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EVA15 Insufflator

LAP-100 EVA15 Insufflation and Smoke Evacuation Tubeset

LAP-200 EVA15 Insufflation and Smoke Evacuation Tubeset

LAP-300 EVA15 Insufflation and Smoke Evacuation Tubeset

CE
0050

User Manual

Note : An online copy of this User Manual and its translations into other languages may be found at :

https://www.palliare.com/resources/product-user-manuals

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Issue Date: **14 Apr 2026**

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1 Introduction

The EVA15 Insufflator is a CO_2 insufflator designed for use with appropriate disposable tubesets for laparoscopic or endoscopic surgical procedures. It offers two modes of insufflation:

1. Start-up mode, used during initial insufflation, and while placing trocars during laparoscopic surgery, whereby flow is periodically altered to achieve a target insufflation pressure based on working cavity pressure measured *periodically*
2. Maintain mode, used once initial insufflation is completed, whereby flow is continuously altered to target insufflation pressure based on working cavity pressures measured *continuously*

Since pressure is continuously measured during Maintain mode, leaks can be rapidly compensated for, so that, for instance, when a surgical tool is removed, or smoke evacuated, there will be minimal effect on insufflation pressure in the working cavity.

The EVA15 Insufflator has a pedal-activated smoke evacuation feature which allows smoke in the working cavity to be evacuated during any mode of insufflation, or for desufflation at the end of a case where no mode of insufflation is selected.

Intended End Users

The intended end users of the EVA15 insufflator with the LAP-100, LAP-200, LAP-300, END-200M and END-200S Tubesets are trained medical personnel, namely surgeons, endoscopists, gastroenterologists and nurses.

Indications for Use

The EVA15 Insufflator with the LAP-100, LAP-200, LAP-300, END-200M and END-200S Tubesets is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, rectum, colon, esophagus, stomach or thoracic cavity with up to 25 mmHg pressure, by filling it with gas and to evacuate surgical smoke.

1.1 Intended Use and Contraindications

Intended Use

The EVA15 Insufflator with the LAP-100, LAP-200, LAP-300, END-200M and END-200S Tubesets is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, rectum, colon, esophagus, stomach or thoracic cavity with up to 25 mmHg pressure, by filling it with gas and to evacuate surgical smoke.

Contraindications

EVA15 used for laparoscopic insufflation with LAP-200 and LAP-300 Tubesets:

Use of the EVA15 Insufflator with the LAP-200 and LAP-300 Tubesets is contraindicated whenever laparoscopy or flexible endoscopy is contraindicated. See the user manual of the laparoscope or endoscope being used for absolute and relative contraindications. This device is contraindicated for hysteroscopic insufflation - it must not be used for intrauterine distension.

EVA15 used for endoscopic insufflation with LAP-100, END-200S and END-200M Tubesets:

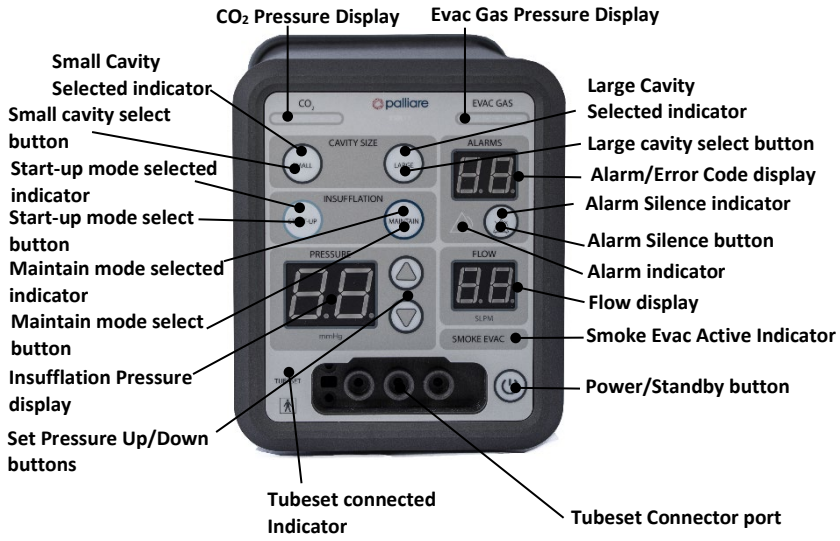
Use of the device is contraindicated whenever flexible endoscopy is contraindicated. See the user manual of the endoscope being used for absolute and relative contraindications.

Target Population

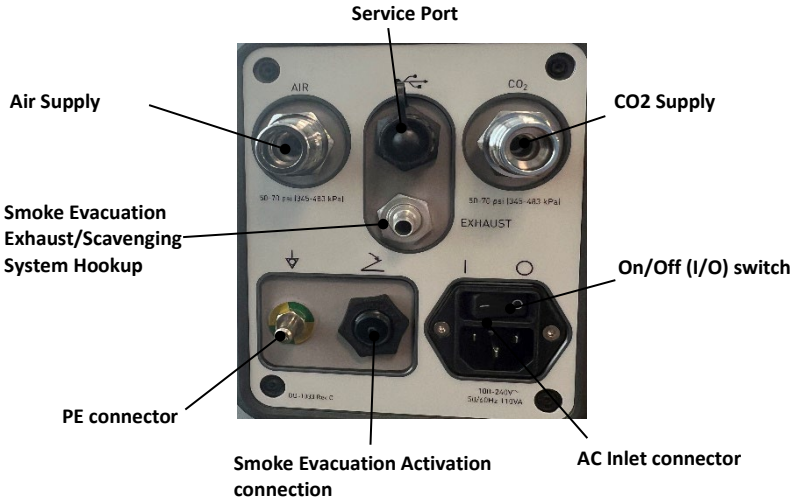
The EVA15 Insufflator is intended for patients undergoing laparoscopic or endoscopic surgery. The EVA15 Endoscopic Tubesets (LAP-100, END-200S, END-200M) are intended for patients undergoing endoscopic surgery, and the EVA15 Insufflation and Smoke Evacuation Tubesets (LAP-300, LAP-200) are intended for patients undergoing laparoscopic surgery.

Note: Any serious incident that has occurred in relation to the EVA15 Insufflator in the European Union should be reported to Palliare Ltd. and the competent authority of the Member State in which the user and/or patient is established. The EVA15 Insufflator is for professional use only.

1.2 Device Buttons and Indicator Labels



EVA15 Insufflator front view



EVA15 Insufflator rear view

Element	*Description*
CO_2 Pressure display	*Indicates CO_2 Supply Pressure*
Evac Gas Pressure display	*Indicates Air Supply Pressure (Air is used for the Evacuation system)*
Alarm/Error Code display	*Displays Alarm or Error Codes*
Standby button	*Pressed to exit or enter Standby*
Insufflation Pressure display	*Displays Working Cavity Pressure or Insufflation Pressure Setting*
Flow display	*Displays Insufflation Flow*
Set Pressure Up/Down buttons	*Used to adjust the insufflation pressure setting up or down*
Start-up mode select button	*Used to enter or exit Start-up mode*
Start-up mode selected indicator	*When lit, indicates that Start-up mode is selected*
Maintain mode select button	*Used to enter or exit Maintain mode*
Maintain mode selected indicator	*When lit, indicates that Maintain mode is selected*
Small Cavity Select button	*Selects that a small cavity is to be insufflated e.g. rectum*
Small Cavity Selected indicator	*When lit, indicates that small cavity is to be insufflated*
Large Cavity Select button	*Selects that a large cavity is to be insufflated e.g. abdomen*
Large Cavity Selected indicator	*When lit, indicates that large cavity is to be insufflated*
Smoke Evac Active indicator	*When lit, indicates that smoke evacuation is active*
Alarm indicator	*When lit, indicates that an alarm is active*
Alarm Silence button	*Silences alarms for 2 minutes*
Alarm Silence indicator	*When lit, indicates that alarms are silenced*
Tubeset connected indicator	*When lit, indicates that an un-expired and functioning tubeset has been connected*
Tubeset connector port	*Used for connecting the tubeset*
Air Supply	*Gas connection for air supply*
CO_2 Supply	*Gas connection for CO_2 supply*

Smoke Evacuation Exhaust/Scavenging System Hookup	*Smoke Evacuation exhaust port. Connect here to dedicated central scavenging system if required.*
Smoke Evacuation Activation connection	*Connection for foot pedal which activates smoke evacuation*
PE connector	*Stud to permit grounding to hospital earth system (Potential Equalization)*
AC Inlet connector	*Connector for AC power cord*
Service Port	*For servicing activities only*

1.3 Warnings

- ***Federal law (U.S.) restricts this device to sale by, or on the order of, a physician.***
- ***Metabolic Acidosis and Resultant Cardiac Irregularity:***
  Prolonged intra-abdominal pressures greater than 20 mmHg should be avoided. This can cause any of the following:
  - ***Decreased respiration with compromised diaphragmatic excursion***
  - ***Decreased venous return***
  - ***Decreased cardiac output***
  - ***Acidosis***
- ***Excessive absorption of CO_2 results from either excessive flow and/or excessive pressure. The abdomen can be adequately distended by pressure in the range of 15-20 mmHg. It is seldom necessary to use an abdominal pressure greater than 20 mmHg. Little intravasation should occur at these levels. Pressures over 20 mmHg are virtually never needed and will increase the amount and rapidity of intravasation. Adequate respirations help avoid problems related to CO_2. The insufflator does not permit an intra-abdominal pressure that exceeds 30 mmHg.***
- ***Operative procedures should only be performed with insufflators capable of flow rates of at least 4-10 L/min. Insufflators with lower maximum flow rates should only be used for diagnostic procedures.***
- ***Idiosyncratic reactions. In patients with sickle cell disease or pulmonary insufficiency use of these devices may pose increased risks of metabolic imbalance related to excessive CO_2 absorption.***
- ***Hypothermia. High-flow rate insufflators may present a potential risk for hypothermia.***
- ***Always position the patient lower than the EVA15 Insufflator to prevent body fluids from leaking into the insufflation or evacuation lines. Fluid may penetrate these lines if the patient is repositioned during surgery. If this occurs, immediately replace the tubeset. When the patient is repositioned onto his or her side, internal tissue may block the insufflation or evacuation lines. Always insufflate through the elevated side of the patient.***

- ***To reduce the risk of electric shock, always disconnect the device from AC power before opening the enclosure for servicing.***
- ***Regularly check the AC power cord and do not use the device if any damage to it (such as frayed wires, cracks, or cut insulation) is evident.***
- ***The EVA15 Insufflator should be mounted on a flat stable surface. When in use, keep the power cord stowed or positioned in a safe manner in order to avoid a tripping or snagging hazard.***
- ***Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service according to the EMC information provided in this user manual (see Appendix B). Using a power cord other than the one supplied by Palliare Ltd. may result in increased emissions from and/or decreased immunity of the EVA15 Insufflator.***
- ***Do not connect the tubeset to the patient during system start-up.***
- ***Only use the EVA15 Insufflator with tubesets and accessories supplied or approved by Palliare Ltd.***
- ***Service of this device should only be performed by a qualified service technician.***
- ***To ensure proper operation, do not make unauthorized modifications to the EVA15 Insufflator or tubesets.***
- ***Wipe the exterior of the device clean with a wipe, pre-moistened with 70% isopropyl alcohol, in accordance with the cleaning instructions provided in this manual before the first use, between each patient use, and as needed. To minimize the risk of contamination between patients, clean the preparation area between each patient use.***
- ***This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. To minimize the risk of fire, use this device in well-ventilated areas away from flammable anesthetics.***
- ***To minimize the risks associated with excess insufflation pressure, maintain continuous observation of the patient and all alarms during use.***
- ***Do not use this device near magnetic resonance imaging (MRI) equipment.***
- ***Only use the EVA15 Insufflator with low pressure wall air and wall CO_2 supplies i.e. less than 70 psi (483kPa), or with gas bottles with pressure regulators which deliver gas at a pressure below 70 psi (483kPa). DO NOT USE GAS BOTTLES WITH UNREGULATED PRESSURE OUTPUT TO SUPPLY THE EVA15 INSUFFLATOR.***
- ***This manual does not include descriptions or instructions for surgical procedures or techniques.***
- ***Use proper technique for lifting the device.***
- ***Do not attempt to lean on or use the EVA15 Insufflator on its table or cart for support.***
- ***The EVA15 Insufflator may only be used by a physician, nurse or medical assistant with the appropriate technical/medical qualifications working under the direction and supervision of a physician.***
- ***No part of the EVA15 Insufflator should be serviced when the insufflator is connected to a patient.***

- ***To avoid the risk of electric shock, this equipment must only be connected to a mains supply with a protective earth.***
- ***Do not touch the service port (USB port) at the rear of the unit, or the two-pin connector within the tubeset connector port at the front of the unit, and the patient at the same time.***
- ***Elevated intra-abdominal pressure can cause significant impairment of cardiac, pulmonary, renal, gastrointestinal, hepatic, and central nervous system function.***
- ***The European Association for Endoscopic Surgery clinical practice guideline on the pneumoperitoneum for laparoscopic surgery recommends to use the lowest intraabdominal pressure allowing adequate exposure of the operative field, rather than using a routine pressure. In patients with limited cardiac, pulmonary, or renal function, abdominal wall lifting combined with low-pressure pneumoperitoneum might be an alternative.***

2 Setting up the EVA15 Insufflator

The EVA15 Insufflator should be mounted on a flat stable surface. Four feet raise the machine off the surface, which permits cooling air to pass into the insufflator via a vent located on the lower surface of the insufflator.

Warning:

- ***To avoid overheating, do not place any material underneath the insufflator which might cover or obstruct the cooling vent.***
- ***Always position the EVA15 Insufflator so that it is easy to remove the power cord from the device quickly, should it become necessary.***

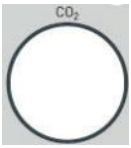
This section describes how to prepare the insufflator for use, including:

- Connecting to air and CO_2 gas supplies
- Connecting to AC power
- Power On/Off
- Connecting the tubeset

The potential equalization connector may be connected to a potential equalization cable, to allow the EVA15 Insufflator and all other equipment in the operating room to be grounded at a common point. This is to prevent current flow from one piece of equipment to another should they have different ground potentials. Any cable used should meet the requirements of DIN42801 standard.

2.1 Connecting to Air and CO_2 Gas Supplies

Connect the supplied air hose to the connector marked AIR at the rear of the EVA15 Insufflator. Connect the other end of the hose to an air supply.



Connect the supplied CO_2 hose to the connector marked CO_2 at the rear of the EVA15 Insufflator. Connect the other end of the hose to a CO_2 supply.

Warning:

- ***Use the EVA15 Insufflator with low pressure medical grade wall air and wall CO_2 supplies i.e. with gas supply pressure less than 70 psi (483 kPa). DO NOT USE GAS BOTTLES WITH THE EVA15 INSUFFLATOR UNLESS A LOW PRESSURE REGULATOR WITH 70 psi (483kPa) OUTLET PRESSURE OR LESS HAS BEEN FITTED TO THE BOTTLE AND THE REGULATOR HAS A LOW PRESSURE GAS OUTPUT FITTING COMPATIBLE WITH HOSES SUPPLIED BY PALLIARE LTD.***

- ***To avoid the risk of hypothermia, any gas used with the EVA15 Insufflator should be supplied at room temperature and preferably above 20°C.***
- ***Only use gas hoses supplied or recommended by Palliare Ltd.***
- ***Keep the gas hoses stowed or positioned in a safe manner in order to avoid a tripping or snagging hazard.***
- ***If using bottled gas, always have a backup bottle readily available for each gas.***
- ***Check CO2 and Air hoses for breakage, occlusions or debris prior to use.***

Note: An air supply is only required if evacuation functionality is being used

2.2 Connecting to AC Power

Insert the power cord into the AC Inlet connector at the rear of the EVA15 Insufflator and plug the power cord into a grounded wall outlet.

Warning:

- ***The EVA15 Insufflator must be connected to a grounded wall outlet or a single-outlet extension only. Do not use multiple-outlet sockets other than those approved by Palliare Ltd.***
- ***Only use the original power cord supplied with the EVA15 Insufflator.***
- ***Keep the power cord stowed or positioned in a safe manner in order to avoid a tripping or snagging hazard.***

Note: To remove mains power from the EVA15 Insufflator, switch off power at the wall outlet (if a switch is provided) and then disconnect the power cord at the outlet. This will isolate as well as disconnect the equipment from the mains supply.

2.3 Power On/Off

Use the switch at the back of the device to turn it on (I) or off (O). At power on, the device performs a Power On Self-Test (POST) lasting 10 seconds. Check that you hear the alarm buzzer beep during POST. After power on, the EVA15 Insufflator will enter Standby.

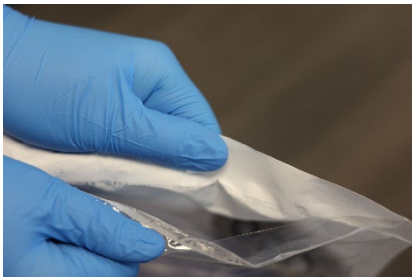
Warning:

- ***During POST, all displays will be lit. Check that all displays are functioning (the number eight (8) will show briefly in all numeric displays).***
- ***Do not connect a tubing set to the EVA15 Insufflator unless it has been powered on and successfully completed POST. If a tubeset is connected, an alarm will sound until you remove the Tubeset and power off EVA15 Insufflator. Power on the EVA15 Insufflator to re-start POST.***

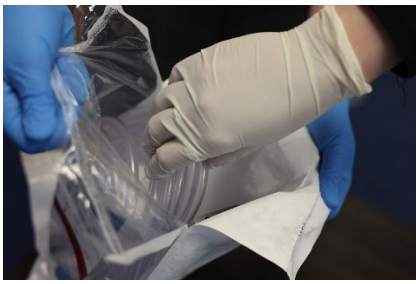
2.4 Connecting the Tubeset

For the LAP-200 or LAP-300 tubeset, with POST completed, remove the tubeset from its packaging as follows

a) A first user outside the sterile field should peel apart the two layers of the package at the V-end as shown below



b) A second user within the sterile field should remove the tubeset taking care not to touch the open edges of the package as shown below



With the insufflator in Standby Mode, connect the sterile LAP-200 or LAP-300 tubeset, shown in Figure 3, as described below. The tubes in the tubeset are color-coded. For abdominal insufflation, the LAP-300 tubeset is designed to be connected to any three standard trocars, each with a luer port, which allows passage of gas to or from the working cavity. For rectal insufflation, the EVA15 Insufflator is suitable for use with any single port access system with three luer ports which allow passage of gas to or from the working cavity. Both the gas delivery line and the smoke evacuation line contain filters to reduce the risk of cross-contamination. The LAP-200 may be connected to any two standard trocars.

Warning:

- ***The LAP-300 and LAP-200 tubesets are only sterile if used before the expiration date and if the packaging is unopened and undamaged. Do not use the LAP-300 or LAP-200 tubeset after the expiration date, if the expiration date on the packaging cannot be read, if any part of the packaging is open or damaged, or if the tubeset is broken or damaged.***
- ***Before use, inspect the tube set for breakage, occlusions, or debris.***
- ***To ensure integrity of the tubeset, always store it away from sources of heat, and in storage conditions specified in Appendix A.***
- ***The LAP-300 and LAP-200 disposable tubesets are packaged and sterilized for single patient use only. Do not reuse, reprocess or resterilize the tubeset. Re-use, re-processing or re-sterilization may compromise the structural integrity of the device and/or lead to a tubeset failure which in turn may result in patient injury, illness or death. Reprocessing or re-sterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious diseases(s) from one patient to another. Contamination of the devices may lead to injury, illness, or death of the patient.***
- ***The tubeset uses a custom connector which allows easy connection to the insufflator. Avoid using excessive force during insertion to avoid damage to the gas connectors on the tubeset.***
- ***To avoid potential tubeset contamination, only unpack the tubeset immediately prior to use.***

2.4.1 Connection of the Tubeset to EVA15 Insufflator

Press the two side tabs inwards, and press in the connector as shown below. In the case of the LAP-100 tubeset (only), the Tubeset connected Indicator will light up if the tubeset is not expired, functional and ready for use.

2.4.2 Connection of the Tubeset to Patient – Abdominal/Thoracic Insufflation

Warning:

- ***When switching to Maintain Mode, to ensure safe operation, always connect the three lines of the tubeset to three separate trocars.***

Connect the grey gas delivery line to the first trocar being inserted or Veress needle. Open the trocar or needle valve to ensure that CO_2 gas can pass into the abdomen. Once cavity pressure has been established, and additional trocars have been placed, the grey gas delivery line may be connected to any of the trocars.

Connect the yellow vacuum line to another trocar, ideally the trocar being used with a smoke generating tool. Open the trocar valve to ensure smoke can be evacuated via that trocar.

Connect the blue pressure sensing line to any other trocar port. Open the trocar valve to ensure that abdominal pressure can be measured.

Note: The LAP-200 tubeset does not have a blue pressure sensing line.

Note: The LAP-100 tubeset has a chip which informs the system of the type of Tubeset, and the features available for that Tubeset. It also tracks the usage life of the Tubeset.

2.4.3 Connection of Tubeset to Patient – Rectal Insufflation

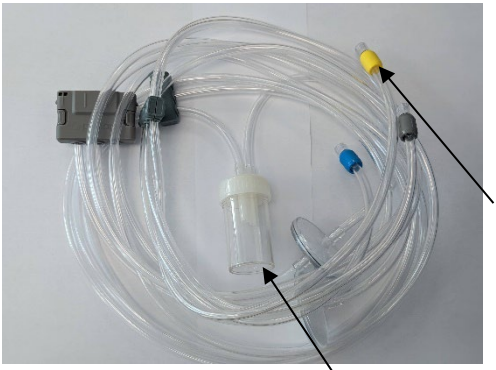
Connect the grey gas delivery tube to a luer port on the single port access system. Open the luer port valve, to ensure that CO_2 gas can pass into the rectum.

Connect the yellow vacuum line to a 5mm trocar and insert into the gel of the access system. Open the trocar luer port valve to ensure that smoke can be evacuated via that luer port.

If present (i.e. LAP-300), connect the blue pressure sensing line to another luer connector on the single port access system. Open the luer port valve to ensure that rectal pressure can be monitored via that luer port.

The tubesets have an integrated fluid trap. The fluid trap should be periodically monitored. If you observe that the fluid trap is more than half-full during insufflation :

- Pause insufflation by pressing the Maintain Button (the green LED will stop illuminating)
- Unscrew the fluid trap from its cap
- Empty the fluid trap
- Re-attach the fluid trap to the cap (note the cap and trap have markers, as shown, which align to act as a guide on the final twist when tightening the cap – the arrow should sit within the line area)
- Press the Maintain Button to resume insufflation



LAP-300 Tubeset

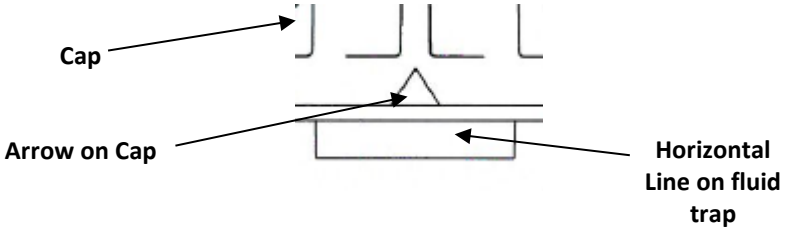


Illustration of cap and fluid trap markers

Warning:

- ***ALWAYS ENSURE THAT THE VALVE OF ANY LUER PORT ON A TROCAR CONNECTED TO THE TUBESET IS OPEN.***
- ***Keep the tubeset positioned in a safe manner in order to avoid a tripping or snagging hazard.***
- ***During the procedure continue to monitor and verify that lines do not get kinked.***
- ***Always position the patient lower than the EVA15 Insufflator to prevent body fluids from leaking into the insufflation or evacuation lines. Fluid may penetrate these lines if the patient is repositioned during surgery. If this occurs, immediately replace the tubeset. When the patient is repositioned onto his or her side, internal tissue may block the insufflation or evacuation lines. Always insufflate through the elevated side of the patient.***
- ***In the event of bodily fluids entering the equipment due to filter failure or any other reason, the EVA15 Insufflator should be removed from service and not used***

again until the unit has been tested, repaired and disinfected by an authorized service center.

- ***Single Use Tubesets should not be used for more than 24 hours***

2.4.4 Connection of LAP-100 Tubeset to Endoscope – Endoscopic Insufflation

Press the tubeset adaptor firmly onto the instrument channel of the endoscope, and connect the tubeset connector to the insufflator as shown in Section 2.4.1 .

During use, maintain visualization of the cavity to ensure appropriate insufflation is being achieved. The LAP-100 tubeset is non-sterile.

Warning:

- ***Inserting a tool in the instrument channel, for example a 2.3mm tool in a 2.8mm channel, or the presence of a leak in the tubing attachment to the instrument channel may affect the accuracy of the insufflator pressure reading. In these situations maintain visualization and adjust insufflation pressure as required. To achieve optimum insufflation, a 3.7mm channel endoscope should be employed if tools are being used in the channel. If tools are not employed in a case, a 2.8mm channel endoscope suffices. If a leak develops in the tubing attachment due to wear from an endoscopic tool, a gauze pad should be used to cover the valve. A high flow reading may indicate a damaged tubing attachment. If the flow reading is high, check that the tubing is well secured to the endoscope, the side-port adaptor cap, if present, is closed and has not been damaged by any endoscopic tool being used.***

3 Using the EVA15 Insufflator

This section describes how to use the EVA15 Insufflator, including:

- Description of insufflation modes
- Selecting insufflation parameters
- Reading the displays
- Using smoke evacuation
- When the procedure is complete

Note: The term working cavity is used to represent the cavity in which surgery is being performed, for example, the abdominal cavity, or the rectum.

3.1 Description of Insufflation Modes

The EVA15 Insufflator offers two modes of insufflation

- **Start-up mode** – is used during initial insufflation of the working cavity, and delivers traditional (i.e. intermittent) insufflation, where the flow is periodically altered to achieve a target insufflation pressure of up to 25 mmHg. Flow is stopped every few seconds to equalize the pressure in the insufflator with that in the working cavity, thereby allowing working cavity pressure to be measured using a pressure sensor inside the insufflator. Flow is then adjusted to target the set pressure value. The EVA15 Insufflator limits flow delivered to 12 SLPM *in this mode*. The term *intermittent* is used to reflect the fact that pressure is measured periodically and not continuously.
- **Maintain mode** – is used once the initial cavity insufflation is complete. During laparoscopic insufflation, when the working cavity pressure is above 5 mmHg, this mode delivers continuous pressure insufflation i.e. where flow is continuously altered to target insufflation pressure based on the working cavity pressure measured *continuously*. If the working cavity pressure is below 5 mmHg, this mode delivers traditional insufflation, as in Start-up mode, until such time as the pressure exceeds 5 mmHg whereby it then automatically reverts to continuous pressure insufflation. In continuous pressure insufflation, by virtue of having a pressure sensing line (blue) connected to the working cavity, there is no need to stop flow periodically to measure pressure. Pressure in the working cavity is therefore known at all times, and flow can be continuously adjusted to achieve the target insufflation pressure. A key advantage of continuous pressure insufflation is that any condition that can lead to escape of gas from the working cavity (e.g. smoke evacuation or removal of a surgical tool), which in turn could lead to a drop in working cavity pressure, can be immediately compensated

for with extra flow. In this mode, the EVA15 Insufflator can deliver up to 40 SLPM, allowing large leaks to be compensated for.

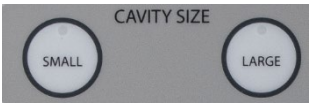
Note: Since continuous pressure insufflation is capable of delivering flows up to 40 SLPM, initial insufflation of the working cavity should always be performed using Start-up mode. Since initial insufflation is normally performed with only the first trocar in place (or using a veress needle), there will usually be no trocar port available to connect the blue pressure sensing line to, which in turn means that continuous pressure insufflation is not possible. ***As a further safety measure, continuous pressure insufflation is not possible during laparoscopic insufflation in Maintain mode until the blue pressure sensing line detects at least 5 mmHg working cavity pressure.***

3.2 Selecting insufflation parameters

3.2.1 Exiting Standby

Press the Standby button to get ready to allow the EVA15 Insufflator to be set up. The pressure display will be on during Standby, so as to allow cavity pressure to be measured, for example, during veress needle placement.

3.2.2 Selecting the Cavity Size



Firstly select whether you wish to insufflate a large or small cavity by pressing either the Small or Large Cavity Select button. Small cavity insufflation should be used for rectal insufflation for example. The Cavity Selected indicator will be lit for the cavity size that is selected. On power-up, the default selection is for Large cavity insufflation e.g. abdominal insufflation.

Note: Should fluid enter the grey CO2 tube, you can purge the CO2 tube by pressing and holding the currently selected Cavity button. 1 lpm CO2 will be delivered for as long as the button is pressed.

3.2.3 Setting the Insufflation Pressure (s)

Two pressure settings can be stored. Press the up arrow key to set the higher pressure and the down arrow key to set the lower pressure. The Pressure display will start flashing showing the current insufflation pressure setting. In the flow display the word “Hi” or “Lo” will confirm which pressure setting you are adjusting.

Adjust the pressure setting value using the up and down arrow keys.

When the desired pressure setting is reached, no further action is required. The setting is automatically accepted, and after 5 seconds the pressure display will resume displaying working cavity pressure, and insufflation will continue as it was before the setting adjustment was made i.e. if the high pressure setting was being used, the insufflator will resume using the high pressure setting, regardless as to whether the high pressure or low pressure setting was adjusted.

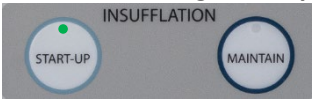
On power-up, the default pressure is the high pressure setting last used on the insufflator.

Note : Physician activated bi-level insufflation (PABI) is not available on laparoscopic tubesets. Please contact your local representative who can advise on tubesets permitting PABI. Where only one insufflation level can be programmed, either the up arrow or down arrow key may be pressed to adjust the single pressure setting, and the words Hi or Lo do not appear in the flow display.

To toggle between the high and low pressure settings, briefly press the foot pedal.

While insufflating with the low pressure settings, the system will beep periodically, and the lower right hand dot on the pressure display will be illuminated

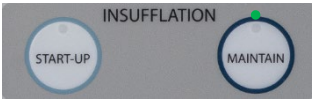
3.2.4 Selecting Start-up mode



After the Veress needle or first trocar is connected to the grey CO_2 gas delivery tube and its luer connector is open, press the Start-Up button. The Start-up mode selected indicator will turn on. This will start a slow and gentle insufflation to bring the working cavity up to target pressure. This mode should be used until all trocars are in place, and all tubeset lines have been connected.

Note : Start-up mode should not be used for insufflation during the procedure as audible and visual alarms are not active (to avoid nuisance alarms during trocar insertion).

3.2.5 Selecting Maintain mode



Once the working cavity pressure has reached to within 2 mmHg of the target insufflation setting, all trocars are in place, and all tubeset lines have been connected, press the Maintain button. The

Maintain mode selected indicator will turn on. This will enable continuous pressure insufflation, which maintains target cavity pressure when there are leaks and during smoke evacuation. Start-up mode should not be used for insufflation during the procedure.

If the working cavity pressure is, or drops to, below 5 mmHg, Maintain mode will switch to delivering traditional insufflation until the pressure increases to above 5 mmHg. While delivering traditional insufflation in Maintain mode, the Maintain mode selected indicator will blink. Once working cavity pressure reaches 5 mmHg, Maintain mode will automatically switch back to delivering continuous pressure insufflation, and the Maintain mode selected indicator will be continuously lit.

Note: Do not use Maintain mode until all trocars are in place, and all tubeset lines are connected

Note: If in Maintain mode and you need to insert an additional trocar, or to remove a trocar for specimen extraction, you should re-select Start-Up mode

Note: Continuous pressure insufflation should not be used if insufflating via a veress needle as the high restriction may lead to Occlusion alarms (Alarm 02).

3.2.6 Stopping Insufflation

To turn off CO_2 delivery, press the Start-Up button (if in Start-Up mode) or Maintain button (if in Maintain mode). Neither mode indicator light will now be lit and CO2 delivery will stop.

Alternatively press the Standby button to place the EVA15 Insufflator in Standby to stop insufflation

Note: If the EVA15 Insufflator loses wall power, when power is restored the desired mode of insufflation and cavity size need to be selected again.

Warning:

- ***Maintain continuous observation of the patient during use to ensure that insufflation is neither excessive nor inadequate***
- ***If cavity pressure appears to differ with the pressure shown on the EVA15 Insufflator display check that all trocar luer connectors are open and that there is no kink in the grey CO2 delivery line.***

3.3 Reading the Displays

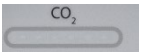
There are three numeric displays and two light bars on the front panel of the EVA15 Insufflator.

The Alarms Display. This display is positioned in the Alarms section of the front panel, and shows a code during machine error or alarm conditions. Alarms are described in more detail in Section 4.

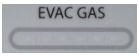
The Pressure Display. This display shows working cavity pressure, or the target pressure setting when the value is being adjusted.

The Flow Display. This display shows gas flow being delivered by the EVA15 Insufflator

Note: SLPM is the volumetric flow as it would be at standardized conditions of 0°C and 1atm (1013 hPa) atmospheric pressure. Actual flow delivered may be significantly greater at high altitude. An estimate of actual flow may be obtained by dividing the SLPM by local atmospheric pressure measured in atmospheres. As an example, at high altitude, with an atmospheric pressure of 700 hPa (0.69atm), 6 SLPM equates to approximately 8.5 L/min.



The EVA15 Insufflator uses CO_2 to insufflate the working cavity. This display gives a graded indication of CO_2 supply pressure with red, orange and green LEDs indicating low, medium and high pressure respectively When only the left-most red light is illuminated, the gas pressure is too low (below 40 psi or 276kPa) the system alarms.



The EVA15 Insufflator uses compressed air to create a vacuum for smoke evacuation. This display gives a graded indication of air supply pressure with red, orange and green LEDs indicating low, medium and high pressure respectively When only the left-most red light is illuminated, the gas pressure is too low (below 40 psi or 276kPa) the system alarms.

Note: A compressed CO2 gas supply may also be used to create a vacuum source. Please contact your local representative who can advise on the appropriate gas connector adapter.

Warning:

- ***Do not start a procedure unless there are adequate air and CO_2 supply pressures, as indicated by green lights being illuminated in the gas pressure displays.***

3.4 Using Smoke Evacuation

The EVA15 Insufflator comes with a pneumatic foot pedal which connects to the rear of the unit. To turn on smoke evacuation, press the foot pedal for less than 1 second. Evacuation will stay on until the foot pedal is pressed again to switch it off. Alternatively, if you press the foot pedal for more than 1.5 seconds, smoke evacuation will stop when you release the foot pedal.

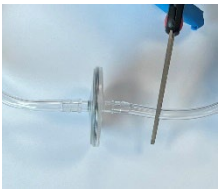
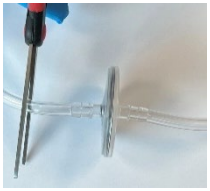
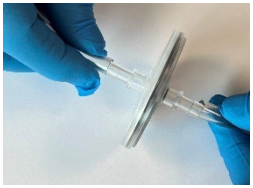
Alternatively, the AutoEvac® accessory, part number DD-1781, where available, may be used to activate and de-activate smoke evacuation. Its tube connects to the same Smoke Evacuation Activation connection (see section 1.2) as the foot pedal. Please see AutoEvac® Instructions For Use, part number DD-1779 for details on use of the AutoEvac® accessory.

Note : Always have the pneumatic foot pedal available as a back-up

Should further dampening of noise from the evacuation system be required, push on an EVA15 Silencing Filter part number DD-1858 as shown.

3.4.1 Replacing a smoke evacuation filter

During long procedures, e.g. entailing smoke evacuation on-time of greater than 90 minutes, the Smoke Evac Active Indicator may start flashing. This means that the smoke evacuation filter needs replacing. To do this, with hands protected by gloves, take a scissors and cut the evacuation tube at each end of the filter and insert replacement filter DD-1949, with the black end of the filter pointing towards the insufflator. Dispose of the old filter in accordance with institutional procedures.

Warning:

- ***If connecting EVA15 to a scavenging line, it should always be to a dedicated central smoke evacuation piping system. Vacuum systems could lead to CO_2 gas wastage and could potentially deflate the working cavity.***
- ***Should the smoke evacuation system fail to provide adequate smoke evacuation, disconnect the yellow vacuum line connector from its port to allow natural evacuation of gas through the port***

3.4.2 Using Smoke Evacuation pedal for end of case desufflation

Check that neither Start-up or Maintain modes are selected. To desufflate the working cavity, turn on smoke evacuation by briefly pressing the foot pedal. Evacuation will continue until you press the foot pedal again or until the cavity pressure reduces to 1 mmHg.

Note: If leaks are significant at the base or top of the trocars, it may not be possible to reduce pressure to as low as 1 mmHg.

Note: It is recommended to perform end of case desufflation to minimize the risk of viral contamination of the use environment.

Note: Pedal activated smoke evacuation is not available for tubesets which offer PABI.

When the Procedure is Complete

Press the Standby button to disable insufflation and smoke evacuation.

Switch off the insufflator at the rear of the unit.

Press in the grey tabs at the side of the tubeset connector, disconnect the tubeset and dispose of it in accordance with hospital, administrative and/or local government policy for the handling, processing, and disposal of biohazardous materials.

4 Alarms

The EVA15 Insufflator has two types of alarms:

- Clinical Alarms indicating that some intervention may be required to continue.
- System Alarms indicating a potential machine issue which may or may not be resolved with user intervention.

When an alarm occurs, the Alarm indicator lights and an alarm code is shown in the Alarms display, accompanied by an audible alarm of 57 dBA. In accordance with IEC 60601-1-8 Table 1, all alarms listed below are treated as *low priority alarm conditions*.

If the cause of the alarm is removed, the alarm code ceases to display and the audible alarm stops sounding. If there are multiple alarms, the highest ranked alarm will be shown. The operator's position is typically 1 meter in front of the EVA15 Insufflator.

To temporarily silence the alarm, press the Alarm Silence button. This will silence the audible alarm for two minutes. The Alarm Silence indicator will be lit for the two minute period. If the Alarm Silence button is pressed during the two minute silence period, the Alarm Silence period is cancelled and the Alarm Silence indicator will switch off.

The table below summarizes possible clinical and system alarms. Follow the corrective actions, in the order shown, until the problem is resolved. The lower the alarm code number, the higher the internal ranking of the alarm. The functionality of the alarm system can be verified as described in Appendix B.

Note : To avoid nuisance alarms during trocar insertion, alarms are not active during Start-up mode. Maintain mode should always be used for insufflation during the procedure.

Warning:

- ***Do not continue to use the system if alarms persist.***
- ***If an alarm condition cannot be resolved, remove the EVA15 Insufflator from service and contact Palliare Technical Support.***
- ***In the event of a front panel failure, e.g. numbers or lights not displaying as expected, power off the EVA15 Insufflator using the power switch at the rear of the unit per Section 2.2, remove it from service and contact Palliare Technical Support.***

Alarm Code	Description	How alarm condition is determined	Corrective action
01	Excess insufflation pressure	When target insufflation pressure is exceeded by 5 mmHg, or pressure is over 26mmHg, for more than 5 seconds this alarm is activated	Check that there is no kink or blockage in any of the lines and that all lines are connected to an open luer connector.
02	Grey Delivery tube blocked	If there is an occlusion, the restriction will cause the pressure inside the EVA15 Insufflator to rise, and this in turn will cause an occlusion alarm	Check that there is no kink or obstructions in the grey CO_2 gas delivery tubing. Check that trocar luer connector is open.
03	System temperature low	If the system temperature falls below 5°C, this alarm is activated.	Check that the EVA15 Insufflator is being used within the environmental conditions specified in Appendix A.
04	System temperature high	If the system temperature sensor rises above 55°C, this alarm is activated.	Check that the EVA15 Insufflator is being used within the environmental conditions specified in Appendix A. Check that the fan grill underneath the insufflator is not blocked or covered

Alarm Code	Description	How alarm condition is determined	Corrective action
05	Blue sensing line disconnect	This alarm is activated if the insufflation pressure line reading drops below pre-specified levels. This alarm also sounds if the pressure sensing line is occluded.	Check that the luer valve on the trocar or access system connected to the blue pressure sensing line is open. Check that the blue pressure sensing line is not disconnected or occluded.
06	Grey delivery tube disconnect	If the EVA15 Insufflator is delivering continuous pressure insufflation in Maintain mode and the measured flow exceeds 30 SLPM for a period in excess of 20 seconds.	Check that grey CO_2 delivery line is connected to the luer port on the trocar or access system. Check that the CO_2 delivery line is not leaking.
07	Insufflation pressure high	When target insufflation pressure is exceeded by 3 mmHg for more than 10 seconds.	Check that there is no kink in the blue pressure sensing line. Check that the blue pressure sensing line is connected to the EVA15 Insufflator and that the luer valve on the trocar or access system connected to the blue pressure sensing line is open. Check that the luer valve on the trocar or access system connected to the yellow vacuum line is open.

Alarm Code	Description	How alarm condition is determined	Corrective action
08	Insufflation pressure low	This alarm is activated if the pressure sensing line senses 5 mmHg pressure below target pressure for more than 20 seconds when the EVA15 Insufflator is delivering continuous pressure insufflation in Maintain mode, or for more than 30 seconds when the EVA15 Insufflator is delivering traditional pressure insufflation in Maintain mode	Check that the CO_2 delivery line is not leaking, disconnected from the trocar or access port and is securely attached to the luer or access port. Check that there is no kink in the grey CO_2 gas delivery or blue pressure sensing lines. Check that the luer valve on the trocar or access system connected to the blue pressure sensing line is open. Check that there is adequate supply of CO_2 to the EVA15 Insufflator
9	CO_2 gas supply low	CO2 supply pressure is less than or equal to 40psi	Replace CO_2 supply, or adjust the CO2 regulator to a pressure within the permissible range specified in Appendix A.
10	CO_2 gas supply high	CO2 supply pressure is greater than 99psi	Adjust the CO2 regulator or supply to a pressure within the permissible range specified in Appendix A.
11	Evac gas supply low	Evac supply pressure is less than or equal to 40psi	Replace air supply, or adjust the air regulator to a pressure within the permissible range specified in Appendix A.
13	Unexpected Restart	Software execution error detected by system	Press Standby button. If alarm code persists, contact technical Support
14	Tubeset expired	Hours of use counted	Replace tubeset
15	Tubeset fault	Communication failure with tubeset	Replace tubeset

Alarm Code	Description	How alarm condition is determined	Corrective action
9x	Power on Self-Test fault	Electronic sensors are tested at power on	Remove tubeset connector, power off and on the system and then re-connect the tubeset connector
Any code not shown in this table or if Corrective action does not resolve problem			Contact Palliare Technical Support.

Note : References to the blue pressure sensing line in the above table are only applicable to the LAP-300 tubeset.

5 Maintenance

This section describes maintenance of the EVA15 Insufflator, including:

- Cleaning
- Periodic maintenance
- Service

5.1 Cleaning

Clean the exterior of the insufflator and preparation area before the first use, and as often as required by institution disinfection procedures. Use a wipe pre-moistened with 70% isopropyl alcohol. The foot pedal may also be cleaned using a wipe pre-moistened with 70% isopropyl alcohol.

Do not allow liquid to penetrate the system.

Warning:

- ***Using other disinfectants or cleaning agents may lead to damage of the user interface***

Note: Cleaning validation has been conducted for 1000 cycles on the EVA15 user interface and 100 cycles on the foot pedal.

5.2 Annual Maintenance

Please see Document DD-2011 EVA15 Annual Maintenance Procedure.

5.3 Disposal

At the end of its service life, dispose of the EVA15 Insufflator in accordance with hospital, administrative and/or local government policy for the handling, processing, and disposal of electronic medical equipment.

Warning:

- ***Follow all applicable Federal and local regulations for disposal of the single use tubeset.***

5.4 Service

Warning:

- ***The EVA15 Insufflator is not serviceable by field service personnel.***

Full service and repair is available from the manufacturer (see Page 42 for contact details). Please contact your local representative who can advise on a number of service plan options.

6 Parts List and Accessories

The EVA15 Insufflator is compatible with the following accessories. Please contact your local Palliare representative before using other accessories.

Description	Part number
EVA15 Insufflation and Smoke Evacuation Tubeset (Box of 10)	LAP-100
EVA15 Insufflation and Smoke Evacuation Tubeset (Box of 10)	LAP-200
EVA15 Insufflation and Smoke Evacuation Tubeset (Box of 10)	LAP-300
EVA15 Insufflator CO_2 Hose DISS 6’	DD-1884
EVA15 Insufflator Air Hose DISS 6’	DD-1885
EVA15 Insufflator CO_2 Hose NIST 6’	DD-1902
EVA15 Insufflator Air Hose NIST 6’	DD-1896
EVA15 Insufflator Power Cord, US	DD-1918
EVA15 Insufflator Power Cord, EU	DD-1919
EVA15 Insufflator Power Cord, UK/Ireland	DD-1917
EVA15 Insufflator Foot Pedal (with Guard)	DD-1852
Annual Tester Kit	DD-1619
EVA15 Silencing Filter (Box of 10)	DD-1858
EVA15 Smoke Evacuation Filter (Box of 10)	DD-1949
EVA15 AutoEvac® Accessory	DD-1781
EVA15 Cart	DD-1928
EVA15 Cart Double Bottle Holder	DD-1929

For the most up-to-date accessories list, contact your local Palliare representative.

7 Cybersecurity

In accordance with the requirements of EU Regulation 2017/745, in order to run the embedded software within the EVA15 Insufflator as intended, the following should be noted:

Minimum requirements concerning hardware – No additional hardware is required to operate the EVA15 software beyond the EVA15 Insufflator system itself

IT networks characteristics – Not applicable since EVA15 cannot be connected to a wired or wireless network

IT security measures – Protection is physical, and the only means to access the EVA15 Insufflator hardware is via use of a tool.

Appendix A: Specifications

Operating modes

Start-Up mode, where flow is periodically altered to achieve a target insufflation pressure based on working cavity pressures measured *periodically*

Maintain mode, where flow is continuously altered to target insufflation pressure based on the working cavity pressures being measured *continuously*

Insufflation Mode	**Flow Range**	**Pressure Range**
Start-Up	0-12 SLPM	Up to 25 mmHg
Maintain	0-40 SLPM	Up to 25 mmHg
Measurement	**Resolution**	**Accuracy**
Pressure	1 mmHg	±1 mmHg
Flow	1 SLPM	±1 SLPM (≤ 10 SLPM) ±10% reading SLPM (>10 SLPM)

Evacuation

Open suction flow >10 LPM

Physical

Dimensions: 33cm (13.0”) (L) x 16cm (6.3”) (H) x 13cm (5.1”) (W)

Weight: 5.6 kg (12.3 lb)

Operating and storage conditions

Operating conditions (EVA15 Insufflator, LAP-100, LAP-200 and LAP-300 tubesets)

Temperature	15 to 35˚C
Humidity	15 to 95% relative humidity (non-condensing)
Atmospheric pressure	700 to 1040 hPa
Altitude	Below 2000m

Storage conditions (EVA15 Insufflator)

Temperature	-20 to 50˚C
Humidity	10 to 95% relative humidity (non-condensing)
Atmospheric pressure	600 to 1040 hPa

Storage conditions (LAP-100, LAP-200 and LAP300 Tubesets)

Temperature	-30 to 35˚C
Humidity	10 to 85% relative humidity (non-condensing)
Atmospheric pressure	600 to 1040 hPa

Note: When not in use for extended periods, store the EVA15 Insufflator in a clean sanitized plastic bag.

Electrical

Mains voltage range 100 – 240 VAC, 50/60 Hz, 110 VA rating.

Fuse designation 1A (T), 250V, Time Delay, 5x20mm cartridge

Applied Part: In accordance with EN60601-1, the tubeset is considered an *applied part*.

Service Port	USB 2.0 Device port, Mini B. Max. voltage D+, D-: 3.6v, VBUS: 5.5v. Max. current 5ma. Minimum 2 MOOP from an IEC 60601-1/IEC60950-1/IEC 62368-1 approved source.
Gas	Insufflation: CO_2 Inlet Pressure range 50-70 psi (345-483 kPa) Evacuation: Air Inlet Pressure range 50-70 psi (345-483 kPa)

Front panel symbols

	Standby On/Off
	Decrement/Increment Setting Value
	Type BF applied part complying with IEC 60601-1.
	Alarm Inhibit
	Alarm

Rear panel symbols

	Potential Equalization point
	Evacuation pedal connection point
	Alternating Current (AC)
I	Power On
O	Power Off

Main label (underside of unit) symbols

	Manufacturer
	Serial number. Digits are of the form: xxxxYYWW-xx where YYWW represents the year and week of manufacture.
	Part number
	IPX 1, degree of water ingress protection provided by enclosure.
	Caution, consult accompanying documents
	CE Mark and Notified Body Number
	Nationally Recognized Testing Laboratory (NRTL) symbol.
	Compliant with Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EC

Additional Tubeset and Box Label symbols

	Does not contain phthalate plasticizers.
	Natural rubber latex is not used in the manufacturing of the product.
	Do not re-sterilize
	Single Use
	Federal law (U.S.) restricts this device to sale by, or on the order of, a physician.
	The tubeset has been sterilized using ethylene oxide
	Do not use if packaging is damaged
	Storage temperature range
	Storage relative humidity range

	Storage atmospheric pressure range
	Keep away from rain
	This way up
	Fragile, handle with care
	Manufacturing Lot Code of Tubeset

A.1 Compliance

International standards	EN 60601-1:2006 + A2:2021, and U.S. and Canadian deviations “Medical Electrical Equipment; General Requirements for Safety” EN 60601-1-2:2015 +A1:2020 “Medical Electrical Equipment - Electromagnetic Compatibility Requirements and Test”.
EN 60601-1 Classification	Class I, Type BF, drip-proof equipment, continuous operation.
WEEE/RoHS Recycling Directive	Waste Electrical and Electronic Equipment and Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (WEEE/RoHS) Recycling Directives. If you are subject to the WEEE/RoHS directives, contact Palliare Ltd. regarding recycling this product.

A.2 Electromagnetic Compatibility

The EVA15 Insufflator is suitable for use in a hospital environment, though not in the vicinity of an MRI system. The system has been tested in accordance with IEC standard IEC 60601-1-2 to ensure that under electromagnetic interference test levels that represent those that might possibly be encountered in a hospital environment, Essential Performance will be met. In accordance with the IEC 60601-1 standard, Essential Performance is defined as the performance necessary *to achieve freedom from unacceptable risk*. For the purposes of meeting the requirements of IEC60601-1, Palliare has defined Essential Performance for an insufflator to be where cavity pressure varies from its target setting by 5 mmHg for more than 5 seconds. If system performance were to be degraded to the level represented by Essential Performance, inadequate cavity pressure might affect the ability to operate effectively in the surgical cavity, or excess pressure might lead to activation of the EVA15 Insufflator pressure relief valve.

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. You might need to take mitigation measures, such as relocating or re-orienting the equipment.

Warning:

- ***Use of the EVA15 Insufflator adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.***
- ***Using a power cord other than the one supplied by Palliare Ltd. may result in increased emissions from and/or decreased immunity of the EVA15 Insufflator.***
- ***Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EVA15 Insufflator, otherwise, degradation of the performance of this equipment could result.***
- ***To ensure electromagnetic compatibility and electrical safety, always ensure all internal earth wires inside the EVA15 Insufflator are re-connected after the unit is serviced.***
- ***Avoid exposure of the EVA15 Insufflator system to known sources of EMI (electromagnetic interference) such as Magnetic Resonance Imaging (MRI) systems, diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID***

devices may not be obvious. If such interference is suspected, reposition the equipment if possible, to maximize distances.

The EVA15 Insufflator has been tested for compliance for each IMMUNITY and EMISSIONS standard or test as follows:

<table>
<tr><th>Immunity test</th><th colspan="2">Compliance Level</th></tr>
<tr><td>Electrostatic discharge (ESD)
IEC 61000-4-2</td><td colspan="2">± 8 kV contact
± 2,4,8,15 kV air</td></tr>
<tr><td>Radiated RF EM fields
IEC 61000-4-3</td><td colspan="2">3 V/m</td></tr>
<tr><td rowspan="7">Proximity fields from RF wireless communications equipment</td><td>Service</td><td>Compliance Level (V/m)</td></tr>
<tr><td>Tetra 400</td><td>27</td></tr>
<tr><td>GMRS 460,
FRS 460</td><td>28</td></tr>
<tr><td>LTE band 13,17</td><td>9</td></tr>
<tr><td>GSM800/900
TETRA 800
iDEN 820
CDMA 850
LTE Band 5</td><td>28</td></tr>
<tr><td>GSM 1800
CDMA 1900
GSM 1900
DECT
LTE Band 1,3,4,25
UMTS</td><td>28</td></tr>
<tr><td>Bluetooth
WLAN 802.11 b/g/n
RFID 2450
LTE Band 7</td><td>28</td></tr>
<tr><td>WLAN 802.11 a/n</td><td>9</td></tr>
</table>

Immunity test	**Compliance Level**
Electrical fast transient/burst IEC 61000-4-4	± 2 kV
Surge IEC 61000-4-5	± 0.5, 1 kV line(s) to line(s) ± 0.5,1,2 kV line(s) to ground
Conducted disturbances induced by RF fields IEC 61000-4-6	3V/m outside ISM Bands 6V/m within ISM Bands
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T (100 % dip in U_T) for 0.5 cycle at 0°,45°,90°,135°,180°,225°,270° and 315°. 0 % U_T (100 % dip in U_T) for 1 cycle at 0°. 0 % U_T (100 % dip in U_T) for 250 cycles (50Hz) or 300 cycles (60 Hz) at 0°. 70 % U_T (30 % dip in U_T) for 25 cycles (50Hz) or 30 cycles (60 Hz) at 0°.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m

Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A

Appendix B: Alarm System

The functionality of the EVA15 Insufflator alarm system can be verified as described below.

Alarm Code	Description	Test Setup
01	Excess Insufflation Pressure	Please see Document DD-2011 EVA15 Annual Maintenance Procedure, Section 2.3.
02	Grey Delivery tube blocked	Please see Document DD-2011 EVA15 Annual Maintenance Procedure, Section 2.6.
03	System temperature low	Place system in a fridge at 0℃ for 60 minutes. Remove and power on the system. Verify that this error code is annunciated.
04	System temperature high	Test on Alarm Code 03 verifies the temperature alarm subsystem.
05	Blue sensing line disconnect	Please see Document DD-2011 EVA15 Annual Maintenance Procedure. Set up as per Section 2.3, Steps 1 - 11. Remove the blue pressure sensing line “1” from the cavity. Alarm 05 will annunciate.
06	Grey delivery tube disconnect	Please see Document DD-2011 Annual Maintenance Procedure. Set-up as per Section 2.3. Remove grey line “7” and block port on cavity bag. Ensure the cavity pressure is below the target pressure by 1 - 2 mmHg. Alarm 06 will annunciate after 20 seconds.
07	Insufflation pressure high	Please see Document DD-2011 Annual Maintenance Procedure. Set up as per Section 2.3, Steps 1 - 11. Apply pressure on the bag to be 3mmHg over target pressure. Alarm 07 will annunciate after 10 seconds.
08	Insufflation pressure low	See Alarm Code 07.
09	CO_2 gas supply low	Please see Document DD-2011 Annual Maintenance Procedure. Test per Section 2.1 or Section 2.2 depending on hospital setup.

Alarm Code	Description	Test Setup
10	CO_2 gas supply high	Test on Alarm Code 9 verifies the CO2 pressure measurement subsystem.
11	Evac gas supply low	Please see Document DD-2011 Annual Maintenance Procedure. Test per Section 2.1 or Section 2.2 depending on hospital setup.
13	Unexpected Restart	This alarm is not testable as it only is announced if an unknown system error has occurred
14	Tubeset expired	Insert and remove the tubeset connector 5 times (LAP-100 only)
15	Tubeset fault	Not testable

In accordance with IEC 60601-1-8, the statistics of distribution of alarm condition delays for the fourteen alarms above is as follows:

Alarm Condition Delay (s)	Number of alarms
Immediate	4
1 second	3
2 seconds	3
5 seconds	1
10 seconds	1
20 -30 seconds	2

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Appendix C EU MDR - Anticipated Undesirable Effects due to Insufflation

The following are anticipated undesirable effects which may arise during laparoscopic insufflation :

Postoperative Pain
Reduced Core Body Temperature
Reduced flow in the common femoral vein
Increased Intracranial Pressure
Decreased Peritoneal Immunity
Cardiac & Hemodynamic Changes
Pulmonary Depression
Decreased Urine Output (Oliguria)/ Anuria
Hypercapnia & Acidosis
Subcutaneous Emphysema
Capnothorax /Pneumothorax
Bradycardia
Pneumonia/ Postoperative Shivering & Hypothermia
Gas embolism
Veress needle puncture leading to gas embolism
Cardiac Arrest
Stroke
Tachycardia
Eye haemorrhage
Otorrhagia
Pneumomediastinum
Vena Cava puncture

The following are anticipated undesirable effects which may arise during endoscopic insufflation :

Postoperative Pain
Cardiopulmonary effects
Mediastinal Emphysema (ME)
Fever
Pneumonia
Capnoperitoneum
Capnothorax /pneumothorax
Capnopericardium / pneumopericardium
Subcutaneous Emphysema (SE)
Gas Embolism
Retroperitoneal CO2
Perforation
Pancreatitis
Barotrauma
Hypercapnia (Headaches, dizziness and vomiting)

Appendix D Residual Risks

In accordance with European Regulation 2017/745, the residual risks when using the EVA15 insufflator are set out below :

Residual Risk	**Worst Case Expected Outcome**
Hypothermia	Perioperative hypothermia has recently been associated with a poorer outcome following surgery. Previous cellular mechanisms in this context have included reduced antigen phagocytosis, and tissue hypoxia secondary to hypothermic vasoconstriction
Gas Embolism	Gas embolisms are a very rare but potentially fatal complication of laparoscopy. The incidence of gas embolisms is estimated to be less than 0.6%, and the leading cause is accidental displacement of a needle or trocar into a blood vessel
Improper placement of the trocar or veress needle	Pneumothorax - Most cases of CO2 pneumothorax (capnothorax) occur during laparoscopic procedures performed near the diaphragm and are caused by accidental diaphragmatic injuries. Only a moderate to severe capnothorax requires the placement of an intercostal chest tube Subcutaneous Emphysema - The reported incidence rate of known Subcutaneous Emphysema ranges from 0.43% to 2.34%. Mild-to-severe, localized or generalized subcutaneous emphysemas generally do not have clinical consequences. It might, however, point to a concurrent pneumomediastinum or pneumothorax, which may equally be its cause or effect.
Perforation during an endoscopic procedure	Mediastinal Emphysema

Warranty

Palliare Ltd. warrants the EVA15 Insufflator to be free from defects in material and workmanship for a period of 12 months from the date of purchase, provided that the unit is operated under conditions of normal use as described in this manual. At its discretion, Palliare Ltd. will make replacements, repairs, or issue credits for equipment or parts that are found to be defective.

THE WARRANTY SET FORTH ABOVE IS THE SOLE AND EXCLUSIVE WARRANTY WITH RESPECT TO THE PRODUCT AND PALLIARE LTD. DOES NOT MAKE, AND HEREBY SPECIFICALLY DISCLAIMS, ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABLITY OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. THE REPAIR, REPLACEMENT OR CREDIT REMEDY SET FORTH ABOVE WILL BE THE SOLE REMEDY FOR BREACH OF WARRANTY. IN NO EVENT SHALL PALLIARE LTD. BE LIABLE FOR LOST PROFITS, LOSS OF GOODWILL, OR INCIDENTAL OR CONSEQUENTIAL DAMAGES EVEN IF PALLIARE LTD. HAS BEEN ADVISED OF THE POSSIBLITY OF SAME.

Exclusions: This warranty does not apply to any unit or individual parts which have been repaired or altered in any way that in Palliare Ltd.'s judgment, affect its ability or reliability, or which has been subjected to misuse, negligence, abuse, or accident.

Unauthorized service may void this warranty.