BETACHEK® C50

Cassette Blood Glucose Monitoring System

User's Manual and Quick Start Guide

Cassette

Integrated Lancing

50 tests

BETACHEK C50

S   M

Model C50-1

Download on the **App Store**

NDP

Preparing the Betachek C50 meter (see back cover for parts list)

1 Remove protective film from the screen

Pull protective tab from the battery compartment.

2 Slide sensor cover to the left as far as it will go. Meter will turn on.

888 mmol/L

3 Insert cassette, close sensor cover

Press Flat

4 Slide open lancet cover

5 Insert lancet and twist off cap

6 Close lancet cover and set desired penetration depth

Performing a test

1 Wash hands in warm water

2 Dry your hands *thoroughly*

3 Open the sensor cover and wait for the wind-on symbol: ↻

4 Turn the thumbwheel until a test zone is in position and screen displays "OK".

OK

5 Press depth selector firmly against selected puncture site, then press S*

BETACHEK C50

*To repeat close and open sensor cover to re-cock

6 Gently squeeze out a small round blood drop.
Use Immediately
Do not allow the drop to dry, run or spread

7 Apply blood

✓ Aim for the red flashing light

✓ Cover illuminated area with blood

8 Results in approx. 5 seconds

9:38 am 28·12
6.8
mmol/L

9 Turn the thumbwheel (to dispose of the used test) until "OK" is displayed.

OK

10 Close the sensor cover. The meter will turn off.

1. Sensor cover
2. Display
3. Sample/settings button
4. Memory recall button
5. Penetration depth selector
6. Lancet holder
7. Lancet
8. Lancet ejector
9. Test cassette
10. Thumbwheel
11. Battery cover
12. Lancet cover
13. Penetration depth indicator
14. Sensor

Contents

Intended use

The Betachek® C50 system is for the quantitative determination of glucose in fresh capillary blood, for the management of diabetes.

Suitable for self-testing only.

The meter may only be used for blood glucose testing by one person.

There is a risk of infections being transmitted if the meter is shared with other people, or if health care professionals use the same meter for testing blood glucose in more than one person. This meter is therefore not suitable for professional use in health care centres, doctors offices or hospitals.

Lancing device

The integrated lancing device is intended for personal use only. It may not be shared with other people. There is a risk of infections being transmitted if the lancing device is used by more than one person, or if health care professionals use this lancing device to obtain blood from more than one person. The lancing device is therefore not suitable for professional use in health care centres, doctors offices or hospitals.

Main features

- No test strip handling - Cassette System
- No waste disposal - Ideal for on the go testing
- Fully integrated lancing device with 10 penetration settings
- Auto priming lancing device
- Wireless automatic data transfer to mobile device
- Results in approx. 5 seconds
- Only 0.6µl sample needed
- Optimal accuracy with RFID coding
- Auto on and auto off
- Large, easy to read screen
- 1 and 2 hour test reminders
- Flagging results
- 500 in meter memory locations with time and date
- 7, 14, 30 and 90 days averaging
- Compact size fits in pocket or purse

System components

- Betachek® C50 Meter and battery
- Betachek® C50 Test Cassette
- Betachek® Control Solutions
- Betachek® Lancets (also compatible with Softclix® Lancets)

1   Getting to know your C50 Meter

Parts summary

1   Sensor cover
2   Display
3   Sample/settings button
4   Memory recall button
5   Penetration depth selector
6   Lancet holder
7   Lancet
8   Lancet ejector
9   Test cassette
10 Thumbwheel
11 Battery cover
12 Lancing device cover
13 Penetration depth indicator
14 Sensor

Button functions

| M |
| :---: |
| Memory - recall test results and averages (sensor cover closed) |
| **S** |
| Sample - fire the lancing device (sensor cover open) |
| Settings menu (sensor cover closed) |
| **S** & **M** |
| Turn meter off |
| System tools menu (sensor cover closed) |

2   Meter set up

Checking the unit of measure

Blood glucose results can be displayed in two different units of measurement (mmol/l or mg/dl). Your meter is factory set to display only one. This unit of measure can be checked during the:

- Display check (See section Checking the display)

mg/dL meter

mmol/L meter

- Numeric display check (See section Test procedure)

mg/dL meter

mmol/L meter
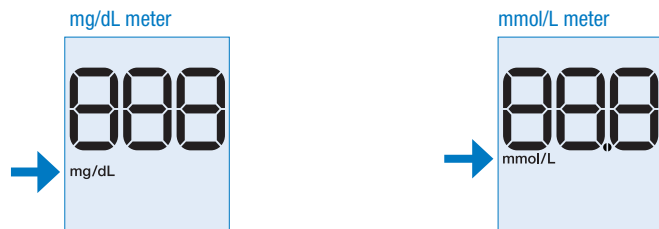
Using the wrong unit of measurement will cause you to misinterpret the results. If you do not know which is the right unit of measurement for you, please ask your doctor.

If the wrong unit is displayed by your meter or if any of the display elements are missing, please contact support@betachek.com to arrange for your meter to be replaced.

Inserting a test cassette

A test cassette must be inserted before testing can begin. Test cassettes are sold separately.

Important: Only remove a test cassette from its container when you are ready to insert it into the meter. The container protects the test cassette against damage and moisture. Once you have loaded a cassette into the meter there is no need to remove it from the meter, unless the meter is being cleaned. Test cassettes must be used within 90 days of opening.
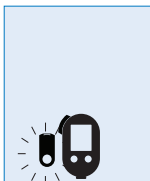
Step 1   Open the sensor cover

Slide the sensor cover in the direction of the arrow as far as it will go.
This will turn the meter on.

Step 2 Insert test cassette

When the insert cassette symbol is displayed, remove cassette from the container and press it into position as shown.

The test cassette should lock into place securely and lie flat in the meter.

Important:
Check the cassette is locked in place. It should not lift out once installed.

Removing a test cassette

After all 50 tests have been used, simply remove the used test cassette and dispose of it in your regular household waste.

Step 1 Slide open the sensor cover

Step 2 Remove test cassette

Push the cassette forward slightly as shown. (There are curved grips on the cassette to press on.)
Next, lift the cassette out.

Test cassette validity

The validity of a test cassette is determined by the use by date and/or the use by period.

The use by date is printed on the packaging and states the date which a test cassette stored in its container is valid until.

After inserting the test cassette into the meter, the test cassette must be used up within a period of 90 days.

Upon insertion, the meter can read the test cassette use by period and displays the countdown of days remaining before expiry, see section Checking the expiry date of an opened test cassette.
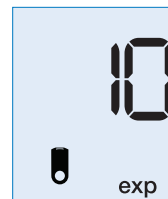
10 days until expiry

You will receive notifications 10, 3, 2 and 1 day(s) before the use by period expires when commencing a test.
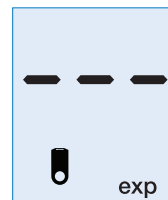
Cassette expired

If either of the two dates are exceeded, the validity of the test cassette has expired and no further tests should be performed.

Remove the expired test cassette and insert a new test cassette to continue testing, see section Inserting a test cassette and Removing a test cassette.

3 Changing settings

In order to properly analyse test results or set reminders you need to set the correct time and date. If the meter is paired to a mobile device, this is done automatically, so you may prefer to go straight to the pairing section. You can still perform a test without adjusting the meter settings.

Enter Settings menu

To enter the Settings menu, hold down the S button for approx. 3 seconds with the sensor cover closed.

To set up meter preferences scroll through the options using the buttons shown below. The flashing item may be changed or accepted.
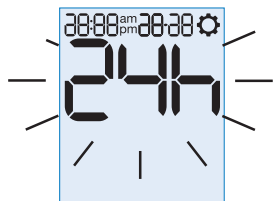
S — Accept

M — Change

Order of Settings menu
Press and hold S button
Time format (24 or 12)
S
Time (Hour)
S
Time (Minute)
S
Date (Year)
S
Date (Month)
S
Date (Day)
S
Date format (dd-mm or mm-dd)
S
Sound (On or Off)
S
Bluetooth (On or Off)
S
Meter off

Step 1 Select time format (24h/12h)

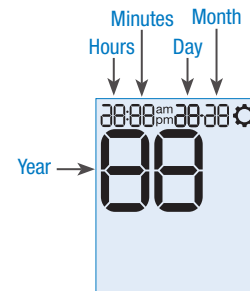Press the M button to switch between options, or, press the S button to accept and proceed to the next step.

Step 2 Set time

24-hour format: Hours ➡ Minutes

12-hour format: Hours ➡ Minutes ➡ am/pm

Press the M button to set the time, or, press the S button to accept and proceed to the next step.

Minutes   Month
Hours   Day
Year

Step 3 Set date

Year ➡ Month ➡ Day

Press the M button to set the date, or, press the S button to accept and proceed to the next step.

Step 4 Set date format

(dd-mm) OR (mm-dd)

Press the M button to switch between options, or, press the S button to accept and proceed to the next step.

Step 5 Turning the sound on and off

Select 🔊 On to turn the sound on OR Select 🔊 OFF for the meter to be silent.

Press the M button to switch between options, or, press the S button to accept and proceed to next step.

Sound ON   Sound OFF
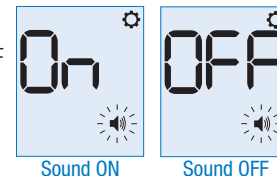
Step 6 Turning the bluetooth on and off (Flight mode)
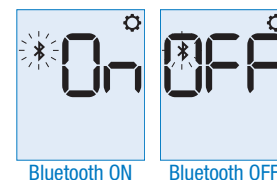
Select ✳ On to turn the bluetooth on OR Select ✳ OFF to turn the bluetooth off.

Press the M button to switch between options, or, press the S button to accept.

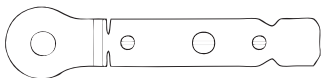The meter will save the settings and turn off.

Bluetooth ON   Bluetooth OFF

4   Preparing the lancing device

Inserting a lancet

The Betachek® C50 meter has an integrated lancing device compatible with Betachek Lancets and Softclix® lancets.

> **Important: The lancing device is intended for personal use only. It may only be used by one person for obtaining blood. If used by other people, there is a risk of infection being transmitted. .**

Step 1   **Open cover**

Push the curved grips as shown and slide the cover away from the meter. It will then spring open.
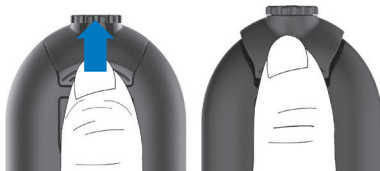
Step 2   **Insert lancet**

Insert the lancet into the lancet holder. Push the lancet in as far as it will go.
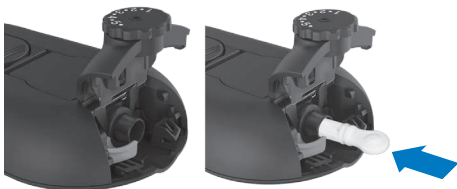
Step 3   **Remove protective lancet cap**

Twist off the protective lancet cap and close the lancing device cover.

Step 4   **Close the lancet cover**

Press the lancet cover down and then slide it back until the cover is closed.

1.

2.
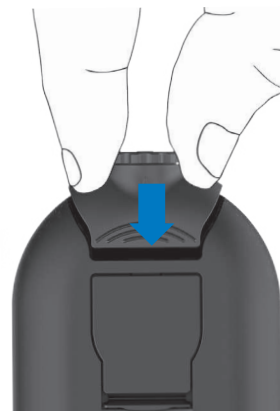
Setting the penetration depth

To produce virtually pain free sampling, you can set the penetration depth to one of 10 settings; "•" being the lowest penetration and 5 being the highest. If you are unsure, begin with 3, and adjust as required.

Turn the penetration depth selector dial until the desired number aligns with the penetration depth indicator see section Parts summary.
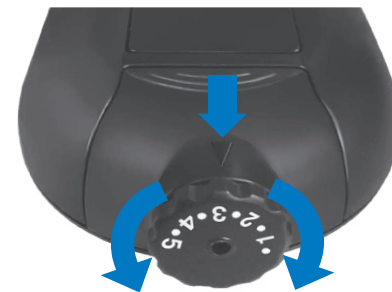
Removing a lancet

Open cover

Push the curved grips as shown and slide the cover away from the meter. It will then spring open.

Step 2 Eject **lancet**

Hold the green lancet ejector and gently pull until the lancet comes out of the lancet holder. Return the lancet ejector to its original position.

Note: Used lancets may be disposed of in household waste. Lancets should first be placed in a suitable sharps container to prevent accidental injury.

5 Performing a blood glucose test

Preparation

You need:

- a Betachek C50 Meter,
- a Betachek C50 test cassette
- a lancet loaded into the C50 meter.

To perform a blood glucose test for the first time, you must:
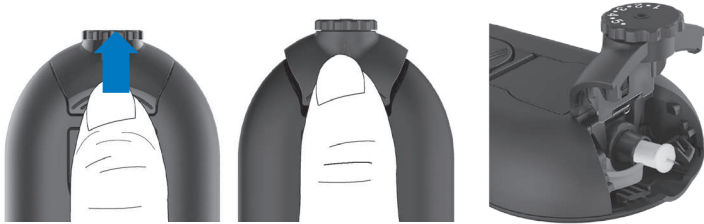
- Load a C50 test cassette into the C50 meter,
- Insert a lancet into the C50 integrated lancing device, and,
- Set the penetration depth of the C50 integrated lancing device

Wash your hands with warm soapy water. This removes traces of glucose from your hands that may contaminate the test sample and increases blood flow to your fingers to make it easier to obtain a blood drop without excessive squeezing.

Important: Dry your hands thoroughly!

Notes on blood glucose testing:

- Only use test cassettes that are within the expiration date.
- Do not rub the blood drop on the test zone when applying blood.
- Only apply blood to the test zone when the blood drop symbol is flashing on the display.
- Only a small drop of blood is required. If you have profuse bleeding select a lower number on the penetration dial to reduce pain and damage to your skin.

Test procedure

Open sensor cover
Slide sensor cover in the direction of the arrow.

The meter will turn on and run a numeric display check.
Check that all the segments are functioning correctly as shown below.

mg/dL meter
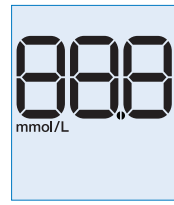
mmol/L meter

Note: If any numeric segments are missing, contact your local distributor or customer service line to change the meter.

The meter will then display the number of tests remaining.

49
tests
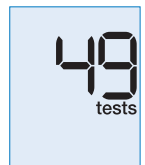
Wind on test
Next the meter will flash arrows in a circle, this indicates the thumbwheel should be turned.
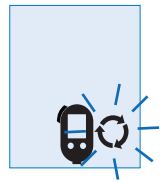
Before blood can be applied, a test zone needs to be moved into position. This is done by turning the thumbwheel.

Thumbwheel

Note: The thumbwheel is locked when the sensor cover is closed.

Turn the thumbwheel in the direction of the flashing arrow to bring a test into position.

If the thumbwheel is turned in the wrong direction a loud clicking noise will be heard. There is no harm caused to the meter if this occurs.

The meter will display the progress with a segment countdown until the test is in place. Slow the winding when only one segment remains.
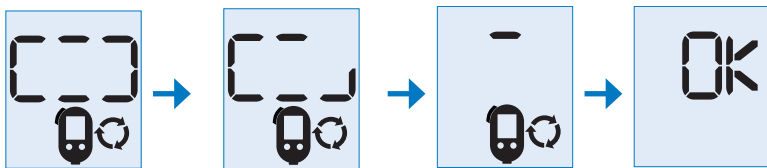
- Start looking for the test when there is only one segment left.
- Keep winding until the meter gives a beep (if sound is on) and displays OK.
- You should see a yellow test zone over the sensor area.

Note: If a test zone is wound too far (past the sensor) an error message will be displayed (E-6). Keep winding until OK is displayed, then close the sensor cover and repeat the test

The meter will then display a flashing blood drop symbol.

- Do not apply blood before the blood drop symbol is displayed.
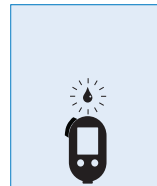
Step 3   Obtain a blood sample

Press your finger firmly against the tip of the lancing device. Press the S button to fire the lancing device.

Gently squeeze the selected finger at the base moving toward the tip. This should be repeated several times to encourage a drop of blood to form.

If the amount of blood is insufficient, close the sensor cover and open it to repeat the lancing step. You may need to select a higher number on the penetration depth adjuster.

Warning: If you have profuse bleeding you need to select a lower penetration depth for the lancet. Excess blood can contaminate the meter and necessitate cleaning of the sensor area. See section Meter maintenance.

Note: You have approx. 2 minutes after the blood drop symbol appears to apply blood to the test zone. If you do not apply blood in this time, the meter will turn itself off and the test zone will be lost.

Step 4 **Apply blood**

- A flashing red light in the test zone will indicate where to put the blood. Aim to cover the red light.
- A small drop is all that is needed.

When a blood drop has been applied, the meter will sound a beep (if sound on) and commence measuring. The flashing hourglass symbol indicates when the test is underway, until a result is displayed.

Test results will be displayed in approx. 5 seconds.

Step 5 **Result**

The meter will display the result with the time and date. The result will automatically be saved to memory.

Do not close the sensor cover if you want to attach a flag to your result.

8:38 am 28.10
124
mg/dL

8:38 am 28.10
6.9
mmol/L
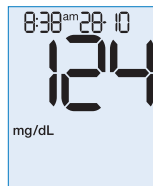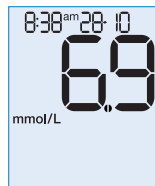
mg/dL meter   mmol/L meter

Note:

The meter will display:

LO   If your test result is lower than 20 mg/dL (1.1 mmol/L)

HI   If your test result is higher than 600 mg/dl (33.3 mmol/L)

Step 6 **Flag result**

- If you want to flag a test result, press the M button repeatedly whilst the result is still displayed.
- When you find the desired flag, press the S button to save the flag with your result. See section Flagging results.

You can not flag a result after you wind off the used test, however you can add a flag at a later time to results uploaded to the Betachek Diabetes Management App. The application is available for free download on the Apple App store.

| Step 7 | **Wind off used test** |

5 seconds after your result is displayed or a flag is selected, the wind symbol is displayed.
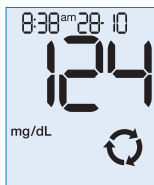
mg/dL meter
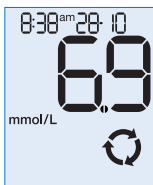
mmol/L meter

Turn the thumbwheel to move the used test into the used test storage compartment of the cassette.

The meter will display the progress with a segment countdown until the used test is in the correct position.
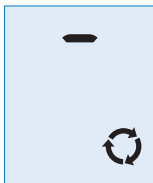
Note: Storing used tests in the used test storage compartment of the cassette reduces the risk of contaminating the meter.

| Step 8 | **Close sensor cover** |

Stop winding when the meter beeps and displays OK. The close sensor cover symbol will then flash.

Close the sensor cover and the meter will turn off.
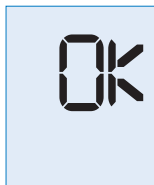
Flagging results

You can flag test results to help you spot blood glucose trends for certain activities and to help describe an event connected with the result.

You can only flag a result whilst it is still being displayed after the test.

| Symbol	Description
🍎	Before meal: Indicates a test performed before a meal.
🍴	After meal: Indicates a test performed after a meal.
🍎 & 🔔	After meal reminder: Indicates a test performed before a meal with an after meal test reminder set.
*	Other: Indicates a test performed after an activity or event of your own choosing e.g. physical activity. (Details can be added on the app.)
🄲	Control Test: Indicates a test obtained using control solution in place of blood.

Press the M button repeatedly until the desired flag is displayed along side your result.

The flag symbols will appear in the following order:

🍎 → 🍴 → 🍎🔔 → * → 🄲 → No Flag
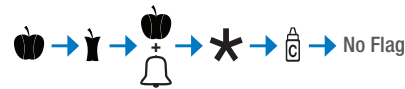
Once you locate the desired flag symbol, press the S button to accept and save the flag.

The following is an example of a test result flagged with the After Meal symbol.
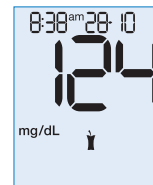
mg/dL meter
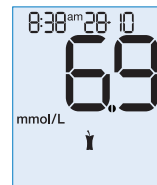
mmol/L meter

Setting the after meal test reminder

If you select the after meal test reminder in the flag menu, you will be prompted to set a time for your test reminder.
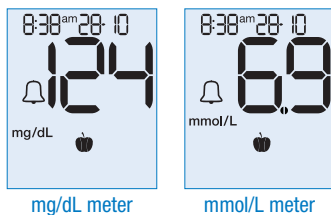
mg/dL meter   mmol/L meter

Press the M button to change between 1 and 2 hour test reminder time options.
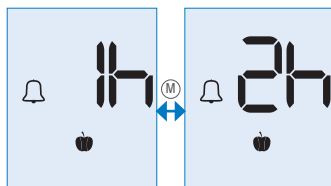
Press the S button to select the time and set the after meal test reminder.

The meter will save the test reminder and your result will be saved with the before meal flag. At the selected time (1 or 2 hours after the after meal test reminder was set) your meter will beep to remind you to perform an after meal test.

The test reminder will sound for 20 seconds. To perform a test or turn off the test reminder, press any button or open the sensor cover. The test result will be saved together with the After Meal flag.

If there is no activity, the test reminder will automatically turn off after 20 seconds.

> **Note:** If a test is done up to 1 hour before the alarm, the test reminder will be cancelled.
>
> If a test is performed within half an hour of the test reminder, the result will be saved with an after meal flag.

6   Memory

Recalling saved test results

The C50 meter stores 500 test results along with the time and date. The meter automatically stores the result in memory each time a test is performed. If 500 results are already stored, then the oldest result is deleted to make space for the newest result.

Press and hold the M button with the sensor cover closed until the last saved (most recent) test result is displayed.

If you flagged the test result, or a system flag was indicated at the time of the test, this will be displayed with your result.

To scroll through earlier results, repeatedly press the M button.

When pressing the M button, the memory number will be displayed. When the button is released, the result will be displayed.

mg/dL meter   mmol/L meter
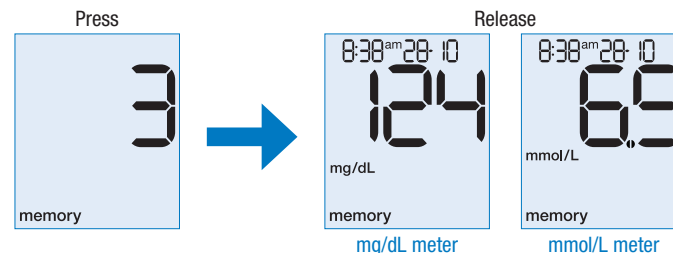
Hold M button down to scroll through results in quick succession.

Press and hold the S and M buttons at the same time for approx. 3 seconds to turn the meter off.

Recalling averages

> **Note:** Time and date must be set to use this function.

The C50 meter can calculate averages from the saved test results for 7, 14, 30 or 90 days.

To enter the memory function (saved test results), press and hold the M button with the sensor cover closed. Then press the S button until 7d is displayed.

The result that appears immediately after releasing the S button is the 7 day average.

Press   Release

mg/dL meter   mmol/L meter
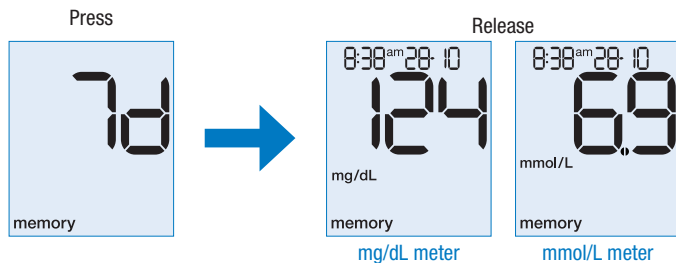
Press the S button repeatedly to scroll through the day averages

7 day ➜ 14 days ➜ 30 days ➜ 90 days

Press the M button to return to saved test results.

Press and hold the S and M buttons at the same time for approx. 3 seconds to turn the meter off.

7   System tools

The System Tools menu allows you to:

- Perform a display check,
- Check your meter's firmware version number,
- Check the number of tests remaining on the cassette, and
- Check the number of days remaining until casette expiry.

> **Note:** The number of tests remaining and the number of days remaining can only be checked if you have a cassette inserted in the meter.
>
> See section Checking the number of available tests remaining and Checking the expiry date of an opened test cassette.

Order of System Tools menu
Press and hold S & M buttons
Display check (release buttons)
M
Check firmware version
M
Number of tests remaining
M
Number of days remaining
M
Meter off

Checking the display

(S) & (M) ➔ Display check - release buttons immediately

The C50 meter has an LCD screen that should be checked periodically to ensure all segments are being correctly displayed.

To enter the System Tools menu, press and hold the S and M buttons for approx. 3 seconds with the sensor cover closed. The meter will perform a display test by lighting up all the segments of the LCD screen. Check that all the segments are functioning correctly as shown below.

Press the M button to proceed through the System Tools menu.

Press the S button to exit the System Tools menu.

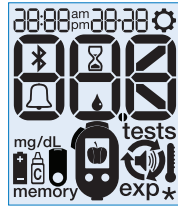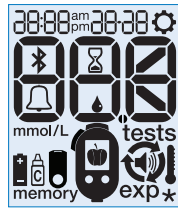> **Note:** If any segments are missing, contact your local distributor or customer service line to change the meter.

mg/dL meter

mmol/L meter

Checking the version number of your meter's firmware

(S) & (M) ➔ LCD test - release buttons ➔ (M) ➔ Firmware version

To check the firmware version number of your meter, press and hold the S and M buttons for approx. 3 seconds with the sensor cover closed. This will run a display check. Release the buttons when the LCD segments are displayed.

Press the M button to view your meter's firmware version number.

Press the S button to exit the System Tools menu.

Checking the number of tests remaining

(S) & (M) ➔ (M) ➔ (M) ➔ Number of tests remaining

The Betachek C50 Meter can automatically track the number of tests left on the test cassette. With the cassette inserted in the meter, press and hold the S and M buttons for approx. 3 seconds with the sensor cover closed. This will run a display check (release the buttons when the LCD segments are displayed).

Press the M button 2 times to view the number of tests remaining.

Press the S button to exit the System Tools menu.

Checking the expiry date of an opened test cassette

(S) & (M) ➔ (M) ➔ (M) ➔ (M) ➔ Number of days remaining

The Betachek C50 Meter can automatically track the validity of the test cassette in the meter. When the cassette is first inserted, the meter will begin to count down the use by period (90 days).

You will receive notifications at 10, 3, 2 and 1 day(s) before the use by period expires when opening the sensor cover.

You can also check the expiry date of an opened test cassette in the System Tools menu.

With the cassette inserted in the meter, press and hold the S and M buttons for approx. 3 seconds with the sensor cover closed. This will run a display check (release the buttons when the segments are displayed).

Press the M button 3 times to view the number of days remaining until test cassette expiry.

Press the S button to exit the System Tools menu.

8 Downloading results for Analysis

Downloading results for analysis

The Betachek Diabetes Management App is free software for Apple® iPhones® and iPads®. Download it from the App Store onto your device.

Results are automatically uploaded to your iphone or ipad, where the Betachek diabetes management app creates graphs and charts. Text, email or print.

BETA CHEK

Download on the App Store

Pairing the Betachek C50 meter with your device

The Betachek C50 Meter allows you to wirelessly synchronise your saved test results with a mobile device. This is done via bluetooth connection between your meter and mobile device.

Step 1 Install Betachek mobile app (mobile device)

You must install the Betachek Diabetes Management application on your mobile device before you can connect to the C50 meter. Go to the Apple App store and search for Betachek Diabetes Management.

Step 2 Turn on bluetooth (mobile device)

Prepare your mobile device for bluetooth pairing - go to settings -turn on bluetooth.

Step 3 Enter pairing mode (Betachek C50)

To put the C50 meter into pairing mode, hold down the 'S' and 'M' buttons simultaneously and keep holding until the flashing bluetooth symbol appears.

Step 4 Open the Betachek App (mobile device)

Open the Betachek app. and go to settings. Under settings go to 'selected device'. The app will search for the Betachek C50 meter and show any meter in range. Press connect when prompted.

Once successfully paired the meter will beep and the bluetooth symbol will stop flashing. The App will show the word 'Paired' under settings » selected device.

Pairing Unsuccessful

If the pairing was unsuccessful, E-0 will appear on the display. Repeat the process ensuring the devices are within 1 meter of each other.

If pairing is still unsuccessful;

a. Double click the home button. Swipe up to shut down the Betachek app.

b. Open the Betachek App. and go to settings/selected device then press Forget

c. Hold down the S and M buttons on the meter until the bluetooth symbol appears.

d. Ensure the mobile device and the Betachek C50 meter are less than 1 metre apart.

e. Open the app and follow pairing instructions

> **Note:** Any tests performed before time and date were set will only be displayed if **ALL** results under filtering is selected.

> **App Refresh:** Once paired all results will download to your mobile device each time the app is opened. To force downloading if the app is open, swipe down on the summary or logbook screens.

> **Flight mode:** See section "changing the settings" to set your meter to flight mode.

> **Time and Date:** When the Betachek C50 is paired with a mobile device the time and date will sync with the mobile device.

9   Checking your meter's accuracy

You can check your meter's accuracy by performing a control test. To perform a control test, Betachek Control Solution is applied to the test instead of blood.

Perform a control test:
- Whenever you open a new test cassette,
- After replacing the batteries,
- After cleaning, or,
- If you are in doubt about a blood glucose result.

At the end of the test, you must flag the result with the "Control Test" flag and select which control solution was used (control 1 or 2).

The meter automatically calculates whether the control test obtained with control solution is correct and informs you of the control result.

> **Note:** Using a control solution other than Betachek Control Solution will give inaccurate or misleading results.

Preparation

Read the package insert which comes with the control solutions.

For a control test, you need:
- Betachek C50 Meter
- Betachek C50 test cassette
- Betachek Control Solution 1 (low glucose concentration) or Betachek Control Solution 2 (high glucose concentration)
- Clean white tissue.

Performing a control test

Note: Control Solution contains a specific amount of glucose. If the cap is left off the control solution bottle, water can evaporate and the glucose concentration can increase. Similarly, when control solution wets the inside of the cap after use, it dries and leaves glucose that contaminates the tip of the bottle. Follow the steps below to deal with this glucose.

Note: Read all the instructions below before attempting a control solution test.

Step 1   Prepare the control solution

a. Remove the cap from the control solution bottle

b. Discard the first drop.

c. Wipe the tip of the control solution bottle clean with tissue

Step 2   Turn on the meter

Slide the sensor cover in the direction of the arrow.

This will turn the meter on and run a numeric display check by lighting up the numeric segments and meter unit of measure. Check that all the segments are functioning correctly as shown.
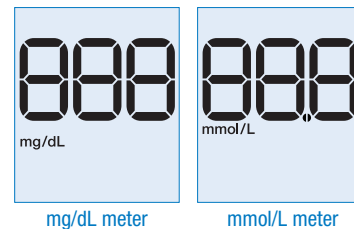
mg/dL meter   mmol/L meter

Note: If any numeric segments are missing, contact your local distributor or customer service line to change the meter.

The meter will display the number of tests remaining, then flash the wind symbol:

Step 3 **Wind on a test zone**

Turn the thumbwheel in the direction of the flashing arrow to bring a test into position.

The meter will sound a beep (if sound on) and display "OK" when a test zone is in position.

Check the blood drop symbol is flashing. (you have 2 minutes to apply the control solution)
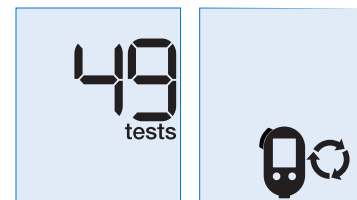
Step 4 **Apply Betachek control solution**

Apply a small drop of control to the test zone, being careful not to touch the test zone with the tip of the control solution.

Warning: The test zone requires a small amount of control solution. To avoid spilling control solution over the sensor area, practice squeezing out one small drop away from the meter.

When the control solution has been applied, the meter will sound a beep (if sound on) and commence measuring. The flashing hourglass symbol indicates when the test is underway, until a result is displayed.

Test results will be displayed in approx. 5 seconds.
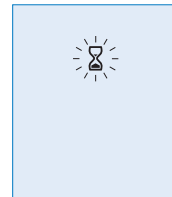
Step 5 **Result**

The meter will display the result with the time and date.

The result will automatically be saved to memory.

Do not turn the meter off.
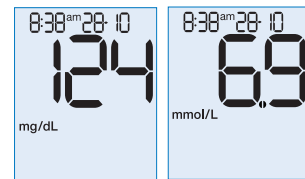
Step 6 **Flagging the control test**

To distinguish this control test result from blood glucose results, you need to flag it as a control test.

a. Press the M button repeatedly whilst the result is still displayed until the "Control Test" flag is displayed.

b. Press the S button to confirm the "Control Test" flag.

c. Press the M button to select between Control 1 or Control 2.

d. Press the S button to save.

Note: You can not flag a result after you wind off the used test. See section Flagging results.

Your meter will automatically check if the control test result is within the acceptable ranges.

Additionally, you can check the result against the acceptable ranges printed on the Test Cassette bottle label.

If the control test result is within the acceptable ranges, the meter will display "OK" along with the "Control Test" flag.

If the control test result is outside the acceptable ranges, the meter will display "E12" along with the "Control Test" flag. See section Symbols, problems and error messages.

Control test within acceptable range   Control test outside acceptable range

Step 7 Wind off used test

Approx. 5 seconds after your control test result is displayed, the wind symbol will appear. Turn the thumbwheel to move the used test into the used test storage compartment of the cassette.

The meter will display the progress with a segment countdown until the tape is in place.

> **Note:** If you applied too much control solution you may dab it with a tissue after the result has been displayed and before winding it into the waste compartment.

Step 8 Close sensor cover

When the test zone is in the storage compartment, the meter will beep (if sound is on) and display "OK". Stop winding. The meter will prompt you to close the sensor cover. Closing the sensor cover will turn the meter off.

Possible sources of error

If the result of the control test is outside the specified concentration range, repeat the control test. If the result of the second test is also outside the specified concentration range, check the following points.

- Did you perform the control test according to the User's Manual?
- Is the test cassette within the expiry date?
- Are the control solutions within their use by date?
- Did you wipe the tip of the control solution bottle before you applied control solution to the test zone?
- Was the drop of control solution that was applied to the test zone free of air bubbles?
- Did you apply the control solution after the beep sounded and the blood drop symbol began flashing on the display?
- Was the area illuminated by the red light completely covered with control solution?
- Did you perform the test within the correct temperature range? (+10°C to +40°C)
- Did you select the correct control solution in the flag menu?
- Did you compare the test result with the acceptable range that corresponds to the control solution you used? (if using the range printed on the cassette container label)
- Is the sensor window of the meter clean?
- Has the control solution been open for less than 3 months?

If you answered no to any of the questions above, make the respective corrections when you perform the next test. If you have taken all of these points into account and the test results are still outside the specified concentration range, contact your customer support and service center.

> **Warning: If a control test produces results that are outside the specified concentration range, it is no longer certain that the meter and test cassette are functioning properly. Blood glucose tests may then produce incorrect results.**

10 Meter maintenance

The meter must be kept clean and stored safely away from water, moisture (<85% humidity), extremes of heat or cold and dust.

Avoid getting blood on the meter. If you do, cleaning the meter is necessary.

Cleaning your meter

Notes on cleaning your meter:

- Use only cold water as a cleaning agent.
- Clean the meter using a lightly moistened cloth or a lightly moistened cotton swab.
- Do not spray anything onto the meter and do not immerse it in any liquid.
- Make sure that no water enters the meter.
- Avoid scratching the sensor window.

Cleaning the exterior of the meter

If the meter or the display is dirty - wipe it using a soft cloth lightly moistened with cold water.

Cleaning the sensor area

You only need to clean the sensor area of the meter if it is visibly dirty or if you are prompted to clean the meter by the message E-4: Measurement sensor dirty (See section Error messages).

Step 1 | **Remove test cassette**

Remove the test cassette prior to cleaning your meter. See section Removing a test cassette.

Step 2 | **Cleaning the cassette bay**

If the cassette bay is visibly dirty, clean the area with a lightly moistened cloth or cotton swab/tip.

Step 3 | **Cleaning the sensor**

If the sensor window is visibly dirty, clean the area with a lightly dampened sponge, cloth or cotton swab. Carefully dab the measurement window and its surrounding area.

Remove any fluff or lint that may remain.

Ensure that the areas you have cleaned are dry. Re-insert test cassette.

Disposal

Used meters carry a risk of infection as they may come in contact with blood during blood glucose testing. Remove the battery and discard your used meter according to local regulations.

Cleaning the lancing device

To prevent the transmission of infections, you must regularly clean and disinfect the lancing device:

- at least once a week,
- when there is blood on the device, and,
- always before someone else handles the lancing device, for example, to assist you.

Preparation

Remove the lancet from the meter. See section Removing a lancet.

Cleaning

Dampen a cloth with water. Wipe the exterior and interior of the lancing device.

Do not immerse in any liquids.

Dry the lancing device with a dry cloth.

Disinfecting

Wipe the lancing device thoroughly with a soft cloth dampened with 70% isopropanol. After disinfecting, allow to air dry.

Replacing the battery

When the battery is almost empty, and the meter is turned on, the low battery warning is displayed. At this point you can still perform approximately 50 more tests.

Change the battery as soon as possible.

You need 1x CR2032 battery.

With a new battery you can perform approx. 1000 tests or test for approx. 1 year. The number of tests can vary depending on the battery manufacturer.

Your saved test results will always remain saved, even when you change the battery, however time and date will be lost when the battery is removed or flat. (Connecting to the Betachek Diabetes App will reset the date or it can be reset by entering settings mode).

If you ignore the low battery warning and allow the battery to run flat, an error message will appear on the display. See section Symbols, problems and error messages.
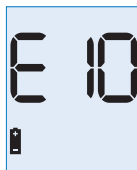
Note:
- Only remove the battery when the meter is turned off.
- Remove the battery if you will not be using the meter for a long time.

Warning:
- Never throw the battery into a fire. It may explode.
- Keep out of reach of children. Swallowing a coin battery can cause death in children in under 2 hours. Seek emergency medical treatment if swallowed!

Step 1 Remove the battery

The battery compartment is located on the back of the meter.

Push the locking catch downwards and remove the battery compartment cover.

Remove used battery.

Step 2 Insert new battery

After removing the old battery, place the new battery in the compartment with the + symbol facing upwards.

Step 3 Replace battery cover

Replace the battery cover by inserting the prong on the lower edge first then press the spring end into position. It will click into place audibly.

11 Test and storage conditions

Temperature

Make sure that the following conditions are met so that the meter and lancing device operate reliably and you obtain accurate results.

Testing

- For blood glucose tests and control solution tests the temperature must be +10°C to +40°C (+50°F to +104°F).

- If the temperature is at the limit of the permitted range: +5°C to +10°C (41°F to 50°F) or +40°C to 45°C (104°F to 113°F), the meter will still allow you to perform a test. However, the thermometer symbol will be displayed and saved with test results obtained within the temperature limits. You will also receive a temperature warning (E11) when the sensor cover is opened. See section Symbols, problems and error messages..

- Tests cannot be performed at temperatures below +5°C and above +45°C. If temperatures exceed these limits, the temperature error appears on the display after opening the sensor cover. You will not be able to use the meter for testing. See section Symbols, problems and error messages.
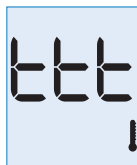
Temperature
error

Warning:
- **Do not use blood glucose results obtained despite the temperature warning as a basis for making therapeutic decisions. These test results could be incorrect. Incorrect results can cause the wrong therapy recommendation to be made and so produce serious adverse health effects.**
- **Never try to speed up warming or cooling of the meter, e.g. in a refrigerator or on a radiator.**

Storage

- Meter without battery and test cassette:-25°C to 70°C (-13°F to 158°F).
- Meter with battery, without test cassette: -20°C to +50°C (-13°F to +158°F).
- Meter with battery and test cassette: +2°C to +30°C (+35.6°F to +86°F).

Note:
- At temperatures above 50°C the battery could leak and damage the meter.
- At temperatures below 5°C the battery may not have enough power to keep the internal clock functioning.

Humidity

Testing

Only perform blood glucose tests at a relative humidity of between 15% and 85%.

Storage

Store the meter in a place with a relative humidity of between 15% and 93%.

Note: Do not store the meter in high moisture areas (e.g. in a bathroom).

Light conditions

Do not perform a test when the meter is exposed to direct sunlight. Go to a shaded place or shade the meter, for example, with your body.

If the meter is exposed to too much light, it does not allow any tests to be performed. In this case the error message E-5 will appear on the display. See section Symbols, problems and error messages.

12 Symbols, problems and error messages

Symbols

Symbols on the display
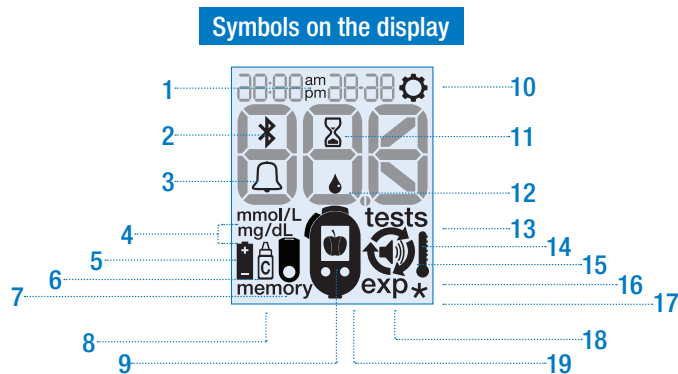
Symbol	Meaning
1 am pm	Additional time information if 12-hour time format is set.
2 ✳	Bluetooth symbol. The meter is attempting to pair with a mobile device.
3 🔔	The alarm bell symbol.
4 mmol/L mg/dL	The unit of measure that your meter uses to display test results (mg/dL or mmol/L).
5 🔋	Low battery warning. You can perform approx. 50 more tests after the symbol first appears.
6 C	"Control Test" flag.
7 🔲	Test cassette symbol.
8 memory	You are in the Memory Menu for test results and averages.

| Symbol	Meaning
9 🍎 or 🍗	"Before Meal" or "After Meal" flag.
10 ⚙	You are in the Settings Menu for time format, time, date and sound.
11 ⏳	Hourglass symbol. A test is underway.
12 💧	Blood drop symbol. You can now apply blood or control solution to the test zone.
13 tests	The number of tests remaining is being displayed. The symbol is preceded by the number of tests remaining.
14 ↻	Wind symbol. Wind on a new test or wind off a used test using the thumbwheel.
15 🔊	You are in the Settings Menu for sound.
16 🌡	If the ambient temperature at the time of testing is or was between 5°C to 10°C or 40°C to 45°C.
17 ✱	"Other" flag.
18 exp	If your test cassette has expired or a test was done using an expired test cassette.
19 📱	Meter symbol. Close sensor cover.

Problems

Problem and possible causes	Solution to the problem
The meter will not turn on	
The battery is flat or there is no battery in the meter.	Insert new battery.
The battery was inserted the wrong way.	Remove the battery and place in the battery compartment as shown.
Extreme temperatures.	Ensure that the ambient temperature is between 5°C and 45°C and wait for the meter to warm up to this temperature.
The meter is defective.	Contact the customer support and service centre.
The time is displayed as 0:00 or 0:00am and the date is 0- 0.	
The time and date were not set or the meter lost power	Insert a new battery and set the time and date.
The meter is turned on, but the display remains blank.	
The display is defective.	Contact the customer support and service centre.

Error messages

When an error occurs, an error message appears on the display and the meter will sound a beep (if sound is on).

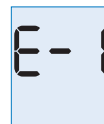If your meter has been dropped, this can also lead to error messages.

If error messages occur frequently, contact your customer support and service centre.
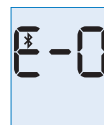
E-0: Bluetooth error
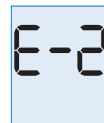
The meter was unable to pair with a device.
Retry the pairing. Make sure the devices are within 1 meter of each other.

E-1: Calibration error

Your meter is out of calibration.
Please contact your customer support and service centre.

E-2: RFID tag error

The information stored on the cassette cannot be read by the meter.
Check that the cassette bay is clean.
Make sure there is a cassette inserted in the meter. Turn the meter off, then on again by closing and re-opening the sensor cover.
If the problem persists, you cannot use the cassette. Please contact your customer support and service centre.
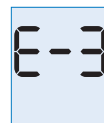
E-3: Used test not wound into waste chamber

If a used test was not wound into the waste chamber and the sensor cover is closed.
Open the sensor cover and wind the used test into the waste chamber. Storing used tests in the waste chamber minimises the risk of soiling the meter.
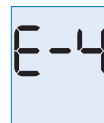
E-4: Blood applied too early/Sensor window dirty

Blood applied before OK or before blood drop symbol appears on the display.
Repeat test with a new test zone. Wait until the flashing blood drop symbol appears on the display before applying blood.

Sensor window dirty.
Clean using lightly dampened cloth or cotton swab. See section Cleaning your meter and lancing device.

E-5

E-5: Too much ambient light
The meter is exposed to too much light.
Go to a shaded place or shade the meter, for example, with your body.

E-6

E-6: Cassette wound too far
Test zone wound past sensor window.
Continue winding test zone into the waste chamber until "OK" appears on the display. Close the sensor cover to turn meter off, or, continue winding to the next test zone.
Cassette wound too far when winding used test into waste chamber.
The cassette has been wound too far causing a fresh test to be withdrawn from the storage chamber. This test must be discarded. Continue winding when prompted until 'OK' appears on the display

E-7

E-7: Insufficient blood
Insufficient blood applied to the test zone.
Start the blood glucose test from the beginning with a new test. Ensure that the area illuminated by the red light is covered with blood.

E-8

E-8: Test cassette error
Test cassette removed while a test is underway.
Replace the test cassette in the cassette bay and start the blood glucose test from the beginning with a new test. Ensure the test cassette is lying flat. See section Inserting a test cassette.
Test cassette wound while a test is underway.
Start the blood glucose test from the beginning with a new test.
Do not wind the test cassette unless the wind symbol is displayed.

E-9

E-9: Test zone error
The test zone is damaged.
Start the blood glucose test from the beginning with a new test.

E 10

E10: Insufficient battery power
There is insufficient battery power to perform a test.
Replace the battery. See section Replacing the battery.

E 11

E11: Temperature warning
If the temperature is at the limit of the permitted testing range
You can still perform a blood glucose or control solution test,however, it is recommended that you allow the meter to cool down or heat up to be within the permitted temperature range for testing.

E 12

E12: Control test error
The control solution test result is not within the acceptable ranges.
If the result of the control test is outside the specified concentration range, repeat the control test. See section Performing a control test.
If the result of the second test is also outside the specified concentration range, see section Possible sources of error.

LO

LO: Low battery warning
The battery is almost empty.
Change the battery as soon as possible. See section Replacing the battery.

ttt

ttt: Temperature warning
If the temperature exceeds the limit of the permitted testing range (<5°C or >45°C).
No tests can be performed. Allow the meter to cool down or heat up until it is within the permitted temperature range for testing.

13 Technical data

Meter name	Betachek® C50
Intended use	For self testing of blood glucose. Not suitable for multi patient testing.
Integrated lancing device	Single patient use only 10 penetration depths Lancet: Betachek® lancets or Softclix® lancets
Test time	Approx. 5 seconds
Measuring method	Reflex photometry
Assay method	FAD GDH
Blood sample	Fresh capillary blood only
Sample size	Minimum: 0.6µl / Maximum: 5µl
Units of measure	Factory set to: mmol/L or mg/dL
Memory	500 results with time and date, averages for 7, 14, 30 and 90 days
Measurement range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)
Power supply	1 battery (type CR2032)
Battery life	Approx. 1000 tests or 1 year
Auto power off	After 60 or 120 seconds depending on operating status
Temperature	During testing: +10°C to +40°C (+50°F to +104°F) During storage without battery and test cassette: -25°C to +70°C (-13°F to +158°F) During storage with battery, without test cassette: -20°C to +50°C (-4°F to +122°F) During storage with battery and test cassette: +2°C to +30°C (+35.6°F to +86°F)
Atmospheric humidity	During testing: 15% to 85% relative humidity During storage: 15% to 93% relative humidity
Altitude	Sea level to 4000m
Meter dimensions	105mm x 58mm x 19.5mm
Cassette dimensions	22.2mm x 13mm x 48.2mm

Meter interface	Bluetooth to connect to smart phone RFID to connect to test cassette
Cassette interface	RFID to connect to meter
Weight	Meter only: 60g Meter with battery and cassette: 70g
Model/Serial Number	Located on meter label
Safety class	III
LED	Class 1
Electromagnetic compatibility	This blood glucose meter meets the electromagnetic immunity requirements as per EN 61326-2-6 and EN ISO 15197 Annex A. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. Its electromagnetic emission is thus low. Interference on other electrically-driven equipment is not anticipated.
Performance analysis	Performance data for the Betachek C50 system was obtained using capillary blood from diabetic patients (method comparison, accuracy), oxygenated venous blood (repeatability) and control solution (reproducibility).
Calibration and traceability	The system is calibrated with freshly obtained capillary blood, containing various glucose concentrations. The glucose values used as reference values are obtained using the YSI method. The YSI method is traceable to a primary NIST standard. Betachek C50 blood glucose monitoring system meets the requirements of EN ISO 15197 (2013). Freshly obtained capillary blood is the only allowable sample. Results displayed are the plasma equivalent. See the instructions for use supplied with the test cassette for further information.

Declaration of Conformity

NDP declares that the Betachek C50 cassette blood glucose meter, conforms with the basic requirements and other relevant regulations of the European Directive; 1999/5/EC

14 Index

15 Explanation of symbols

⌂ Manufactured by

⊠ Expiry date

CE 0123 This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.

IVD In vitro diagnostic medical device

📖 Read instructions before use

🌡 Storage temperature range

⚠ Important information accompanies this product

EC REP Authorised representative in the European Community

LOT Lot number

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