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EQUIPMENT CART WITH CYLINDER HOLDER

INSTALLATION AND OPERATING MANUAL

OPTIKON 2000 S.p.A.

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OPTIKON 2000 SpA is an ISO 9001 and ISO 13485 certified company which manufactures surgical and diagnostic devices for ophthalmology.

Its products are manufactured to satisfy the requirements of 93/42/EEC Medical Devices Directive.

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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 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 in all cases. 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 liable for safety, reliability and performance only if:

- upgrades, calibrations, repairs are carried out by OPTIKON 2000 S.P.A. authorized personnel
- the system is used in accordance with its instructions for use
- the mains electric installation to which the system is connected complies with the IEC or UL Safety Regulations

IMPORTANT NOTICE

Every effort has been made to have all the illustrations and information accurately represent the product and its operation as it actually was at the time this operation manual was printed. Changes in some items may be made during the life of this manual, so that we may effectively continue to meet the requirements of users. On occasion, these changes may be made without notice.

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2 LIMITED WARRANTY CONDITIONS

All OPTIKON 2000 S.P.A. equipment and accessories sold and installed in the European Union are guaranteed against defective workmanship and faulty parts for ONE YEAR, from the date of the invoice. Warranty on consumable materials is limited to the first use.

Please, inquire with your local Optikon Distributor for warranty conditions in countries outside the European Union.

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

Warranty includes the research of causes of the faults, reparation of the defect and a final inspection of the unit, or part(s).

This warranty does not cover the results of misuse, accident, abuse and tampering or alteration done by anyone other than personnel authorized by OPTIKON 2000 S.p.A.

OPTIKON 2000 S.P.A. reserves the right to ascertain, in case of faults, whether or not the equipment and/or its accessories have been altered, tampered with, in any way, or have been damaged by improper use.

OPTIKON 2000 S.P.A. also reserves the right to modify the equipment and/or its accessories whenever operating techniques necessitate modification(s).

No warranty will be recognized if serial number of the equipment and/or accessories attributed by OPTIKON 2000 S.P.A. is missing, tampered and/or not clearly readable.

Warranty does not include expenses for return shipment of equipment and accessories: all expenses for transport, packing etc. are to be borne by the purchaser.

In case of an expressly requested intervention of our technicians, all travel and hotel expenses will be debited to the client.

OPTIKON 2000 S.P.A. cannot be held liable for damages caused by transportation. If this is the case, the customer should apply at once to the carrier that handled the consignment.

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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.
- DO NOT USE THE SYSTEM IN THE PRESENCE OF FLAMMABLE ANAESTHETICS, MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.
- 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.
- 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 REAR PANEL 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.
- DO NOT EXCEED THE FOLLOWING MAXIMUM LOAD LIMITS:

Equipment tray 25Kg

OVERLOADING THE CART MAY CAUSE MECHANICAL FAILURES AND POSSIBLE HARM FOR THE PATIENT AND/OR THE OPERATOR.

- 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 STRENGHT, PLUG TO THE CART COMPATIBLE OPTIKON EQUIPMENT ONLY (SEE COMPATIBILITY CHART IN THE TECHNICAL SPECIFICATIONS).
- **CAUTION: ELECTRIC SHOCK HAZARD**. AVOID DRIPPING WATER ON THE ELECTRIC RECEPTACLE OF THE CART. IF THE ELECTRIC RECEPTACLE GETS WET, DISCONNECT THE CART FROM MAINS AT THE WALL OUTLET END BEFORE TRYING TO REMOVE THE WATER.
- 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.

4 SYMBOLS AND MARKINGS

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
	ALTERNATE CURRENT
	DIRECT CURRENT
	PROTECTIVE EARTH
	ATTENTION CONSULT ACCOMPANYING DOCUMENTATION
	OPEN (POWER DISCONNECTED FROM THE MAINS)
	CLOSED (POWER CONNECTION FROM MAINS)
	TYPE B APPLIED TO THE PATIENT (BODY)
	TYPE BF FLOATING PART APPLIED TO THE PATIENT (BODY-FLOATING)
	SEPARATE COLLECTION OF WASTE ELECTRICAL/ELECTRONIC EQUIPMENT

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5 GENERAL INFORMATION

5.1 SYSTEM DESCRIPTION

The Optikon equipment trolley with cylinder holder 183001 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 housing for CO2 or N2O gas cylinders, and relevant cylinder holders (spring).

The base of the cart is provided with antistatic wheels, with locking system.

5.2 CONTROLS AND INDICATORS

All controls and indicators are located on the rear of the cart.

1. POWER (ON/OFF MAINS SWITCH/PILOT LAMP)

   This illuminated rocker switch controls the sockets to power the consoles hosted by the cart. Provided that the mains switches of the single consoles are left to the on position, this switch will energize or de-energize all the surgical system.

2. MAINS POWER CONNECTION FOR HOSTED CONSOLES.

   Three mains sockets allow connecting the mains power for the hosted surgical consoles.

3. PROTECTION COVER

   This transparent lid has been designed to prevent the use of the mains sockets to connect any device other than an approved Optikon console. The lid must be removed by a qualified technician when the console is first installed. The lid must be restored in place once the equipment has been installed.

4. MAINS INLET AND FUSE HOLDER

The power cord to energize the cart must be connected to this inlet. Use only the supplied cord or a Medical grade power cord. The socket also hosts two fuses that interrupt the mains power in case of fault in the cart or in the hosted consoles.

5. TAG (MARKINGS)

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

5.3 TECHNICAL SPECIFICATIONS

PARAMETER	SPECIFICATION
Manufacturer:	OPTIKON 2000 S.p.a.
	via del Casale di Settebagni, 13
	00138 Rome - Italy
Model:	183001 equipment cart
Regulatory compliance:	93/42/EEC Medical Devices Directive (MDD)
Technical standards:	EN 60601-1
ELECTRICAL SPECS	
Input voltage:	220-230/240 Volt 50 Hz 100/120 Volt 50/60 Hz
Line fuses:	220/240 Volt: 6.3 A T
	100/120 Volt: 16 A T
Max output power	1kW
MECHANICAL SPECS	
MAXIMUM LOAD:	
Equipment tray	25 Kg
Degree of protection against harmful ingress of water	IPX0
Level of safety of its use in the presence of an inflammable anaesthetic mixture containing air or oxygen or nitrous oxide	NOT SUITABLE

DIMENSIONS

HEIGHT:	106 cm
WIDTH:	57.5 cm
DEPTH:	54 cm
WEIGHT:.....	24 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) Weight and dimensions shown are approximate.
2) Specifications are subject to change without notice.

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6 INSTALLATION AND OPERATING PROCEDURE

6.1 INTRODUCTION

This section details a recommended installation and operational checkout procedure for the Optikon Equipment Cart 183001. 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 mechanical assembly operation for the cart and a series of cable and tubing connections for the control console and the accessories 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

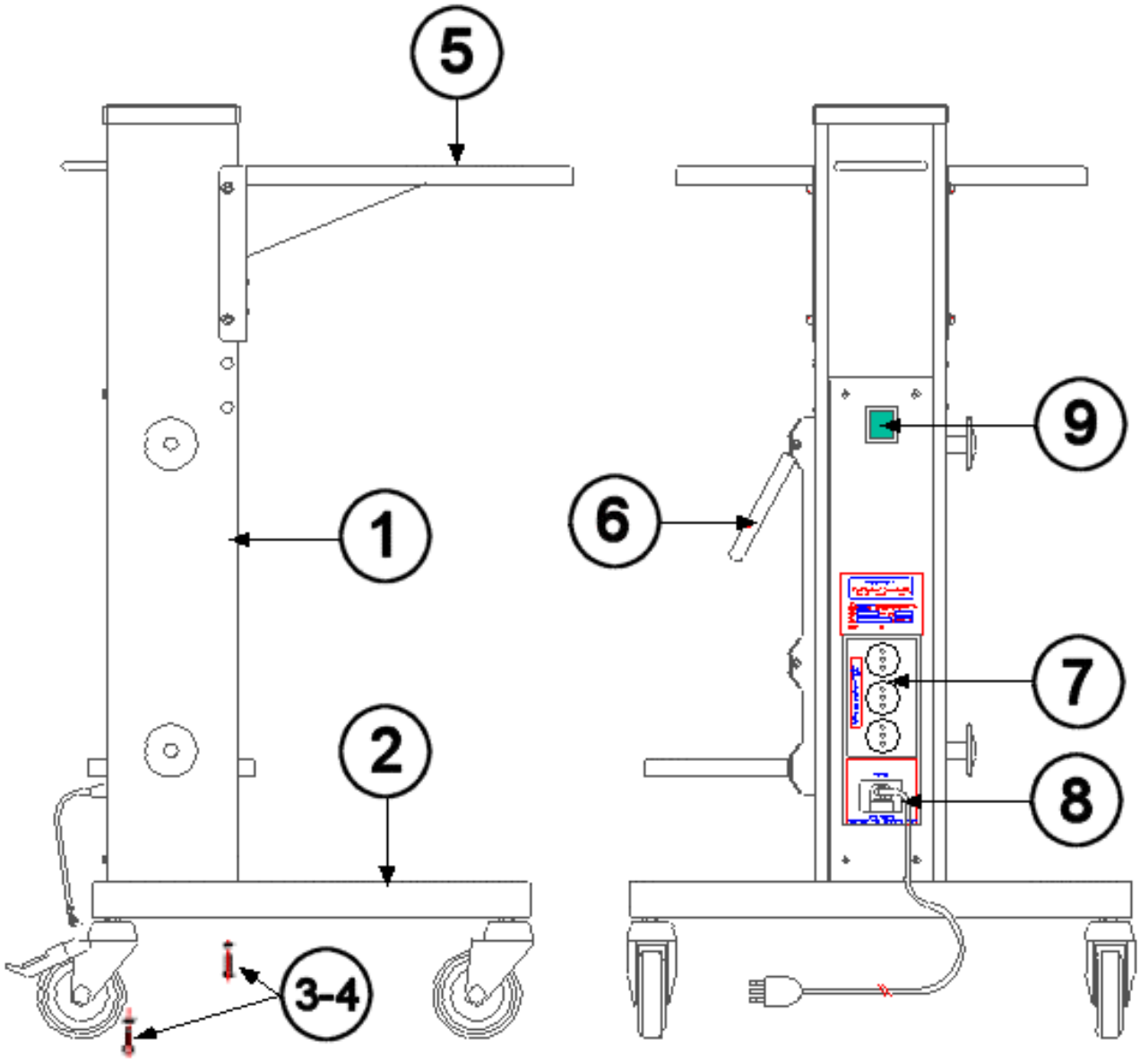
This instrument was carefully inspected, mechanically and electrically, prior to shipment.

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. Without documentary evidence, claim cannot be filed.

6.3 INSTALLATION

Unpack the cart and then refer to the following figure for the assembly instructions.



a. Assemble the cart column (1) on the base with wheels (2) using the screws (3) and the washers (4) and the supplied Allen wrench.

b. Assemble the equipment tray (5) at the desidered height using the supplied screws and washers and Allen wrench.

c. Assemble the cylinder holder (6) in the suitable holes, according with cylinder's height.

d. Place the Optikon Console on the equipment tray.

e. Remove the protection cover covering the electric sockects (7) and plug in the power cord for the equipment console. Re-install the protection cover.

f. Plug the supplied mains power cord to the 183001 receptacle (8) and into the wall mains outlet.

g. Switch on the equipment and the cart (9), then proceed according to the hosted equipment user manual.

6.4 SHUT DOWN PROCEDURE

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

1. Depress the "Power" switch on the rear of the cart column to power down the console and the cart.
2. Unplug power cord from wall outlet and roll it around the mushroom style supports on the side of the column. Be sure to pull the plug, not the cord.
3. Place the system footswitch on the base of the cart, rolling the cable on the supports at the side of the column.
4. Cover the hosted equipment and the cart with a drape to protect from dust.

6.5 MAINTENANCE AND CARE

The 183001 Optikon Equipment Cart with cylinde holder 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 equipment tray.

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 TROUBLE SHOOTING 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
A.C. POWER	
System completely inoperative.	a) A.C. power cord not connected. Connect power cord to the cart and the power source. b) A.C. line fuse blown.Replace the line fuses. c) Mains switch off.Check the position of the mains switch locate on the rear of the cart