OG*Care*

NO CODING GLUCOMETER

USER'S MANUAL

In-Vitro Diagnostic aid for self testing of GLUCOSE

When history generates the future...

OG*Care*

MEM

110

mg/dL

3- 5   10:40 am

M   C

biosys

BSI
Biochemical
Systems
International
www.biosys.it

CONTENTS:

WELCOME

Thank you for selecting the OGCare BGMS (Blood Glucose Monitoring System). Follow steps for using the system in this manual. Before using your monitoring system for the first time, please read this manual carefully.

INTENDED USE

This OGCare Blood Glucose Monitoring System is intended for the quantitative measurement of the concentration of glucose in whole blood from fingertip, palm and forearm by diabetic patients or healthcare professionals as an aid in the management of diabetes. It is intended for use outside of the body (in vitro diagnostic use) and not for diagnosis of or screening for diabetes, nor for use on neonates or arterial blood. The alternative site testing (palm and forearm) in this system can only be used during steady-state blood glucose conditions.

APPLICATION

OGCare Test Strips are for in vitro diagnostic use only.
The OGCare Meter is not a substitute for your healthcare professional.
Use the OGCare Meter in conjunction with your healthcare program.

TEST PRINCIPLE

Glucose in the blood sample reacts with glucose oxidase (GOD) on the test strip and a harmless DC electrical current is produced. This current is measured by the OGCare Meter and displayed as your blood glucose result. The strength of these currents changes with the amount of glucose in the blood sample.
The OGCare Meter automatically interprets this reaction.
Blood glucose results from test strips that are plasma-referenced are approximately 11% higher than those obtained with whole-blood referenced test strips.

SPECIAL FEATURES

Accurate results in 5 seconds with using only 0.5 µL blood sample.
The OGCare system applies the auto coding system.
Store up to 300 test results. Your meter was set at the factory to the unit used in your country.

USAGE AND STORAGE

• Before using your monitoring system, please place it in the environment of system's normal operating temperature ranging 10-40°C (50-104°F) for about 20 minutes.
• Don't allow dust and foreign bodies into test strip slot in order to avoid affecting the system's accuracy.
• Don't decompose, demolish, repair or transform the system at any time.
• Don't put the system near any electromagnetic field. (e.g. TV, microwave oven, mobile phone)
• Don't allow the monitoring system to collide with others during usage.
• Keep away from direct sunlight and humid environment for long time.
• Please use a soft cotton cloth to wipe the system.
• Don't use a corrosive product (e.g. Benzene, Acetone) to wipe the monitoring system.

IMPORTANT TEST STRIP INFORMATION

• Use test strips immediately after retrieving from the vial.
• Keep the test strip vial tightly closed at all times.
• Take test strips out with clean, dry hands for accurate results.
• Do not use test strips beyond the expiration date printed on the package since they may cause inaccurate results.
• Never reuse a test strip that has had either blood or control solution applied to it. The OGCareTest Strip is for one time use only.
• Before the test you must make sure that the code number on the meter is identical with the one on the test strip vial.
• Be sure to check the glucose measurement unit on the meter before the test.
• Store in capped vial in a cool and dry environment between 5-30℃ (41-86°F).
• Keep away from direct sunlight and heat. Do not refrigerate.

CAUTION:
OGCare Meter is for use only with OGCare Strips

SAFETY INFORMATION

- Before using the system, please read this manual carefully.
- The meter and test strips should be handled at same temperature.
- For accurate results, keep the OGCare blood glucose monitoring system at test place under the operating temperature 10-40°C (50-104°F) for more than 20 minutes before testing.
- The OGCare Blood Glucose Monitoring System shows accurate results between 10-40°C (50-104°F).
- Do not store the meter, test strips, lancing device and lancet in a place where the children can reach easily.
- Please disinfect instruments and parts for blood collection.
- Do not reuse the test strips.
- The used test strips and lancets should be handled carefully.
- The OGCare Blood Glucose Monitoring System is for testing outside of the body (in vitro diagnostic use). Safety Information.

#HEALTHCARE PROFESSIONAL INFORMATION

Healthcare professionals performing blood glucose tests with this system on multiple patients must always wear gloves and should follow the infection control policies and procedures approved by their facility.

• When using the OGCare meter follow always the recognized procedures for handling objects that are potentially contaminated with human material.
• Practice the health and safety policy of your laboratory or institution.
• A drop of blood is required to perform a blood glucose test.
• Only capillary blood can be used.
• Avoid air bubbles when using pipettes.
• Refrigerated samples should be brought to room temperature slowly before testing.

#OGCARE METER
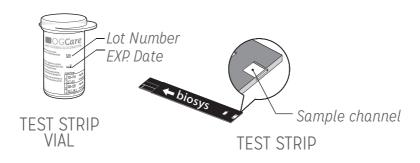
FRONT

Display

"M" Button

"C" Button

Test strip slot

BACK

USB port

Battery lid

Serial number

OG*Care*
Meter

IVD ⚠ CE
0344

☒ ⬛ 3V
2 x CR2032

SN

▮▮ 🔬 Biochemical
Systems
International
Made in Italy   Arezzo - Italy

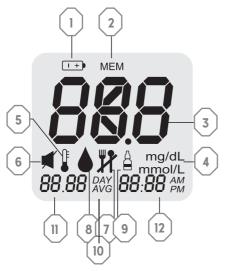# OGCARE TEST STRIPS

Lot Number
EXP. Date

TEST STRIP VIAL

Sample channel

TEST STRIP

• Use OGCare Test Strip with the OGCare Meter.
• Please check the expiration date of test the strips before use.
• Please write the opening date of the new test strip vial in order to avoid using the expired products.

EXPLANATION OF THE DISPLAY

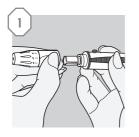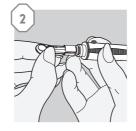|		
1	🔋	**Low Battery Warning**
2	MEM	**Stored test result**
3	888	**Test results**
4	mg/dL mmol/L	**Unit of measurement**
5	🌡	**Temperature error**
6	🔇	**No beep**
7	🍴	**Pre/post meal mark**
8	♦	**Ready to test**
9	🧪	**Control solution**
10	AVG	**Average result**
11	88.88	**Month/Date**
12	88:88	**Time**

DISINFECTION BEFORE TEST
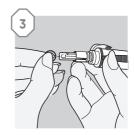
- Before test, please clean hands with soap and water and then dry then well.
- You can also use an alcoholic cotton cloth to clean the finger.
- Please wait until the alcohol disappears completely.

PERFORMING A BLOOD GLUCOSE TEST

1. Turn the cap counterclockwise to remove it.

2. Insert the lancet into the lancet holder and push down firmly until it is fully seated. Do not twist the lancet.

3. Twist the protective disk until it separates from the lancet.
Replace the lancing device cap. Turn it clockwise until it is snug.
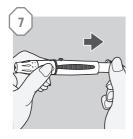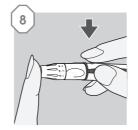
4. Insert a test strip to turn on the meter. Push it all the way in until it will go no further. Avoid bending the test strip.

*5.*The meter identifies the code number automatically. Compare the code number display with the code number on the test strip vial. If they do not match try again with an another test strip. If the problem happens with another test strip, please contact to Customer Service.

6. When the blood symbol appears, the meter is ready for testing.
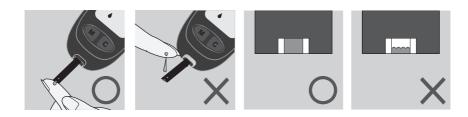
7. Select the puncture depth if necessary with the lancing device cap. Activate the lancing device by pulling back the barrel until it clicks. If it does not click, the lancing device may have been activated when the lancet was inserted.

8. Hold the lancing device firmly against your finger. Press the release button.

9. Gently squeeze your finger to assist the flow of blood.
Do not squeeze excessively on the puncture site.

10. Put blood on top of the test strip. When you hear the beep sound, you have enough blood in the test strip. After five seconds, the test result will appear.

NOTICE:
When the blood sample is not sufficient, the display will show the message of 'Er 4'.(Please refer to error messages in this manual.)

CAUTION:
• *Do not drop the blood directly on the end of the test strip. The sample channel at the end of the strip should be filled with blood.*
• *When you hear the beep sound, you have enough blood in the test strip.*

Display for unit mg/dL | *Display for unit mmol/L*
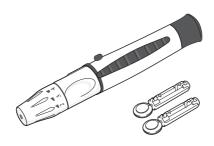
11. The test result will appear after the meter counts down 5 seconds.
During count down, please do not shake it.
12. After 5 seconds, you can hear the beep sound: the screen will display test result.
After taking the strip out, the meter will be turned off automatically.

NOTICE:
If the test result is abnormal, please retest with a new test strip. If the new test result has also problems, please refer to the Troubleshooting in this manual.
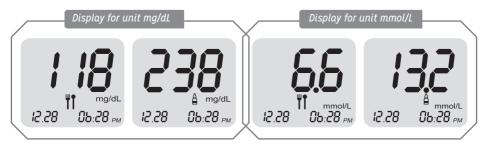
FLAGGING TEST RESULTS

Display for unit mg/dL

Display for unit mmol/L

If you wish to flag post-meal results or control solution results, you can flag the meal or control solution mark using 'M' or 'C' button with the test result shown on the display, and the test strip still in the meter. When you push the 'M' or 'C' button the meal mark or control solution mark will be toggled.

NOTICE:
The 14 days average result does not include test results with the control solution mark.

 # HANDLING THE USED TEST STRIP

1. After testing, please write the test result in the logbook every time.
When you ask the doctor please take the logbook out:
it is helpful for your treatment.
2. Use the strip ejector located backward of the meter to remove the used test strip.
3. After taking the test strip out, the meter will be turned off automatically.
4. The used test strip should be handled carefully.

ALTERNATIVE SITE TESTING (AST)

Contact your healthcare professional before you begin using anyone of these alternative sites to test your blood glucose.

1. Alternative site results may be diferent from fingertip results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise).
2. Use alternative site testing only two hours or more after taking insulin, two hours or more after a meal, two hours or more after exercise.
3. Do not use alternative site testing if you are pregnant, or if you are aware that your glucose level is not as stable as usual, or if you think you have hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar), or at times when you think your blood glucose may be rising or falling rapidly.
4. Do not use alternative site testing if your alternative site testing results do not match the way you feel.

Do not rely on test results at an alternative sampling site, but use samples taken from the fingertip, if any of the followings applies:

- you think your blood sugar is low
- you are not aware of symptoms when you become hypoglycemic
- the site results do not agree with the way you feel
- after a meal
- after exercise
- during illness
- during times of stress

CAUTION:
• *Do not change your treatment because of just one result.*
• *Never ignore symptoms of high or low blood glucose.*
• *If your blood glucose does not match how you feel, perform a fingertip/palm test to confirm your result. If the fingertip/palm result still does not match how you feel, call your healthcare professional.*

LANCING AND SAMPLING FROM AN ALTERNATIVE SITE

Sampling from your palm or forearm allows you to use your fingertips less often. You may find that obtaining a blood sample from an alternate site is less painful than using a fingertip. Getting a blood sample from your forearm or palm is different from getting a sample from your fingertips.

Forearm sampling
Choose a fleshy area of the forearm away from bone, visible veins and hair. Sometimes there is less blood flow to the forearm than to the fingertips. To help you get a large enough drop of blood, you may gently massage or apply warmth to the site to increase blood flow.

Forearm

Palm sampling
Choose a fleshy area on the palm below your thumb or pinky finger. Select a spot with no visible veins and away from deep lines which may cause your blood sample to smear.

Palm

NOTICE:
• You may need to wait a little longer to get a large drop of blood from the forearm or palm. Do not squeeze the site excessively.
• If the sample drop of blood runs or spreads due to contact with hair or with a line in your ventral palm, do not use that sample.
Try puncturing again in a smoother area.

 # USING THE SET-UP MODE

1. Press "M" button for 3 seconds, you will hear the beep, the screen will show the whole symbols of the system.

2. After 1 second, the 'SEt' will be displayed on the screen.

3. Setting Month: when month blinks, press and release "C" button until the correct month appears. Press 'M' button to set and move to date set mode.
4. Setting Date: when date blinks, press and release "C" button until date appears. Press 'M' button to set and move to time set mode.
5. Setting Time Format: the meter can be set in an AM/PM 12-hour default format. Press 'C' button to shift to 24-hour format. After selecting the time format, press 'M' button to set and move to hour setting mode.

6. Setting Hour: when hour blinks, press and release "C" button until the correct hour appears. Press 'M' button to set and move to minute set mode.

7. Setting Minute: when minute blinks, press and release "C" button until correct minute appears. Press 'M' button to set and move to year set mode.

8. Setting Year: entering the year mode, the screen will show the number "11". This number stands for the 2011 year. Press 'C' button until the correct year appears. Press 'M' button to set and move to the beeper on/off mode.

Display for unit mg/dL | *Display for unit mmol/L*

9. Glucose measurement unit: your new meter has the glucose measurement unit set to "mg/dL" or "mmol/L".

You cannot change the unit. Otherwise, please contact your Customer Service.

CAUTION:
- *Use of the wrong glucose measurement unit may cause you to misinterpret your blood glucose level and incorrect treatment.*

- *Consult your healthcare professional if you have any questions about blood glucose measurement units.*

10. Beeper ON/OFF: your new meter has the beeper preset to "On".
You can set the beeper to "Off" with pressing 'C' button, if you prefer this will
not work during the system functioning.
Press 'M' button to set and move to the next mode.

DELETING TEST RESULTS
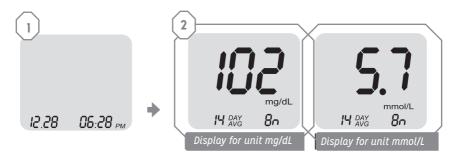
1. Turn on the meter by pressing button 'M' for 3 seconds to enter the Set-Up mode
2. Display shows the "SEt" when enter Set-Up mode.
3. Press and release 'M' button until the screen will show the word 'dEL'
briefly.

4. If you wish to leave the test results in the memory select "NO" option. You can toggle the option with 'C' button. Press 'M' button to move to the next set mode.

5. If you wish to delete the all test results from the memory, toggle the option to set "YES" and press 'M' button.

6. After deleting, the screen will appear as in the picture.

By pressing again 'M' button the meter will be turned off.

REVIEWING TEST RESULTS

Display for unit mg/dL   *Display for unit mmol/L*
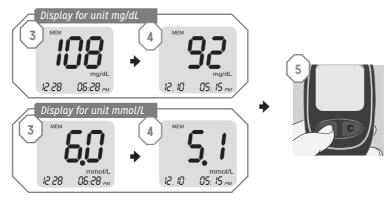
1. Begin with the meter off. Press 'M' button, you will hear a beep sound and
the meter will be turned on .
The screen will display the date and time.
2. After 2 seconds, the last 14 days average result will be displayed

Display for unit mg/dL

Display for unit mmol/L

3. Press 'C' button once, the screen will show the most recent test result.
4. Each time pressing 'C' button, the screen will show the previous test result.
5. After completing the reviewing, press 'M' button to turn off the meter.

NOTICE:
If you don't make any changes, the meter will be turned off automatically after 100 seconds.

DOWNLOADING TEST RESULTS TO A PC

You can transfer the test results from the OGCare Meter to a computer, where they can be summarized in a report with graphs and tables.
To make use of this feature, you need OGCare Link Software and the OGCare Link Cable .

For more information, please contact your Customer Service or visit our Website at www.biosys.it
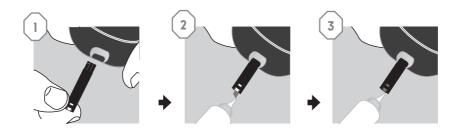
WHEN PERFORM CONTROL TESTS

Performing a control test lets you know that your meter and test strips are working properly to give reliable results.
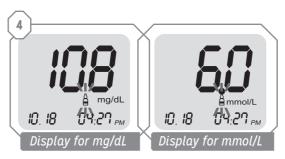
You should perform a control test when:
- You open a new box of test strips.
- You left the test strip container open.
- You want to check the meter and test strips.
- Your test strips were stored in extreme conditions of temperature or humidity.
- You dropped the meter.
- Your test result does not agree with how you feel.
- You want to check if you are testing correctly.

PERFORMING A CONTROL SOLUTION TEST

1. Insert the test strip. Then the code number will appear. Be sure the meter
and teststrip codes match. If they do not, please contact your Customer Service.
2. Shake well before using the control solution. Discard the first drop.
Wipe the dispenser tip. Hold the drop to the narrow channel in the top edge of
the test strip.
3. When the confirmation window is full, the meter will begin with the beep sound.

| Display for mg/dL | Display for mmol/L |

4. Mark all control solution test with 'Control Solution Mark' to distinguish them from blood glucose test results in the meter memory.

Marked control solution tests will not be included in your averages.
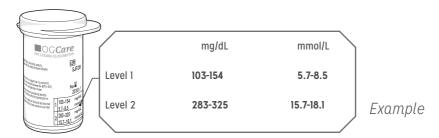
CAUTION:
If you continue to get control solution test results that fall outside of the range printed on the vial, the system may not be working properly.
Do not use the meter. Please contact your Customer Service.
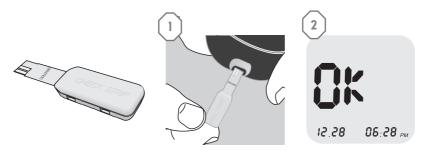
UNDERSTANDING CONTROL SOLUTION TEST RESULT

	mg/dL	mmol/L
Level 1	**103-154**	**5.7-8.5**
Level 2	**283-325**	**15.7-18.1**

Example

· The label on the vial of test strips show acceptable range for both level 1 and 2 of control solution.

· The result obtained should fall within this range.

Be sure to compare the result with the correct level of control solution.

· Each batch of test strips has different ranges of control solutions.

 # PERFORMING THE CHECK STRIP TEST

OGCare Glucose Check Strip only tests the function of the meter.

To test the entire system, please rely on the results from testing a control solution.
1. Begin with the meter off, insert the OGCare Glucose Check Strip in the meter's test strip slot.
2. If the "OK" Message is not displayed on the screen after inserting the Glucose Check Strip, please contact your Customer Service.

 # CLEANING YOUR METER

Caring for your OGCare meter is easy. Just keep it free of dust.
If you need to clean it, follow guide lines carefully to help you to
get the best performance possible:

· Make sure the meter is off
· Gently wipe the meter's surface with a soft cloth slightly dampened
  with one of these cleaning solutions:
- 70% isopropyl alcohol
- Mild dishwashing liquid mixed with water 10% household bleach
  solution made on the same day
· Make sure you squeeze off excess liquid from the cloth before you
  wipe the meter's surface.
· Do not get moisture in the test strip or test strip slot.
· Do not spray any cleaning solution directly onto the meter.
· Do not put the meter under water or liquid.
· Do not pour liquid into the meter.

REPLACING BATTERY

1. When the energy of the batteries is not enough, the screen shows and blinks the battery mark.
It indicates that the energy left could operate testing about 50 times more. In this period, we suggest that you should replace the battery.
After replacing the battery, the stored results will remain, but the date and time need to be reset.

2. Open the battery lid and replace the old batteries with the news ones (CR2032).

SCREEN MESSAGES

MESSAGES	DESCRIPTION	SOLUTION
Er 1 12:28 06:28 PM	*Test Strip is used or damaged.*	Use a new test strip
Er2 12:28 06:28 PM	*Blood sample was applied to the test strip before the blood symbol (🔻) appeared on the screen.*	Apply blood sample to the test strip after the blood symbol appears on the screen.
Er3 12:28 06:28 PM	*Temperature is too hot or too cold for the system to work properly.*	The operating temperature should be 10~40°C (50~104°F). Please use the system after about 20 minutes.
Er4 12:28 06:28 PM	*The blood sample is not enough for measurement because of abnormally high viscosity or insufficient volume*	Repeat test with a new test strip.

MESSAGES	DESCRIPTION	SOLUTION
Er5	*You put the wrong strip.*	Please check if the strip is OGCare. Please check the strip is inserted properly. Please test once again with a new test strip.
Er6	*This error is shown when the meter itself finds out internal problems.*	Please contact Customer Service
HI	*The result is higher than 600mg/dL(33.3mmol/L). It indicates that the value of your blood glucose is too high.*	Retest with a new test strip. If 'Hi' mark appears again, please call your healthcare professional immediately.
Lo	*The result is lower than 20mg/dL(1.1mmol/L). It indicates that the value of your blood glucose is too low.*	Retest with a new test strip. If 'Lo' mark appears again, please call your healthcare professional immediately.

TROUBLESHOOTING

CAUSES	SOLUTIONS
The meter does not work after the blood is applied	Make sure the test strip is inserted into the test strip slot completely. Check whether the test strip has foreign bodies adhered. Make sure the blood is applied to the test strip correctly. Make sure the test strip inserted direction is correct and repeat test.
Test result is abnormal.	Check whether the test strip has foreign bodies adhered or exposed for long time. Check whether the test strip is used. Check whether the test strip has become invalid. Check whether the test strip vial opening date has passed more than 3 months. Make sure the meter code and test strip code match.
The thermometer mark (🌡) appears on the screen.	Keep the meter and test strip into the operating range of temperature 10~40°C (50~104°F). You should use it after about 20 minutes. If the thermometer mark appears always the on the screen, please call to Service Center.
The meter does not work after inserting test strip.	Make sure the test strip is inserted into the strip slot completely. Make sure the battery shows positive side facing upward.

SPECIFICATIONS

PRODUCT NAME	*OGCARE*
MODEL NAME	*GLUCOMETER*
CALIBRATION	*PLASMA-EQUIVALENT*
SAMPLE VOLUME	*0.5 µL*
TEST STRIPS TYPE	*OGCARE STRIPS*
RESULT RANGE	*20-600 MG/DL (1.1-33.3 MMOL/L)*
TEST TIME	*5 SECONDS*
METER POWER SOURCE	*DC 3V (CR2032) X 2*
BATTERY LIFE	*APPROXIMATELY MORE THAN 1000 TESTS*
MEMORY	*300 TEST RESULTS (INCLUDING DATE AND TIME)*
DATA OUTPUT	*USB DATA TRANSFER CABLE*
DISPLAY	*LCD (BACKLIGHT IS OPTIONAL)*
OPERATING TEMP.	*10-40°C (50-104°F)*
OPERATING HUMIDITY	*10-90% RH*
STORAGE TEMP	*5-30°C (41-86°F)*
DIMENTIONS	*18X51X88 (MM)*
WEIGHT	*APPROXIMATELY 48 GR (WITH BATTERY)*

WARRANTY

The makers guarantee that the OGCare Blood Glucose Meter shall be free of defects in material and workmanship for a period of three years. This guarantee is valid from the date of purchase. The guarantee extends only to the original purchaser and is not transferable. The warranty ceases to apply under the following conditions:

. The meter is damaged as a result of incorrect use.
. The meter is damaged as a result of natural disasters (e.g. typhoon, earthquake etc.)
. The meter is damaged as a result of demolition.
. The meter is damaged because you use products which are not compatible with our products.

SYMBOLS

KEEP AWAY FROM SUNLIGHT	WARNING	MANUFACTURER	LOT	Temperature Range	CATALOGUE NUMBER	Autorized representative in the EU
	⚠	▟	LOT		REF	EC | REP
VALIDITY DATE	IVD	📖	DATE OF MANUFACTURE	SINGLE USE	SN	DIRECT CURRENT
	IN VITRO DIAGNOSTIC	REFERENCE MANUAL			SERIAL NUMBER	

EMC TEST RESULTS

· It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.

· It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.

· Do not use this instrument in proximity of sources of strong electromagnetic radiation, as these may interfere with the proper operation.

DISPOSING OF YOUR METER

During blood glucose measurement the meter itself may come into contact with blood. Therefore used meters therefore carry a risk of infection. Please dispose of your used meter - after removing the battery - according to the regulations applicable in your country. For information about correct disposal, please contact your local council and authority. The meter falls outside the scope of European Directive 2002/96/EC (Directive on waste electrical and electronic equipment (WEEE)).

WARRANT CARD (3 YEARS)

Name: .... **Age:** **Sex:** [M] [F]

Address: .... **City:** .... **zip code:** ....

Tel. .... **Serial No.(Back of the Meter)**............................

Date of purchase: .... **Place of purchase:** ....

Notes :

....

ADDITIONAL SUPPLIES

The following supplies and accessories are available from your authorized Biochemical Systems International representative, pharmacies, or your medical/surgical supply dealer:
Control Solutions
Glucose Control Solution Level 1
Glucose Control Solution Level 2
Check Strip
Connecting cable
Software to download data

■OG*Care*

NO CODING GLUCOMETER

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