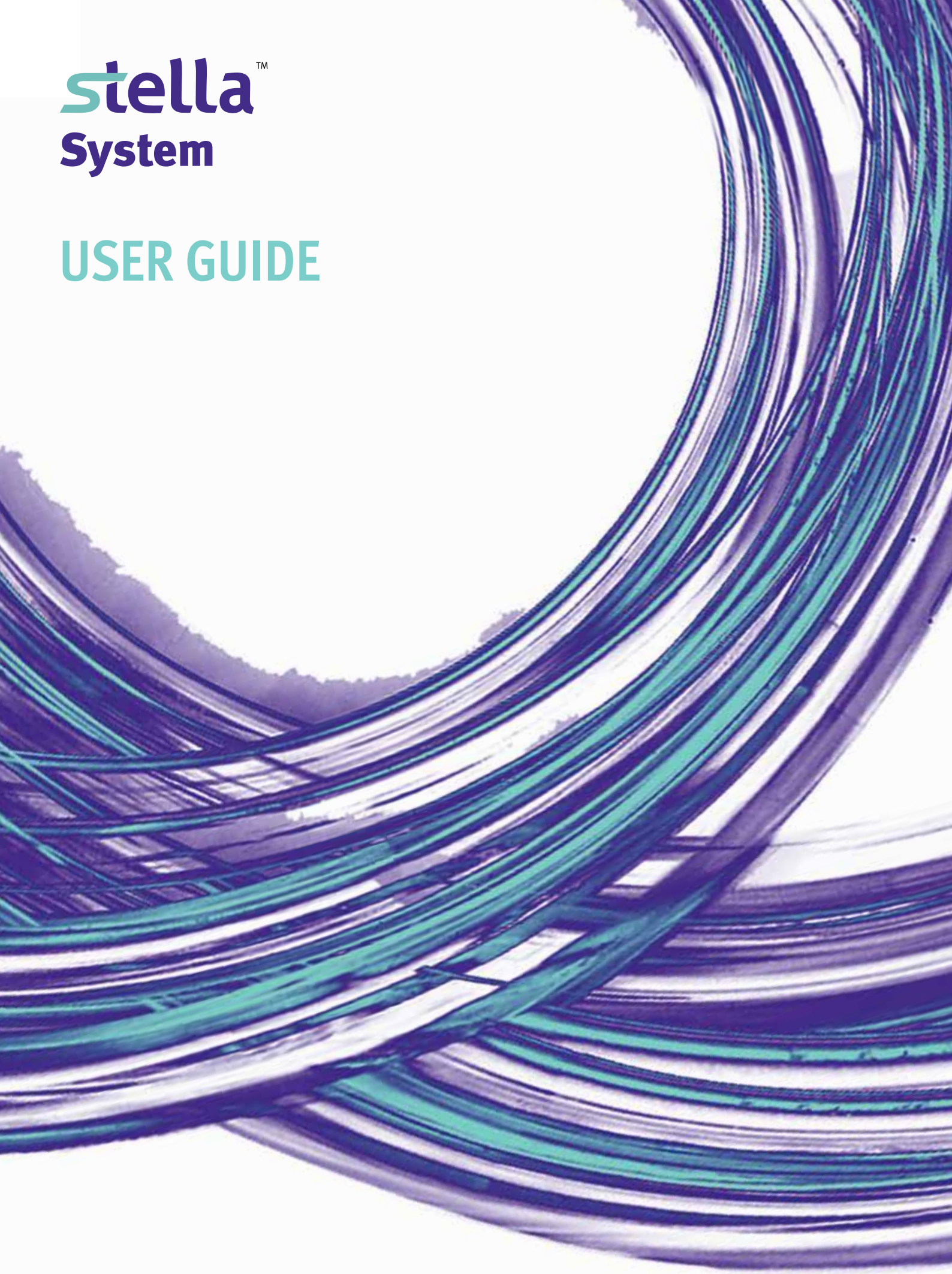
stella™
System

USER GUIDE



CONTENTS

The Operating Instructions in this manual outline general safety guidelines for the correct operation of the Stella System, applicable to all variants.

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

The Stella System can only be used in combination with Tristel Fuse for Stella for automated disinfection.

The Stella System can only be used in combination with Tristel Clean for Stella for automated cleaning.

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 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 and process chemicals prior to use.

For professional use only.

Do not use Stella for the disinfection of surgical equipment or medical instruments intended for autoclaving.

SECTION ONE

INTENDED USE

SECTION ONE: INTENDED USE

The Stella System is a semi-automated washer disinfector designed specifically for the disinfection of invasive and non-invasive, heat sensitive, non-lumened and single-lumened medical devices.

PRODUCT VARIANTS

stella™ System A

Indication for Use: For the high-level disinfection of non-lumened medical devices, such as nasendoscopes, transoesophageal echocardiogram probes, transvaginal probes, transrectal probes, manometry catheters and laryngoscopes.

stella™ System B

Indication for Use: For the high-level disinfection of non-lumened (see above) and single-lumened medical devices, such as hysteroscopes, cystoscopes, intubation endoscopes and bronchoscopes.

stella™ System C

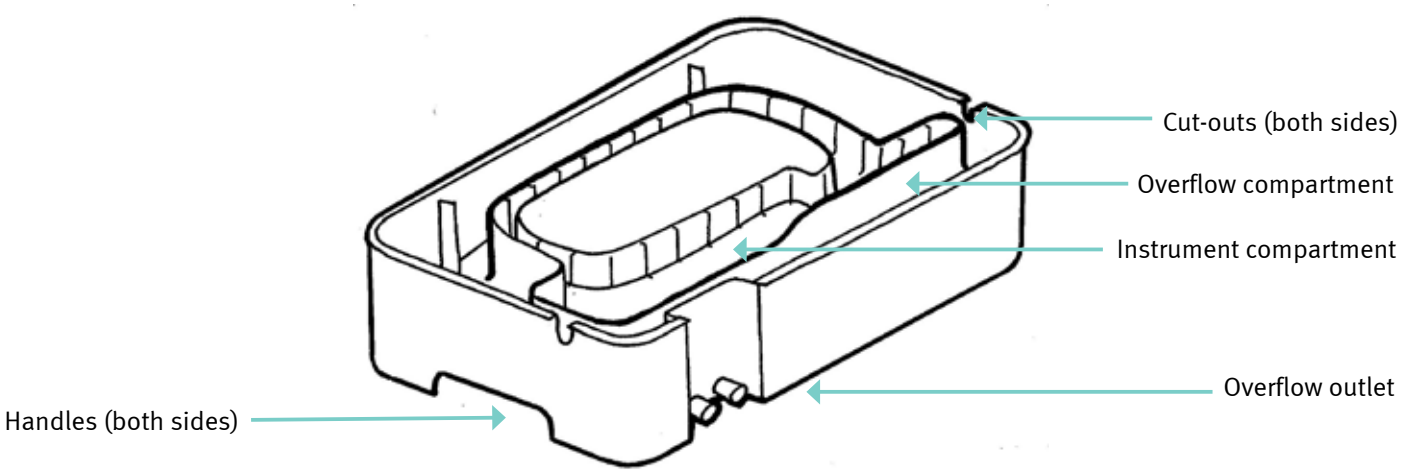
Indication for Use: For the cleaning and high-level disinfection of single-lumened and non-lumened medical devices, such as those listed above.

SECTION TWO

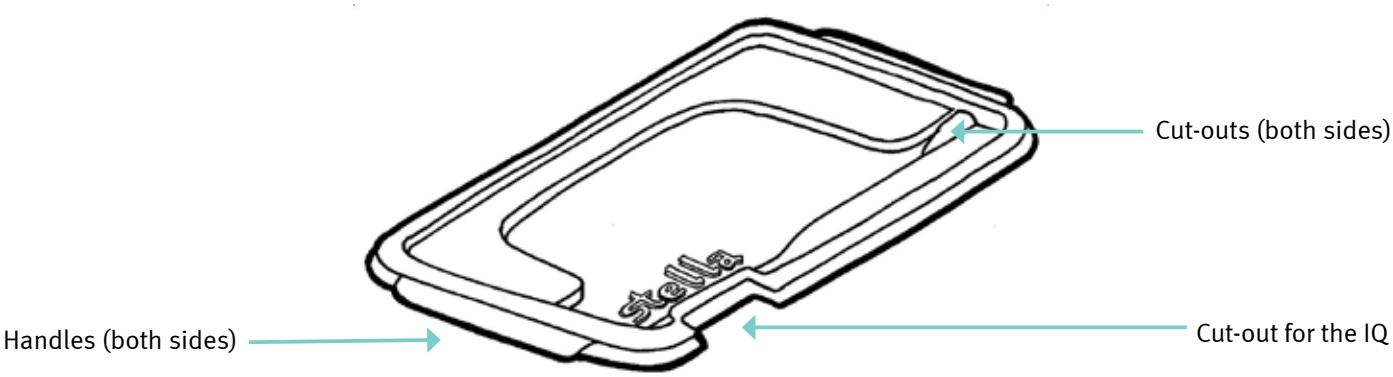
COMPONENTRY

SECTION TWO: COMPONENTRY

STELLA BASE



STELLA LID



ACCESSORIES

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

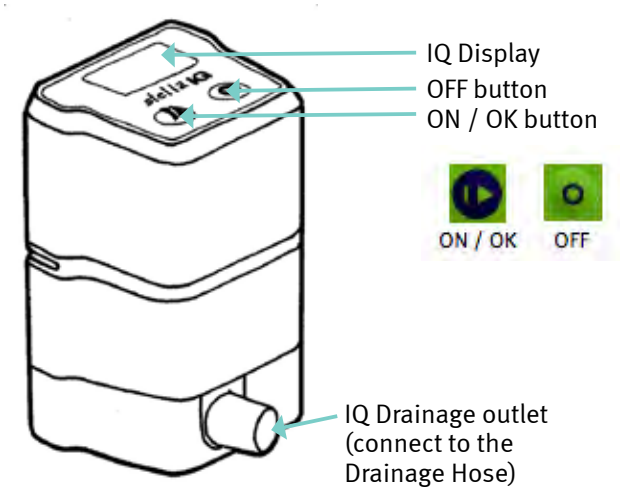
Drainage Outlet Cap for covering outlets of the Base during transportation. The Cap should not be used on a full tray of disinfectant. It is for containing disinfectant residues only.

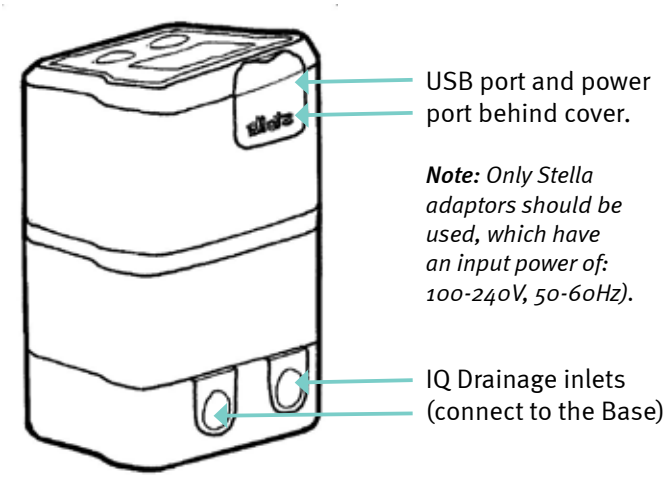
The grommets close the cut-outs when they are not being used.

The Stella Jug for preparation of Tristel Fuse for Stella and Tristel Clean for Stella working solutions.

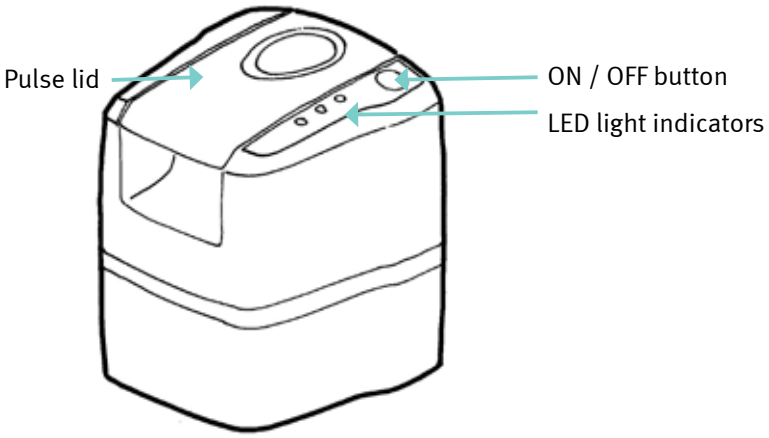
The Drainage Hose for draining out any excess liquid, and disinfectant after the completed contact time.

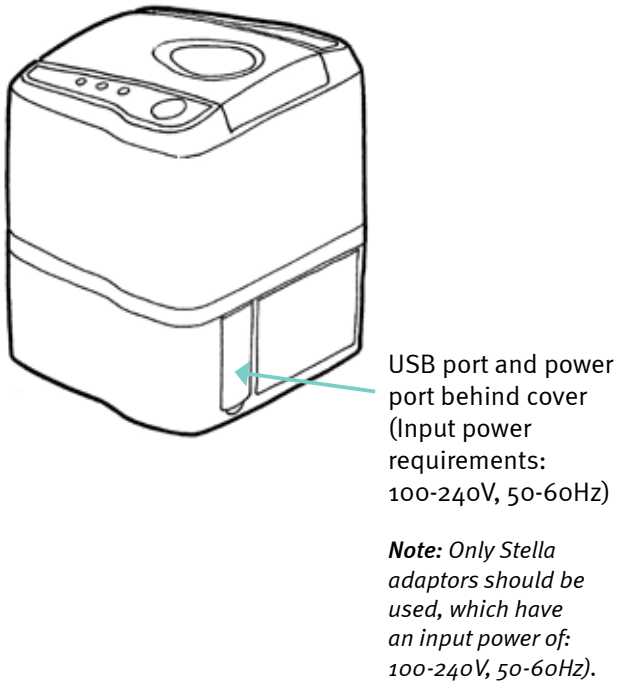
STELLA IQ



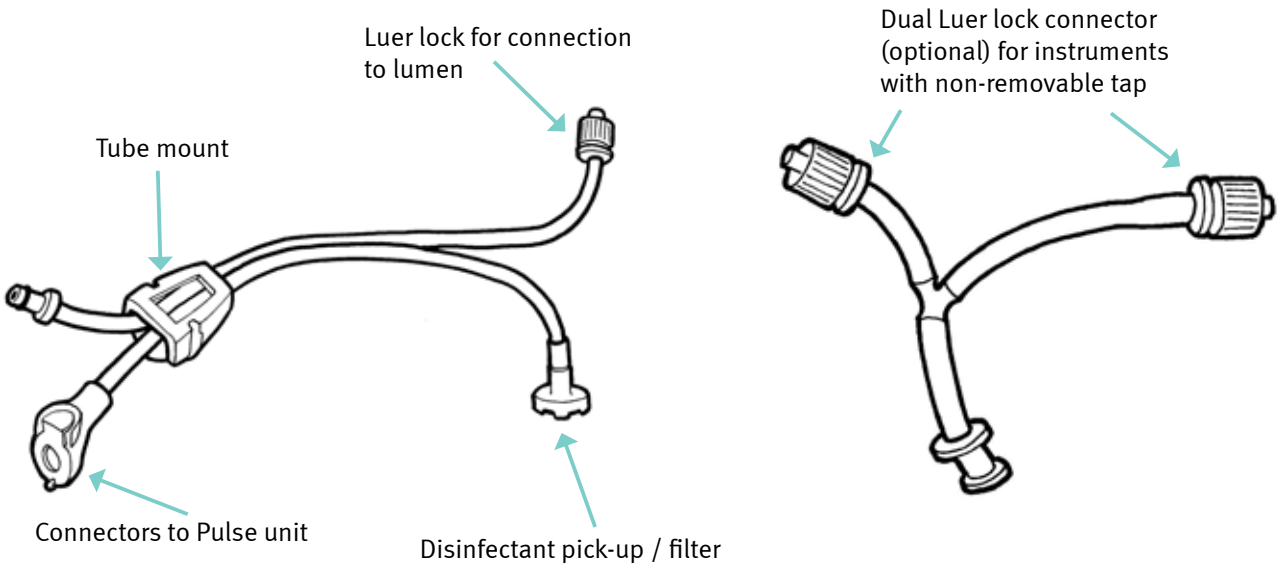


STELLA PULSE



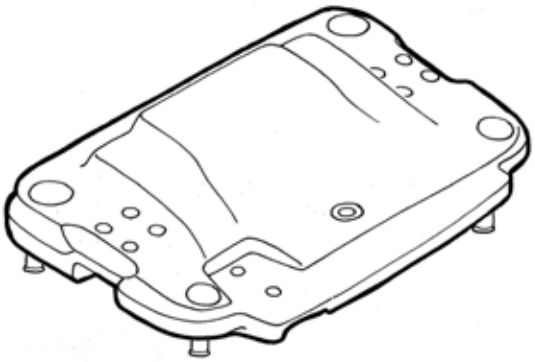


PULSE TUBE SET



STELLA CRADLE

STELLA A



STELLA B AND C

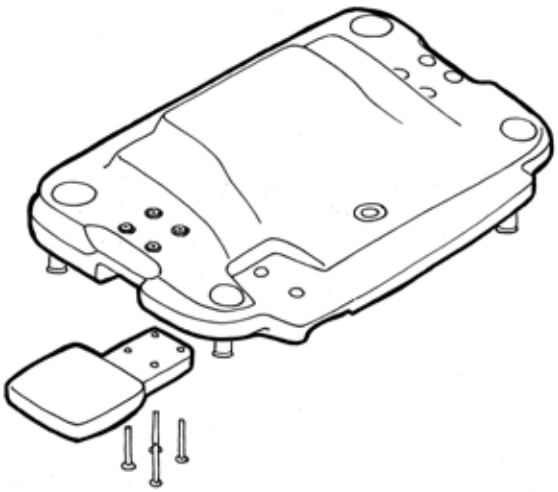


TABLE OF COMPONENTS

Components	Stella A	Stella B	Stella C
Stella Pack	✓	✓	✓
Stella IQ Pack	✓	✓	✓
Stella IQ	✓	✓	✓
Power Adaptor	✓	✓	✓
USB Cable	✓	✓	✓
Base (Tray)	✓	✓	✓
Lid	✓	✓	✓
Drainage Hose	✓	✓	✓
Instructions for Use	✓	✓	✓
Quick Guide Wall Chart	✓	✓	✓
Help Guide Wall Chart	✓	✓	✓
Stella Pulse Pack		✓	✓
Stella Pulse		✓	✓
Stella Pulse Tube Set		✓	✓
Power Adaptor		✓	✓
Stella Cradle Pack	✓	✓	✓
Cradle	✓	✓	✓
Assembly Instructions	✓	✓	✓
Stella Cradle Shelf Pack		✓	✓
Cradle Shelf		✓	✓
Shelf Fixings		✓	✓
Assembly Instructions		✓	✓
Stella System Toolbox		✓	✓
Small Parts Tray and Lid	✓	✓	✓
Stella Lube	✓	✓	✓
Grommets (2)	✓	✓	✓
Drainage Outlet Cap		✓	✓
Stella Pump Hose Replacement Kit		✓	✓
Surrogate Lumen Kit		✓	✓
Dual Luer Lock Connector		✓	✓
Stella Jug	✓	✓	✓
Manual Emergency Kit	✓	✓	✓

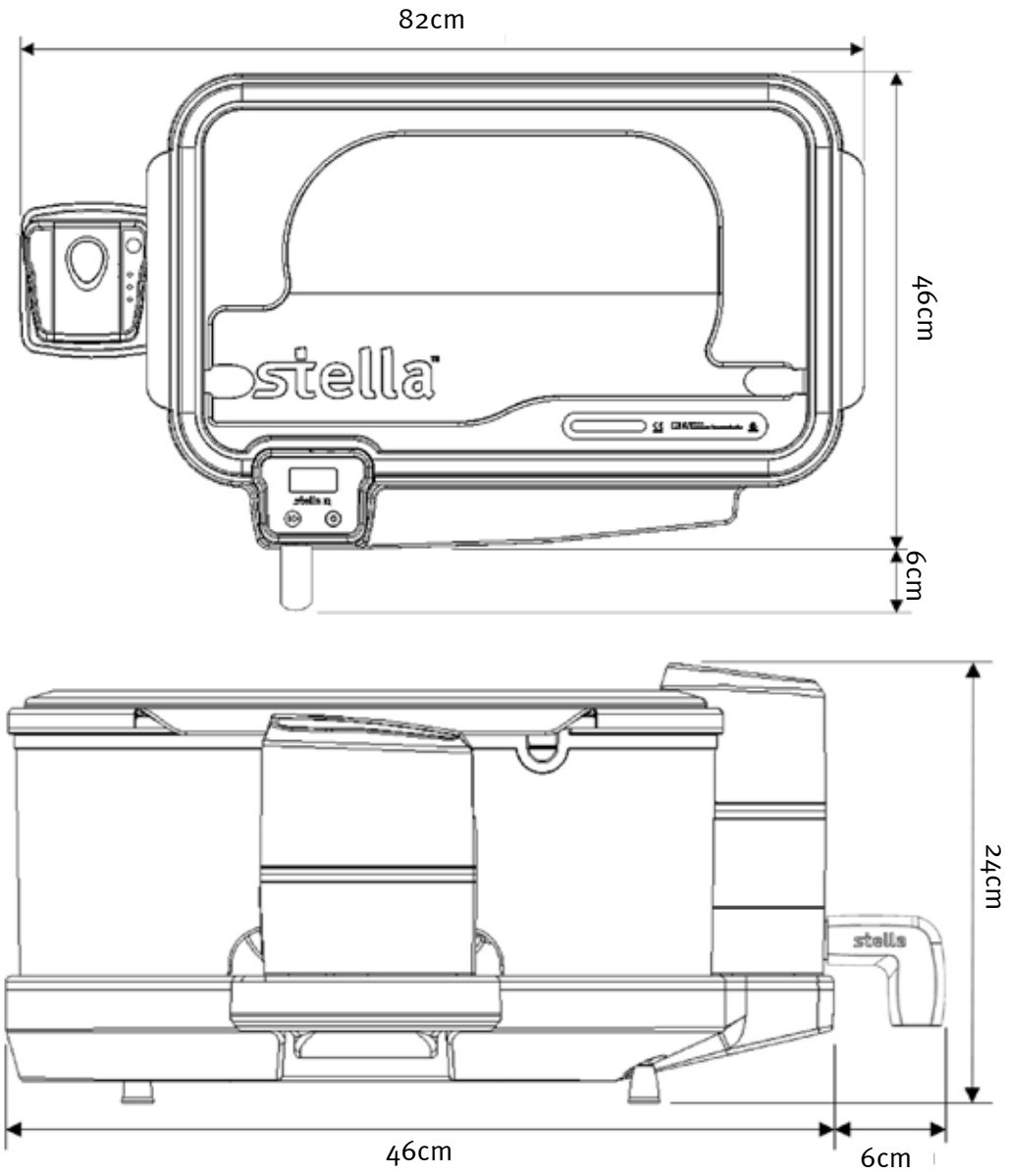
SPECIFICATIONS AND STORAGE

Stella System A: 70cm x 46cm x 24cm (avg.)

Stella Systems B and C: 82cm x 46cm x 24cm (avg.)

Base and Lid: 70cm x 48cm x 18cm

Drainage Hose: 6cm



The Base and Lid can be easily stacked and transported. When empty the weight is 5.5kg.

The drainage outlet cap can be used when transporting the Base to contain any small droplets of disinfectant left in the Base.

IQ and Pulse should be operated and charged in temperatures between 10-35°C with a maximum allowable humidity of 90%.

IQ and Pulse should be stored in temperatures between 10-40°C.

SECTION THREE

GETTING STARTED

SECTION THREE: GETTING STARTED

- Remove all components from their packaging.
  Ensure all components of the Stella System are clear and free of debris.
- Inspect components for damage. If damaged, report to a local Stella Agent.
- Use the supplied power adaptors to charge the IQ and Pulse for 12 - 16 hours before first use.
- Install the Stella Suite Software.

INSTALLING THE STELLA SUITE SOFTWARE

Stella Suite is the software that allows the user to download important information relating to the IQ and Pulse, and events relating to the disinfection cycle.

Windows is a supported operating System for Stella Suite, Apple is not supported.

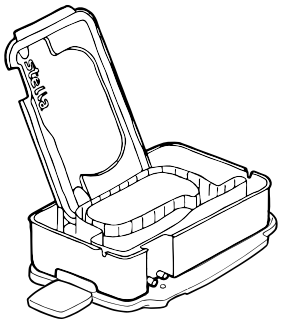
Stella Suite Software is available via the Stella product page on www.tristel.com/stella, please download it using a PC or Laptop prior to using the Stella System, following the instructions on the screen.
If an update or additional components are purchased, please ensure you install the relevant firmware for your Stella package. Refer to your local Stella Agent if you are unsure.

SETTING UP THE STELLA SYSTEM

Assemble the Cradle as illustrated in the Componentry section. Once the cradle is positioned for use, adjust the feet using the spirit level.

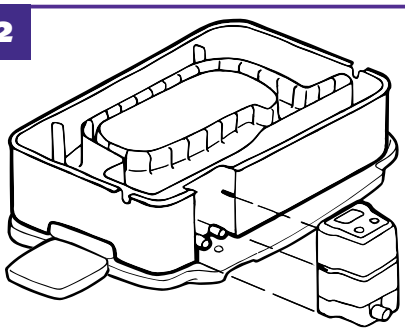
It is important to ensure that Stella is operated on a stable and level surface.
Otherwise, the automatic sensor that triggers the cycle will not operate reliably.

1



Once level, place the Base onto the Cradle. Stand the Lid in an upright position at the rear of the Base.

2

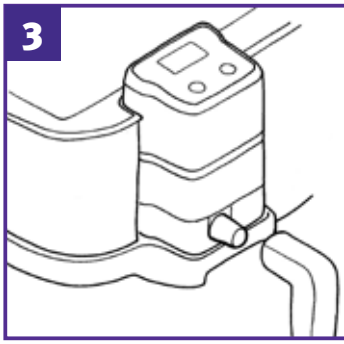


Firmly attach the IQ to the Base.

Failure to ensure the correct connection may result in a leak.

The drainage outlets from the Base slide into the drainage inlets in the IQ.

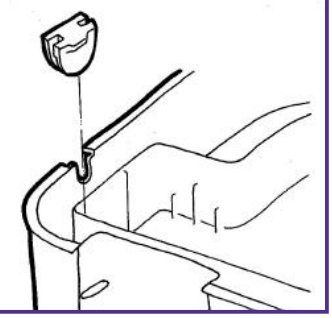
3



Firmly connect the Drainage Hose to the IQ and ensure the end of the tube is directed into a sink or waste container.

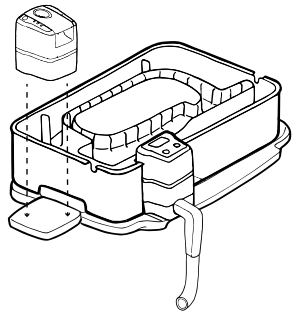
Ensure that the end of the Drainage Hose is in a downward position and not immersed in the waste solution, i.e. ensure there is an air gap.

4



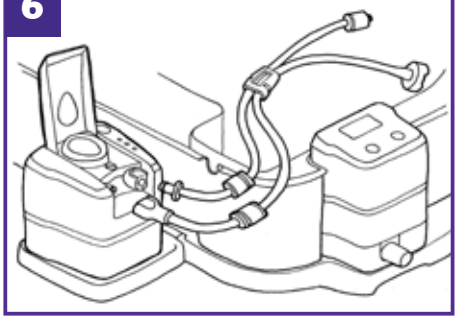
Apply the grommets into the tray cut-outs.

5



Step 5 and 6 relate to Stella B and C only. Place Pulse on the Cradle Shelf

6



Remove the grommet nearest to the Pulse. Attach the Tube Set to Pulse by matching the male and female connectors. Place the green tube mount provided firmly on to the Base cut-out.

Ensure that the disinfectant pick-up/filter is sitting in the inner compartment of the Base.

SECTION FOUR

HOW TO USE

SECTION FOUR: HOW TO USE

STELLA SYSTEM A

- Ensure the medical instrument has been cleaned according to the hospital standard procedures before performing high-level disinfection with Stella System A. Tristel Clean for Stella, Tristel Pre-Clean Wipe or Tristel Clean are recommended. Please refer to the medical device manufacturer's care card or material compatibility approval list.
- Disinfect hands and wear appropriate Personal Protective Equipment (PPE) when handling disinfectants and medical devices.
- Do not attempt to move Stella whilst it is filled with solution.

Step 1

Push the 'ON' button on the IQ until you hear a beep and follow the instructions shown on the screen. IQ performs a short self-check.

Step 2

When prompted by IQ, place the clean instrument into the Base inner compartment. Position the instrument in a way that best fits the shape of the compartment, ensuring any connecters or non-immersible parts are placed outside of the tray via the designated cut-outs. If the instrument is completely submersible, seal the cut-outs with the grommets provided.

Instruments that do not fit correctly in the instrument compartment must not be used in the Stella System. Ensure that the Stella lid can be completely closed.

Step 3

Any small re-usable parts from the instrument should be placed in the Small Parts Tray with the Lid closed and positioned into one of the two positions available within the Base inner compartment, to the left or right of IQ.

Step 4

Prepare Tristel Fuse for Stella working solution in accordance with the user instructions.

Step 5

When prompted by IQ pour five litres of Tristel Fuse for Stella disinfectant into the Base inner compartment. *It is recommended to position the Stella Jug on the outer wall of the Base, just right of IQ, and tilt the Jug slowly, supporting the base of the Jug with one hand. All five litres must be added. The disinfectant will overflow over the edges of the inner compartment into the overflow compartment of the Base. It will drain out immediately.*

If Tristel Fuse for Stella is not added to Stella within 10 minutes, the cycle will be automatically aborted by IQ.

Step 6

Allow up to 10 seconds for the liquid sensor to detect the Tristel Fuse for Stella working solution in the Base. The correct level of disinfectant automatically triggers the contact time count down. An audible beep confirms the start of the five-minute disinfection cycle.

Step 7

Place the Lid onto the Base, ensuring it is closed tightly. Closing the Lid will displace more disinfectant solution into the overflow compartment. IQ displays the five-minute contact time countdown.

Do not turn off IQ during the contact time as this will lead to ineffective disinfection and the disinfection cycle will be recorded as invalid, with no validation code.

Step 8

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.*

**Based on clinical and toxicological studies. NOTE: for ophthalmology devices a rinsing step IS required. Follow your hospital and manufacturer guidelines for information on rinsing requirements.*

Step 9

When the Base is empty, you will hear a beep indicating that the cycle is complete. Press the OK button to acknowledge that the cycle is complete. The disinfected instrument can now be removed for immediate use or placed in storage.

Follow hospital procedures for instrument drying and storage.

Step 10

Press the OK button again to confirm the removal of the instrument, prompting IQ to display a Validation Code. This Validation Code should be noted in the Stella Quality Audit Trail Record Book.

Failure to confirm the removal of the instrument will result in the IQ display back light shutting down after 15 minutes. After 30 minutes IQ will also shut down. When the unit is turned on again, the Validation Code can still be retrieved by pressing the OK button.

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

SHUTDOWN PROCEDURE FOR STELLA SYSTEM A

Turn off IQ by pressing the OFF button. You will hear a beep indicating that IQ is switching off.

If IQ is not turned off manually, it will automatically shut down after 15 minutes to save the battery. It is recommended to turn off IQ immediately after use to save the battery life.

After IQ has been switched off, it can be detached from the Stella Base.

With the drainage outlet cap fitted into place, the Base can be used as a transportation unit. Wipe the unit down with a paper towel to remove any drops or spills from the drain.

STELLA SYSTEM B

- Ensure the medical instrument has been cleaned according to the hospital standard procedures before performing high-level disinfection with Stella System B. Tristel Clean for Stella is recommended. Please refer to the medical device manufacturer's care card or material compatibility approval list.
- Disinfect hands and wear appropriate Personal Protective Equipment (PPE) when handling disinfectants and medical devices.
- Do not attempt to move Stella whilst it is filled with solution.

Step 1

Push and hold the ON button on IQ until you hear a beep. Push and hold the ON button on Pulse until you hear a beep. IQ performs a short self-check. IQ automatically connects to Pulse and a Bluetooth sign confirms the connection. This will remain visible throughout the operation. Follow the instructions shown on the IQ screen.

Step 2

When prompted by IQ, place a clean instrument into the Base inner compartment. Position the instrument in a way that best fits the shape of the compartment, ensuring any connectors or non-immersible parts are placed outside of the tray via the designated cut-outs. If the instrument is completely submersible, seal the cut-outs with the grommets provided.

Instruments that do not fit correctly in the instrument compartment must not be used in the Stella System. Ensure the Lid can be completely closed.

Step 3

Attach the Pulse Tube Set Luer lock connector to the instrument's lumen port.

Step 4

Any small re-usable parts from the instrument should be placed in the Small Parts Tray with the lid closed and positioned into one of the two positions available within the Base inner compartment, to the left or right of IQ.

Step 5

Prepare Tristel Fuse for Stella working solution in accordance with the user instructions.

Step 6

When prompted by IQ pour five litres of Tristel Fuse for Stella working solution into the Base inner compartment.

It is recommended to position the Stella Jug on the outer wall of the Base, just right of IQ, and tilt the Jug slowly, supporting the base of the Jug with one hand. All five litres must be added. The disinfectant will overflow over the edges of the inner compartment into the overflow compartment of the Base. It will drain out immediately.

If Tristel Fuse for Stella is not added to Stella within 10 minutes, the cycle will be automatically aborted by IQ.

Step 7

Allow up to 10 seconds for the liquid sensor to detect the Tristel Fuse for Stella solution in the Base. The correct level of disinfectant automatically triggers the contact time count down. An audible beep confirms the start of the disinfection cycle.

Step 8
Place the lid onto the Base, ensuring it is closed tightly. Closing the lid will displace solution into the overflow compartment. IQ displays five-minute contact time countdown.

Do not turn off IQ during the contact time as this will lead to ineffective disinfection and the disinfection cycle will be recorded as invalid, with no validation code.

Step 9
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.*

**Based on clinical and toxicological studies. NOTE: for ophthalmology devices a rinsing step IS required. Follow your hospital and manufacturer guidelines for information on rinsing requirements.*

Step 10
When the Base is empty, you will hear a beep indicating that the cycle is complete. Press the OK button to acknowledge that the cycle is complete. The disinfected instrument can now be removed for immediate use or placed in storage.

Follow hospital procedures for instrument drying and storage.

Step 11
Press the OK button again to confirm the removal of the instrument, prompting IQ to display a Validation Code. This Validation Code should be noted in the Stella Quality Audit Trail Record Book.

Failure to confirm the removal of the instrument will result in the IQ display back light shutting down after 15 minutes. After 30 minutes IQ will also shut down. When the unit is turned on again, the Validation Code can still be retrieved by pressing the OK button.

SHUTDOWN PROCEDURE STELLA SYSTEM B

Turn off IQ by pressing the OFF button. You will hear a beep indicating that IQ is switching off. When IQ is turned off, Pulse will switch off automatically.

If IQ is not turned off manually, it will automatically shut down both IQ and Pulse after 15 minutes to save the battery life. It is recommended to turn off IQ immediately after use to save the battery.

After IQ has been switched off, it can be detached from the Base.

With the drainage outlet cap fitted into place, the Base can be used as a transportation unit. Wipe the unit down with a paper towel to remove any drops or spills from the drain.

STELLA SYSTEM C

- Ensure the medical instrument has been pre-cleaned according to the hospital standard procedures before performing decontamination or cleaning and high-level disinfection with Stella System C. Tristel Clean for Stella is recommended.
- Disinfect hands and wear appropriate Personal Protective Equipment (PPE) when handling chemical agents and medical devices.
- Do not attempt to move Stella whilst it is filled with solution.

Step 1

Push and hold the ON button on IQ until you hear a beep Push and hold the ON button on Pulse until you hear a beep. IQ performs a short self-check. IQ automatically connects to Pulse and a Bluetooth sign confirms the connection. This will remain visible throughout the operation. Follow the instructions shown on the IQ screen.

Step 2

When prompted by IQ, place a manually pre-cleaned instrument into the Base inner compartment. Position the instrument in a way that best fits the shape of the compartment, ensuring any connectors or non-immersible parts are placed outside of the tray via the designated cut-outs. If the instrument is completely submersible, seal the cut-outs with the grommets provided.

Instruments that do not fit correctly in the instrument compartment must not be used in the Stella System. Ensure the Stella lid can be completely closed.

Step 3

Attach the Pulse Tube Set Luer lock connector to the instrument's lumen port.

Step 4

Any small re-usable parts from the instrument should be placed in the Small Parts Tray with the lid closed and positioned into one of the two positions available within the Base inner compartment, to the left or right of IQ.

Step 5

Prepare five litres of Tristel Clean for Stella solution in accordance with the user instructions.

Step 6

When prompted by IQ, pour five litres of Tristel Clean for Stella working solution into the Base inner compartment.

It is recommended to position the Stella 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. All five litres must be added. The detergent solution will overflow over the edges of the inner compartment into the overflow compartment of the Base. It will drain out immediately.

Step 7

Place the lid onto the Base ensuring it is closed tightly. Closing the lid will displace more detergent solution into the Base overflow compartment. IQ displays the five-minute contact time countdown.

Step 8
After the completed contact time Stella drains the detergent solution automatically. The draining process may take up to one minute.

If a disinfection cycle does not follow within 15 minutes IQ will go to sleep to maintain battery life. If a disinfection cycle does not follow within 30 minutes the cycle will be automatically aborted by IQ, a new cleaning cycle must be started.

Step 9
Prepare Tristel Fuse for Stella working solution in accordance with the user instructions.

Step 10
When prompted by IQ pour five litres of Tristel Fuse for Stella working solution 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. The disinfectant solution will overflow over the edges of the inner compartment into the overflow compartment of the Base. It will drain out immediately.

If Tristel Fuse for Stella is not added to Stella within 10 minutes, the cycle will be automatically aborted by IQ.

Step 11
Allow up to 10 seconds for the liquid sensor to detect the Tristel Fuse for Stella working solution in the Base. The correct level of disinfectant automatically triggers the contact time count down. An audible beep confirms the start of the five-minute disinfection cycle.

Step 12
Place the Lid onto the Base ensuring it is closed tightly. Closing the Lid will displace more disinfectant solution into the overflow compartment. IQ displays the five-minute contact time countdown.

Do not turn off IQ during the contact time as this will lead to ineffective disinfection and the disinfection cycle will be recorded as invalid, with no validation code.

Step 13
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.*

**Based on clinical and toxicological studies. NOTE: for ophthalmology devices a rinsing step IS required. Follow your hospital and manufacturer guidelines for information on rinsing requirements.*

Step 14
When the Base is empty, you will hear a beep indicating that the cycle is complete. Press the OK button to acknowledge that the cycle is complete. The disinfected instrument can now be removed for immediate use or placed in storage.

Follow hospital procedures for instrument drying and storage.

Step 15

Press the OK button again to confirm the removal of the instrument, prompting IQ to display a Validation Code. This Validation Code should be noted in the Stella Quality Audit Trail Record Book.

Failure to confirm the removal of the instrument will result in the IQ display back light shutting down after 15 minutes. After 30 minutes IQ will also shut down. When the unit is turned on again, the Validation Code can still be retrieved by pressing the OK button.

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

SHUTDOWN PROCEDURE STELLA SYSTEM C

Turn off IQ by pressing the OFF button. You will hear a beep indicating that IQ is switching off. When IQ is turned off, Pulse will switch off automatically.

If IQ is not turned off manually, it will automatically shut down both IQ and Pulse after 15 minutes to save the battery life. It is recommended to turn off IQ immediately after use to save the battery life.

After IQ has been switched off, it can be detached from the Base.

With the drainage outlet cap fitted into place, the Base can be used as a transportation unit. Wipe the unit down with a paper towel to remove any drops or spills from the drain.

SECTION FIVE

MAINTENANCE

SECTION FIVE: MAINTENANCE

BATTERY MANAGEMENT

Always ensure IQ and Pulse are fully charged.

IQ will display the battery status for the full Stella System. If you have Stella System B or C, IQ will also display the battery status for Pulse. There are five indicators of charge, which will determine how many cycles can be performed.

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

Step 1

The power adaptor plug comes in two parts. Before use, fit the pins and the backing together ensuring they have clicked into place.

To replace the power plug pins, press the release button, and remove.

Step 2

Disconnect IQ and Pulse from the Base and plug in the power adaptor via the power port on the back of the IQ and Pulse units.

Only the supplied power adaptor should be used. The use of other adaptors may damage the equipment or cause malfunction.

Do not charge IQ or Pulse whilst they are attached to the Base or near solution. Ingress of solution will cause damage or malfunctions to the equipment.

Step 3

Once plugged in, IQ will display the status of the charging.

LUBING IQ

During set up and every six months, Lube should be applied to the IQ drainage inlets to ensure the IQ is connected securely onto the Base.

Step 1

Wearing gloves, take a small amount of Lube and apply to the perimeter of each drainage inlet.

Ensure the Lube is applied evenly. Do not apply Lube to the IQ drainage outlet, where the Drainage Hose is attached.

BLUETOOTH PAIRING PROCESS

The software on IQ and Pulse are already paired when supplied together.
However, if either unit is replaced, they must be paired again.

Step 1
Press the ON button to turn on IQ and Pulse.

Step 2
In quick succession to Step 1, on the IQ press the ON button two more times until the Bluetooth Pulse Search logo appears and the Bluetooth begins to search.

Step 3
Once the Bluetooth link is established, any available Pulse units will be indicated on screen with their product serial numbers.

Step 4
Choose your Pulse unit by scrolling the list and pressing the ON button for a minimum of four seconds until you hear a beep and a Bluetooth Pairing Complete graphic displays. Stella is now ready to use.

BARCODE VALIDATION

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

Step 1
Connect the power adaptor to the mains power and IQ. Alternatively connect the USB to the PC and connect to IQ. (It is the connection to an electrical source (mains or PC) that enables the service screen selection where the change mode of operation is located on IQ).

Step 2
Press IQ 'ON' button four times to enter the screen setting the barcode option. There are two options available:

- Validation code without barcode

- Validation code with barcode

Step 3
The option that is set is described in the top half of the graphic with a black background. To change the option, the ON key must be held for 3 seconds.

Step 4

When changing the barcode option, the user must press ON to confirm the change.
Remove the USB cable from IQ, and push the ON Button once.

Validation code without barcode	Validation code with barcode
Press ON to confirm	Press ON to confirm

Step 5

Press the OFF key and remove the power adaptor or USB plug.

Step 6

Stella is now ready to use with the selected barcode option.

Example of validation barcode;

DOWNLOADING

Each Stella cycle record is stored on IQ. This data should be frequently downloaded and stored as per hospital protocols. For a download to take place, Stella Suite Software must be installed on a PC or Laptop.

There are two options for downloading the data from IQ.

VIA USB CABLE

Step 1

Open Stella Suite, and connect the USB cable to your PC or Laptop and the IQ unit.

IQ must be turned off. The connection port can be found on the back of the IQ, under a protective cover.

Step 2

IQ will automatically detect the USB connection and the LED screen will light up. *Do not press the ON button.*

Step 3

The USB Download symbol will appear on the IQ screen. On the Stella Suite toolbar, select the download option to begin transferring data.

Step 4

Once downloading is complete, disconnect the USB cable. IQ will automatically turn off.

Remove the USB cable and reseal the protective cover on the IQ unit. Replace IQ back onto the Base before use.

VIA BLUETOOTH

Step 1

Enable Bluetooth communications on your PC.

Step 2
Press the IQ ON button once until you hear a beep. Whilst the Stella logo is displayed, press the ON button again to display Bluetooth Download.

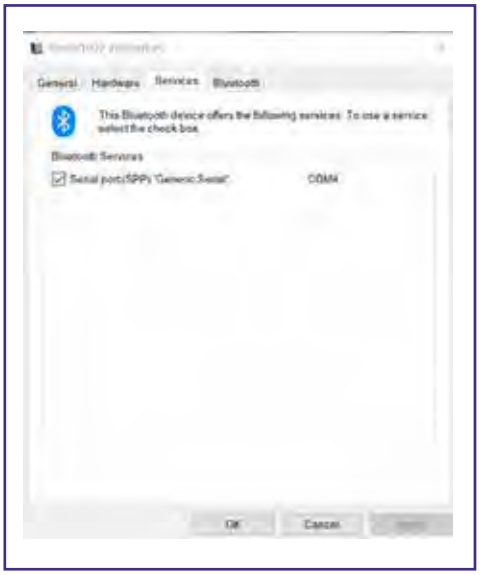
The following instructions may vary depending on the Windows operating system being run. The following instructions are for Windows 10.

Step 3
On the PC locate Control Panel\Hardware and Sound\Devices and Printers. Select 'Add Device'.

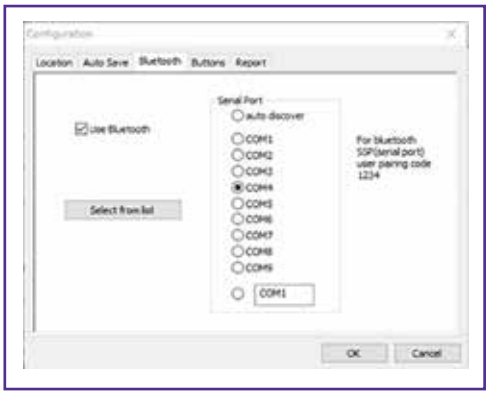
Step 4
Select Stella (the serial number will show), then 'Next', the IQ will then be assigned into the 'Device and Printers' window.

If asked for a pairing code, use 1234.

Step 5
Right click on the Stella device listed, select Properties, then select the Services Tab. Note the COM port number shown.



Step 6
Open the Stella Suite. On the Stella Suite tool bar select File – Configure to open the Configuration window. Click the Bluetooth tab and then 'Select from List', select the allocated COM port number and OK.



Step 7
On the Stella Suite click on Download and Yes to confirm the PC time clock is set to the correct time. The Progress window will show progress of the Event log download to the Stella Suite. Once the download is completed switch off IQ by pressing the OFF button.

REPLACING THE PUMP HOSE

The Stella B Pump Hose should be changed every 1,000 disinfection cycles.
The Stella C Pump Hose should be changed every 500 disinfection cycles.
The Stella Suite Report shows the number of cycles completed.

The equipment you will need for the Pump Hose replacement process:

- Pulse
- Pump Hose Replacement Set
- Flat Head Screwdriver located in the Toolbox

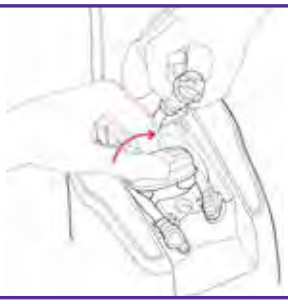
1

Ensure Pulse is turned off. Lift the green cover on Pulse. Using a flat head screwdriver, unscrew the clear window and remove it from Pulse.

2

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.

3



Insert the new Pump Hose into 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.

The Pump Hose connectors will not fit if they are not connected to the correct sides of Pulse.

4

Replace the window, ensuring that the back ridge is pushed back correctly into Pulse and then fix the screw securely, taking care not to over tighten. *Pulse will not operate if the window is not replaced correctly.*

Each new 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, a spare part is ordered.

REPLACING THE TUBE SET

The Stella B Tube Set should be replaced every 4,000 disinfection cycles.
The Stella C Tube Set should be replaced every 2,000 disinfection cycles.
The Stella Suite Report shows the number of cycles completed.

Remove the Tube Set from Pulse and attach the replacement Tube Set to Pulse by matching the male and female connectors. Place the green tube mount provided firmly on to the Base cut-out.

CLEANING AND DISINFECTING STELLA

Tristel Clean for Stella and Tristel Fuse for Stella working solutions can be used for the cleaning and disinfection of the Stella System.

To clean the Stella System, dispense enough Tristel Clean for Stella working solution to saturate a cloth, then squeeze to remove excess solution. Use the damp cloth to wipe the system until visibly clean, including IQ and Pulse.

To disinfect the Stella System, dispense enough Tristel Fuse for Stella working solution to saturate a cloth, then squeeze to remove excess solution. Use the damp cloth to wipe the system, including IQ and Pulse. Ensure a contact time of five minutes. Dry with a soft cloth.

DISPOSAL

The Base, Lid and Small Parts Tray can be disposed to plastic waste once decontaminated. The IQ and Pulse units contain batteries and electronic components and must be disposed of in accordance with local regulations. The components should be decontaminated using chemical disinfectants prior to disposal, as recommended in **cleaning and disinfecting Stella.**

SECTION SIX

TROUBLESHOOTING AND FREQUENTLY ASKED QUESTIONS

SECTION SIX: TROUBLESHOOTING AND FREQUENTLY ASKED QUESTIONS

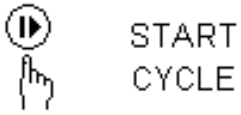
GRAPHIC AND ALERTS

Cycle Will Not Start

Five litres of Tristel Fuse for Stella working solution have been added to Stella but the disinfection cycle does not start.

Ensure the Stella Cradle is level so the liquid sensor is able to detect the *solution.*

Refer to Section 3, Getting Started for instructions on how to level the Cradle.

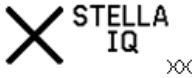


X Stella xx/ X Stella IQ xx/ X Stella Pulse xx

In the event of equipment errors that cannot be resolved on site an X graphic will display.

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

 Stella xx/  Stella IQ xx/  Stella Pulse xx



In the event of an operator error or an equipment error or an equipment error that may be resolved on site, a ⚠ graphic will display with a number and may be followed by other graphics. Refer to the troubleshooting below and on the Help Guide Wall Chart. If the error cannot be resolved, or is not listed, contact your Stella Agent and advise them of the error code and graphics.

STELLA IQ SCREEN	WHAT HAPPENED?	WHAT SHOULD BE DONE?
No graphic. Disinfection cycle will not automatically start	Stella does not detect that five litres of solution has been added. Either Stella is not level, or the full five litres of Tristel Fuse for Stella has not been added.	• The Cradle should be levelled using the built-in spirit level. • Ensure the bubble is in the centre circle of the spirit level. If it is not, use the Cradle feet to adjust the Cradle until the bubble comes to the centre of the spirit level. • When the inner compartment is full, also observe the waterline to see that it is level. • Ensure that all five litres of working solution have been added. Overflow when the lid is put into place, forces disinfectant over the inner compartment rim. This provides a fully disinfected inner chamber.
	Five litres of Tristel Fuse for Stella have been added to Stella but the disinfection cycle does not start. If the Drainage Hose is not flowing in a downward direction, solution may have been forced back into the IQ creating a moisture blockage.	• Ensure that the Drainage Hose connected to Stella IQ falls in a downward direction to the drain.
	The Stella Pulse Bluetooth link to the IQ has been lost during the disinfection cycle. Either there has been an interruption from other Bluetooth equipment, or there is not enough power in the equipment and the Bluetooth link has been lost.	• The disinfection cycle has not successfully completed and must be repeated. • Check that both the IQ and Pulse units are charged and have more than 25% battery power. If not, put on a full 12-16 hour charge. • If there is other wireless equipment e.g. wireless phone, Wi-Fi equipment, mobile phone, in close proximity that may be interfering with the equipment it will need to be moved away. • Turn off Stella IQ and Pulse. Start the Bluetooth communication process again by first switching on Pulse then IQ. • If the issue persists, it may be a power issue, contact your Stella Help Desk contact.

	Stella IQ has detected an obstruction in the ball valve. There may be an obstruction in the ball valve area, or the ball valve may have become dry with long term storage or age.	• There is no disinfectant in the Base when this error code presents. • Remove Stella IQ from the Base and inspect the IQ drainage outlets for blockages with foreign objects and remove any debris. • Turn the equipment on and off several times. If this does not resolve, refer to your Stella Help Desk contact for the ball valve cleaning procedure, then 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 Stella Service Centre.
	Stella IQ and Pulse firmware are not compatible.	• Open Stella Suite and connect the IQ via USB cable to the computer. Go to the Help menu and “Check for firmware updates”. • When completed, repeat the process with Stella Pulse. • If Stella Suite is not installed, visit www.tristel.com/stella and install Stella Suite Software then complete the steps above.
	Stella Pulse has detected a blockage in the instrument.	• The disinfection cycle has not completed successfully. Disinfectant in the Base will be drained to waste. • Check the instrument for blockages. • Restart the disinfection cycle. • If the problem persists, contact your Stella Help Desk contact.
	Stella is not detecting solution, either the Pulse tube set disinfectant pick-up filter is not submerged in the instrument inner compartment, the instrument tap is closed, the Pulse tube set left-hand connector to Pulse is not connected correctly to Pulse, or the instrument is not connected correctly to the Pulse tube set Luer lock.	• Check the Pulse tube set left-hand connector to Pulse is clicked into the Pulse. • Check the Pulse tube set disinfectant pick-up filter is submerged in the instrument inner compartment. • If the instrument has a tap, check that the tap is open. • Check that the Pulse tube set Luer lock connector to lumen is attached to the instrument correctly. • Check that the instrument tap is open. • Push the ‘ON’ button to confirm. You will have three opportunities to confirm before the system will abort the cycle.
	Stella has identified that the instrument has not been connected to the Pulse tube set Luer lock connector, and/or the metal connector is not under the solution.	• Check that the Pulse tube set Luer lock connector is attached to the instrument correctly. • Check that the Pulse tube set Luer lock metal connector is under the solution. • Push the ‘ON’ button to confirm. You will have three opportunities to confirm before the system will abort the cycle.
	Tristel Fuse for Stella disinfectant is not detected. Either the Pulse tube set Luer lock metal connector is not below the solution line, the Pulse tube set disinfectant pick-up filter is not submerged in the inner compartment, the incorrect dilution of solution has not been added, or the disinfectant pick-up filter is blocked	• The disinfection cycle has not completed successfully. Disinfectant in the Base will be drained to waste. • A new cycle must be started with Tristel Fuse for Stella disinfectant added and mixed in the right dilution. • Ensure the Pulse tube set disinfectant pick-up filter is submerged in the inner compartment. • Check that the disinfectant pick-up filter is not blocked. • Ensure the Pulse tube set Luer lock metal connector is below the solution line when pouring in the solution.

FAQs

POWER

Why is IQ or Pulse not powering up or operating intermittently?

IQ will not start a cycle if there is not enough charge in the batteries to finish a full cycle. Place IQ and Pulse on charge for 12 - 16 hours. If IQ or Pulse still fails to power up, contact your Stella Agent.

Why is my IQ and Pulse not charging correctly?

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

As IQ and Pulse batteries age, their capacity to store energy decreases. IQ and Pulse batteries have an in-use life of 3 - 5 years. After this time, they may need replacing.

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

HARDWARE

Why is water leaking from the Stella Base?

Check IQ is attached firmly to the Base. Ensure that the Drainage Hose is attached and is watertight. Applying Lube (for instructions, see Maintenance section of this manual) will assist a firm fit to the Base.

Why is water leaking from the Valve outlet?

Excess liquid will exit the outlet when Stella is filled. When filling the instrument compartment with five litres of solution, a small amount of liquid will flow into the overflow compartment and out through the Drainage Hose at the start of a cycle.

If there is a continuous leak throughout the cycle, the Valve may not have closed correctly.

Remove IQ from the Base.

If the system is operating with IQ only, press the ON button so that the Valve inside IQ closes.

If the system is operating with IQ and Pulse, press the ON button on IQ and Pulse so that the Valve inside IQ closes.

Make sure the black power cover is firmly sealed over the USB and power adaptor.

Flush by pouring a small Jug of cold water into the right-hand IQ drain inlet. Take care to direct the drainage outlet on the left-hand side towards the sink, and avoid water contacting the top of the unit. Even though the valve is closed, water will still drain slowly from the drainage outlet.

Gently shake the IQ unit and then hold down the OFF button for 5 seconds. (In some cases you may have found that the IQ wanted to start a disinfection cycle by itself as you were cleaning the sensor. If this happens, let it finish the cycle by itself as if it were connected to the Base).

Reattach the IQ and Drainage Hose to the Base. Run a cycle to test if the issue has been cleared. If the problem persists, contact your Stella Agent.

Why are water leaks appearing from the electronics enclosure power cap?

Discontinue use immediately and contact your Stella Agent.

COMMUNICATION

USB: Why is my Firmware not upgrading?

IT services may need to complete the software installation. Check the USB cable is in good condition with no cable damage, broken or visible wires.

Check plug connections are in good working order.

Check the Stella Suite software installed on your computer is the latest version. The latest available version of Stella Suite software is available via the Stella product page on tristel.com.

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 on 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: Why is my 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. Stella Suite Software must be installed onto the computer, and the Bluetooth link configured according to the Bluetooth device instructions used on the computer.

Why will IQ or Pulse not power up after a firmware update?

The firmware update may not have completed successfully. The update should be repeated. Open the Stella Suite, connect IQ to the PC via a USB Cable. Select ‘help’, then select the product you wish to update. This should be completed for both IQ and Pulse units.

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.

Why is there an alarm going off after a 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”.

I have downloaded my events, why can I not see them on the system anymore?

By default, the Stella Suite will only download events that took place since the last download. 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.

DAMAGE

If goods are damaged during delivery, it is the user’s responsibility to contact a Stella Agent.
If the equipment is dropped during use, the user should attempt to run a cycle through Stella to check it is operating correctly. If damage has occurred, contact a Stella Agent.

SECTION SEVEN

WARRANTY

SECTION SEVEN: WARRANTY

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 Product, supplied by the Company is twelve (12) months shown from the date of invoice.
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, expressed 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.

SECTION EIGHT

COMPLIANCE

SECTION EIGHT: COMPLIANCE

TECHNICAL SPECIFICATIONS

TECHNICAL SPECIFICATIONS	
Power adaptor	FRIWO Model No. FW 7660M/12 GPP10-M (1950082)
AC mains	100~240Vac, 50/60Hz, 205~110mA, Interchangeable mains plugs
DC Output	12V ±2%, 800mA, 2.5mm DC Jack, (+) centre
Isolation Protection	Class II - AC mains and DC output are electrical safety isolated
Working Temperature	0°C ... +40°C
Storage Temperature	-20°C ... +70°C
Humidity	5% to 95%
Ingress Protection	IP40
Atmosphere Pressure	70-106kPa
Maximum Altitude	2.6km above sea level
Weight	160gm
Low Voltage Directive Safety Standard	IEC/EN 60601-1 ED, IEC60601-1, ES60601-1 AS/NZS 3112, VDE EN50075, EN60950-1, UL1310
EMC Directive	EN 60601-1-2, IEC EN 61326-1
Cable Length	1.8m
Stella IQ	
Input Voltage	12Vdc, 300 mA
Ingress Protection	IP64 With Power cover closed. Dust tight, protected from water splash
Pollution Degree	Assessed to pollution degree 3. Conductive pollution is to be expected
Humidity	10% to 90%
Weight	840gm
Working Temperature	10°C ~ 35°C
Transport Temperature	-20°C to +50°C
Storage Temperature	-10°C to +40°C
Charge Temperature	10°C ~ 35°C
Low Voltage Directive	IEC/EN 61010-1, 61010-2-040 Part 2 – Washer Disinfectors
EMC Directive	IEC EN 61326-1
Battery Pack	Part No. 210AAHCB4BMLQM, 4.8V NiMH, 2000mAh, 117gm
Battery Standard Charge	200mA (0.1C) 16hrs, 6Vmax
Battery Service Life	IEC Cycles test ~ 500, (IEC 61951-2)
Stella Pulse	
Input Voltage	12Vdc, 650 mA
Ingress Protection	IP64 With Power cover closed. Dust tight, protected from water splash
Pollution Degree	Assessed to pollution degree 3. Conductive pollution is to be expected
Humidity	5% to 90%

Weight	1560gm
Working temperature	10°C ~ 35°C
Storage temperature	-10°C to +40°C
Transport temperature	-20°C to +50°C
Charge temperature	10°C ~ 35°C
Low Voltage Directive	IEC/EN 61010-1, 61010-2-040 Part 2 – Washer Disinfectors
EMC Directive	IEC EN 61326-1
Battery Pack	Part No. 450LAH10YQM, 12V NiMH, 4500mAh, 622gm.
Battery standard charge	450mA (0.1C) 16hrs, 15Vmax
Battery Service Life	IEC Cycles test ›250, (IEC 61951-2)
Stella Base with Lid	70cm x 48cm x 18cm
Base capacity	5Litres
Weigh	5.5kg when empty
Stella Cradle	84cm x 48cm

REGULATORY COMPLIANCE

The Stella System is CE marked as a Class IIb medical device as per the Medical Device Directive 93/42/EEC and the 2007/47/EC amendments thereto, for washer disinfectors intended for disinfecting invasive medical devices and Low Voltage Directive (LVD) 2014/35/EU.

	Council Directive (EU) 2017/745 of 5 April 2017 concerning medical devices
Directive (LVD) 2014/35/EU	Low Voltage Directive (LVD) 2014/35/EU enforced 23 April 2016
Directive (EMC) 2014/30/EU	Electromagnetic Compatibility (EMC) 2014/30/EU enforced 20 April 2016
BS EN ISO 13485:2016	Medical Devices - Qualitative management systems. Requirements for regulatory purposes
BS EN 60601-1:2006 +A12:2014	Medical electrical equipment. General requirements for basic safety and essential performance – (Relating to Power Adaptor)
AS 61010.1:2003(R2016) BS EN 61010-1:2010+A1:2019 IEC 61010-1 3.1: 2017	Medical Electrical Equipment. Part 1: Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements
BS EN 61010-2-040:2015 Part 2-040	Safety requirements for electrical equipment for measurement, control and laboratory use – Particular requirements for sterilisers and washer disinfectors used to treat medical devices
BS EN 61326-1:2013 IEC 61326-1:2012	Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements
BS EN 62366-1:2015	Medical devices. Application of usability engineering to medical devices
BS EN 62304:2006+A1:2015	Medical device software. Software life-cycle processes
BS EN 61000-3-2:2014 IEC 61000-3-2:2014 Ed 4.0	Electromagnetic compatibility (EMC) - limits for harmonic current emissions
BS EN 61000-3-3:2013 IEC 61000-3-3:2013 Ed 3.0	Electromagnetic compatibility (EMC) - limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems
AS/NZS CISPR 11:2011 BS EN 55011:2009 CISPR11: 2009 + A1: 2010	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement.
AS/NZS 61000-4-2:2013 BS EN 61000-4-2:2009 IEC 61000-4-2:2008	Electromagnetic compatibility (EMC) - testing and measurement techniques – electrostatic discharge immunity test
AS/NZS 61000-4-3:2013 BS EN 61000-4-3:2006 +A1: 2010 IEC 61000-4-3:2006 +A1:2007+A2:2010	Electromagnetic compatibility (EMC) - testing and measurement techniques – radiated, radio frequency, electromagnetic field immunity test

ELECTROMAGNETIC EMISSIONS AND IMMUNITY IEC 61326-1:2013 STELLA

For electromagnetic emissions the Stella System has been tested for compliance to IEC 61326-1, CISPR11 Group 1, Class B. Testing has been performed using the following parts 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	1.8m DC lead	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 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 IQ and Pulse from the Base and keep it clear from wet areas.

CLOSE POWER CAP

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

Declaration for compliance: The Stella System complies with all IEC 61326-1 Test Levels of this collateral standard for power frequency magnetic field immunity requirement.

IEC 61326-1:2013 TABLE 1 – BASIC IMMUNITY

Declaration for compliance: The Stella System complies with all IEC 61326-1 Test Levels of this collateral standard for power frequency magnetic field immunity requirement.

MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY				
Immunity test requirements for equipment intended to be used in a basic electromagnetic environment.				
Port	**Phenomenon**	**Basic Standard**	**Test value**	**Performance Criterion**
Enclosure	Electrostatic Discharge (ESD)	IEC 61000-4-2	4 kV contact discharge 8 kV air discharge	B B
	Electromagnetic Field	IEC 61000-4-3	3 V/m (80 MHz to 1 GHz) 3 V/m (1.4 GHz to 2 GHz) 1 V/m (2.0 GHz to 2.7 GHz)	A A A
	Power frequency magnetic field	IEC 61000-4-8	3 A/m (50 Hz, 60 Hz)	A
AC Power (Including protective earth)	Voltage dip	IEC 61000-4-11	0% during half cycle 0% during 1 cycle 70% during 25/30 cycles	B B C
	Short interruptions	IEC 61000-4-11	0% during 250/300 cycles	C
	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	0.5 kV)/1 kV)	B
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
DC power (including protective earth)	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	0.5 kV)/1 kV)	B
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
I/O signal/ control (including functional earth)	Burst	IEC 61000-4-4	0.5 kV (5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	1 kV	B
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
Mains power quality should be that of a typical domestic or hospital environment. If disturbance occurs, it may be necessary to position the Stella System further from sources of power frequency magnetic fields or install magnetic shielding.				

IEC 61326-1:2013 TABLE 2 – EMISSIONS

Declaration for compliance: The Stella System complies with CISPR11, group 1, Class B, IEC 61000-3-2 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 standard**	**Test level**
RF emissions energy level	CISPR 11	Group 1 - RF energy only for its internal function
RF emissions environment category	CISPR 11	Class B - All establishments including domestic
AC power - Conducted emissions	CISPR 11	150 kHz - 30 MHz
Enclosure - Radiated emissions	CISPR 11	Group 1 equipment - 30 MHz to 1 GHz (OATS)
AC power - Harmonic emissions	IEC 61000-3-2	Measurement up to 40th harmonic
AC power - Flicker	IEC 61000-3-3	Traceable results only - Complies
Electromagnetic environment – guidance		
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.		
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.		

IEC 60601-1-2:2007 (5.2.2.1) TABLE 3

Declaration of compliance: The Stella System is a 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 150 kHz to 80 Mhz 3 V/m 80 MHz to 2.5 GHz	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.

[A] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast 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.

[B] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

IEC 60601-1-2:2007 (5.2.2.1) TABLE 4

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

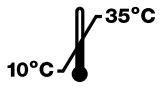
The Stella System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The end user of the Stella System can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters)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

GLOSSARY OF THE GRAPHICAL SYMBOLS USED ON THE STELLA SYSTEM

OBSERVE ALL SYMBOLS – SYMBOLS ARE FOR YOUR SAFETY AND ENVIRONMENTAL PROTECTION	
	**Read instructions before use** This instruction manual contains information for the safe use and handling of the Stella system and power supply. In explains the installation and the mains adaptor power supply for charging the Stella units.
	**IQ Graphic indicating user error or equipment error that may be resolved on site** • In the event of an operator error or an equipment error that may be resolved on site, this symbol will be displayed • Note whether the system is for Stella, Stella IQ or Stella with Pulse and the number following • Note if any other graphics are shown • Refer to the troubleshooting guide or Help Guide Wall Chart • If the error cannot be resolved, or is not listed, contact your Stella Agent and advise them of the error code details and graphics
	**Prevent shock-hazard** • Always read the instruction manual first before using the power supply • Risk of electric shock - Use approved Power Adaptor only • While charging place Stella units and power adaptor in a dry area • Do not use power adaptor in wet areas • Never use a power adaptor with damaged housing or cable • Never modify the power adaptor or opens its housing • Connect the power adaptor to a regular power outlet • Protect connectors from moisture and damp areas
	**Prevent property damage** • Never carry the power adaptor by its electrical cable or pull at the cable • To remove the adaptor from the power outlet always pull on the plug, never the cable • The DC power cable must be installed safely to avoid tripping over • Disconnect the power supply during thunderstorms • Only use original spare parts or accessories supplied with the power adaptor • Keep power covers closed when Stella units are in use
	**Personnel protection** • Wear protective clothing and protective eye wear during use • Do not place Stella units on charge in wet areas • Keep working area and walkways clear of obstacles • Ensure appropriate safety precautions are observed during use • Ensure adequate lighting is provided for the Stella system working area • Identify areas for potential leakage and rectify before use • In the event of spillage clean and dry the area immediately
	**Operating Temperature** Operation 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.
	**For indoor use only** Use Stella system in designated area for decontamination of medical devices.
CE 2797	**CE Mark** The Stella Devices conform to the Medical Device Directive 93/42/EEC as amended by 2007/47/EC.
FC	**FCC Mark** The Stella system complies to the Federal Communications Commission Regulation FCC 47 CFR Part 15, Subpart B (Unintentional Radiators).

IP64	**Ingress Protection** Protected against dust ingress and water spray from all directions with Power covers closed. Limited ingress may occur.
	Bluetooth enabled
	USB enabled
	Disposal Recycle in accordance with the WEEE Directive. Under the European Directive 2012/19/EU this electronic device must not be disposed of to normal waste. Dispose of the Stella system, power adaptor and batteries via the designated take-back system. Contact your local supplier.
RoHS COMPLIANT	**Restriction of Hazardous Substances - RoHS 3** Under the European Directive 2015/863 this electronic device complies with the maximum levels for restricted substances.
	Material can be recycled
SN	**Serial Number**
LOT	**Lot Number**
	Date of manufacture
	Fragile. Handle with care
DO NOT STACK	**Do not stack pallets**

MANUFACTURER

Tristel Solutions Limited
Lynx Business Park, Fordham Road, Snailwell,
Cambridgeshire, CB8 7NY, United Kingdom
T +44 (0)1638 721 500 - **F** +44 (0)1638 721 911
E mail@tristel.com - **W** www.tristel.com

CE 2797 The Stella system is CE marked as a Class IIb medical device as per the Medical Device Directive 93/42/EEC as amended by 2007/47/EC.

EC REP Tristel NV, Smallandlaan 14 B, 2660 Antwerp, Belgium

STL/019/Issue 16-September 2020

SECTION NINE

STELLA AGENTS

SECTION NINE: STELLA AGENTS

AUSTRALASIA

NEW ZEALAND

Tristel New Zealand Limited
23 Birch Avenue
Judea, Tauranga
New Zealand
T +64 7 577 1560
E mail-nz@tristel.com

AUSTRALIA

Tristel Pty
40/328 Reserve Road
Cheltenham, VIC 3192
Australia
T +1300 680 898
E mail-au@tristel.com

EUROPE

UNITED KINGDOM & REST OF THE WORLD

Tristel Solutions Limited
Lynx Business Park
Fordham Road, Snailwell
Cambridgeshire
CB8 7NY
United Kingdom
T +44 (0)1638 721 500
E mail@tristel.com

FRANCE

Ecomed Services
130, Boulevard de la Liberté
59000 Lille
France
T +33 (0) 3 66 88 01 84
E info@ecomed.eu

BELGIUM

Ecomed Services
Smallandlaan 14B
2660 Hoboken
Belgium
T +32 (0)3 889 26 40
E info@ecomed.eu

GERMANY & AUSTRIA

Tristel GmbH
Karl-Marx-Allee 90A
10243 Berlin
T +49 (0)30 5484 4226
E vertrieb@tristel.de

ICELAND

Icepharma
Lynghálsi 13
110 Reykjavík
Iceland
T +354 540 4324
E icepharma@icepharma.is

ITALY

Tristel Italia S.r.l.
Via dei Mille, 10
20129 Milano
Italy
T +02 83520915
E info@tristel.it

PORTUGAL

Teprel – Equipamentos Médicos, S.A.
Adress: Rua D. Marcos da Cruz, 1997 – 1º Poente
4455-482 Perafita
Portugal
T +351 22 999 9880
E info@teprel.com

REPUBLIC OF IRELAND

Brennan & Company
61 Birch Avenue
Stillorgan Industrial Park
Stillorgan, Co. Dublin
Republic of Ireland
T +353 (1) 295 2501
E enquiries@brennanco.ie

ROMANIA

Timberstar SRL
Strada Narciselor Nr.8,
Sângeorgiu de Mureş 547530,
Romania
T +40 265 265 110
E office@timberstar-medical.ro

RUSSIA

Tristel International Ltd
5 Koloncova Street,
Mytishchi,
Moscow region, 141009
Russia
T +7 (495) 766-87-73
E info@tristelrussia.ru

DENMARK

ViCare Medical A/S
Birkerød Kongevej 150B
3460 Birkerød
Denmark
T +45 45 82 3366
E info@vingmed.dk

FINLAND

Otoplug Oy
Osuusmyllynkatu 7
33700 Tampere,
Finland
T +358 40 5789 330
E otoplug@otoplug.fi

NORWAY

Vingmed AS
Solbråveien 13
1383 ASKER
Norway
T +47 67 58 06 80
E info@vingmed-as.no

SWEDEN

Vingmed AB
Box 576
SE-175 26 JÄRFÄLLA
Sweden
T 08-583 593 00
E info@vingmed.se

SWITZERLAND

ANKLIN AG
Bodenmattstrasse 34
4153 Reinach
Switzerland
T +41 61 717 55 55
E info@anklin.ch

SLOVENIA

Medip d.o.o.
Taborska cesta 4
1290 Grosuplje
Slovenia
T +386 3177 3989
E info@medip.si

EUROPE

MALTA

Associated Equipment
Lourdes Square
Rihan Avenue
San Gwann, SGN2010
Malta
T (+356) 21384347
E purchasing@associated-equipment.com

SPAIN

Vesismin S.L.
C/ Llucà 28, 5º planta
08028-Barcelona
Spain
T +34 934 09 53 01
E vesismin@vesismin.com

NORTHERN IRELAND

SMC
Units 6 & 7
Carrowreagh Business Park
Dundonald
BT16 1QQ
Northern Ireland
T +44 (0) 2890 410 136
E info@smcni.com

ASIA AND MIDDLE EAST

CHINA

Tristel Medical Equipment (Shanghai) Ltd
Room 203, 277 Danshui Road
Huangpu District
Shanghai 200025
China
T +86 (21)8016 2555
E 888@tristel.com

TAIWAN

Meta-Medic Co., Ltd.
16/F - 1,
No. 738 Zhongzheng Road
Zhonghe District
New Taipei City, Taiwan
T +886 2 2369 8172
E product@mediunion.com.tw

HONG KONG & MACAU (SAR)

Tristel Asia Limited
21st Floor, Union Park Tower
168 Electric Road
Fortress Hill
Hong Kong
T +852 2895 6968
E customerservicehk@tristel.com

ISRAEL

Sachar Medical Technologies
20 Zvi Berkman St.
Petach Tiquwa
4927976
Israel
T + 972(7)75513925
E sachar.medtech@gmail.com

SINGAPORE

EO Medical Pte. Ltd.
29 Media Circle
#04-23
Singapore 138565
T +65 6100 5060
E orders@eo.com.sg

PAKISTAN

Uniprom Healthcare
L-151, 2nd Floor
Sehba Akhter Road Block 13-G
Gulshan-e-Iqbal
Karachi
Pakistan
T +92 (41) 871 3751
E info@unipromhealthcare.com

SAUDI ARABIA

Fal Care Trading Est.
P.O.Box: 48520
Jeddah 21414
Saudi Arabia
E info@cayane.net

SOUTH KOREA

HP&C Limited
12, Yeongdong-daero 71 gil
Gangnam-gu Seoul,
South Korea 135-848
T +82-2-553-7895

UNITED ARAB EMIRATES, BAHRAIN, KUWAIT, QATAR, OMAN & JORDAN

Fal Care FZE
Saif desk Q1-09-108/B PO Box 514484 Sharja
United Arab Emirates
E info@falcare.com

MALAYSIA

Tristel Malaysia Sdn. Bhd, A-25-3A Pinnacle PJ
Lorong Utara C
46200 Petaling Jaya
Selangor Darul Ehsan
Malaysia
T +603 79317791
E tristelmalaysia@tristel.com

AFRICA

SOUTH AFRICA

Be Safe Paramedical
58 Promenade Road
Muizenberg
Cape Town
7945
South Africa
T +27 (0) 21 788 4681
E info@be-safe.co.za

For all other areas, please contact our headquarters in the United Kingdom.


Tristel
WE HAVE CHEMISTRY.