Reference Manual

BioTube™ Applicator 125/625-1

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0 Preface

0.1 Disclaimer

The information contained in this document is believed to be correct, but Watson-Marlow Limited accepts no liability for any errors it contains and reserves the right to alter specifications without notice.

If the product is used in a way not intended or described by Bio Pure Technology Limited (BioPure) or any Watson-Marlow Fluid Technology Solutions (WMFTS) company, then the protection, performance, and/or lifespan may be negatively affected.

0.2 Original instructions

This reference manual has originally been written in English. Other language versions of this reference manual are a translation of the original instructions.

0.3 Trademarks

BioTube™ is a registered trademark of Bio Pure Technology Limited.

TABLE OF CONTENTS

1 Introduction to the document

1.1 Information types

Specific non-safety information is presented throughout this document in the following format:

Information type	Explanation
Glossary definitions	Words in bold and lower case are defined in the glossary. These words are only shown in bold when first used in this document.
Note	A note is a piece of additional information to consider. A note is indicated by a superscript.

1.2 Document scope

This document is the reference manual, for all models of a BioTube™ Applicator. It contains information on the safe use of the product during all tasks of the product lifecycle.

1.3 User groups

This document must only be referenced by a responsible person.

1.3.1 Responsibility

Prior to a task, a responsible person must use these instructions to:

- Ensure product is within scope of Intended Use: See section 3.2
- Do a risk assessment to identify hazards, and methods to reduce risks, in accordance with the user organisations control measures, such as working procedures and suitable Personal Protective Equipment. See section 2.3
- Produce operator instructions for a designated operator based upon the user's specific tube assembly fixtures, components and production assembly order.
- Train a designated operator.

A designated operator must only use the operator instructions prepared by their responsible person for reference.

2 Safety

2.1 Safety symbols

The following safety symbol are used on the product, packaging and in these instructions:

Symbol	Name	Description	Section of manual to reference
	Single designated operator only	Indicates that it is mandatory that the product is only to be used by a single designated operator.	• 8.1.2.1 • 8.2.2
	Crushing hazard	Indicates that there are moving parts that can cause trapping or crushing injuries.	• 11.3.1.1 • 11.5.2.3
	Potential hazard	Indicates that an appropriate safety instruction should be followed, or a potential hazard exists.	• 13.5.1.1 • 9.2.4 • 13.5.1.2 • 13.5.1.3 • 13.5.1.3.1 • 13.5.1.3.2
	Two person lift	Indicates that the product is heavy, and a two person lift is mandatory using suitable PPE.	• 5.2.2 • 5.2.3 • 8.2.2 • 15.2
	Wipe down only	Indicates that the product is suitable for cleaning by wipe down only.	• 12.1.1
	Refer to reference manual	Indicates to refer to this reference manual in order to find out the nature of potential hazards and any actions which have to be taken to avoid them.	• All sections and content
	PPE required	Indicates Personal Protective Equipment (PPE) must be worn prior to a task.	• 9.2.3.1 • 11.3.2.1 • 13.5.1.1.1

2.1.1 Location of safety symbol labels on a BioTube™ Applicator

Safety symbol labels are located on a BioTube™ Applicator as shown in the following picture and explanation table.

Item	Description	Item	Description
1	Single designated operator only	5	Crushing hazard [1]
2	Two person lift	6	Potential hazard (Compressed air)
3	Wipe down only	7	Potential hazard (Product weight)
4	Wear correct PPE	8	Refer to reference manual (All sections and content)

NOTE[1]	Located on integrated shutdown safety cover.

2.1.2 Replacing safety symbol labels

If the safety labels on the product become accidentally damaged, contact your local WMFTS representative for information on obtaining replacements.

2.2 Safety signals

Signals indicate a possible hazard. Signals are used in these instructions when immediately relevant to the information, task or procedure.

2.2.1 Signals: With risk of personal injury

Signals indicating risk of a personal injury are presented when relevant to a task in this format:

WARNING

The WARNING signal word indicates a hazard. Risk of serious injury or death exists if the hazard is not avoided. Equipment or property damage may also occur.

 A safety symbol indicates a hazard with personal injury risk.	Hazard information—Information to explain: • What could happen • How to avoid hazard

CAUTION

The CAUTION signal word indicates a hazard. Risk of minor or moderate injury exists if the hazard is not avoided. Equipment or property damage may also occur.

 A safety symbol indicates a hazard with personal injury risk.	Hazard information—Information to explain: • What could happen • How to avoid hazard

2.2.2 Signals: With risk of equipment or property damage only

Signals indicating risk of equipment or property damage only are presented when relevant to a task in this format:

NOTICE

The NOTICE signal word indicates a hazard. Risk of equipment or property damage only.

Hazard information—Information to explain:

- What could happen
- How to avoid hazard

2.3 Personal Protective Equipment (PPE)

The following minimum PPE, suitable for use in a class 7 cleanroom, will be required during specific tasks:

- Safety glasses
- Safety boots
- Gloves
- Gown

A responsible person must determine the suitability of the PPE for:

- The user's environment and application.
- Use of Isopropyl Alcohol 70 % as a wipe down only cleaning agent. See section 12
- If additional PPE is required prior to a task.

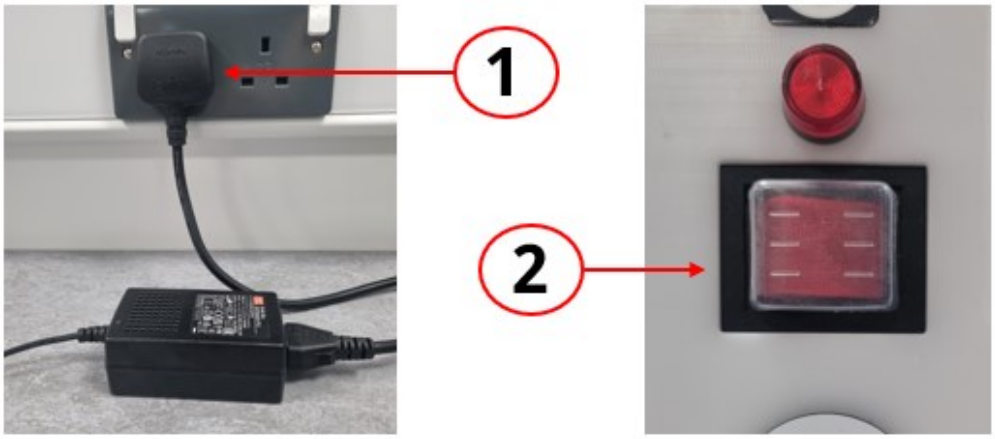
2.4 Product damage—Remove from service

In the event of product damage: Do not continue to operate the product. The product must be removed from service by a responsible person. See section 15.

2.5 Emergency electrical power shutdown

In an emergency, the electrical power must be isolated from the machine by removing the power plug from its socket. The electrical power switch is a convenience feature, to allow the machine to be turned on and off, during intermittent use, without removing the power plug.

The power switch is not designed as an emergency shutdown device. These items are shown in the following pictures and explanation table:



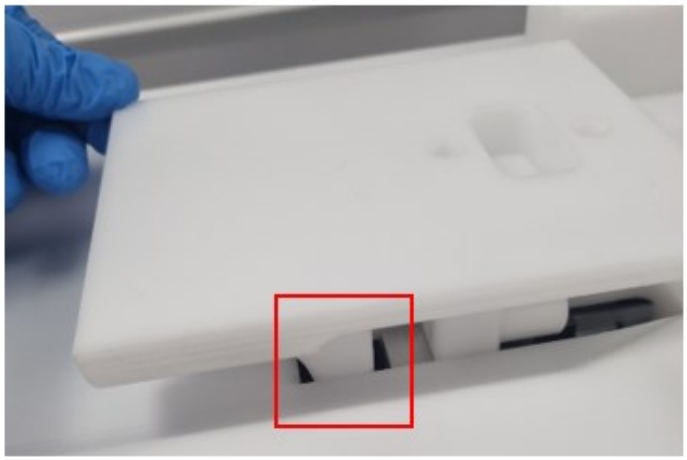
Item	Name
1	Geographical AC power plug [1]
2	Electrical power on/off switch

NOTE[1]	The geographical AC power plug varies by model, See section 10.1.1 for more information.

2.6 Safety features

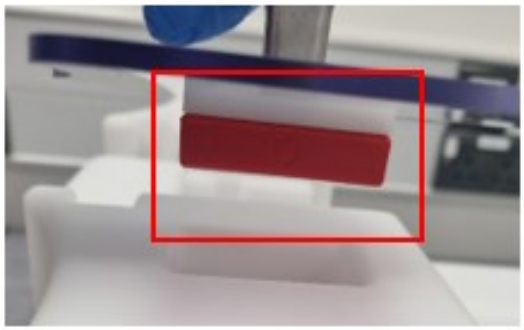
2.6.1 Cradle interlock

The cradle interlock is a primary safety device, which allows the machine to only become operable when a cradle is both in place and contacting an integrated safety limit switch.



2.6.2 Integrated shutdown safety cover

The integrated shut down safety cover is a secondary safety device, which allows the machine to only become operable when the safety cover is closed by electrical contact with a sensor connected to the integrated interlock actuator.



2.6.3 Two handed control system

The dual actuator buttons are a secondary safety feature. Both buttons must be pressed simultaneously[1] in order for the machine to operate. If either button is released, the machine will abort its cycle.

NOTE[1]	The buttons must be pressed with 0.5 seconds of each other. If this does not happen the blue light will come on and a cycle reset will be required. See section 11.5.1

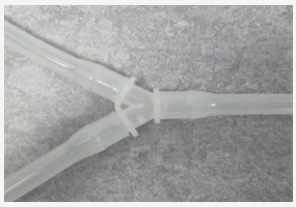
2.6.3.1 Specific hand placement

The actuator buttons must be pressed simultaneously with a specific hand placement as shown in the following picture until the cycle has completed.

3 Product overview

3.1 Product introduction

A BioTube™ Applicator is a semi-automatic, Programmable Logic Controlled (PLC), single operator pneumatic machine, designed to join a range of pharmaceutical tubing and components without the use of lubricants, to produce the following tube assemblies.

Single tube assembly	Filter tube assembly	Y connector tube assembly
		

3.1.1 Overview of tube assembly creation process

An overview of tube assembly sequence using a filter assembly, as an example is provided in the following table.

STEP 1	STEP 2	STEP 3	STEP 4
Filter assembly installed on cradle and placed inside the BioTube™ Applicator.	Tubing placed in jaws and tube support.	When the dual actuator buttons are pressed, the tube is pneumatically clamped, while the cradle moves horizontally to push a barb into the tube.	Completed tube and filter assembly.
			

3.2 Intended use

A BioTube™ Applicator is designed to join a range of pharmaceutical tubing and components without the use of lubricants, with the following restrictions:

- Use by a single designated operator only.
- Use in a restricted safe area, where no other person is within 2 m (6.56 ft) of the designated operator when the operator has two hands on the actuator buttons.
- Use with BioPuredesigned application specific, interchangeable tube assembly fixtures only.
- Use in an ISO 14644 Class 7 cleanroom only.

3.2.1 Prohibited use

The following applications are prohibited from use:

- Use in an environments which require explosion proof certification.
- Use in applications which are directly life sustaining.

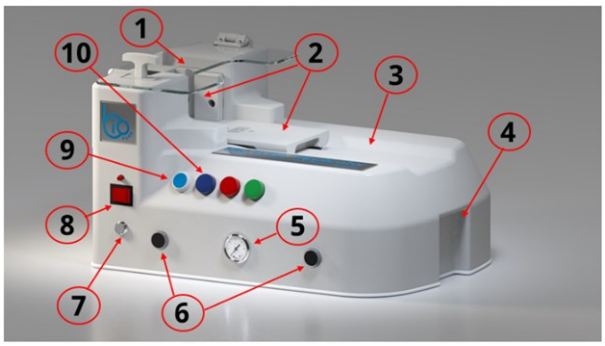
3.3 Tube assembly fixtures

A tube assembly is created by a BioTube™ Applicator using interchangeable tube assembly fixtures, which are designed by BioPure for a specific user application.

An overview of these tube assembly fixtures is provided in the following table.

Item	Picture	Purpose	Variations
Tube support		Supports the tubing during assembly	Variations to suit tubing from 3.2 mm - 25.4 mm (1/8” to 1”) internal diameter
Jaws		Clamps the tubing during the assembly	Variations: • Standard • Extended • Raised
Cradle		Holds a specific fixture	Variations: • Type 1: Mandrel holder • Type 2: For Y connector • Type 3: For capsule filters
Mandrel		Holds barb for connection to tubing	Variations to suit BioBarbs from 3.2 mm - 25.4 mm (1/8” to 1”) internal diameter
Mandrel holder		Supports mandrel	No variation—Suitable for full range of Mandrels

3.4 BioTube™ Applicator: General arrangement



The full product general arrangement is provided below:

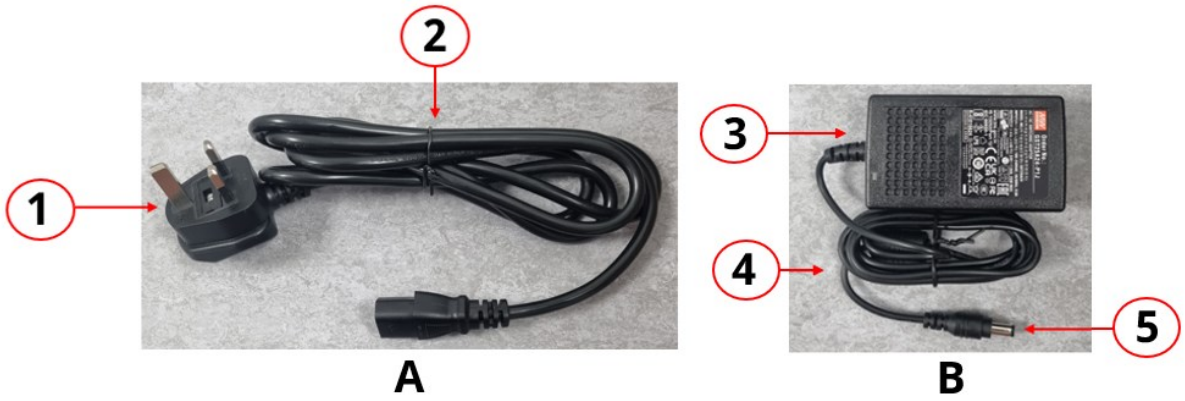
Item	Description	Item	Description
1	Integrated shutdown safety cover	8	Electrical power On/Off switch
2	Location of cradle, jaws, tube support, mandrel and mandrel holder	9	Cycle reset facility
3	Main body	10	Cycle indicator lights
4	Recess to aid grip when lifting and carrying	11	Electrical DC power supply connection
5	Air pressure gauge	12	Air exhaust filter (connected to air output connection)
6	Dual actuator buttons	13	Air input connection
7	Pecking stroke count switch (key lockable)		

3.5 Power supply introduction

The BioTube™ Applicator operates by +24 DC voltage from the power supply assembly supplied with the machine. The power supply assembly converts a 100-240 V AC 50-60 Hz power supply to the +24 V DC required by the machine. The use of the supplied power supply assembly is mandatory. No other power supply may be used.

3.5.1 Power supply assembly: General arrangement

The power supply assembly is comprised of two main parts (A + B) which connect to each other. See following picture and table for explanation.



Part	Item	Explanation
A	1	Power plug (Geographical[1] based on model/product code)
	2	AC power supply cable (Geographical[1] based on model/product code)
B	3	Power supply unit which converts AC voltage to 24 V DC voltage, with integrated DC power cable and DC power connector (Male)
	4	Integrated DC power cable
	5	Integrated DC power supply connector (+ 24 V DC, Male)

NOTE[1]

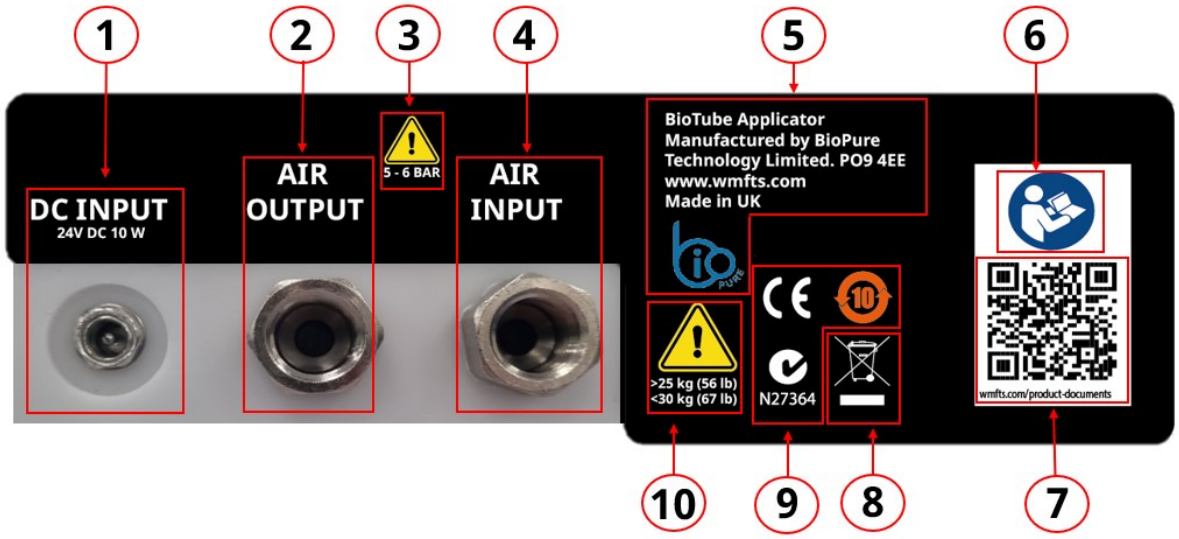
There are two unique models of a BioTube™ Applicator, based upon the geographical region :

Geographical region	Product code	Power plug
Europe	BTA125/625-1-EU	European
United Kingdom	BTA125/625-1-UK	UK

3.6 Product marking

3.6.1 Marking—Rear label

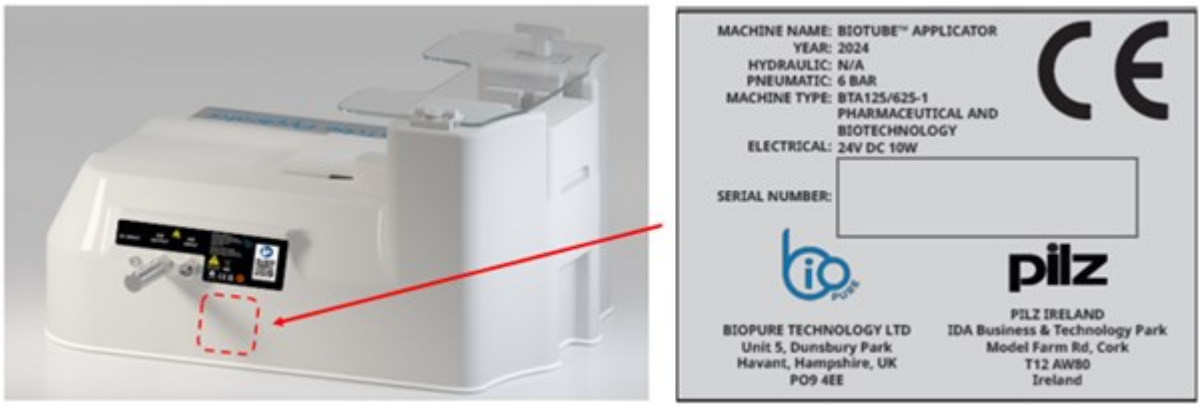
The product label is at the rear of the product.



Item	Description	Item	Description
1	Electrical DC power supply connection (Female)	6	Safety symbol: Refer to these instructions prior to a task
2	Air output for connection of the exhaust filter	7	QR code for link to these instructions
3	Safety symbol for compressed air. See section 9	8	Disposal Symbol (not household waste)
4	Air input for connection of the compressed air	9	Compliance symbols
5	Product manufacturer contact details	10	Safety symbol for product weight. See section 5.2.2 for lifting and carrying procedures

3.6.2 Marking—CE marking plate

A CE marking plate is attached to the BioTube™ Applicator containing all required information.



3.7 Product code

The purchase of a BioTube™ Applicator by product code, includes 3 major groups of product codes:

- **Group 1**: The machine itself based upon the geographical region.
- **Group 2**: Tube assembly fixtures designed by BioPure for the application.
- **Group 3:** Tube assembly consumables (Tubing, Bio Barbs, Filter Barbs) for use with the machine to create the desired tube assembly.

Items from each of these groups must be purchased in order to produce a desired tube assembly.

3.7.1 Group 1: Machine

As detailed in the table below, the product code of the BioTube™ Applicator, depends on the geographical region of its intended use:

Geographical region	Product code	Power plug
Europe	BTA125/625-1-EU	European
United Kingdom	BTA125/625-1-UK	UK

3.7.2 Group 2: Tube assembly fixtures

The tube support, jaws, cradle, mandrel and mandrel holder are of a specific design by BioPure for each application. These items must be purchased in addition to a BioTube™ Applicator.

Contact your local WMFTS representative, to discuss the product codes for ordering these items.

3.7.3 Group 3: Tube assembly consumables (Tubes, Bio Barbs, Filter Barbs)

For product codes of WMFTS products which are suitable for use with the BioTube™ Applicator to produce a desired tube assembly, contact your local WMFTS representative.

3.8 Specifications

This section provides an overview of specifications. Detailed installation specification is provided when relevant to the installation task.

3.8.1 Physical specification of BioTube™ Applicator

The physical specification of the BioTube™ Applicator is provided below.

3.8.1.1 Intended environment and operating conditions

The product must be installed such that no part exceeds the environment limits provided in the following table:

Item	Specification
Ambient temperature range	5 °C to 40 °C (41 °F to 104 °F)
Maximum humidity (non-condensing)	Maximum relative humidity 80 % for temperatures up to 31 °C (88 °F), decreasing linearly to 50 % relative humidity at 40 °C (104 °F).
Maximum altitude	1,000 m (3,281 ft)
Environment	Indoor use only, in a ISO 14644 Class 7 cleanroom, where any chemicals in the environment, which a BioTube™ Applicator may be exposed to, are chemically compatible[1] with the materials of construction.
Ingress protection	A BioTube™ Applicator does not have an ingress protection rating.

NOTE[1]	See section 16 for a list of materials of construction to determine chemical compatibility.

3.8.1.2 Noise

A BioTube™ Applicator can produce a maximum noise of <70 db(A) at 1 m.

3.8.1.3 Cycle time

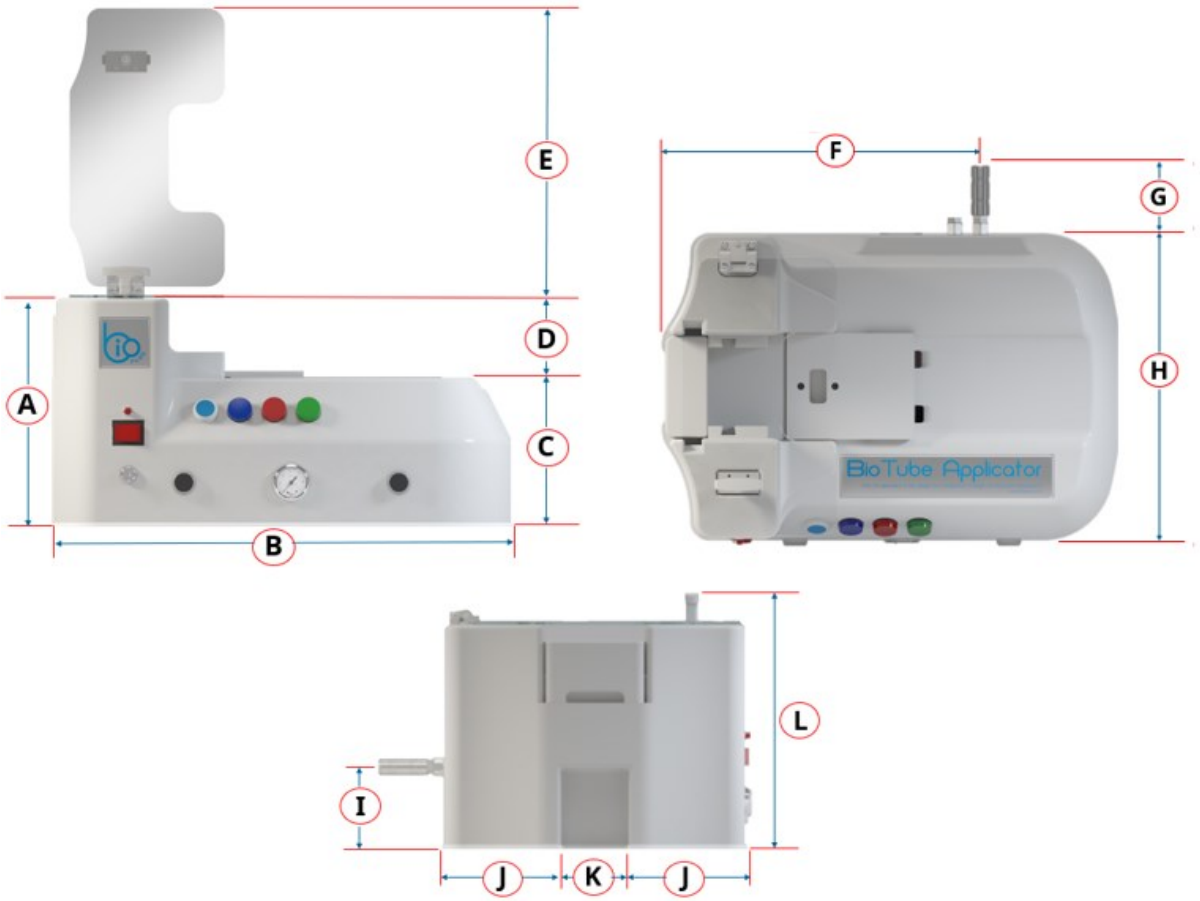
A BioTube™ Applicator has a cycle time of 6 seconds per pecking stroke. For example at pecking stroke count setting 4, the cycle time is 24 seconds for a full cycle .

3.8.1.4 Weight

The weight of all BioTube™ Applicator models is 25 kg to 30 kg (55.1 lbs to 66.1 lbs)[1]. This weight excludes the power supply assembly, tube assembly fixtures, and protective case.

NOTE[1]	The weight range is due to material weight tolerance.

3.8.1.5 Dimensions



A		B		C		D		E		F	
mm	in	mm	in	mm	in	mm	in	mm	in	mm	in
272	10.7	537	21.1	173	6.8	99	3.9	338	13.3	372	14.6
G		**H**		**I**		**J**		**K**		**L**	
mm	in	mm	in	mm	in	mm	in	mm	in	mm	in
76	3.0	359	14.1	97	3.8	140	5.5	80	3.1	309	12.2

3.8.2 Compressed air specification

Product requires compressed air of the following specification.

Item	Specification
Air supply quality	Dry[1], filtered (≤25 µm) air in accordance with EN ISO 4414
Inlet pressure	5 bar min to 6 bar max (72.5 PSI min to 87.0 PSI max)
Flow rate	35 L/min (1.23 cfm)

NOTE[1]	The air must not be lubricated with oil.

3.8.3 Electrical power specification

3.8.3.1 DC power supply specification

The BioTube™ Applicator requires DC power, of the following specification:

Item	Specification
Voltage from power supply assembly	+24 V DC input
Maximum voltage fluctuation	±10 % of nominal voltage
Rated power	10 W
Connector on BioTube™ Applicator	Female

The power supply assembly converts a 100-240 V AC 50-60 Hz power supply to the +24 V DC required by the machine.

3.8.3.2 Power supply assembly: Specification

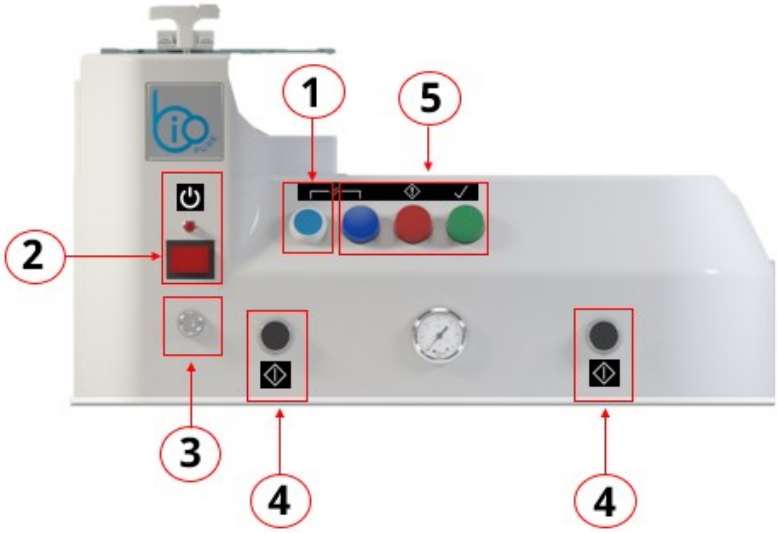
The specification of the power supply assembly is provided in the following table:

Item	Specification
Name	Mean Well GST25A24-P1J
Rated power	25 W maximum
Input voltage	100-240 V AC 50-60 Hz
Overvoltage category	II
Output current	1.04 A maximum
Output voltage	+24 V DC
Total length	3 m (9.84 ft) from geographical power plug to DC power connection.
Insulation class	1
IP rating	No IP rating
Geographical power plug	Non locking
In rush current	Cold start (35 A, 115 V AC), (65 A, 230 V AC)

3.9 Control overview

3.9.1 Controls

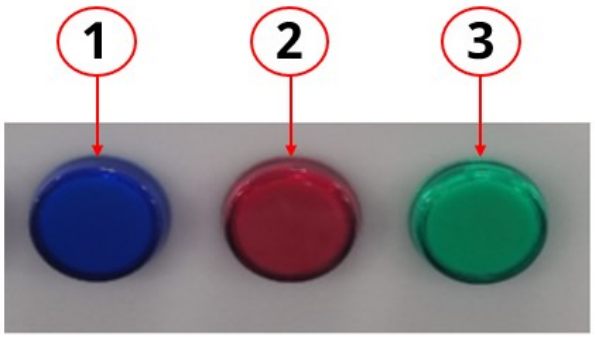
A BioTube™ Applicator, has the following controls and cycle indication:



Item	Name	Explanation
1	Cycle reset button	Resets the cycle if the cycle has not been completed correctly.
2	Power switch	Turns the machine on and off.
3	Pecking stroke selector (Key lockable)	Sets the number of automatic strokes (1 to 4) of the cradle to tube when the actuator buttons are pressed.
4	Cycle actuator buttons	The actuator buttons must be pressed with both hands, and held until the cycle has been completed. The cycle will automatically abort if either button is released.
5	Cycle status light indicators	Indicates the status of the cycle.

3.9.2 Cycle status indication lights

When the actuator buttons are pressed the machine carries out a cycle. The status of the cycle is shown on the machine by the light indicators:



Item	Light		Indicates	Illuminated when:	Extinguished when:
1		Blue	Cycle reset	Cycle reset button is pressed Or a cycle reset is required	Cycle reset is complete
2		Red	Cycle error or interruption	Safety integrated shutdown safety cover is open Cycle has not completed correctly Another fault has occurred (detected by PLC)	Integrated shutdown safety cover is closed Cycle has completed correctly
3		Green	Cycle completed	Cycle is completed	When next cycle starts

4 Storage

4.1 Storage conditions

The product must be stored according to the following conditions.

Item	Specification
Temperature	-25 °C to 70 °C (-13 °F to 158 °F)
Humidity (non-condensing)	Maximum relative humidity 80 % for temperatures up to 31 °C (88 °F), decreasing linearly to 50 % relative humidity at 40 °C (104 °F).
Location	• Indoors • Not in direct sunlight • In original packaging • Dry

5 Transportation, lifting and carrying

5.1 Part 1: Chapter requirements, specification, and information

5.1.1 Protective packaging case

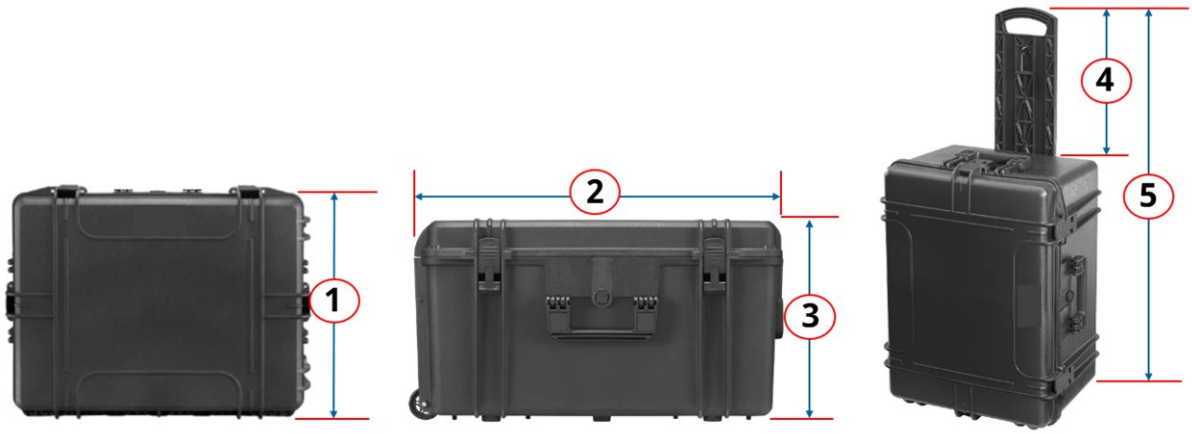
The product is supplied in a polypropylene protective packaging case.

5.1.1.1 General arrangement

The case has an integral trolley and extendable handle.

Item	Explanation
1	Extendable moving handle
2	Carrying handles (3 in total: Left, middle, right)
3	Integrated trolley wheels

5.1.1.2 Case dimensions



1		2		3		4		5	
mm	**in**	**mm**	**in**	**mm**	**in**	**mm**	**in**	**mm**	**in**
528	20.8	687	27.0	376	14.8	363	14.3	1050	41.3

5.1.1.3 Packed weight

Weight of case		Weight of BioTube™ Applicator		Total packed weight	
kg	Ibs	kg	Ibs	kg	Ibs
11	24.3	25 to 30	55.1 to 66.1	36 to 41	79.4 to 90.4

NOTE[1]	The weight range is due to material weight tolerance.

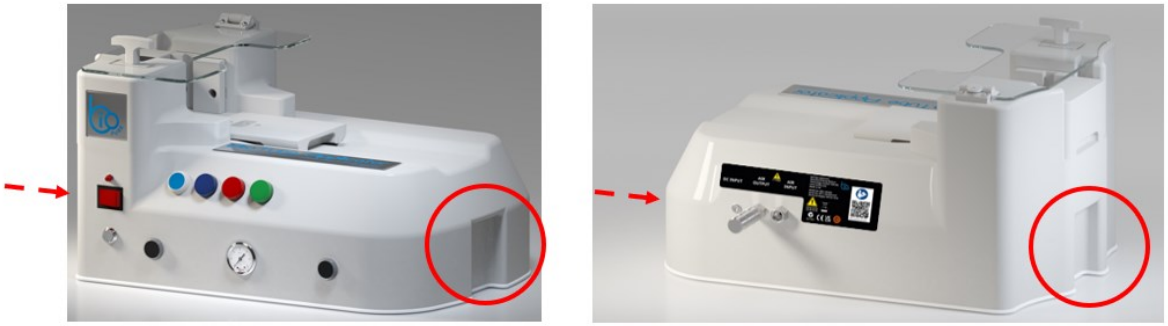
5.1.1.4 Case care

Once the BioTube™ Applicator, has been removed from protective case, retain the case and its inner foam inserts, for future storage and transportation[1].

NOTE[1]	A BioTube™ Applicator requires returning to BioPure for a service after 16,500 hours of continuous operation.

5.1.2 Recesses

The BioTube™ Applicator has two recesses as shown in the following picture. They can be used to help with grip or stabilisation when conducting a two person manual handling technique during lifting and carrying of the product.



5.2 Part 2: Chapter procedures

5.2.1 Procedure: Transporting the protective case

STEP 1	STEP 2	STEP 3	STEP 4
From the storage rest position, check the lid is locked closed, then place the case on its side with the extendable moving handle at top.	Pull the handle up to extend	Pull the case along using its trolley wheels.	Store the case in the storage rest position when the move is complete, by reversing steps 1 and 2.
			

5.2.2 Procedure: Lifting and carrying protective case

CAUTION

Product is heavy and may cause an injury or damage to the product or case.

A fully packed product weighs 36 kg to 41 kg (79.4 lb to 90.4 lb). When lifting or carrying the case, use a two person manual handling technique, using the case handles, while wearing suitable PPE in accordance with the user's organisations risk assessment.

To lift the case.

1. Wear suitable PPE.
2. Extend the carrying handles out from each side of the case. Use a two man manual handling technique in accordance with the user organisations polices to lift the case using the carrying handles.

3. When the list if complete, place the extended carrying handles back down, and store the case in the storage rest position.

5.2.3 Procedure: Lifting and carrying the BioTube™ Applicator

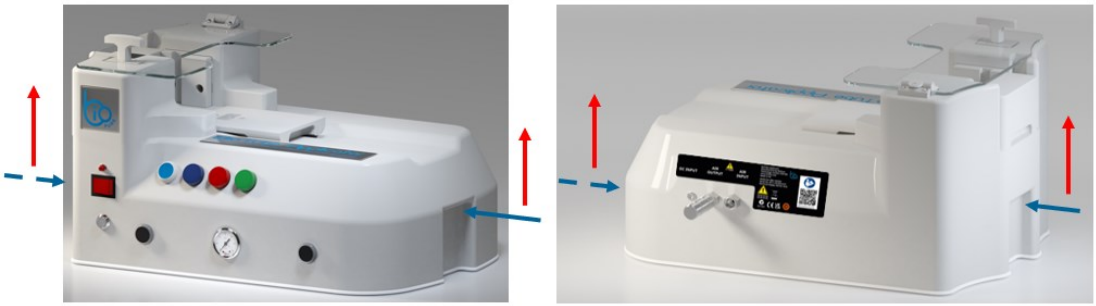
CAUTION

Product is heavy and may cause an injury or damage to the product or case.

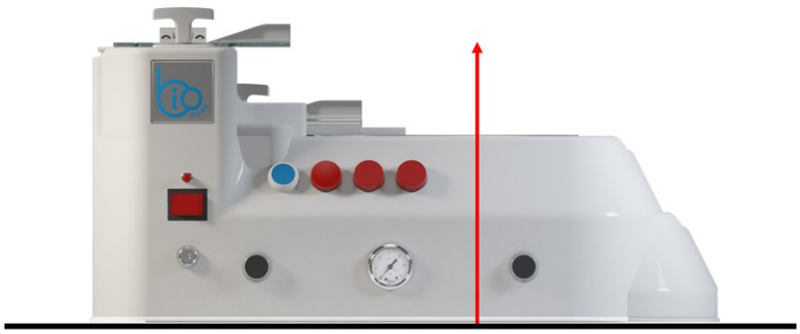
A BioTube™ Applicator weighs 25 kg to 30 kg (55.1 lb to 66.1 lb). Use a two person manual handling technique, using the recesses on the side of the product, while wearing suitable PPE in accordance with the user's organisation risk assessment. Do not lift the product by any other place than the recesses, such as the air exhaust filter or the integrated shutdown safety cover.

To lift the BioTube™ Applicator.

1. Wear suitable PPE.
2. Locate the recesses (shown by blue arrows) on each side of the machine, that can be used to place hands for stabilisation when lifting and carrying. Use a two man manual handling technique in accordance with the user organisations polices to lift the product.



3. When the lift if complete, place the product upright on a prepared surface.



6 Unpacking

6.1 Components supplied

The product will come with the following items included within the packaging / foam inserts inside the case.

6.1.1 In the protective case

- Selected model of product
- Safety information leaflet with QR code link to these instructions
- Declaration of Conformance
- Power supply assembly Part A: Geographical AC power cable with integrated power plug
- Power supply assembly Part B: Power supply unit (AC to DC) with integrated DC power connection to machine
- Compressed air supply hose
- Air exhaust filter

6.1.2 In separate packaging

The following tube assembly fixtures are sold and packaged separately

- Specific Tube support
- Specific Jaws
- Specific Cradle
- Specific Mandrel and Mandrel Holder

6.2 Procedure: Unpacking, and inspection of the BioTube™ Applicator

1. Use the procedures in See section to move and place the protective case on a level surface in the stored rest position in a suitable location, such as a clean room airlock.

2. Remove the transport straps from the protective case.
3. Open the protective case. The BioTube™ Applicator sits upright in the case so the safety screen is uppermost.
4. Use procedure from section 5.2.3 to lift BioTube™ Applicator out of the protective case.
5. Carefully remove all other parts from the protective case.
6. Check that all components from section 6.1 are present.
7. Inspect components for damage in transit. If anything is missing or damaged, contact your WMFTS representative immediately.
8. Store the protective case[1] for use at a later date.

NOTE[1]	Do not dispose of the protective case or its inner foam inserts. The case will be required for future storage and transportation of the product, such as a service.

6.3 Procedure: Unpacking, inspection and packaging recycling or disposal of tube assembly fixtures

1. Carefully remove all parts from the packaging.
2. Check that all components from section 6.1 are present.
3. Inspect components for damage in transit. If anything is missing or damaged, contact your WMFTS representative immediately. Do not attempt to install a product which is damaged.
4. Recycle or dispose of the packaging according to local procedures.

7 Installation—Overview

7.1 Installation chapter sequence

Installation is provided in the following sequence:

1. Installation—Chapter 1: Location and mounting
2. Installation—Chapter 2: Compressed air
3. Installation—Chapter 3: Electrical power

Follow the installation in the specific sequence above—The instructions have been written in a specific order to ensure product has:

- Located and mounted prior to further installation.
- Electrical power installed prior to first time operation.

7.2 Installation chapter structure

Each of the installation chapters are divided into two main parts:

1. Part 1: Installation requirements, specification, and information for the chapter.
2. Part 2: Installation procedures for the chapter.

8 Installation—Chapter 1: Location and mounting

A BioTube™ Applicator is designed to be placed on a horizontal surface such as a bench, table or plinth, without securing to the surface.

8.1 Part 1: Chapter requirements, specification, and information

8.1.1 Intended environment and operating conditions

The product must be installed such that no part exceeds the environment limits provided in the following table:

Item	Specification
Ambient temperature range	5 °C to 40 °C (41 °F to 104 °F)
Maximum humidity (non-condensing)	Maximum relative humidity 80 % for temperatures up to 31 °C (88 °F), decreasing linearly to 50 % relative humidity at 40 °C (104 °F).
Maximum altitude	1,000 m (3,281 ft)
Environment	Indoor use only, in a ISO 14644 Class 7 cleanroom, where any chemicals in the environment, which a BioTube™ Applicator may be exposed to, are chemically compatible[1] with the materials of construction.
Ingress protection	A BioTube™ Applicator does not have an ingress protection rating.

NOTE[1]	See section 16 for a list of materials of construction to determine chemical compatibility.

8.1.2 Intended product mounting

8.1.2.1 Restricted area

The BioTube™ Applicator must be mounted in an area that has restricted access, such that another person, must not be closer than 2 m (6.56 ft) to the designated operator while the dual actuator buttons are being pressed.

8.1.2.2 Area around the product

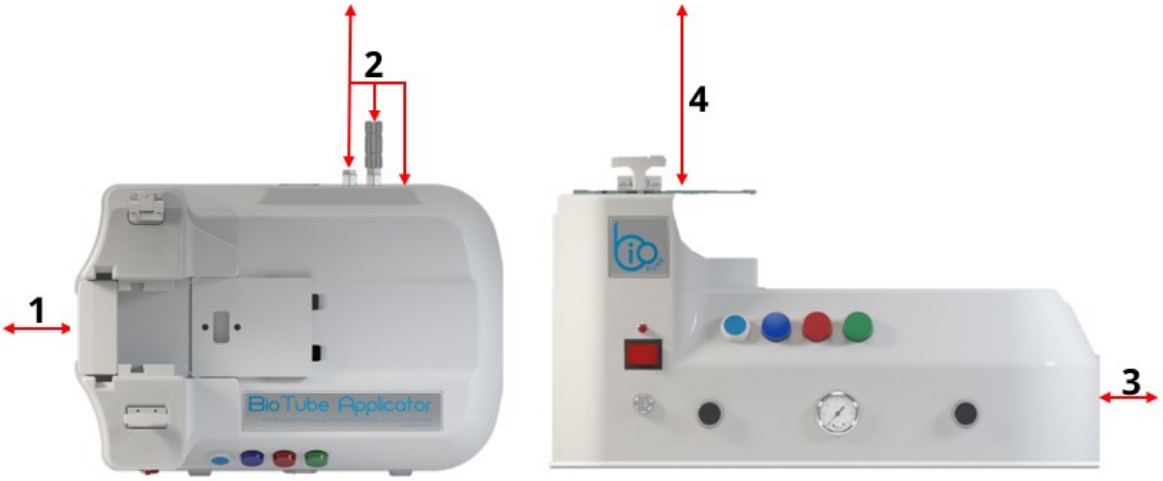
8.1.2.2.1 LIGHTING

A lighting survey is required to ensure suitable lighting in the area around the machine prior to a task.

8.1.2.2.2 INSTALLATION CLEARANCES

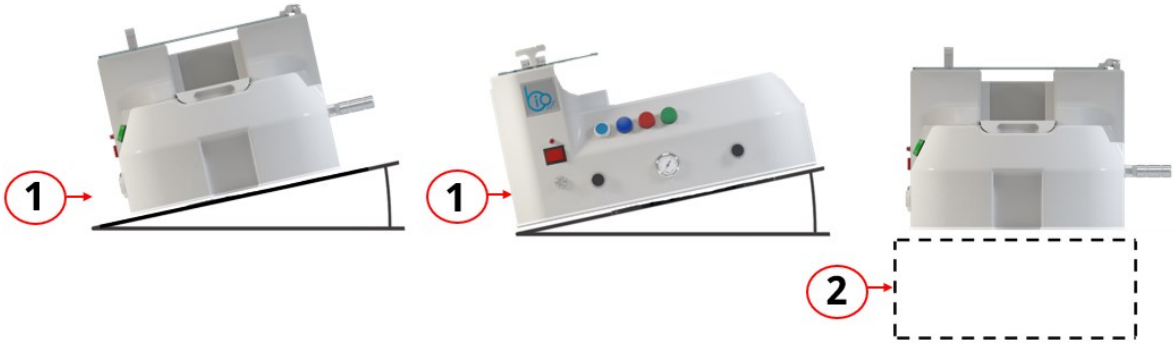
The product must always be accessible to enable additional installation, operation, cleaning, maintenance, troubleshooting, decommissioning or access the electrical power disconnecting device. Access points must not be obstructed or blocked.

The minimum installation clearances are provided in the illustrations and following table:



Item	Minimum clearance	Explanation of required clearance
1	1000 mm (39.4 in)	• Longer lengths of tubing to be inserted without damage to tubing • Access for lifting
2	1000 mm (39.4 in)	Access the back of the machine to: • Install and remove compressed air items and maintain a bend radius • Install and remove electrical power supply assembly and maintain a bend radius • Observe the rear label of the product
3	1000 mm (39.4 in)	• Access for lifting • Clearance for movement of cradle variations
4	700 mm (27.6 in)	Opening and closing of integrated shutdown safety cover

8.1.2.3 Surface and orientation



Item	Explanation
1	Install the product on a secure, horizontal and level surface.
2	The surface must be: • Suitable to ensure that product is at a comfortable height for operation. • Rated to support full weight of complete assembly and associated products. • Of an ergonomic height for operation. • Free of vibration.

8.2 Part 2: Chapter procedures

8.2.1 Chapter pre-installation checklist

Prior to following the installation procedures in this chapter, carry out the following pre-installation check to ensure:

1. All information and requirements in part 1 of this installation chapter is understood and ready for chapter installation.
2. Ensure the product is unpacked and not damaged

If there is a problem with any of the pre-installation checklist items, do not proceed to the installation procedures in this chapter, until the matter is resolved.

8.2.2 Procedure: Placing and mounting the product

1. Ensure the chapter pre-installation checklist is complete.
2. Ensure the surface on which the product is to be mounted is ready.
3. Place the product in the designated mounting place of the restricted area using the procedure from section 5.2.3 to lift and carry the BioTube™ Applicator.

CAUTION

Product is heavy and may cause an injury or damage to the product or case.

A BioTube™ Applicator weighs 25 kg to 30 kg (55.1 lb to 66.1 lb). Use a two person manual handling technique, using the recesses on the side of the product, while wearing suitable PPE in accordance with the user's organisation risk assessment. Do not lift the product by any other place than the recesses, such as the air exhaust filter or the integrated shutdown safety cover.

9 Installation—Chapter 2: Compressed air

A BioTube™ Applicator uses compressed air to pneumatically operate the tube assembly fixtures.

9.1 Part 1: Chapter requirements, specification, and information

9.1.1 Compressed air specification

Product requires compressed air of the following specification.

Item	Specification
Air supply quality	Dry[1], filtered (≤25 µm) air in accordance with EN ISO 4414
Inlet pressure	5 bar min to 6 bar max (72.5 PSI min to 87.0 PSI max)
Flow rate	35 L/min (1.23 cfm)

NOTE[1]	The air must not be lubricated with oil.

9.1.2 External devices

9.1.2.1 Isolation and pressure release

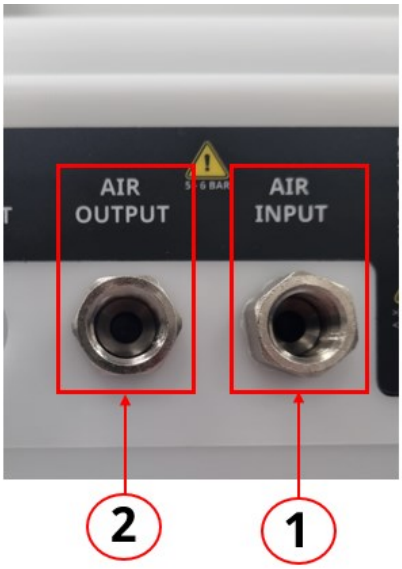
The main compressed air supply system must feature an air pressure isolation device and method of safely releasing pressure at the compressed air supply hose to air supply connection point, when required, such as for a maintenance activity.

9.1.2.2 Pressure regulator

The air supply will require a pressure regulator, at the compressed air supply hose to air supply connection point for fixed pressure air supply systems which operate at a higher pressure than 6 bar (87.0 PSI).

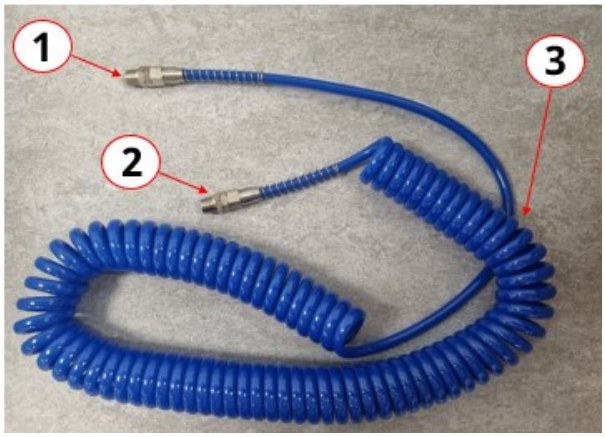
9.1.3 Air connections

There are two air connections on a BioTube™ Applicator located on the rear panel.



Item	Name	Purpose	Specification
1	Air input connection	For connection to the air supply	Female connector, ¼" Rc (BSPT) thread
2	Air output connection	For connection of the exhaust filter	Female connector, ¼" Rc (BSPT) thread

9.1.3.1 Compressed air supply hose



A compressed air supply hose is supplied with a BioTube™ Applicator to the following specification:

Item	Name	Specification
1	Hose air supply connector	Male connector, ¼" BSPT thread, Swivel type
2	Hose inlet connector to BioTube™ Applicator	Male connector, ¼" BSPT thread, Swivel type
3	Hose portion	• Length: 6 m (19.84 Ft), end to end • Maximum pressure: 10 Bar (145 PSI)

9.1.3.2 Air exhaust filter

The exhaust filter is supplied with a BioTube™ Applicator, which enables air to be directly exhausted by the machine, within a ISO 14644 class 7 cleanroom environment.

The exhaust filter is a consumable item which must be replaced every 2 years or when required due to a blockage. For further information see section 13.

9.2 Part 2: Chapter procedures

9.2.1 Items required for chapter installation

The following items are required to complete the chapter installation procedures.

- Open ended fixed size wrench to hold the BioTube™ Applicator air input and output connections.
- Open ended fixed size wrench to hold the compressed air supply hose connections.
- PTFE tape[1] for use with the air supply hose connectors.

NOTE[1]	PTFE tape is not required for installation of the air exhaust filter.

9.2.2 Chapter pre-installation checklist

Prior to following the installation procedures in this chapter, carry out the following pre-installation check to ensure:

1. The product has been installed in accordance with previous installation chapter(s).
2. All information and requirements in part 1 of this installation chapter is understood and ready for chapter installation.
3. The compressed air supply hose and exhaust filter are not damaged and to hand.
4. All items and tools for connection of the product to the compressed air supply are to hand.

If there is a problem with any of the pre-installation checklist items, do not proceed to the installation procedures in this chapter, until the matter is resolved.

9.2.3 Chapter safety while following procedures

9.2.3.1 Mandatory PPE

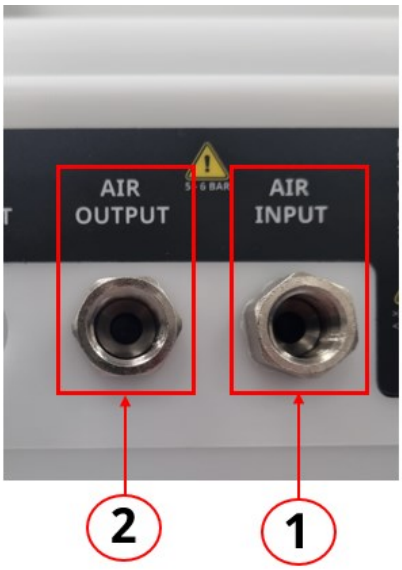
PPE must be worn while following procedures in this chapter.

CAUTION

PPE is required when connecting and setting the air supply to the BioTube™ Applicator. Failure to do so may result in an injury as a result of hose whip or an overpressure event created by incorrect installation.

9.2.3.2 Mandatory use of a tool

When following procedures in this chapter, the female air connections on the machine must be held with a wrench while either the air exhaust filter or the air supply hose connector is tightened.



CAUTION

Do not tighten the hose air supply connector or exhaust filter to the BioTube™ Applicator without holding the corresponding air connections with a wrench.

Failure to do so may result in a connection becoming loose inside the machine, resulting in permanent damage and a hazard to operation.

9.2.4 Procedure: Installation of exhaust filter

1. Complete the pre-installation checklist. See section 9.2.2
2. Wear suitable PPE.
3. Check that exhaust filter is not damaged or blocked.
4. Check the compressed air supply to the BioTube™ Applicator is not yet connected.
5. Hold the air output connection with a suitable sized wrench, then simultaneously screw in exhaust filter, until hand tight.

NOTICE

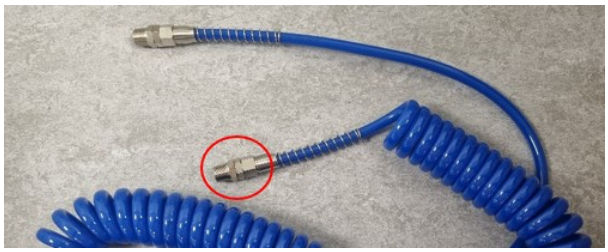
When installing the exhaust filter:

- Do not use PTFE tape—This is not necessary for a plastic component and could create a blockage.
- Do not use a tool on the exhaust filter, only on the air output female connector. The exhaust filter must only be hand tight.

A final check for air leaks takes place in the next procedure, during the compressed air supply installation.

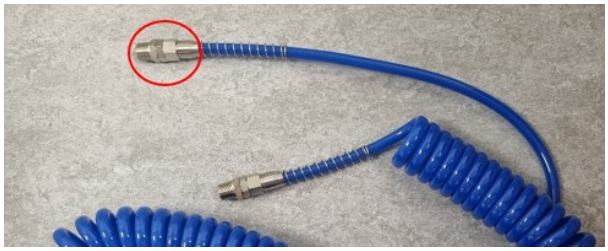
9.2.5 Procedure: Installation of compressed air supply to a BioTube™ Applicator

1. Wear suitable PPE.
2. Complete the pre-installation checklist provided in 9.2.2
3. Check the air exhaust filter is installed in accordance with procedure 13.5.1.1
4. Check the intended compressed air supply to the BioTube™ Applicator is isolated at the point of hose connection.
5. If an air pressure regulator is being used, set the compressed air supply regulator to 0 bar (0 PSI).
6. Identify both connectors on the air supply hose. See section 9.1.3.1
7. Apply PTFE tape to the compressed air supply hose connectors. Do not allow PTFE tape to block the end of either connector.
8. Hold the female air input connection with a suitable sized wrench, then simultaneously screw in the male hose inlet connector to BioTube™ Applicator until hand tight.



9. Using two wrenches, hold the air input connection with one wrench and use the other wrench to tighten the hose inlet connector to BioTube™ Applicator. The connection should look the same as in the following picture:

10. Connect the compressed air supply hose to the user's air supply, in accordance with the user organisations procedures, using the compressed air supply connector shown in the following picture:



11. Turn on the compressed air supply.
12. Observe the pressure gauge on the front of the BioTube™ Applicator. If a pressure regulator is being used, slowly increase the compressed air pressure regulator until the pressure gauge shows the 5 to 6 bar (72.5 PSI min to 87.0 PSI max) required air pressure.
13. Check the compressed air hose routing to ensure that it cannot create a hazard, such as tripping or accidental movement of the machine both during and after installation.
14. Check for leaks of compressed air from the:
    1. Exhaust filter connection
    2. BioTube™ Applicator compressed air connection
    3. Compressed air supply

    If leaks are found, tighten the connections a little bit at a time until the leak stops.

10 Installation—Chapter 3: Electrical power

10.1 Part 1: Chapter requirements, specification, and information

10.1.1 Power supply introduction

The BioTube™ Applicator operates by +24 DC voltage from the power supply assembly supplied with the machine. The power supply assembly converts a 100-240 V AC 50-60 Hz power supply to the +24 V DC required by the machine. The use of the supplied power supply assembly is mandatory. No other power supply may be used.

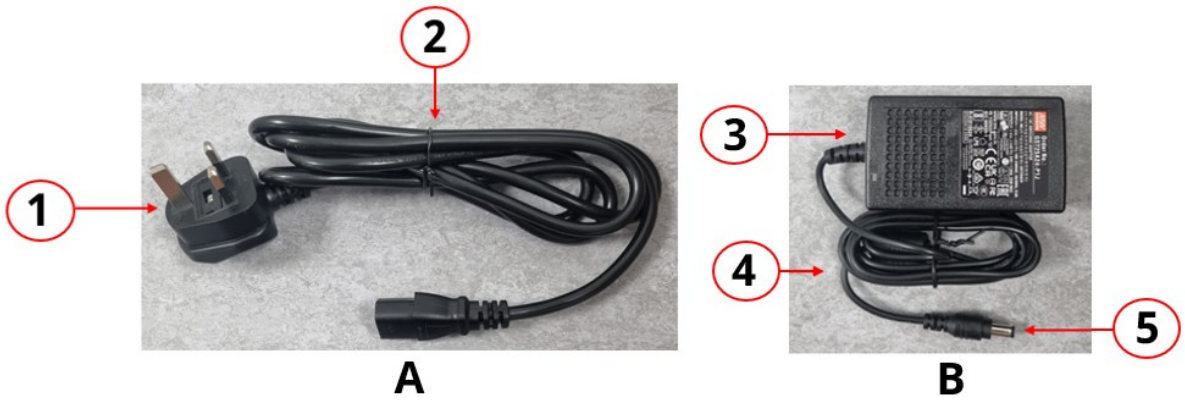
10.1.2 Power supply On/Off switch

The power on/off switch is a convenience feature, to allow the machine to be turned on and off, without removing the power plug from the socket, such as during regular but intermittent use.

The red power indicator light illuminates to indicate the machine is receiving power and the switch is in the ON position.

10.1.3 Power supply assembly: General arrangement

The power supply assembly is comprised of two main parts (A + B) which connect to each other. See following picture and table for explanation.



Part	Item	Explanation
A	1	Power plug (Geographical[1] based on model/product code)
	2	AC power supply cable (Geographical[1] based on model/product code)
B	3	Power supply unit which converts AC voltage to 24 V DC voltage, with integrated DC power cable and DC power connector (Male)
	4	Integrated DC power cable
	5	Integrated DC power supply connector (+ 24 V DC, Male)

NOTE[1]

There are two unique models of a BioTube™ Applicator, based upon the geographical region :

Geographical region	Product code	Power plug
Europe	BTA125/625-1-EU	European
United Kingdom	BTA125/625-1-UK	UK

10.1.4 Power supply assembly: Specification

The specification of the power supply assembly is provided in the following table:

Item	Specification
Name	Mean Well GST25A24-P1J
Rated power	25 W maximum
Input voltage	100-240 V AC 50-60 Hz
Overvoltage category	II
Output current	1.04 A maximum
Output voltage	+24 V DC
Total length	3 m (9.84 ft) from geographical power plug to DC power connection.
Insulation class	1
IP rating	No IP rating
Geographical power plug	Non locking
In rush current	Cold start (35 A, 115 V AC), (65 A, 230 V AC)

10.1.5 DC power supply connector location

The female BioTube™ Applicator DC power supply connector is located on the back panel.

10.1.6 DC power supply specification

The BioTube™ Applicator requires DC power, of the following specification:

Item	Specification
Voltage from power supply assembly	+24 V DC input
Maximum voltage fluctuation	±10 % of nominal voltage
Rated power	10 W
Connector on BioTube™ Applicator	Female

The power supply assembly converts a 100-240 V AC 50-60 Hz power supply to the +24 V DC required by the machine.

10.1.7 External devices

10.1.7.1 AC power supply stabilising equipment

If the quality of the AC power supply cannot be guaranteed, the use of appropriate commercial electrical supply stabilising equipment is recommended.

10.1.7.2 AC power plug geographical socket

The geographical socket which the power plug is connected to must feature a Residual Current Detector (RCD) socket with Ground Fault Circuit Interrupter (GFCI) protection in accordance with local regulations.

10.1.7.3 Replaceable fuse

The UK model contains a replaceable 3 Amp fuse, BS 1632 in the AC power plug.

All other geographical power plugs do not feature a replaceable fuse.

10.1.7.4 Electrical power disconnecting device (Electrical isolation)

The power plug is the electrical power supply disconnection device. The power plug is non locking, for connection to a corresponding power plug socket with RCD/GFCI protection.

The machine must be positioned so that the power plug is easy to reach in order for emergency access to isolate the machine from the electrical supply.

The power plug must not be removed from the AC power cable for permanent electrical connection of the machine.

10.2 Part 2: Chapter procedures

10.2.1 Chapter pre-installation checklist

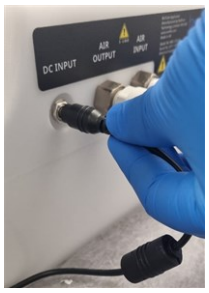
Prior to following the installation procedures in this chapter, carry out the following pre-installation check to ensure:

1. The product has been installed in accordance with previous installation chapter(s).
2. All information and requirements in part 1 of this installation chapter is understood and ready for chapter installation.
3. The power supply assembly is not damaged.

If there is a problem with any of the pre-installation checklist items, do not proceed to the installation procedures in this chapter, until the matter is resolved.

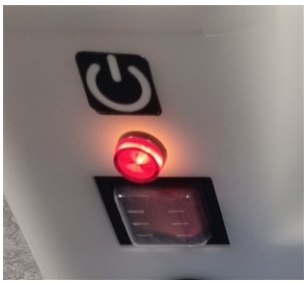
10.2.2 Procedure: Connecting to the power supply

1. Complete the pre-installation checklist provided in section 10.2.1
2. Ensure the geographical power plug socket is isolated from the power supply and ready for connection.
3. Push the male DC power connection on part B of the power supply assembly into the female DC power supply connection on the back of the BioTube™ Applicator.



4. Push part A and Part B of the power supply assembly together at the power supply unit.

5. Push the AC power plug into the power plug socket.
6. Check the power supply assembly routing to ensure that it cannot create a hazard, such as tripping or accidental movement of the machine both during and after installation.
7. Turn on the power supply to the power plug socket.
8. Toggle the power on / off switch to ON. The red light will illuminate.



11 Operation

A responsible person must produce operator instructions based upon the user's specific tube assembly fixtures, consumables, and production assembly order.

A designated operator must only use the operator instructions prepared by their responsible person for reference.

11.1 Section purpose

This section provides guidance based upon generic procedures and information, to assist a responsible person with the preparation of operator instructions.

11.2 Pre-operation checklist

A responsible person should consider a pre-operation checklist, to ensure the installation is safe for first time operation.

Ensure:

- A responsible person has installed the product in accordance with all installation chapters.
- A responsible person has trained and designated an operator.
- Power cable assembly is not damaged.
- The electrical power supply disconnecting device is easy to reach and operate for electrical power isolation when required.
- The compressed air supply hose is not damaged.
- The integrated shutdown safety cover is not damaged.
- The specified tube assembly fixtures for the application are to hand.
- The correct tubing and barb components are to hand for the application.

If there is a problem with any of the pre-installation checklist items, do not proceed to operate the product, remove from operation, until the matter is resolved.

11.3 Safety

11.3.1 Hazards that may occur during operation

The following hazards may occur during operation of the product.

11.3.1.1 Moving parts

CAUTION

The product has moving parts during operation. To prevent trapping or crushing injuries carefully follow the relevant operating procedures.

11.3.2 Chapter safety while following procedures

11.3.2.1 Mandatory PPE

PPE must be worn while following procedures in this chapter.

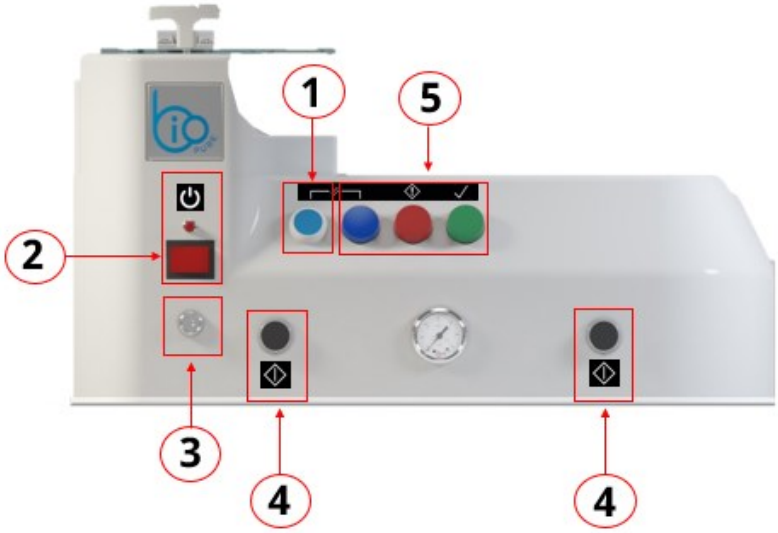
CAUTION

PPE is required to be worn during operating procedures. Failure to do so may result in an injury.

11.4 Control overview

11.4.1 Controls

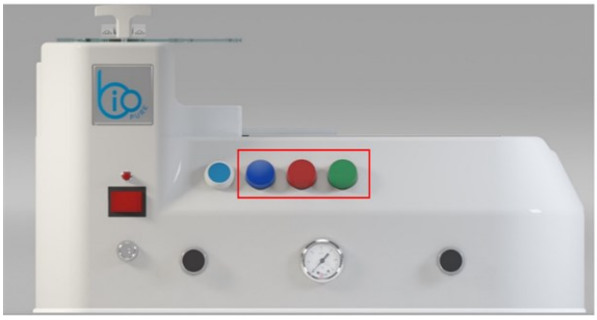
A BioTube™ Applicator, has the following controls and cycle indication:

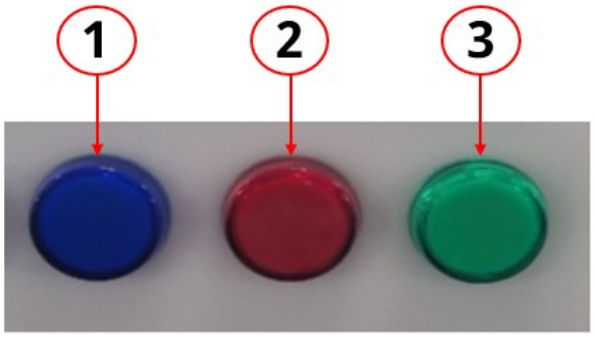


Item	Name	Explanation
1	Cycle reset button	Resets the cycle if the cycle has not been completed correctly.
2	Power switch	Turns the machine on and off.
3	Pecking stroke selector (Key lockable)	Sets the number of automatic strokes (1 to 4) of the cradle to tube when the actuator buttons are pressed.
4	Cycle actuator buttons	The actuator buttons must be pressed with both hands, and held until the cycle has been completed. The cycle will automatically abort if either button is released.
5	Cycle status light indicators	Indicates the status of the cycle.

11.4.1.1 Cycle status indication lights

When the actuator buttons are pressed the machine carries out a cycle. The status of the cycle is shown on the machine by the light indicators:





Item	Light		Indicates	Illuminated when:	Extinguished when:
1		Blue	Cycle reset	Cycle reset button is pressed Or a cycle reset is required	Cycle reset is complete
2		Red	Cycle error or interruption	Safety integrated shutdown safety cover is open Cycle has not completed correctly Another fault has occurred (detected by PLC)	Integrated shutdown safety cover is closed Cycle has completed correctly
3		Green	Cycle completed	Cycle is completed	When next cycle starts

11.5 Tube assembly creation

Generic procedures for the creation of a final tube assembly operator instructions are provided in this section.

These procedures are provided in the following order:

1. Explanation on how to reset a cycle if interrupted.
2. Pre-operation set up, such as cradle stops.
3. Set pecking stroke count.
4. Installation of Jaws to be referenced in a later procedure.
5. Installation of tube support to be referenced in a later procedure.
6. Install a filter barb into a tube.
7. Install a BioBarb into a tube.
8. Install a Y connector into a tube.

11.5.1 Cycle reset

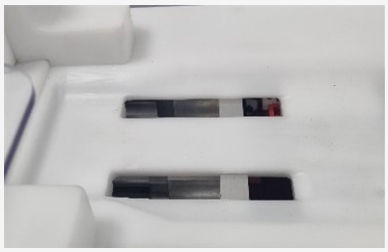
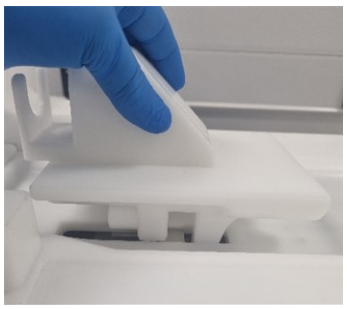
The machine has a cycle reset feature, which is designed to return all tube assembly fixtures to their home position. A cycle reset will be required when any of the following scenarios occur:

- An actuator button has been released before a cycle has completed.
- The integrated shutdown safety cover being raised.
- Both actuator buttons have not pressed with 0.5 seconds of each other.

A cycle reset can only take place if a cradle is installed. If this is required follow procedure 11.5.1.1 before the cycle reset procedure 11.5.1.2

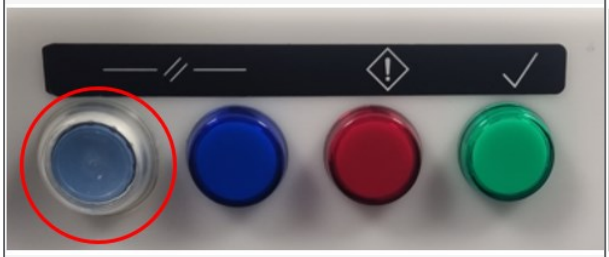
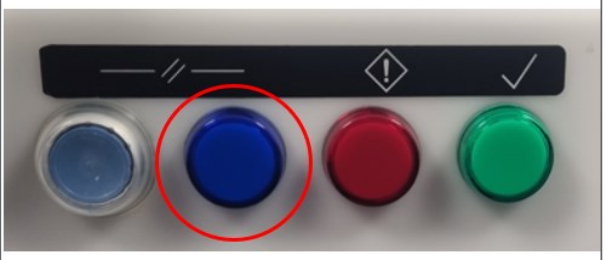
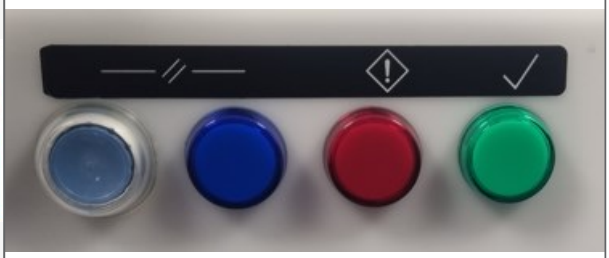
11.5.1.1 Procedure: Install cradle prior to cycle reset

Install cradle using the following procedure:

STEP 1	STEP 2	STEP 3
Check that the sliding mechanism and tracks are clean and clear	Place selected cradle into position over the sliding mechanism and tracks	Ensure cradle fully engages at the bottom
		

11.5.1.2 Procedure: Carry out a cycle reset

To carry out a cycle reset, use the following procedure:

STEP 1	
Press blue reset button. Blue cycle indicator light will illuminate	
	
STEP 2	
Press the two actuator controls simultaneously to reset Blue cycle indicator light will extinguish, and red indicator light will extinguish. The BTA is now ready for the next cycle	
	

11.5.2 Pre-operation set up

Prior to starting a tube assembly procedure, it is necessary to:

- Ensure the specified tube assembly fixtures are to hand.
- Ensure the opening and closing force of the integrated shutdown safety cover hinge matches the designated operator.
- Check the correct cradle stops are installed on the cradle.

11.5.2.1 Specified tube assembly fixtures

The tube assembly fixtures will depend upon the final design by BioPure and the user's organisation application requirements.

A responsible person must include precise information in the operator instructions on the tube assembly fixtures for identification by the designated operator.

11.5.2.2 Procedure: Adjustment of the integrated shutdown safety cover hinge

The friction of the integrated shutdown safety cover hinge is factory set and should not require adjustment under normal operating conditions. If adjustment of the opening and closing force of the cover is required for a specific designated operator, use this procedure:

1. Locate the adjustment screw on the top of the integrated shutdown safety cover as shown in the following picture.

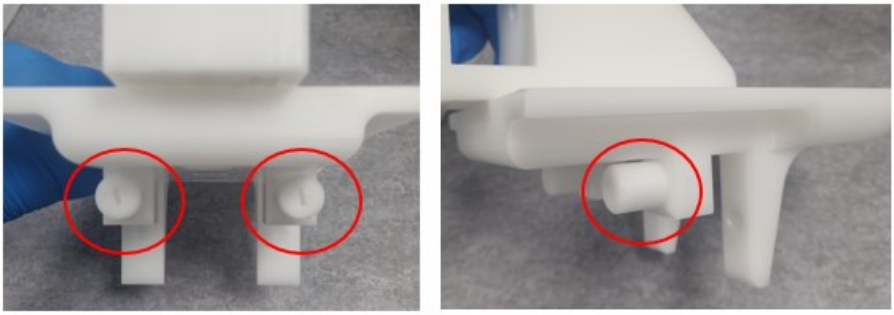
2. Turn the screw in the required direction, provided by the following table:

Direction to turn screw	Explanation
Clockwise	Increase friction (more force to close)
Anti-clockwise	Decease friction (less force to close)

3. Check the cover can close fully. If not re-adjust the screw.

11.5.2.3 Check the correct cradle stops are installed on the cradle

The cradle stops are matched to the application during the BioPure tube assembly fixture design process.



In some variable applications these cradle stops will need to be changed to a different size.

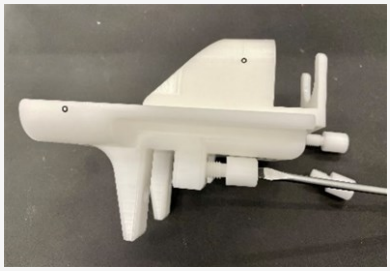
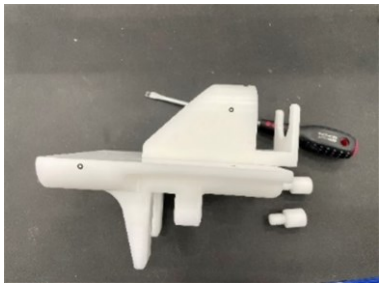
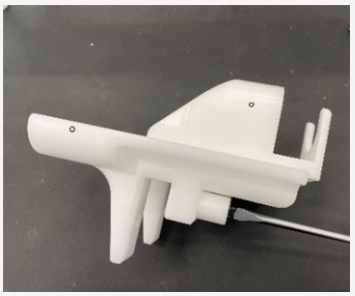
A responsible person must include precise information in the operator instructions, in order for the operator to be able to check and if necessary, change the stops prior to a procedure.

CAUTION

The cradle stops are critical to the stopping of the cradle. If the incorrect cradle stops are installed, there is risk of an injury and/or damage to the machine or fixture. The operator must identify, check and if necessary, change the cradle stops prior to a procedure.

11.5.2.3.1 PROCEDURE: CHANGING CRADLE STOPS

If the cradle stops require changing, follow this procedure:

STEP 1	STEP 2	STEP 3
Unscrew the cradle stops using a flat head screwdriver	Place the removed cradle stops to one side	Select the new cradle stops, lightly screw in by hand, then hand tighten with a flat head screwdriver
		

11.5.3 Set pecking stroke count

The pecking stroke count allows the operator to set the number of automatic strokes (from 1 to 4) of the cradle, when the actuator buttons are pushed and held in.

The pecking stroke count setting will need to be undertaken during the pre-production set up of a tube assembly production run.

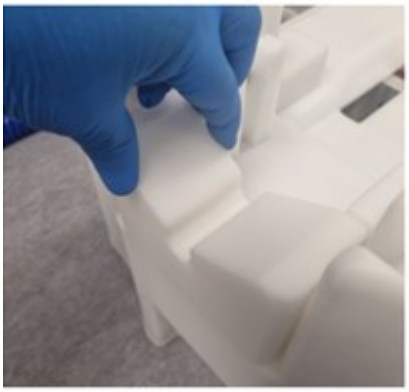
Once the selected pecking stroke count has been established the key must be removed and placed away from the operator, so that the pecking stroke count cannot be accidentally adjusted.

11.5.3.1 Procedure how to set the pecking stroke count

1. Insert key into pecking stroke count switch.
2. Turn the key to the required pecking stroke count.
3. Carry out a tube assembly operation to determine if the peck stroke count setting is suitable. If not turn the key to another setting, and repeat an operation to check.
4. Once satisfied remove the selector key and put in a safe place prior to starting a production run.

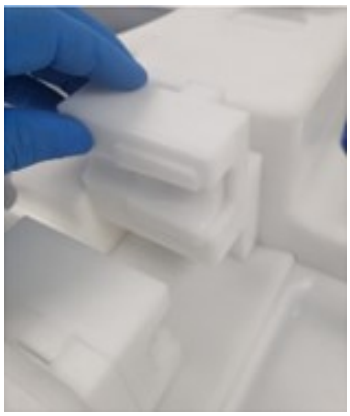
11.5.4 Procedure: Insert tube support

A Tube Support is inserted into a BioTube™ Applicator as shown in the following sequence:

STEP 1	STEP 2
Check that tube support guide key ways are clean and clear from obstructions	Place tube support guide into key-ways and slide down until support engages at the bottom
	

11.5.5 Procedure: Insert jaws

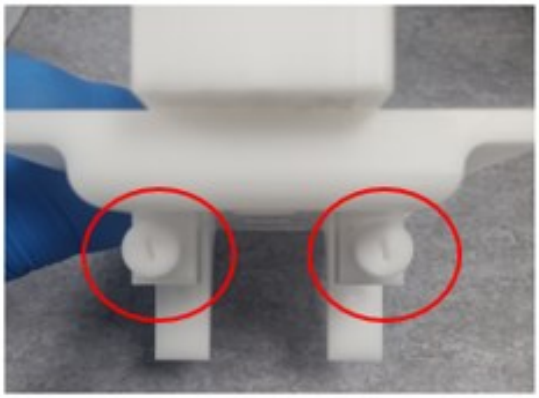
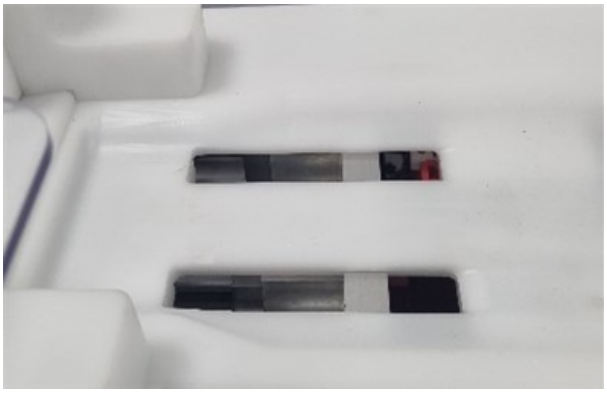
Jaws are inserted into a BioTube™ Applicator as shown in the following sequence:

STEP 1	STEP 2	STEP 3
Check that jaw guide keyways, to the right of the tube support are clean and clear	Place each jaw, one at a time, into guide keyway and slide down	Ensure each jaw fully engages at the bottom
		

11.5.6 Procedure: Install a filter barb into a tube

11.5.6.1 Pre-procedural check

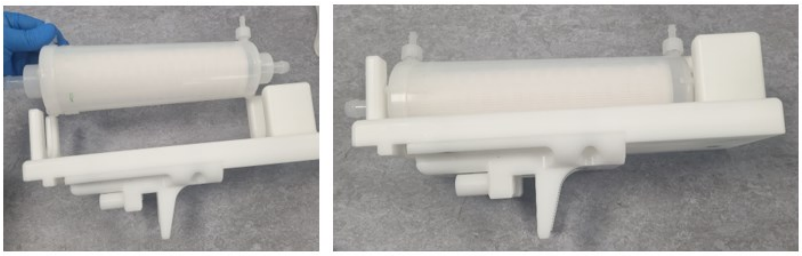
Prior to starting this procedure, do a pre-procedure check:

STEP 1	STEP 2
Check the correct stops are installed on the cradle. See section 11.5.2.3	Check the sliding mechanism is in the position shown. If not carry do a cycle reset using procedure 11.5.1.1
	

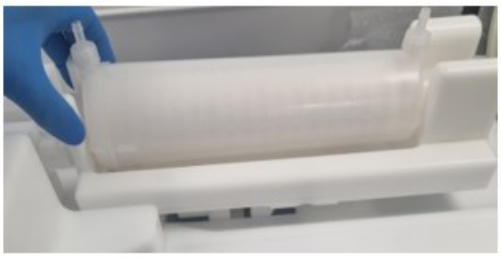
11.5.6.2 Main procedure: Install a filter barb into a tube

This is an example of a procedure for installing a filter barb into a tube. The actual procedure will depend on the specific design of the tube assembly fixtures and production application.

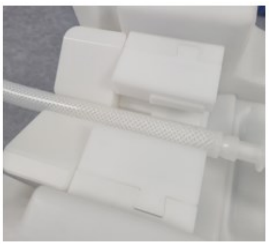
1. Open the integrated safety cover (the red cycle error light will illuminate).
2. Install selected Tube Support in accordance with section 11.5.4
3. Install selected Jaws in accordance with section 11.5.5
4. Select the correct size Cradle for the filter and insert Filter into Cradle as shown.



5. Insert filter and cradle into BioTube™ Applicator by placing the selected cradle over the open tracks in the top of the BioTube™ Applicator. Push the cradle down until it fully engages in the tracks.



6. Feed tubing over the Tube Support and Jaws, then at an approximate 45° angle from above, push the end of the tubing over the Filter Barb so that the end of the tube is sufficiently engaged with the front of the Barb.
7. Position the tube through the Jaws and Tube Support, pushing firmly to locate the tube into the Tube Support.



8. Close the integrated shutdown safety cover, ensuring that it correctly engages into position, indicated by the red cycle error light going off.

9. Check the correct pecking stroke count is being used. If not, follow procedure 11.5.3.1

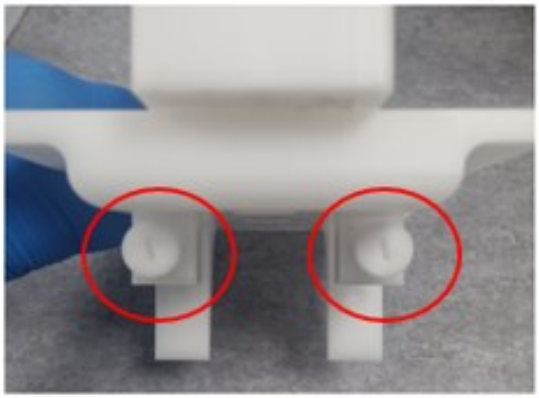
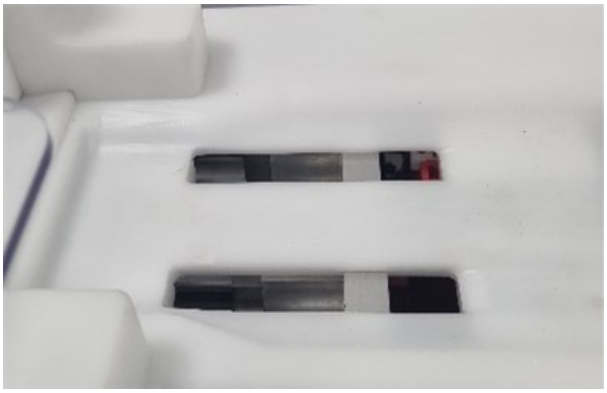
8. Push in both actuator buttons until the cycle has completed, indicated when the green indicator light illuminates.

11. Lift integrated shut down safety cover.
12. Remove filter and tube assembly from cradle. Repeat all steps as many times are required for a production run.

11.5.7 Procedure: Install a Bio Barb into a tube

11.5.7.1 Pre-procedural check

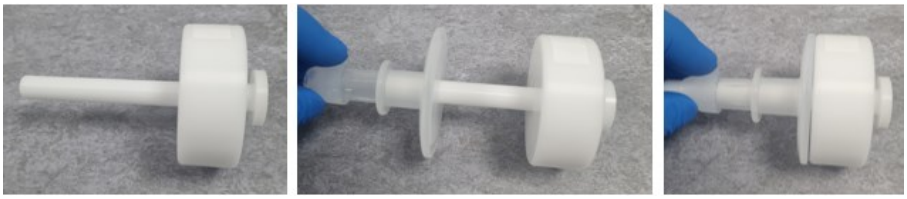
Prior to starting this procedure, do a pre-procedure check:

STEP 1	STEP 2
Check the correct stops are installed on the cradle. See section 11.5.2.3	Check the sliding mechanism is in the position shown. If not carry do a cycle reset using procedure 11.5.1.1
	

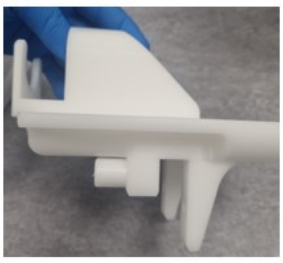
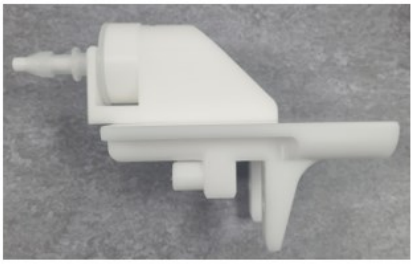
11.5.7.2 Main procedure: Install a Bio Barb into a tube

This is an example of a procedure for installing a Bio Barb into a tube. The actual procedure will depend on the specific design of the tube assembly fixtures and production application.

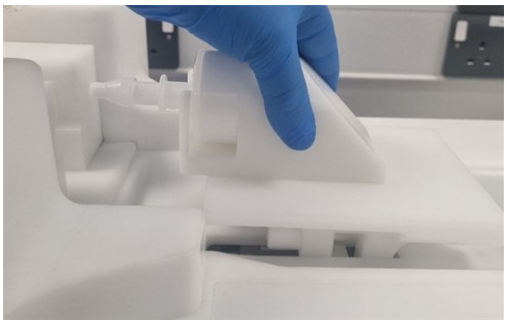
1. Open the integrated safety cover (the red cycle error light will illuminate).
2. Install selected Tube Support in accordance with section 11.5.4
3. Install selected Jaws in accordance with section 11.5.5
4. Select the correct size mandrel and holder cradle for the barb fitting to be used.
5. Insert barb fitting by sliding onto mandrel as shown in the picture sequence.



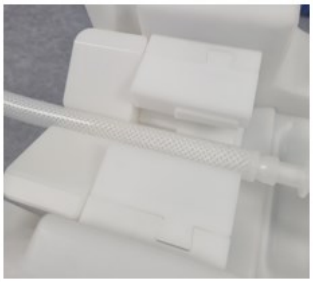
6. Insert barb and mandrel into mandrel holder.

7. Insert mandrel holder cradle assembly into BioTube™ Applicator by placing the selected cradle over the open tracks in the top of the BioTube™ Applicator. Push the cradle down until it fully engages in the tracks.



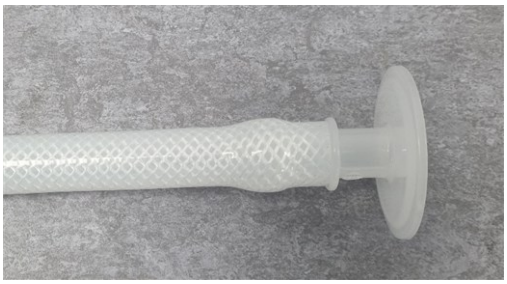
8. Feed tubing over the Tube Support and Jaws, then at an approximate 45° angle from above, push the end of the tubing up to the Barb so that the end of the tube is sufficiently engaging with the front of the barb.
9. Position the tube through the jaws and Tube Support, pushing firmly to locate the tube into the Tube Support.

10. Close the integrated shutdown safety cover, ensuring that it correctly engages into position. This is indicated by the red cycle error light going off.

11. Check the correct pecking stroke count is being used. If not, follow procedure 11.5.3.1
12. Push in both actuator buttons until the cycle has completed. This is indicated when the green indicator light illuminates.

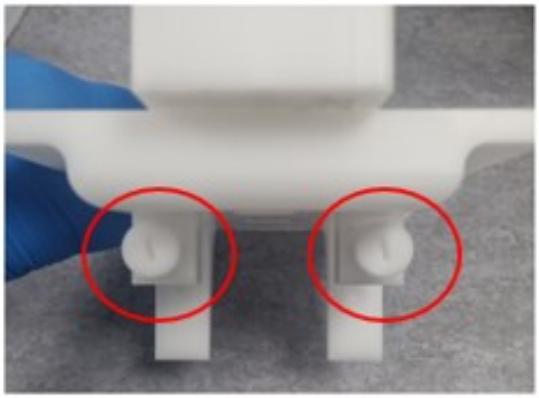
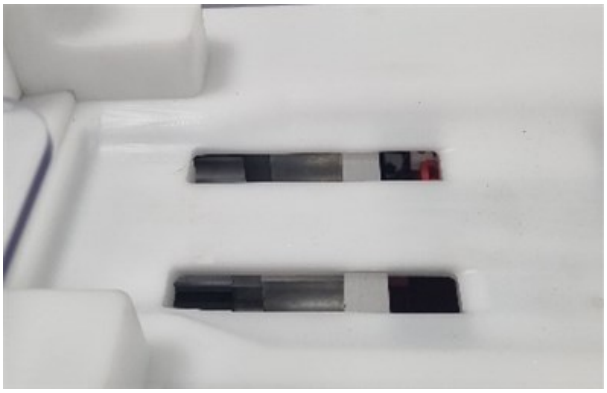
13. Lift integrated shut down safety cover.
14. Remove barb and tube assembly. Repeat as many times are required for a production run.



11.5.8 Procedure: Install a Y connector into a tube.

11.5.8.1 Pre-procedural check

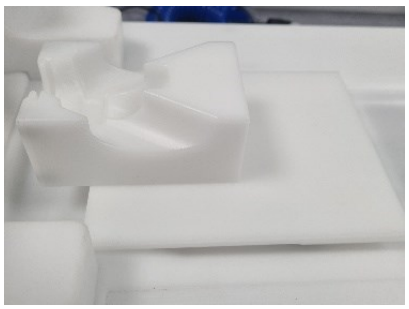
Prior to starting this procedure, do a pre-procedure check:

STEP 1	STEP 2
Check the correct stops are installed on the cradle. See section 11.5.2.3	Check the sliding mechanism is in the position shown. If not carry do a cycle reset using procedure 11.5.1.1
	

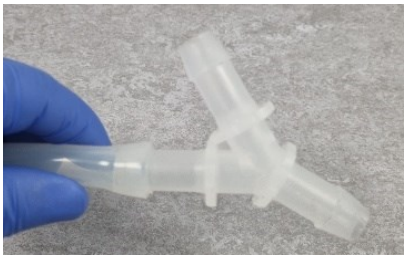
11.5.8.2 Main procedure: Install a Y connector into a tube

This is an example of a procedure for installing a Y connector into a tube. The actual procedure will depend on the specific design of the tube assembly fixtures and production application.

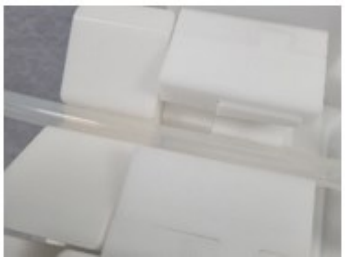
1. Open the integrated safety cover (the red cycle error light will illuminate).
2. Install selected Tube Support in accordance with section 11.5.4
3. Install selected Jaws in accordance with section 11.5.5
4. Select the correct size Y connector holder cradle for the application.
5. Insert Y connector cradle into BioTube™ Applicator by placing the selected cradle over the open tracks in the top of the BioTube™ Applicator. Push the cradle down until it fully engages in the tracks.



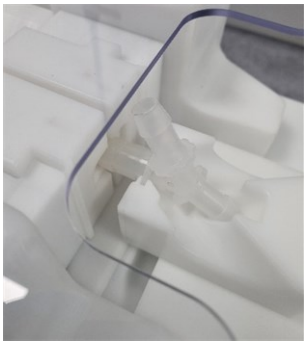
6. Insert tubing onto first piece of the Y connector.



7. Place the Y connector into the holder cradle so that the tubing is towards the jaw
8. Ensure that the tubing runs through the jaws and rests in the tube support.

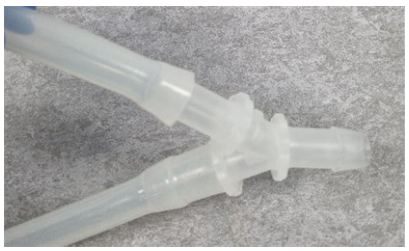


9. Close the integrated shutdown safety cover, ensuring that it correctly engages into position. This is indicated by the red cycle error light going off.



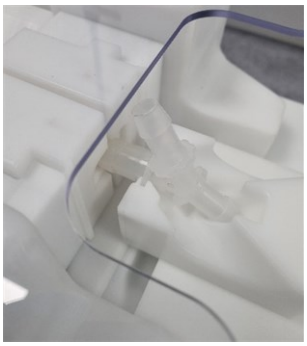
10. Check the correct peck stroke count is being used. If not, follow procedure 11.5.3.1
11. Push in both actuator buttons until the cycle has completed. This is indicated when the green indicator light illuminates.

12. Lift integrated shut down safety cover.
13. Insert tubing onto second piece of the Y connector.



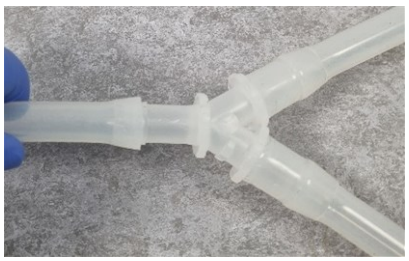
14. Place the Y connector into the holder cradle so that the second piece of tubing is towards the jaws.
15. Ensure that the tubing runs through the jaws and rests in the tube support.


16. Close the integrated shutdown safety cover ensuring that it correctly engages into position. This is indicated by the red cycle error light going off.

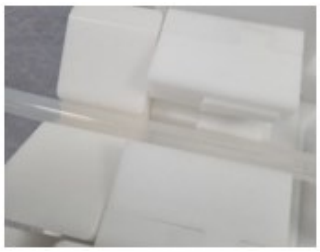


17. Check the correct pecking stroke count is being used. If not, follow procedure11.5.3.1
18. Push in both actuator buttons until the cycle has completed. This is indicated when the green indicator light illuminates.

19. Lift integrated shutdown safety cover.
20. Insert tubing onto third piece of the Y connector.

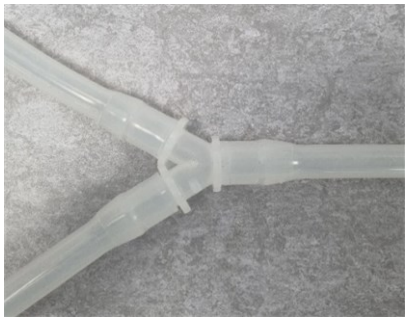


21. Place the Y connector into the holder cradle so that the third piece of tubing is towards the jaws.
22. Ensure that the tubing runs through the jaws and rests in the tube support.

23. Close the integrated shut down safety cover, ensuring that it correctly engages into position. This is indicated by the red cycle error light going off.
24. Check the correct pecking stroke count is being used. If not, follow procedure 11.5.3.1
25. Push in both actuator buttons until the cycle has completed. This is indicated when the green indicator light illuminates.

26. Lift integrated shutdown safety cover.
27. Remove the Y connector and tubing assembly. Repeat all steps as many times are required for a production run.



12 Cleaning

A BioTube™ Applicator may be cleaned using the information in this section. The exhaust filter is not cleanable, it must be replaced if it becomes blocked. See section 13

12.1 Machine cleaning overview

A BioTube™ Applicator, may only be cleaned by wipe over, using a lint free cleanroom wipe. Any other application, such as the spraying or pouring of liquids is not approved.

The only approved cleaning agent for a BioTube™ Applicator is Isopropyl alcohol (70 %)[1].

NOTE[1]	Other common names for Isopropyl alcohol (70 %) are: • IPA 70 % • Isopropanol (70 %)

Prior to using Isopropyl alcohol (70 %) cleaning agent, a responsible person must:

- Do a risk assessment
  - Consider flammability of Isopropyl alcohol (70 %)
- Create a specific procedure based upon the user organisations risk control measures, such as ventilation and suitable PPE, using the following general procedure.

12.1.1 General procedure for guidance

1. Wear suitable PPE.
2. Remove the power plug from the socket to remove all electrical power.
3. Remove the tube assembly fixtures.
4. Prepare a clean dry lint free cleanroom wipe with the cleaning agent.

CAUTION

Risk of injury or damage to the machine. The machine is only designed for wipe down cleaning, do not spray or pour any liquids in or on to the machine surfaces.

5. Clean the machine and tube assembly fixtures by lightly wiping all exposed surfaces until all residue has been removed.
6. Allow any residual solution to evaporate from surfaces.
7. Dispose of the lint free cleanroom wipe. in accordance with the user organisations policies.
8. Reinstall the tube assembly fixtures.
9. Check that the power on/off switch is in the off position, then reconnect the power plug.
10. Bring product back into operation and check operation of product after cleaning.

13 Maintenance

13.1 Servicing

A BioTube™ Applicator will require a service by BioPure when it reaches 16,500 hours of continuous operation. The machine must be returned in its protective case. Contact your local WMFTS representative for more information on the service and return process.

Do not perform a service like task on the machine, such as to lubricate the integrated shutdown safety cover hinge or other item. Neither the BioTube™ Applicator, nor the power supply assembly have user serviceable parts and are not to be dismantled.

13.2 Approved maintenance tasks

Only the following maintenance tasks are approved:

1. Periodic inspection. See section 13.3
2. Replacement of specific items. See section 13.4

No other maintenance activity or repair of a BioTube™ Applicator must be undertaken.

If the machine requires maintenance or repair beyond the information in sections (13.3, or 13.4) of this reference manual, contact your local WMFTSrepresentative to discuss returning of the machine to BioPure for maintenance or repair.

13.3 Periodic inspection

The product should be periodically inspected for the following as required, by the user's organisations inspection schedule:

- Loose parts or screws
- Secure connections (power cable, or compressed air)
- Clean air exhaust filter
- Security of safety devices
- General wear on moving parts, such as cracking.
- Damage to air hose
- Damage to power supply cable
- In date servicing of main air supply
- Other damage not listed

Do not attempt to remove the casing to inspect the internal parts.

13.4 Replacement items

13.4.1 Replaceable fuses

The UK model contains a replaceable 3 Amp fuse, BS 1632 in the AC power plug.

The fuse is not a WMFTS spare part. Follow procedure 13.5.2.1 to replace this fuse.

There are no replaceable fuses in either Europe model AC power plug, or inside the BioTube™ Applicator itself.

13.4.2 Replaceable spare parts

The following parts may be replaced in their entirety with brand new Watson-Marlow items.

Item	Product code	When to be replaced.
Clean air exhaust filter	MR101362	• Usage after two years • When the system fails to operate normally
A/C power cable with power plug (Part A of power supply assembly)	• Europe model: MN101263 • UK model: MN101264	Damage to cable or power plug
Power supply unit, with integrated cable and DC power connector (Part B of power supply assembly)	MN101238	If the power supply fails or damage
Tube support, cradle, jaws, mandrel, or mandrel holder	Contact your local WMFTS representative	Due to wear
Compressed air supply hose	MR101363	If the hose develops a leak

13.5 Item replacement procedures

This section provides procedures on the replacement of spare parts in this order:

1. Compressed air spare parts.
2. Electrical power spare parts.

13.5.1 Replace compressed air items

13.5.1.1 Chapter safety while following procedures

13.5.1.1.1 MANDATORY PPE

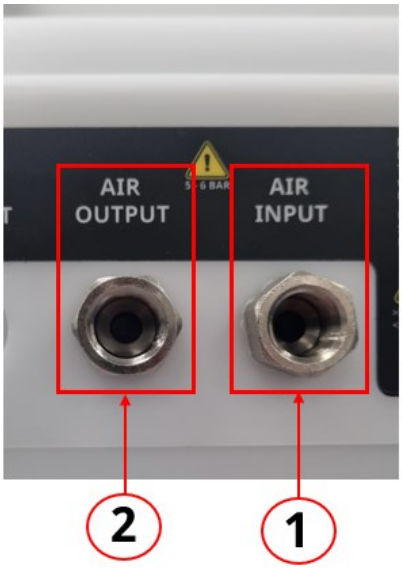
PPE must be worn while following procedures in this chapter.

CAUTION

PPE is required when connecting and setting the air supply to the BioTube™ Applicator. Failure to do so may result in an injury as a result of hose whip or an overpressure event created by incorrect installation.

13.5.1.1.2 MANDATORY USE OF A TOOL

When following procedures in this chapter, the female air connections on the machine must be held with a wrench while either the air exhaust filter or the air supply hose connector is tightened.



CAUTION

Do not tighten the hose air supply connector or exhaust filter to the BioTube™ Applicator without holding the corresponding air connections with a wrench.

Failure to do so may result in a connection becoming loose inside the machine, resulting in permanent damage and a hazard to operation.

13.5.1.2 Procedure: Replace air exhaust filter

Follow this procedure to remove and install the air exhaust filter.

13.5.1.2.1 PROCEDURE: REMOVE AIR EXHAUST FILTER

1. Wear suitable PPE.
2. Switch the power on / off switch on BioTube™ Applicator to off. The red light will be extinguished.
3. If using a local air pressure regulator, set the main air supply pressure on the pressure regulator to 0 bar (0 PSI).
4. Isolate the BioTube™ Applicator from the main air supply and release any residual pressure in the compressed air supply hose.

CAUTION

When releasing pressure from the compressed air supply hose, be sure that the hose cannot suddenly move and create a whipping hazard.

5. Hold the air output connection with a suitable sized wrench, then simultaneously unscrew the air exhaust filter from the connection.

13.5.1.2.2 PROCEDURE: INSTALL REPLACEMENT AIR EXHAUST FILTER

1. Obtain a replacement air exhaust filter
2. Wear suitable PPE.
3. Check that exhaust filter is not damaged or blocked.
4. Check the main compressed air supply is isolated from the BioTube™ Applicator.
5. If using a local air pressure regulator, check that the pressure is still set to 0 bar.
6. Hold the air output connection with a suitable sized wrench, then simultaneously screw in the exhaust filter until it is hand tight.

NOTICE

When installing the exhaust filter:

- Do not use PTFE tape—This is not necessary for a plastic component and could create a blockage.
- Do not use a tool on the exhaust filter, only on the air output female connector. The exhaust filter must only be hand tight.

7. Turn on the main compressed air supply. If using an air pressure regulator, while watching the pressure on the BioTube™ Applicator pressure gauge, set regulation at 5 Bar to 6 Bar.
8. Operate the BioTube™ Applicator, checking for leaks from the air exhaust filter. If a leak is present, tighten further a little at a time.

13.5.1.3 Procedure: Replace compressed air supply hose

Follow this procedure to remove and install thecompressed air supply hose.

13.5.1.3.1 PROCEDURE: REMOVE COMPRESSED AIR SUPPLY HOSE

1. Wear suitable PPE.
2. Switch the power on / off switch on BioTube™ Applicator to off. The red light will be extinguished.
3. If using a local air pressure regulator, set the main air supply pressure on the pressure regulator to 0 bar (0 PSI).
4. Isolate the BioTube™ Applicator from the main air supply and release any residual pressure in the compressed air supply hose.

CAUTION

When releasing pressure from the compressed air supply hose, be sure that the hose cannot suddenly move and create a whipping hazard.

5. Hold the air input connection with a suitable sized wrench, while simultaneously unscrewing the air supply hose connection at the BioTube™ Applicator.
6. Remove the compressed air supply hose from the user's air supply in accordance with the user organisations procedures.
7. Remove the compressed air supply hose and place to one side.

13.5.1.3.2 PROCEDURE: INSTALL REPLACEMENT COMPRESSED AIR SUPPLY HOSE

1. Obtain a replacement compressed air supply hose.
2. Follow the compressed air supply hose installation procedure 9.2.4

13.5.2 Replace electrical items

This section provides procedures on the replacement of electrical power spare parts in this order:

1. Replace fuse in UK model power plug.
2. Replace power supply assembly or part A or B.

13.5.2.1 Procedure: Replace fuse in UK model power plug

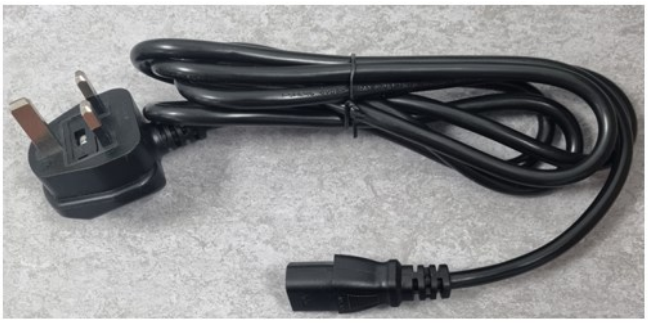
The UK model contains a replaceable 3 Amp fuse, BS 1632 in the AC power plug.

To replace this fuse:

1. Turn the electrical power switch to off.
2. Switch off power to the power socket.
3. Remove the power plug from the power socket.
4. Remove the fuse from the power plug.
5. Replace with a 3 Amp fuse, BS 1632.
6. Reconnect the power plug to the power plug socket.
7. Restore power to the power plug socket.
8. Turn the electrical power switch to on.
9. Check the BioTube™ Applicator has turned back on. If not repeat, steps 1 to 8, checking the fuse is installed correctly.

13.5.2.2 Procedure: Replace power supply assembly B

The power supply assembly is comprised of two main parts (A + B) which connect to each other.



A

B

Either part is available as WMFTS spare part. To replace either part or the entire power supply assembly use the following procedure:

13.5.2.2.1 PROCEDURE: REMOVE THE POWER SUPPLY ASSEMBLY

1. Turn the electrical power switch to off.
2. Switch off power to the power socket.
3. Remove the power plug from the power socket.
4. Remove the DC power connector from the back of the BioTube™ Applicator.
5. Separate part A and Part B of the power supply assembly.
6. Obtain a replacement of the required part, or both parts.
7. Dispose of the part no longer required in accordance with local regulations.

13.5.2.2.2 PROCEDURE: RE-INSTALL THE POWER SUPPLY ASSEMBLY

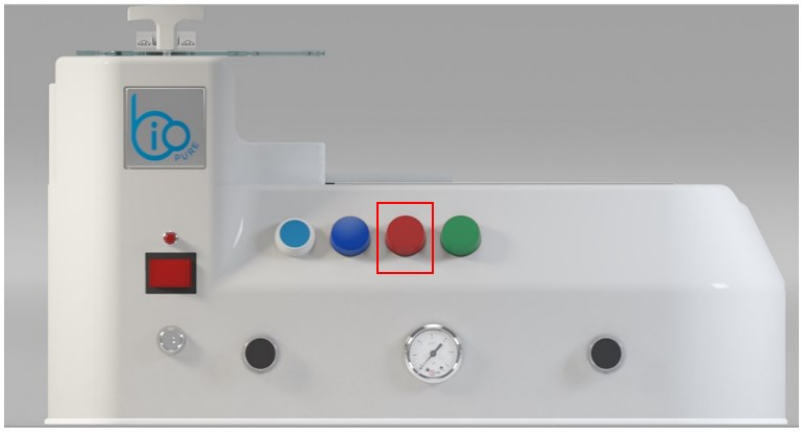
To re-install the power supply assembly, follow the installation procedure 10.2.2.

14 Troubleshooting, technical support, and warranty

This section will provide information on troubleshooting. If the problem cannot be solved, information on how to seek technical support along with our comprehensive warranty is provided at the end of this section.

14.1 Errors

A BioTube™ Applicator can only indicate an error created during a cycle using the cycle error indicator light.



The indication of the status light is provided the following table:

Light indication	Explanation
Illuminated red light	Illuminated when: • Integrated shutdown safety cover is open • Cycle has not completed correctly • Cradle is not installed • Incorrect installation of cradle Extinguished when: • Integrated shutdown safety cover is closed • Cycle has completed correctly • Reset cycle has completed

.

14.2 Troubleshooting

Should the product fail to operate, carry out the following checks.

Problem	Possible cause	Possible solution
Failure to start	No power to product	Check the Power supply assembly is: • Connected together (Part A to B) • Plugged into and switched on at the power socket • Not damaged
	PLC reboot required	Disconnect from the electrical power supply for 30 seconds.
Failure to operate	Compressed air supply	Check compressed air supply is connected to the compressed air inlet.
		Check the air supply is between 5 to 6 bar on pressure gauge.
		Ensure air exhaust filter is not obstructed or blocked.
	Safety devices	Ensure integrated shutdown safety cover is fully closed. If not closing fully check hinge adjustment. See section 11.5.2.2
	Operator	The dual actuator buttons must be pressed within 0.5 seconds of each other.
	Cradle location	Check that the cradle is fully located.
	PLC reboot required	Disconnect from the electrical power supply for 30 seconds.

If the problem cannot be solved, contact the Technical Support of WMFTS. See section 14.4.1

14.3 Reporting unexpected faults

If any unexpected faults or failures are experienced report them to your WMFTS representative.

14.4 Product support

Should you be unable to resolve a problem, or have another query please contact your local WMFTS representative for technical support.

14.4.1 Technical support

This product is supported by Watson-Marlow Fluid Technology Solutions.

Watson-Marlow Limited
Bickland Water Road
Falmouth, Cornwall
TR11 4RU
United Kingdom
Phone : +44 1326 370370
Website : https://www.wmfts.com/

14.4.2 Manufacturer

This product is manufactured by Bio Pure Technology Limited, a Watson-Marlow Fluid Technology Solutions company.

Bio Pure Technology Limited
Unit 5
Dunsbury Park
Fitzwygram Way
Havant
PO9 4EE
Phone: +44 2392 499000
Website: https://www.wmfts.com

14.4.3 Authorised EU Representative

Pilz Ireland
Model Farm Road
Cork
Ireland
Phone: +353 22 4804940 or +353 22 4804994

14.5 Warranty

Bio Pure Technology Limited (BioPure) warrants this product to be free from defects in materials and workmanship for one year from the date of shipment, under normal use and service.

BioPure's sole responsibility and the customer's exclusive remedy for any claim arising out of the purchase of any product from BioPure is, at BioPure's option: repair, replacement, or credit, where applicable.

Unless otherwise agreed in writing, the foregoing warranty is limited to the country in which the product is sold.

No employee, agent or representative of BioPure has the authority to bind BioPure to any warranty other than the foregoing unless in writing and signed by a director of BioPure. BioPure makes no warranty of the fitness of its products for a particular purpose.

In no event:

1. shall the cost of the customer's exclusive remedy exceed the purchase price of the product.

2. shall BioPure be liable for any special, indirect, incidental, consequential, or exemplary damages, however arising, even if BioPure has been advised of the possibility of such damages.

BioPure shall not be liable for any loss, damage, or expense directly or indirectly related to or arising out of the use of its products, including damage or injury caused to other products, machinery, buildings, or property. BioPure shall not be liable for consequential damages, including, without limitation, lost profits, loss of time, inconvenience, loss of product being pumped, and loss of production.

This warranty does not obligate BioPure to bear any costs of removal, installation, transportation, or other charges which may arise in connection with a warranty claim.

BioPure shall not be responsible for shipping damage of returned items.

14.5.1 Conditions

- Products must be returned by pre-arrangement to BioPure, or a BioPure approved service centre.
- All repairs or modifications must have been made by Bio Pure Technology Limited, or a BioPure approved service centre or with the express permission in writing of BioPure, signed by a manager or director of BioPure.

14.5.2 Exceptions

- Consumable items including tubing and barbs are excluded.
- Repairs or service necessitated by normal wear and tear or by lack of reasonable and proper maintenance are excluded.
- Products which, in the judgement of, BioPure have been abused, misused, or subjected to malicious or accidental damage or neglect are excluded.
- Failure caused by electrical surge is excluded.
- Failure caused by incorrect or sub-standard system wiring is excluded.
- Damage by chemical attack is excluded.
- Failure caused by UV light or direct sunlight.
- Any attempt to disassemble a BioPure product will invalidate the product warranty.

BioPure reserves the right to amend these terms and conditions at any time.

14.6 Returning product

Before returning a product:

1. The product must be removed from operation by a responsible person. See section 15.2
2. The product must be thoroughly cleaned / decontaminated. A decontamination declaration, confirming this must be completed and returned to BioPure in advance of the item being shipped.

You are required to complete and return a decontamination declaration stating all fluids that have been in contact with the equipment being returned to us.

On receipt of the declaration, a Returns Authorisation Number will be issued. BioPure reserves the right to quarantine or refuse any equipment that is not displaying a Returns Authorisation Number.

Please complete a separate decontamination declaration for each product and use the correct form that denotes the location you wish to return the equipment to.

To obtain a decontamination declaration document for completion, contact your local WMFTS representative.

15 Product end of life, removal from operation, and disposal

This section covers:

- End of product life.
- Removing a BioTube™ Applicator from operation.
- Product recycling and disposal.

15.1 Product end of life

A BioTube™ Applicator has an expected asset life of 10 years, based on service, installation and use in accordance with this manual.

The product may reach its end of life sooner due to damage or improper use.

15.1.1 Product damage

Product damage may be caused by:

- Abrasion due to vibration
- Incorrect installation or operation
- Twists or bends
- Chemicals in the operating environment

In the event of product damage to any of the above items, the product must be removed from operation by a responsible person. See section 15.2

Contact your local WMFTS representative to discuss the repair or replacement.

15.2 Removing a BioTube™ Applicator from operation

A BioTube™ Applicator must be removed from operation, when:

- The product has become damaged or has not been installed correctly.
- The product has completed 16,500 hours of continuous operation and requires a return to BioPure for service.

To remove a BioTube™ Applicator from operation use the following procedure

1. Wear suitable PPE.
2. Remove the tube assembly fixtures and place them in a safe place.
3. Turn the electrical power switch to the off position.
4. Turn off power to the electrical socket.
5. Remove the power plug from the electrical socket.
6. Unplug the DC power connection from the back of the machine.
7. Place the power cable assembly to one side in a safe place.
8. Remove the exhaust air filter using procedure 13.5.1.2.1
9. Remove the compressed air supply hose using procedure 13.5.1.3.1
10. Place the product in its protective case, using the procedures in section 5

CAUTION

A BioTube™ Applicator weighs 25 kg to 30 kg (55.1 lbs to 66.1 lbs). Use a two person manual handling technique, while wearing suitable PPE in accordance with the user's organisations risk assessment.

To re-install the machine, follow all procedures in the installation chapters.

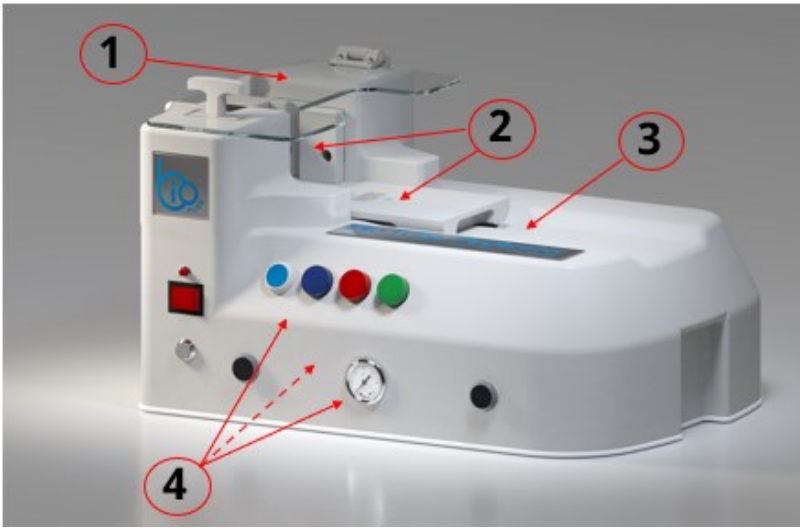
15.3 Product recycling and disposal

Materials of construction are provided in section 16 to enable a responsible person to determine whether the product can be recycled or must be disposed of.

Recycle or dispose in accordance with the user organisations geographical waste regulations.

16 Materials of construction

A BioTube™ Applicator has the following materials of construction.



Item		Material of construction
1	Integrated shutdown safety cover	Polycarbonate
2	Tube assembly fixtures	Polyoxymethylene-copolymer
3	Main structure	Polyoxymethylene-copolymer
4	Components (Internal)	Polyvinylchloride, Copper, Stainless Steel
	Components (External)	Glass, Stainless steel, Aluminum

17 Compliance

A BioTube™ Applicator, is designed to the following EU Directives, UK regulations, and standards:

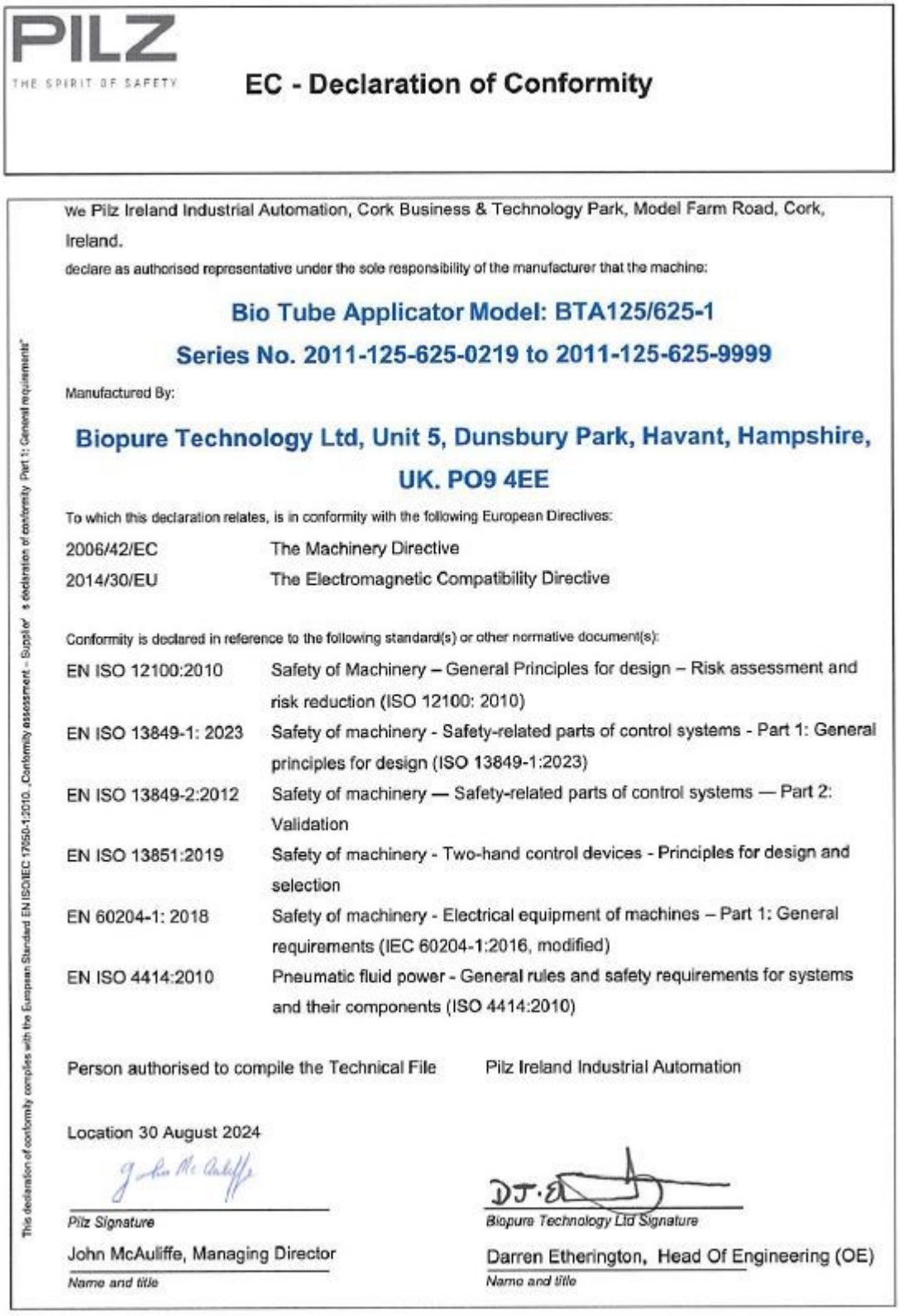
17.1 EU Directives

Designation	Title
2006/42/EC	Machinery Directive
2014/30/EU	EMC Directive
2011/65/EU	Restriction of Hazardous Substances Directive (RoHS)

17.2 Standards

Designation	Title
BS EN ISO 12100:2010	Safety of machinery - General principles for design - Risk assessment and risk reduction
BS EN 60204-1:2018	Safety of machinery. Electrical equipment of machines. General requirements
BS EN ISO 13849-1:2015	Safety of machinery. Safety-related parts of control systems. General principles for design
BS EN ISO 13849-2:2012	Safety of machinery. Safety-related parts of control systems. Validation
BS EN ISO 4414:2010	Pneumatic fluid power. General rules and safety requirements for systems and their components

17.3 EC - Declaration of Conformity



PILZ
THE SPIRIT OF SAFETY

EC - Declaration of Conformity

We Pilz Ireland Industrial Automation, Cork Business & Technology Park, Model Farm Road, Cork, Ireland.

declare as authorised representative under the sole responsibility of the manufacturer that the machine:

Bio Tube Applicator Model: BTA125/625-1

Series No. 2011-125-625-0219 to 2011-125-625-9999

Manufactured By:

Biopure Technology Ltd, Unit 5, Dunsbury Park, Havant, Hampshire, UK. PO9 4EE

To which this declaration relates, is in conformity with the following European Directives:

2006/42/EC	The Machinery Directive
2014/30/EU	The Electromagnetic Compatibility Directive

Conformity is declared in reference to the following standard(s) or other normative document(s):

EN ISO 12100:2010	Safety of Machinery – General Principles for design – Risk assessment and risk reduction (ISO 12100: 2010)
EN ISO 13849-1: 2023	Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design (ISO 13849-1:2023)
EN ISO 13849-2:2012	Safety of machinery — Safety-related parts of control systems — Part 2: Validation
EN ISO 13851:2019	Safety of machinery - Two-hand control devices - Principles for design and selection
EN 60204-1: 2018	Safety of machinery - Electrical equipment of machines – Part 1: General requirements (IEC 60204-1:2016, modified)
EN ISO 4414:2010	Pneumatic fluid power - General rules and safety requirements for systems and their components (ISO 4414:2010)

Person authorised to compile the Technical File — Pilz Ireland Industrial Automation

Location 30 August 2024

Pilz Signature

John McAuliffe, Managing Director
Name and title

Biopure Technology Ltd Signature

Darren Etherington, Head Of Engineering (OE)
Name and title

This declaration of conformity complies with the European Standard EN ISO/IEC 17050-1:2010, „Conformity assessment – Supplier´s declaration of conformity Part 1: General requirements"

18 Glossary

Term	Definition
Designated operator	An operator selected by a responsible person who will be trained in the sole use of the machine.
Ground Fault Circuit Interrupter (GFCI) protection	Fast acting circuit breaker designed to shut off electrical power in the event of a ground fault.
Hazard	Source of potential harm.
Lifecycle	The full life of the product from date of delivery of the product to disposal.
Residual Current Device (RCD) socket	Designed to protect from fatal electric shocks, by automatically switching off electricity when there is a fault, such as bare wires, overheating or an earth fault.
Responsible person	A person, competent in their area of expertise, in or acting on behalf of the user's organisation responsible for: Product application selection, installation, safe use of the product by operators, cleaning, maintenance, troubleshooting or decommissioning.
Signal	Indicates a possible hazard.
Task	An action involving doing something with a BioTube™ Applicator machine in some way such as installation, operation, cleaning, maintenance, decommission, or disposal.