



multiCareⁱⁿ

USER'S MANUAL

*In-Vitro Diagnostic
aid for self testing*



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The system

Thank you for choosing **multiCare-in** system.

multiCare-in is a new system, useful for the monitoring of glucose, cholesterol and triglycerides in the blood.

multiCare-in has two different technologies:

- amperometric, with **multiCare-in** in glucose electrodes strips.
- reflectometric, with **multiCare-in** cholesterol and triglycerides strips.

Self –monitoring of glucose, cholesterol and triglycerides could be helpful, but the treatment to be applied has to be anyway agreed with the physician.

Information about multiCare-in system line

The **multiCare-in** system line includes all is the necessary for the analytes check:

- **multiCare-in** meter
- **multiCare-in** strips
- lancing device
- sterile lancets
- **multiCare-in** control solutions
- **multiCare-in** data manager software

Read carefully the instruction for use inside the box of **multiCare-in** strips that you want to use and read carefully the instruction for use of the lancing device that are inside the **multiCare-in** meter box.

Glucose
Electrodes
Strip



Cholesterol
Strip



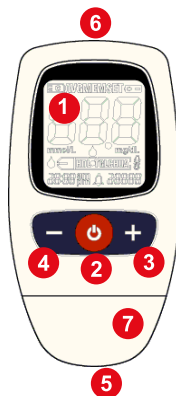
Triglycerides
Strip



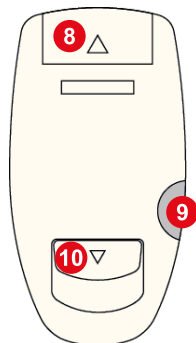
The meter

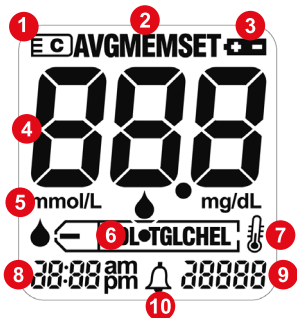
1. Display – Shows test results, messages, and results stored in memory.
2. Power Button – Press this button to:
 - a. Turn on the meter or turn off the meter.
 - b. Enter the SET mode in the STANDBY mode.
 - c. Go to the next step in the SET mode.
 - d. Exit the SET mode and enter the STANDBY mode.
3. “+” Button -- Press this button to:
 - a. Enter the MEMORY mode.
 - b. Recall previous stored results in the MEMORY mode.
 - c. Change parameters displayed and increase values in the SET mode.
4. “-” Button – Press this button to:
 - a. Enter the MEMORY mode.
 - b. Recall next stored results in the MEMORY mode.
 - c. Change parameters displayed and decrease values in the SET mode.
 - d. Reset the test results.
5. Test Strip Slot – Insert test strip here.
The meter automatically enters the TEST mode when a test strip is inserted.
6. PC Connector – Transfers data from the meter to a computer.
7. Cover – Open this for cleaning.
8. Battery Cover.
Put your finger on this to let the battery cover slide.
9. Data-chip Slot – Insert the data-chip.
10. Ejector – Press to discharge the used strip.

Front



Rear





The display

1. Data-chip inserting.
2. Meter's mode.
3. Low battery warning.
4. Test results and messages.
5. Unit of measurement.
6. Test analytes.
7. Abnormal temperature warning.
8. Time.
9. Day and month.
10. Alarm.

The mode

The **multiCare-in** has three modes.

You can check the present mode of the meter by seeing the top of display.

1. Standby Mode

Press and release the power button.

A strip-shaped symbol will twinkle and the meter will display the data chip number, time and date.

2. Memory Mode

Press and release the “+” or “-” button in the standby mode.

The meter will display a “MEM” symbol on the top of the display.

3. Set Mode

Press and release the power button in the standby mode.

Press again the power button for 3 seconds.

The meter will display a “SET” symbol on the top of the display.

When switch on the meter, check that the date and the hour are correct.

Coding the meter

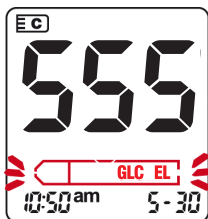
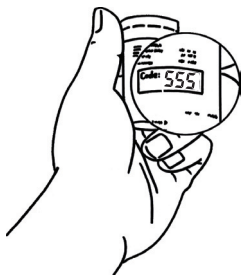
The **multiCare-in** meter uses a data-chip that is inside the strips box. It will be necessary to change the data-chip in the following cases:

- a. before using a new strips box
- b. when you want to change the analyte

1. Remove the data-chip from the strips box.
2. Insert the data-chip in the proper space in the lateral part of the meter.
3. Gently press the data-chip up to the complete insertion.



4. Press power button and check the three digit number is the same of the one printed on the strips vial.



5. If the data-chip is not inserted, it is impossible to perform the measurement.
6. Analytes:

GLC EL=GLUCOSE ELECTRODES



(BLUE)

CH = CHOLESTEROL

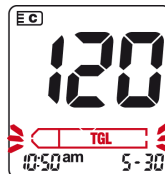
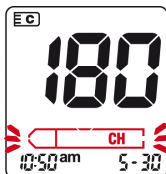


(GREEN)

TGL=TRIGLYCERIDES



(YELLOW)





How to obtain a drop of blood

To perform a measurement with **multiCare-in** System, it is necessary to withdraw a drop of capillary blood using the following procedure:

- Wash the hands with hot water to increase the blood circulation in the fingers to make easier the withdrawal of blood.
- Dry well the hands.
- Check that the finger to be pricked is completely dried.
- Prepare the lancing device that is inside the **multiCare-in** kit by inserting the sterile lancet.

Read carefully the instruction for use of the lancing device contained in the meter kit.

Use a new, not damaged lancet for each prick and use the lancing device only on yourself.

Before the inserting, verify that the lancets and the protection of the lancets are intact.

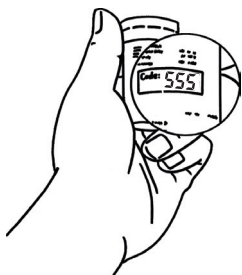
Only a lancet protection intact can guarantee sterile lancet.

Store the protection of the lancet in order to use it to seal the lancet after use.



Application of the blood

Read carefully the instruction for use of the strips that you want to use to perform the measurement.



- 1.** Press the Power button after inserted data-chip.
The number that appears on the display has to match the one printed on the strips vial.
If it does not match, contact Customer Service.

- 2.** Take a strip from the vial and insert it in the meter with the printed or coloured part on the upper side. You will hear a click and the meter will emit an acoustic signal.



Procedure to test glucose:

- 3a.** Perform the prick on the finger with the lancing device.
Apply a drop of blood on the part of the strips that comes outside the meter.
Let the strip aspirate the blood up to see the moving segments on the display.

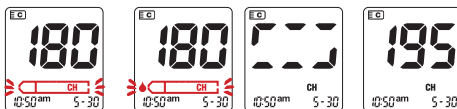
If the volume is not sufficient the measurement does not start.

Procedure to test cholesterol and triglycerides

3.b.1 Sit down for one minute with the arm along the body.

Massage the finger to be pricked in order to increase the blood flow. Prick the finger , remove the first drop with a sterile gauze and gently press the finger to obtain a second drop. Without touching and pressing the finger on the strip, apply the drop on the white circular area of the strip that comes out of the meter.

Wait until moving segments will appear on the display.



3.b.2 After insertign the strip, if “F” (Female) on the left and “M” (Male) on the right will appear on the display. Press the corresponding button (“-“ for”F” or “+” for “M”) to select the gender. After about two seconds, “b” (before meal) on the left and “a” (after meal) on the right will appear on the display. Press the corresponding button (“-“ for”A” or “+” for “P”) to select the letter. The selected letter will remain two seconds on the display. After that, the code and the blinking drop will appear on the display, indicating that the meter is ready to receive the blood.

Follow 3.b.1 for the blood application.

4. The meter will emit an acoustic signal and the result will be visualised on the display and automatically stored in the memory of the meter (refers to the instruction for use, that you are using to know the reading time).

5. Press the ejector key to remove the strip that you used, pointing the meter down for the low.



Warnings

If the results obtained do not correspond to the well being of the user, proceed with a check up of the **multiCare-in** instrument and contact your physician.
If extreme results are obtained, too high (Hi) or too low (Lo), contact your physician immediately.

Warnings

When the measuring is finished, it is possible to turn OFF the **multiCare-in** instrument. The instrument will shut down automatically after 60 seconds if not used for other operations.

The measured value, along with date and time, will be saved in position 1 in the memory of the instrument.

The values previously measured will be saved in positions 2, 3 etc. starting from the most recent. How to recall from the memory a measured value and how to erase memorized values is described on page 12.



The strips and the used materials have to be properly disposed, avoiding contamination. The meter has to be disposed following the Electric and Electronic Waste law.

In a laboratory and in a hospital, the procedures of biological safety must be followed when handling potentially infected material, in particular when measurements are performed on different patients.

To avoid infections clean the instrument regularly and dispose of the used strips in a way that there is no risk of infections for other people.



The strips



The strips

The correct use of the **multiCare-in** strips is very important for obtaining accurate results. Therefore it is important to keep in mind the following:

- The strips are sensitive to light and humidity: keep the strips only in their original vial.
- Protect the vial from direct sunlight and keep at a temperature between 5 and 30 °C (41-86°F).
- Use the strips immediately after removing from the vial and close the vial immediately with its cap.
- The strips must not be used after the expiry date.
- When first opening, write the date on the vial: the strips must be used within 90 days after the vial has been opened.
- Do not use strips that are damaged.
- Carefully read the instructions contained in the package of strips.
- Take measurements only with original **multiCare-in** strips.





The Control Solutions

Read carefully the instruction for use of the control solution that you want to use.

It is possible to check the working of the **multiCare-in** instrument using the **multiCare-in** control solutions.

The control solutions can be obtained as a separate accessory through specialized retailers.

The control solution is applied on the strip just like blood.

When testing is done with the control solution, the obtained result must be within the interval as shown on the label of the strip's vial.

In this way, it is possible to learn how to use the **multiCare-in** properly and at the same time, check if it is working.

Write the date of opening on the vial when the solution is opened for the first time.

The control solution must be used within 90 days from first opening, if the expiry date is valid.

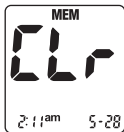
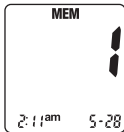
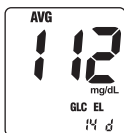
When to carry out a working check up using the control solutions:

- When suspecting a possible defect of the **multiCare-in** instrument.
- When suspecting the possibility of a malfunction or wrong measurement.

The result obtained with the control solutions has to be deleted by the memory of the meter in order to not interfere with the average calculation of the glycaemia.

Control
solutions





Memory functions: recalling and deleting result from the memory

The **multiCare-in** meter stores up to 500 test results for all analytes, letting you review them in order from the recent ("1") to the oldest ("500").

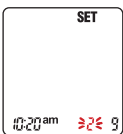
If you insert the data-chip of glucose into the meter, you allow to recall only previous glucose test results. It's all the same for other analytes.

1. Press and release the "+" or "-" button in the STANDBY mode.
The meter will enter MEMORY mode and the average of test results is displayed.
2. While pressing the "+" or "-" button, memory number will be displayed. If you hold down the "+" or "-" button, the meter scrolls quickly and only memory positions are displayed. A result is not shown until you release the button. When release the "+" or "-" button, the corresponding result will be displayed.
3. Repeat step 2 to see the remaining stored results.
4. Keep the power button pressed and then press the "-" button for 1 second to delete one test result stored in the meter.
5. Press "-" button for 5 seconds together with the power button to delete all test results stored in the meter.



Modification of settings

General
settings



1. Press and release the power button to select the month.

Press and release the “+” or “-” button up to reach the correct month.



2. Press and release the power button to select the day.

Press and release the power button to change.



3. Press and release the power button to choose the date format.

Press and release the “+” or “-” button to choose between month-day (mm-dd) or day-month (dd-mm).



4. Press and release the power button to change the year. Press and release the “+” or “-” button up to reach the actual year.

The meter allows to change the year from 2007 to 2017.



5. Press continuously the power button for 3 seconds. The meter will enter in the SET mode and it will be possible to change the hour.

Press and release the “+” or “-” button up to reach the correct hour.



6. Press and release the power button to change the minutes. Press and release the “+” or “-” button up to reach the correct minutes.

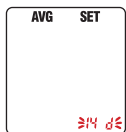




7. Press and release the power button to change the hour format. Press and release the “+” or “-” button to choose between 12 or 24 hours.

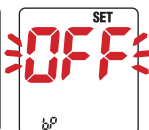
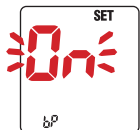


8. Press and release the power button to change the unit of measurement. Press and release the “+” or “-” button to choose between mg/dL and mmol/L.



9. Press and release the power button to select how many days you want the average of results. Press and release the “+” or “-” button up to reach the wished number of days (0,7,14,21,28 days-“0” means that the meter will not show any average of the measurements).

Setting the acoustic signal





1. Switch on the meter and press continuously the power button to enter in the SET mode. Press and release the power button up to see “bp” fixed and “On” blinking on the display.
2. Press the “+” or “-” button to activate or not the acoustic signal.

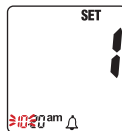
Setting the alarms



Follow these instructions to set the alarms:

1. Press and release the power button of the meter. Press the power button continuously to enter in the SET mode. Press and release up to see the icon of the alarm fixed and “0” blinking.

- 
- 
2. Press the “+” or “-” button to select the number of the alarm to be set (0, 1, 2, or 3).
 3. Press the power button again to select the hour and the minutes related to the alarms that you are setting.
 4. You can exit by the SET mode in every moment by pressing continuously the power button for three seconds.




The alarms are not activated if they are set on 12.00 or 0.00.



Enabling data transfer to a computer



All the test results stored in the **multiCare-in** can be downloaded to a computer.



1. Install the software according to the manufacturer's instructions.
2. Insert the cable into the USB port of the computer and the jack of the cable into the meter.
3. Press and release the power button. “PC” will appear in the meter's display.
4. Set up your computer software to receive information from the meter. After the data has been transferred, you can turn off the meter by pressing the power button and remove the jack cable from the port of the meter.



Care and maintenance

For glucose measurement it is necessary a particular cleaning procedure only if blood or other material (debris, dust, etc.) come into direct contact with the plastic support of the reader. If so, use only a wet cloth, moistened by water or alcohol solution of 70%, to clean the external parts of the instrument.

Since for cholesterol or triglycerides measurement the instrument uses an optical measuring method, its components must be kept clean. To clean the optical components, lift the front cover and use a wet cloth on the glass surface of the optics. After the cleaning, dry the plastic support of the reader, without scratching it.

For taking measurements on different people, like in a hospital for example, clean the instrument after every measurement with a solution 70% alcohol before proceeding with the next measurement.

Preservation and measuring conditions

To assure the accuracy of each measurement, it is important to meet some conditions.

The measurement with **multiCare-in** strips has to be performed between 10 and 40 °C (50-104°F). The **multiCare-in** kit (meter and strips) has not to be stored at temperature lower than 5°C(41°F) and over 30°C(86°F).

Note

If the instrument is too cold or too hot (ex. after being in a car at very low or high temperatures), allow it to cool down or to heat up slowly at room temperature (about 20 minutes).

Error messages

Error
messages



E01
10:20 AM 5-19



E02
10:20 AM 5-19



E03
10:20 AM 5-19



E04
10:20 AM 5-19



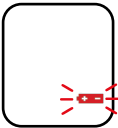

Error message	Problem	Solution
E01	The temperature is out of the allowed range.	Place the instrument in an area with temperature between 10°C (50°F) and 40°C (104°F) and wait for the instrument to equilibrate with the external temperature, before performing the measurement.
E02	The strip is used or the reactive area is coloured.	Use a new strip to perform the measurement.
E02	The blood was applied on the strip before waiting for the drop blinking on the display.	Take a new strip, insert it in the instrument and, only after visualized blinking drop on the display, aspirate the blood on the strip.
E02	The reading window is dirty.	Open the plastic cover where you insert the strip and clean the glass window using only water. Dry the glass without scratch it. Do not use solvents or soap. Close the plastic counter and repeat the test.
E03	The strip is removed from the meter without applying the drop of blood.	Switch off the meter by Power button. Insert the strip again and aspirate the blood on the strip without remove the strip from the strip-holder.
E04	The strip that you are using does not correspond to the parameter of the data-chip.	Remove the data-chip and use the one corresponding to the strip that you want to use and check that the parameter symbol on the display is the same of the one printed on the strip.

Error messages

Error message	Problem	Solution
E05	Data-chip error	Remove the data-chip and insert it again. If E05 still remains, contact Multicare customer Service.
E06	The blood is not enough	Repeat the test and apply more blood.
E07	The data-chip is not inserted	Insert the data-chip corresponding to the strips that you want to use.
LO	The result is lower than the limit of that parameter (see also instruction for use of the strips)	If the result does not correspond to the personal sensations, repeat the test, applying a big drop of blood. If LO is obtained again, contact your physician for additional information.



Error messages

Error message	Problem	Solution
	<p>HI</p> <p>Value is higher than the limit of reading of that parameter.</p>	<p>Contact immediately your physician and repeat the test at hospital laboratory.</p>
		<p>Get new batteries.</p>
		<p>Replace the batteries before taking a measurement.</p>
		<p>Check expiry date of the strips and use new strips to perform the measurements. Blinking result is not saved in the memory.</p>

Substituting the batteries

The **multiCare-in** instrument houses two lithium batteries 3V (type CR 2032).

If the battery icon is blinking, the charge is low and the battery must be replaced before taking a measurement.

Always insert a new battery and not a used one.

Shut down the instrument before removing the battery.

Check out the new battery to see if it is of the right type before placing.

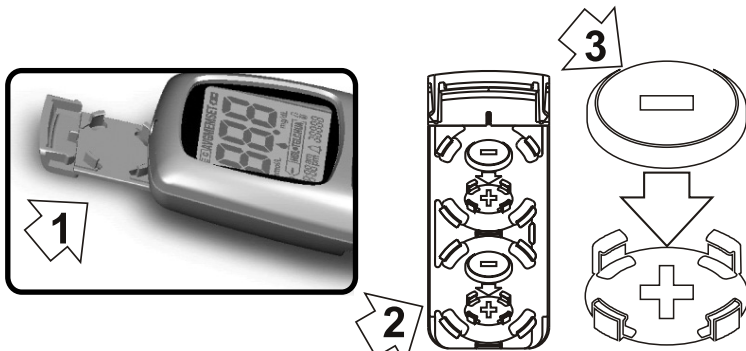
How to change the battery:

- Open the sliding rear panel of the instrument (1).
- Remove the battery from the plastic holder (2).
- Place the new battery so that the type is readable. The negative side of the battery must be at the top (3).
- Close the back cover until a click is heard.

Flat batteries can be disposed of through recycling centers.

Note

If the battery is replaced or simply removed for more than 60 seconds, it is necessary to set time and date again.





Information on the conditions of warranty

Warranty

Biochemical Systems International Srl grants to the customer that the instrument will be free of material defects and manufacturer handling for 3 years starting from the purchasing date. During such period, Biochemical Systems International Srl should replace the defected instrument with an equivalent version or the same model after verifying the defect.

Such warranty is subject to exception and limitation as described below. The warranty is limited to the replacement due to defects in some parts and handling. Instruments that present defects due to damages caused from improper use, alteration, negligence, technical assistance performed from not authorised personnel, accident, abuse or by using strips which are different from **multiCare-in** will not be replaced.

Biochemical Systems International Srl reserves the right to apply technical modifications to the instrument **multiCare-in** without the obligation to insert such specification to those products already introduced in the market.

Any other warranty will be granted for this product unless the replacement option described above. Every responsibility for special, indirect or consequential damages is excluded.





Cognome/Vorname/First name/Prenom/Nombre

Nome/Name/Surname/Nom/Appellido

Via/ Strasse/Street/Rue/Calle

CAP & Luogo/PLZ & Ort/Town & Post code/Località/C.P. & Localidad

Telefono/Telefon/Telephone/Téléphone/Teléfono

Telefax/Fax/Faxnummer

E-mail

Numero di serie/Seriennummer/Serial number/Numéro de série/Numéro de serie

Data di acquisto/Kaufdatum/Date of purchase/Date d'achat/Fecha de compra

In conformità al D.L.gs. 196/2003 sulla tutela dei dati prsonali, la informiamo che le informazioni che vorrà fornirci saranno trattate al fine di inviarle il materiale da lei richiesto ed elaborare elettronicamente con l'adozione di misure idonee a garantire la sicurezza.

AUTORIZZO

NON AUTORIZZO

Data/Datum/Date/Fecha

Firma/Unterschrift/Signature

Spedire a / Send to / Envoyer à / Enviar a / Senden zu :

Spett.le

BIOCHEMICAL SYSTEMS INTERNATIONAL s.r.l.

Via G. Ferraris, 220 - 52100 Arezzo - Italia

GAR ED2008 REV01-.JEDFS





Symbols used on the packaging



Follow instructions



In-Vitro-Diagnosticum




Use until...



Batch number...



Store at temperatures between

3 V 
2xCR 2032

3V direct current and battery type



CE mark



Do not dispose the instrument in the urban waste. Perform a separated collecting specific for Electric and Electronic waste or give the instrument to the distributor when you buy a new one or when you want to substitute it. Please refer to local update regulation.





Performance

Performance

Measurement range:	10-600 mg/dl (0.6-33.3 mmol/l) glucose electrodes 130-400 mg/dl (3.3 - 10.2 mmol/l) cholesterol 50-500 mg/dl (0.56-5.6 mmol/l) triglycerides
Power source:	2x3V lithium button cell, type CR 2032. The battery can be used for approx. 1 year with 3 measurements per day (approx. 1000 measur.)
Dimensions:	97 mm - length 49 mm - height 20.5 mm - width
Weight:	65 g (incl. battery)
Display:	LCD
Temperature limits:	10 to 40 °C (50 °F to 104 °F)
Humidity limits:	0% to 90% relative humidity (non-condensing)
Memory capacity:	500 measured values with time and date
Interface for data processing:	Connecting cable
Special requirements for electromagnetic radiation:	The CE mark on the device indicates that it complies with the requirements of the EC directives 89/336/EEC relating to electro-magnetic compatibility 73/23/EEC for electrical equipment intended for use in areas of specific voltage levels
Hint for Healthcare Professionals:	The appropriate legal provisions apply or the use of multiCare-in . The accuracy of the instrument should be checked after 3 years
Waste management disposal when the meter is unusable:	Please refer to local updated regulation!





Customer Service

Web: www.biosys.it
e-mail: multicarein@biosys.it
Phone: 0039.0575.984164

CE
0344



Biochemical Systems International Srl
Arezzo - Italy

ED2013 MAGGIO-E





multiCare[®]in



BIOCHEMICAL SYSTEMS INTERNATIONAL s.r.l.
Via G. Ferraris, 220 - Arezzo Italia
<http://www.biosys.it>
e-mail: multicare@biosys.it

