Control Unit

Operators Instruction Manual

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in poor performance and, or patient complications. This instruction manual contains essential information on using this instrument safely and effectively.

The operation of the OpClear Control Unit and the OpClear Disposable Procedure Kit must be by a physician or medical personnel under the supervision of a physician who is trained in laparoscopic surgery, including insufflation. This manual, therefore, does not explain or discuss laparoscopic surgery.

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1. INDICATIONS FOR USE

The OpClear Control Unit provides on demand medical grade CO_2 and a saline solution to the OpClear Disposable Procedure kit which is a Laparoscope distal window cleaning device for the removal of visual obstructions on the lens such as blood, peritoneal fluid, smoke particulate, fat, condensation/fog and other tissue particulates that may obscure vision during laparoscopic surgical procedures.

2. CONTRAINDICATIONS

The OpClear Control Unit and the OpClear Disposable Procedure Kit are not intended for use when minimally invasive techniques are contraindicated.

3. COMPATIBILITY

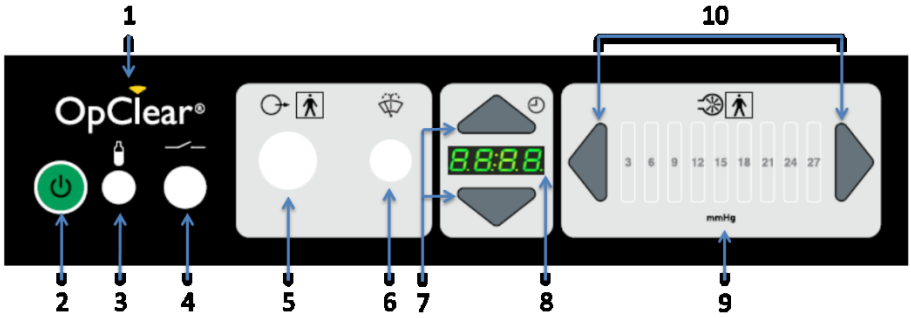
The OpClear Control Unit is designed to work with the following OpClear Disposable Procedure Kits and laparoscopes only.

OpClear Part #	Description	Length	Compatibility
CS-SR10-00	OpClear 10mm x 0°	328mm	Stryker, Olympus Endoeye
CS-SR10-30	OpClear 10mm x 30°	328mm	Stryker, Olympus Endoeye
CS-OS10-00	OpClear 10mm x 0°	300mm	Olympus
CS-SZ10-00	OpClear 10mm x 0°	314mm	Storz , Olympus HD
CS-SZ10-30	OpClear 10mm x 30°	314mm	Storz , Olympus HD

4. DESCRIPTION

See Section 17 for symbol descriptions.

4.1 Front Panel Visible Indicators and Functions



1. **OpClear Logo**
   Illuminated when power connected.
2. **Standby Button with Status Indicator Light Ring**
   Press to switch between standby and active.
   Status Indicator; Green OK, solid yellow low alarm, flashing yellow medium alarm.
3. **Supply Pressure Indicator**
   Green indicates sufficient CO_2 level, yellow low CO_2 level and flashing yellow out of CO_2.
4. **Activator Port**
   Footswitch connection.
5. CO_2 **to Patient Port**
   Disposable CO_2 connection.
6. **Wash Port**
   Disposable wash connection.
7. **Up and Down Buttons**
   Up and Down buttons to adjust the Demist Timer settings.
8. **Demist Timer Display**
   Shows the set time and count down for demist function. It also displays instructions and error messages. (See section 15).

9. **Abdominal Cavity Pressure Indicator**
   This indicator shows the abdominal pressure in mmHg. Each light represents 3mmHg. The default setting Green LED lights will display until the pressure reaches 18 mmHg. LED lights then flash yellow if the pressure is 18 mmHg and above. If a different cut out pressure has been selected Green LED lights will display up to that pressure. The cut out pressure will be displayed in Amber. This display is for indication only.
10. **Left and Right Buttons**
    These are used to adjust the abdominal cavity pressure display.

4.2 Back Panel

1. **Power Inlet and On/Off Switch**
   Mains power connection, fuse and switch.
2. **Equipotential Bond Point**
   Provides point for equipotential bonding.
3. **CO_2 Inlet**
   CO_2 supply hose connection.

4. **USB Port**
   Service and calibration only.

5. CONTENTS & ACCESSORIES

The OpClear Control Unit requires minimal set-up for clinical use. The shipping box contains the OpClear Control Unit, Footswitch, country specific Power Cord, country specific CO_2 supply hose and Operator's Instruction Manual. Please match all items in the package with the components listed above and inspect each item for damage. If the instrument is damaged, a component is missing or you have any questions, do not use the instrument; immediately contact Cipher Surgical Limited or your local agent.

The OpClear Disposable Procedure Kits are purchased separately.

6. WARNINGS AND PRECAUTIONS

This equipment must only be used in conjunction with a working insufflator with a functioning cavity pressure alarm. DO NOT USE the OpClear Disposable Procedure Kit or OpClear Control Unit as a primary or secondary insufflation device.

Only connect to medical grade CO_2 gas supplies that have a pressure of less than 74 Bar. Never use any other type of gas.

This equipment is for use only by qualified medical personnel trained in the use of Laparoscopic surgery and Insufflation.

To avoid the risk of electric shock, the OpClear Control Unit must only be connected to supply mains with protective earth.

To avoid the risk of electric shock, only use the power cables supplied by Cipher Surgical Limited.

Only use either the high pressure hose for CO_2 cylinder or the low pressure hose for theatre CO_2 gas pipeline supplied by Cipher Surgical Limited. Cipher Surgical Limited is not liable for any injury or damage caused due to improper CO_2 gas cylinder or pipeline connection.

Only open the CO_2 gas supply valve after correctly connecting the OpClear Control Unit to the CO_2 gas cylinder or CO_2 theatre supply using the hoses supplied. Opening the CO_2 supply valve before correctly connecting the equipment will result in liquid CO_2 flowing into the hose. The CO_2 channels inside the OpClear Control unit may freeze and prevent proper CO_2 gas flow.

If a gas leak is noted from within the OpClear Control Unit, terminate its use immediately and contact Cipher Surgical Limited.

Do not spill or spray fluids, immerse the OpClear Control Unit or operate in moist environments. This may result in damage to the device and creates a risk of shock or fire. If fluids enter the OpClear Control Unit cease use immediately and disconnect the power to the unit. The unit must be returned to the manufacturer for testing prior to use.

Always keep the gas cylinder in the upright position. Fasten the cylinder to a wall or another stable structure to prevent it from toppling.

If the OpClear Control Unit emits a warning, for intra-abdominal over-pressurisation the unit will not deliver any more gas to the patient until the pressure has reduced below the set threshold.

Following any mains power disruption or failure, immediately remove the OpClear Disposable Procedure Kit and Laparoscope from the patient and recommence the OpClear Control Unit set up procedure.

No modification of the OpClear Control Unit and OpClear Disposable Procedure Kit as supplied is allowed

Use of accessories and cables other than those specified may result in unpredictable performance or decreased performance of the product.

Never lubricate the equipment or any hose connections with grease, oil or any substance. This could result in grease, oil, or other foreign matter penetrating into the OpClear Control Unit, impeding proper operation and preventing proper flow of CO_2.

Never apply excessive force to the power cord, such as bending, straining, twisting or squeezing.

There are no internal user serviceable parts. For service or fault, return the OpClear Control Unit to an authorised Cipher Surgical Limited service facility.

Disconnect the power cord either from the back panel of the generator or from the wall to isolate the OpClear Control Unit from supply mains power. Ensure access to these points is kept clear.

Should blood or other body fluids back flow through the OpClear tube set these may clog the filter. If body fluids back flow to the filter, stop the use of OpClear and replace the OpClear Disposable Procedure Kit.

Do not insert the combined Laparoscope and OpClear Disposable Procedure Kit into the patients' abdominal cavity until OpClear Control Unit operating start-up & self-check procedure has been completed. The control unit must not be switched ON or OFF whilst the combined Laparoscope and OpClear Disposable Procedure Kit is inserted in the patient.

Read the OpClear Disposable Procedure Kit Instructions for Use for Laparoscope set up assembly to the OpClear Disposable device.

6.1 PRECAUTIONS

Electromagnetic interference may occur on this instrument near equipment marked with this symbol  and this includes portable and mobile RF (Radio Frequency) communications equipment such as cellular phones. If electromagnetic interference occurs, mitigation measures may be necessary, such as reorienting or relocating this instrument, or shielding the location. See Section 17.10.

The Front Panel Membrane of the OpClear Control Unit is very sensitive. Do not use sharp metal objects on the panel Membrane

Do not attempt to remove the back or bottom screws or open the OpClear Control Unit. Such actions will invalidate the warranty and could create a hazardous condition.

Do not restrict the vents of the OpClear Control Unit, as they provide the required airflow for cooling.

If the OpClear Control Unit is moved out of the operating room, maintain control of the Control Unit and cart when moving it.

The equipment must be completely dry prior to storage. Residual moisture can present an infection risk.

Make sure no dust or other foreign matter penetrate the connection ports.

Do not store the OpClear Control Unit, Footswitch, Cables and Hoses in direct sunlight.

Do not attempt to repair the OpClear Control Unit.

6.2 AUDIBLE ALARMS

The OpClear Control Unit has two audible alarms, with differing levels of priority. See Section 17.8.

The low priority audible alarm is a double beep every 20 seconds and will sound whenever:

a. The system has a low supply of CO_2, but enough to continue operating.
b. Performing the self-test at start-up.
c. When performing manifold purge.
d. A valid disposable unit is not connected.
e. The depressurisation of the manifold supply is complete.

The medium priority audible alarm will sound three repeating beeps:

a. The self-test at start up at start-up fails.
b. When there is insufficient supply pressure of CO_2.
c. The manifold purge fails.
d. The priming of the disposable fails.
e. The cavity pressure exceeds the user set point, will silence only when pressure is below user set point again.
f. The system has supplied more than 2.33 litres in the preceding 60 seconds.
g. The system has a functional error.
h. The control unit is depressurising the manifold supply.

Alarms cannot be by-passed and can only be silenced by using the Standby Button to enter the Standby State. In this event, immediately remove the OpClear Disposable Procedure Kit and Laparoscope from the patient and recommence the OpClear Control Unit set up procedure.

Note: A single beep is sounded upon footswitch compression.

7. INSTALLATION & CONNECTION

During the installation and connection procedure do not attempt to simultaneously touch the patient and the OpClear Control Unit.

7.1 Installation of the OpClear Control Unit

- Inspect the Unit for any damage, breakage or surface marking or indentation or irregularities. In the event that you discover such, do not use the OpClear unit and contact your Cipher Surgical Representative.
- Place the OpClear Control Unit on its feet on a level stable work surface, stack or cart sufficient for the size and weight of the OpClear Control Unit above the level of the patient's abdomen.
- Place this Instruction Manual near the OpClear Control unit or in another easily accessible location.

7.2 Connecting to an AC mains supply.

- Confirm that the mains power is OFF before connecting.
- Connect the power cord supplied directly to a hospital grade AC outlet (wall mains outlet) and OpClear power inlet.
- Ensure the power cord is secure so it will not be accidentally dislodged during the operation.

7.3 Connecting the medical grade CO_2 gas supply

7.3.1 Connecting the high pressure hose to the cylinder

- Remove the hose from its plastic bag and remove dust cap from the inlet connector of the cylinder hose
- Inspect the cylinder hose for damage, cracks and other irregularities. Attach the cylinder hose to the CO_2 Inlet on the rear panel of the OpClear Control Unit. Only tighten by hand and do not use excessive force.

- When using the cylinder hose attach the hose connector to the cylinder as appropriate for the type of cylinder, ensure the cylinder contains sufficient CO_2 and change if required.
- Confirm that the OpClear Control Unit and CO_2 gas Cylinder are correctly connected then gently open the gas cylinder's valve.

7.3.2 Connecting to the medical (theatre supply)low pressure gas pipeline

- Remove the hose from its plastic bag and remove dust cap from the inlet connector hose
- Inspect the hose for damage, cracks and other irregularities. Attach the hose to the CO_2 Inlet on the rear panel of the OpClear Control Unit. Only tighten by hand and do not use excessive force.
- Connect the gas outlet connector of the hose to the CO_2 connector of the medical gas pipeline.
- Confirm that the OpClear Control Unit and CO_2 low pressure hose are correctly connected then gently open the gas supply.

8. OPERATION

The operation of the OpClear Control Unit must be by a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical Laparoscopic techniques.

8.1 Procedure

1. Turn on the ON-OFF (1) Switch on the Rear Panel. The OpClear Logo on the Front Panel will illuminate. The OpClear Control Unit will be inactive.
2. Press the Standby button (1) on the OpClear Control Unit Front Panel to turn the unit on. The System Status Indicator (2) will turn Amber as the Control Unit performs a self-test. A system failure will be indicated by the System Status Indicator flashing and an alarm sounding - consult the troubleshooting section in this manual.
3. The OpClear Control Unit will determine if sufficient CO_2 pressure is detected. If the pressure is sufficient the system will perform an automatic high pressure purge and the Supply Pressure Indicator (3) will be Green. If the pressure is below the requirement to operate the OpClear Control Unit the Indicators will flash Amber and an alarm will sound - consult the troubleshooting section in this manual.
4. Connect the Footswitch to the Activator Port (4) on the OpClear Control Unit front panel and position the Footswitch in easy reach of the camera operator.
5. Connect the OpClear Disposable Procedure Kit tube set to the OpClear Control Unit CO_2 to Patient (5) and Wash connectors (6) on the front panel (This is detailed in the OpClear Disposable Procedure Kit Instructions for Use)
6. Ensure the Saline cartridge has been filled.
7. Connect the appropriate Laparoscope to the OpClear Disposable as described in the OpClear Disposable Procedure Kit Instructions for Use.

8. The System Status Indicator will be Amber.
9. Compress and release the footswitch once. The OpClear Control unit will prime the disposable wash tube and deliver a purge of CO_2 through the OpClear Disposable Procedure Kit expelling any theatre air in the tube set and filter
10. On successful completion the System Status Indicator will turn Green. If the System Status Indicator flashes amber consult the trouble shooting section 16 in this manual.
11. The Up and Down buttons (9) may be used to set the time for which the Demist function runs when activated as displayed on the Demist Timer Display (8). To activate this function the operator needs to press and hold the footswitch for more than 2 seconds, then release the footswitch. This will turn on or off the Demist function, indicated by an "F" on the display. The Time display will display the remaining time and count down in half minute increments. (See section 16 Troubleshooting for other messages on this display.)
12. The OpClear Control Unit is set to a default upper abdominal pressure safety cut out 18 mmHg as displayed on the Abdominal Cavity Pressure Indicator (11). If the physician requests a higher or lower cut out this can be selected by pressing left and right buttons (10). If the abdominal pressure reaches the safety cut out pressure the System Status indicator will flash yellow, the alarm will sound and the OpClear Control Unit will not permit the flow of CO_2 or wash through the OpClear Disposable Procedure Kit. Once the abdominal pressure has decreased below the selected setting normal operation will continue. On power down the OpClear Control Unit will return to the 18 mmHg default mode.
13. The OpClear Control Unit and OpClear Disposable Procedure Kit are now ready for clinical use.
14. Each compression of the foot pedal delivers a single wash cycle, the system then requires 2 seconds to reset. During the

2 seconds reset period it is not possible to deliver another wash cycle.

8.2 After Use

1. Disconnect the OpClear Disposable from the OpClear Control Unit.
2. Disconnect from the CO_2 gas cylinder
    a. Close the gas cylinder valve
    b. Press and hold the standby button to release the pressure from the manifold (approximately 25 seconds).
        i. The display will show ***dEP*** , the supply pressure indicator will flash yellow and the unit will have a medium alarm sound until complete.
        ii. The display will now show ***CdEP*** , the supply pressure indicator will be yellow and have a low level alarm sound.
    c. Disconnect the high pressure hose from the CO_2 gas cylinder, then from the Control Unit and store in a safe place.
3. Disconnect from the medical CO_2 gas pipeline
    a. Disconnect the low pressure hose from the theatre supply first.
    b. Disconnect the low pressure hose from the Control Unit and store in a safe place.
4. Switch OFF the Power ON-OFF Switch on the Rear Panel. This will isolate all circuits in the OpClear Control Unit.
5. Disconnect the power cord from the hospital AC outlet, and from the OpClear Control Unit and store in a safe place.
6. Disconnect the OpClear foot switch and store in a safe place.

9. CLEANING & DISINFECTION INSTRUCTIONS

Before cleaning, thoroughly inspect the OpClear Control Unit for any signs of damage, cracks, or improper mechanical function. Do

not use the OpClear Control Unit if there are signs of damage. Notify an authorised Cipher Surgical representative for repair.

9.1 OpClear Control Unit and Front Panel Membrane Cleaning

- Clean the Control Unit, Front Panel Membrane and the connectors following hospital protocols.
- If the Control Unit becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant wipe before reuse. The following chemical disinfectants are approved for use with the Control Unit: Isopropyl Alcohol – 70% or Sodium hypochlorite solutions (0.25% - 0.50%).
- Use a soft, clean wipe lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.

9.2 Footswitch Cleaning

- Clean the footswitch in accordance with the hospital protocol. If the footswitch becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant before reuse. The following chemical disinfectants are approved for use: Isopropyl Alcohol – 70% or Sodium hypochlorite solutions (0.25% - 0.50%).
- Use a soft, clean wipe lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.

10. STORAGE OF OpClear CONTROL UNIT, FOOTSWITCH & CONNECTION HOSES

- Disconnect all power cords, coil them loosely and do not crush or bend them when storing. Handle the OpClear Control Unit carefully as it can be damaged if dropped on a hard surface.
- Store the equipment at room temperature in a dry, well ventilated environment.

- Coil the footswitch cord loosely: do not crush or bend it when storing.
- Handle the footswitch carefully as it can be damaged if dropped on a hard surface.

11. MAINTENANCE / SERVICING

The OpClear Control Units must only be maintained by Cipher Surgical.

Before returning the OpClear Control Unit for repair contact your local distributor. Please provide a description of the Control unit malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem.

Servicing is performed on the OpClear Control Unit to ensure and maintain its consistently high performance. This is normally accomplished on a 2 year cycle and must be carried out by Cipher Surgical or a Cipher Surgical appointed engineer. It is recommended that the OpClear Control Unit is not used until the servicing has been completed.

12. DISPOSING OF THE OpClear CONTROL UNIT (Environmental Protection)

The OpClear Control Unit packaging materials can be recycled.

The OpClear Control Unit and accessories must not be disposed of at the end of life with other waste. To recycle the equipment, obtain return instructions from the Cipher Surgical Customer Service Department or contact your local sales representative to discuss local waste disposal solutions and processes.

The OpClear Control Unit poses disposal risks similar to consumer electronics such as computers. There are no radioactive substances or hazardous liquids that may leak in or from the OpClear Control Unit.

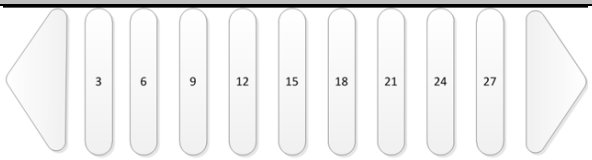
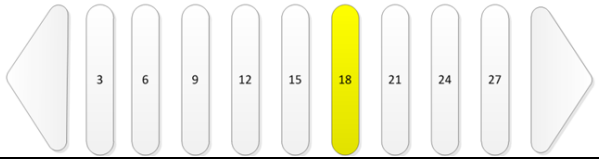
13. INFORMATION AND ERROR MESSAGES

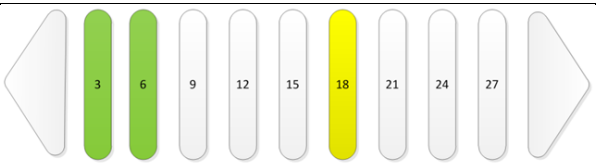
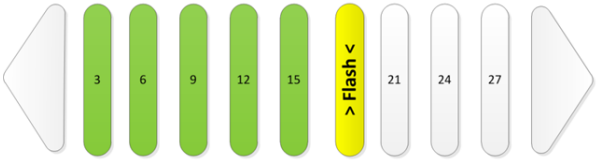
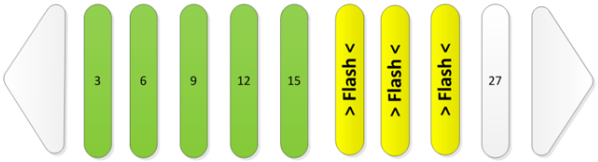
13.1 Display Panel

Condition	Display Pattern	Meaning
Awaiting Supply Pressure		Insufficient supply pressure
Manifold Purge		Purging air from supply and manifold
Manifold Purge Error		Purge of supply and manifold not successful
Awaiting Disposable		No disposable detected.
Disposable read error		Disposable not recognised / valid
Await Prime		The system is waiting to prime Disposable.
Prime Error		Prime of CO2 saline disposable not successful
Set Time		The time set for the Demist timer to run
Remaining time		Demist is active, this is the live countdown
CO2 pressure warning		Supply pressure below 4.5 but above 1.2 bar
Over pressure		Cavity pressure exceeding limit set

Over Flow		Too much gas delivered in last 60 seconds
Service and Calibration		Unit in service and calibration mode
System Error		System Error Code
Firmware Version		Shown during self-test at start-up
Depressurising		Releasing pressure to manifold
Depressurise Complete		CO2 supply pressure removed for hose disconnection

13.2 Cavity Pressure Display

Description	Indicator Display
Power Off	
Limit set to 18mmHg	

Limit set to 18mmHg, pressure over 6mmHg.	
Limit set to 18mmHg, pressure at 18mmHg.	
Limit set to 18mmHg, pressure over 24mmHg.	

14. TROUBLESHOOTING

Problem	Possible Cause	Solution
No Power to the Control Unit	The power cord is not connected	Connect Power Cord
	The AC Mains Electrical Power ON-OFF Switch on the Rear Panel is not set to ON	Turn Power ON
	The unit has an electrical fault	Contact Distributor or Manufacturer
No indicator Lights on front panel	The power cord is not connected	Connect Power Cord

Problem	Possible Cause	Solution
	The AC Mains Electrical Power ON-OFF Switch on the Rear Panel is not set to ON	Turn Power ON
	The unit has an electrical fault	Contact Distributor or Manufacturer
Laparoscope lens cleaning is not possible	The System Status Indicator is Yellow	Turn Power OFF and Turn Back ON
	The System Status Indicator is flashing Yellow	Ensure nothing is plugged into the USB Port on the Rear Panel. Turn Power OFF and Turn Back ON
	The System Status Indicator is Yellow: the system has encountered an error.	Turn Power OFF and Turn back on. If fault continues, contact Manufacturer
	Supply Pressure Indicator is flashing Yellow: Insufficient CO_2 supply pressure.	Connect and turn on CO_2 supply.
	The abdominal pressure has exceeded the selected setting	Reduce gas pressure: Open stopcock on Cannula.
	The OpClear Disposable Procedure Kit is not connected	Connect the OpClear Disposable Procedure Kit

Problem	Possible Cause	Solution
	The OpClear Disposable Procedure Kit tube set is collapsed or bent	Correct the collapsed or bent area
	The Footswitch connector is loose	Remove and reinsert the connector
	The gas cylinder is not in the upright position	Place the gas cylinder in an upright position
ALARM		
Excessive abdominal pressure warning continually sounds	Excessive gas pressure has been released by other equipment	Reduce gas pressure: open stopcock
Insufficient gas supply warning continually sounds	The gas supply valve is closed	Open Valve
	Remaining gas volume in cylinder is insufficient	Replace the gas cylinder with a new one
	The cylinder hose is not connected	Connect hose correctly
	The hose to the medical gas pipeline is not connected	Connect hose correctly
System Status warning continually sounds	Malfunction of Control Unit	Turn Power OFF and Turn Back ON
	Continuing malfunction of the Control Unit	Return Control Unit

15. SYMBOLS USED ON LABELLING

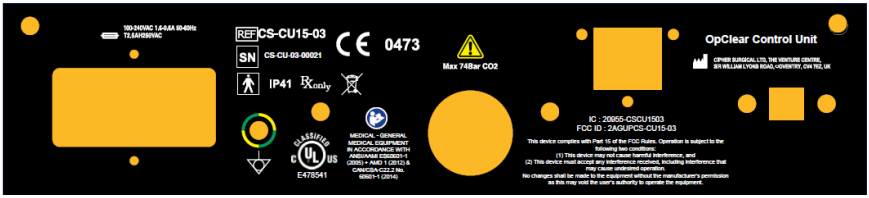
	MODEL NUMBER
	EQUIPOTENTIAL BOND POINT
	MANUFACTURER
	SERIAL NUMBER
	MEDICAL DEVICES DIRECTIVE 93/42/EEC AS AMMENDED
	DO NOT DISPOSE OF IN HOUSE HOLD WASTE

	FOLLOW INSTRUCTIONS FOR USE AND INSTRUCTION MANUAL
	TYPE BF APPLIED PART
	CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician
	FUSE RATING
	PATIENT ABDOMINAL CAVITY PRESSURE
	DEMIST TIMER
	CO_2 TO PATIENT CONNECTOR

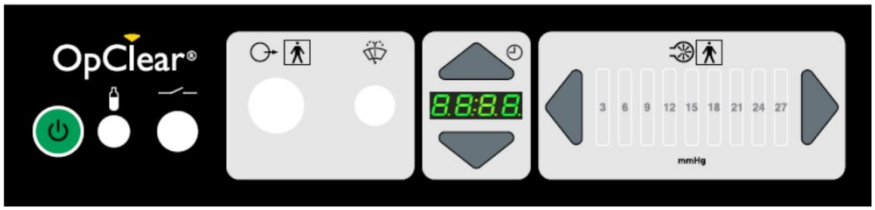
	WASH CONNECTOR
	ACTIVATOR
	CO_2 SUPPLY PRESSURE
FCC ID	The Federal Communications Commission identification number
IC	Industry Canada Certification Number
	Underwriters Laboratories Certified Classification Mark for authorised coverage in Canada and United States of America

16. LABELS

16.1 Control Unit Back Panel label



16.2 Control Unit Front Panel label



17. OpClear CONTROL UNIT SPECIFICATIONS

17.1 Operating environment

It is recommended that system is kept within the following Environmental Conditions:

- Operating Temperature +5°C to +25°C.
- Relative Humidity 20% to 90% non-condensing.
- Atmospheric Pressure 800 hPa to 1100 hPa.
- Storage Temperature -18°C to +38°C.

17.2 Applicable Gas: CO_2 medical grade gas

- Maximum delivery pressure to OpClear Control Unit to be less than 74bar
- Max delivery pressure from Control Unit 1.25bar +/- 0.1bar.

17.3 Weight and Dimensions OpClear Control Unit

- Weight 4.8 kg.
- Height 85mm maximum, Width 330mm maximum, Depth 300mm maximum.

17.4 Power Supply

- Universal AC Input/Full range Power Supply Unit.
- Input: 100-240V 50-60Hz

17.5 Fuses

- Power Inlet Module Fuses
- Fuse T2.5AH250V

17.6 Medical CO_2 Gas Inlet via Flexi Hose Assembly for Cylinder and Pipeline

- BS 341-3:2002 Outlet connection 8.

17.7 Footswitch

- Cipher Part Number CS-CUFS-02.

17.8 Alarm

This is designed to Meet IEC 60601-1-8.

- 975 Hz Fundamental Frequency.
- Measured auditory alarm signal sound pressure range:
  - Sound pressure level of:
    - Normal operating conditions – 58dB
    - Alarm condition – 64dB
  - Measurements at 1m from the front of the equipment.
- Two sound priority (low 2 beeps, medium 3 beeps repeating)

17.9 Accessories

17.9.1 CO_2 Gas Supply Hoses

Country specific, details and specifications are supplied separately.

17.9.2 Power Cables

Country specific, details and specifications are supplied separately.

17.10 Portable and Mobile RF Communications

Recommended separation distances between portable and mobile RF communications equipment and the OpClear Control Unit (Table 6 EN 60601-1-2:2007)

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d)in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

17.11 Federal Communications Commission (FCC) Regulatory Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

No changes shall be made to the equipment without the manufacturer's permission as this may void the user's authority to operate the equipment

17.12 Industry Canada Regulatory Statement

This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions:

(1) This device may not cause interference; and

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

The OpClear Control Unit complies with the safety requirements for RF exposure in accordance with RSS-102 Issue 5 for Portable Controlled Use conditions.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1) l'appareil ne doit pas produire de brouillage;

2) l’appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d’en compromettre le fonctionnement.

L'unité de contrôle OpClear est conforme aux exigences de sécurité pour l'exposition RF conformément aux RSS -102 Issue 5 pour utilisation conditions contrôlées portables.

18. LEGAL NOTICE: ATMEL SOFTWARE FRAMEWORK

19. DECLARATION OF CONFORMITY

The OpClear Control Unit meets the provisions of the Council Directive 93/42/EEC and the following harmonised standards:

19.1 UL Declaration

E478541

MEDICAL – GENERAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH ANSI/AAMI ES60601-1 + AMD 1 (2012) &
CAN/CSA-C22.2 No. 60601-1 (2014)

19.2 Electrical Safety

IEC EN 60601-1 Issue: 2005/12/15 Ed:3.0 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; Corrigendum 1: 12/2006; Corrigendum 2: 12/2007.

IEC 62366:2008 Medical devices. Application of usability engineering to medical devices.

IEC 60601-1-6: 2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

IEC 60601-1-8: 2006 General Requirements Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.

IEC EN 60601-1-2: 2007 General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

19.3 Software

IEC / EN 62304:2006 Medical device software -- Software life cycle processes.

19.4 Gas Regulator

EN ISO 10524-1:2006 - Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices
EN ISO 10524-4:2008 - Pressure regulators for use with medical gases - Part 4: Low-pressure regulator

19.5 Design & Manufacturing

BS EN ISO 13485:2012 Medical devices -- Quality management systems -- Requirements for regulatory purposes.

19.6 Labelling

BS EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.

19.7 User Information / Instructions

EN 1041:2008 Information supplied by the manufacturer of medical devices.

19.8 Risk Management

BS EN ISO 14971:2012 Medical devices. Application of risk management to medical devices.

20. NOTIFIED BODY

AMTAC Certification Services Ltd, Intertek Testing Services NA Ltd, Davy Avenue, Knowlhill, Milton Keynes MK5 8NL. Identification number 0473.

21. MANUFACTURER

The OpClear Control Unit is manufactured by Cipher Surgical Limited, The Venture Centre, Sir William Lyons Road, Coventry CV4 7EZ. www.ciphersurgical.com.
Cipher Surgical Limited is registered to ISO13485: 2012.

Cipher Surgical Limited
The Venture Centre
Sir William Lyons Road
Coventry
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www.ciphersurgical.com