



HemoPoint® H2 Meter User Manual

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Important Information

Before installing and using the printer, please read the following items carefully.

1.1 Welcome!

Congratulations on purchasing the Alere **HemoPoint® H2** System. Before you begin using your new Alere **HemoPoint® H2** System we strongly recommend you read this manual completely, with particular attention to the following section with its introductory explanations and safety notes.

1.2 Explanation of the Graphic Symbols



DANGER!

The DANGER symbol!

This symbol warns of situations or actions that could lead to serious damage to the health of the user or a patient.



WARNING!

The WARNING symbol!

This symbol warns about incorrect handling that could cause measuring errors or damage to the instrument or any accessories used.



TIP

The TIP symbol!

Alongside this symbol we provide useful additional information about the current matter.

1.3 Safety Notes

It is essential that you read the following notes, in order to avoid risks to persons and damage to the meter and other equipment. Alere does not accept responsibility for damage arising from non-observance of the following notes.



WARNING!

Follow the User Guide!

Each time the meter is used, precise knowledge and attention to these operating instructions is required. Only use the Alere **HemoPoint® H2** System for the purpose which will be described in Section 2.



Danger of Fatal Electric Shock!

- Under no circumstances should you open the AC power adaptor. There are no elements inside which require servicing or maintenance.
- Never use a mechanically damaged AC power adaptor – live connections might be exposed.
- The AC power adaptor is not waterproof. Therefore, never let liquids come into contact with it. A lightly dampened cloth, however, can be used to clean it when disconnected. Please see the notes on care in Section 6.
- Only use the AC power adaptor in a socket that has been properly installed.



Check that the AC voltage and frequency printed on the AC power adaptor label match your electrical socket and whether the shape and configuration of the plug contacts are compatible for this connection.



Not to be used in areas where there is a risk of explosion!

The instrument is not approved for use in areas where there is a risk of explosion.



Keep the meter away from liquids!

The Alere **HemoPoint® H2** Meter is not waterproof. Fluids entering the instrument could destroy the electrical and optical components in the meter. A lightly dampened cloth, however, can be used for cleaning. Please see the notes on care in Section 6.



Allow the instrument to reach room temperature!

Particularly on changing from a cold into a warm environment (i.e. after storage or transport) condensation can form inside and on the outside of the instrument. Wait an appropriate time (approx. 1 hour), before you connect to the main power supply or switch on the instrument.

Only use original equipment!

Only attach equipment that is expressly approved for use with the Alere **HemoPoint® H2** System. Alere does not guarantee the function of the instrument when other equipment is used.

Never open the meter!

There are no parts in the meter that require customer maintenance. Repairs can only be carried out by Alere personnel. Further notes on maintenance can be found in Section 6.

Do not force the microcuvette holder!

The Alere **HemoPoint® H2** Microcuvette holder is very important for the quality of testing. Therefore mechanical force on the holder should be avoided and only the designated Alere **HemoPoint® H2** Microcuvettes should be used. For cleaning purposes the Alere **HemoPoint® H2** Microcuvette holder can be removed from the Alere **HemoPoint® H2** Meter after a mechanical locking device is released. Notes on this can be found in Section 6.

Intended Use

The Alere **HemoPoint® H2** System is intended for the quantitative determination of hemoglobin (Hgb) in whole blood of adults, infants, and children in a professional point-of-care setting. It consists of a dedicated meter and individual, single-use Alere **HemoPoint® H2** Microcuvettes filled with reagents.

Using the Alere **HemoPoint® H2** Microcuvette, a small amount of arterial, venous or capillary blood is taken up by capillary action. The filled Alere **HemoPoint® H2** Microcuvette is inserted into the Alere **HemoPoint® H2** Meter, the color produced by the chemical reaction in the Alere **HemoPoint® H2** Microcuvette is measured, and the Hgb value is displayed. The Alere **HemoPoint® H2** Microcuvettes are intended to be used only once and must be disposed after use as potentially infectious waste, in accordance with the current regulations applicable to your establishment.

The Alere **HemoPoint® H2** System is designed for use in medical practices and in clinical laboratories to assist in medical diagnostic investigations. In addition it can be used in emergency and intensive care units and in medical facilities such as blood banks. This test system has been approved for use in laboratories with Waived status as defined in 452 CFR 493.15(c)(a).

ALERE DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES OF THE MERCHANTABILITY AND FITNESS PERTAINING TO THIS PRODUCT WHICH ARE NOT EXPRESSLY DETAILED IN THIS USER MANUAL OR A WRITTEN AGREEMENT BETWEEN THE BUYER AND SELLER OF THIS PRODUCT.

ALERE MAINTAINS THAT THIS PRODUCT CONFORMS TO THE INFORMATION CONTAINED IN THIS USER MANUAL. PURCHASER MUST DETERMINE THE SUITABILITY OF THE PRODUCT FOR THEIR PARTICULAR USE. USE ONLY IN ACCORDANCE WITH THIS USER MANUAL AND OTHER LABELING INSTRUCTIONS.

Setting Up

3.1 Unpacking the Alere HemoPoint® H2 Meter

Before you set up the Alere **HemoPoint® H2** Meter, first check that all the items are present and undamaged (see Illustration 1).

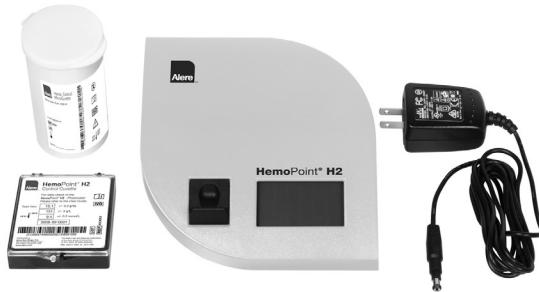


Illustration 1: (1) Alere **HemoPoint® H2** Meter and (1) AC power adaptor.

Materials Provided

- One (1) Alere **HemoPoint® H2** Meter
- One (1) Meter User Manual
- One (1) Quick Reference Guide
- One (1) Control Cuvette
- One (1) Optics Cleaner
- One (1) AC power adaptor

Additional Materials Required but Not Provided

- Latex Gloves
- Sampling devices for capillary blood collection
- Biohazardous waste container
- Alcohol swabs and gauze for cleaning puncture site
- Alere **HemoPoint® H2** Microcuvettes
- Alere™ Hemoglobin Controls (optional)
- Alere **HemoPoint® H2** Optics Cleaner



What is your Voltage?

Check that the AC voltage and frequency printed on the AC adaptor label match your electrical socket and whether the shape of the plug is compatible for this connection. If not, do not connect the Alere **HemoPoint® H2** Meter to the electrical socket under any circumstances. Contact Alere in this case.

3.2 Setting Up the Alere HemoPoint® H2 Meter

Select a suitable place for setting up the Alere **HemoPoint® H2** Meter, according to the following criteria:

- Avoid direct sunlight
- Avoid strong electromagnetic fields
- Avoid direct influence from ionizing radiation
- Avoid rapid temperature fluctuations (keep away from heaters, open windows, ventilators, fans or air-conditioning, etc.)
- Avoid wet areas (i.e. wash basins)

Place the Alere **HemoPoint® H2** Meter on a level counter adjacent to a power socket. Make sure there is enough room for the microcuvette holder to be freely accessible.



Illustration 2: Setting up the Alere HemoPoint® H2 Meter.

3.3 Switching the Alere HemoPoint® H2 Meter On and Off

3.3.1 Using for the First Time



Allow the Alere HemoPoint® H2 Meter to reach room temperature!

Changing from a cold to a warm environment (i.e. after storage or transport), condensation can form both on the inside and the outside of the Alere **HemoPoint® H2** Meter. Wait at least 1 hour, before you connect the Alere **HemoPoint® H2** Meter to a power supply.

As the built-in battery has not yet been charged, the Alere **HemoPoint® H2** Meter must first be connected to the power adaptor (supplied) and plugged into an electrical socket until the battery is **completely** charged.



This procedure is necessary in order for the capacity of the battery to be checked and the charge indicator to function correctly. Further information on this can be found in Section 6.2 “Charging and Care of the Battery”.

3.3.2 To Operate Using the Power Adaptor

Use the power adaptor to operate the Alere **HemoPoint® H2** Meter, noting the following steps when connecting the power adaptor:

1. Insert the small round plug on the connecting cable of the power adaptor into the appropriate socket (6VDC) at the back of the Alere **HemoPoint® H2** Meter.



Illustration 3: Connecting the power adaptor.

2. Next, insert the power adaptor plug into an appropriate electrical socket. The Alere **HemoPoint® H2** Meter itself does not have a power On/Off switch.

Please be patient after plugging the Alere **HemoPoint® H2** Meter into the electrical socket. It may be 4 or 5 seconds before anything appears on the display. This does not indicate a fault but is related to various initialization steps within the Alere **HemoPoint® H2** Meter. Following this initialization phase, the display illuminates and a welcome screen appears briefly, after which the instrument is ready to operate.



Illustration 4: Welcome display screen.

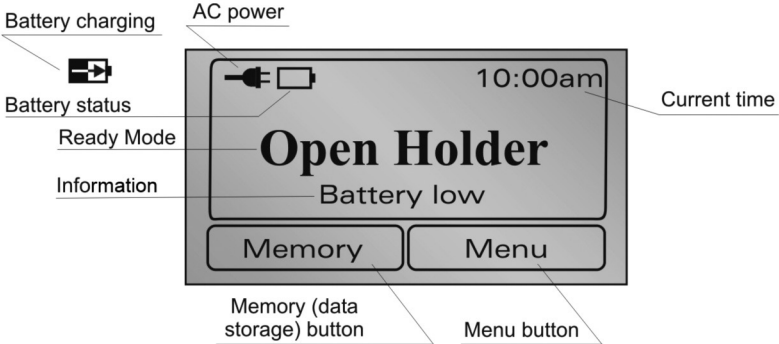


Illustration 5: Display in ready mode (Open Holder).

The individual symbols and their meanings are explained in Section 3.3.5 “Displays and Symbols in the Ready Mode”.

Now you can either start your testing, view results in the memory, or carry out adjustments in the Menu.



You can find tips on this in Sections 4 “Sampling and Testing Procedure”, 5.2 “Memory (Data Storage)” and 5.3 “Menu Functions”.

If the Alere **HemoPoint® H2** Meter is not in use for some time, it switches into the energy-saving, Stand-by mode (see Section 3.3.4 “Stand-by Mode”).

3.3.3 Battery Operation

The Alere **HemoPoint® H2** Meter automatically switches to battery operation when you unplug the power adaptor from the electrical socket, or from the instrument (assuming, of course, that the battery is sufficiently charged).

When the battery is fully charged it will operate for a period of at least 100 hours.



Tips on charging the battery and battery maintenance can be found in Section 6.2 “Charging and Care of the Battery”.



To avoid problems while testing during battery operation, also note the tips in Section 3.2 “Setting up the Alere **HemoPoint® H2** Meter”.

3.3.4 Stand-by Mode

The meter does not have a separate On/Off-switch. It is designed so that it automatically switches to the Stand-by mode when you are not operating the instrument for a certain time (approximately 5 minutes). The display will go blank in the Stand-by mode.



This elapsed time can be changed in Section 5.3.8.5 “Setting the Stand-by Time”.

The Stand-by mode reduces power usage to a minimum.

There are (3) three ways of switching the instrument ON again:

- Touch the Touchscreen.
- Open or close the Alere **HemoPoint® H2** Microcuvette holder.
- Plug the meter into an electrical power supply.

3.3.5 Displays and Symbols in the Ready Mode

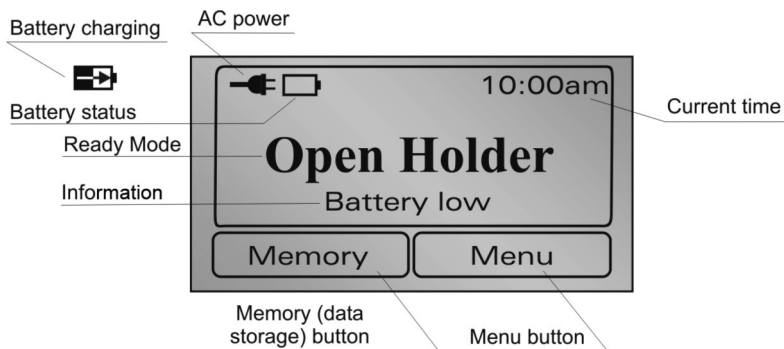


Illustration 6: Display in ready mode (Open Holder).

Sampling and Testing Procedure

4.1 Taking a Sample

4.1.1 Notes on Using the Alere HemoPoint® H2 Microcuvette

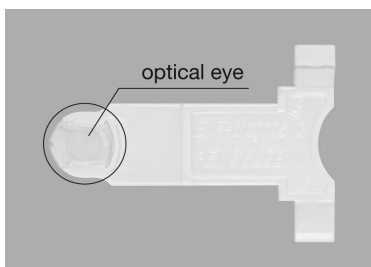


Illustration 7: Microcuvette

The Alere **HemoPoint® H2** Microcuvette is the most sensitive component in the Alere **HemoPoint® H2** System. It is therefore necessary to handle the cuvette carefully, paying particular attention to the following conditions:

1. Each Alere **HemoPoint® H2** Microcuvette can only be used once! The Alere **HemoPoint® H2** Microcuvette is designed for single use. The cuvette is coated during manufacturing with all the reagents necessary for determining the hemoglobin concentration in the blood sample. As soon as the blood is taken into the Alere **HemoPoint® H2** Microcuvette, a reaction occurs (within 1 minute).

2. The Alere **HemoPoint® H2** Microcuvette is sensitive to moisture! The Alere **HemoPoint® H2** Microcuvette will absorb moisture therefore the cuvettes are supplied in a special airtight container that contains a drying agent. This drying agent assures that any moisture is readily absorbed during storage.

Pay attention to the following notes, to preserve the integrity of the Alere **HemoPoint® H2** Microcuvette:



- Store the cuvettes only in the original container and at room temperature (59-86°F / 15-30°C).
- Only remove one cuvette at a time from the container and then immediately close the lid. Make sure that the lid is completely closed by pressing it down as far as it will go.

The Alere **HemoPoint® H2** Microcuvette shelf life is reduced once the lid is opened. See the Alere **HemoPoint® H2** Microcuvette container label for additional information. Please make a note of the date of opening on the container label.

3. The Alere **HemoPoint® H2** Microcuvette is a precision optical component!

The Alere **HemoPoint® H2** Microcuvette is analyzed optically in the Alere **HemoPoint® H2** Meter. The measured absorption is proportional to the hemoglobin concentration. The light from the light source should penetrate through the sample to the photo detector with the least possible influence from the Alere **HemoPoint® H2** Microcuvette. Therefore it is important not to touch the optical eye of the cuvette with fingers or sharp objects (see Illustration 7).

4. The Alere **HemoPoint® H2** Microcuvette is only designed for in-vitro testing!
5. The reagents that coat the inner walls of the Alere **HemoPoint® H2** Microcuvette are harmful and must not be swallowed.

4.1.2 Taking a Sample of Capillary Blood

1. Take out a Alere **HemoPoint® H2** Microcuvette from the original container and immediately close the lid.



Please note Section 4.1.1
“Notes on Using the Alere **HemoPoint® H2** Microcuvette”.



Illustration 8: Preparing to take a blood sample.

2. Make sure that your patient is sitting comfortably. There should be good blood circulation in the hand from which you wish to take blood, i.e. it should be warm and relaxed.



If in doubt, the hands can be warmed in warm water.



Illustration 9: Stimulating the circulation.

3. Lightly massage the fingers, in order to stimulate the circulation.



Warning, Risk of Infection!

Please wear suitable protective gloves!



Only use the middle or ring finger. The patient should not be wearing a ring on the finger used for sampling.



Illustration 10: Disinfecting the puncture site.

4. Disinfect the puncture site and allow to dry.



Illustration 11: Sticking the finger.

5. Press lightly on the fingertip and puncture with a suitable sampling device on the side of the fingertip.



Sticking the fingertip on the side is less painful and the blood flow is better. To ensure having a spontaneous flow of blood use a sampling device with a proper depth size (2.25 mm).

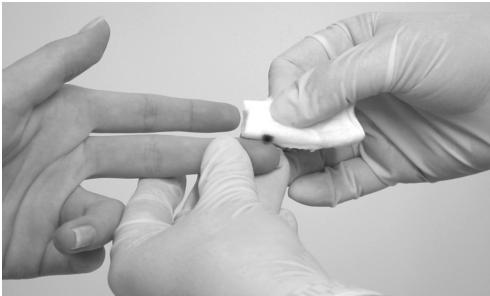


Illustration 12: Blotting the first drop of blood.

6. Blot away the first drop of blood then, if necessary, press gently once again to get a drop of blood which is large enough to fill the Alere **HemoPoint® H2** Microcuvette completely. Avoid “milking”. (For additional information about obtaining a capillary blood sample, read the latest CLSI guideline. Order information may be found at www.clsi.org.)

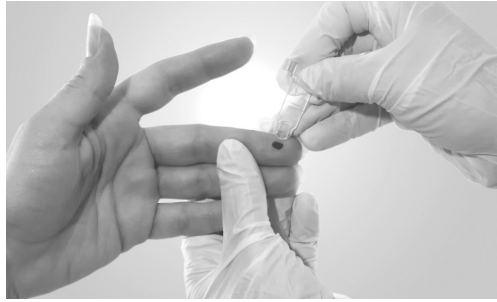


Illustration 13: Filling the cuvette.

7. Hold the center of the Alere **HemoPoint**[®] **H2** Microcuvette in the middle of the drop of blood and wait until the Alere **HemoPoint**[®] **H2** Microcuvette is filled completely. DO NOT fill from the side as this could create air bubbles in the Alere **HemoPoint**[®] **H2** Microcuvette optic window and result in an erroneous result.



WARNING!

Ensure that the Alere **HemoPoint**[®] **H2** Microcuvette cavity is completely filled and free of air bubbles. DO NOT try and top-off Alere **HemoPoint**[®] **H2** Microcuvette if not filled completely. Repeat the process with a new drop of blood and a new Alere **HemoPoint**[®] **H2** Microcuvette.

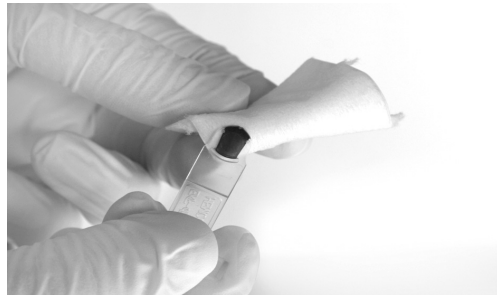


Illustration 14: Removing excess blood.

8. In order to avoid contamination of the Alere **HemoPoint**[®] **H2** Microcuvette holder, remove excess blood from the outside of the Alere **HemoPoint**[®] **H2** Microcuvette by carefully wiping off with a gauze or lint-free tissue.



WARNING!

Please note, do not remove any blood from the Alere **HemoPoint**[®] **H2** Microcuvette cavity. DO NOT try and top-off Alere **HemoPoint**[®] **H2** Microcuvette if not filled completely. Repeat the process with a new drop of blood and a new Alere **HemoPoint**[®] **H2** Microcuvette.

The Alere **HemoPoint® H2** Microcuvette sample can now be tested immediately or within 10 minutes. **DO NOT** read Alere **HemoPoint® H2** Microcuvette after 10 minutes. For further steps, please read Section 4.2 “Performing the Test”.

4.1.3 Taking a Sample of Venous or Arterial Blood

The Alere **HemoPoint® H2** Meter can be used for determination of hemoglobin in venous or arterial blood samples if the blood collection date is not longer than 24 hours and the sample was stored refrigerated (2-8°C). Prepare the sample for testing as follows:

1. Remove sample tube from the refrigerator and bring it to room temperature (15-30°C).
2. Mix the sample well (i.e. by a mechanical rotator or by inverting by hand).
3. Take out a Alere **HemoPoint® H2** Microcuvette from the container and immediately close the lid.



Please note Section 4.1.1 “Notes on Using the Alere **HemoPoint® H2** Microcuvette”.

4. Pipette a sufficient drop of blood on a non-absorbent material (i.e. plastic film).
5. Hold the center of the Alere **HemoPoint® H2** Microcuvette in the middle of the drop of blood and wait until the Alere **HemoPoint® H2** Microcuvette is filled completely (see Illustration 15). **DO NOT** fill from the side as this could create air bubbles in the Alere **HemoPoint® H2** Microcuvette optic window and result in an erroneous result.

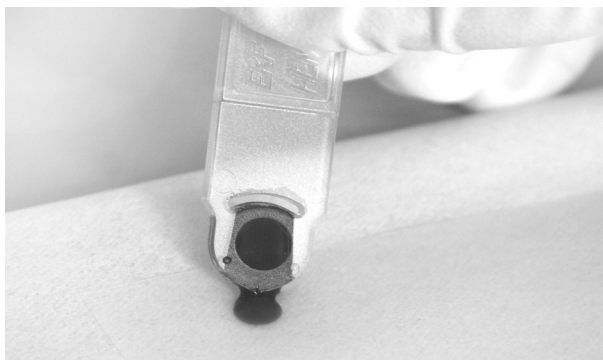


Illustration 15: Taking a sample of venous or arterial blood.



Ensure that the Alere **HemoPoint® H2** Microcuvette cavity is completely filled and free of air bubbles. **DO NOT** try and top-off Alere **HemoPoint® H2** Microcuvette if not filled completely. Repeat the process with a new drop of blood and a new Alere **HemoPoint® H2** Microcuvette.

6. In order to avoid contamination of the Alere **HemoPoint® H2** Microcuvette holder, remove excess blood from the outside of the Alere **HemoPoint® H2** Microcuvette by carefully wiping off with a gauze or lint-free tissue (see Illustration 14).



Please note, do not remove any blood from the Alere **HemoPoint® H2** Microcuvette cavity. **DO NOT** try and top-off the Alere **HemoPoint® H2** Microcuvette if not filled completely. Repeat the process with a new drop of blood and a new Alere **HemoPoint® H2** Microcuvette.

The Alere **HemoPoint® H2** Microcuvette sample can now be tested immediately or within 10 minutes. **DO NOT** read Alere **HemoPoint® H2** Microcuvette after 10 minutes. For further steps, please read Section 4.2 “Performing the Test”.

4.2 Performing the Test

(“Hgb limit” mode ON with the “Hematocrit” mode ON)

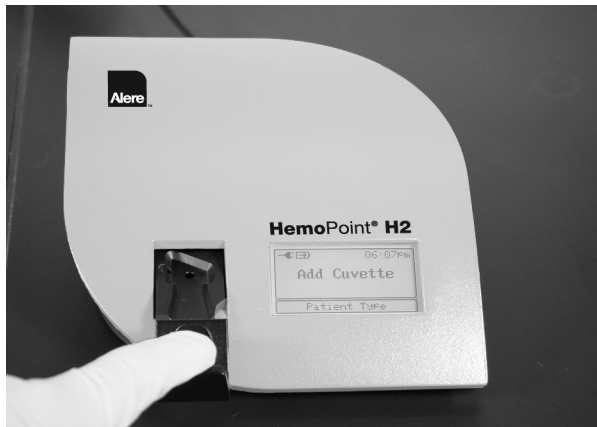


Illustration 16: Opening the Alere **HemoPoint® H2** Microcuvette holder.

1. Open the Alere **HemoPoint® H2** Microcuvette holder completely.

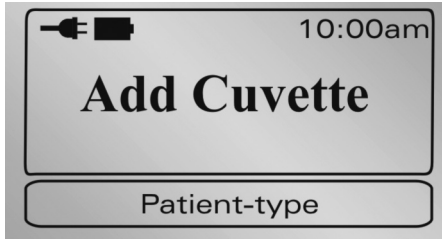


Illustration 17: Display "Add Cuvette".



The instrument will check the optical performance of the measuring system. This process takes approx. 1 – 2 seconds. Release the Alere **HemoPoint® H2** Microcuvette holder and do not touch it again until the process is finished and an audible signal (beep) occurs.

2. If you have the “Hgb limit” mode activated and set the normal range for each patient type (see Section 5.3.5 “Hgb Mode and Limits”), the display will show the “Patient type” buttons that can be selected before testing occurs. Select the patient type by touching the appropriate button. If you select “NO”, then no patient range will be displayed or printed with the result.

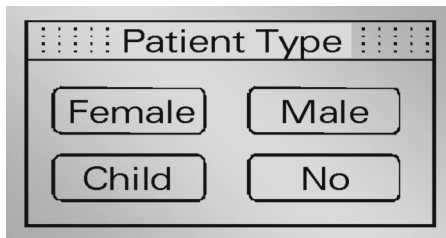


Illustration 18: Display to select "Patient Type".

In case you wish to change or cancel the selected patient type, simply touch the “Patient Type” button and make another selection.

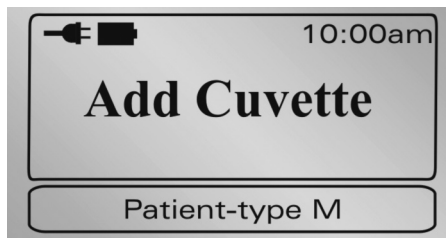


Illustration 19: Display after a patient type (male) is chosen.

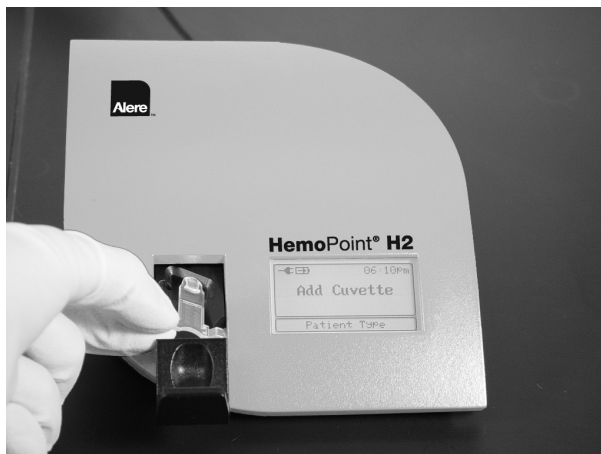


Illustration 20: Inserting the cuvette.

3. Insert the appropriate patient microcuvette (example, Male) into the Alere **HemoPoint® H2** Microcuvette holder as shown in Illustration 20, making sure the Alere **HemoPoint® H2** Microcuvette is properly inserted into the holder.
4. Push gently on the Alere **HemoPoint® H2** Microcuvette holder and it will close automatically. **DO NOT** force!
5. Testing of the Alere **HemoPoint® H2** Microcuvette begins automatically (see Illustration 21).



WARNING!

Ensure the Alere **HemoPoint® H2** Microcuvette holder closes completely, otherwise the Alere **HemoPoint® H2** Microcuvette will not be positioned correctly in the Alere **HemoPoint® H2** Meter and this will cause an incorrect result.

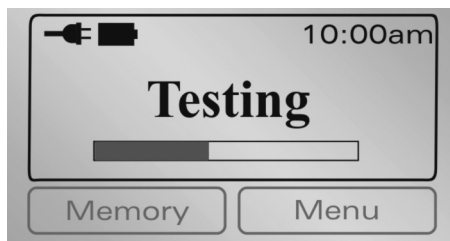


Illustration 21: Display during the testing cycle.



TIP

The testing time varies according to the hemoglobin concentration and can take between 10 – 60 seconds.



Patient Types: M ... Male, F ... Female, C ... Child
Symbols for exceeding Hgb-limits: H ... Result above upper limit threshold
L ... Result below lower limit threshold
Illustration 22: Display showing the test result.

6. Read the test result.



You can now make a note of the result(s). Pressing the OK button is not absolutely necessary. It merely produces a confirmation of the result, while the meter changes to the ready mode display. Opening the Alere **HemoPoint® H2** Microcuvette holder will start a new testing cycle.

The hemoglobin result is displayed with the selected patient type and may be marked with an (H) High or (L) Low if the result falls outside the selected patient normal range. An estimated Hematocrit result will be displayed if the “Hct mode” is activated (see Section 5.3.8.1 Hematocrit Mode). The measured result(s) is stored and can be recalled later from the memory (data storage) which can hold up to 4000 patient results (see Section 5.2.1 “Displaying Results from Memory”).

If you have connected a printer, the current test result will be printed out immediately. Further information about connecting a printer can be found in Section 5.4.1 “Connecting a Printer”.

If you prefer the display shows the result in another type of unit, you can change it as described in Section 5.3.4 “Setting the Units”.

7. Open the Alere **HemoPoint® H2** Microcuvette holder, take out the used Alere **HemoPoint® H2** Microcuvette and dispose properly (see Section 6.4 “Proper Disposal”). Keep the Alere **HemoPoint® H2** Microcuvette holder closed when meter is not in use.



TIP

When the holder is opened, a new testing cycle is started and the Alere **HemoPoint® H2** Meter checks the optical performance of the measuring system and automatically becomes ready for a new cuvette to be inserted.

If you do not want to perform another test, simply close the Alere **HemoPoint® H2** Microcuvette holder again. The test cycle will be cancelled.

4.3 Quality Control

4.3.1 AutoCheck

The Alere **HemoPoint® H2** AutoCheck performs an internal check of the meter's optic system every time the Alere **HemoPoint® H2** Microcuvette holder is opened. If regulatory quality control checks are required, the quality control check should be performed using Alere™ Hemoglobin Controls.

4.3.2 Blank Reading

All the optical and mechanical components involved with the measuring cycle are carefully manufactured with extremely small tolerances. This is essential for the proper function of the Alere **HemoPoint® H2** Meter.

Always carry out a blank reading whenever you have removed the Alere **HemoPoint® H2** Microcuvette holder (i.e., cleaning, replacing with a new Alere **HemoPoint® H2** Microcuvette holder).

A blank reading can be performed as follows:

1. Open the Alere **HemoPoint® H2** Microcuvette holder completely.



TIP

The text in the display reads “Add Cuvette”.

2. Close the Alere **HemoPoint® H2** Microcuvette holder, without inserting a cuvette.



TIP

In this case the meter does not start testing. After approx. 2 – 3 seconds the display will read “Open Holder”. If the instrument does not show “Open Holder”, there is possibly a malfunction. Please consult Section 7 “Troubleshooting”.

4.3.3 Alere HemoPoint® H2 Control Cuvette

The Alere **HemoPoint® H2** Control Cuvette supplied with the Alere **HemoPoint® H2** Meter can be used for a simple check of the Alere **HemoPoint® H2** Meter's calibration.



Illustration 23: Control cuvette.

The Hgb value and the permitted deviation of the Alere **HemoPoint® H2** Control Cuvette are stated on the storage box label. All Alere **HemoPoint® H2** Meters have a specific calibration due to the tolerances in the mechanical and electronic components. The Alere **HemoPoint® H2** Control Cuvette is only calibrated for the instrument with which it is delivered, i.e. the Hgb value stated on the storage box label is only valid for that one Alere **HemoPoint® H2** Meter, and could lead to completely different results on another Alere **HemoPoint® H2** Meter.



If you have several Alere **HemoPoint® H2** Meters, keep track of each Alere **HemoPoint® H2** Control Cuvette for each Alere **HemoPoint® H2** Meter.

*When not being used, keep the Alere **HemoPoint® H2** Control Cuvette in the original storage box. It is optimally protected there against breakage and contamination.*

To test the Alere **HemoPoint® H2** Control Cuvette, proceed as follows:

1. Open the Alere **HemoPoint® H2** Microcuvette holder completely and wait until the meter displays “Add Cuvette”.
2. Take the Alere **HemoPoint® H2** Control Cuvette out of the storage box and place it in the Alere **HemoPoint® H2** Microcuvette holder.
3. Close the Alere **HemoPoint® H2** Microcuvette holder completely.



The Alere **HemoPoint® H2** Meter tests the Alere **HemoPoint® H2** Control Cuvette and shows the result after a few seconds.

4. Compare the result with that stated on the storage box label. The result must lie within the stated range. Record the control result!



If the Hgb result falls outside the range of the Alere **HemoPoint® H2** Control Cuvette, there is evidently a problem. Please consult Section 7 “Troubleshooting” in this regard.

If the original control cuvette is lost or damaged, a new Alere **HemoPoint® H2** Control Cuvette must be assayed. Please contact Alere™ Technical Support at (1) 866-216-0073 to discuss options for replacing your Alere **HemoPoint® H2** Control Cuvette.

4.3.4 External Quality Control

If additional quality control is required by local or other regulations, external control material may be used. For this purpose, we recommend the use of Alere™ Hemoglobin Controls.

There are a variety of hemoglobin controls on the market today. Alere only recommends the use of the Alere™ Hemoglobin Controls, since we cannot guarantee the compatibility of other brands of controls on the Alere **HemoPoint® H2** System.

Thoroughly mix the controls before use (see the control package insert for directions).



Compare the values obtained with the Alere™ Hemoglobin Controls against the stated reference values. If the Hgb result falls outside the range of the Alere™ Hemoglobin Controls, there is evidently a problem. Please consult Section 7 “Troubleshooting” in this regard.

Further functions

5.1 Touchscreen

5.1.1 General

The Alere **HemoPoint® H2** Meter has been equipped with a touchscreen. The touch sensitive surface is divided into various individual segments. According to the current operating mode, these segments can be defined as operating buttons.

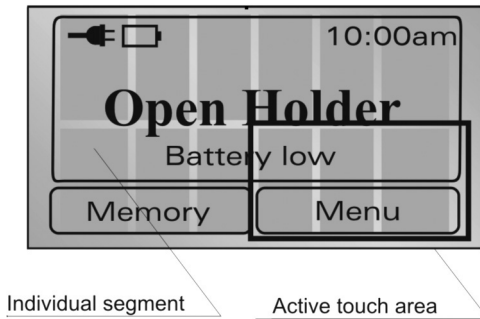


Illustration 24: Divided touchscreen.

The buttons in the lower part of the display are enlarged to allow easy operation. As can be seen in Illustration 24, the sensitive area of these buttons extends into the middle of the display, so it is not difficult to operate them.









WARNING!

A touchscreen is a delicate electronic component. Therefore please note the following instructions:

- Only touch the touchscreen lightly with fingertips.
- Avoid sharp objects such as ball-point pens, fingernails, etc.
- Only clean the touchscreen with a soft cloth that is lightly dampened with water or a mild cleaning solution. Follow the instructions given in Section 6.1 “Cleaning and Disinfection of the Instrument”.

5.1.2 Meaning of the Buttons / Navigation

| | |
|---|---|
|  | Software button, calls up appropriate function such as Memory or Menu. |
|  | “UP” button, selects the next higher listed item or increases the numerical value. |
|  | “DOWN” button, selects the next lower listed item or decreases the numerical value. |
|  | “ESC” button, leaves the menu screen or rejects changes. |
|  | “OK” button, selects the next lower menu screen or confirms a selection. |
|  | Shows a button that is inactive. |

5.2 Memory (Data Storage)

The instrument is equipped with data storage, which can store up to 4000 results.

5.2.1 Displaying Results from Memory

Access to the data storage is possible only if the Alere **HemoPoint® H2** Meter is in the ready mode (Open Holder).

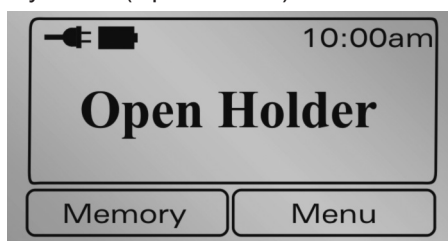



Illustration 25: Display screen, ready mode (Open Holder).

 Press this button to display the test data.

You will see the following screen display, for example:

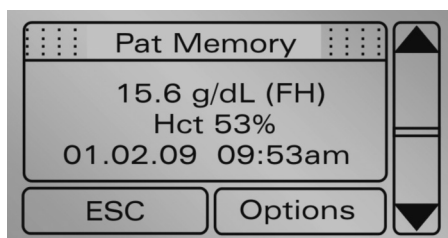


Illustration 26: Display screen, data storage.

The entry displayed is the most recent result.



Press this button to display preceding results until you reach the first entry on the list.



Press this button to display successive results, until you reach the last entry on the list.



Press this button (Escape) to leave the memory (data storage).



Press this button to select the menu “Options”. In this menu you will find additional functions for printing and for deleting results.

Further information in this regard can be found in Sections 5.2.2 and 5.2.3.






If correlation is activated (see Section 5.3.1 “Information about the Alere **HemoPoint® H2** Meter”) you may see - - - or +++ symbols at any position in the data storage. This indicates that the real results cannot be shown with the current settings of the correlation function, because they exceed the testing range.

If the estimated Hematocrit mode has been activated the hematocrit result will be displayed as well (see Section 5.3.8.1 “Hematocrit Mode”).

5.2.2 Printing Out Results

In order to print out from memory (data storage) you must have a printer connected. Instructions for this can be found in Section 5.3.8.2 “Print Mode”.

You can print out results as follows:

- From the memory (data storage) display, press the button .
- Select the entry “Print” using the buttons  .
- Confirm the selection with , to print out the results, otherwise press , in order not to print.








Printing out the results can take a few seconds. Following printing, the Alere **HemoPoint® H2** Meter changes back again to display the memory (data storage).

5.2.3 Deleting the Stored Test Data

With this function the entire data storage (all results) is deleted.

To delete the data storage, proceed as follows:

- From the memory (data storage) display, press the button  .
- Select the entry “Delete” using the buttons.  
- Confirm the selection with , to delete the data storage, otherwise press , in order to not delete.



After deleting, the instrument changes back again to display memory (data storage) – “Empty”.

5.3 Menu Functions

The Alere **HemoPoint® H2** Meter has various possible settings that can be accessed through the menu function.

Access to the menu is possible only if the Alere **HemoPoint® H2** Meter is in the ready mode.

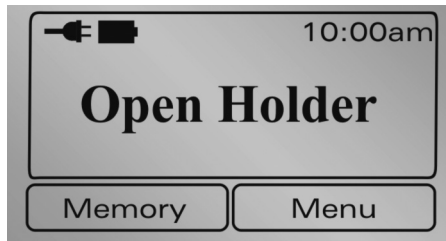


Illustration 27: Display screen, ready mode.



Press this button to access the Menu.

You will see the following screen display:



Illustration 28: Display screen, Menu.



Press this button to scroll up to desired menu entry.



Press this button to scroll down to desired menu entry.



Press this button to select the next higher menu level, or to leave the menu.



Press this button to select the next lower menu level, to adjust settings, or to display information.

5.3.1 Information about the Alere HemoPoint® H2 Meter

Information about the Alere **HemoPoint® H2** Meter and the status of various components can be found under the menu item “Info”.



You can scroll up or down with the arrow buttons.



With this button you can leave the information display again.

The following information is displayed:

| Test Count | |
|-----------------|--|
| Total: | Total number of tests performed on this instrument |
| Today: | Number of tests performed today |
| Battery: | Number of tests performed using battery power |
| Battery | |
| | Remaining battery charge |
| Memory | |
| | Pat: Number of new test results / number of test results |
| Serial No. | |
| | Serial number of the Alere HemoPoint® H2 Meter |
| Model No. | |
| | Model number of the Alere HemoPoint® H2 Meter |
| Version | |
| | Software Version |
| | Electronic hardware |
| | Mechanical hardware |

Adaptation

Correlation function to conform the output of results with different devices and/or methods.

$$y = m * x + n$$

m ... correlation factor

n ... offset

if $m = 1$ and $n = 0$ (factory defaults) the function is not active

The correlation can only be enabled by authorized personnel on special request. Contact Alere™ Technical Service Department for additional information.

SPN

The current **S**ervice **P**rocess **N**umber, needed by Servicing

5.3.2 Setting the Date

The function of setting the current date can be found under “Menu”, sub-menu “Date”. Setting the date is important for the correct relationships of the results from the memory (data storage) or for printing out the results.

The format to enter the date depends on the date format setting (see Section 5.3.7.2 “Setting Date Format”).



The arrow buttons increase or decrease the numerical value in each case.



Press this button to reject the entry and to leave the adjustment.



Press this button to confirm the current setting and to access the next entry. After entering the last value, the settings are stored and you leave the adjustment menu.

5.3.3 Setting the Time

The function of setting the Alere **HemoPoint® H2** Meter to the current time can be found under “Menu”, sub-menu “Time”. Setting the time is important for the correct relationships of the results from the memory (data storage) or for printing out the results.

The format to enter the time depends on the time format setting (see Section 5.3.7.3 “Setting Time Format”).

The functions of the individual buttons can be found in Section 5.3.2 “Setting the Date”.

5.3.4 Setting the Units

The function of setting the units can be found under “Menu”, sub-menu “Unit”. This gives you the ability to set the test unit for the hemoglobin value you wish to use. This setting influences all test displays, including the results in the memory (data storage) and the printer.

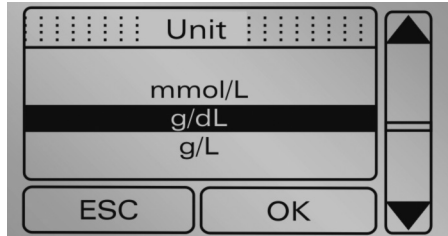


Illustration 29: Display screen, Unit

You can select the following units:

- mmol/L
- g/dL (default)
- g/L



Select the appropriate entry using the arrow buttons.



Press this button to reject the selection.



Press this button to confirm the selection.

5.3.5 Hgb Mode and Limits

The function of enabling the Hgb mode and setting the limits can be found under “Menu”, sub-menu “Hgb limits”. This gives you the ability to enable or disable the Hgb mode and to set the normal range limits of each patient group. This setting influences all test displays, including the results in the memory (data storage) and the printer.

Limits can be set for the following groups of patients:

- Adult Male - (13 – 18 g/dL) default
- Adult Female - (11– 16 g/dL) default
- Child - (11 – 16 g/dL) default

Limits can be set within 5 – 25.5 g/dL (0.31 – 15.81 mmol/L).



TIP

While the “Hgb limits” mode is activated, the lower limits must show different values than the upper limits of all groups of patient. Otherwise the “Hgb-limits” mode will be inactive.

5.3.6 Setting the Display Contrast

The LCD display contrast is strongly dependent for technical reasons on the environmental temperature. You can set the contrast by entering “Menu”, sub-menu, “Contrast”. Default setting is “3”. Higher numbers will darken the screen.



Please be very careful when setting the contrast. At certain temperatures you can no longer read anything on the display under certain conditions with some contrast settings. Should you accidentally store these settings by pressing the OK button, the instrument must be reset. You can read about this in Section 7 “Troubleshooting”.

The function of the individual keys can be found in Section 5.3.2 “Setting the Date”.

5.3.7 Settings

In this menu some general format settings can be found.

5.3.7.1 Setting the Language

The Alere **HemoPoint® H2** Meter supports various languages. The function of setting the language can be found under “Menu”, sub-menu “Settings”, sub-menu “Language”. This gives you the ability to set the Alere **HemoPoint® H2** Meter to the language you wish to use.

The following languages are supported:

- English (default)
- German
- Spanish

The function of the individual keys can be found in Section 5.3.4 “Setting the Units”.

5.3.7.2 Setting Date Format

Under the “Menu”, sub-menu “Settings”, sub-menu “Date Format” the output format of the date can be set. This affects the output of data record in the memory (data storage) and the printout of the results.

The following settings are supported:

- DD.MM.YY (Day.Month.Year)
- MM/DD/YY (Month/Day/Year) (default)
- DD/MM/YY (Day/Month/Year)
- YY-MM-DD (Year-Month-Day)

5.3.7.3 Setting Time Format

Under “Menu”, sub-menu “Settings”, sub-menu “Time Format” the output format of the time can be set. This affects the output of data records in the memory (data storage) and the printout of the results. The following settings are supported:

- 12 hours (default)
- 24 hours

5.3.7.4 Setting the Power Frequency

Under “Menu”, sub-menu “Settings”, sub-menu “Frequency” the frequency of the electrical current can be set. In the United States 60 Hz is the norm. The following settings are supported:

- 50 Hz
- 60 Hz (default)

The function of the individual keys can be found in Section 5.3.4 “Setting the Units”.

5.3.8 Menu Options

To keep the main menu clear, all functions that are used less frequently have been placed under the menu item “Options”.

5.3.8.1 Hematocrit Mode

Display of an estimated hematocrit value can be activated in “Menu”, sub-menu “Options”, sub-menu “Hematocrit”. The hematocrit value will be calculated using the formula $Hct = F \times Hgb$ [g/dL], with $F = 2.94$. A true hematocrit test is not determined with this system.



The use of this formula is allowed only within the normal hemoglobin range, means from 12.0 g/dL (7.44 mmol/L) – 18.0 g/dL (11.16 mmol/L). If the Hgb result is outside this range then the estimated hematocrit result will not be calculated and “N/A” will appear.

5.3.8.2 Print Mode

To print-out test result(s) and result(s) from the memory (data storage), the Alere **HemoPoint® H2** Meter printer function must be turned on.

Under “Menu”, sub-menu “Options”, sub-menu “Print Mode” select “Standard” to turn on the print function.

5.3.8.2.1 Print Mode Examples

5.3.8.2.1.1 Hgb Limit Mode (Off) Hematocrit (On)

```
Alere - HemoPoint H2
Name .....: _____
ID .....: _____
14.09.11 04:08pm
Hgb .....: 16.7 g/dL
Hct .....: =49%
Version.....: 2.08.1b
Serial No...: 3005-07-0001
Cust. Serv. : 877-441-7440
```

5.3.8.2.1.2 Hgb Limit Mode (On), Hematocrit (On)

Value is in the normal range

```
Alere - HemoPoint H2
Name .....: _____
ID .....: _____
14.09.11 04:08pm
Hgb .....: 16.7 g/dL
Hct .....: =49%
Hgb Limits
Male .....: 13.0-18.0 g/dL
Female ...: 11.0-16.0 g/dL
Child .....: 11.0-16.0 g/dL
Version.....: 2.08.1b
Serial No...: 3005-07-0001
Cust. Serv. : 877-441-7440
```

5.3.8.3 Setting the Tone Signal

Under “Menu”, sub-menu “Options”, sub-menu “Tone” the signal can be switched ON or OFF. This adjustment affects the button signals as well as the signals that sound at the end of the current test.

5.3.8.4 Setting the Backlight Mode

Under “Menu”, sub-menu “Options”, sub-menu “Backlight” the backlight can be switched ON or OFF when under battery operation. If turned ON the backlight is temporarily switched on for all entries and actions. Under electrical power operation the backlight is always on.

Note: The backlight consumes power from the battery, and therefore shortens the operation time of the instrument under battery operation.

5.3.8.5 Setting the Stand-by Time

The Alere **HemoPoint® H2** Meter is equipped with integrated energy management. If the Alere **HemoPoint® H2** Meter is not used for a certain time, it switches into the stand-by mode (see Section 3.3.4 “Stand-by Mode”). Under this menu, you can set the number of minutes the Alere **HemoPoint® H2** Meter will remain active (ON), after which the instrument will switch off.

Under “Menu”, sub-menu “Options”, sub-menu “Stand-by” the stand-by time can be set according to your preference. Use the appropriate arrow key to either increase or decrease the stand-by time (in increments of 1 minute).

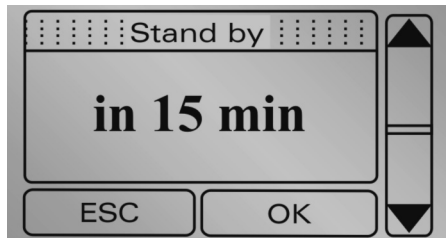


Illustration 30: Display screen, Stand-by.

5.3.8.6 The Service Menu

Under “Menu”, sub-menu “Options”, sub-menu “Service”, this menu item is intended for an authorized Alere™ Technical Service representative only.

5.3.9 Information on Contacting Us

Information on how to contact Alere if you need further help or if you wish to place an order is found under “Menu”, sub-menu “Contact”. This information can also be found in Section 13 “Contact Alere”.

5.4 Connecting Accessories

The Alere **HemoPoint® H2** Meter is equipped with a serial interface at the back of the instrument.



Illustration 31: Interface socket.



Only instruments specifically intended for the purpose should be connected to this interface socket, using the appropriate connecting cable. To avoid short circuits, keep sharp metallic objects away from the sockets.

5.4.1 Connecting a Printer

The Alere **HemoPoint® H2** Meter supports the connection of the Alere™ Universal Printer (Alere™ item #55115). The Alere™ Universal Printer can be ordered through your authorized Alere distributor.

With the use of a printer you can print each patient's test result immediately or print patient result(s) from memory (data storage) later (see Section 5.2.2 "Printing Out Results").

5.4.1.1 Connecting the Printer Cable

To connect the printer to the Alere **HemoPoint® H2** Meter a special printer cable (Alere™ item #52217) must be purchased separately from an authorized Alere **HemoPoint® H2** distributor.



Please only use the cable intended for this purpose, otherwise both the Alere **HemoPoint® H2** Meter and the printer may be seriously damaged.

Maintenance

6.1 Cleaning and Disinfection of the Instrument

6.1.1 Housing and Touchscreen



It is essential to follow the instructions in Section 1.3 “Safety Notes”. Disconnect the power adaptor from the electrical connection before proceeding.

Cleaning the housing and touchscreen is best accomplished with a lint-free cloth, **lightly** dampened with clean water. For more stubborn soiling, a **mild** soap solution may be used. For disinfection, standard solutions can be used for surface disinfection provided they **do not** contain alcohol or other solvent.



The housing is equipped with a high-quality lacquered surface. Please do not use any harsh cleaning agent or solvent otherwise the surface can be damaged and the Alere **HemoPoint® H2** Meter will look unsightly.



Before cleaning the touchscreen, open the Alere **HemoPoint® H2** Microcuvette holder.

6.1.2 Alere HemoPoint® H2 Microcuvette Holder

The Alere **HemoPoint® H2** Microcuvette holder can be removed from the instrument for cleaning. Proceed as follows:

- Disconnect the power adaptor from the electrical connection before proceeding.
- Open the Alere **HemoPoint® H2** Microcuvette holder until you feel a resistance and the holder will not extend further.
- Press down the silver pin on the left-hand side (bottom) of the Alere **HemoPoint® H2** Microcuvette holder with a ball-point pen and draw the Alere **HemoPoint® H2** Microcuvette holder forward at the same time.



Illustration 32: Removing the Alere HemoPoint® H2 Microcuvette holder.

The Alere **HemoPoint® H2** Microcuvette holder can now be cleaned with a mild soap solution. For disinfection, standard solvent-free preparations can be used.

To replace the Alere **HemoPoint® H2** Microcuvette holder, simply push it in the correct position into the opening in the housing until it engages.



Please wait until the Alere **HemoPoint® H2** Microcuvette holder is completely dry before replacing it. Do not use any cleaning agent for cleaning the Alere **HemoPoint® H2** Microcuvette holder that could leave scratches on its surface.

6.1.3 Optical Unit

The optical unit is situated inside the Alere **HemoPoint® H2** Meter and has no direct contact with the Alere **HemoPoint® H2** Microcuvette therefore no routine cleaning is needed. Cleaning the optical unit can become necessary if the measured maximum light intensity of the photometric light source no longer achieves the appropriate level required for testing. The optical unit should be cleaned when the following error message is displayed: **Dirty Optics – Use Optics Cleaner** (see Illustration 33, Display screen, Measurement Error).

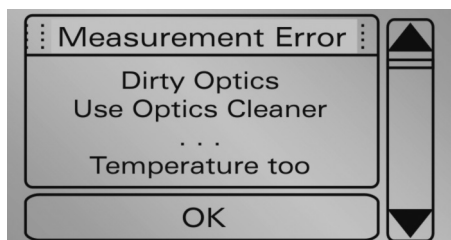


Illustration 33: Display screen, Measurement Error.

For cleaning the optical unit the use of a special Alere **HemoPoint® H2** Optics Cleaner is recommended. You received an Alere **HemoPoint® H2** Optics Cleaner in your Alere **HemoPoint® H2** System kit. Additional Alere **HemoPoint® H2** Optics Cleaners can be obtained through an authorized Alere distributor. Please follow the instructions for use that can be found in the package insert that comes with the Alere **HemoPoint® H2** Optics Cleaner.



Cleaning the optical unit is a delicate operation inside the instrument. Please do not use any cleaning agents other than original Alere **HemoPoint® H2** Optics Cleaner.

6.1.4 Power Adaptor



Care! Danger of fatal electric shock!

It is essential to follow the instructions in Section 1.3 “Safety notes”. Disconnect the power adaptor from the electrical connection before proceeding.

The power adaptor can be cleaned and disinfected in the same way as the instrument housing (see Section 6.1.1 “Housing and Touchscreen”).

6.2 Charging and Care of the Battery

The Alere **HemoPoint® H2** Meter is equipped with a NiMH (Nickel Metal Hydride) battery. The capacity of the battery is calculated on the basis of being sufficient for 100 hours of measuring operation. As with many other components, the battery will lose capacity over time. Frequent partial discharging and re-charging accelerates this process. By observing a few “golden rules” you can considerably influence the life span of the battery:

6.2.1 Charging Procedure

To maintain the battery’s full capacity, the battery should always be discharged as completely as possible before being recharged again.

The instrument is designed so that the battery will immediately recharge when it is connected to the power adaptor.



To conserve the battery capacity, from time to time leave the instrument in battery operation mode until it is almost fully discharged.



Illustration 34: Display screen when battery is discharged.

6.2.2 Charging Time

The battery charging time depends on the charge remaining and can be fully charged in 9 hours.



If you recharge it overnight, the battery will be fully charged and ready for use.

After recharging, it is not necessary to disconnect the Alere **HemoPoint® H2** Meter from the electrical connection. Overcharging the battery is impossible.

6.2.3 Self Discharge

Self-discharging is a typical property of batteries. Even when you are not using the instrument, the battery slowly discharges and later reaches the deeply discharged phase, which can damage the battery.



IMPORTANT!

Fully charge the battery at least once a month.

6.3 Repairs



Care! Danger of fatal electric shock!

It is essential to follow the instructions in Section 1.3 “Safety Notes”.

If your instrument does not function as expected, i.e. if the measured results are not credible, or you are getting incorrect reports from the instrument, try to solve the problem initially with the aid of Section 7 “Troubleshooting”.

If you require assistance, contact Alere™ Technical Service department at 1-866-216-0073.

6.4 Proper Disposal

It is the responsibility of the user to arrange proper disposal of the individual components.

- The Alere **HemoPoint® H2** Microcuvettes and containers for potentially infectious solutions (Hemolysate, control bloods, etc.) must be disposed of in accordance with the regulations in force in your establishment.
- The Alere **HemoPoint® H2** Meter and electronic accessories must be disposed of according to the regulations for the disposal of electronic components, after removing the battery.
- The battery must be disposed of according to the regulations for the disposal of old batteries.

Troubleshooting

Before you call Alere™ Technical Service department or send the instrument in for repair, please try to define or solve the problem with the help of this section.



Care! Danger of fatal electric shock!

It is essential to follow the instructions in Section 1.3 “Safety Notes”.

7.1 Problem Solving

| No Display, No Response to Entries | |
|------------------------------------|---|
| Battery is empty | Power the instrument with the power adaptor; allow the battery to recharge completely. |
| Battery is defective | Instrument can only be operated when powered with the power adaptor. |
| Software does not respond | Perform a reset of the instrument (see Section 7.2 “Resetting of the Alere HemoPoint® H2 Meter ”). |

| Battery Problems | |
|---------------------------------------|--|
| Error message: “Defective battery” | A battery problem was found. Following this message the battery is switched off. The instrument can only be operated when powered with the power adaptor. -> Contact Alere™ Technical Support. |
| No battery symbol displayed | The battery has been switched off by the instrument. The instrument can only be powered with the power adaptor. -> Contact Alere™ Technical Support. |

| Battery Problems | |
|--|--|
| The battery operation time is too short. The instrument switches off without previous warning. | <ul style="list-style-type: none"> • Always leave the instrument connected to the power adaptor until the charging process has been completed. • The battery has deteriorated and should be replaced. <p>-> Contact Alere™ Technical Support.</p> |

| Power Adaptor Problems | |
|---------------------------------------|--|
| No plug symbol displayed | <ul style="list-style-type: none"> • Power adaptor not powered from the electrical source. • Instrument plug not connected. • Wrong power adaptor. • Defective power adaptor. <p>-> Contact Alere™ Technical Support.</p> |
| Error message "Wrong power supply" | Disconnect the wrong adaptor immediately and connect with the correct adaptor. |
| Error message "Voltage too low" | <p>When operated with the power adaptor:</p> <ul style="list-style-type: none"> • Wrong power adaptor connected. |

Problems with QC Measurements and Sample Measurements

| | |
|--|--|
| <p>Test results are not realistic.</p> <p>Control blood test result is out of range.</p> | <ul style="list-style-type: none"> • Defective or superimposed Alere HemoPoint® H2 Microcuvette. • Air bubbles in the Alere HemoPoint® H2 Microcuvette. • Sampling error (see Section 4.1 “Taking a Sample”) • Wrong or unsuitable control blood. Incorrect control level. • Alere HemoPoint® H2 Microcuvette holder not properly engaged; replace Alere HemoPoint® H2 Microcuvette holder (see Section 6.1.2 “Alere HemoPoint® H2 Microcuvette Holder”). • Dirty Optical unit; clean optical unit (see Section 6.1.3 “Optical Unit”). • Alere HemoPoint® H2 Microcuvette is not correctly positioned into the Alere HemoPoint® H2 Microcuvette holder. • The Alere HemoPoint® H2 Meter must be only used with Alere HemoPoint® H2 Microcuvettes. |
|--|--|

Error and Information Messages

| | |
|--|--|
| <p>Information message</p> <p>“Temp. too high”</p> | <ul style="list-style-type: none"> • Ambient temperature is too high. Operate the instrument within the correct temperature range. |
| <p>Information message</p> <p>“Temp. too low”</p> | <ul style="list-style-type: none"> • Ambient temperature is too low. Operate the instrument within the correct temperature range. |
| <p>Information message</p> <p>“Low battery”</p> | <ul style="list-style-type: none"> • Low battery operation time. Power the instrument from the power adaptor to recharge the battery. • If the battery is not recharged, the instrument will switch off after a while. |

Error and Information Messages

| | |
|--|--|
| <p>Error message “Measured value too high”</p> | <ul style="list-style-type: none"> • Wrong or unsuitable sample material (see Section 8 “Technical Data”). • Wrong sampling (see Section 4.1 “Taking a Sample”). • Defective or superimposed Alere HemoPoint® H2 Microcuvette. |
| <p>Error message “Dirty Optics – Use Optics Cleaner”</p> | <ul style="list-style-type: none"> • Dirty Optical unit; clean unit (see Section 6.1.3 “Optical Unit”). • Alere HemoPoint® H2 Microcuvette holder not properly opened or closed; repeat testing procedure. • Alere HemoPoint® H2 Microcuvette holder not properly engaged; replace Alere HemoPoint® H2 Microcuvette holder (see Section 6.1.2 “Alere HemoPoint® H2 Microcuvette Holder”). • Ambient temperature too high. • Defective optical unit <p>-> Contact Alere™ Technical Support.</p> |
| <p>Error message “Memory is full”</p> | <ul style="list-style-type: none"> • At least 4,000 test values have been stored. <p>-> Delete memory.</p> |

System Error

| | |
|---|--|
| <p>Error message “CRC ROM” “CRC RAM” “CRC EEPROM”</p> | <ul style="list-style-type: none"> • Internal problem of instrument; operation not possible. <p>-> Contact Alere™ Technical Support.</p> |
|---|--|

System Error

| | |
|---|--|
| <p>Error message</p> <p>“Defective electronics”</p> | <ul style="list-style-type: none"> • Alere HemoPoint® H2 Microcuvette in the closed Alere HemoPoint® H2 Microcuvette holder when the instrument is switched on; remove the Alere HemoPoint® H2 Microcuvette. • Dirty Optical unit; clean unit (see Section 6.1.3 “Optical Unit”). • Internal problem of instrument; operation not possible. <p>-> Contact Alere™ Technical Support.</p> |
|---|--|

Display Screen is Hard to Read.

| | |
|--|---|
| <p>Display contrast setting is unsuitable.</p> | <p>Reset the display contrast (see Section 5.3.6 “Setting the Display Contrast”).</p> |
|--|---|

Instrument Will Not Switch On.

| | |
|---|---|
| <p>Battery is discharged.</p> | <p>Plug in the power adaptor.</p> |
| <p>Software does not respond.</p> | <p>Carry out a “Reset” (see Section 7.2 “Resetting of the Alere HemoPoint® H2 Meter”).</p> |
| <p>Instrument does not react when connected to the power adaptor.</p> | <p>Check the connections and that all plug contacts are correctly seated.</p> |

Instrument Switches Off Too Quickly or Too Slowly.

| | |
|-------------------------------------|---|
| <p>Stand-by time is unsuitable.</p> | <p>Reset the stand-by time (see Section 5.3.8.5 “Setting the Stand-by Time”).</p> |
|-------------------------------------|---|

Instrument Does Not React to Opening or Closing the Cuvette Holder.

| | |
|---|---|
| <p>Battery is discharged (Display shows nothing).</p> | <p>Connect the power adaptor.</p> |
| <p>Software does not react.</p> | <p>Carry out a “Reset” (see Section 7.2 “Resetting of the Alere HemoPoint® H2 Meter”).</p> |

Background Illumination Does Not Work.

| | |
|---|--|
| Power adaptor is not connected. | Connect the power adaptor. |
| Backlight illumination is not turned on under the battery backlight mode. | Turn the backlight mode on (see Section 5.3.8.4 “Setting the Backlight Mode”). |

Tone Signal Does Not Work, or Does Not Work Properly.

| | |
|---------------------------------|---|
| Tone signal is set incorrectly. | Adjust the tone signal (see Section 5.3.8.3 “Setting the Tone Signal”). |
|---------------------------------|---|

Display Texts are Not Shown in your Language.

| | |
|------------------------------|--|
| Language is set incorrectly. | Reset the language (see Section 5.3.7.1 “Setting the Language”). |
|------------------------------|--|

Time Displayed is Incorrect.

| | |
|--------------------------|--|
| Time is set incorrectly. | Reset the time (see Section 5.3.3 “Setting the Time”). |
|--------------------------|--|

Date Shown in the Printout or Data Storage is Incorrect or Will Not be Displayed as Expected.

| | |
|---------------------------------|--|
| Date setting is incorrect. | Reset the date (see Section 5.3.2 “Setting the Date”). |
| Date format is set incorrectly. | Set the date format (see Section 5.3.7.2 “Setting Date Format”). |

Time Shown in the Printout or Data Storage is Incorrect or Will Not be Displayed as Expected.

| | |
|--------------------------|--|
| Time is set incorrectly. | Reset the time (see Section 5.3.3 “Setting the Time”). |
|--------------------------|--|

Time Shown in the Printout or Data Storage is Incorrect or Will Not be Displayed as Expected.

| | |
|---------------------------------|---|
| Time format is set incorrectly. | Set the time format (see Section 5.3.7.3 “Setting Time Format”). |
|---------------------------------|---|

Incorrect Units are Shown.

| | |
|--------------------------------|--|
| Setting of units is incorrect. | Set the units of measurement (see Section 5.3.4 “Setting the Units”). |
|--------------------------------|--|

Printer Does Not Print.

| | |
|---|--|
| Incorrect type of printer. | Connect to an Alere™ Universal printer. (see Section 5.4.1 “Connecting a Printer”). |
| Printer not “online”. | Switch the printer to online mode (see operating instructions for the printer). |
| Incorrect, or incorrectly connected, printer cable. | Use an original printer cable from Alere or check that the plug contacts are correctly seated (see Section 5.4.1.1 “Connecting the Printer Cable”). |

7.2 Resetting of the Alere HemoPoint® H2 Meter

The “Reset” serves to transfer the Alere **HemoPoint® H2 Meter** to its default settings, without changing user-specific settings significantly. The settings for contrast, date and time are lost.

The reset button can be found on the underside of the Alere **HemoPoint® H2 Meter**.



Illustration 35: Location of the reset button.

To reset the Alere **HemoPoint® H2 Meter**, simply press the button using a narrow object such as a ballpoint pen or paperclip.



Illustration 36: Confirmation display, Reset

Technical Data

8.1 Alere HemoPoint® H2 Meter

| | |
|--|---|
| Measuring procedure | Optical absorption photometry. |
| Source | Dual-Color-LED 570 / 880 nm |
| Dominant wavelength of source | 1st wavelength: 570 ± 5 nm 2nd wavelength: 880 ± 10 nm |
| Spectral half value width of the source | 1st wavelength: 15 ± 3 nm 2nd wavelength: 50 nm |
| Receiver | Photodiode 350 – 820 nm |
| Measuring range | 0 – 25.6 g/dL |
| Sample material | Venous, arterial, or capillary human blood. |
| Sample carrier | Alere HemoPoint® H2 Microcuvette. |
| Sample size | 8 µL |
| Linearity | 0- 20.0 g/dL ± 0.3 g/dL >20.0 g/dL ± 0.7 g/dL |
| Measuring time | Dependent on concentration, 10 – 60s. |
| Memory (data storage) | Up to 4000 results, including date and time. |

| | |
|----------------------------------|---|
| Dimensions (LxWxH) | 6.25 in. x 6.5 in. x 2.5 in. |
| Weight | 1.3 lbs. |
| Power supply | AC Power adaptor: Input: 100- 250 V AC / 50-60Hz Output: 6 VDC Integrated battery: Voltage: 3.6V Capacity: 2000mAh (ca. 100 h operation time) |
| Power | maximal: 3 W typically: 1.2 W minimal: 30 mW |
| Interface | Printer (RS 232 C) |
| Environmental temperature | Room temperature (15 – 40°C) |

8.2 Alere HemoPoint® H2 Microcuvette

| | |
|-------------------------------------|---|
| Type | Alere HemoPoint® H2 Microcuvette, coated with reagents for determining the hemoglobin value in venous, arterial, or capillary blood. |
| Volume in the cuvette cavity | 8 µL |
| Reagents | Sodium desoxycholate, sodium nitrite, sodium azide, non-reactive additives. |
| Material | Polystyrene |
| Storage | Room temperature (15 – 30°C), dry storage in the original containers. |
| Dimensions (LxWxH) | 1.5 in. x 1.0 in. x 0.125 in. |

Reference Range

9.1 Normal Range

Different blood hemoglobin values have been reported in the literature (1,2,3,4).

| | |
|------------------------------|------------------|
| Adult Males: | 13.0 – 18.0 g/dL |
| Adult Females: | 11.0 – 16.0 g/dL |
| Children (2 yrs to teenage): | 11.0 – 16.0 g/dL |
| Infants (post-natal) | 10.0 – 14.0 g/dL |

The highest Hgb concentrations are usually measured in neonates.

Due to the wide range of conditions (dietary, geographical, smoking, exercise, recumbency, etc.), which affect reference values, it is recommended that each laboratory establish its own expected ranges.

9.2 Understanding your Result

Hemoglobin is the oxygen-carrying pigment and main component of red blood cells. Low hemoglobin levels may indicate anemia, recent hemorrhage or fluid retention. Elevated hemoglobin levels may indicate hemoconcentration from polycythemia or dehydration.

1. Fandek N, Moreau D, Newell KC, Ofner A, eds. *Clinical Laboratory Tests – Values and Implications*. 2nd ed. Springhouse: Springhouse Corporation, 1955: 328pp.
2. Demott Wayne R, Tilzer Lowell L, Hematology. In: Jacobs DS, Demott WR, Finley PR, Horvat RT, Kasten jr BL, Tilzer LL, eds. *Laboratory Test Handbook*. Hudson: Lexi-Comp, 1992: 517-626.
3. Wallach J. eds. *Interpretation of Diagnostic Tests – A Synopsis of Laboratory Medicine*, 4th ed. Boston/Toronto: Little Brown and Co. 1986: 6pp.
4. Painter Pennell C, Cope June Y, Smith Jane L, Appendix. In: burtis CA, Ashwood ER, eds. *Tietz Textbook of Clinical Chemistry*. Philadelphia: WB Saunders, 1994: 2161 – 2217.

Appendix

10.1 Replacement Parts and Consumer Materials

| Catalog No. | Description | Ordering |
|-------------|--|----------|
| 80549 | Alere HemoPoint [®] H2 Microcuvettes 2 Containers @ 50 microcuvettes each (100 tests) | 1 kit |
| 88772 | Alere [™] Hemoglobin Controls Set of 2 dropper bottles: 1 x Hgb control-low, 1 x Hgb control-high | 1 set |
| 52219 | Alere HemoPoint [®] H2 Optics Cleaner For cleaning the optical unit | 5 pcs. |
| 55115 | Alere [™] Universal Printer Thermal printer with power adaptor | 1 pc. |
| 52217 | Printer Cable For connecting the Alere [™] Universal Printer to the Alere HemoPoint [®] H2 Meter | 1 pc. |
| 52220 | Alere HemoPoint [®] H2 Microcuvette Holder | 1 pc. |
| 52218 | Power Adaptor for the Alere HemoPoint [®] H2 Meter | 1 pc. |
| 55118 | Alere HemoPoint [®] H2 Meter | 1 pack |
| 26280 | Alere HemoPoint [®] H2 User Manual - English For Alere HemoPoint [®] H2 Meter | 1 pc. |

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Glossary of Symbols

| | | |
|--|--|---|
|  <p>Do not reuse</p> |  <p>Use by</p> |  <p>Batch code</p> |
|  <p>Catalog number</p> |  <p>Consult instructions for use</p> |  <p>Manufacturer</p> |
|  <p>Contains sufficient for < N > tests</p> |  <p><i>In-vitro</i> diagnostic medical device</p> |  <p>Store at 15 - 30°C</p> |
|  <p>Caution, Consult Accompanying Documents</p> |  <p>Contents</p> |  <p>Waste Electronics and Electronic Equipment</p> |

Contact Alere

Alere™ Technical Support

Contact one of the following Alere™ Technical Support Care Centers or your local distributor if you have any questions regarding the use of your Alere™ product. You may also contact us at www.alere.com.

| Region | Phone | E Mail Address |
|--------|--------------------|--------------------------------|
| US | + (1) 866-216-0073 | HemoPoint.H2.Support@alere.com |

Alere™ Customer Support

Contact the following Alere™ Support Care Center or your local distributor for order and billing assistance. You may also contact us at www.alere.com.

| Phone | E Mail Address |
|------------------------------|--------------------------|
| + (1) 877-441-7440, option 1 | clientservices@alere.com |

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