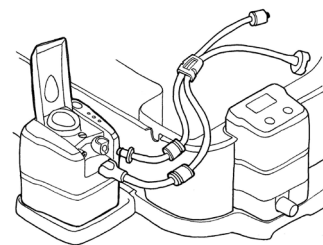
The drain tube must be in a downward position to ensure free water flow.



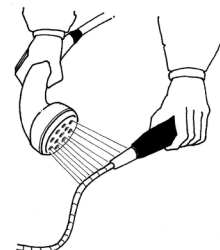
Place Pulse on the Cradle Shelf. Remove the grommet from the left cut-out of the Base.



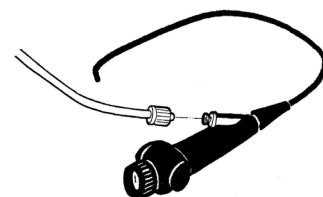
Attach Pulse tube set to Pulse by matching the male and female connectors. Place the green tube mount provided with Pulse tubing firmly onto the cut-out. Ensure that the disinfectant pick-up / filter is sitting in the inner compartment.



Pre-clean all instruments and devices before disinfecting them in Stella. Follow the medical device manufacturers' guidance.



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



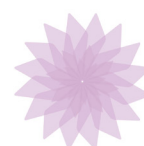
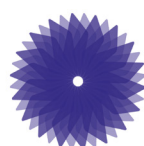
If the instrument is not equipped with a compatible fitting, please contact the scope manufacturer/distributor to obtain an adaptor.



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



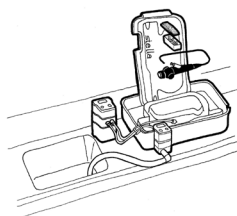
Push the 'ON' button on the IQ until you hear a sound and follow the instructions shown on the screen.

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.



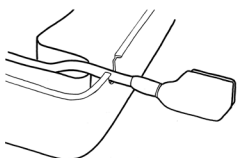
Instruments that do not fit correctly in the instrument compartment must not be used in Stella.



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.

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.

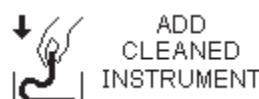


In the background, Pulse performs a short self-check.

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.

Stella IQ:

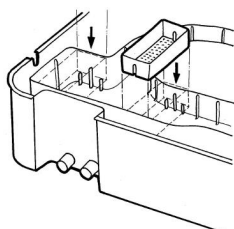
Illustration

Description

Display

Stella Pulse:

Description



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

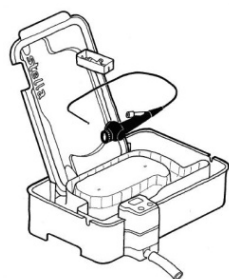
There are two positions within the instrument compartment where the Small Parts Tray is best positioned, one to the left and one to the right of the IQ.

When the instrument is properly placed into the instrument compartment and connected to Pulse make up 5 litres of Tristel Fuse for Instruments disinfectant solution.



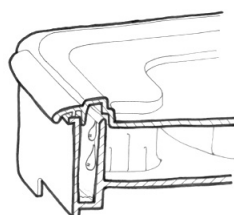
Follow the Fuse for Instruments instructions for use and refer to the Material Safety Data Sheet.

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



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 Instrument disinfectant. The liquid will overflow over into the overflow compartment.

Stella IQ:

Stella Pulse:

Illustration

Description

Display

Description



Pour the disinfectant carefully to avoid or minimise splashes. Refer to the disinfectant Material 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.



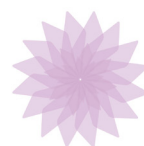
Please check the Stella IQ display for the disinfection symbol. On rare occasions the cycle may have to be started manually. In this case Stella IQ will ask you to press the 'ON' button as indicated on the display.



Stella Pulse has a fluid detection system that detects the presence of the Fuse for Instruments 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.

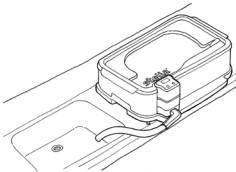








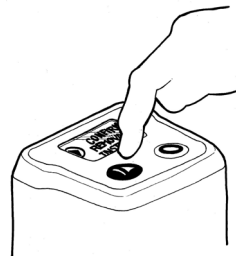

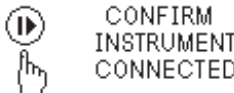


If the instrument is not attached to the Stella Pulse tube set, a fail notification graphic and sound alternating with a message reporting 'instrument unhooked' will be displayed. If the instrument is not connected within 30 seconds Stella will drain the disinfectant and report an incomplete cycle.



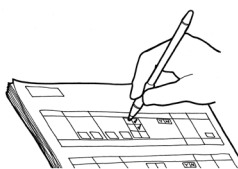
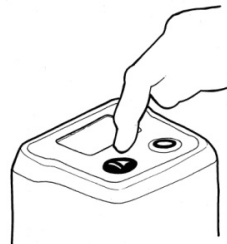

Stella IQ:


Stella Pulse:

Illustration	Description	IQ Reference		Description
	Fit the Lid onto the Base.		DISINFECTING	<p>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.</p> <p>When Pulse stops, the green LED light flashes momentarily indicating standby.</p>
	The IQ displays the countdown of the remaining disinfection time (contact time).		DISINFECTING	
	The animated arrow in the LCD graphic confirms that Pulse is pumping.		DISINFECTING	
	When the pump stops the animated arrow remains stationary.		DISINFECTING	
<div><p><i>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.</i></p></div>				
	After the contact time Stella automatically drains the disinfectant from the Base.		STELLA DRAINING	<p>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.</p> <p>This is indicated by the solid green LED light.</p>
	The animated arrow in the LCD graphic confirms that Pulse is operating. The draining process may take up to one minute.			
	When the Stella is empty there is an audible reminder that the cycle is complete.			
<div><p><i>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.</i></p></div>				
	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	<p>Pulse returns to Standby which is indicated by the flashing green LED light.</p>
			CONFIRM INSTRUMENT CONNECTED	

Stella IQ:


Stella Pulse:

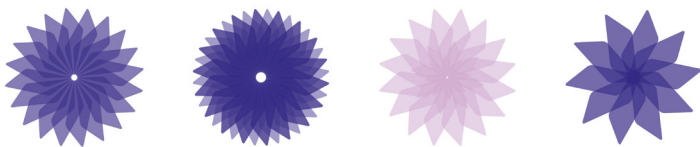
Illustration	Description	IQ Reference		Description
	<p>Upon pressing the 'OK' button, a validation code is displayed.</p> <p>This validation code should be noted in the traceability book for future reference.</p>	<p>VALIDATION CODE</p> <p>FMQP-56</p>		<p>If a new cycle is started, Pulse follows the instruction from the Stella IQ. The disinfection cycle starts from the beginning.</p>
	<p>The IQ asks if a new cycle should be started and prompts the user to press the 'OK' button.</p> <p>A new cycle can immediately be started by pressing the 'OK' button again.</p>	 RESTART CYCLE		

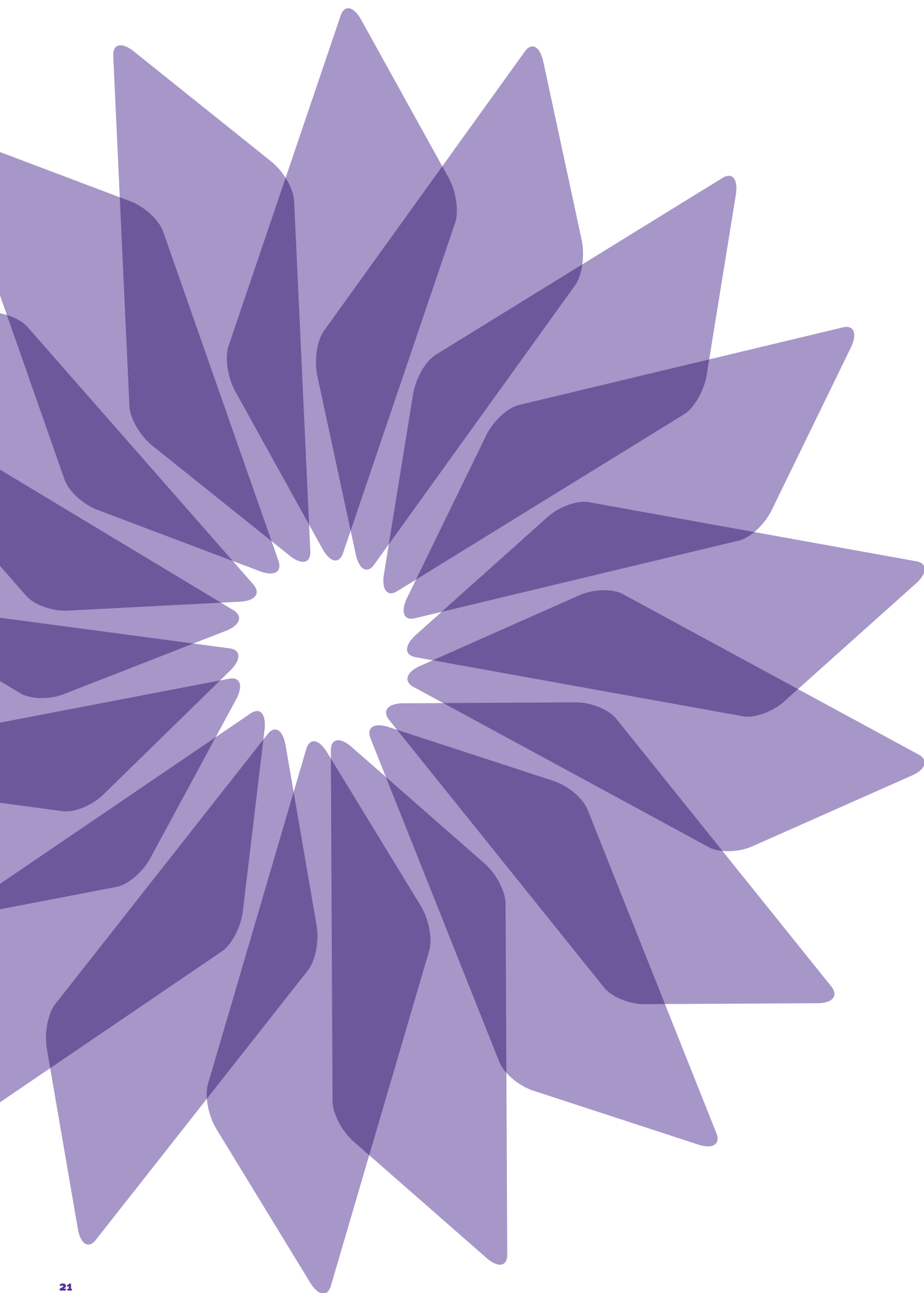


Failure to confirm removal of the instrument will result in the LCD backlight shutting down after 15 minutes to maintain battery life. The audible beep is also turned off at this stage. If after 30 minutes 'confirm removal of instrument' has not been confirmed, Stella IQ will shut down. When the unit 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.
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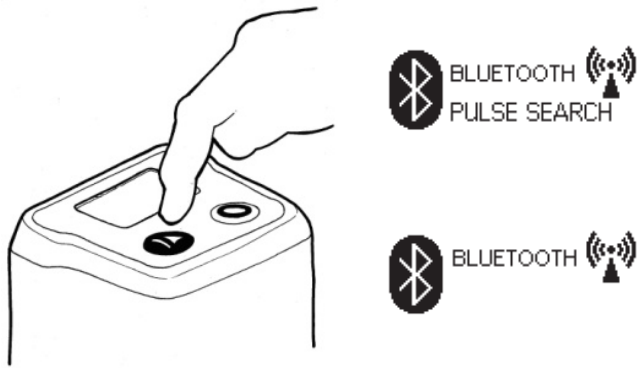


4 Maintenance instructions

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.

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. 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. Wear gloves. 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

2. Lift the green cover on Stella Pulse

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

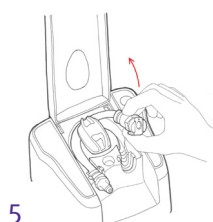
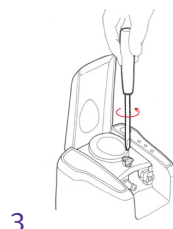
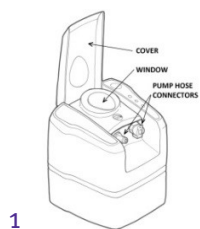
4. Remove the pump hose by lifting the pump hose connector on one side. Turn the green pump head clockwise to lift the curved hose, and then lift the pump hose connector on the second side.

5. 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.

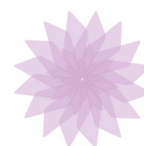
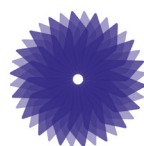
6. Replace the window, ensuring that the back ridge is pushed back correctly into Stella Pulse, and then fix the screw securely, taking care not to over tighten.



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.













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

Charging

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

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.

Illustration

Description

IQ Reference

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

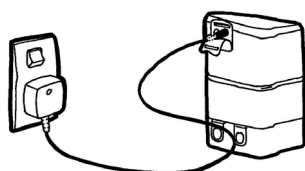


Do not charge Stella IQ or Pulse whilst they are attached to the Base or near any forms of liquid.



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

Pulse battery indicators



Top Light
Power status

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.

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

Illustration



Stella Suite

Description

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.

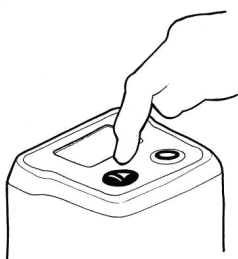
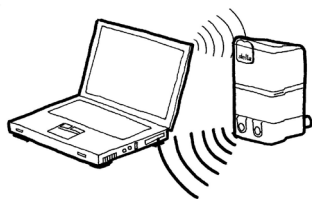
IQ Reference



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

Illustration



Stella Suite

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).

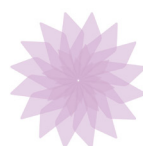
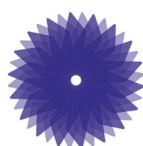
Once the link is established, Stella IQ displays an active signal.

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.

IQ Reference



Cleaning, Disinfection and Sterilisation of Stella, IQ and Pulse

Stella: Base, Lid and Small Parts Tray

After use, clean the internal and external surfaces to remove any visual debris. Mild detergents may be used if required but do not use abrasive cleansers or pads on the plastic parts.

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.

Alternatively Tristel Jet for Surfaces provides high level disinfection for the Base, Lid and Small Parts Tray. Other chemistries must be confirmed for compatibility.

Cosmetic changes will present in the Base and Lid if they are autoclaved in excess of 100 autoclave cycles. The Base, Lid and Small Parts Tray and Lid are made from a material which is suitable for autoclaving on an infrequent basis.

Stella IQ and Pulse

All outer surfaces of the IQ and Pulse, the power adaptors and the USB cable can be high-level disinfected using a compatible surface disinfectant.



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.

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

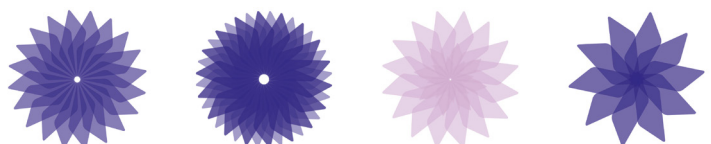
In the event of damage to parts within the Stella System, contact the manufacturer or your local Stella Service Agent to purchase replacement parts.

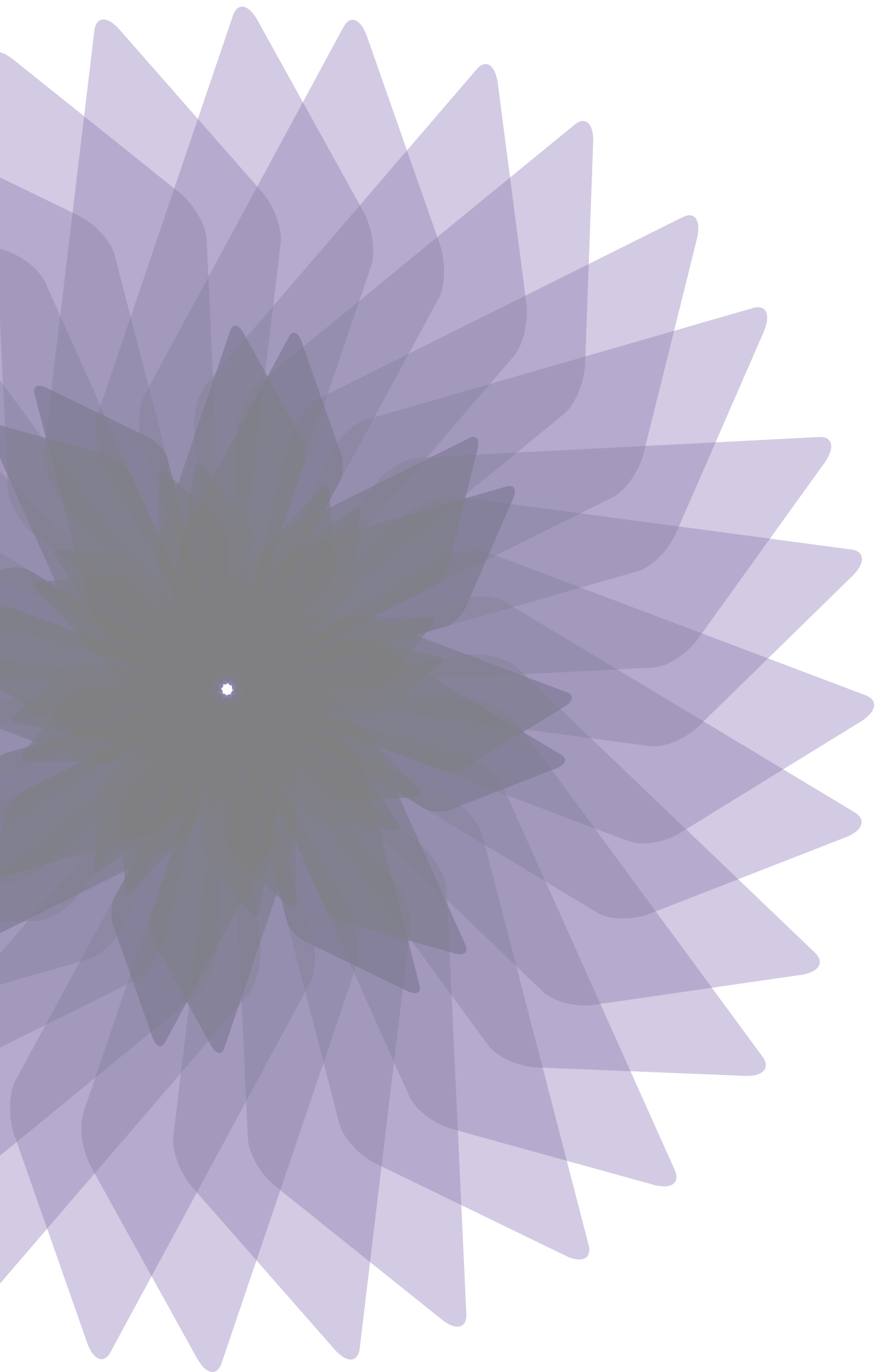
If you experience a problem with the operation of the Stella System, please refer to the Troubleshooting section of this manual.

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.





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

Charging

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

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			Charging complete.	When charging, the battery is full only when the full battery graphic is displayed.
PULSE				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.
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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 and when the battery display indicates low battery.



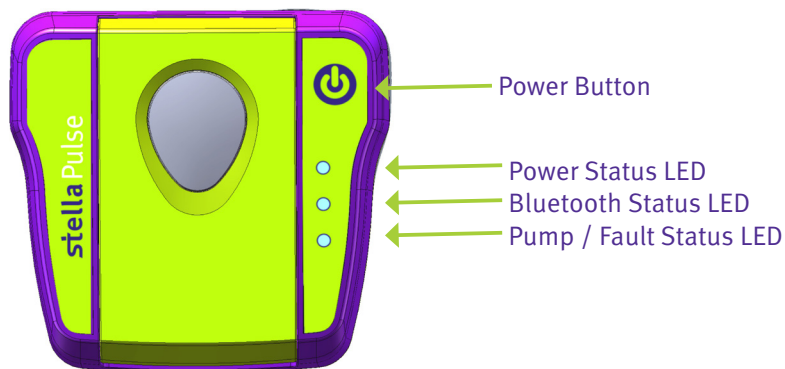
Cycles are indicative. As the product ages the cycle numbers will decrease.



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

Pulse LED Lights

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



Power Status LED

Green light constant.

Green light flashing on and off.

Yellow/Orange light flashing on and off.

Battery Charged.

Battery Low.

Charge battery.

Charging - when adaptor is plugged in this indicates charging is in progress.

Bluetooth Status LED

Blue light flashing on and off.

Blue light constant.

No light.

Bluetooth Search Mode.

Bluetooth link established.

Off – no Bluetooth link.

Pump Status LED

Green light constant.

Green light flashing on and off.

Red light flashing.

Red light constant.

Pump operating.

Pump ready – in standby mode.

Pump failure.

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	<p>5 Litres of Tristel Fuse 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.</p>	<p>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.</p>
 	<p>In the event of a user error, or a problem that may be resolvable on site, a graphic will display.</p>	<p>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.</p>
 	<p>Stella IQ has detected an obstruction and the ball valve will not close.</p>	<p>There is no disinfectant in the Base.</p> <p>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.</p> <p>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.</p>
 	<p>Stella Pulse Bluetooth link has been lost.</p>	<p>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.</p> <p>If this frequently occurs, the Pulse battery may have aged. Contact your Service Centre.</p>

LCD Graphic

What has happened?

Troubleshooting



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/using-stella/updatestella and install Stella Suite Software



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

110/111/112/114



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 happened?

Troubleshooting



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.



Tristel Fuse Disinfectant is not detected

The disinfection cycle has not successfully completed and must be repeated.

Stella has not detected Tristel Fuse for Instruments. The cycle has failed: water will be automatically drained from Stella.



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 Agent.

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.

Frequently Asked Questions cont.

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.

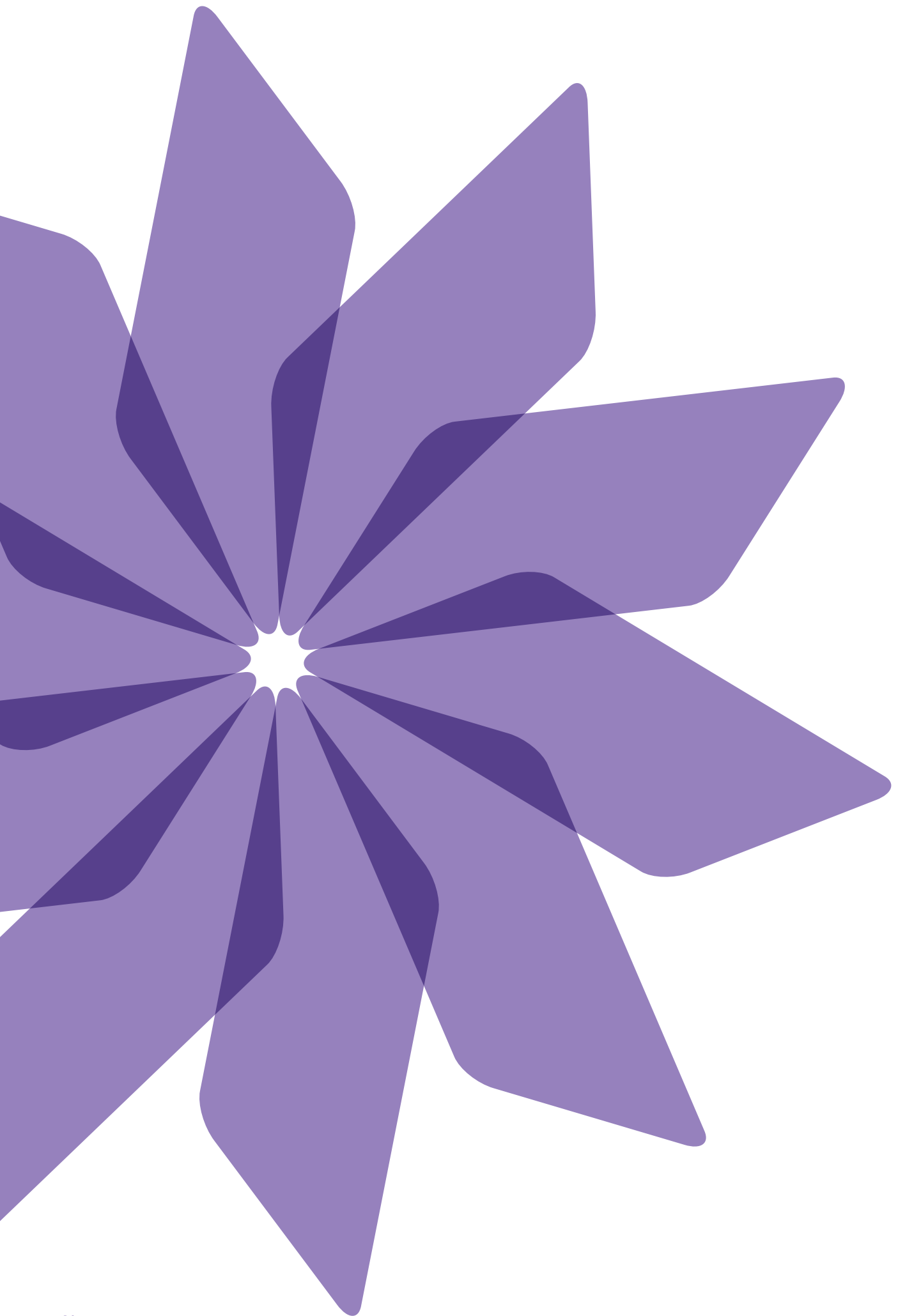
Check that the Stella System is located on a level and stable surface. If not, Stella Cradle can be used to level your Base .

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.		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.
	Do not stack pallets.		Complies to 47 Code of Federal Regulations, part 15 and part 18, of the Federal Communications Commission regulations (relevant to the USA only).
	Material can be recycled.		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.
	Read instructions before use.		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.
	Lot number.		Bluetooth enabled.
	Serial number.		Ingress protection: Totally protected against dust; protected against water sprays from all directions: limited ingress may occur.
	USB enabled.		
	DC supply requirements and polarisation.		
	Date of manufacture.		



6 Regulatory and 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:

EN 13485:2003	Medical Devices - qualitative management systems – requirements for regulatory purposes
EN 60601-1:2006	Medical Electrical Equipment. Part 1: General requirements for safety
EN 60601-1-2:2007	Electromagnetic Compatibility for medical devices
EN 61000-3-2:2006	Electromagnetic compatibility (EMC) - limits for harmonic current emissions
EN 61000-3-3:1995	Electromagnetic compatibility (EMC) - limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems
EN 61000-4-2:1995	Electromagnetic compatibility (EMC) - testing and measurement techniques – electrostatic discharge immunity test
EN 61000-4-3:2006	Electromagnetic compatibility (EMC) - testing and measurement techniques – radiated, radiofrequency, 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 radiofrequency fields
EN 61000-4-8:1994	Electromagnetic compatibility (EMC) - testing and measurement techniques - power frequency magnetic field immunity test
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 sterilisers and washer disinfectors used to treat medical devices
BS 5452	Specification for Hospital Hollow ware - clauses 9,10 and 11 (only relating to the lid and base)
EN 1041:2008	Information supplied by the manufacturer with Medical Devices
2002/96/EC	Waste Electrical and Electronic Equipment (WEEE Directive)
2002/95/EC	Restrictions of Hazardous Substances (ROHS Directive)

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	
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	<p>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.</p> <p>Recommended separation distance:</p> $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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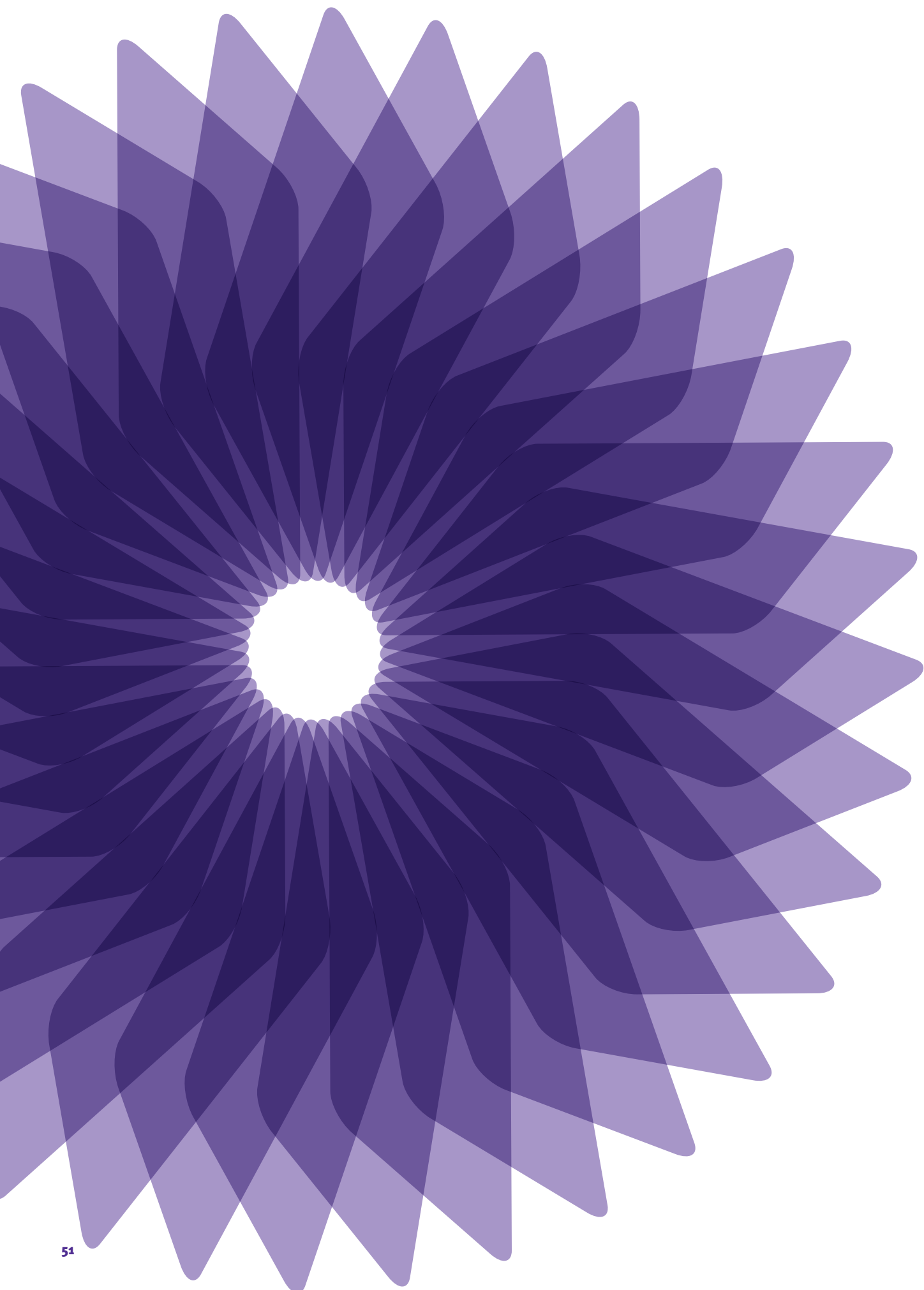
The Stella system is CE marked as a Class IIb medical device as per the Medical Device Directive MDD 93/42/EEC and the 2007/47/ EC amendments thereto.

STL/019/Issue 10/Oct 2014

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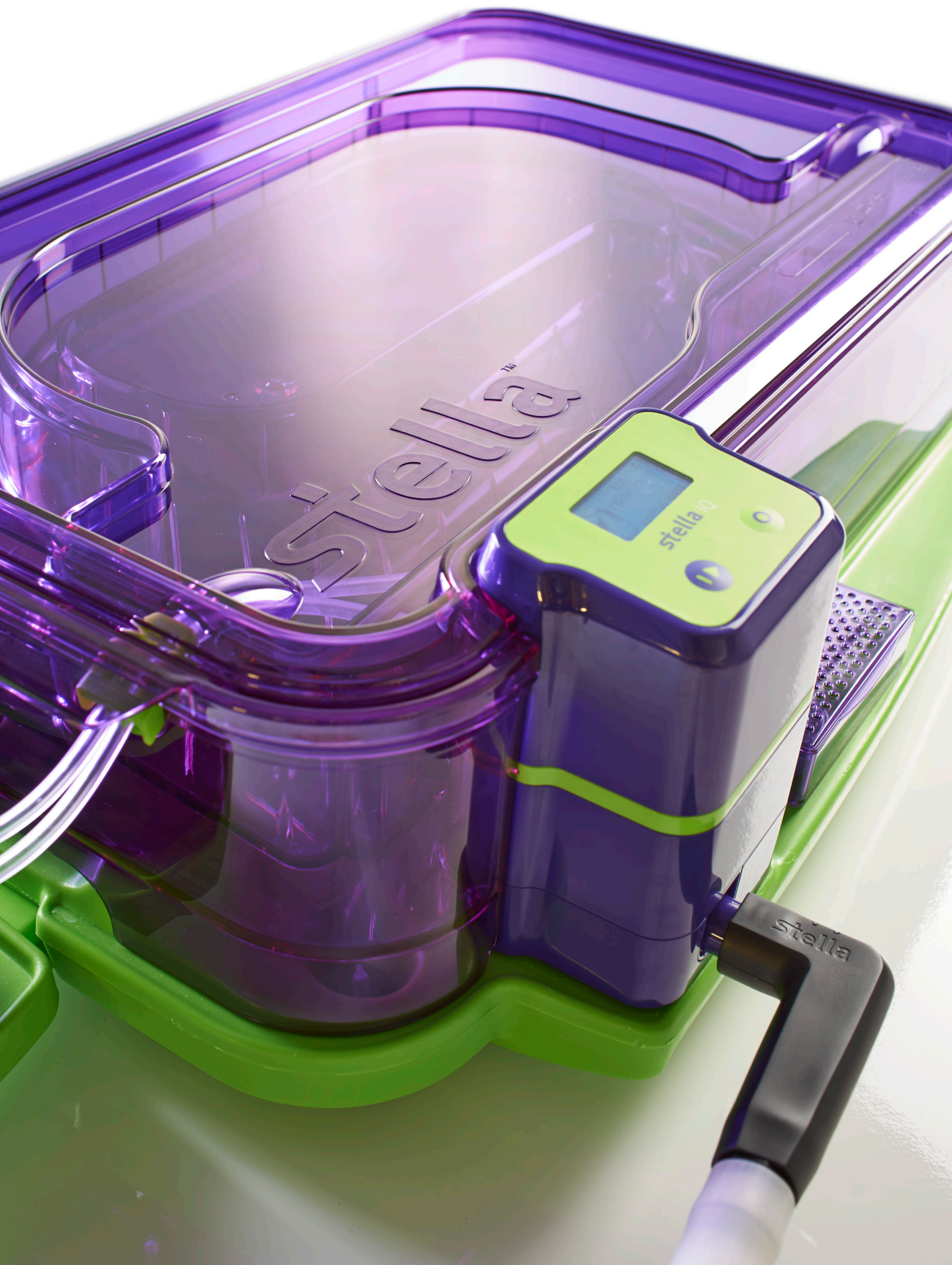
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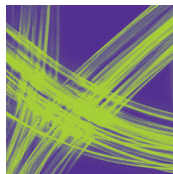
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