

# INSTRUCTION MANUAL



# INSTRUCTION MANUAL





# Key to symbols



The instructions for use of the **Lipovisor™** are provided so that the user is in possession of all the information necessary for the safe use of the device and all its accessories; for any queries regarding the use of the instrument, safety issues, or about this or any other **Lipovisor™** documents, you can always contact the **Lipovisor™** dealer in your area or visit our website www.lipovisor.com

The information provided in this manual refers exclusively to the device to which it is attached.

It is advisable to follow carefully all instructions in the documentation supplied with the **Lipovisor™** device. Failure to understand or follow the instructions may cause:

- death or injury to the patient
- wounding of the operator
- wounding of a third party
- damage to the device or the instrumentation



This document contains useful and specific instructions for the safe and effective use of the **Lipovisor™** device Please keep the operating instructions together with the device.

The use of the Lipovisor™ medical device is dependent on a complete knowledge and awareness of the contents
of this manual; nevertheless, this manual may be PERIODICALLY UPDATED WITHOUT NOTICE. As a result it is the re sponsibility of the user to verify any updates of the user manual PRIOR TO USE, by logging on to the following website
http://www.lipovisor.com/last-issue

Lipovisor<sup>™</sup> is a unique medical device, developed and tested by a team of doctors and technicians, which highlights in an immediate and realistic manner the condition of the fat tissue of the human body. Lipovisor<sup>™</sup> performs a scan which visually highlights, with three-dimensional images, the amount of fat deposits present, before, during and after liposuction and liposculpture procedures, by means of high-definition technologies. Indeed, we know that, in cosmetic or therapeutic treatments such as liposculpture, **lipodrainage** and similar treatments for reducing and/or shaping fat tissue in the human body, the technician needs to know as accurately as possible the amount and distribution of such tissue, in order to identify which part should be removed. In similar operations it is actually essential to maintain a certain amount of fat tissue in order to reshape the silhouette of the body; while, conversely, a deficiency or an inadequate fat accumulation could cause major undulations of the skin resulting in severe imperfections, which would be unpleasant for the person undergoing the procedure. In the latter case it would be necessary to proceed to a second operation to remove excess fat, with obvious discomfort for the patient. The removal of excessive fat tissue would also cause considerable inconvenience, as it would produce permanent depressions in the skin, which are difficult to remedy in a definitive manner. Typically, in these kinds of evaluations, the technician or surgeon will rely solely on their own manual perception, which makes it difficult to determine with absolute precision the amount of fat to be removed and above all the amount not to be removed.

The **Lipovisor™** can overcome these drawbacks, making the detection of fat tissue in the human body accurate and reliable, allowing you to carry out computerized, high precision liposuction or liposculpture (HDL - High-Definition Liposuction).

# Computerized high definition liposuction

Lipovisor<sup>™</sup> is a device that makes it possible to determine exactly the amount and distribution of fat tissue or any fat formation in the human body. The device is non-invasive, and its use is simple and immediate. It allows the precise measure-

ment of the distribution and amount of fat tissue present in a given part of the human body, with high-precision images shown on the monitor.

The exclusive use of the energy signals transmitted selectively highlights the quantity of fat cells present under the skin without damaging any anatomical structure.



**NON-INVASIVE:** thanks to a non-invasive probe, when the 3L 3D-HD **Lipovisor**<sup>TM</sup> sensor comes into contact with the skin it takes measurements, showing the surgeon the real time the colour variations depending on the adipose tissue layer present in the patients' fat on a HD monitor.

**USES:** ambulatory use, in the operating room and post operative with appropriate probes and sterilised covers. It instantly and exclusively reads the various thickness measurements of the adipose tissue, processing them into realistic three-dimensional images.

**EASE OF USE FOR THE DOCTOR:** the completely intuitable, simplified icon-based interface featuring software created with guided paths, as well as acoustic and visual signals that are immediately intuitable, allow recovering precious moments and avoiding misinterpretations during the surgical intervention.

DOCUMENTED RESULTS: before, during, and post operation with the possibility of precise comparisons.

**NO SIDE EFFECTS:** the device is a non-invasive solution that is even more effective in performing highly precise liposuction procedures (HDL - High Definition Liposuction).

**ELECTRONIC MEDICAL RECORDS:** at the end of the postsurgical consultation, ask your doctor to provide you with the electronical medical record processed by **Lipovisor**<sup>TM</sup> on a USB flash drive or a CD. It will contain all the three-dimensional scans performed on the patient.

# Benefits and application of Lipovisor™

he main advantage of **Lipovisor™** is that it can perform a real-time scan of the adipose layer (fat).

The **Lipovisor™** is extremely easy to use, and allows you to visualize with great precision, on the incorporated colour monitor, the thickness of the layer of fat, type of fat present and the precise location of the fat to be removed.

In other words with the **Lipovisor**<sup>TM</sup> you can perfectly control the layer of fat tissue that is being removed before, during and after the liposuction or liposculpture procedure, allowing the surgeon to perform the procedure with much more precision and to carry out HDL (High-Definition Liposuction).

The **Lipovisor™** can be used successfully by plastic and cosmetic surgeons to perform all liposuction and liposculpture procedures to a high level of accuracy.

Indeed, liposuction should not be used just for the removal of fat, but to reshape the body according to the different directions and planes.



This is very important if you consider that the fat cells, once removed, will not form again. It is fundamental to perform a thorough pre-operative examination of each patient. The distribution of excess fat tissue will change depending on whether the patient is in a standing or lying position. This is when the surgeon's abilities and observation skills become a determining factor during the operation.

In similar operations it is actually essential to maintain a certain amount of fat tissue in order to reshape the silhouette of the body; while, conversely, a deficiency or an inadequate fat accumulation could cause major undulations of the skin resulting in severe and unpleasant imperfections.

In the latter case it would be necessary to proceed to a second operation to remove excess fat, which is undesirable for both the surgeon and the patient. The removal of excessive fat tissue would also cause considerable inconvenience, as it would produce permanent depressions in the skin which are difficult to remedy in a definitive manner.

Typically, in these kinds of evaluations, the technician or surgeon will rely solely on their own manual perception, which makes it difficult to determine with absolute precision the amount of fat to be removed and above all the amount not to be removed.

he purpose of computerized high-definition liposculpture (HDL - High-definition liposuction) is to avoid the above-mentioned drawbacks, by detecting the fat tissue before, during and after surgery.

The **Lipovisor™** makes it possible to determine exactly the amount and distribution of fat tissue or any fat formation in the human body.

Computerized high-definition liposculpting with the use of **Lipovisor™** is simple and immediate. It allows accurate measurement of the distribution of the amount of the tissue present in a given part of the body, as it provides a graphical representation of the fat tissue that is as close to reality as possible.



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Lipovisor<sup>™</sup> is a unique system, developed and tested by a team of doctors and technicians, which highlights in an immediate and realistic manner the condition of the fat tissue of the human body. Lipovisor<sup>™</sup> performs a scan, which visually highlights, with three-dimensional images, the amount of fat tissue before, during and after liposuction and liposculpture procedures, by means of high definition technologies. Indeed, we know that, in cosmetic or therapeutic treatments such as liposculpture, lipodrainage, lipofilling and similar treatments for reducing and/or shaping fat tissue in the human body, the technician needs to know as accurately as possible the amount and distribution of such tissue, in order to identify which part should be removed. In similar operations it is actually essential to maintain a certain amount of fat tissue in order to reshape the silhouette of the body; while, conversely, a deficiency or an inadequate fat accumulation could cause major undulations of the skin resulting in severe and unpleasant imperfections. In the latter case it would be necessary to proceed to a second operation to remove excess fat, with obvious discomfort for the patient. The removal of excessive fat tissue would also cause considerable inconvenience, as it would produce permanent depressions in the skin which are difficult to remedy in a definitive manner. Typically, in these kinds of evaluations, the technician or surgeon will rely solely on their own manual perception, which makes it difficult to determine with absolute precision the amount of fat to be transferred to the patient. With **Lipovisor™** it is possible to overcome these drawbacks, making the detection of fat tissue in the human body accurate and reliable, allowing you to carry out computerized, high-precision lipofilling or liposculpture (HDL - High-definition liposuction).

# Computerized high definition lipofilling

Lipovisor<sup>™</sup> is a device that can be used to determine exactly the amount and distribution of any fat tissue or fat formation in the human body. The device is non-invasive, and its use is simple and immediate. It allows the precise measurement of the distribution and amount of fat tissue present in a given part

of the human body, with high-precision images shown on the monitor.

The exclusive use of the energy signals transmitted selectively highlights the amount of fat cells present under the skin without damaging any anatomical structure.



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**PAINLESS**: thanks to an ultra-sensitive probe that simply comes into contact with the skin and sends the values to the computer, thereby highlighting the fat layer.

**USE**: Can be used in an outpatient setting or in the operating room, with sterilized, disposable probes. It instantly and exclusively reads the various measurements of the thickness of fat tissue, which are then displayed as realistic three-dimensional images.

**EASY TO USE FOR THE DOCTOR:** This technique allows you to accurately read the amount of fat to be transferred during the lipofilling procedure, eliminating unsightly postoperative outcomes.

**COMPACT AND EASY TO HANDLE**: thanks to its small size, ergonomic handle and flexible cables, it is simple to use and easy to manoeuvre. There are two different sized probes for large and small fat deposits.

**DOCUMENTED RESULTS**: before and after the operation, the results can be compared accurately.

**NO SIDE EFFECTS**: the device is non-invasive, and is the most effective solution for a high-precision liposculpture procedure.



# Benefits and application of Lipovisor™

The main advantage of **Lipovisor**<sup>TM</sup> is that it can perform a real-time scan of the adipose layer (fat).

The **Lipovisor™** is extremely easy to use, and allows you to visualize with great precision, on your own colour monitor, the thickness of the layer of fat, the type of fat present and the precise location of the fat to be removed during the lipofilling procedure.

In other words with **Lipovisor™** you can control perfectly the layer of fat tissue that is being transferred before, during and after the lipofilling procedure, allowing the surgeon to perform the procedure with much more precision and to carry out HDL lipofilling (High-definition liposuction).

The **Lipovisor™** can be used successfully by plastic and cosmetic surgeons to perform all lipofilling, liposuction and liposculpture procedures to a high level of accuracy.

Indeed, liposuction should not be used just for the removal of fat, but to reshape the body according to the different directions and planes.



This is very important if you consider that the fat cells, once removed, will not form again. It is fundamental to perform a thorough pre-operative exam of each patient. The distribution of excess fat tissue will change depending on whether the patient is in a standing or lying position. This is when the surgeon's abilities and observation skills become a determining factor during the operation.

In similar operations it is actually essential to maintain a certain amount of fat tissue in order to reshape the silhouette of the body; while, conversely, a deficiency or an inadequate fat accumulation could cause major undulations of the skin resulting in severe and unpleasant imperfections.

In the latter case it would be necessary to proceed to a second operation to remove excess fat or transfer it, which is undesirable for both the surgeon and the patient. The addition of excessive fat tissue would also cause considerable inconvenience, as it would produce permanent depressions in the skin which are difficult to remedy in a definitive manner. Typically, in these kinds of evaluations, the technician or surgeon will rely solely on their own manual perception, which makes it difficult to determine with absolute precision the amount of fat to be transferred to the patient. The purpose of computerized high-definition liposculpture **(HDL - High-definition liposuction)** is to overcome the above-mentioned drawbacks, by detecting the fat tissue before, during and after surgery.

The **Lipovisor™** makes it possible to determine exactly the amount and distribution of fat tissue or any fat formation in the human body.

Computerized high-definition lipofilling with the use of **Lipovisor™** is simple and immediate. It allows the distribution and quantity of the fat tissue to be transferred to a given part of the body to be measured accurately, and then provides a graphical representation, accompanied by images, of the fat tissue that is as close to reality as possible.



# Benefits of Lipofiling and application of Lipovisor<sup>™</sup> ...

There are numerous known advantages in using lipofilling compared to the use of other materials for increasing and re-shaping body volumes:

- Body re-shaping: a single intervention combines liposuction and an increase in volume.
- More natural than implants or artificial fillers
- Minor invasiveness: the only incisions necessary are those used to introduce the suction and re-injection tubes.
- No rejection: the fat is autologous, i.e. it comes from the same patient.
- Less re-absorption over time compared to artificial fillers (hyaluronic acid)

A system for processing fat tissue to obtain regenerative cells and stem cells is feasible in the sterile environment of the operating room and during the procedure itself in a day-hospital. Fat removed from the patient is then enriched with stem cells extracted from the fat.

Several studies have confirmed that the higher concentration of regenerative stem cells aids in fat tissue grafting. Reduced volume, asymmetry and tube-shaped breasts are the classic reasons for using this technique associated with **Lipovisor**<sup>TM</sup>.

# Benefits of Lipofiling and application of Lipovisor™

Breast augmentation using regenerative cells derived from fat tissue involves the removal of the fat tissue on a medium to large scale depending on the case. So there are in fact two combined procedures, and generally, liposuction involves the hip, abdomen, trochanter, thigh and knee areas. The patient, then, will benefit from a re-shaping of both the breast and body.

With **Lipovisor™**, once the fat has been removed, it is treated to remove excess fluid and loaded into 1cc syringes, then injected bilaterally using very fine needles, above and below the mammary gland.

This process can be repeated until the desired correction has been achieved. In this way the dual effect is a reduction of excess fat in certain areas, and an increase in the volume of the breast at the same time. There will be no scarring to the breast as the needles used do not leave any marks.

The fat tissue is a potential reserve supply of adult stem cells similar to those derived from bone marrow. However, fat tissue has several advantages over bone marrow.



Lipovisor<sup>™</sup> is fully motorized; the monitor is opened by placing the hands on the sides of the Lipovisor<sup>™</sup> device.

In the operating room the plastic surgeon uses the appropriate buttons on the handle of the sensor to move the monitor around the patient as necessary, in order to carry out the procedure.

Using the motorized **Lipovisor™** the surgeon can position the medical device monitor so that it is best visible to him, without the need for another operator.

The technologies used in the **Lipovisor™** are the most advanced, and are the result of over 10 years of study. Indeed, in order to help the operator and reduce the time spent in the clinic and in the operating room, we have created a completely intuitive medical device. The selection sequence is guided step by step; at every section only the permitted function is seen as active.

The **Lipovisor™** is the superb result of tests carried out by a team of doctors and technicians.



Installed in the operating room, **Lipovisor™** is an innovative device, the result of over 10 years of studies, tests and trials carried by a team of doctors and technicians.

In the operating room, the fixed **Lipovisor**<sup>TM</sup> is integrated with the operating room lighting system. The motorised mechanisms and the sensors allow the operator to safely move the arm of the **Lipovisor**<sup>TM</sup> monitor into the best visible position for the operator, in order to perform surgery on the patient.

The infrared lights on the arm of the fixed **Lipovisor™** automatically identify the area on the patient where the work is taking place. With this innovative solution, the surgeon, using the appropriate left and right buttons on the handle of the area scanning sensor, moves the lighting arm, and the **Lipovisor™** monitor is automatically placed in the best visible position for the surgeon. The monitor, unlike the one installed on the surgeon's personal **Lipovisor™**, measures 16-9 and 32 inches.

The fixed in-clinic **Lipovisor™** is equipped with a touch-screen console which controls all operating functions.

**Button** - an actionable area of the screen (typically a marked icon so as to appear "clickable" or "actionable" by the user in some way).

Symbol - a pictogram that recalls a concept or a specific object.

**Clickable symbol** - a symbol that can be "enabled" by the video. It actually acts as a button, the difference being in that it is rarely used in the common workflow. For example to go to the edit page of the surgeon data or if you are in the 'women patients' section and you want to remove the filter "women" to return to the patients register.

**Pdf, Portable Document Format** - the portable document format, commonly known as PDF, is a file format suitable for representing documents in a manner independent of the hardware and software used to generate or view them. To view and print PDF documents, a suitable programme, such as Adobe Reader installed on your computer, must be used. Transponder - an electronic device that contains data and information. The data transmission technology used can be either RFID or NFC.

Home page - a screen of the Lipovisor<sup>™</sup> that is shown after the user authentication procedures (fingerprint and password). The home page in the Lipovisor Master is the patient register while in Lipovisor Surgery it is the "transponder page". Wi-Fi or Wi-Fi network - indicates a technology and related devices that allow the Lipovisor<sup>™</sup> (and other devices that use such technology) to connect to the corporate network, which in turn can be connected to the Internet. With the system's Wi-Fi, Lipovisor<sup>™</sup> can use the services provided by the in-house internal network as well as the Internet.

# Key to symbols and buttons



### **POWER OFF**

To turn off the Lipovisor or go back to the home page as required



# START LIPOVISOR

To start up the device



## SAVE

To save the current data and return to the previous level

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## REGISTER

Personal data input - name, surname, social security number, patient's contact details, date and place of birth, address, weight, height and gender.

Any other email communications.

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# Key to symbols and buttons



## **BLUE INDICATOR**

The area of the display at the centre of video screen, which shows different information relating to the context of use, such as a 3D model of the patient, area to be scanned, free measurement and surgery measurement.



# GREEN INDICATOR

like the blue indicator, the colour green indicates a positive situation



## RED INDICATOR

like the blue indicator, the colour red indicates a negative situation or a situation requiring attention



## CIRCULAR INDICATOR

fat thickness indicator using coloured sectors and a central number

# Key to symbols and buttons



## **GREEN FINGERPRINT**

icon indicating that the fingerprint scan has been successful



## **RED FINGERPRINT**

icon indicating that the fingerprint scan has not been successful



## PARTIAL BODY 3L

3D image of the patient, with detail of the area to be scanned.

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**Il Lipo**visor



### PARTIAL BODY SELECT

3D image of the patient, with detail of the area that has been scanned, which shows different colour shades identifying different thicknesses of fat.



## PARTIAL BODY 3L

3D image of the patient with a zoom function that can capture the whole length of the patient, down to the specific area to be scanned.



# WI-FI

A screen for the Wi-Fi connection, e.g. when choosing Wi-Fi, entering the password or when the system communicates messages about the connection.

# Key to symbols and buttons



### NFC, NEAR FIELD COMMUNICATION

this indicates the data transfer to and from the NFC transponder



button to activate lipo-scanning of the patient



## PATIENTS REGISTER

button to access the patient register, where you can select which patient to operate on.



**3S BUTTON** enables 3S scanning of the patient.



# NEW BUTTON

to enter details of a new patient



## MAN ICON

tells the Lipovisor display toshow only the male patients. This is the first step in finding the patient on which the surgeon will operate.



## WOMAN ICON

indicates that patients selected are filtered by female gender in the patient register; this is displayed when the Lipovisor is in the register mode of an individual patient

It can be used to activate the "free measurement" function



## FREE MEASUREMENT

can be used to activate the "free measurement" function

# Key of symbols and buttons



### PRINT

this button can be pressed to produce the document corresponding to the current operation. Although a printer is shown on the button, there is no printer connected to the Lipovisor and the document is produced in the form of a PDF document that is sent via email or transferred by the transponder.



#### CONFIRM

this button can be used to confirm the current operation. When the Confirm butt is pressed, the Lipovisor continues with the current operation.



### ACCEPT

this button can be pressed when the Lipovisor communicates an informational message to the user, and the surgeon presses the button to notify the Lipovisor that he has read and accepted the message



### SELECT

this button can be pressed when there are several choices (for example the list of areas to be operated on), and the surgeon has selected the one on which he intends to operate; he then presses the select button to continue.

# ....

# Key of symbols and buttons



### TRANSFER

this button can be pressed to activate the data transfer function to the transponder. In general, this button activates a subsequent screen in which you are asked to move the transponder near to the Lipovisor, where the transponder reader is located.



### TRY AGAIN GREEN

this button can be pressed to repeat the last operation, or in any case the current operation. Green indicates that the operation has been successful, and although there are no errors in the workflow that prevent the current sequence from being executed, the surgeon may repeat it if he so wishes. For example, this button can be pressed after the surgeon has performed a 3D scan which was successful

but he intends to repeat it with better or different lighting conditions.



### TRY AGAIN RED

this button can be pressed to repeat the last operation or the current operation. Red indicates that there is one or more errors in the workflow that do not allow the current sequence to continue being executed; the operation has not been successful and it is necessary for the surgeon to repeat it. For example: The surgeon has performed a lipo-scan but for some reason it is not successful. The surgeon has entered an incorrect password and the operation must be repeated.

# Key of symbols and buttons



### SCANNER START POINTER

on the 3D model of the patient, this indicates the point at which the surgeon positions the Lipovisor sensor and begins lipo-scanning.



### CONTROL BALL

a ball-type button, which can be dragged in order to rotate the model or models that are displayed. The surgeon operates the control ball by sliding his finger on it in different directions.



## SURGERY ICON

this indicates that we are operating in surgery mode. In some special conditions this may be pressed to return to the previous level.



## "SURGEON" ICON/BUTTON

indicates that the operation displayed relates to the surgeon; for example, surgeon's data are being entered or one of the surgeon's parameters are being configured.



# Safeguarding the plastic surgeon

It is well known that liposuction, the re-shaping of a patient's body, is an extremely complex surgical procedure due to the absence of references on how much fat tissue is to be removed from the patient.

With the **Lipovisor™** we give the plastic surgeon an extremely precise tool for checking the thickness of the fat tissue.

This innovative technique for measuring fat tissue prevents the plastic surgeon from creating dips, depressions and unsightly blemishes that are visible only after surgery.

The aim of computerized high-definition liposculpture (HDL - High-definition liposuction) has the sole objective of safeguarding the surgeon's work and giving patients the best that cosmetic surgery technology can offer.

Indeed, the functions of the **Lipovisor™** include a series of printing sequences of documents for each process of acquisition of the areas and for all meetings with the patient.

The purpose of printing documents is merely to safeguard the surgeon, and for this reason, at the end of every stage, the Lipovisor<sup>™</sup> processes a PDF form to be attached to the patient's medical records.


#### Surgery

It is well known that liposuction, the re-shaping of a patient's body, is an extremely complex surgical procedure due to the absence of references on how much fat tissue is to be removed from the patient.

With the Lipovisor<sup>TM</sup> we give the plastic surgeon an extremely precise tool for checking the thickness of the fat tissue.

This innovative technique for measuring fat tissue prevents the plastic surgeon from creating dips, depressions and unsightly blemishes that are visible only after surgery.

Computerized high-definition liposculpture (HDL - High-definition liposuction) has the sole objective of safeguarding the surgeon's work and giving patients the best that cosmetic surgery technology can offer.

Note: At the end of the procedure in the operating room, with the transfer folder of the patient, the surgeon presses the Print button to activate the built-in Lipovisor™ Wi.fi and send an email to the email client of the surgeon, and the clinic.

**Note:** After the email has been sent to the patient's email client either the clinic or the doctor can print the attachment from the folder, which shows all the data relating to the visit to the clinic, the pre-operation appointment and the surgery itself. The document contains sensitive data relating to the patient, the privacy form, the surgeon's data, patient demographics, and the list of pathologies.

**Note:** The printed PDF is marked **Lipovisor™** with a machine code provided by the manufacturer when the license is activated.

t power up and after the surgeon has been identified, the device will display all available Wi-Fi networks. The surgeon chooses a network and enters the password.

After connecting to the Wi-Fi, the password is stored and will not be requested again in the future.

- Choose one of the active networks
- Type in your password in the box

**Note:** Each time the **Lipovisor™** is switched on, all active Wi-Fi networks are displayed. The device will use the network that is present in the database.



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# Entering the Wi-Fi key

After selecting the Wi-fi connection, enter the Wi-Fi access Key.



# Description ot the WI-FI

**Lipovisor™** is equipped with an integrated Wi-Fi system.

This indicates a technology and related devices that allow the **Lipovisor™** (and other devices using this technology) to connect to the corporate network, which in turn can be connected to the Internet.

With the system's Wi-Fi connection, this can use the services provided by the company's internal network as well as the Internet.



#### Remote support for Lipovisor™

For any problems you may experience with Lipovisor<sup>™</sup>, we have set up a Call Centre which is at your disposal 24 hours a day to resolve any faults that the Lipovisor<sup>™</sup> medical device may encounter. Thanks to the innovative technologies installed in the Lipovisor<sup>™</sup>, we can remotely perform a complete check of the medical device and sensors. In case of failure, the operator should contact the Call Centre and provide the serial number of the medical device. Our technician remotely checks the Lipovisor<sup>™</sup> technical page for any problems, and provides the surgeon with the support necessary to resolve the issue. There is also a phone number in international format (e.g. 0039 0971 650474) to enable communication in case the freephone number cannot be reached by the telephone server. The technician may ask for additional information in order to provide full assistance.



#### Lipovisor<sup>™</sup> technical page



### Lipovisor<sup>™</sup> assistance check

The **Lipovisor™** is equipped with an integrated complete checking system. With this innovative system we offer our customers an excellent service. Our medical equipment is timed. At the end of the period set by the manufacturer, the **Lipovisor™** requires the operator to connect the medical device to an Ethernet connection to ensure continued operation.

The manufacturer can check the device and inform the customer of any anomalies in the functioning of the Lipovisor™.





Pagina check			
45° Sensor Min 45 ° Sensor Max	attora finestra Check 45	Calibration	
90 * Sensor Min 90° Sensor Max	Check 90	Reset Calibrate	
Last measure 1,2	Free Measure		
System Message	- A-		
> Startup sequence ok			
ull Lipovisor			

# Lipovisor optional extras



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Remodelled expanded foam, colour chosen from RAL chart

Leather cover according to customer's choice





45° sensor

...lipovisor

**4** USB Transponder / Wireless Key





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# Size Lipovisor™ ••••



# Description of Lipovisor™

1 Power key on / off

#### 2 Socket 220V





**5** Blue flashing LED



### Sequences for switching on the Lipovisor™

- Plug the power cord into the 220V, 230V or 110V power connector, depending on the country of use.
- Turn on the Lipovisor<sup>™</sup> with the Lipovisor<sup>™</sup> Power On/Off button 1, then wait a few seconds.
- Place hands on both sides of the medical device for 30-40 seconds.
- The **Lipovisor™** monitor will open automatically.
- The LED light in the Lipovisor<sup>™</sup> logo indicates the opening of the motorized monitor.



# Description of Lipovisor™

**5** Lipovisor illuminated logo to the left



- **7** 17" HD Monitor
- 8 Motorisation



# Description of the Lipovisor™ **...**

9 Motorized connector





## Description of the Lipovisor™

Inserting the electrical connector

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With the fingerprint reader, the surgeon has access to the patients' folder. When entering his data in the **Lipovisor™** medical device, the surgeon is required to enter his fingerprints.

### Operating sequences of the Lipovisor™

With the opening of the engine monitor **Lipovisor™** automatically opens the connector cable port where to insert the female connector on the detector adipose tissues.

The plastic surgeon with this sequence can begin to use the medical equipment.

Female connector on the machine
Male connector on the sensor cable
otorized slot on the machine





Note: All connectors are Fischer, CE Certified to ISO13485 - for medical use.

The coupling of the connectors is labelled with a red dot that identifies the correct position to insert the connector. Incorrect insertion may result in breakage of contacts.

# Description of Lipovisor<sup>™</sup> sensor



- 17 45° Sensor
- 18 Sensor on/off button
- 19 Motorization command key, right side
- 20 Button command engine Left



The **Lipovisor™** is equipped with two sensors which are automatically recognized by the medical device depending on the selected area to be suctioned during surgery.

90° sensor. The 90° sensor is used for the following areas of surgery:

Upper abdomen, lower abdomen, lower back, neck, right arm, left arm, right ankle, left ankle, right outer thigh, left outer thigh, right saddle bag, left saddle bag, right hip, left hip, back of right knee, back of left knee, right calf, left calf, right inner thigh, left inner thigh, inner right knee, inner left knee, breast and other areas identified by the surgeon.

**45° sensor**. The 90° sensor is used for the following areas of surgery: upper right breast, upper left breast, neck, inner right arm and inner left arm.

Note: The sensor can be enabled at any time.

**Note:** The sensor carries out an automatic check when it is initialized by holding the sensor **start** button down. After the beep the sensor will be enabled.

**Note:** During the surgical procedure involving lipofilling of fat into the breasts, the surgeon can make use of both of the sensors supplied with the **Lipovisor™** without any limitation to the predefined area.

# Protections sterile on Lipovisor™

• Place the appropriate covers sterile monitors Lipovisor™



# Sterile protectors for the Lipovisor<sup>™</sup> sensor

• Place the appropriate sterile covers on the monitor of the Lipovisor™



### Lipovisor<sup>™</sup> shutdown

The **Lipovisor™** can be shut down in the following operating situations:

- Configuration error
- Password or fingerprint error
- Register menu
- Lipovisor<sup>™</sup> Master Home page
- Lipovisor<sup>™</sup> Clinic Home page

#### SHUTDOWN SEQUENCE

- Press the **shutdown** button on the Lipovisor monitor.
- Wait for the software to shut down.
- Place both hands on the sides of the device for 30-40 seconds.





1 ON / OFF power button

- **2** Blue flashing light
  - At the end of the automatic shutdown of the monitor, pull out the power cord.

Important notice: the lid of the Lipovisor<sup>™</sup> must not be forced: please wait for it to close automatically.



# Installing Lipovisor<sup>™</sup> sensor in outpatient Pre surgery, Surgery and Post surgery

- Plug the power cord into the appropriate slot on the Lipovisor<sup>™</sup>.
- The left and right buttons activate the motor to rotate the **Lipovisor™**.
- Press the **start** button on the sensor and hold down for a few seconds.
- Wait for the sound signalling that the sensor has been initialised.
- The sensor automatically carries out a check.

**Note:** At each outpatient session for Pre-surgery, surgery and post-surgery, the sensor check activates when the sensor connector is connected to the **Lipovisor™** and the initialization button is pressed.

The purpose of the sensor check is to ascertain that the sensor itself is operating properly, and that the correct sensor is being used for the part which will be operated on.

The system also determines certain parameters associated with the skin and fat of the patient, which are briefly identified as **High-Resolution mode**, **Medium-Resolution mode** and **Low-Resolution mode**.

In the event of a malfunction of the sensor, the **Error 01** message is displayed and the surgeon can either press the button **Please try again**, which allows him to perform a further check of the sensor, or the **SOS mode** button, which allows him to use the other sensor in place of the faulty one.

### Description Sensor Lipovisor<sup>™</sup>



**Note:** When scanning the breast during the preoperative consultation, the surgeon can use all available sensors supplied with the **Lipovisor™** with no limitation on the predefined area.

2

### Check SOS mode - Bring the sensor in contact with the skin .

The **sensor check** is carried out in each session in which it is necessary to perform Lipo measurement. At each outpatient pre-surgery, surgery and post-surgery consultation, the sensor is checked when the connector is linked up to the Lipovisor and the initialization button is pressed.

The purpose of the sensor check is to ascertain that the sensor itself is operating properly, and that the correct sensor is being used for the part which will be operated on.

The system also determines certain parameters associated with the skin and fat of the patient, defined briefly as **high-resolution mode**, **medium-resolution mode** and **low-resolution mode**.

In the event of a malfunction of the sensor, the **Error 01** message is displayed and the surgeon can either press the button **Please try again**, which allows him to perform a further check of the sensor, or the **SOS mode** button, which allows him to use the other sensor in place of the faulty one.

If the problem persists, call the **Lipovisor™** technical service.

Lipovisor<sup>™</sup> asks the surgeon to move the sensor near to the fat tissue.



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#### Check SOS mode - Do not move the sensor

**Lipovisor™** asks the surgeon not to move the sensor during calibration.



# Check SOS mode - High resolution

Lipovisor<sup>™</sup> an use the High-Resolution parameter.



#### Check SOS mode - Medium resolution

Lipovisor<sup>™</sup> can use the **Medium-Resolution** parameter.



#### Check SOS mode - Low Resolution

**Lipovisor™** can use the **Low-Resolution** parameter.



#### Activation of the SOS mode

Activation of the SOS Mode



# Description of Lipovisor<sup>™</sup> 3D Boby scanner

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1 Power On/Off

#### 3D scanner capture camera

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3 Marker supplied

The **Lipovisor™** features a 3D body scanner, which can be operated as follows:

- Turn on the 3D body scanner.
- Press the capture button on the 3D scanner.
- Scan the patient with the 3D scanner.
- Upon completion of the capture, press the button on the Lipovisor™. Capture from 3D Body Scanner.
- After about 30 seconds the patient 3D image will be displayed on the Lipovisor monitor.
- Press the Save Data button on the Lipovisor<sup>™</sup> monitor to confirm.
- Remove capture from the **Lipovisor™**.

**Note**: During the pre-op, the plastic surgeon will draw on the patient the areas to be aspirated or remodelled in the operating room, using the special marker supplied with the **Lipovisor™**.

**Important**. Draw only the outer contour of the area on the patient with the special marker supplied with the **Lipovisor™**. All marks other than the outer contour of the area should be shown using a different marker.



#### Installing the Lipovisor<sup>™</sup> license

The license is pre-installed by the manufacturer using the data provided when the purchase contract for the **Lipovisor™** medical device was signed.

- The surgeon places his hands on the sides of the Lipovisor™.
- Wait until you see the flashing blue lights on the cover of the Lipovisor™.
- Remove hands from the **Lipovisor™**.
- Wait for the motorized opening of the Lipovisor<sup>™</sup> monitor.
- Wait for the software to load.
- Fill in the license activation form.
When the device is switched on, the software is loaded and the boot screen appears (i.e. the **Lipovisor™** logo), operated in "pulse" mode, that graphically displays the progress of the start-up process. The pulse animation ends when the start-up process is complete. During start-up the **Lipovisor™** performs the main system auto-tests, and when these are completed,

it is ready to work.

If the system experiences a fault that potentially prevents operations from continuing, this will be indicated by the device, and in some situations, will prevent the equipment from operating, making it necessary to contact the customer service centre (see Assistance page).

In general, when the **Lipovisor**<sup>TM</sup> has successfully completed the start-up sequence, i.e. the error reporting step, it will be able to operate properly and continuously.



After the system start-up, the surgeon can perform the initial configuration, completing the fingerprint procedure and entering the password and personal data. After completing this procedure, the **Lipovisor™** will be ready for use by the registered surgeon. The first configuration is performed only once at the first start-up, immediately after the purchase of **Lipovisor™**. After the system has been configured, it will no longer be necessary to enter the surgeon's data when the device starts up; the system will be ready to operate straight away.

The first **Lipovisor™** configuration consists of three steps:

- Entering fingerprint
- Entering password
- Entering personal data

When the surgeon has correctly completed all three of these steps, the **Lipovisor**<sup>TM</sup> will be ready to operate. If even one of these three operations is halted or generates an error, the **Lipovisor**<sup>TM</sup> will remain in "first configuration" mode, meaning that it will not save any of the data entered, and the first configuration will need to be repeated at the next start-up.

**Note.** The **Lipovisor™** will not work if the first configuration is not carried out correctly. In case of any problems, contact the manufacturer or the customer service centre.

**Note.** The surgeon is required to enter the data relating to him correctly. If any of the information is incorrect, you will need to contact the manufacturer and/or the customer service centre.

#### First configuration /Entering the surgeon's fingerprint ....

On the first configuration, the surgeon is required to acquire his fingerprint for future identification and authorisation of access to his patients' personal details.

The system requests the surgeon to place his thumb on the sensor (the right thumb is the surgeon is right-handed or the left thumb if he is left-handed).

The surgeon places his thumb on the sensor and the system takes an initial capture of the fingerprint, immediately followed by a second for comparison. If the two captures, carried out in rapid succession, prove to be a match, the fingerprint is stored in the **Lipovisor™** and will be used to grant access to the system. Where the fingerprint capture is not successful

(no match) the error message **fingerprint setting error** will be displayed, and the operation must be repeated.



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The Fingerprint Error page is shown when, on the first configuration of the **Lipovisor™**, the fingerprint has not been captured correctly.

The capture of the fingerprint may fail due to any of the following reasons:



- The user moves his finger during the capture.
- The finger is not in contact with the sensor surface.
- The user is wearing gloves during the capture
- The sensor surface is not perfectly clean.
- There is an object on the sensor that is positioned in between the sensor and the finger (e.g. a layer of plastic, albeit transparent, or a sheet of paper).

When the fingerprint capture fails and the **Fingerprint Error** page is displayed, the user has two possible choices:

- Turn off the device
- Contact the customer service centre (especially if the problem persists).

### First configuration / Entering the surgeon's password **...**

On the first configuration, after the surgeon's fingerprint has been successfully captured, the surgeon is required to enter a password.

The password must have certain strength characteristics, which the **Lipovisor™** itself will indicate as the password is typed in.

For example, a strong password must contain:

- contain both upper and lower case letters
- contain digits
- contain signs of punctuation
- not contain commonly used words
- contain at least 8 characters

Note that, for security reasons, only dots or asterisks appear instead of the characters while the password is being entered. Great care must be taken when entering the password.



## Entering the password

Type in your password.



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If the password is entered incorrectly on 5 failed attempts, the **Lipovisor™** displays the **password setting error** message and prompts the user to contact the **Lipovisor™** customer service centre.



A 'surgeon' icon is displayed in the bottom right-hand corner of the screen to indicate that the entry of surgeon's details is in progress.

Another icon will be displayed to indicate when patient's details are being entered.

NOME	COGNOME	
CODICE FISCALE	DATA DI NASCITA	LUOGO DI NASCITA
PESO	ALTEZZA	SESSO
DOMICILIO		
INDIRIZZO LAVORO		
E-MAIL	TELEFONO RETE FISSA	
<b>.⊪Lipo</b> visor™	TELEFONO CELLULARE	$\odot$

The personal information entered by the surgeon must match the information given when the **Lipovisor**<sup>TM</sup> was purchased. Please note that the **Lipovisor**<sup>TM</sup> is configured to take into account the specificities of the country of use as well as those of the surgeon operating the device, which means that the **Lipovisor**<sup>TM</sup> must be used exclusively by the buyer.

By way of an example, just think of the possibility that the surgeon can be left or right-handed, or the different voltage rating depending on the country in which the device is used.

Compliance with these requirements is mandatory.





## Activate the system

The system is ready to use - there is no need to log in again. The Home Page will be displayed.



#### Daily use of the Lipovisor™

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Each time the Lipovisor<sup>™</sup> is switched on after the first configuration, the user's fingerprint and password will be requested.

#### **Fingerprint recognition**

When the fingerprint request is displayed, the surgeon shall place his finger on the appropriate sensor. The fingerprint is compared with the print set on the first configuration, and if the two fingerprints match, the surgeon will be prompted to enter his password.

In the event that the surgeon's fingerprint does not match the one set on the first configuration, contact the manufacturer and/or the customer service centre.



After the fingerprint has successfully been recognised, the surgeon is required to enter his password. Asterisks are displayed when the password is typed in, to prevent anyone who may be nearby from reading it.

If the password is entered incorrectly, an error message will be displayed and the system allows the user to try again up to a



limit of 10 failed logging attempts, after which the system must be switched off.

**Note:** If the surgeon forgets his password, contact the manufacturer and/or the customer service centre.

## Ok - Access to system allowed

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When the surgeon has been properly identified by his fingerprint and correct password, the system will be ready for use.



The **fingerprint error** message is displayed whenever there is an error in the capture of the fingerprint. If you enter a password that does not match that entered, the **password error** page is displayed.



If you enter an incorrect password, you can press the **try again** button and type in the password again.

After 5 consecutive errors the only option will be to press the power button to turn off the system.

#### Lipovisor<sup>™</sup> Master Home page

In **Lipovisor™ Master** the **Lipovisor™** Home Page appears after completion of the authentication process by the surgeon (fingerprint and password).

On the Master Home Page the surgeon can perform a series of operations:

- turn off the **Lipovisor™** by pressing the power button;
- carry out a Free Measurement by pressing the appropriate button;
- Access the **Surgery** mode by pressing the **Surgery** button.
- Access the patients register by pressing the Patients **Register** button.

The buttons can be activated by dragging them onto the large symbol to the initial letter of the word "activation" in almost every language in the world (activation in English and French, etc.), as well as being the logo of the **Lipovisor™** manufacturer. The process of dragging, rather than simply pressing the button, prevents accidental activation, and is a guarantee that the surgeon wishes to willingly carry out the operation.



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The Patients Register page can be accessed from the **Lipovisor™ Master** Home Page, by pressing the appropriate button. The Patient Register page allows the following operations:

• Return to the Home Page using the **Home** button marked with the letter 🥃



- Add a new patient (**new button**)
- Search for a female patient (woman button)
- Search for a male patient (man button)

#### Adding a new patient

• The surgeon accesses the page after pressing the **New** button from the **Patient Register** page.

• Enters all the data of the patient concerned and presses the **Print** button.

## Adding a new patient

Access the page after pressing the **New** button from the Patient Register page. Enter all of the following patient data:

- name
- surname
- address
- tax code
- postcode/ZIP code
- city
- country
- landline phone number
- mobile phone number
- email address



#### Entering patient pathologies

After entering the patient's personal details, the clinical data can be entered. **Lipovisor™** shows a list of pathologies, and the surgeon selects those relating to the patient, and confirms them by pressing the **Confirm** button.

	DATI PAZIENTE
Furnatore	A
Gravidanze	
Aborti	
Obesità	
Alcolismo	
Protersdi Dentali	
Problemi Personali Anestesie	
Problemi Familiari Anestesie	
Malattle Respiratorie	
Respirazione	
Malattie Vascolari	
Malattie Croniche	· · · · · · · · · · · · · · · · · · ·
<b>.⊪lipo</b> visor™	

# Entering clinical data

The surgeon can either select the clinic where the patient will be operated on, by choosing it from the list of clinics that he has created, or enter a new clinic.

	DATI PAZIENTE ELENCO CLINICHE
Centro "Lazzaro Spallanzani"	1
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<b>.11 Lipo</b> visor	

The **Print** button can be used to produce the document containing patient data, privacy data and the release form. The pdf file containing the data can be emailed or placed on the **Lipovisor™ key** to be printed at a later time from a computer connected to the printer. The computer must be equipped with software that can read pdf documents, such as Adobe Reader.

Regardless of the manner in which they were sent and printed, these documents must be signed by the patient. This is a mandatory step in order to continue. The **Lipovisor™** is very much geared towards safeguarding the surgeon and the clinic, and prevents the user from continuing if there is the risk that even a small formality may be overlooked, such as the patient's signature.

To ensure that the surgeon has printed the document, there is a key phrase next to the space reserved for the patient's signature, which must be typed into the Lipovisor in order to continue the operation flow for the that patient. The **Lipovisor™** will not continue with the operations of those patients who have not signed the documents, or where the **verification** key phrase has not been entered. During the outpatient appointment, the operator presses the **Print** button to produce the documents to be signed by the patient. To inform the **Lipovisor™** that the patient has signed the documentation, the surgeon enters a key-phrase on-screen, which appears at the bottom of the printed document.

**N.B.** Although the documents are in pdf format, and are visible on any computer equipped with a pdf reader, the key phrase becomes visible only on the printed document and not on screen.

If the surgeon notices a mistake in the patient's data, he will not ask the patient to sign the document. He must press the **Lipovisor™** button, which takes him back to the previous step, i.e. the patient data screen, where he can make corrections and then proceed to print the document.

**Note.** Patient data is not saved until the procedure has been completed correctly, with the inclusion of the key phrase that indicates that the privacy document has been signed. After the key phrase has been entered correctly, corresponding to the patient's privacy documents, the Lipovisor goes to the **Free Measurement Pre-consultation -** page.



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When the surgeon accesses the patient page in Outpatient mode, the patient's personal and clinical data have already been entered and the surgeon should proceed to perform the free measurement. However the **Lipovisor<sup>TM</sup>** must first ensure that the documents have been duly signed by the patient.

When the key-phrase page is displayed, the surgeon is required to enter the key-phrase displayed on the printed documents. Once this has been verified, the surgeon can carry out one of the following actions:

- Take a free measurement of the patient's fat tissue.
- Press the Patient data button (stethoscope symbol) if any changes need to be made
- Return to the home page by pressing the Lipovisor<sup>™</sup> symbol
- Turn off the Lipovisor<sup>™</sup> by pressing the off button.

#### Patient in Outpatient mode

After entering the patient's data, the Lipovisor shows the **Free Measurement** page which allows the operator to freely measure the patient's fat.

Since at this stage the surgeon will make a simple measurement without any surgical intervention, the **Lipovisor™** provides only the measurement of fat thickness.



The free measurement indicator shows the thickness of the fat in centimetres, measured with the probe at the exact point where the fat is located. In addition to the numeric indicator, there is also a graphical indicator, consisting of a proportional number of lit-up sectors that are coloured in correspondence with the different levels of fat thickness.

The colour relating to the maximum value of the fat is dark green, while the colour for the minimum value (zero) of fat is dark red. In general, the red, indicating that there is little or no fat, conveniently alerts the surgeon, while the green, indicating a lot of fat, indicates a more comfortable situation for the intervention. Between these two extremes there are different colours in different gradations corresponding to the different values measured.

The surgeon is required to ensure that the sensor is always in contact with the skin until the scanning of the area is completed.

If the surgeon moves the sensor away from the patient's skin, the measurement shown on the screen is invalid. Under certain conditions the **Lipovisor**<sup>TM</sup> is likely to detect this situation, but this is not guaranteed. It is up to the surgeon to verify that the sensor remains in contact with the skin and also that does not come into contact with other materials extraneous to the patient's body.

#### Searching for patients

The Lipovisor provides a workflow designed to prevent any manual operations that could lead to errors and omissions. This flow is also highly optimized to avoid unnecessary operations that cause delays and inefficiencies. This is why the search option was created. When the surgeon wishes to see a patient whose personal data have already been entered

into the **Lipovisor™**, he begins the search by pressing either the woman button or the man button, which displays the list of patients undergoing treatment, already classified by gender. If the name of the patient the surgeon is searching for does not appear on the screen, the surgeon can scroll up and down through the list until he finds it.

If the number of patients is very high, the surgeon can press the initial letter of the name or surname and the **Lipovisor<sup>TM</sup>** will display only the list of patients whose name or surname contains the letter selected.



With this simple search mechanism: man/woman plus a letter, the name of the patient should already be visible in the first screen of search results, otherwise the surgeon can scroll up and down through the list.

Searching for patients begins with the patient register page, by pressing the **Man** or **Woman** button on the **Patient Register** page already seen above (the page here is displayed for your convenience only).

#### Searching for female patients

On the patient register page, the surgeon presses the **Women** button to display the **Search Female Patients** page. Pressing a letter button will display the list of patients with that letter.

The surgeon can then scroll up and down through the list.

When the relevant patient has been identified, the surgeon clicks on the name and the patient page opens, in the mode relating to the status (outpatient, pre-surgery, surgery, post-surgery) Press the **Woman** button to return to the patient register (this user path is very rare in the daily flow of work, so an actionable symbol is used rather than a button).



#### Search for male patient

This screen is shown if you pressed the **Man** button in the patient register page.

If the surgeon presses the **Man** button on the patient register page, the **Search Male patients** page is displayed. Pressing a letter button will display the list of patients with that letter.



The surgeon can then scroll up and down through the list.

When the relevant patient has been identified, the surgeon clicks on the name and the patient page opens, in the mode relating to the status (outpatient, pre-surgery, surgery, post-surgery) Press the **Man** button to return to the patient register (this user path is very rare in the daily flow of work, so an actionable symbol is used rather than a button).

### Search for Surgery patients

This screen is displayed when you search for Male patients or Female patients in the Search page.

If the surgeon has pressed the **Surgery** button on the search page, the **Search Surgery patients** page is displayed, where only the patients who will undergo surgery are displayed.

Pressing a letter button will display the list of patients with that letter.

The surgeon can then scroll up and down through the list.

When the relevant patient has been identified, the surgeon clicks on the name and the patient page opens, in the mode relating to the status (outpatient, pre-surgery, surgery, post-surgery) Press the **Lipovisor™** symbol to return to the patient register (this user path is very rare in the daily flow of work, so an actionable symbol is used rather than a button).



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It is well known that liposuction, and reshaping of the body of a patient is an extremely complex surgical procedure due to the absence of reference marks. For this reason it is advisable for the surgeon to mark only the outer contour of the area on the patient, with the appropriate marker supplied with the **Lipovisor**<sup>TM</sup>. All marks that are not the outer contour of the area should be identified using a different marker.

With the patient in a standing position.

- take measurements using a measuring tape, and write them on the patient's body in order to draw the areas from which fat will be removed (e.g. buttocks and belly).
- using the reference marks on the patient's body, measure the distance of the areas to be scanned.
- this method allows the surgeon to mirror the right and left parts of the patient's body.
- marks should be drawn on the patient's body according to the surgeon's description.
- do not use cameras equipped with Wi-Fi which could disturb or interfere with the Lipovisor™ technology.



#### Ppre surgery consultation

By pressing the **Surgery** button from the **Lipovisor™** home page, the **Lipovisor™** activates the guided procedure for the pre-op consultation.

The first step consists of creating a three-dimensional model of the patient which is activated by pressing the **3S** button.

The **Lipovisor™** provides instructions for carrying out the process and the surgeon uses the **3D** sensor to capture the 3D model.

On completion of the capture procedure, the **Lipovisor™** screen displays the 3D model or silhouette of the patient, and the following buttons appear:

- 3D Model of the patient
- **3L** button that activates the scan with the Lipovisor fat sensor
- M Free measurement



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- Accept
- Retry
- 3S button that allows the operator to carry out the three dimensional scan at any time, with the body scanner

When the pre-surgery consultation is activated, a completely empty area is shown, which will then be filled with the silhouette and the three-dimensional scan of the patient.

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The surgeon presses the **3S** button to perform the **3D** scan of the patient. When the scan is completed, the threedimensional image appears on the screen. Only at this point does the **3S** button become active, and the surgeon can perform the selection and scan using the fat sensor.

It is possible to zoom in on the three-dimensional model by touching the screen with two fingers (usually the index finger and thumb).



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To zoom in on the three-dimensional model using the **Zoom In** function the surgeon moves his fingers on the screen (away from each other).

Conversely, moving his fingers towards each other will perform the **Zoom Out** function.



#### Selecting areas to operate (list creation) - Pre-Surgery appointment

On the patient's three-dimensional model, the surgeon selects the areas to be scanned, identifying each of them by name. Each area is selected using the **Lipo** sensor.

• **3L** scan of a single area.



As the area is scanned, it acquires a colour that varies according to the layer of fat underneath the skin.


#### Pre-Surgery - List of areas on which to operate

After the surgeon has specified the patient to be operated on, a page appears showing the list of areas of the patient's body on which to operate, which have already specified in the pre-Surgery consultation.

This page displays all the parts of the patient which will be operated on, and which were selected in the pre-surgery consultation.

The surgeon selects the part on which he will operate, and confirms by pressing the **Confirm** button. The **Lipovisor™** then shows the area to be operated on, on the **Surgery - Area to Operate** page. After operating on the selected part, the **Lipovisor™** again shows the page 'List of areas on which to operate' with the difference that the areas which have been operated on are shown by a graphic symbol in order to indicate to the surgeon which are the areas still to be operated on.

When the surgeon has operated on all the specified areas and the entire list is completed, the **Lipovisor™** remains on the **Surgery - list of areas on which to operate** page until the surgeon presses the Surgery symbol to return to the **Surgery** Home Page. When the **Surgery** symbol is pressed, the **Lipovisor™** saves the patient data and returns to the home page.

Example: for the specified patient, the surgeon has identified three areas: Inner thigh, Abdomen and Buttocks.



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This page shows the pre-set area which will be operated on. Here the surgeon can:

- rotate the model using the control ball.
- take a measurement using the Free Measurement button and access the Surgery Free Measurement page
- perform a new scan of the area using the 3L button that accesses the area check scan page



• Press the Lipovisor<sup>™</sup> logo to return to the Home Page.

While working on a specific area, the surgeon can perform a lipo scan to check the fat in the area on which he is operating. The scan can be repeated as many times as required, by pressing the **3L** button on the previous screen

The area to be scanned, which has already been specified in the pre-consultation, is displayed in grey on the main viewer. The **Lipovisor™** indicates in grey the area to be scanned, along with a pointer which shows where the surgeon must position the sensor. The surgeon places the sensor at the point indicated on the patient's **3D** model and moves it in all directions, in order to examine the whole area. As the surgeon moves the sensor on the patient, the corresponding point in the 3D model is coloured accordingly (see colour scale table).

The surgeon should cover the whole area with the sensor, directing it towards the parts that have not yet been scanned.

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Either of the following two scenarios can be found in the operating room:

- the surgeon uses the Lipovisor<sup>™</sup> Master which he brought with him into the operating room. He already visited the patient and needs to search for the patient's details; or
- the surgeon uses the Lipovisor™ Clinic, a version of the Lipovisor™, which is specifically designed to work efficiently in operating rooms, where stable equipment and multi-user facilities are installed, compared to the clinic of a single surgeon.

### Surgery (operating room) - Lipovisor™ Clinic

Lipovisor Surgery is the version of Lipovisor<sup>™</sup> specially devised for the operating room. It takes into account some of the characteristics of the operating room, such as:

- Multi-user facilities
- Compliance with certain requirements on electrical and radio-frequency transmissions
- Type of operations carried out (outpatient appointments and check-ups are not carried out in the operating room)

The **Lipovisor™ Surgery** therefore works on only one patient at a time without processing the data relating to other patients. All patient appointments (outpatient, pre- and post-surgery) are carried out using a **Lipovisor™ Surgery** supplied to the surgeon.

In the operating room, **Lipovisor™ Surgery** is configured to recognize the data contained in the patient transponder. A page appears with the message **Bring the transponder near Lipovisor Surgery**.

# Lipovisor Clinic Home page

After start-up the operator accepts commands from this page, with two options available:

- turn off the **Lipovisor™** by pressing the power button.
- go to the transponder page by pressing the **Transponder** button.



To operate on the current patient, the surgeon must insert the corresponding transponder into the USB port on the **Lipovisor**<sup>TM</sup>. The transponder contains the data relating to the patient to be operated on.

The surgeon inserts the transponder into the USB port so that the **Lipovisor™** can acquire the patient data. If the acquisition fails, the **Error 03** page appears, which allows the surgeon, by pressing the **Try again** button, to read the transponder again.

If an error occurs when reading the transponder, the operator should:

- bring the transponder nearer to the sensor
- make sure it is correctly orientated
- try restarting the Lipovisor™

In case of repeated errors in reading the transponder, after following the suggestions listed above, contact the Lipovisor<sup>TM</sup> customer service centre.



#### Transfer from Lipovisor<sup>™</sup> Dr. Master to Lipovisor<sup>™</sup> Clinic **...**

Insert the transponder into the USB port; or, if the surgeon has a USB / wireless transponder, ensure that it is turned on and placed close to the **Lipovisor<sup>TM</sup>**.

By pressing the **Transfer** button, the **Lipovisor™** downloads the patient's medical records to the transponder.

- at the request of the **Lipovisor™**, insert the transponder into the USB port.
- Wait for the confirmation tone indicating that the file has been downloaded.
- After the beep, the operator can remove the transponder and take it with him into the operating room.

Note: When the patient's data file has been transferred to the Transponder, an email is also sent to the clinic.

**Note:** If the plastic surgeon enters an email that does not refer to the clinic or the clinic has lost or did not receive the email, in the event of litigation, the clinic may refer to the **Lipovisor™** manufacturer in order to recover any missing data. The transaction will entail the payment of a fee.

#### Surgery - List of areas on wich to operate

After the surgeon has selected the patient to be operated on, a page appears showing the list of areas of the patient's body on which to operate, as specified in the **pre-Surgery visit**.

This page displays all the parts of the patient which will be operated on, and which were selected in the pre-surgery appointment. The surgeon selects the part on which he will operate, and confirms by pressing the **Confirm** button. The

Lipovisor<sup>™</sup> will then show the area to operate on in the Surgery - Area on which to operate page. After operating on the selected part, the Lipovisor<sup>™</sup> again shows the page List of areas on which to operate with the difference that the areas which have been operated on are shown by a graphic symbol in order to indicate to the surgeon which are the areas still to be operated on.

When the surgeon has operated all specified areas and the entire list is completed, the **Lipovisor<sup>TM</sup> Surgery - List of areas on which to operate** page remains active until the surgeon presses the Surgery symbol, and then returns to the Surgery Home Page. When the **Surgery** symbol is pressed, the **Lipovisor<sup>TM</sup>** saves the patient data and returns to the home page.

**Example:** for the specified patient, the surgeon has identified three areas: Inner thigh, Abdomen and Buttocks.



This page shows the pre-set area which will be operated on, and the surgeon can any of the following operations:

- rotate the model using the control ball.
- take a free measurement using the Free Measurement button to access the Surgery Free Measurement page



- rescan the area using the **3L** button that accesses the **Area check scan** page
- return to the Home Page by pressing the **Lipovi**sor<sup>™</sup> logo.

### Surgery - Surgery Free Measurement

The **Lipovisor™** measures the fat thickness while it removes it in the operating room,.



Surgery Free Measurement is used by the surgeon during surgery to remove fat in areas and depths that he has determined during the **Pre-Surgery** visit.

The **Surgery Free Measurement**, compared to the free measurement used in the clinic, enables the surgeon to set a limit on the thickness of residual fat. In practice, the surgeon uses the + and - keys to set the depth to which he wishes to remove the fat, and begins to operate on the patient using surgical instruments (cannula or other instruments), while carrying out real-time checks with the **Lipovisor**<sup>TM</sup> which continually reports on the thickness of the fat (in millimetres). If the residual fat reaches the thickness limit set by the surgeon, the **Lipovisor**<sup>TM</sup> emits a warning sound and a visual alarm in order to draw the surgeon's attention.

The **Surgery Free Measurement** differs from outpatient measurement or free measurement only in that there is a limit set, which is also known as "limited measurement".

The **Surgery Free Measurement** indicator shows the size of the fat in centimetres, measured by the probe at the exact point where it is located. In addition to the numeric indicator, there is also a graphical indicator, consisting of a proportional number of lit-up sectors that are coloured in correspondence with the different levels of fat thickness.

The colour relating to the maximum value of the fat is deep blue while at the minimum value (zero) it is dark red. In general, the red, indicating that there is little or no fat, conveniently alerts the surgeon who is performing the operation, while the blue, indicating a lot of fat, represents a more comfortable situation. Between the two extremes represented by the red and the blue there are different colours with different gradations corresponding to the different values measured.

The operator makes sure that the following requirements are met:

• The The sensor must always stay in contact with the skin until the scanning of the area is completed. Please note! If the surgeon moves the sensor away from the patient's skin, the measurement shown on the screen is considered invalid, and the alarm function will not be

significant and is therefore unusable.

- Under some special conditions the Lipovisor<sup>™</sup> can detect this situation, but this is not guaranteed.
- It is up to the surgeon to verify that the sensor remains in contact with the skin, and that it never comes into contact with other materials extraneous to the patient's body.



**Important Note.** During the operation, when the thickness of the fat reaches the set limit, the **Lipovisor™** indicates this with a flashing **STOP** sign, and an unmistakable sound to alert the surgeon.



While working on a specific area, the surgeon can perform a **Lipo** scan to check the fat in the area on which he is operating. The scan can be repeated as many times as required, by pressing the **3L** button on the previous screen. The area to be scanned, which has already been specified in the pre-consultation, is displayed in grey on the main viewer.

The **Lipovisor™** indicates in grey the area to be scanned, along with a pointer which shows where the surgeon must position the sensor. The surgeon places the sensor at the point indicated on the **3D** model of the patient and moves it in all directions, in order to examine the whole area. As the surgeon moves the sensor on the patient, the corresponding point in the model **3D** is coloured accordingly (see colour scale table). The surgeon should cover the whole area with the sensor, directing it towards the parts that have not yet been scanned.



The operator makes sure that the following requirements are met:

- The sensor must always stay in contact with the skin until the scanning of the area is completed.
- After starting the scan he should never raise the sensor away from the patient's skin and move it to a new point. He can move it in any direction he likes, but it must always remain in contact with the skin without being raised away from it.
- Contact may be lost with the skin, but the sensor must be repositioned at the same spot where contact was interrupted.
- In short, if you move the sensor away from the skin it must be put back in the same spot.
- If the sensor loses contact with the skin there are two possibilities:
- If you wish to continue the scan, reposition the sensor in the same spot, or
- the current scan is to be considered to have come to an end;
- press retry and re-scan the area.

**N.B.** Under certain conditions, the **Lipovisor**<sup>TM</sup> may detect that the sensor has lost contact with the skin and reports it appropriately by offering the surgeon the choice to terminate the scan, continue or rescan. **Prescription number 2** - The sensor must be kept in a horizontal position with the buttons precisely at the top. If this requirement is not met the scan is to be considered invalid. When the surgeon realises the error, he can repeat the scan by pressing **Try again**. Under certain conditions the **Lipovisor**<sup>TM</sup> itself can detect the error and report it, prompting the surgeon to repeat the scan.



By pressing the transfer button, the **Lipovisor™** downloads the patient's medical records to the Transponder.

- At the request of the Lipovisor<sup>™</sup>, insert the transponder into the USB port.
- Wait for the confirmation tone indicating that the file has been downloaded.
- After the beep the operator can remove the transponder and take it with him to activate the Lipovisor™ Master.

Note. When the patient's data file has been transferred to the Transponder, an email is also sent to the clinic.

**Note.** If the plastic surgeon enters an email that does not refer to the clinic or the clinic has lost or did not receive the email, in the event of litigation, the clinic can refer to the **Lipovisor™** manufacturer in order to recover any missing data. This operation entails the payment of a fee.

#### Compare - Post-operative appointment

The post-surgery appointment gives the surgeon the opportunity to perform a new 3D scan of the patient and to compare it with the one carried out prior to surgery. In this way, it is possible to highlight the main differences between the condition of the patient before and after surgery.

During the post-operative appointment the surgeon performs a 3S scan of the patient, and the scan is immediately compared with the 3D model of the patient which was acquired at the Pre-surgery appointment. The **Lipovisor<sup>TM</sup>** highlights the differences between the two models.

When the print button is pressed the **Lipovisor™** sends via email the pdf file containing all the documentation.

By pressing the off switch the **Lipovisor™** returns to the Home Page.

**Lipovisor**<sup>TM</sup> shows the two models side by side to facilitate the comparison of any differences.



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### Print the documents and CD burning

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The surgeon can print the medical records and make them available to the patient. The **key-phrase** only needs to be entered at the outpatient appointment.

At the end of the post-operative appointment the surgeon may decide to give the patient a summary of the operation on a USB stick or a CD, which contains all the three-dimensional scans performed on the patient.

#### OVERVIEW

- The use of the Lipovisor™ medical device is dependent on a complete knowledge and awareness of the contents of this manual; nevertheless, this manual may be PERIODICALLY UPDATED WITHOUT NOTICE. As a result it is the responsibility of the user to verify PRIOR TO USE any updates of the user manual, by logging on to the following website **http://www.lipovisor.com/ last-issue**
- Lipovisor™ is an electronic device that is produced in accordance with the harmonized standards that presume CE conformity and compliance with the essential requirements necessary for obtaining this marking.
- Lipovisor™ is a medical device that complies with Directive 93/42/EEC, which has been implemented by Italian Legislative Decree no. 46 of 24.02.1997, published in the Official Gazette no. 54 of 06.03.1997.
- the manufacturer confirms compliance with the CEI 62 standards that define the structural safety requirements of electro-medical equipment; in particular, this ensures that close attention has been paid to maintenance procedures to be carried out by the user, as well as those prescribed by Legislative Decree no. 46, Annex "1" of 24.02.1997, point 13.6 "d", which consequently recommends that the user carry out preventive & corrective maintenance and, if necessary, extraordinary maintenance using the REQUIREMENTS CONTAINED IN THIS MANUAL, as well as observing all regulations and applying all "best practices", i.e. "best practices carried out in a workmanlike manner in order to maintain the Lipovisor™ device a in perfect and safe operating condition." The manufacturer takes responsibility for any damage caused through the use of the Lipovisor™ medical device, limited to broader notions permitted by law, and provided that the equipment has been used in accordance with the requirements of this manual and that all maintenance procedures set out by the manufacturer and by applicable regulations have been observed by the user; it is up to the user to provide evidence that he has used the device properly and in compliance with all applicable standards.

The **Lipovisor™** device must be used in accordance with Italian decrees no. 81 of 09.04.2008 and no. 106, 03.08.2009, as amended, on the safety of workers in relation to the equipment made available to them. The equipment must be used in accordance with the laws and regulations on safety and be SUBJECT TO SUITABLE PREVENTIVE, CORRECTIVE AND EXTRAORDINARY MAINTENANCE SCHEDULES. The user must adhere to the CEI 62 standards that also set out maintenance, storage and safe requirements for the use of electromedical equipment in medical environment.

### Patient safety 🔬 🎄 🚮 🍽

- Being an electro-medical device that emits radio waves, the **Lipovisor™** device inherently adopts all national and international safety regulations limiting their emissions within the limits set out by these regulations; however, it is recommended that the user should not use the Lipovisor<sup>™</sup> device on patients who, by way of example and not limited to, have:
  - ⇒ pacemakers

•

- ⇒ stimulation electrodes
- ⇒ monitoring devices
- ⇒ metal implants
- In any case it is strongly recommended that surgeons **operate in environments equipped with defibrillator and an external pacemaker**, in order to effectively deal with any unexpected rare events.
- The Lipovisor<sup>™</sup> should not be used on patients who are:
  - ⇒ pregnant
  - ⇒ suspected pregnancy
- Being an electromedical device, the use of the Lipovisor<sup>™</sup> involves carrying out careful electrical safety checks in relation to direct contact with the patient. By way of example and not limited to, special care must be taken in:
  - ⇒ macroshock

the passage of current through the patient's body caused by accidental external contacts

#### ⇒ microshock

the passage of current through the internal organs of the patient caused by the electric dispersion relating to the probes of the unit.

By way of example, and not limited to, some of the physio-pathological effects caused by an electric current passing through the human body are:

- $\Rightarrow$  tetanisation
- ⇒ respiratory arrest
- ⇒ ventricular fibrillation
- ⇒ burns
- While using the **Lipovisor™** it is ABSOLUTELY NECESSARY TO CONSIDER THE PATIENT VERY VULNERABLE TO ELECTRIC SHOCKS, as the clinic and surgery context can cause life-threatening situations for the patient;
- it is only permitted to use the Lipovisor<sup>™</sup> in conjunction with electric or electronic electromedical or nonelectromedical equipment, which has previously been proven to create no interference with the proper operation of the device, or to be affected by the device;
- the use of the Lipovisor<sup>™</sup> in conjunction with any electrical or electronic electromedical or non-electromedical equipment is to be considered the sole responsibility of the user, who assumes the risks to the fullest extent permitted by law, and thus bears the sole responsibility of ALL interoperability tests carried out on the equipment, as well as the consequences of such combined use.

## General safety 🔬 🖄

- The **Lipovisor™** must only be used in full compliance with ALL the requirements of electrical safety set out in the manual, as well as ALL legal requirements;
- $\Rightarrow$  By way of example, but not limited to, the following is recommended:
- ⇒ In case of any doubt about the efficiency of the device, shut it down immediately, disconnect it from the mains and consult the customer service for subsequent checks.
- ⇒ The **Lipovisor™** radio frequency device should only be used in areas that comply with applicable electrical standards, specific to medical environments.
- $\Rightarrow$  Only use mains supply sockets that are properly grounded.
- $\Rightarrow$  The device should only be powered up after ensuring that the sources of supply correspond to the rating plate data: power supply voltage, frequency and maximum output current. In case of any doubt, do not power up the device, and consult the customer service for subsequent checks.
- ⇒ Do not carry out any improper electrical connections, such as forcing plug prongs into unsuitable sockets or make precarious connections of any kind.
- ⇒ Do not use electrical connections which have not been tested as being perfectly complete and functional.
- $\Rightarrow$  Do not use extension cords, power strips, or any other device that has not been approved.
- ⇒ Inform the service engineer of any maintenance discrepancies even if these are only suspected.
- $\Rightarrow$  Avoid using the device in the vicinity of cutting elements, sharp tools or any kind of equipment that may affect the reliability of the electrical connections.
- $\Rightarrow$  If the device is used with accessories not included in the supply, such as extension cords, or any other equipment, these must comply with the minimum compatibility characteristics, and ensure performance capabilities NOT INFERIOR to those set out for the device.

- $\Rightarrow$  Avoid using flammable and/or accelerant components when operating the device.
- $\Rightarrow$  Do not allow liquids to come into contact with the device.
- $\Rightarrow$  Do not use the device if you suspect that it has come into contact with liquids.
- $\Rightarrow$  Always use the device and all accessories supplied on a horizontal, stable and rigid surface, so as to allow safe usage and to ensure that the device or accessories do not fall accidentally.
- ⇒ Do not use the device on soft or unstable surfaces; this includes, by way of example and not limited to, blankets, pillows, beds, etc.
- ⇒ During use, do not cover the device with cloths, towels or any other material.
- $\Rightarrow$  Leave a free space of at least 15cm around the device in order to allow for ventilation of the cooling grids, as well as easy operability around the device.
- $\Rightarrow$  Do not expose the equipment to direct sunlight.
- $\Rightarrow$  Avoid any misuse or any type of usage not set out in the user manual.

Being an electro-medical device that emits radio waves, the **Lipovisor™**, inherently adopts all national and international safety regulations limiting their emissions within the limits set out therein. However, it should not be used near equipment that receives or transmits radio signals, which, although unlikely, could cause minor interference. In any event, the device does not cause interference with computers, fixed or mobile telephone networks.

## Risk management 🔬 🖄

- As with all electromedical devices, the use of the **Lipovisor™** is subject to a careful evaluation of the inhirent risks, including the following, by way of example and not limted to:
- ⇒ technical defects

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- $\Rightarrow$  misinterpretation of the functions of the equipment and accessories
- ⇒ insufficient knowledge of the safety methods to be applied
- $\Rightarrow$  insufficient or incorrect maintenance of the equipment and accessories
- $\Rightarrow$  improper use of the equipment and accessories
- $\Rightarrow$  using improper combinations of accessories and equipment
- $\Rightarrow$  use of non-conforming accessories
- $\Rightarrow$  faults or problems relating to the electrical power supply
- $\Rightarrow$  failures or problems related to the environment in which the equipment is being used

External cleaning of the Lipovisor™ must be carried out periodically, and in any case before each use, respecting the following minimum procedural conditions:

 $\bigwedge$  Make sure that the product is switched off and that the power cord is unplugged from the power socket.

Clean the surface of the Lipovisor™ using soft sterile cloths which have been moistened with a liquid solution composed of 70% water and 30% denatured ethyl alcohol. It is advisable to vigorously wring the cloth before using it. Following the same precautions described above, also disinfect surfaces using a liquid suitable for the purpose. Do NOT use abrasives, solvents, acids or bases;

∧ NEVER immerse the Lipovisor™ and/or the supplied accessories in water or other liquids.

▲ Before using the Lipovisor™ device, make sure all parts are completely dry, paying particular attention to the electrical connections.

### Supply

- The power supply for the **Lipovisor™** must comply with the following rating:
  - ⇒ Voltage 110 / 230 / 240 volts +/- 10%
  - $\Rightarrow$  Frequency 50/60 Hz  $\pm$  1%
  - → Max 30VA

The **Lipovisor™ Master Dr** is supplied with the following accessories:

- 90° sensor
- Lipovisor<sup>™</sup> power cable
- Lipovisor<sup>™</sup> sensor cable
- Lipovisor™ glass keyboard
- Lipovisor™ USB Key Transponder
- Lipovisor™ USB / Wireless Key Transponder
- Lipovisor™ multimedia CD

All accessories, consumables and optional extras MUST be used in accordance with the instructions provided in this manual. Any other use will be considered misuse, and should be absolutely avoided.

•	Lipovisor™ sterile protections	od.	12001)
•	<b>ipovisor</b> <sup>™</sup> sensor sterile protections	od.	12002)
•	Lipovisor <sup>™</sup> power cable sterile protections	od.	12003
•	Lipovisor™ USB Transponder Key(c	od.	12004)
•	Lipovisor™ USB / Wireless Transponder Key	od.	12005)
•	Lipovisor™ multimedia CD	od.	12006)

Quote the code next to each item when ordering optional extras.

All accessories, consumables and optional extras MUST be used in accordance with the instructions provided in this manual. Any other use will be considered misuse, and should be absolutely avoided.

•	Lipovisor™ USB Transponder Key	)07)
•	Lipovisor™ 45° Sensor	)08)
•	Lipovisor™ Trolley	)08)

Quote the code next to each item when ordering optional extras.

All accessories, consumables and optional extras MUST be used in accordance with the instructions provided in this manual. Any other use will be considered misuse, and should be absolutely avoided.

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