

User manual

Ganzfeld dome

BM 6007IL

Rev. 01 date:02/07/2012



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Warning

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The only warranties from Biomedica Mangoni for their products are forth in the express warranty statements accompanying such products.

Nothing contained in this guide has an additional warranty.

The Biomedica Mangoni can not be held responsible in any way for any errors or omissions contained herein.

Safety Information

To reduce the risk of injury from fire or electric shock, when you use this product always follow the safety precautions.

You should read and understand all instructions in the documentation provided with the instrument.

Follow all warnings and instructions marked on the product.

Before attempting cleaning, switch off the instrument.

Do not install or use the machine near water, or when you are wet.

Install the device in a stable manner, so that it is firm and safe.

Install the product in a protected location where no one can step on or trip over the power cord and damage it.

There are no user serviceable parts the user can carry out repairs. Refer servicing to qualified service personnel.

In case of malfunction, contact the supplier.

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Installation

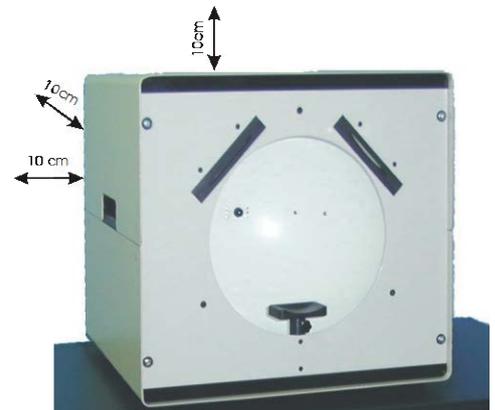
The unit is supplied as a package along with the User's Manual for proper installation and commissioning, a power cable, a serial cable and a USB cable for connecting the camera. It also provides a basic software for remote management from PC. On request we can provide 1 or more filters to be placed in the neutral or colored light stimulation or that the lighting.

Locating the Unit

The stimulator BM6007IL requires air circulation around the container and therefore requires special care about its placement, for the minimum distances refer to the drawing on the side.

Ambient

Ambient temperature between +5 and +45 ° C.
 Relative humidity between 20% and 80% non-condensing.
 Atmospheric pressure 700 to 1060 hPa.
 The instrument must not be exposed to chemicals.
 Avoid places where the tool may come in contact with water.



Connecting to the power

Turn off the stimulator bringing the power switch to the O position
 Connect the power cord to the instrument.
 Make sure that the power supply has a voltage rating equal to that of the data plate of the instrument.
 Plug the other end of the cable into a power outlet equipped with a ground connection.

Cleaning

Clean the outside of the instrument with a dry cloth; Do not use water or detergents for cleaning.

Connecting the outputs of the instrument

All control signals are on the connectors on the rear panel.
 Turn off the instrument bringing the power switch to the O position

WARNING

Do not turn the instrument until the completion of the connections.

Do not install the unit under the following conditions:

- Temperature and / or humidity is too high or too low
- Ambient concentration of chemical vapors.

Maintenance

The unit requires no special care.

Cleaning is the only thing the user needs to pay attention.

The frequency with which should be carried out depends on environmental conditions. Switch off the device.

Clean the exterior with a soft dry cloth.

Do not use detergents, alcohol or any other liquid.

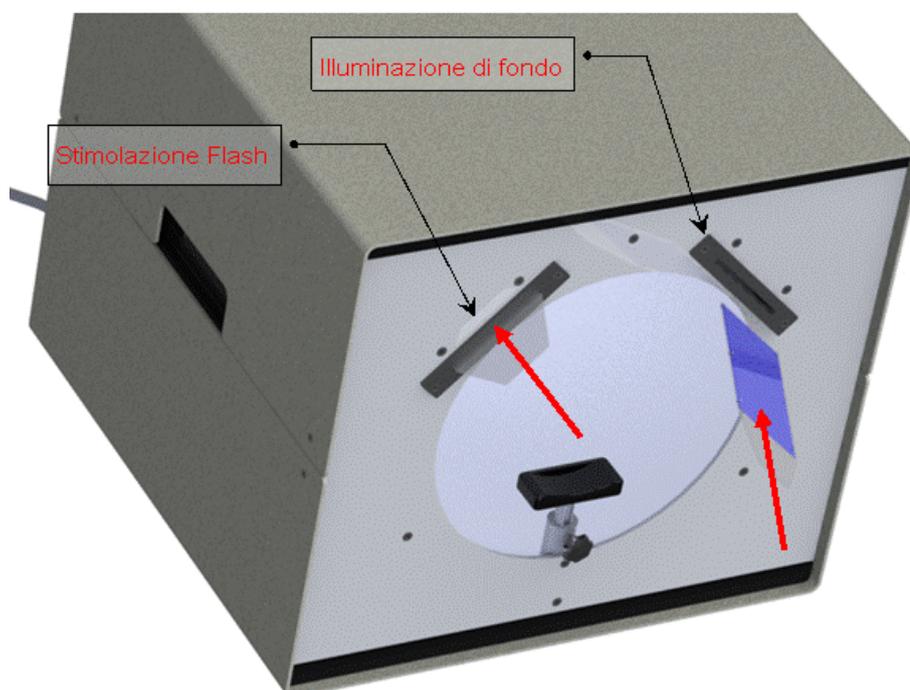
Description of instrument

The ganzfeld dome BM6007IL is a device for both research and clinical applications, allows you to create flash stimuli in a controlled ambient with background lighting and control all the parameters regarding the electrooculography (Arden test). The stimuli are calibrated in both flash Cd/m² that in logarithmic units compared to a standard flash. You can manually insert neutral or colored filters for the stimulation or for the background lighting.

The instrument meets all specifications contained in Directive Electrical safety IEC 62-5 regarding medical equipment.

Front panel

The front panel presents the access opening to the dome for the patient with adjustable chin and the housings for the neutral density filters or colored for the stimulus and only colored background lighting.

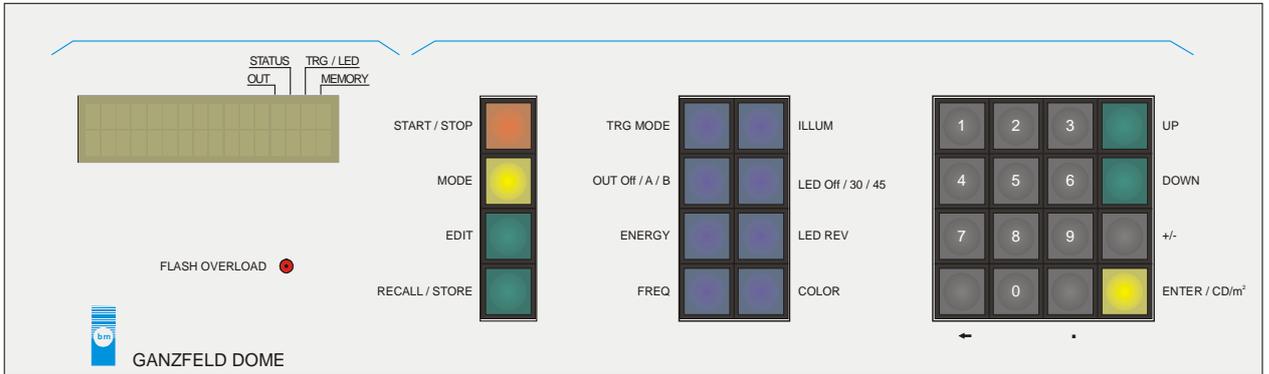


Inserting colored filters

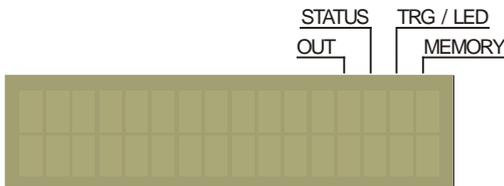
The BM6007L dome has both stimulation flash the backlight is white light, to carry out tests with colored light can be inserted in front of the light source of the appropriate filters (Optional). On the front of the dome there are 2 openings as shown in figure, the left for the filter to the lightning flash, the right for the background illumination, insert the filter in front of the opening angle of about 25 degrees downward and slide it inward until it stops. Make sure that the insertion is complete, otherwise a part of white light would filter inside the dome distorting the exam.

Lateral panel

On the side of the instrument is located the control panel that contains an alphanumeric display with 16x2 characters, which displays the settings of the instrument; a keyboard 28 keys for setting parameters.



Display



The display can indicate either one of the parameters of stimulation simultaneously with the main indications of the state of operation. There is an LED that indicates the attainment of the maximum output power from the stimulator.

FLASH OVERLOAD

- OUT: indicates which output is selected (0 for OFF, I for Internal and E for External).
- STATUS: indicates the enabling or not the output of the stimulus a symbol '||' means that the stimulator is in stop, a symbol '=>' that the stimulus is present at the output.
- TRG / LED: In flash mode indicates the trigger source; 'I' for internal trigger, 'E' for external, 'C' for the trigger coming from a computer connected to the external programming.
In EOG mode indicated the lighting of the target LED
- MEMORY: Indicates the memory currently in use, if the parameters have been modified without a subsequent storage and the indication " 0 ".
- FLASH OVERLOAD: Indicates the achievement of maximum output power of the stimulator..

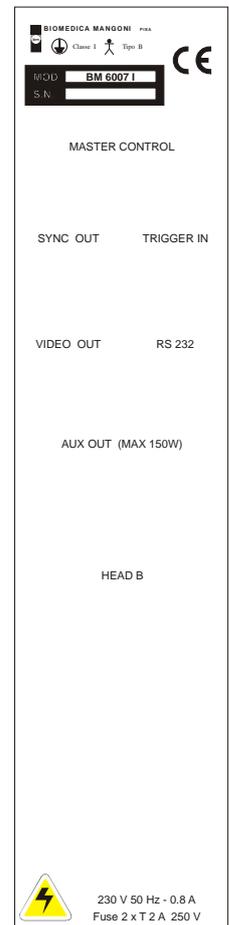
Rear panel

- On the rear panel are:
- one VDE plug for power supply;
 - one VDE socket;
 - a plug D25 for the connection of an external head;
 - a plug D9 for RS232 interface;
 - a USB socket for internal camera;
 - a socket 36 poles for BM2001 interface;
 - a BNC for trigger input;
 - a BNC for trigger out.

Polarity of trigger out

The polarity of the trigger out (SYNC OUT) can be set as follow:

- press PREADAPT key and switch on the instrument;
- the display will request the sync polarity output;
- release PREADAPT key and press '0' for negative or '1' for positive.



FUNCTIONING OF THE INSTRUMENT

When you turn the instrument is in flash mode, to change the operating mode, press the MODE button, the set parameters are those related to the memory 1 for all modes of operation.

COMMANDS

The operating modes are selected by the MODE key and are as follows: Flash, Flash dual flash, Slow Flash and EOG.

In flash mode is possible to generate stimuli flash with or without lighting.

In the EOG the instrument is used as a light with the ability to turn on the LED mire in manual mode.

Flash – Double flash – Slow flash mode

START/STOP: This command works only on the internal trigger and has two modes of operation: in Single mode each keystroke causes the generation of a stimulus, in Repeat determines alternately the starting and stopping of the stimuli at the set frequency
N.B. In repeat mode, if it has been set to an adaptation period, the start begins the adaptation, the stimulation start automatically at the end of this period. To skip the adaptation press the enter button

TRG MODE: Select one of the following triggers for the timing of the stimulus flash:
Internal Single sets the generation of the stimulus manually.
Internal Repeat sets the internal trigger repeatedly. Only in this way has enabled the ability to set an adaptation period.
Computer select the trigger that comes from the computer connected to the external programming.
External + sets the external trigger and sync on the rising edge.
External - sets the external trigger and sync on the falling edge.

ILLUM: allows you to set the intensity of background, the unit of measurement used is Cd/m^2 ; set the value using the numeric keypad and confirm it with the ENTER/ CD/m^2 . When the adaptation time is different from zero, the request of intensity are two, the first corresponds to the intensity during the period of adaptation, the second one during stimulation. logic management background lighting of the dome BM6007 is designed to provide the correct light intensity inside the dome ganzfeld considering lighting environment; before lighting the lamp is measured intensity in the dome (the one provided by the light ambient) and generated only the amount of light needed to reach the desired intensity. If the intensity provided by the environment is higher than required, the interior lamp stays off.
N.B. the intensity of illumination is set immediately unless the adaptation time is different from zero, in which case the actual execution of the command takes place at the time of starting the stimulation.

MODE: sets the mode of operation of the stimulator, the first time that the button is pressed is indicated on the current operation mode, the pressures successive determine the variation of the mode in the following order: Flash -> Double Flash -> Slow Flash ->EOG.

OUT OFF/A/B: Select the output.

LED Off/30/45: turns on or off the led central fixation

EDIT: Allows you to insert an adaptation time before the start of stimulation; pressing the button displays the current time of adaptation; the set value must be confirmed by pressing the ENTER key. When you press START / STOP, before the start of the stimuli, the generator will begin the period of adaptation to lighting set. For the value of background lighting during this period see the command ILLUM

- ENERGY:** Allows you to set the power of the stimulus flash and / or the units' power measurement; pressing the button once displays the currently selected power, the change can be made either using the UP and DOWN, sliding all the possible values, or by entering the value directly via the numeric keypad; the set value must be confirmed by pressing the ENTER key. If a power entered via the keypad is not obtainable, the stimulator will set the one closest to the required value. Pressing the button twice to enter Setup the unit of measure of the power of the stimulus flash, continuing to press the energy, you set alternately Cd/m^2 or UL
- LED REV:** Not used.
- RECALL/STORE:** recalls or stores the parameter set. To recall a set of parameters from memory press RECALL / STORE; the instrument display will indicate at this point "Recall"; using the number keypad press the number (1 to 9) for the set of parameters required; after making the choice, the parameters will be set immediately. To store a new set instead, press the button twice RECALL / STORE; the display will show "Store"; press at this point the number (1 to 9) relative to the location of memory to use. The set of parameters stored in the memory n. 1 will be used for setting up the instrument at power up..
- FREQ:** sets the frequency of the internal trigger; pressing the button displays the currently selected frequency, the modification can be done either using the UP and DOWN, sliding all the possible values, or by entering the value directly via the numeric keypad, the value set must be confirmed by pressing the ENTER key. If a frequency entered via the keypad is not obtainable, the stimulator will set the one closest to the required value.
- COLOR:** Not used.

E.O.G. mode

- START/STOP:** Disable / enable the lighting to the value set by the command ILLUM.
- TRG MODE:** non used.
- ILLUM:** sets the intensity of the illumination of background, the unit of measurement used is Cd/m²; set the value using the numeric keypad and confirm it with the ENTER / CD / m². the intensity of illumination is set immediately, to switch off the lamp without changing the setting, press the START / STOP.
- MODE:** sets the mode of operation of the stimulator, the first time that the button is pressed is indicated on the current operation mode, the pressures successive determine the variation of the mode in the following order: Flash -> Double Flash -> Slow Flash ->EOG.
- OUT OFF/A/B:** Select the output.
- LED Off/30/45 :** sets the operation of the LEDs; the sequence is OFF-> 30-> 45-> OFF-> The first press displays the current mode.
- EDIT:** not used.
- ENERGY:** not used.
- LED REV:** Sets the period of reversal (lighting time) of the LEDs.
- RECALL/STORE:** recalls or stores the parameter set. To recall a set of parameters from memory press RECALL / STORE; the instrument display will indicate at this point "Recall"; using the number keypad press the number (1 to 9) for the set of parameters required; after making the choice, the parameters will be set immediately. To store a new set instead, press the button twice RECALL / STORE; the display will show "Store"; press at this point the number (1 to 9) relative to the location of memory to use. The set of parameters stored in the memory n. 1 will be used for setting up the instrument at power up..
- FREQ:** not used.
- COLOR:** not used.

Technical specifications

Mechanical Specifications:

Dimensions:	cm 40 x 51 x 44 (L x P x H)
Dome Diameter	40 cm
Hole Diameter	30 cm
Chin rest	vertically adjustable

Electrical Specifications:

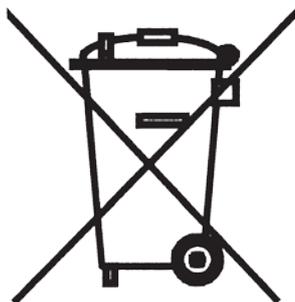
Power Supply:	85 – 264 Vac
Power Demand:	150W
Flash Lamp:	HiPower White LED
Flash Intensity:	da 0,001 a 100 Cd/m ² /sec
Flash Intensity compared to the standard I.S.C.E.V.:	from -3.5 to +1,5 U.L.
Flash Repetition Rate:	from 0.1 to 50 flash/sec., manual repetition.
Background Illumination Lamp:	HiPower White LED
Background Illumination intensity	adjustable 0-1000 Cd/m ²
EOG Sights	High efficiency LEDs placed at 0 ±30 e ±45 degree
Calibration:	All the calibrations are factory made.
Settings:	Manual through the front panel keyboard or remote by computer.
Camera	USB

Warranty

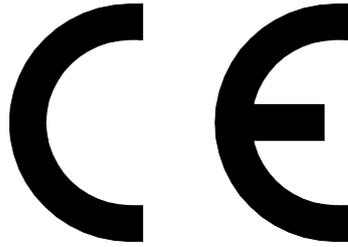
1. The Biomedica Mangoni guarantees from the date of purchase for a period of two years, that the instrument is free from defects in materials
2. The warranty applies only to defects caused by normal use and not by:
 - a. Improper maintenance
 - b. Improper use
 - c. Unauthorized modifications
3. In the event of a product defect during the warranty period, the Biomedica Mangoni, at its discretion repair or replace the product itself.
4. For shipment to the company for repair, use the original packaging; the Biomedica Mangoni not recognize the collateral damage in transit with a non-compliant packaging.
5. Instruments for repair must be sent to the following address prior permission from the staff of the company.

<p>Biomedica Mangoni Via Carducci, 13 Ghezzano – loc. La Fontina 56010 PISA - ITALY</p>
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Disposal



This symbol on the product or on its packaging indicates that this product must not be disposed of with your other household waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service.



DECLARATION OF CONFORMITY

Product name: Ganzfeld dome mod. **BM6007IL**
Manufacturer: Biomedica Mangoni S.n.c.
di Mangoni Giuliano & C.
Via Garibaldi, 179 - 56124 PISA

Name of company quality management representative: Giuliano Mangoni

Norme applicate: CEI EN 60601-1 Medical electrical equipment
Part 1: General requirements for basic safety and essential

CEI EN 60601-1-2 Medical electrical equipment:
Part 1-2: General requirements for basic safety and essential
performance - Collateral Standard: Electromagnetic disturbances -
Requirements and tests

Biomedica Mangoni s.n.c. declares that the above mentioned product meet requirements and provisions of Council directive 93/42/EEC as amended by directive 2007/47/EEC for medical devices

Pisa, 23/06/2013

Giuliano Mangoni

Management software

This software replicates the settable functions through the keyboard of the ganzfeld dome BM6007. Is used for connecting an RS232 serial port, the default port is COM1 but can be changed by editing the file "setting.txt" with a common text editor such as Windows Notepad and write the port number to use.

The modes of operation of the ganzfeld stimulator are 5:

- Flash
- EOG
- FERG (specific version only)
- Double Flash
- Slow Flash



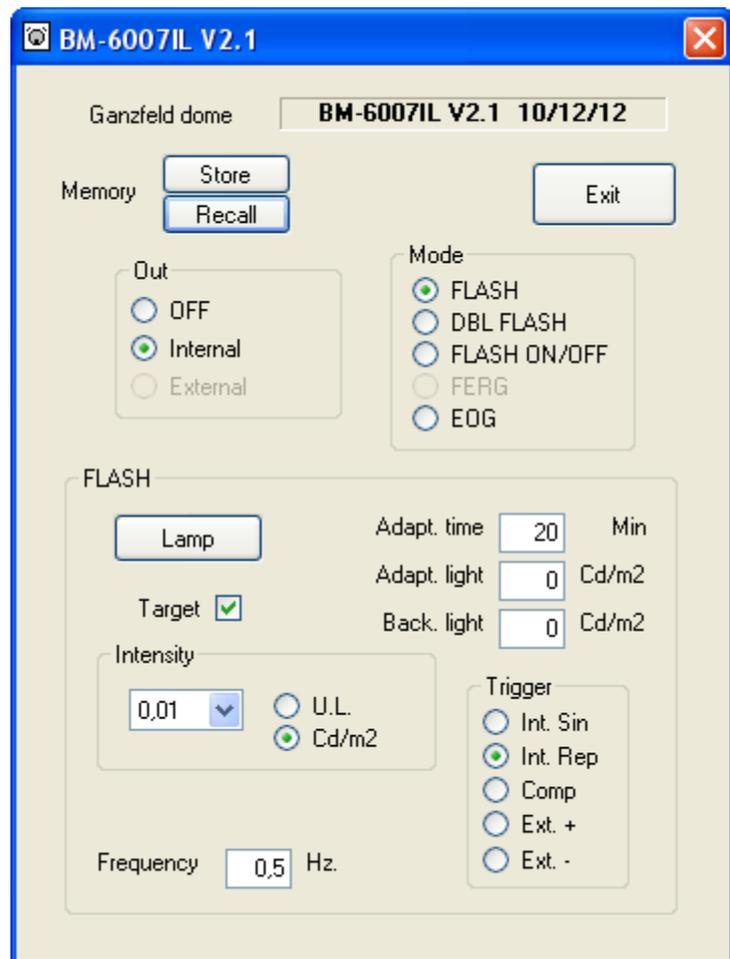
Flash / Double F. / Slow F. mode

Trigger section

- Int. Sin (Internal single) when pressing the "Lamp" button, the stimulator generates a lightning flash at the power set.
- Int. Rep (internal repetitive): the pressure of the button the stimulator starts the stimulation to the set power and frequency, or starts the adaptation if the value "Adapt. time" is not equal to 0, the stimulation is stopped at the next pressure "Lamp" button.
- Computer: The instrument accepts the trigger signal from the computer connected through the door "Master Control"
- Ext+ /Ext-: stimulator generates a lightning flash when there is respectively a front rise / fall to the signal applied to the BNC connector labeled "TRIGGER IN".

OUT section

- OFF: stop the generation of the lightning flash; (on the BNC connector marked with the SYNC OUT may be present the synchronization signal).
- Internal: enables the internal flash lamp.
- External: the stimulation is generated by the optional external flash lamp connected to the rear connector marked "Head B".



The following parameters can be set manually, once you type the value, confirm with "Enter" key on your keyboard.

- Adapt. time: adaptation time (in minutes)
- Adapt. light: backlight in adaptation (in cd/m2); enabled only if Adapt. time is different from 0
- Back. light: backlight (in cd/m2) during stimulation flash.
- Target: Switch central LED of dome
- Frequency: repetition frequency of stimulation (only on Int Rep.)

Intensity section (FLASH Mode)

- U.L. Elect.: sets the powers of the stimulus in logarithmic units.
- Cd/m2: sets the powers of the stimulus in Cd/m²



Intensity section (Double F. mode)

In this mode, the ganzfeld performs the stimulus with two consecutive flashes; the two intensities are set by selecting one of the available values from the ones presented in the drop-down boxes 1 and 2;

- Delay: Time in msec. Between the first and the second flash.
- U.L. Elect.: Sets the powers of the stimulus in logarithmic units.
- Cd/m2: Sets the power of the stimulus in Cd/m2

Intensity section (Slow F. mode)

In this mode, the flash strobe has a duration adjustable from 100 to 5000 msec.;

Flash int.: Intensity of the flash in Cd/m2.

-Duration.: Flash flash duration in msec

EOG mode**OUT section**

-OFF: stop the generation of the lightning flash; (on the BNC connector marked with the SYNC OUT may be present the synchronization signal).

-Internal: enables the internal flash lamp.

-External: the stimulation is generated by the optional external flash lamp connected to the rear connector marked "Head B".

LED section

-OFF: Turn off the LEDs

-30: enables the intermediate LEDs light

-45: enables the extremes LEDs light

The following parameters can be set manually, once you type the value, confirm with "Enter" key on your keyboard.

-Illumination: set the backlight

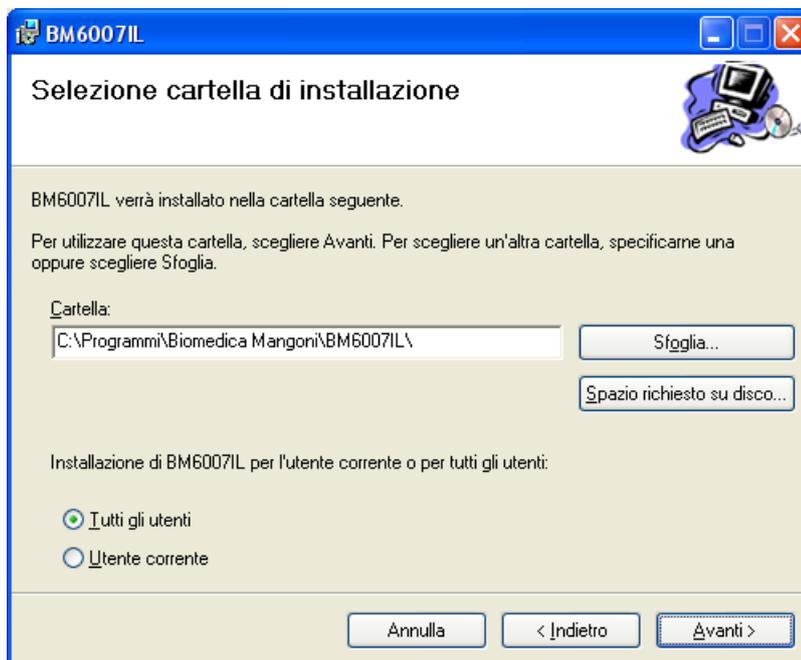
-Rev. period: sets the frequency of the LED lighting.

Storage management parameters

After pressing the Store or Recall button appears the left window; type the number of the memory location to store or recall and confirm with OK

Software installation

Run the Setup.exe found in the CD and follow the instructions.



To run the software select BM6007IL from Program menu.