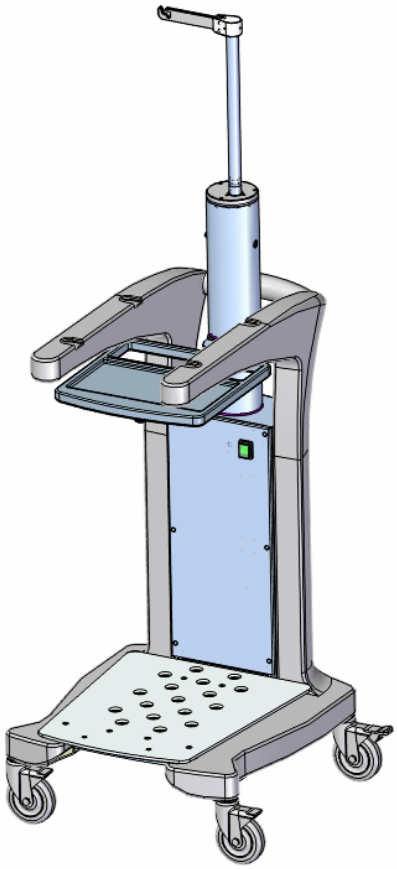
Cod. 181004EN
2014-10-13 Rev. A



EQUIPMENT CART
WITH ELECTRIC I.V. POLE

INSTALLATION AND OPERATING MANUAL

OPTIKON 2000 S.p.A.

Via del Casale di Settebagni 13 - 00138 Rome – Italy
Tel. +39 06 88884355 – Fax +39 06 8888440
e-mail: sales@optikon.com - www.optikon.com

OPTIKON 2000 S.p.A. is an ISO 9001 and ISO 13485 certified company that manufactures surgical and diagnostic devices for ophthalmology.

All OPTIKON 2000 products are manufactured in compliance with the requirements of Directive 93/42/EEC on medical devices.

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1. DISCLAIMER

OPTIKON 2000 S.p.A. requires the user of this system to carefully read specific warnings found in this manual. It is the responsibility of the user to provide its personnel with a thorough understanding of the equipment operation before use. In no event shall Optikon 2000 S.p.A. be liable for any injury, incidental or consequential damages incurred by the purchaser, users or patients as a result of operation of the product.

Use of this system is a matter of professional medical judgment. Optikon 2000 S.p.A. is not responsible for any clinical problem resulting from mishandling this equipment and makes no medical recommendations.

OPTIKON 2000 S.p.A. declares to be responsible for the safety, reliability and performance only if:

- updates, calibrations and repairs are carried out by personnel which has been authorised by OPTIKON 2000 S.p.A.;
- the system is used in compliance with the user instructions;
- the mains electric installation to which the system is connected complies with the IEC Safety Regulations.

IMPORTANT NOTICE:

Every effort has been made so that all the illustrations and information precisely represent the product and its operation as they were at the time this manual was printed. It is possible, however, that during the existence of this manual modifications have been made in order to continue to effectively satisfy the needs of the users. At times, such modifications are made without advance notice.

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2. LIMITED WARRANTY CONDITIONS

All the OPTIKON 2000 S.p.A. instruments and accessories sold and installed in the European Union are guaranteed against manufacturing and material defects for ONE YEAR from the invoicing date. The guarantee on the consumable material is limited to the first use of the apparatus.

For the warranty conditions outside the European Union, contact your authorised OPTIKON 2000 S.p.A. distributor.

All items covered by warranty will be repaired or replaced free of charge.

The warranty includes the research for the defect's cause, repair of the failure and final inspection of the unit or components

This warranty does not cover any problems which are the result of improper use, accidents, incorrect use and tampering or modifications made by persons who are not part of the authorised OPTIKON S.p.A. technical service.

OPTIKON 2000 S.p.A. reserves the right to verify, in case of failures, if the instrument and/or its accessories have been modified or tampered with in any way, or if they have been damaged by improper use.

OPTIKON 2000 S.p.A. also reserves the right to modify the instrument and/or its accessories in the event operating techniques require such modifications.

The warranty is not valid if the serial number of the instrument and/or accessories attributed by OPTIKON 2000 S.p.A. is missing, tampered with and/or unreadable.

The warranty does not include the expenses for returning the instrument and accessories: all charges for shipping, packaging etc. shall be borne by the buyer.

In the event of an explicit request for work by OPTIKON technicians, all travelling and lodging expenses shall be charged to the customer.

OPTIKON 2000 S.p.A. is not liable for damages caused during transport. If this occurs, the customer must immediately notify the carrier that handled the delivery.

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3. WARNINGS

Care in the handling of surgical equipment and instruments is one of the first principles in an operating-room, and no amount of warnings can take place of such care.

NOTE: THIS INFORMATION IS BELIEVED TO BE CURRENT AT THE TIME OF PUBLICATION, BUT IS PROVIDED WITHOUT WARRANTY OF ANY KIND AND WE ASSUME NO RESPONSIBILITY WITH RESPECT THERETO.

The following warnings will aid the user to provide adequate safeguards to assure safe, trouble free performance:

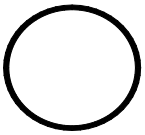
- ALL MEDICAL PERSONNEL SHOULD READ AND UNDERSTAND THE INSTRUCTIONS IN THIS MANUAL AND THE MANUAL OF THE EQUIPMENT CONNECTED TO THE CART PRIOR TO THE SYSTEM IS USED. DO NOT ATTEMPT TO USE THE SYSTEM IF IT FAILS TO PERFORM AS SET OUT IN THE OPERATION PROCEDURES, IN THESE MANUALS.
- USE OF THE SYSTEM SHOULD BE RESTRICTED TO QUALIFIED MEDICAL PERSONNEL.
- USE OF THIS SYSTEM IS A MATTER OF PROFESSIONAL MEDICAL JUDGMENT IN ALL CASES. OPTIKON 2000 S.p.A. IS NOT RESPONSIBLE FOR ANY CLINICAL PROBLEM RESULTING FROM MISHANDLING THIS INSTRUMENT AND MAKES NO MEDICAL RECOMMENDATIONS.
- THE SYSTEM SHOULD NEVER BE USED IN THE PRESENCE OF FLAMMABLE ANAESTHETICS, DISINFECTING AGENTS, CLEANING AGENTS, ETC., DUE TO POSSIBLE FIRES OR EXPLOSION.
- TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT REMOVE COVER (OR BACK). REFER SERVICING TO QUALIFIED SERVICE PERSONNEL
- THE "OPTIKON EQUIPMENT CART" SHOULD BE CONNECTED TO A MAINS SUPPLY ONLY AS MARKED ON THE REAR PANEL. TO GUARANTEE SAFETY, A HOSPITAL GRADE POWER CORD AND PLUG MUST BE USED, THE UNIT MUST BE GROUNDED. USE EXCLUSIVELY THE MAINS POWER CABLE PROVIDED OR A CABLE THAT IS IN COMPLIANCE WITH SAFETY REGULATIONS.
- FOR OPERATING SAFETY DO NOT INSTALL THE SYSTEM IN A LOCATION WHERE IT WILL BE EXPOSED TO HEATING EQUIPMENT OR RADIATORS. DIRECT SUNLIGHT AND ANY OTHER SOURCE OF EXTREMELY HIGH TEMPERATURES.
- BE SURE THAT THE POWER SWITCH ON THE LEFT SIDE OF THE CART IS OFF WHEN PLUGGING IN, OR REMOVING THE POWER CABLE FROM A WALL OUTLET. TURN OFF THE MAIN POWER SWITCH WHENEVER THE EQUIPMENT IS NOT IN USE.

- EXCHANGING FUSES SHOULD BE DONE A FEW MINUTES AFTER THE MAINS SWITCH HAS BEEN TURNED OFF.
- REPLACE FUSE AS MARKED.
- NEVER LIFT OR MOVE FOOTSWITCH BY THE CABLE. DAMAGE MAY RESULT.
- DO NOT EXCEED THE FOLLOWING MAXIMUM LOAD LIMITS:
  MAYO TRAY: 2KG
  EQUIPMENT TRAY 30KG
  BOTTLE HOOK 1KG
  OVERLOADING THE CART MAY CAUSE MECHANICAL FAILURES AND POSSIBLE HARM FOR THE PATIENT AND/OR THE OPERATOR.
- THE POLE EXTENDS UP TO A MAXIMUM OF APPROX. 235cm OF HEIGHT: DO NOT PLACE THE CART UNDER LOW CEILING.
- DO NOT TILT THE CART MORE THAN 10° IN ANY DIRECTION.
- TO AVOID RISK OF SMOKE OR FIRE, WHEN PLUGGING HOSTED EQUIPMENT TO THE CART, DO NOT EXCEED THE SPECIFIED MAXIMUM ELECTRIC LOAD (SEE TECHNICAL SPECIFICATIONS AND THE LABELING OF THE CART).
- TO AVOID POSSIBLE ELECTRIC SHOCK TO THE PATIENT DUE TO EXCESSIVE LEAKAGE CURRENT OR INSUFFICIENT DIELECTRIC STRENGTH, PLUG TO THE CART COMPATIBLE OPTIKON EQUIPMENT ONLY (SEE COMPATIBILITY CHART IN THE TECHNICAL SPECIFICATIONS).
- DO NOT DISPOSE OF THE TROLLEY AS UNSORTED MUNICIPAL WASTE. COLLECT IT SEPARATELY ACCORDING TO THE LOCAL LAWS/REGULATIONS ON DISPOSAL OF WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT.
- MOVE THE CART USING THE HANDLE ONLY (see the label placed on the cart).

4. SYMBOLS

The following symbols are often used on medical equipment, with the function of delivering information and warnings in a limited space.

The user should become acquainted to these symbols before using the equipment.

SYMBOL	DESCRIPTION
	ALTERNATING CURRENT
	DIRECT CURRENT
	PROTECTIVE EARTH
	CAUTION SYMBOL
	READ THE INSTRUCTIONS IN THE MANUAL
	OPEN (DISCONNECTED FROM THE POWER MAINS)
	CLOSED (CONNECTED TO THE MAINS POWER)

	SEPARATE COLLECTION OF ELECTRICAL/ELECTRONIC DEVICES
	DO NOT PUSH
	PRODUCER
	DATE OF MANUFACTURE
	TYPE B APPLIED PART

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5. GENERAL INFORMATION

5.1 SYSTEM DESCRIPTION

The Optikon equipment cart 181004 has been designed to host the Optikon surgical systems console and to move them conveniently in the Operating Room area. It is also provided with a mayo tray mounted on a swing arm for sustaining the surgical instruments connected to the console during the setup and the surgical procedure. An electric bottle raiser holds the container of balanced saline solution used as irrigation source. The bottle's height can be adjusted with a switch with rocker action situated on the column and/or controlled by the connected console.

The I.V. pole controller is interfaced to the hosted console that can read and memorize the bottle position set by the user in the various surgical functions. It can read and store the position of the bottle set by the surgeon. This position can be recorded in a user program, together with other operating parameters and subsequently recalled and restored.

5.2 CONTROLS AND INDICATORS

5.2.1 POWER (MAINS SWITCH AND WARNING LAMP).

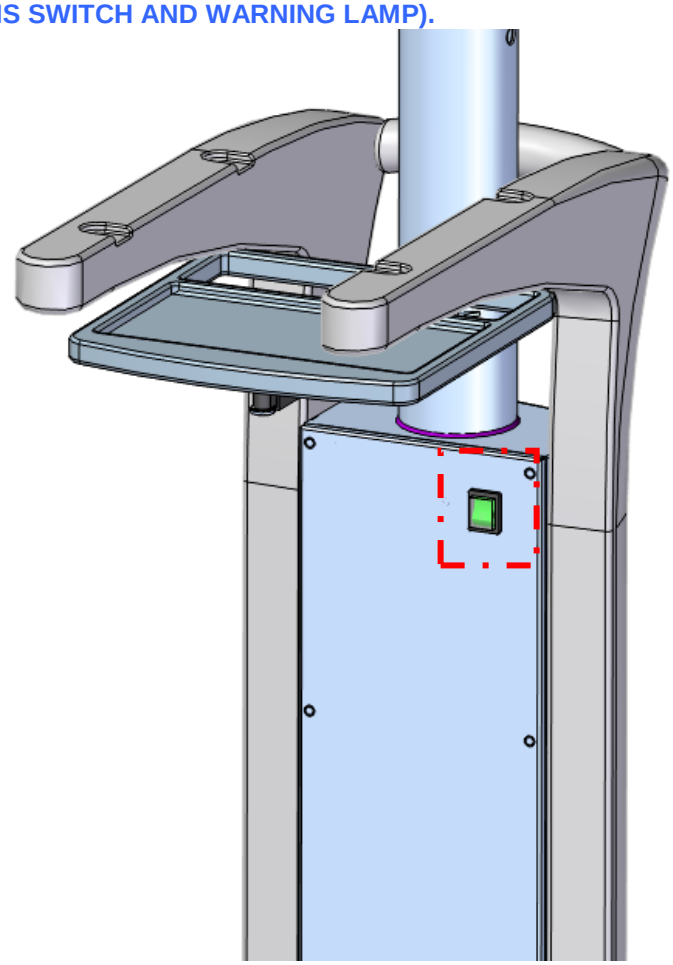


Fig. 1

This switch, fitted with a warning lamp, is placed on the front of the cart and controls both the electric bottle raiser inside the cart and the mains sockets housed on the cart. If the switches of the individual consoles are left on permanently, this switch is able to turn the entire surgical system on/off.

5.2.2 PROTECTIVE COVER (Fig. 2)

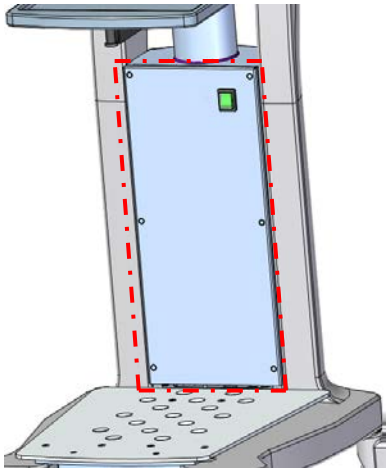


Fig 2

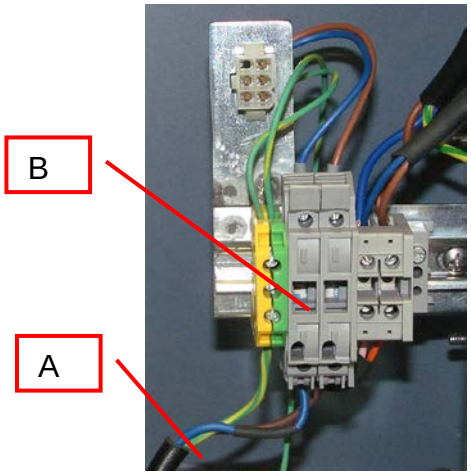
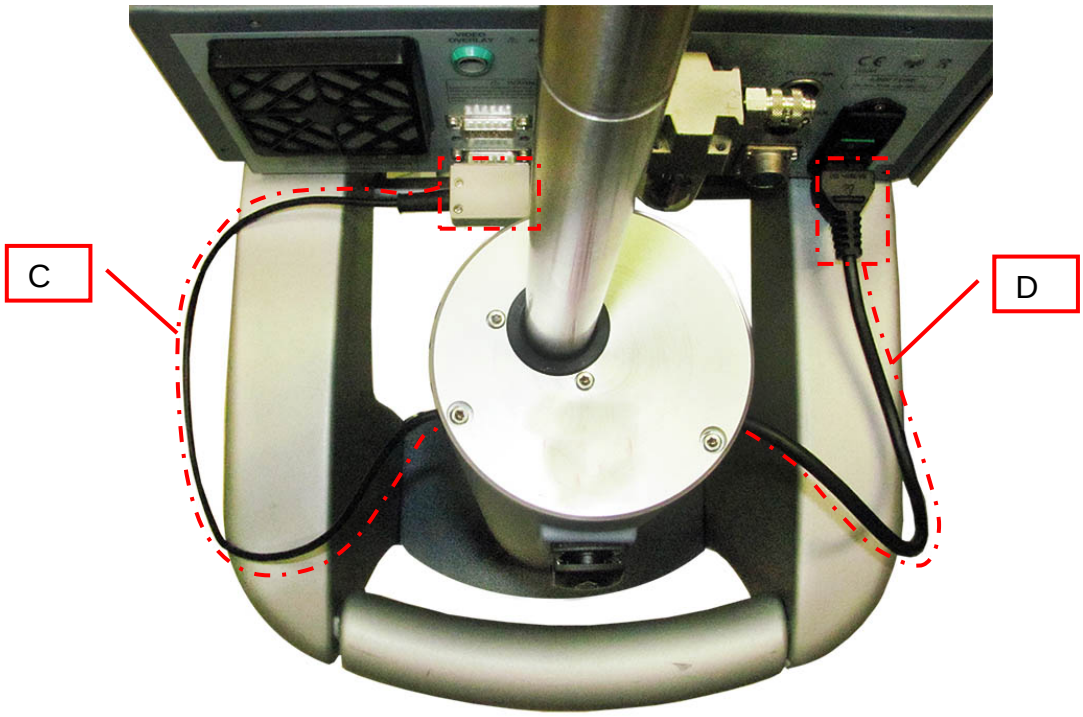


Fig 3

This protective cover must be removed at the time the cart's consoles are installed, by a qualified technician, if the power cord is to be changed. When the installation is completed, the cover must be refitted to protect the electrical part of the cart. The terminal block for the power cord (A) and the fusebox (B) is placed underneath the protective cover (Fig.3).

5.2.3 CABLES CONNECTED TO THE INSTRUMENT



INTERFACE CONNECTOR (C)
Enables the console housed on the cart to control the electric bottle raiser. The console must be connected to the cart by means of the signal cable provided with the latter.

MAINS SOCKET FOR THE CONSOLES HOUSED ON THE CART (D)
The mains socket enables you to supply the surgical consoles housed on the cart.

TAG (MARKINGS)
Provides serial number, electrical rating and other information as required by EN 60601-1

5.3 TECHNICAL SPECIFICATIONS

PARAMETER	SPECIFICATIONS
Manufacturer:.....	OPTIKON 2000 S.p.A. Via del Casale di Settebagni 13 00138 Roma - Italia

Model.....	I.V. Pole cart
Regulatory conformity:	93/42/EEC Directive on medical devices
Technical standards.....	EN 60601-1
Classification.....	Class I

ELECTRICAL SPECIFICATIONS

Input voltage:.....	100-240 V 50/60 Hz
Fuses:.....	(2) T6,3A H
IV Pole power consumption	40 VA
Maximum connectable power	1 KVA

I.V. POLE

Maximum Height:	235cm approx
Maximum travel:.....	70cm approx
Control:	Switch with rocker action The height can be saved in a user programme by the connected instrument. See the instrument's user manual for further details.
Compatibility:	The electric I.V. pole interface is compatible with the following Optikon equipment. Pulsar Minimal Stress, Pulsar^2,Antares 2000

PARAMETER	**SPECIFICATIONS**

MECHANICAL SPECIFICATIONS

Maximum Load:

Mayo tray:	2 kg
Equipment tray.....	30 kg
I.V.Pole	1 kg

Degree of protection against
harmful ingress of water:..... : IPX1
Degree of safety for use in the presence
Of a flammable anaesthetic mixture unsuitable

DIMENSIONS

Height	235 cm (Pole extended)
Width	52 cm
Depth	64 cm
Weight.....	52 Kg

5.4 CIRCUIT DIAGRAMS

OPTIKON 2000 S.p.A. will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are repairable.

NOTE:
1) The weight and dimensions indicated are approximate.
2) Specifications are subject to change without notice.

6. INSTALLATION AND OPERATING PROCEDURE

6.1 INTRODUCTION

This section details a recommended installation and operational checkout procedure for the Optikon Equipment Cart 181004.

The operational checks, however, which are performed after the system installation to verify instrument operation, must be performed exactly as indicated and should not be regarded as recommended practice or as encouragement for surgical operating room procedures.

To bring your system in operation, a series of cable and tubing connections between cart and control console, footswitch, handpieces and I/A system must be made.
Follow the installation and operating instructions carefully in a step by step manner and, within a short time, you will have gained all the knowledge needed for successful operation of your surgery system.

6.2 INITIAL INSPECTION

This instrument was carefully inspected, mechanically and electrically, prior to shipment.
Before unpacking the OPTIKON Equipment Cart, inspect the carton for damage. If it is damaged, be especially careful when inspecting the contents for any mechanical damage which may have occurred during shipment, and test the electrical performance. If physical damage is found, you should apply at once to the carrier that handled the consignment (mail, railways or forwarding agents) and have an appropriate certificate established.
If damage of a mechanical nature is discovered or if the instrument does not match the specifications, immediately inform the shipping company and the nearest OPTIKON service center, which will repair or replace the instrument.

6.3 INSTALLATION

Remove the cart from its packing and follow the installation instructions.

a. Take the bottle raiser extension, screw it onto the end of the bottle raiser shaft, tightening it by hand. Lock the arm by tightening the dowel on the head of the extension (see Fig4). Make sure you align the arm as in Fig. 5

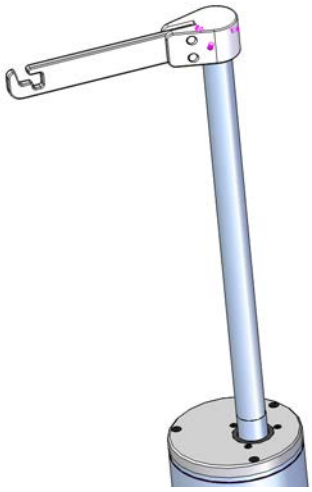


Fig.4

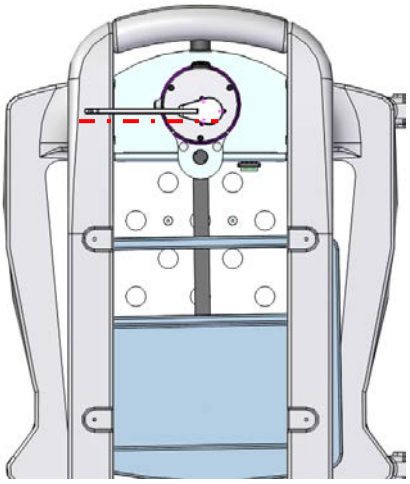


Fig. 5

2)

a. Place the Optikon console on the instrument shelf.
b. The cart comes with one European cord and one US cord. If you need to change the cord see paragraph. 6.6.
c. Turn on the console and the cart with their respective power switches, then proceed as indicated in the console's instruction manual.

6.4 SHUTDOWN PROCEDURE

If the Optikon cart is not being used for an extended period, the following procedure should be observed:

1. Set the pole to the minimum height.
2. Turn the cart and the housed instruments off at the mains switch on the front of the cart.
3. Disconnect the cart's cord from the mains socket and wrap it round the rear cable reel. To disconnect the cord, pull out the plug, do not pull the cord.
4. Place the system pedal on the cart's foot platform.
5. Cover the hosted equipment and the cart with a drape to protect from dust.

6.5 MAINTENANCE

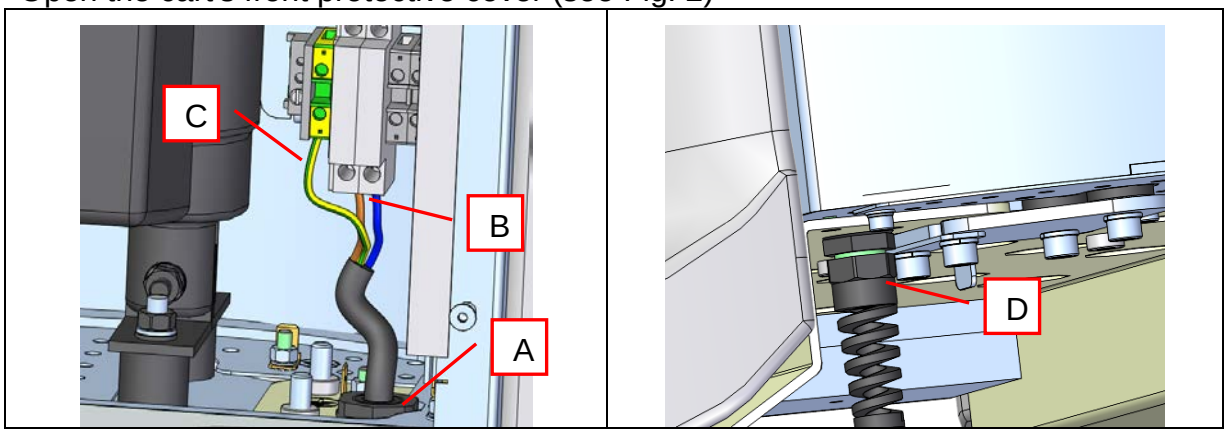
The 181004 Optikon Equipment Cart requires very few attentions to provide you with a long lasting satisfactory service.
The medical personnel must take the responsibility to keep existing instruments and equipment functioning properly. The following simple steps serve as practical guidelines in establishing your care and maintenance program:

1. The Optikon Equipment Cart and the hosted console(s) should be stored in a clean and dry environment at room temperature.
2. In order to remove salt solution deposits or other residuals, periodically clean the cart and the control console with soft dusting cloth dampened with distilled water. If necessary use only neutral detergent.
3. Do not move the cart or equipment footswitch by pulling on their respective cables.
4. Do not overload the mayo tray and/or the equipment tray.

6.6 CHANGING THE POWER CORD

The Optikon 181004 cart has two power chords, one European and one US. To change the cord:

1. Open the cart's front protective cover (see Fig. 2)



2. Remove cables B and C from the terminal block, loosen nut A and remove cable D. Then replace the cord.

   NB: make sure you connect the earth wire correctly.

3. Re-close the cart's front protective cover.

NOTE:

OPTIKON 2000 S.p.A. reserves the right to change design and specifications without notice because of its policy of continuous product research and development.

CAUTION

- **DO NOT USE SYNTHETIC DETERGENTS OR OIL-BASED SOAPS.**
- **DO NOT USE ALCOHOL, SOLVENTS, OR ABRASIVES ON THE CART OR THE CONTROL CONSOLE.**

7. TROUBLESHOOTING GUIDE

The TROUBLE-SHOOTING GUIDE lists some malfunctions which may occur, the symptoms and the corrective actions.
If the system remains inoperative even after performing the corrective actions indicated below, contact OPTIKON 2000 S.p.A. sales/service department.

SYMPTOMS	CORRECTIVE ACTION
	Mains power supply
System completely inoperative	a) A.C. power cord not connected. Connect power cord to the cart and the power source. b) Blown mains fuses. Replace the mains fuses (See 5.2.2). c) Mains switch off. Check the position of the mains switch locate on the rear of the cart
	I.V.Pole
Pole does not move during startuptest	Check the cable connecting the pole interface to the console.
Pole stops at a wrong position against an obstacle(i.e. low ceiling)	The electric I.V. pole features a torque protection system. Remove the obstacle and restore the proper bottle position .