NAMRØL

Gyneris 3M

Art. nº. SN-870E

Thank you for choosing NAMROL products.

The equipment you have purchased has been designed and manufactured to meet your present needs and, thanks to its in-built versatility and adaptability, your future needs too.

Before using this unit it is good practice to read this handbook carefully and keep it safely.

This will provide you with a full understanding of the unit, will allow you to make the best use of its potentiality and maintain top-level performance, safety and reliability throughout its working life.

And, whatever circumstance may arise, you can count on the professionalism of your NAMROL. dealer, the expertise of his technicians and our reliability as constructors.

NAMROL MEDICAL

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Safety Instructions

Before installing and using the equipment, carefully read the instruction manual and ensure that all directions and instructions contained are fully understood. It includes important safety information for installation, operation and maintenance!

If the equipment is used for any purpose other than that for which it was designed and as described in this instruction manual, such use will invalidate the manufacturers warranty and guarantee!

The control unit may only be opened by the manufacturer or by an expert approved and authorised by the manufacturer.

When unpacked, check the contents of the delivery to en sure that all parts have been included and that nothing has been damaged during transit. In the event of any doubt, please contact our customer service department.

Never use the equipment with a damaged mains power supply cable. Do not jam or kink the cable and do not allow it to rest on any hot object (e.g. radiator, lamp, etc)!

If the mains cable is damaged in any way, immediately disconnect the equipment from the mains power supply. Please consult our customer service department before using again.

Before connecting to the mains power supply ensure that the voltage (V) shown on the type plate corresponds with the power supply available!

Under no circumstances may the mains plug be disconnected from the socket with wet hands. Never attempt to remove the plug from the socket by pulling the connecting cable!

Do not use in damp surroundings and do not splash with liquid!

In the event of any liquid or foreign body entering the inner of the control unit, immediately disconnect the equipment from the mains power supply! Please consult our customer service department before using again.

Always isolate from the mains power supply by disconnecting the mains plug before cleaning!

WARNING!

Always isolate from the mains power supply by disconnecting the mains plug before cleaning!

Unpacking and installation

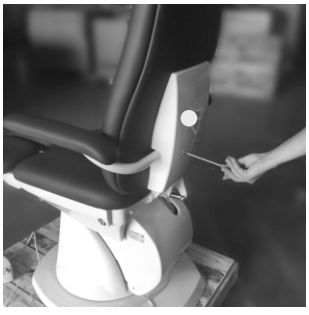
Open the top of the packaging, check the condition of the chair, if everything is correct, remove the box upwards.

Loosen the fastening of the chair and remove the plastic protection.

Put the backrest in upright position by holding the top.

Fix with the supplied 4 screws and keys of 5mm and 3mm.

Place the back cover, softly tighten the screws with the washers. Put the white cap on the head of both screws. Check operation and the chair will be ready for use.



P0 Reset

Positioning choice (up)

Positioning choice (down)

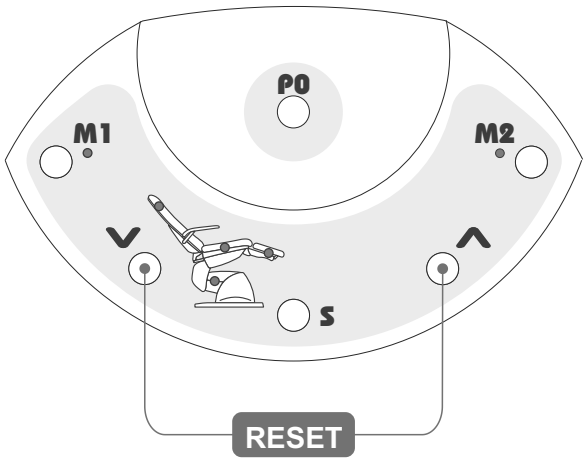
M1 Programmed working memory 1

M2 Programmed working memory 2

S Movement Selection (base, seat and backrest)

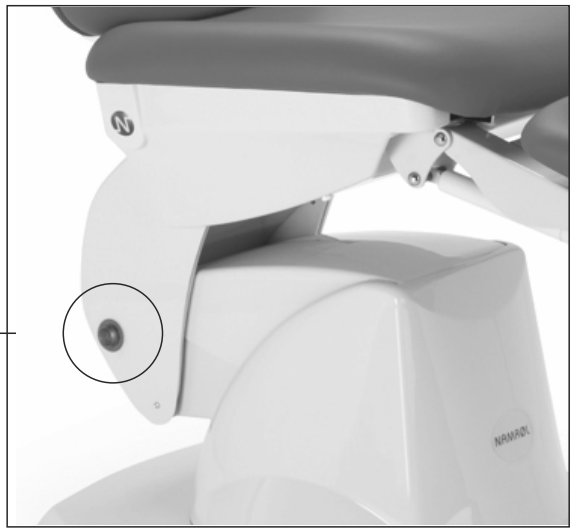
STOP For emergency stop press any button.

RESET (Failure: 4 flashing LEDs). Reset by pressing the two arrows at the same time for 10 seconds.



RESET SYSTEM MOTOR

Power ON/OFF
and reset system



SWITCH ON

Press the green switch on button on the left side of the chair.

CHAIR MOTION

To move the chair to the desire position, press S for select the motor and after press up or down

MEMORIES AND RETURN TO INITIAL POSITION (P0) USE

Initial position: Press PO reset button.

Memory use: Press M1 or M2 button during two seconds, the chair will automatically move to the programmed position.

In case of emergency stop during an automatic movement, press any button.

PROGRAM WORKING MEMORIES.

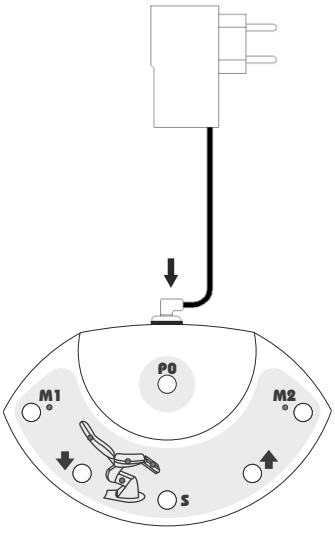
. After a reset, move the chair to the desired position.

. Press and hold S and then M1 or M2 during 5 seconds.

. An acoustic signal will confirm the correct position.

BATTERY CHARGE WIRELESS FOOT CONTROL (OPTIONAL).

Connect the charger connection pedal. minimum load of 8 hours. Preferably recharged at weekends.



ROTATION

Gyneris can rotate 360º.

Unlock: step on the lever and turn it to the right.

Block: turn the lever to the left.

ARMRESTS

Armrests are independently one another; they remain parallel to the seat even if the distance between them changes together with the inclination of the backrest. Armrests are easily tipping, in order to help climbing up and going down from the chair. Patient can reach the chair both frontally and sideways.

Caution! Danger of electrick shock!. Disconnect from the mains power supply before cleaning.
Note:
Do not allow that oil or any care products come in contact with the upholstery because this can damage it. We recommend the use of an upholstery protection, e.g. a towelling cover.
If oil comes in contact with the upholstery, remove immediately.

To clean and disinfect the external surfaces of the podiatry chair (plastic, painted and upholstered parts) use standard commercially available disinfectants and check that the listed active substances do not exceed maximum concentrations indicated below:

- Glutaraldehyde 2%:10%
- Ethanol 96%:40%
- Formaldehyde:0.01%
- Glyoxal:0.15%
- Propanol:35%

WARNING!

Do not exceed indicated concentrations. Do not use products containing alcohol, ammoniac, abrasive substances or benzene. Wipe disinfected areas with a wet cloth (disinfectants may attack surfaces even where diluted).
Apply products with a soft disinfectant-dampened cloth: do not spray the disinfectant directly onto equipment as it could infiltrate the unit/chair and compromise proper operation.
NAMROL. cannot be held liable for any damages deriving from failure to observe the warnings and instructions contained in this handbook.

GENERAL INSTRUCTIONS

- Keep the base constantly clean in order to avoid accumulation of organic deposits within the coverings and consequent stinking odours.
- Absolutely avoid pouring of liquids on the base; in case of accidental pouring, dry as soon as possible.

WARNINGS

Purpose of the equipment:
The podiatry equipment is intended for professional podiatrists as an aid to in-surgery operations that concern affections of the foot and their treatment. These equipments have been designed and constructed for use with patients of all ages.
Neither the podiatry unit nor the podiatry chair can be used in presence of flammable anaesthetic gas mixtures.
When treating patients with pace-makers or similar devices the operator must take the necessary precautions: refer to the specific literature on the matter.
Do not exceed the loads indicated in the “technical specifications” section.
Do not remove the labels on any unit/chair devices. Should these deteriorate replace them.
Power supply:
Make sure that the unit/chair electrical power supply is powered via an external differential cut-out switch with a 16A current-carrying capacity and a 10mA trip threshold.
Make sure that equipmentr power supply is separate.
Make sure that the podiatry unit power supply is fitted with an efficient grounding (earth)system and that wiring complies with the standards in force.
Climate:
Under extreme conditions (heat, cold, humidity)it is advisable to let a few hours pass between unpacking the equipment and using it for the first time. This precaution provides the time needed to eliminate any condensation that may have formed inside the packaging.

Power supply	230 V AC single phase/50Hz *115V AC (USA/CANADA)
Operating voltage	24 volts
Chair absorption	2.5 A
Liftable load	250 Kg.
Arm-rest load capacity	40 Kg. each
Back-rest load capacity	60 Kg
Chair weight	97 Kg
Chair dimensions	710mm x 795mm x 1385mm H.

IDENTIFICATION

The chair can be identified by the ID plate, positioned under the right arm-rest. This ID plate gives the serial number.

When requesting assistance or ordering spare parts from C.S.S. always quote the equipment serial number.

SYMBOLE

Alternating Current	~
Earth	⏚
Voltage (230 V)	⚡
WARNING:see operating instructions before use	⚠
EC declaration of conformity.	CE
Customer Support Service (task to be effected only by qualified technical staff).	🔧

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DECLARACIÓN DE CONFORMIDAD UE

EU Declaration of Conformity

Reglamento de Productos Sanitarios2017/745

Medical Devices Regulation 2017/745

Fabricante: *Manufacturer:*	**NAMROL MEDICAL, S.L.**
Dirección: Address:	C/. Progrés, 24-26 08850 Gavà, Barcelona
Número de Registro Único *Single Registration Number (SRN):*	ES-MF-000006718

DECLARA BAJO SU RESPONSABILIDAD, QUE EL PRODUCTO:
DECLARES UNDER ITS SOLE RESPONSIBILITY THAT THE:

Nombre comercial: *Trademark:*	GYNERIS
Código UDI-DI *UDI-DI code:*	08437023142608
Producto: *Product:*	SILLÓN GINECOLÓGICO *GYNECOLOGY CHAIR*
REF:	SN-870E
Finalidad prevista *Intended purpose:*	Examen y tratamiento ginecológico Examination and gynecology treatments

CUMPLE CON LOS REQUISITOS ESENCIALES DEL REGLAMENTO:
CONFORMS WITH THE ESSENTIAL REQUIREMENTS OF THE REGULATION:

REGLAMENTO (UE) 2017/745 *Regulation (EU) 2017/745*	Reglamento de Productos Sanitarios *Medical Devices Regulation*
Clasificación *Classification*	**Clase I productos sanitarios** *Class I medical devices*
Regla *Rule*	**Regla 1, capítulo III, Anexo VIII** *Rule 1, chapter III, Annex VIII*

Cumple con las siguientes normas internacionales:
Applied Standards in full or in part:

EN 62366:2009	Dispositivos médicos. Aplicaciones de la ingeniería de aptitud de uso de dispositivos médicos. / *Medical devices–Application of usability Engineering to medical devices*
ISO 14971:2019	Aplicación de la gestión de riesgos a los productos sanitarios. / *Application of risk management to medical devices*
UNE-EN ISO 13485:2013	Productos sanitarios. Sistemas de gestión de la calidad. Requisitos para fines reglamentarios. / *Medical devices. Quality system control*
UNE-EN ISO 15223-1:2013	Productos Sanitarios. Símbolos a utilizar en las etiquetas, el etiquetado y la información a suministrar / *Graphical Symbols for use in the labelling of medical devices*
UNE EN 1041:2014	Información proporcionada por el fabricante de productos sanitarios / *Information supplied by the manufacturer with medical devices*
UNE-EN 60601-1 2012–	Parte 1: Requisitos generales para la seguridad básica y funcionamiento esencial. / *Part 1: General requirements for basic safety and essential performance*
UNE-EN 60601-1-2:2008	Equipos electromédicos. Parte 1-2: Requisitos particulares para la seguridad básica y características de funcionamiento esencial. Norma colateral: Compatibilidad electromagnética. Requisitos y ensayos. / *Part 1-2: General requirements for basic safety and essential performance - Collateral StandarSO 009 SOPORTE CON FRENO d: Electromagnetic compatibility - Requirements and tests*

Nombre /*Name:* Guillermo Lorman

Firma / *Signature:*

Fecha / *Date:* 01/04/2024
Gavá, Barcelona

Cargo: Director General
Position: General Manager

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