


MEDICAL DEVICE DESCRIPTION

Ref.	SURGYSONIC MOTO G
<p>Product Image</p>	
<p>Destination of use</p>	<p>The SURGYSONIC MOTO G is a medical device which can be used in general surgery of hard tissues and soft tissues in the following fields:</p> <ol style="list-style-type: none"> 1. dental, for bone and implant surgery, endodontics and periodontal surgery; 2. maxillo-facial surgery, ENT, Orthopedics, Neurosurgery and general surgery of hard tissues; 3. for wound management field for debridement, surgery of soft tissues, for interventions on bedsores, for the removal of necrotic tissue surface in the dermatological field (for the removal of necrotic tissue from the bottom of the ulcerative lesion, for the cleaning and cleansing of the same - debridement). <p>The unit manages the ultrasonic handpiece which has also the following field of use: surgery field, where it is necessary to make cuts and/or incisions of bone (Osteotomy) and/or hard tissues in general and/or soft tissues.</p>

Product description	<p>The SURGYSONIC MOTO G medical device is a surgical equipment characterized by a control issuing of an ultrasonic vibration for hard and soft tissues surgery.</p> <p>The unit manages a piezoelectric handpiece operating through an ultrasonic vibration (available also with Led). The SURGYSONIC MOTO G medical device manages also a micromotor handpiece with an accurate torque control of the motor.</p> <p>The SURGYSONIC MOTO G medical device is a powerful and versatile surgical machine.</p>
MANUFACTURER	
Esacrom srl – Via Zambrini, 6/A – Imola (BO) Italy	
TECHNICAL DATA	
Voltage Supply	230Vac 50/60Hz - 115 Vac 50/60Hz
Nominal power	170 [VA]
Console weight	4,5 [Kg]
Handpiece cable length	2000 [mm]
Hydraulic circuit flow	From 5 to 50 [ml/min]
Fuses	EXTERNAL FUSES F1-F2=T 1,6A (230Vac) F1-F2=T 3,15A (115Vac) INTERNAL FUSES F1=1xT 1A, F2=1xT 0,5A, F3=1xT 5A

Piezoelectric data	<p>The console allows to set the ultrasound vibration frequency, the ultrasound power and the water flow (70 different power levels combinable with 10 different levels of vibration).</p> <p>VIBRATION: 20/200 [μm] FREQUENCY: 22/35 [KHz] FUNCTIONS: High, Medium, Low, Turbo, 3D Mode</p> <p>Possibility of manual setting of this default functions during use (power parameter from 0 to 70 with step of 1 point, vibra parameter from 0 to 100 with step of 10 point, pump parameter from 0 to 100 with step of 1 point). All variations can be memorized selecting MEM button. For Medium and Low function the maximum power to be set is 50. 10 programs are available for each function.</p> <p>POWER: 50W High 50W Medium 50W Low 70W Turbo 70W 3D Mode</p> <p>HANDPIECE WEIGHT: 182 [g] – <i>with connection cable</i></p> <p>Note: for 3D Mode function 3D Mode=Torsional mode: This mode includes the Sweep type wave. In this mode the vibration frequency moves dynamically and continuously. The frequency moves automatically, for example: to 70 to then return to 80, move to 90 to then return again to 80, according to the type of density of the hard tissue on which the tip find to be used. It is an advantage and a benefit for the treatment on the interested surgical area.</p>
Packaging	Transport case in box – dimensions: 24,5x44x61,5 [cm]
CLASSIFICATION	
Dir.93/42/CEE-Dir. 2007/47/CE	Class IIb
EN 60601-1	Class I Type B
RDM (Medical Devices Repertory Registration n.)	1357078/R
CND (Medical Device National Classification Code)	Z12019099 (VARIOUS EQUIPMENT FOR FUNCTIONAL EXPLORATIONS AND THERAPEUTIC INTERVENTIONS NOT OTHERWISE CLASSIFIED)

GMDN (Global Medical Device Nomenclature Code)	36273 Ultrasonic surgical system generator <i>An electrically-powered component of an ultrasonic surgical system intended to generate a high frequency electrical current that is converted, typically within a handpiece, into an ultrasonic oscillation to fragment hard and/or soft tissue cells upon contact with a vibrating tip. It is used in a variety of surgical disciplines (e.g., arthroscopy, gynaecology, neurosurgery, dental/craniomaxillofacial reconstructive surgery); it is not dedicated to dental applications. It provides the controls and monitoring functions for the system during the procedure, and typically regulates energy to the system via a foot-switch; integrated suction/aspiration function may be included</i>
UMDNS (Universal Medical Device. Nomenclature System Code)
CPV 2007 Public procurement code	33100000-1 Medical equipments.
APPLICABLE STANDARD AND DIRECTIVES	
Directives:	Medical Devices: Dir. 93/42/EEC as modified Dir. 2007/47/EEC Machines: Dir. 2006/42/EEC
Standards:	Electrical safety: EN 60601-1; EN60601-1-6; IEC 62304; IEC 62366 Electromagnetic compatibility: es. EN60601-1-2
HOMOLOGATIONS-APPROVALS	
CE 0051 Certification – Notified Body IMQ – certificate EEC n°874/MDD	
PRESERVATION	
Sterility:	Not sterile DM
Sterilization method:	Not sterile DM
Expiry:	Not sterile DM
INSTALLATION	
Installation area	Installation on a table/cart, far from heat sources
Environmental parameters	Temperature: from 5° to 40°C Humidity: less than 90%
Electrical connection	By removable supply cable
UPS Power Supply	At the user's discretion according to the safety procedures in use at user facility
Gas network connection	Not necessary
Water supply Connection	Not necessary

Connection data

Not necessary

MAINTENANCE

The device is maintenance free. The only **maintenance routine** in charge to the user are:

- Cleaning, disinfecting and sterilizing the handpiece and tips
 - Cleaning and disinfecting the console
- Replace the irrigation line and the cooling solution

The manner in which these activities are to be made are shown in the **user manual**.

In order to maintain the standards of **electrical safety** guaranteed by Esacrom srl it is suggested to carry a functional check and verification of compliance with safety EN60601-1 for medical devices, to be performed with secure - tester, **AT LEAST ANNUALLY**.

Immediate maintenance by Esacrom srl or authorized personnel, must be performed if:

- (1) the medical device has been subjected to external mechanical stresses, such as serious falls;
- (2) the medical device has been subjected to severe overheating, for example, if left near a source of intense heat;
- (3) it's doubted that liquids could have penetrated inside;
- (4) the casing or other parts of the medical device are damaged, broken or missing;
- (5) the functionality of the medical device appears altered.

Access to the internal parts of the equipment has to be done by personnel authorized technician by Esacrom srl. For repair activities and additional information is necessary to contact Esacrom srl.

Technical assistance of the medical device SURGYSONIC MOTO G is provided primarily by Esacrom srl.

DISPOSAL

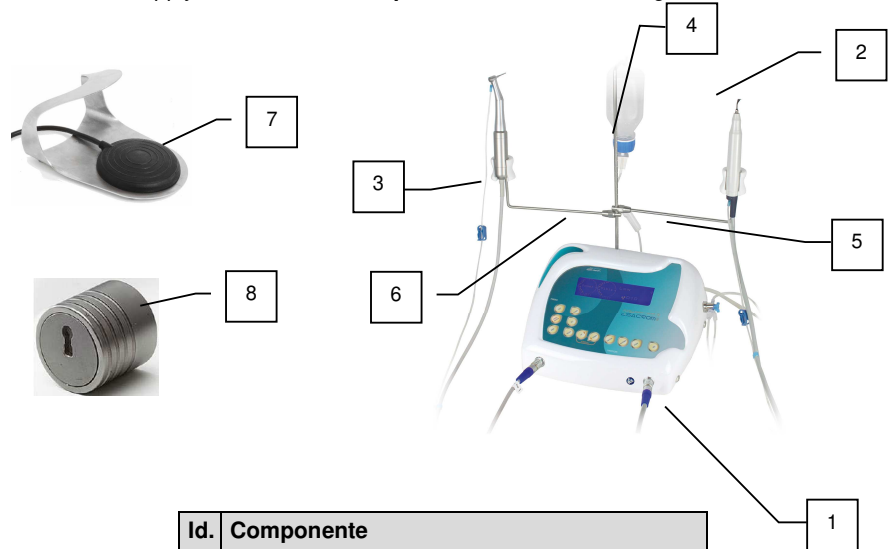
For the UE territory: According to European Directive Rohs 65-2011-UE and transposed into national legislation Disposal of AEE.

EXTRA UE: According to national rules on the disposal of electronic equipment for medical use.

STANDARD EQUIPMENT

Description

In addition an irrigation tube, an electric cable, 2 fuses 1,6 A 250 V, tray, surgery port, the warranty certificate, the conformity declaration and the user manual, default parameters, biological risk, Book Tips will be included to the package. The bag is also supplied. With each device Esacrom supply the **Production Report** filled with date and signature



Id.	Componente
1	Console complete of peristaltic pump
2	Ultrasonic Handpiece (piezo) with cable
3	Micromotor handpiece with cable
4	Metal bar for cooling liquid
5	Ultrasonic handpiece holder
6	Micromotor handpiece holder
7	Pneumatic pedal
8	Torque wrench for the tips of ultrasonic handpiece

User Manual is supplied.

The medical device has a **GRAPHIC** display and a keyboard with tactile buttons with great power illumination.

Accessories

Irrigation line

Brand: OMNIA - SET IRR 32.F0271.00

Tips

SURGYSONIC MOTO G devices are supplied with a set of tips. The complete list of available tips is published in the "Depliant" attached to the User Manual.



The only tips to be used with Esacrom device are ONLY ESACROM tips.

WARRANTY

Console 2 Years ; Handpieces 1 year