# Omnitest® plus

## CHECKLIST: ACCURACY COMPLAINTS

PROBLEM:

**ASSUMED ABNORMAL VALUE (CHAPTER A, B, C, D)**

**DIFFERENT VALUE THAN REFERENCE DEVICE (CHAPTER E, F)**

HAVE READY:

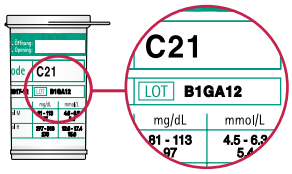
Device, a test strip from the same vial as the used test strip, check strip and control solution Omnitest® plus Control.

Omnitest® plus serial number SN

_____

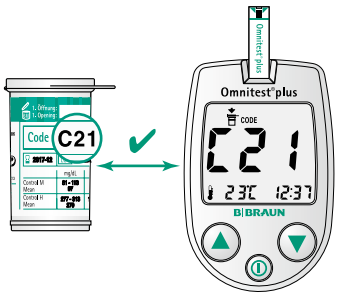

Omnitest® plus test strip lot LOT

_____




## PROBLEM: ASSUMED ABNORMAL VALUE

### A: HANDLING CHECK




Did you set the code as indicated on your test strip vial?

NO → Did you already perform a measurement?

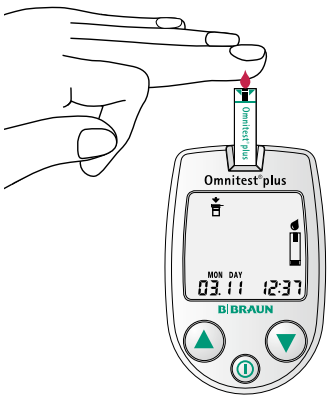
YES → Please re-insert the test strip and set the code as indicated on your test strip vial.

NO → Please insert a new test strip and set the code as indicated on your test strip vial.

YES → CONTINUE WITH HANDLING CHECK (NEXT PAGE).

## PROBLEM: ASSUMED ABNORMAL VALUE

### A: HANDLING CHECK




Did you wash your hands?
- NO → Even invisible food residues affect the measurement results. Please repeat test.
- YES ↓

Did you use a fresh drop of blood?
- NO → A smeared drop of blood may affect the result. Please repeat test.
- YES ↓

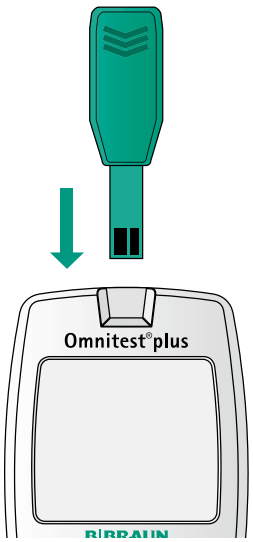
Did you apply your sample in one step?
- NO → Do not add blood to the test strip more than once. Please repeat test.
- YES ↓

Did you remove your finger after the countdown has started?
- NO → The test strip had enough blood when the countdown started. Applying blood afterwards may affect the measurement.
- YES ↓

IT APPEARS THIS IS NOT A HANDLING PROBLEM. SEE SECTION B: DEVICE

## PROBLEM: ASSUMED ABNORMAL VALUE

### B: DEVICE CHECK




Please insert the check strip (the check strip is part of the packaging).

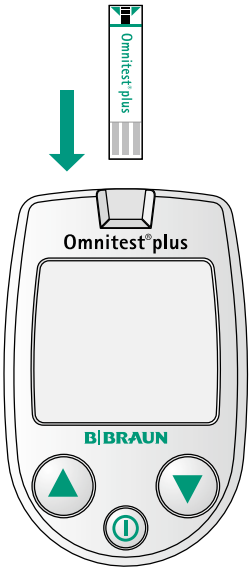
OKAY:
OK
is displayed.


DEVICE IS WORKING PROPERLY.
PLEASE SEE SECTION C: TEST STRIP

NOT OKAY:
Error message
is displayed.


DEVICE IS DEFECTIVE.
PLEASE START COMPLAINT PROCESS:
SEND THE METER IN FOR REPLACEMENT

## C: TEST STRIP CHECK




Have you measured a second time with a new test strip?

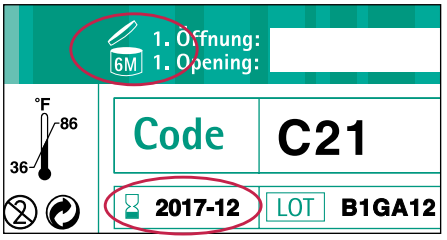
NO → Please measure again with a new test strip.

STILL PROBLEMS?

YES

Please check expiry date ⌛ and shelf life 6M on the test strip label of the vial. Shelf life is always six months after first opening, but no longer than the expiry date.

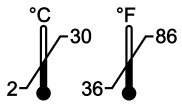
Are your strips still within the shelf life and expiry date?




YES

NO

Were the test strips stored at the correct temperature?




NO

YES

Are you sure the test strip vial has not been opened and the test strips have not gotten damp?

NO

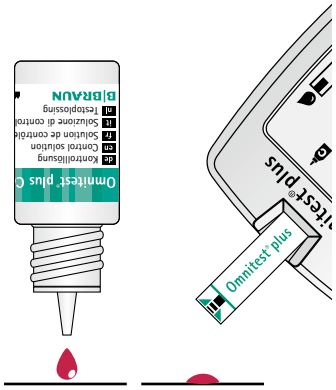
YES

WE ASSUME THE TEST STRIPS ARE OKAY.
PLEASE SEE SECTION D:
DEVICE AND TEST STRIP

PLEASE USE NEW TEST STRIPS FROM A NEW TEST STRIP VIAL. YOUR CURRENT TEST STRIPS CAN NO LONGER BE USED.

# PROBLEM: ASSUMED ABNORMAL VALUE

## D: DEVICE AND TEST STRIP CHECK



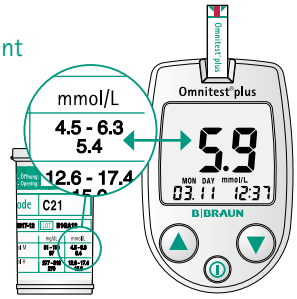

Do you have the control solution Omnitest® plus Control for your meter?

NO → We will send the control solution. FOLLOW UP CALL WHEN DELIVERED!

YES

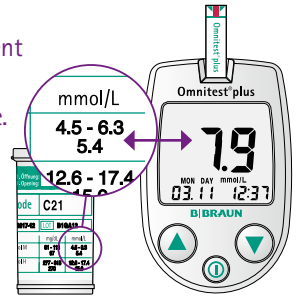
Please measure with the control solution. The measurement result should be within the range shown at the test strip vial of the used test strip.

Measurement okay, in range.




ASK YOUR DIABETES CARE PROFESSIONAL FOR ADVICE AS TEST STRIP, DEVICE AND HANDLING WERE CORRECT!

Measurement not okay, not in range.



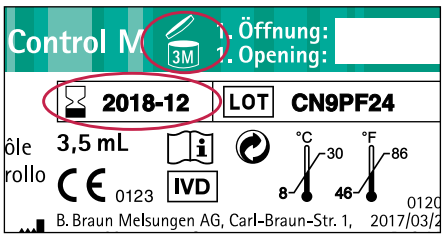

Did you clean the tip before using the control solution?

YES

NO → Please clean the tip and repeat the test with the control solution.

STILL PROBLEMS?

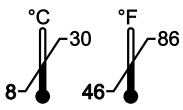
Please check expiry date and shelf life on the control solution label on the container of your control solution. Shelf life is always three months after first opening, but no longer than the expiry date. Is your control solution still within the shelf life and expiry date?




YES

NO → Do not use this control solution, since the results may be inaccurate.

Was the control solution stored at the correct temperature?




NO → Do not use this control solution, since the results may be inaccurate.

YES

Was the temperature of the measurement components (control solution, meter, test strip) in a range of 20-25°C?

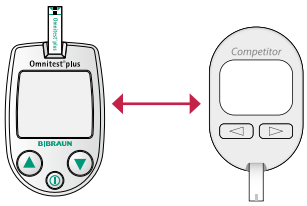
NO → Please repeat the test within the correct temperature range of 20-25°C for all components.

YES

THERE IS AN ISSUE WITH THE DEVICE OR TEST STRIP. PLEASE START COMPLAINT PROCESS: SEND IN THE TEST STRIPS OF THE VIAL USED FOR THE MEASUREMENTS AS WELL AS THE EXACT MEASURED VALUES OF THE PATIENT.

# PROBLEM: DIFFERENT VALUE THAN REFERENCE DEVICE

## E: DIFFERENT VALUE THAN COMPETITOR HANDHELD METER



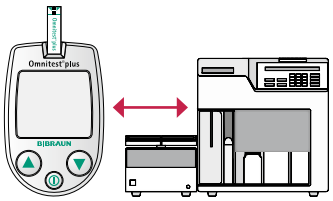

DO NOT COMPARE TWO HANDHELD METERS!

We cannot determine whether one or both devices are wrong or both devices show the right result within the tolerance range.
The correct result might also be in between.

IF YOU WANT TO COMPARE THE RESULTS WITH ANOTHER METER, PLEASE USE A LABORATORY DEVICE IN THE CORRECT WAY ACCORDING TO SECTION F: LABORATORY DEVICE

TO CHECK THE CORRECT FUNCTIONALITY OF YOUR DEVICE, PLEASE SEE ALSO SECTION B: DEVICE

## F: DIFFERENT VALUE THAN LABORATORY DEVICE




Laboratory device (name, manufacturer): _____

Were both samples taken at the same time and from the same puncture site?
- NO → Repeat the measurement with a blood sample taken at the same time with the same puncture site.
- YES ↓

Were both samples taken from the same blood sample (both capillary blood)?
- NO → Repeat the measurement with the same blood sample.
- YES ↓

What type of blood was used for the lab device?

**Plasma.**

Plasma is okay, since Omnitest® plus is calibrated against plasma. ↓

Was the blood sample centrifuged immediately after collecting the blood sample (within 10 min.)?
- NO → Was the natural glycolysis inhibited?
  - NO → Repeat the measurement with a new blood sample. The glycolysis may lead to a wrong low reading.
  - YES ↓
- YES ↓

**Whole Blood.**

Wrong. Repeat the reference measurement with plasma blood sample as Omnitest® plus is plasma-calibrated and can only be compared with plasma blood sample of a lab device.

What are the measured values of both devices?

Laboratory device: _____ Omnitest® plus: _____

↓

We assume that the laboratory device test result is correct.
Please compare: Is the Omnitest® plus result within the ISO standard?

| Blood glucose level | Tolerance range |
|---|---|
| ≥ 100 mg/dL (5.55 mmol/L) | ± 15 % |
| < 100 mg/dL (5.55 mmol/L) | ± 15 mg/dL (0.83 mmol/L) |

- YES ↓ THE OMNITEST® PLUS DEVICE IS WORKING PROPERLY
- NO ↓ THE OMNITEST® PLUS DEVICE MAY BE INACCURATE. PLEASE FOLLOW THE INSTRUCTIONS IN SECTION A: HANDLING