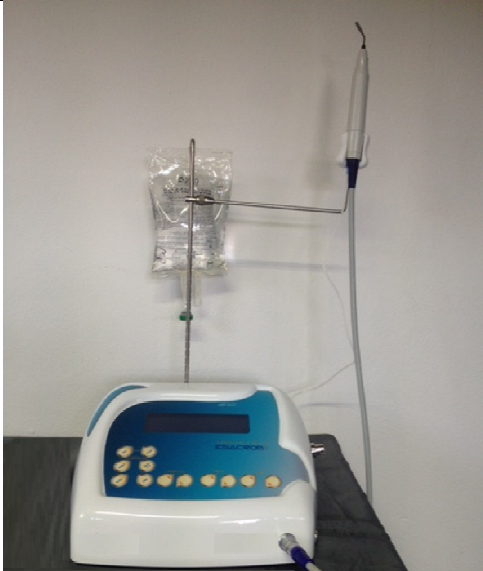


MEDICAL DEVICE DESCRIPTION

Ref.	SURGYSONIC II G
Product Image	
Destination of use	<p>The SURGYSONIC II G is a medical device which can be used in general surgery of hard tissues and soft tissues in the fields:</p> <ol style="list-style-type: none"> 1.dental, for bone and implant surgery, endodontics and periodontal surgery; 2.maxillo-facial surgery, ENT surgery, orthopedics, neurosurgery and general surgery of hard tissues; 3. in surgery of soft tissues: 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 II G medical device is a surgical equipment characterized by a control issuing an ultrasonic vibration for hard and soft tissues' surgery.</p> <p>The unit manages a piezoelectric handpiece operating through an ultrasonic vibration (can be also a Led Handpiece). The SURGYSONIC II 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 - 115Vac 50/60Hz
Nominal power	170 [VA]
Console weight	4,5 [Kg]
Handpiece cable lenght	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 usable 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 modification can be memorized selecting MEM key. For Medium and Low function the maximum power to be set is 50. 10 programs are available for each function.</p> <p>POWER: 70W 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 modality includes the Sweep type wave. In this modality 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 hard tissue density on which the tip is working. It is an advantage and a benefit for treatment on the surgical area.</p>
Packaging	Transport case in box – dimensions: 24,5x44x61,5 [cm]
CLASSIFICATION	
Dir.93/42/CEE-Dir. 2007/47/CE	Class IIb

	TECHNICAL SHEET
	Surgysonic II G

EN 60601-1		Class I Type B	
RDM (Medical Devices Repertory Registration n.)		9355/R	
CND (Medical Device National Classification Code)		Z129099 (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/craniofacial 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 CE 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	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 **routine** maintenance in charge to the user are:

- Cleaning, disinfecting and sterilizing the handpiece and tips
- Cleaning and disinfection console
- Replace tubing and 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 advisable to carry a functional control and verification of compliance with safety EN60601-1 for medical devices, to be performed with secure - tester, **AT LEAST ANNUALLY**.

Immediate maintenance by the 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 extensive heating, for example, if left near a source of intense heat;
- (3) it is doubtful that liquids can be 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 the internal parts should be done by service personnel authorized by Esacrom srl. For repairs and additional information is necessary to contact Esacrom srl.

Technical assistance of the medical device SURGYSONIC II G is supplied primarily by Esacrom srl.

DISPOSAL

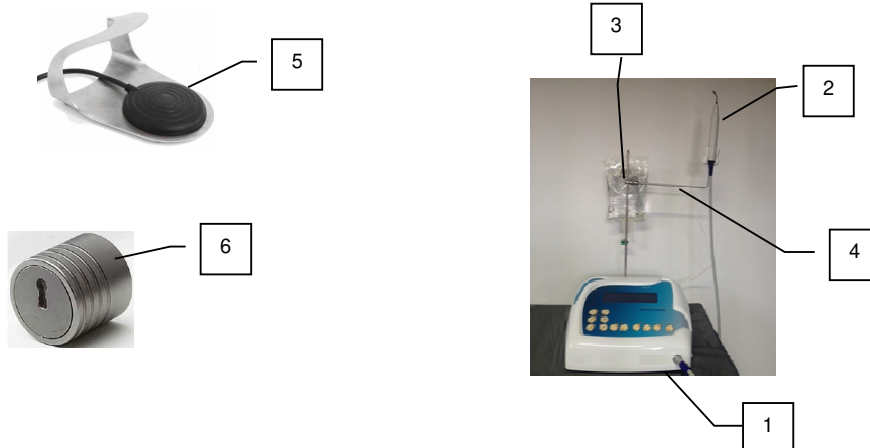
For the EU territory: According to European Directive Rohs 65-2011-UE and transposed into national legislation Disposal of AEE.

EU Extra: 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 declaration, 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	Metal bar for cooling liquid
4	Handpiece holder
5	Pneumatic pedal
6	Torque wrench

User Manual is supplied.

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

Accessories

Irrigation line

Brand: OMNIA - SET IRR 32.F0271.00

Tips



SURGYSONIC II G devices are supplied with a set of tips. The complete list of available tips is published in the "Brochure" attached to the User Manual Guide
The only tips to be used with Esacrom device are ONLY ESACROM tips.

WARRANTY

Console 2 Years ; Ultrasonic Handpiece (piezo) with cable : 1 year