ORL OTOSMART COMPACT UNIT

WARNINGS AND PRECAUTIONS

0.1. SAFETY SYMBOLS AND INDICATIONS

	Caution
	Type B apparatus
	Manufacturer
	Serial number
	Alternating current
	Reference to the instruction manual/brochures. "safety signal".
	Operating instructions
	Protective earth
	Waste electrical and electronic equipment
	Actuating pedal.

0.2. WARNINGS

 THE FOLLOWING INFORMATION IS OF GREAT IMPORTANCE FOR SAFETY AND MUST BE TAKEN INTO ACCOUNT WHEN USING THIS DEVICE.

 IF PERSONAL INJURY AND/OR MATERIAL DAMAGE TO THIRD PARTIES SHOULD OCCUR AS A RESULT OF INCORRECT OR IMPROPER USE OF THE DEVICE, POOR MAINTENANCE AND CARE, REPAIR BY UNQUALIFIED OR UNAUTHORISED PERSONNEL, OR FAILURE TO FOLLOW THE INSTRUCTIONS GIVEN IN THIS MANUAL, OPTOMIC ESPAÑA S.A., THE MANUFACTURER OF THIS EQUIPMENT, ASSUMES NO LIABILITY FOR SUCH DAMAGE.

 THE EQUIPMENT CONTAINS ELECTRONIC COMPONENTS THAT MAY DAMAGE THE ENVIRONMENT IF NOT PROPERLY MANAGED. AT THE END OF THE UNIT'S USEFUL LIFE, NATIONAL AND LOCAL REGULATIONS REGARDING ENVIRONMENTAL WASTE MANAGEMENT MUST BE FOLLOWED. ALTERNATIVELY, THE EQUIPMENT MAY BE RETURNED TO OPTOMIC ESPAÑA S.A. FOR FURTHER CONTROL AND MANAGEMENT OF THESE COMPONENTS.

 IF LIQUIDS ENTER THE DEVICE, IT MUST BE CHECKED BY QUALIFIED PERSONNEL BEFORE BEING USED AGAIN.

NOTE: MAINTENANCE OF THE VENTILATION GRILLE:
CLEAN EVERY 6 MONTHS WITH THE HELP OF A HOOVER.

 LEAVE THE VENTILATION GRILLE AT THE FRONT AND REAR OF THE UNIT FREE.

 THE USER MUST ENSURE THAT THE POWER AND EARTHING CONNECTIONS ARE CORRECT FOR THE CORRECT OPERATION OF THE EQUIPMENT.

 THE EQUIPMENT NEEDS TO BE INSTALLED AND PUT INTO OPERATION A S INDICATED IN THE EMC CHAPTER OF THIS MANUAL.

 PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENT MAY AFFECT THE OTOSMART COMPACT UNIT.

THE USER MUST CONNECT THE EQUIPMENT WITH THE COMPONENTS PROVIDED BY THE MANUFACTURER. FAILURE TO DO SO MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE EQUIPMENT.

EQUIPMENT SHOULD NOT BE USED ADJACENT TO OTHER EQUIPMENT; IF ADJACENT USE IS NECESSARY, THE EQUIPMENT SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

0.3. QUALIFIED TECHNICAL STAFF

The repair of the OTOSMART COMPACT unit, regardless of its importance, must be carried out exclusively by qualified technical personnel who have passed the training course given by OPTOMIC ESPAÑA S.A. to authorised technicians for this purpose.

It is the full responsibility of the user, or the authorised distributor, to verify that such qualified and authorised technical personnel are present.

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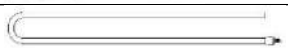
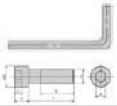
SUCTION HOSE	
PRESSURE HOSE	
REAR PANEL: 6 X SCREWS M6X20 ALLEN KEY	
INSTRUMENT SUPPORT: 6 X SCREWS M4X8 ALLEN SPANNER	

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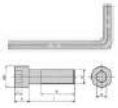
GLOVE CARRIER: 2 SCREWS M4X10 ALLEN KEY 2,5	

NOMENCLATURE

1	BOX	11	SUCTION HOSE
2	BOX	12	PRESSURE HOSE
3	BOX	13	SIDE INSPECTION DOOR
4	BOX	14	MAIN SWITCH
5	STORAGE AREA	15	REGLETA
6	STORAGE AREA	16	PEDAL CONNECTION
7	AUXILIARY BALLOON	17	VENTILATION GRILL
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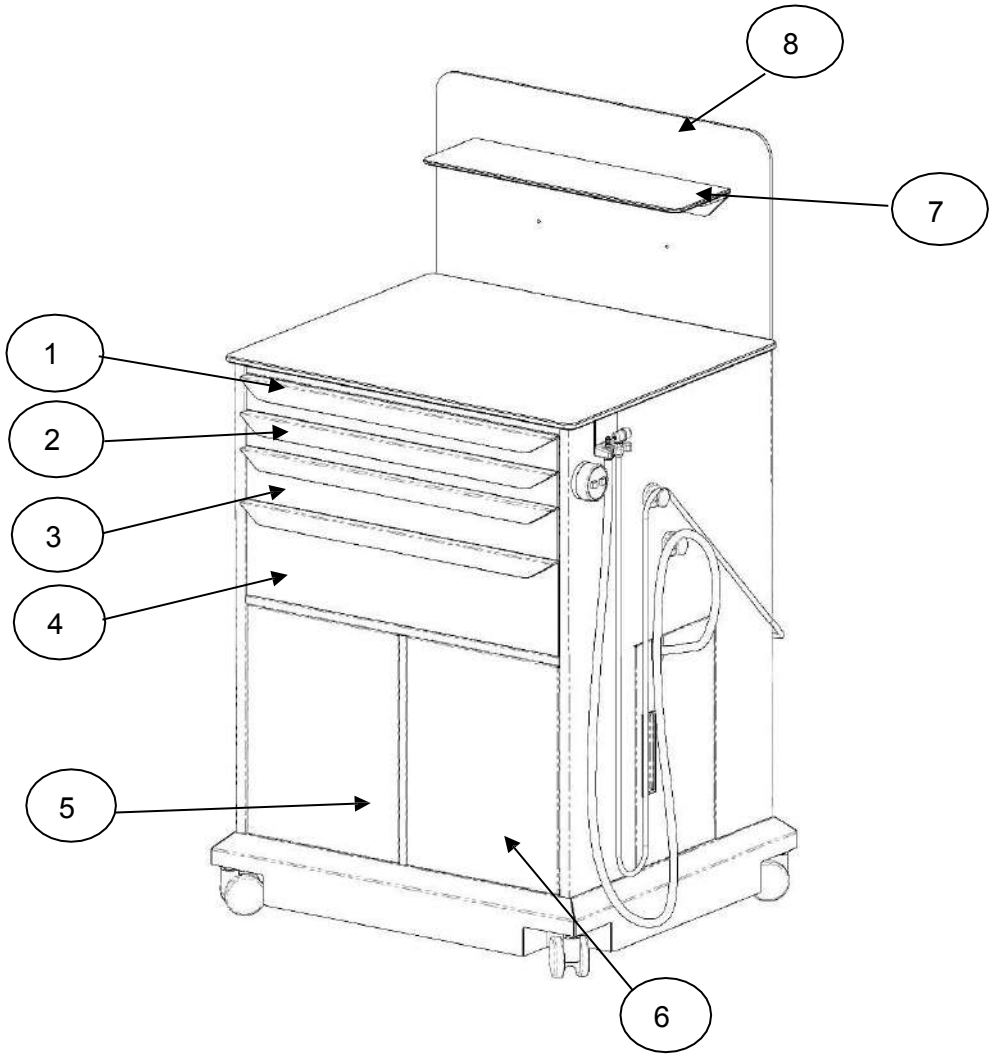

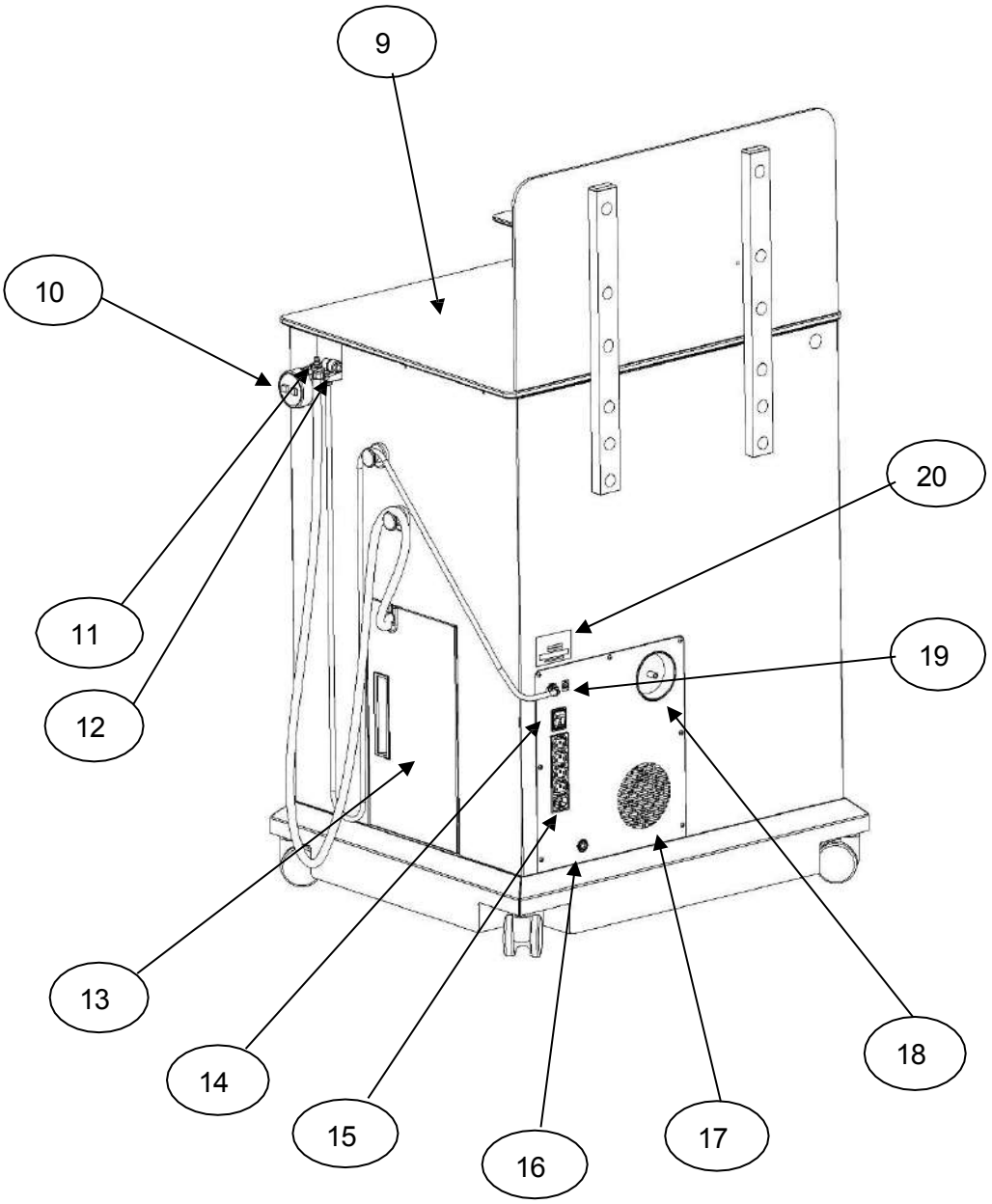
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USO

The OTOSMART COMPACT unit is intended for use in a healthcare facility and is designed to optimise space.

The OTOSMART COMPACT unit also allows endoscopy equipment to be installed on it, whether cameras and cold light sources, stroboscopy units or other equipment manufactured by OPTOMIC or with equipment of any other brand on the market.

Its use is indicated for the speciality of:

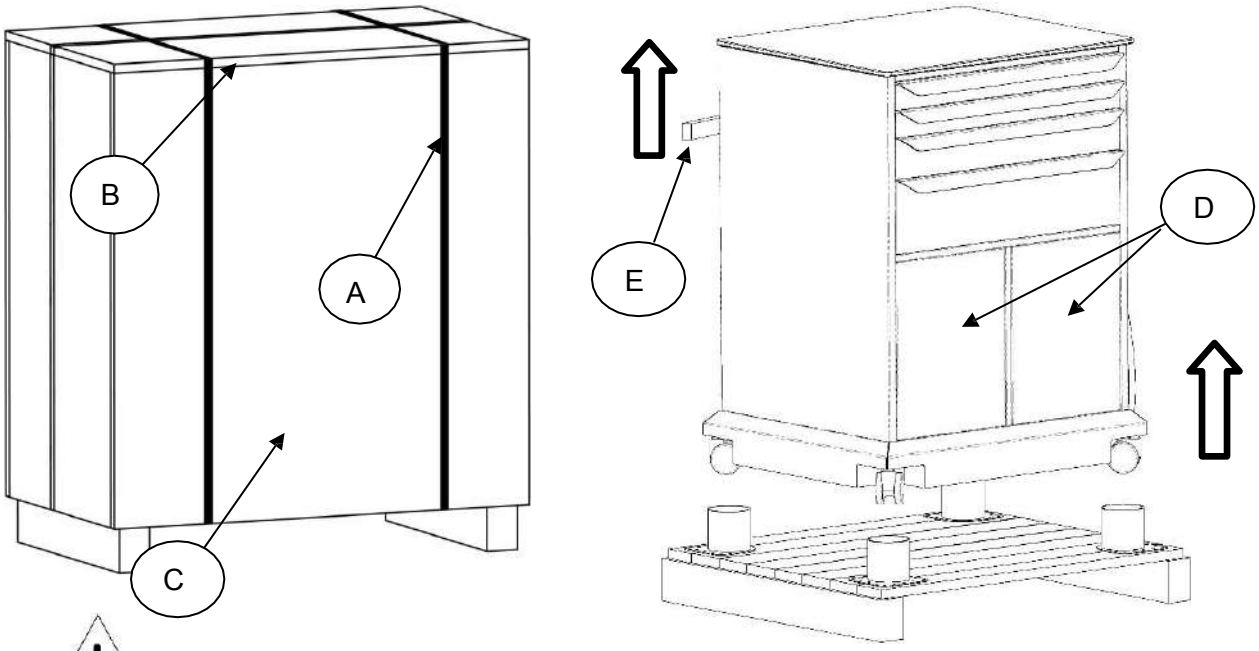
- **OTORHINOLARYNGOLOGY.**

UNPACKING AND C O M M I S S I O N I N G

5.1. PACKAGING

The ENT unit is supplied in its own transport packaging.

1. Remove the packing tape **[A].**
2. Remove the drawer cover **[B].**
3. Remove the wooden sides **[C].**
4. Open doors **[D].**
5. Reach into the upper part of the door casing and, holding the transport bar **[E]**, lift the unit out of the packaging.



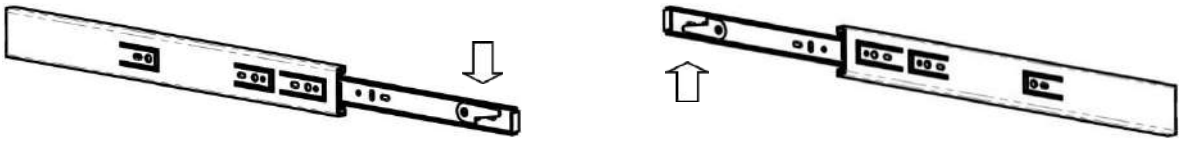
IMPORTANT: This operation must be performed by at least 2 people, do not attempt to lower the unit from the pallet by one person,

IMPORTANT: given the weight of the equipment, it must be moved with **great caution**, always assisted by people who are used to moving heavy loads. These movements must be carried out carefully, protecting legs and feet and making sure that no element, animal or child gets in the way.

If it is necessary to remove weight from the unit for positioning, proceed as follows:

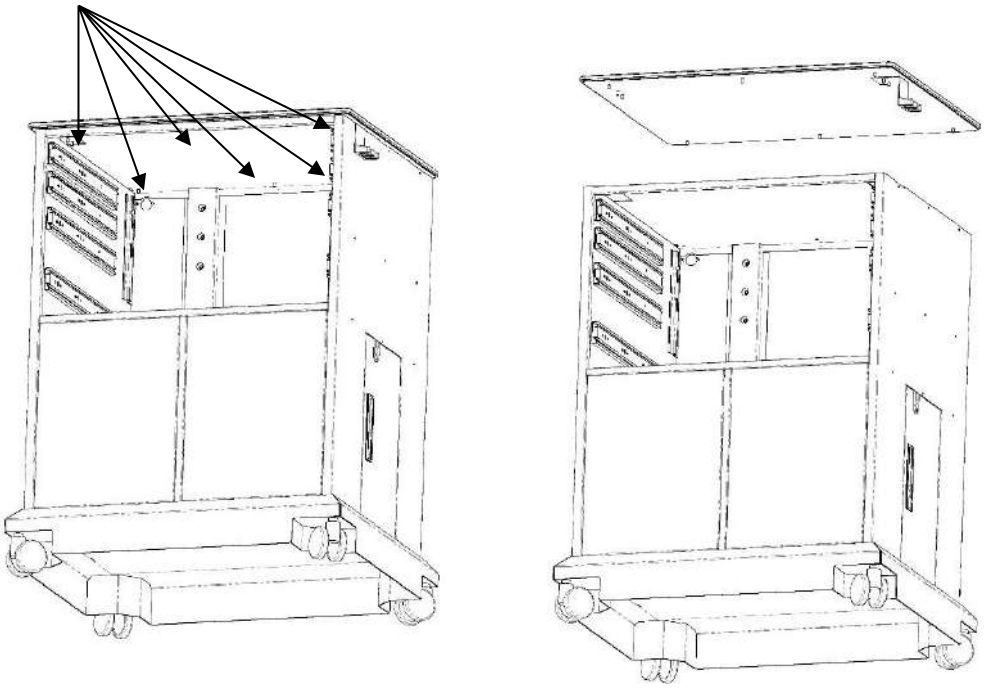
1. Remove drawers:

   Open the drawer and raise the tab on one of the slides and lower the other tab on the opposite slide, pull it outwards and pull the drawer out.



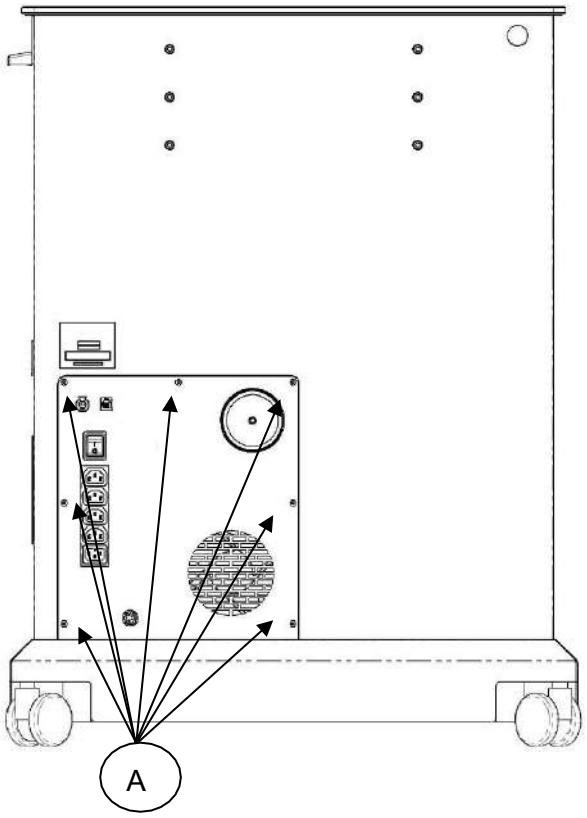
2. Remove worktop:

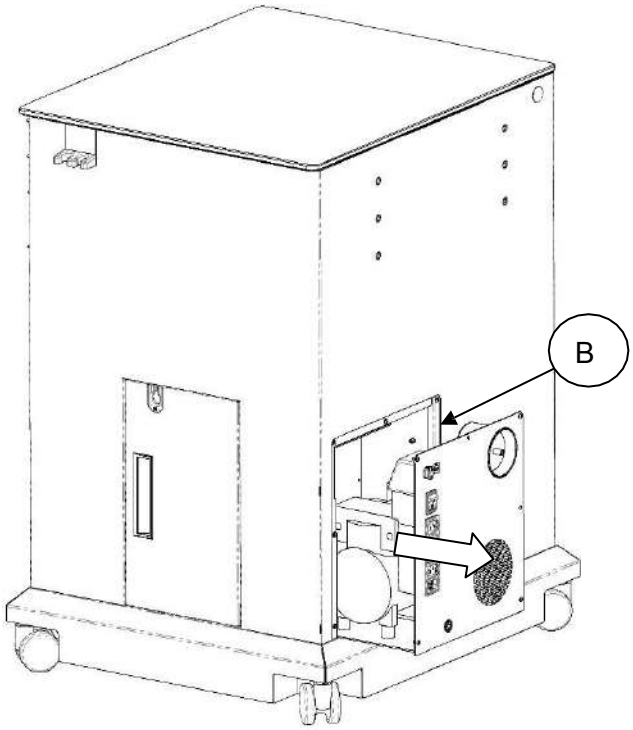
   Remove the 6 nuts that connect the worktop to the unit by removing the four drawers. Once the nuts have been removed, remove the worktop.



3. Remove the pump:

   Unscrew the back plate where the fan is located **[A]**, remove it and disconnect the plate and the pneumatic connections **[B].**

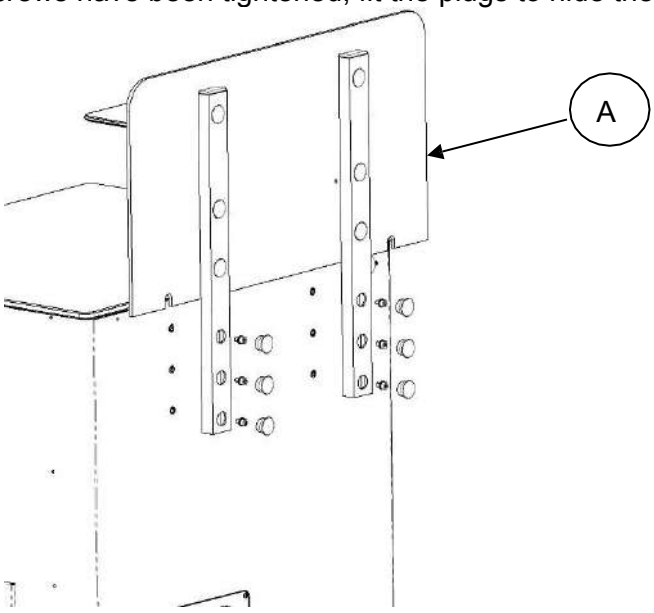




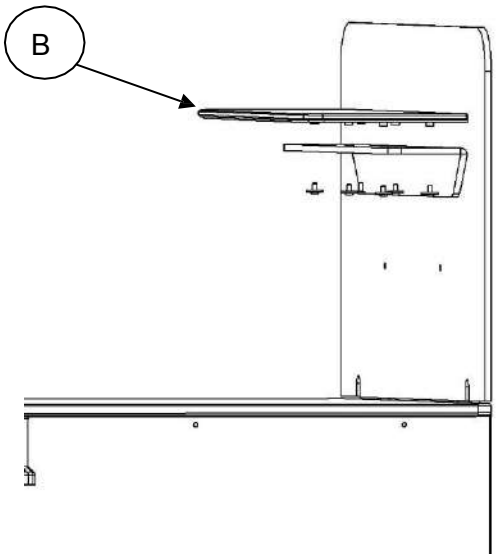
5.2. COMMISSIONING

Fitting the rear panel **[A]** and the instrument support **[B]**.

Remove the transport bar, then use the Allen key and the six screws to fix the panel **[A]** to the unit, once the screws have been tightened, fit the plugs to hide the screws.



Fit the instrument holder **[B]** to the rear panel using the M4 screws with the Allen key.



Make the connections of the suction hose **[C]** to the vessel and the pressure hose **[D]** to the connector.

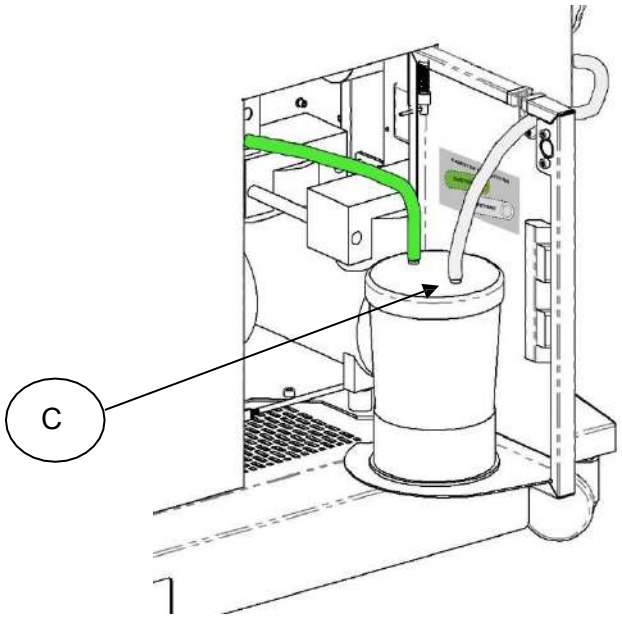
Connect the cable of the function selector switch to its connector **[E].**

Place the unit in the workplace, connect the terminal block **[F]** to the mains to power it, checking that the mains voltage corresponds to that of the equipment's labelling **[G],** and also check that the mains earth connection is in good condition and that it connects perfectly to the equipment.

Lock the rear wheels **[H]** to prevent them from moving. Remove the

wrapping from the secretion canister.

Once these steps have been carried out, please refer to the section "Verification of the installation" **Section 12** of this manual, in order to carry out the relevant verifications.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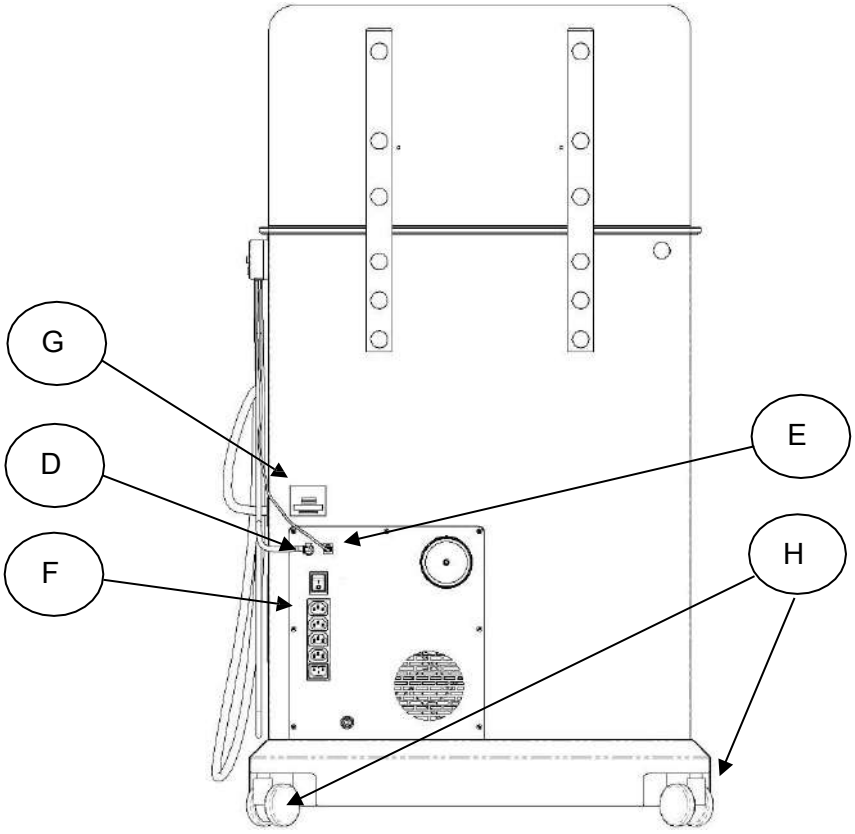

G
D
F
E
H

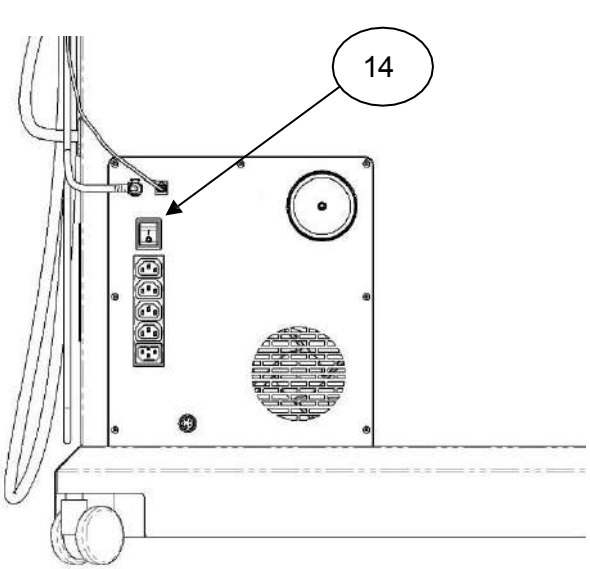
OPERATION OF THE UNIT

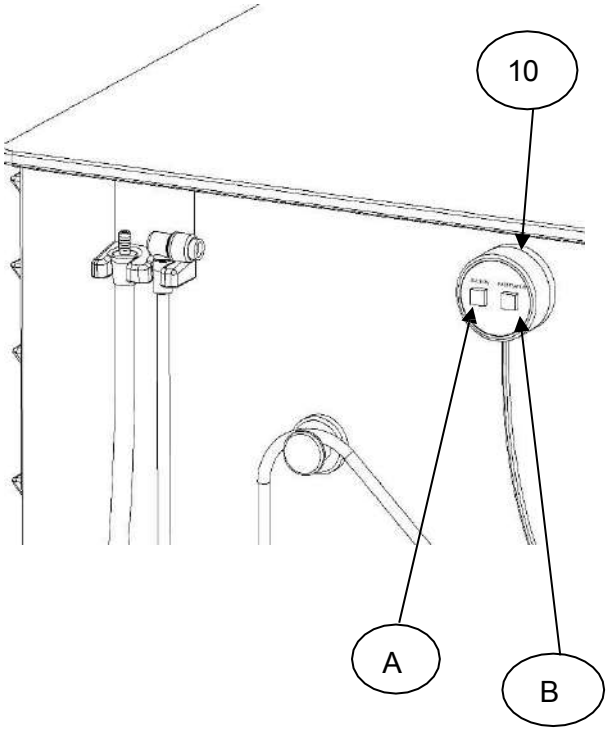
6.1. MOBILE AND AUTONOMOUS

It is a unit that can be moved with a certain ease, being a completely autonomous unit for its transport, once its location has been decided, the steps of section **5.2 must be** carried out. With each new location of the unit, the steps of section **5.2 must** also be carried out.

6.2. UNIT ON/OFF

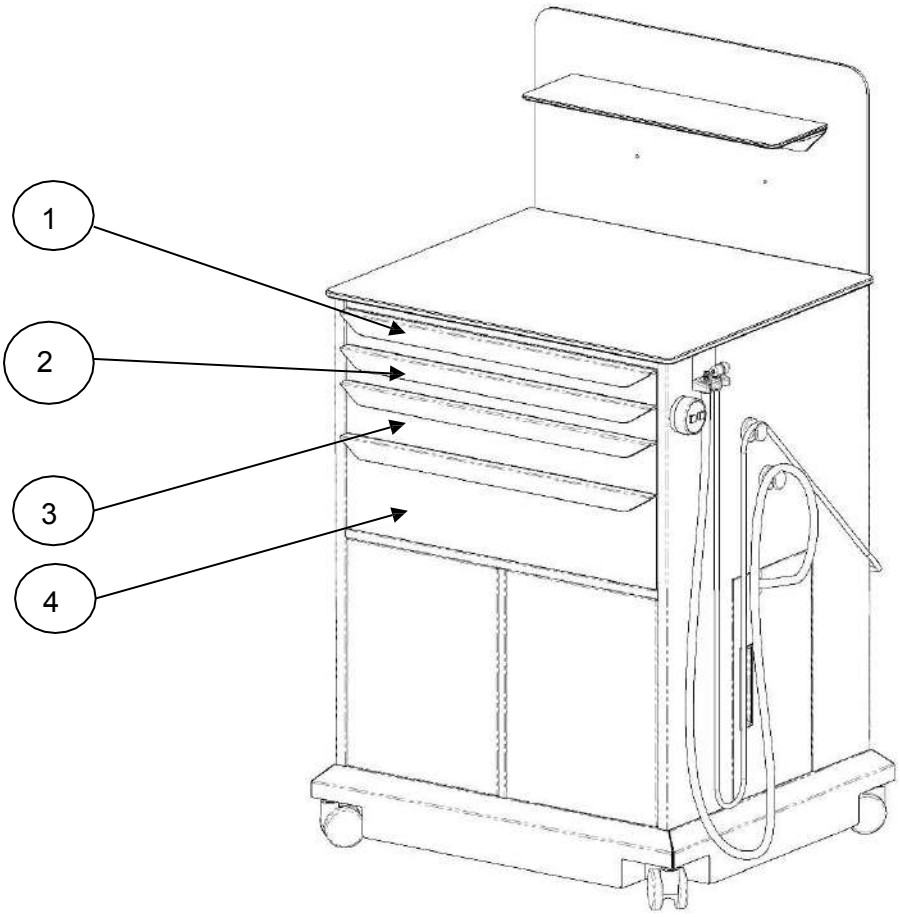
Once the unit is connected to the mains, press the switch **[14]** on the back of the cabinet. To use the suction of the unit, activate the suction pump by pressing suction **[A]** on the function selector **[10]**. To use the pressure, press insufflation **[B]** on the function selector **[10]**. To end the operation, in both cases, press the function selector [**10]** again.



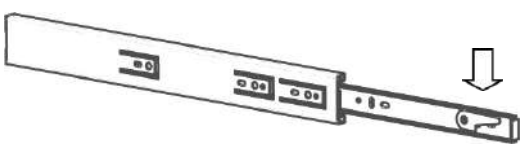


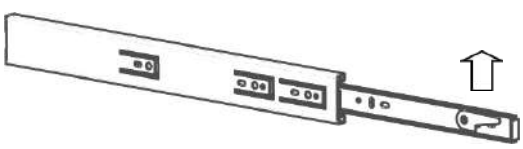
6.3. BOXES

- The unit is equipped with three drawers with steel runners with soft closing system **[1,2,3]**, to store medical instruments, with optional stainless steel trays to organise the medical instruments, with adjustable divisions. One of them is larger to store bulky items such as boxes of gloves, cotton wool, gauze, medicines, bottles with liquids and others.
- And a drawer at the bottom **[4]**, with a larger capacity, for larger and somewhat heavier items.



Pulling out a drawer: Open the drawer and lift up the tab on one of the slides and pull down the other tab on the opposite slide, pull out and pull out the drawer.

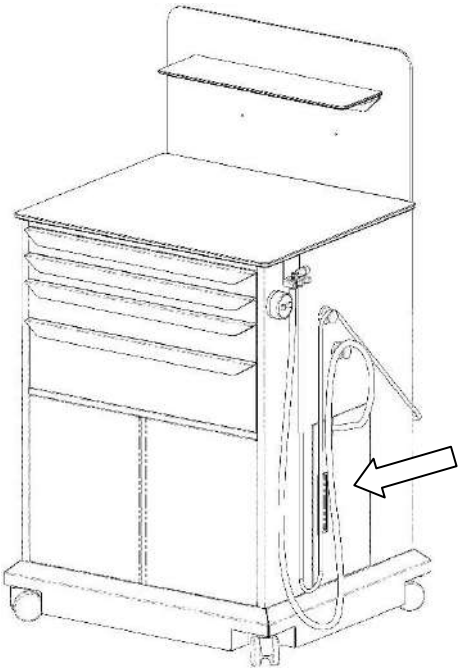


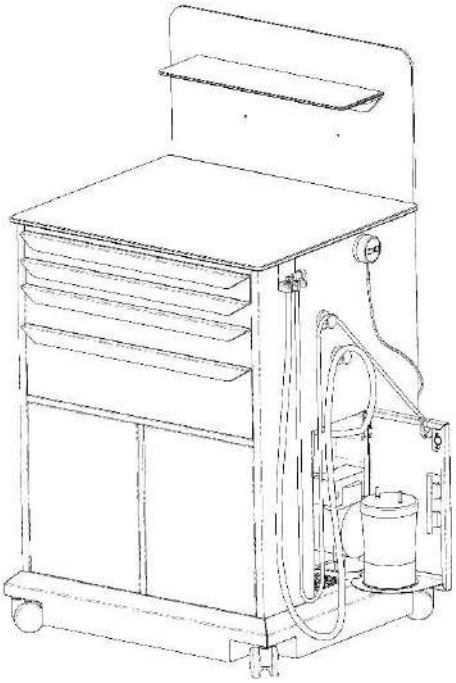


6.4. VASO

The secretion cup is located inside the side door.

IMPORTANT: Take the secretion canister from its housing and remove the secretion canister wrapper.





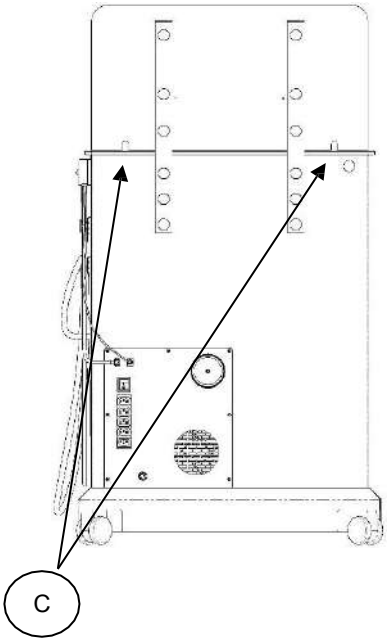
6.5. CONNECTIVITY

Connectivity 110V or 240V

To connect endoscopy or other equipment to the unit, via an IEC male-female cable, and then pass the cable through the rear slot **[C]**.

Connect the short cable to the power strip to supply the equipment (4 devices can be connected).

NOTE: Always check the voltage that appears on the labelling **[20]** and verify that it matches the voltage of the equipment to be connected. The equipment can supply 300 VA (120V~) or 1200 VA (240 V~) through the power supply outputs.

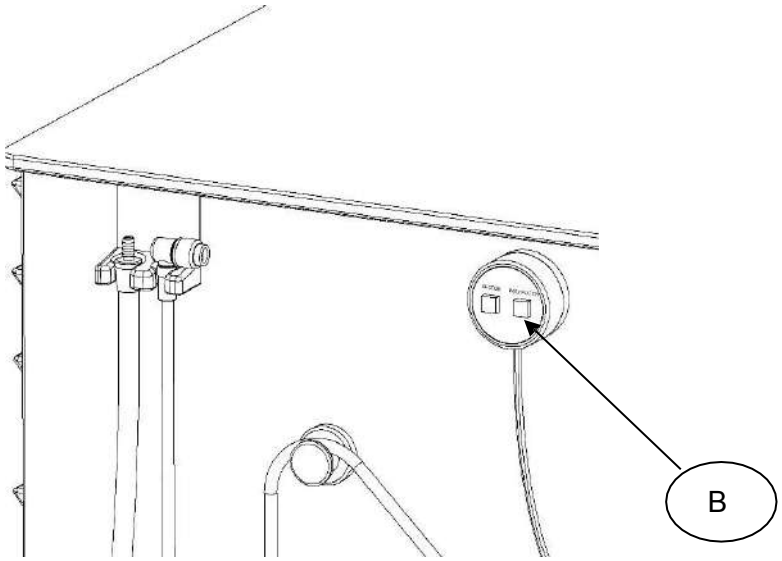


6.6. PRESSURE

The OTOSMART COMPACT unit has a pressure system for continuous use, with a maximum working time of 30 minutes, as a safety measure for accidental switch-on, without risk to the patient or operator. The pressure limit is 2bar.

To activate and deactivate the pressure, press "INSUFFLATION" **[B]** to start and press the "INSUFFLATION" **[B]** button again to deactivate the pressure function.

After 30 minutes of use, the compressor will cut off the power supply in order to avoid power consumption due to accidental start-up. If more minutes of pressure are required, simply press the "INSUFFLATION" button **[B]** again.



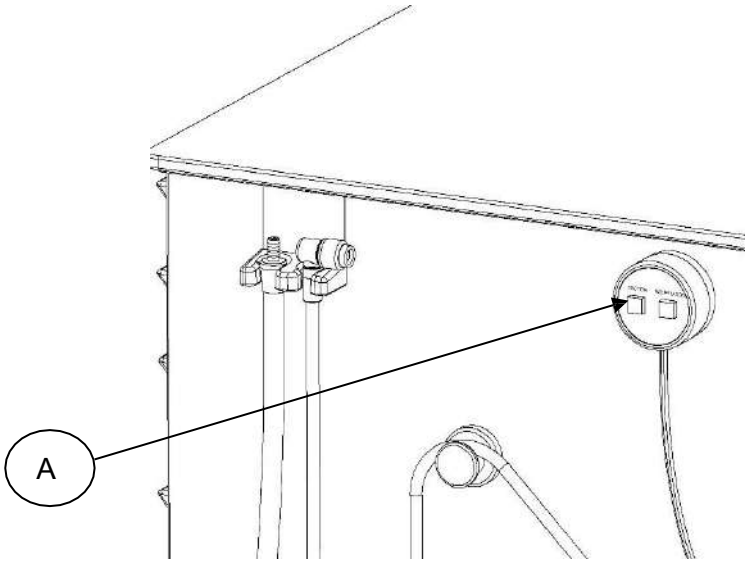
6.7. ASPIRATION

The OTOSMART COMPACT unit is equipped with an intermittent (max. 30 min.) high vacuum and high flow rate suction system (flow rate 55 l/min) for 230 V~ units. For units operating at 120 V~, the suction system has a cycle operation, where the operation is 20 min. of suction on and 10 min. of suction off.

The OTOSMART COMPACT unit is equipped with a powerful, independent suction system and a 1-litre tank.

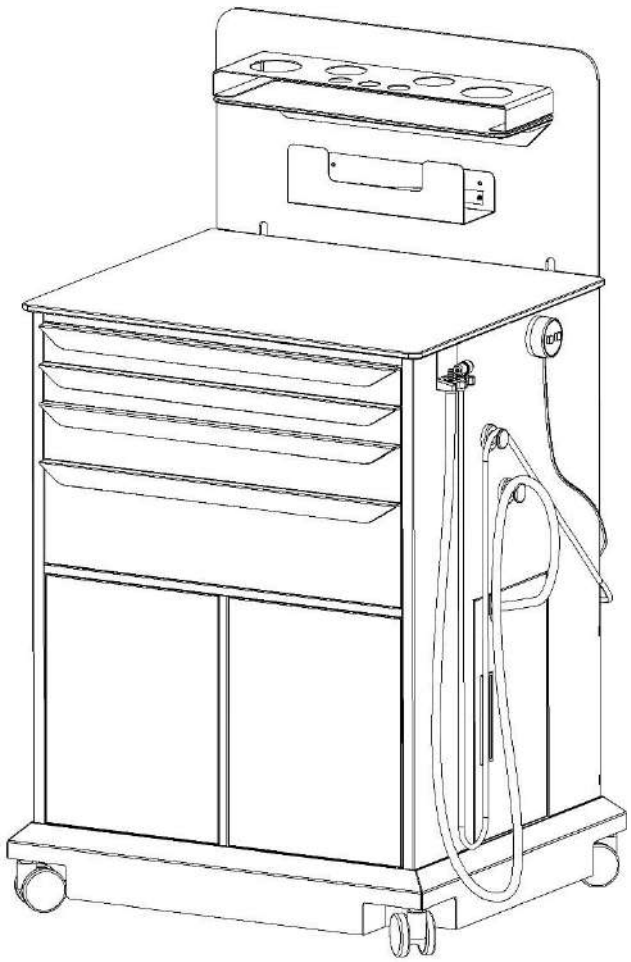
To activate and deactivate the suction, press "SUCTION" **[A]** to start and press the "SUCTION" **[A]** button again to deactivate the suction function.

After 30 minutes of use, the suction pump will cut off the power supply to avoid power consumption due to accidental start-up. If more minutes of pressure are required, simply press the "SUCTION" button **[B]** again.



6.8. INTEGRATED ENDOSCOPY TOWER

The surface that integrates the unit serves to place the endoscopy equipment and others, perfectly replacing the conventional endoscopy tower and saving the space of this one.



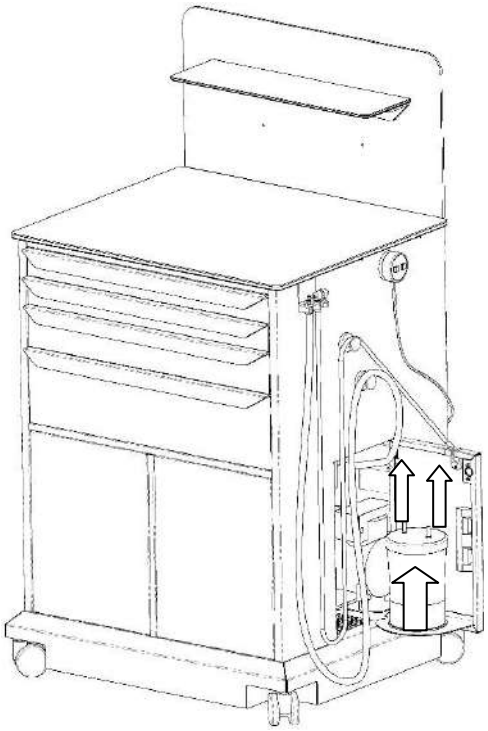
MAINTENANCE

- CLEANING OF THE VESSEL

1. Open the side door
2. Remove the hose connections to the vessel.
3. Remove the cup and clean it with a disinfectant solution.

Disinfectant	Manufacturer
Dismozon plus	Bode Chemie, Hamburg
Green & Clean SK	Metasys, Rum (Austria)
Sani- Cloth active	Ecolab, Düsseldorf

4. To replace the glass and leave it in perfect use, do the opposite operation.

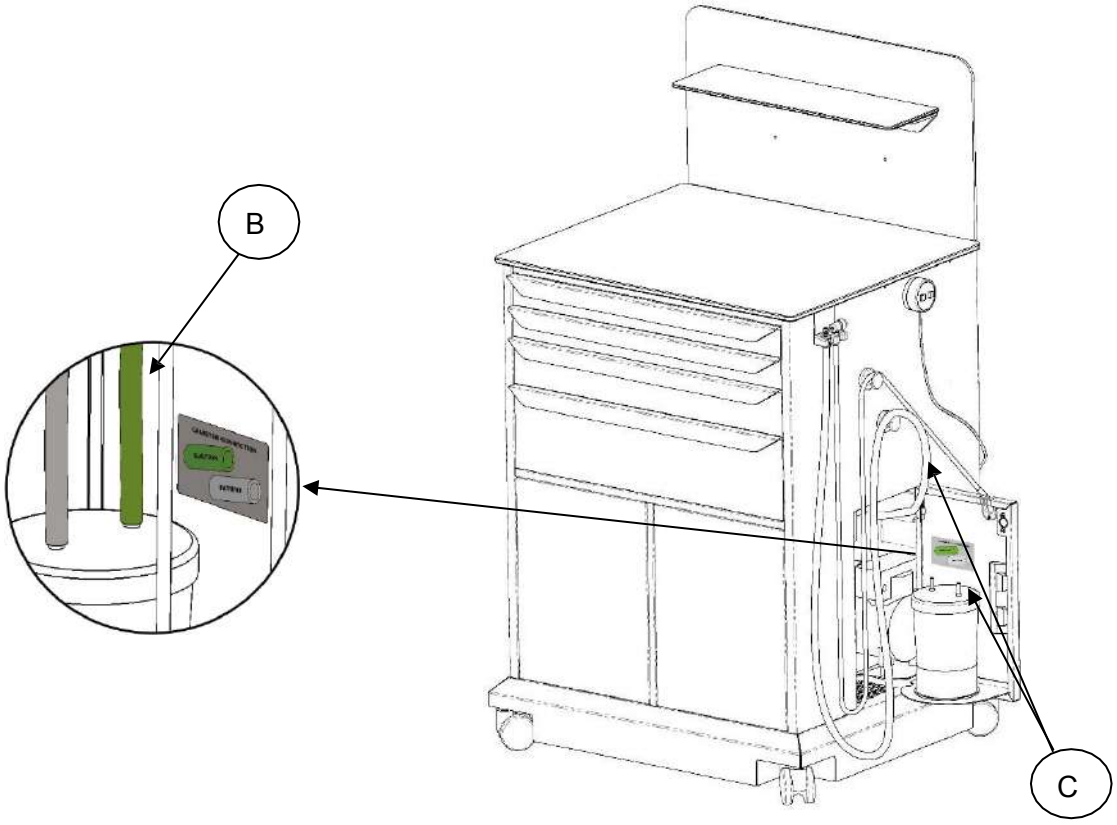


- CLEANING OF THE SECRETION SUCTION CIRCUIT.

1. Place water with a solution of detergent or disinfectant in a container.
2. Suction this solution with the pump to clean the circuit.

- REPLACEMENT OF THE SECRETION SUCTION CIRCUIT:

1 Open the side door.
2 Remove the green hose from the bacteriological filter and the vessel **(B).**
3 Remove the chalk hose from the glass, wall bushing and support **(C)**.
4 Put the new hoses in the same position.



- REPLACEMENT OF BACTERIOLOGICAL FILTERS:

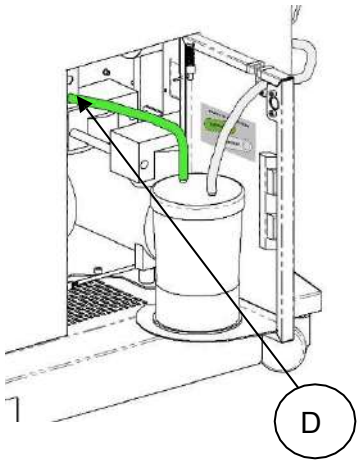
5 Open the side door.

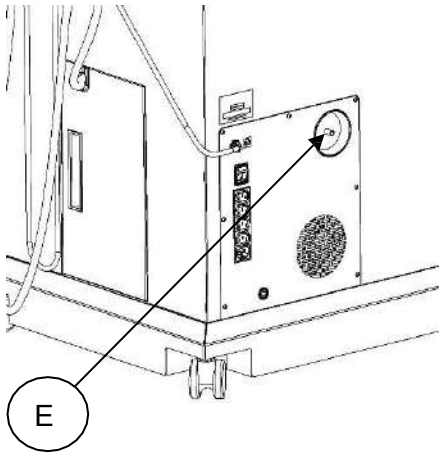
6 Bacteriological filter of the suction system **[D]**:

- Remove the green hose that connects the filter cup and the filter, located on the inside.
- Remove the filter in use and replace it with a new one.
- Connect the green hose that connects the filter to the vessel to the filter.

7 Bacteriological filter of the pressure system **[E]**:

- Remove the filter in use and replace it with a new one.





NOTE:

The bacteriological filter Ref. 67639056, should be renewed periodically and should never exceed 10 hours of use (not life), although a weekly visual check is recommended.
The filter has an instantaneous blocking quality when it receives any liquid. This is a protective measure.
If the filter becomes partially clogged due to excessive moisture or water droplets, the pump will have less suction power and the filter must be replaced.

- MAINTENANCE OF THE VACUUM PUMP:

No maintenance is required on the pump.

- COMPRESSOR MAINTENANCE

No maintenance is required.

- CLEANING OF THE EQUIPMENT

Disconnect the equipment from the mains
Clean the surfaces of the equipment with a cloth dampened with a very diluted detergent or disinfectant solution, then rinse several times with a cloth dampened with water. Dry thoroughly with a dry cloth. Never allow the liquid to penetrate inside the equipment.

To clean and disinfect the external surfaces of the device, use a clean cloth, slightly dampened with a disinfectant soap solution (solution according to the manufacturer's instructions) and rinse it with several other cloths dampened with water. Be very careful not to get water or moisture inside the device.

- MAINTENANCE AND ANNUAL INSPECTION

Manufacturer's specifications:

OPTOMIC ESPAÑA S.A. stipulates that the device must be inspected by a professional expert on a regular basis to check its function and electrical safety. This inspection must be carried out annually. Regular inspections can help to anticipate and prevent possible malfunctions and disturbances and thus increase the safety and average life of the device.

- Security Test:

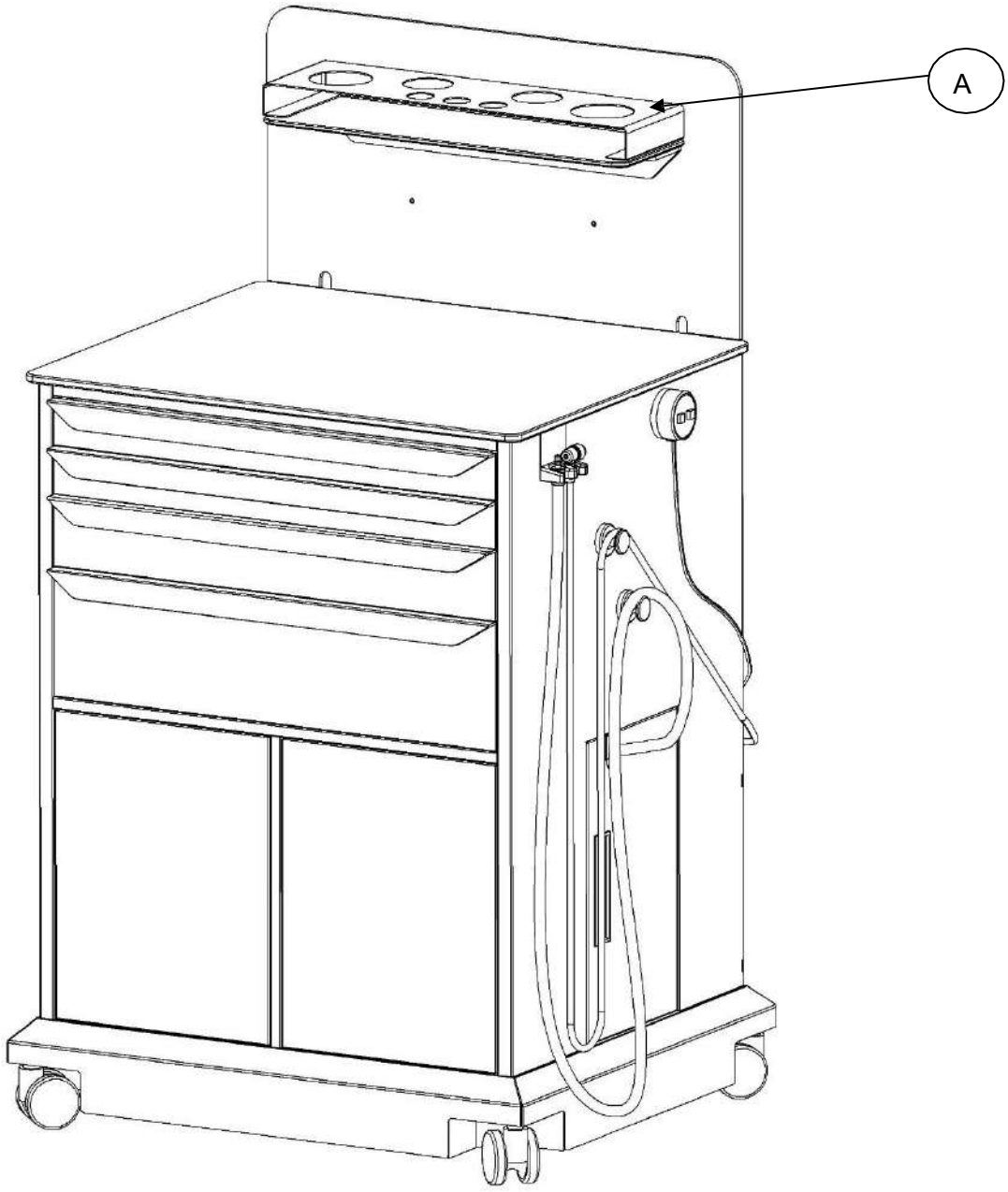
Carry out a visual check. Particular attention should be paid to the following:

- The indications and labels on the device are clearly legible.
- The mechanical condition allows safe operation.
- There shall be no dirt that could adversely affect the device.
- Measure the shunt currents according to EN 60601-1 and EN 60601-1-1.

ACCESSORIES

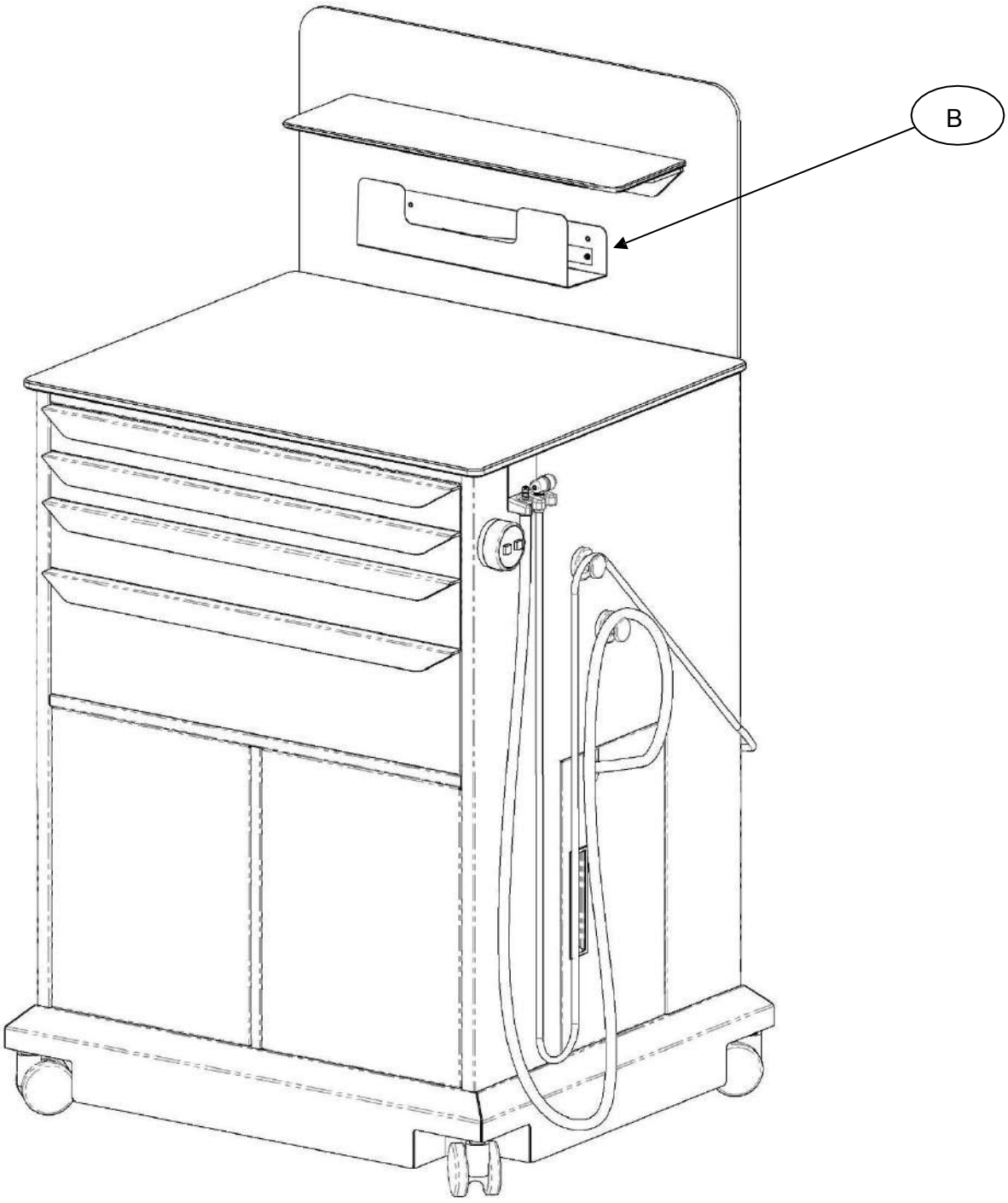
8.1. UTENSIL HOLDER

Support **[A]** for the placement of the various tools to be used in the practice.



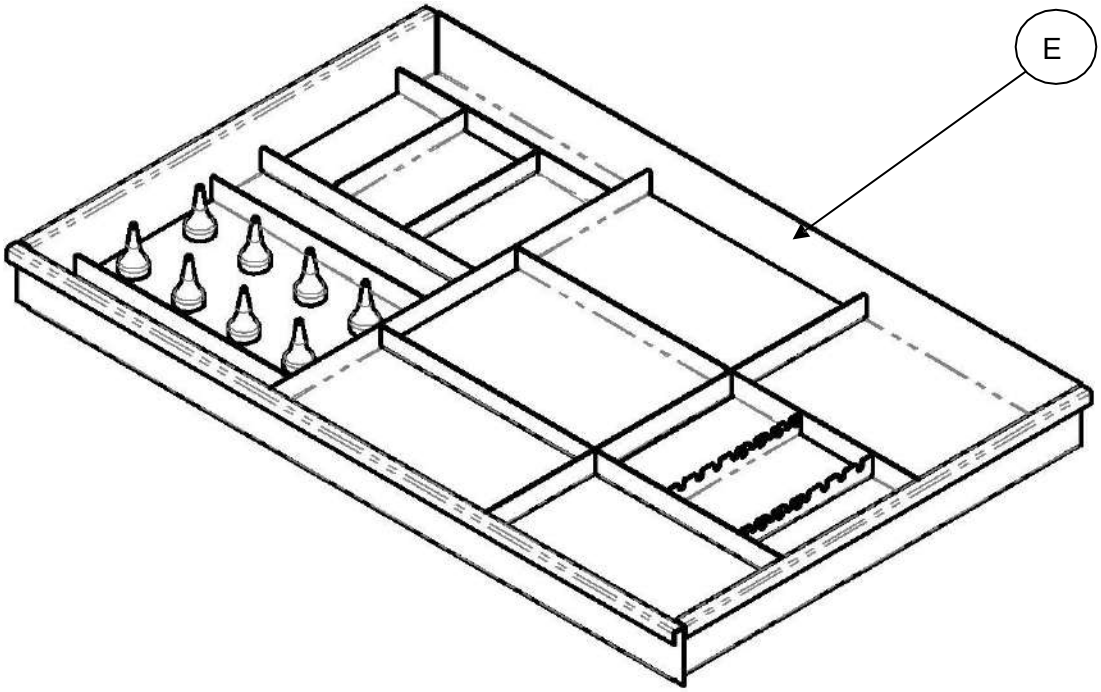
8.2. GLOVE BOX HOLDER

Holder **[B]** for the placement of an examination glove box



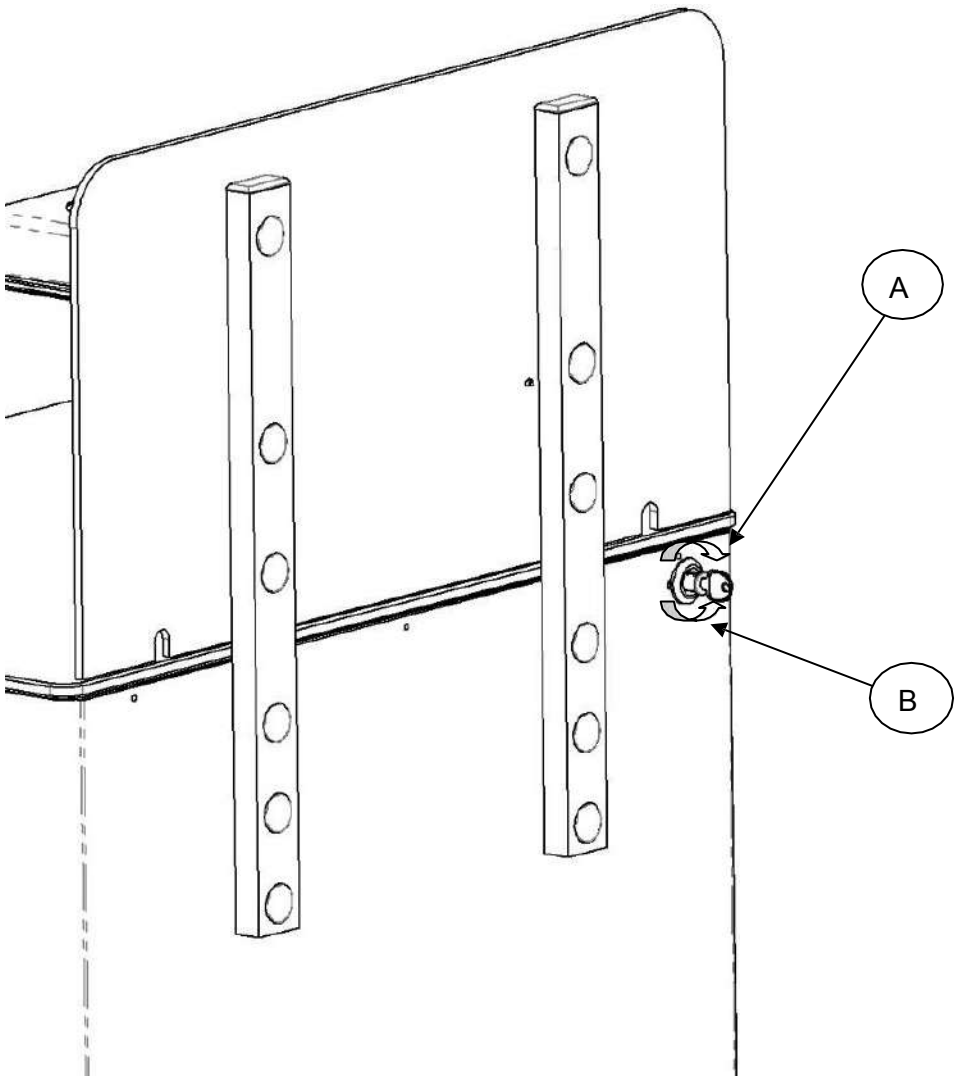
8.3. MODULAR DRAWER TRAYS

As an accessory for the three upper drawers, modular dividers **[E]**, in mirror-polished stainless steel, can be fitted for the storage of instruments, utensils, specula, etc.



8.4. SECURITY LOCK FOR DRAWERS

Key locking system for the drawers. It can also be extended to the drawer insert and the instrument drawer. Movement **[A]** locks the drawers, and movement [B] locks the drawers. **[B]** Unlocks the opening of the drawers.



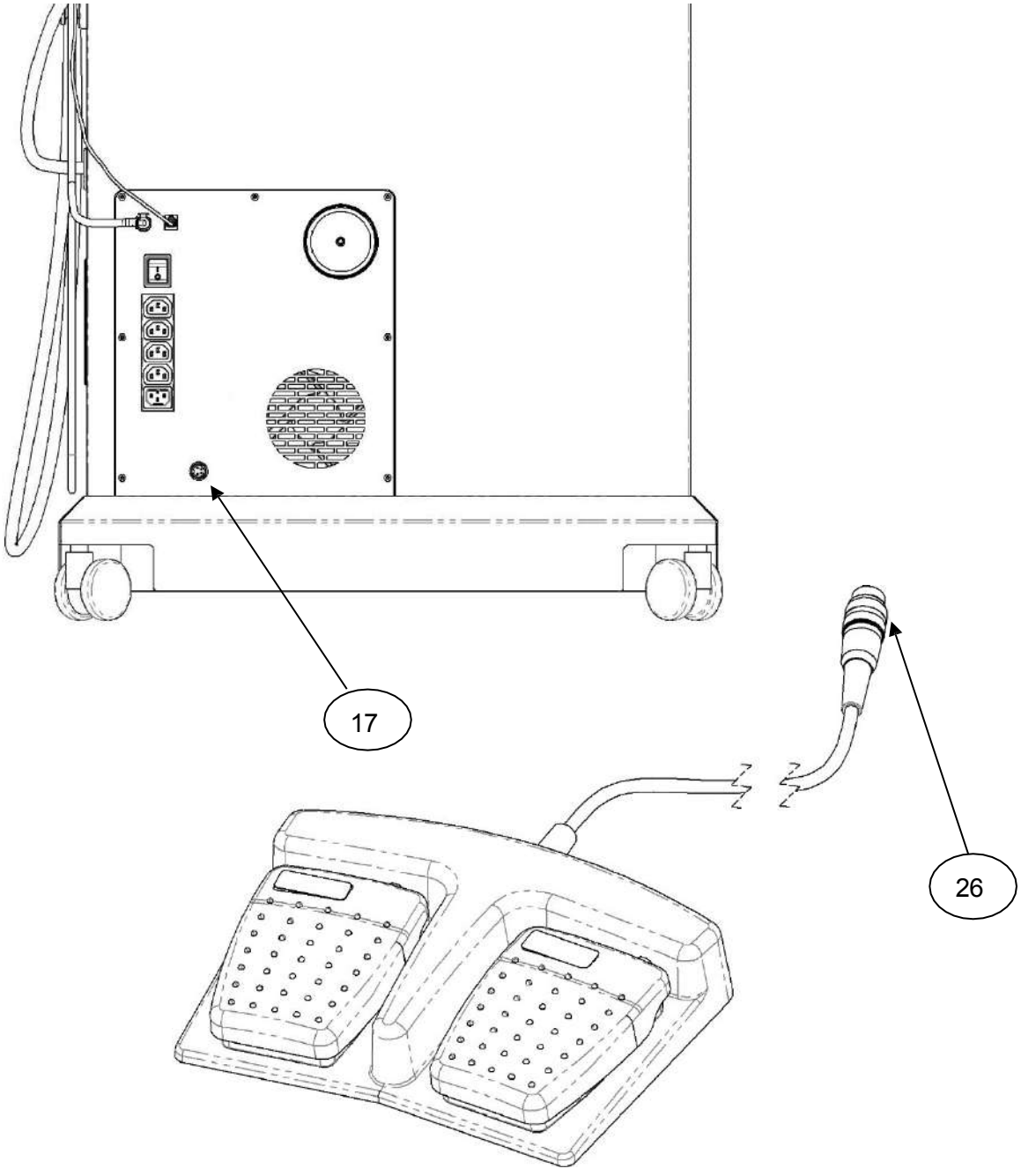
8.5. FOOT CONTROL

Insert the end of the pedal cable **[26]** into the rear connector **[17]** to perform its function.

Special care must be taken when connecting, as the connector is polarised and has only one connection position.

Press the pedal with "Suction" text to vacuum

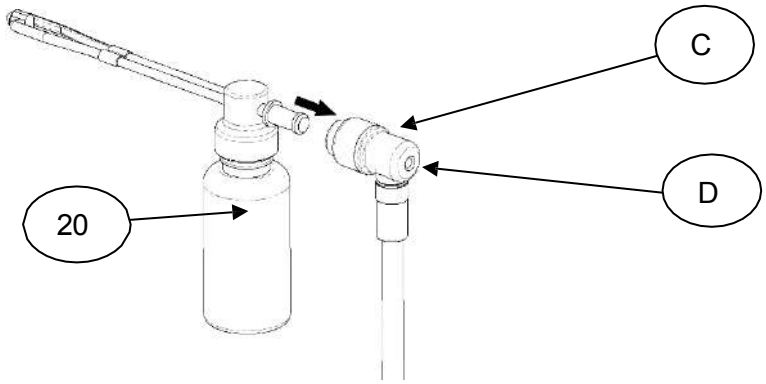
Press the foot pedal with the text "Insufflation" to ulilise the air compressor.



8.6.SPRAY BOTTLE

The OTOSMART PLUS unit includes a sprayer **[20].**

Connect the spray bottle **[20]** to the adapter end **[C]** of the pressure system. For spraying, cover the air return hole **[D]** so that the compressed air flows out of the atomiser.



Additional spray bottles are available on request for different uses.

FAILURES

When you have an equipment failure problem, please refer to the following solution chart:

PROBLEM	POSSIBLE CAUSE	ACTION
• The OTOSMART PLUS unit does not work.	• Disconnection of the unit. • The unit is not switched on. • Defective plate. • Suction motor defective. • Pressure motor defective.	• Connect. • Turn on the switch. • Contact the technical service. • Contact the technical service. • Contact the technical service. •
• The suction of the unit does not work.	• Bad hanger connection. • Damaged electronic board.	• Hang the hose correctly. • Contact the technical service.
• The suction pump works, but does not suck in.	• Filter is blocked, due to liquid suction. • Disconnection of the tube in any of its parts. • Suction cup badly plugged. • Breakage of the vessel or pipe. • The glass is full. • Vacuum regulator in minimum position.	• Change filter. • Locate the section and connect it. • Put the lid on the beaker correctly. • Replace. • Empty it. • Move the regulator to higher vacuum positions.
• Pressure does not work	• Bad hanger connection. • Damaged electronic board.	• Correctly connect the hanger. • Contact the technical service.
• The pressure pump works, but no pressurised air comes out.	• The filter is blocked. • Disconnection of the tube in any of its parts. • Breakage of a pipe. • Pressure regulator in minimum position.	• Change filter. • Locate the section and connect it. • Replace. • Move the regulator to higher positions pressure.
• Incorrect opening of drawers.	• Guide in poor condition.	• Contact the technical service.
• Glass breakage.	• Strike.	• Replace it.

If you have not been able to remedy the fault, you should contact an official service centre.

RETURN OF THE DEVICE

If it is necessary to return the device, it must be returned in its original packaging. OPTOMIC ESPAÑA S.A. cannot be held responsible for any damage or defects caused during transport that are due to poor packaging or incorrect handling. When returning the device, please enclose the following information:

- Owner's name
- Owner's address
- Serial number of the device
- Description of the defect

TECHNICAL SPECIFICATIONS

Classification of medical equipment .....IIa

.....Applicable partType B

ELECTRICAL

Mains connection .....230V~230V~ 50Hz

Mains connection .....120V~120V~ 60Hz

Maximum power demand of suction pump 230 .....V~460 VA

Maximum power demand of the pressure pump 230 V~.....440 VA

Maximum power demand of the suction pump 120 V~.....370 VA

Maximum power demand of the pressure pump 120 V~ .....430 VA

Maximum consumption of the unit 230 V~.... .....2100 VA

Maximum power consumption of the unit 120 V~.... .....1100 VA

Maximum output power 230 .....V~1200 VA*.

Max. output power 120 .....V~300 VA*.

Electrical protection according to UNE EN 60601/IEC .....601Class I

Conducted EMC degree of protection .....B

Radiated EMC degree of protection .....B

Maximum suction flow .....rate70 l / min

.....Maximum continuous vacuum650 mm Hg

Maximum pressure flow rate.....60 l / min

Maximum pressure

.....pres sure2 Bar

Power .....cable3000 mm

Short .....angled cable500 mm

Suction Pump Internal Fuse (120 V~).....T6,3A

MATERIALS

MaterialsSteel sheet, ABS, flame-retardant class-Fire Prof. No. UL94HB

Safety glass.....Tempered

Colours.....Available in various colours

MECHANICALS

Dimensions (without accessories) .....71(W) x 130(H) x 62(D) cm

Weight (without accessories).....133 kg

Maximum permissible load per .....drawer23 kg

Max. load distributed between worktop and .....shelves30 kg

Maximum total .....distributed load150 kg

*Read section 6.6 connectivity.

PERMISSIBLE ENVIRONMENTAL CONDITIONS

Permissible ambient condition in use2~+35ºC ....., 20~90%RH, non-condensing

Permissible environmental condition in transport... .....-10~+70ºC, 10~95%RH, non-condensing

Permissible ambient condition in storage .....-10~+70ºC, 10~95%RH, non-condensing

Atmospheric pressure0 .....7 - 106 KPa

Electromagnetic compatibility

- This equipment is intended for use in all establishments, including domestic establishments and those directly connected to the public low-voltage supply network that feeds buildings used for domestic purposes.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The OTOSMART PLUS ORL Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the OTOSMART PLUS ORL Unit should ensure that it is used in such an environment.		
Emissions testing	**Compliance**	**Electromagnetic environment - Guidance**
RF Emissions CISPR11	Group 1	The OTOSMART PLUS unit uses DR energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in electronic equipment in the vicinity.
RF Emissions CISPR11	Class B	The OTOSMART PLUS unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations / flicker emission IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The OTOSMART PLUS ORL Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the OTOSMART PLUS ORL unit should be aware that the OTOSMART PLUS ORL unit is intended for use in the electromagnetic environment specified below. ensure that it is used in such an environment.			
Immunity test	**Test level of the IEC 60601 Standard**	**Level of compliance**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV per contact ±8kV through air	±6 kV through contact ±8kV through air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Fast transients/bursts IEC 61000-4-4	±2 kV for mains supply lines. ±1kV for input/output lines	±2 kV for mains supply lines. ±1kV for input/output lines	The quality of the power supply network should be that of a typical commercial or hospital environment.
Shock wave IEC 61000-4-5	±1 kV line to line ±2kV line to ground	±1 kV line to line ±2kV line to ground ±2kV line to ground	The quality of the power supply network should be that of a typical commercial or hospital environment.
Voltage dips, interruptions and voltage variations on power supply input lines IEC-61000-4-11	<5% U_T (drop > 95% in U_T) for 0.5 cycles 40% U_T (60% drop in U_T) for 5 cycles 70% U_T (30% drop in U_T) for 25 cycles <5% U_T (>95% drop in U_T) for 5 s	<5% U_T (drop > 95% in U_T) for 0.5 cycles 40% U_T (60% fall in U_T) for 5 cycles 70% U_T (30% drop in U_T) for 25 cycles <5% U_T (>95% drop in U_T) for 5 s	The quality of the mains power supply should be that of a typical commercial or hospital environment. If the user of the OTOSMART PLUS requires continuous operation during power interruptions, it is recommended that the OTOSMART PLUS ORL unit is powered from an uninterruptible power supply or a battery.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should be at levels characteristic of a typical location of a typical commercial or hospital environment.
NOTE U_T is the AC supply voltage before application of the test level.			

<table>
<tr><th colspan="4">Guidance and Manufacturer's Declaration - Electromagnetic immunity</th></tr>
<tr><td colspan="4">The ORL OTOSMART PLUS unit is intended for use in the electromagnetic environment specified below. The customer or the user of the OTOSMART PLUS ORL unit should ensure that it is used in the electromagnetic environment specified below.
such an environment.</td></tr>
<tr><th>Immunity test</th><th>Test level of IEC 60601 standard</th><th>Level of compliance</th><th>Electromagnetic environment - Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

RF radiated
IEC61000-4-3</td><td>3 Vrms
from 150 KHz to 80 MHz

3 V/m
from 80 MHz to 2.5 GHz</td><td>3 Vrms

3 V/m</td><td>Mobile and portable RF communications equipment should be used no closer to any part of the OTOSMART PLUS, including cables, than the recommended separation distance at the transmitter frequency.

Recommended separation distance

d= 1,2√P

d= 1,2√P 80 MHz to 800 MHz

d= 2,3√P 800 MHz to 2,5 GHz

Where P is the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
The field strengths from the fixed RF transmitter, as determined by the site survey, [a] should be less than the compliance level in each frequency range. [b]
Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz the higher frequency range applies. NOTE 2 These guidelines are not applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transformers, such as base stations for cellular/wireless radio telephones) and land mobile radios, amateur radio stations, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the ORL OTOSMART PLUS unit is used exceeds the applicable RF compliance level above, the ORL OTOSMART PLUS unit should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorientation or relocation of the OTOSMART PLUS.

[b] Over the frequency range 150 KHz to 80 MHz, the field strength should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communication equipment and the ORL OTOSMART PLUS unit

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

Maximum rated output power of transmitter W	**Separation distance according to the frequency of the transmitter m**		
	150 kHZ at 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz at 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz at 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	1.20	1.20	2.30
10	3.79	3.79	7.27
100	12.00	12.00	23.00

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

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

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

INSTALLATION VERIFICATION

 After installation, connect the OTOSMART PLUS unit to the mains and carry out the following checks before use:

Requirements for the verification of the installation of the medical device and its verification.

REQUIREMENT	VERIFICATION
The rear panel and the shelf are correctly positioned and fixed.	
The unit is switched on and off.	
The secretion cup does not have a wrapper.	
The teams for endoscopy are connected with the angled cable OPTOMIC No. KC 7955.	
The hose from suction hose is correctly connected to the secretariats	
The hose from hose is correctly connected to its connector.	
Pressing "SUCTION" activates the suction pump.	
Pressing "INSUFFLATION" activates the compressor.	
All cables are perfectly laid, there is no entrapment.	
The suction hose is perfectly positioned, there is no entrapment.	
The pressure hose is perfectly positioned, with no bottlenecks in its route.	

MAINTENANCE SHEET

All maintenance, repair or modification work shall be recorded on the following maintenance sheet, dated and signed by the company or person carrying out the work.

WORK CARRIED OUT TEAM NO.	REPAIRED BY	DATE	SIGNATURE

ANY REPAIR OR MODIFICATION WAS CARRIED OUT BY AN EXPERT, OBSERVING THE SAFETY REGULATIONS ACCORDING TO UNE EN 60601/IEC 601.

14. ANNOTATIONS