



Thank you for choosing the Lactate Pro™ 2. This operating manual explains how to use the Lactate Pro™ 2 to measure the blood lactate level. Please read this manual carefully before use. If you have any questions, please contact our authorized distributor(s).

## Chapter 1 Introduction

### ⚠ WARNING

This product can be easily influenced by hematocrit and oxygen partial pressure in blood. **Do not** use it to diagnose the following patients and diseases.

- Patients being treated in intensive care units
- Patients undergoing critical care treatment
- Patients having been administered biguanide
- Neonates and pregnant women
- Definite diagnoses of lactic acidosis

### 1.1 Intended Use

The Lactate Pro™ 2 is for quantitatively measuring the lactate level in fresh capillary whole blood. It is intended for use outside of the body (*in vitro* diagnostic use). You can measure the blood lactate level by using this product and Lactate Pro™ 2 Test Strip together. **Do not** use it for any other purposes.

### 1.2 Measurement Principle

Lactate in the blood reacts with the reagent in the test strip and this produces a small electrical current. The strength of this current is proportional to the concentration of lactate in the blood. The meter measures this current and calculates your blood lactate level.

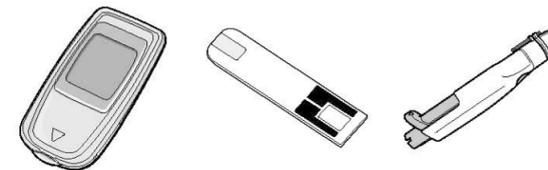
### 1.3 What's Included

- Lactate Pro™ 2 (meter)
- Carrying case
- Operating Manual

## Chapter 2 Before Tests

### 2.1 What You Need for Each Test

- Lactate Pro™ 2 (meter)
- Lactate Pro™ 2 Test Strip\*
- Lancing device\*



- Lancets\*
- Alcohol cotton pads\*

\* The Lactate Pro™ 2 Test Strip, lancing device, lancets and alcohol cotton pads are sold separately.

### ⚠ WARNING

Keep the meter, test strips and other items away from young children. Small items are choking hazards.

### 2.2 Cautions on Using the Meter

#### ⚠ CAUTION

- For accurate test results, allow the meter to adjust to the surroundings for at least 20 minutes.
  - Temperature: 5 to 40 °C (41 to 104°F)
  - Humidity: 20 to 80% RH (Relative Humidity)
- **Do not** store or use the meter where:
  - There are sharp temperature fluctuations.
  - Humidity is high enough to cause condensation (bathroom, drying room, kitchen, etc.).
  - There is a strong electromagnetic field (microwave oven, cell phone, etc.).
- **Do not** use the meter after it has been dropped in liquid or liquids have entered inside, even if dried afterwards.
- Keep hands away from the test strip slot on the meter. A thermo sensor is housed inside the meter to obtain accurate test results.
- **Do not** apply blood directly to the test strip slot on the meter.
- **Do not** drop and damage the meter.
- **Do not** touch the meter or the test strip with wet hands.

### 2.3 Cautions on Using the Test Strips

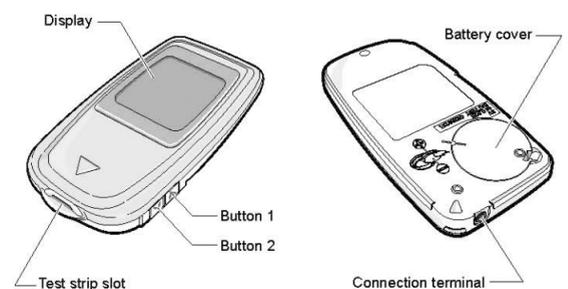
#### ⚠ CAUTION

- Use only the Lactate Pro™ 2 Test Strip for testing with the Lactate Pro™ 2. **Do not** use other test strips as it causes inaccurate test results.
- **Do not** use test strips beyond their expiration date. The expiration date is written on the aluminum pack next to "Exp."
- Store test strips in a dry environment at a temperature between 1 and 30 °C. **Do not** freeze. Avoid direct sunlight.
- Always use a test strip soon after removing it from its aluminum pack.
- The test strips are for single-use only. **Do not** use test strips that have already absorbed blood or control solution.

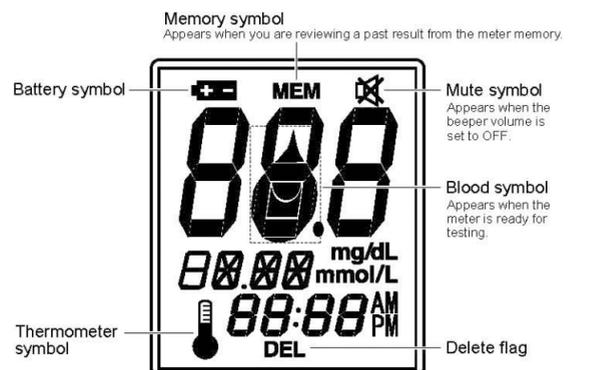
For details of the test strips, read the package insert that comes with the test strips.

### 2.4 Meter Parts

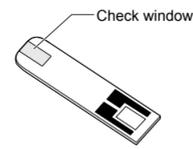
- Lactate Pro™ 2



### 2.5 Display



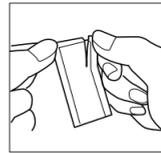
## 2.6 Lactate Pro™ 2 Test Strip



## 2.7 Inserting Test Strips into the Meter

Insert the test strip into the meter as described below.

1. With clean, dry hands, remove 1 test strip from the aluminum pack.



### NOTE

- Do not cover the check window with your fingers.
- Do not apply blood to the test strip before inserting it into the meter.

2. Insert the test strip fully into the test strip slot. You will hear a beep when the meter turns on. A full display appears. A flashing blood symbol and the most recent test result appear on the screen.



Start blood sampling when the current date and time appears.



### NOTE

- For the mg/dL spec meter, "mg/dL" appears instead of "mmol/L".
- A test result with a thermometer symbol or a delete flag does not appear as a previous test result.
- When 4 minutes and 30 seconds passes after inserting a test strip, you will hear a beep every 5 seconds. The meter turns off automatically after another 30 seconds. In this case, remove the test strip once and insert it back into the test strip slot.
- If nothing appears on the screen, remove the test strip and insert it back into the test strip slot. If there is no change, replace the battery. If this does not work, contact your distributor.
- When an error code appears, refer to chapter 8 "If a Message Appears" and take the necessary steps.

## Chapter 3 Blood Sampling

### 3.1 Cautions on Blood Sampling

#### ⚠ WARNING

- Use extreme care when handling blood. Incorrect handling can cause you or people around you to be infected by pathogenic microorganisms. Follow these warnings to reduce the risk of infection.

#### ⚠ CAUTION

- Do not share the same lancet or lancing device with anyone to avoid the risk of infection by pathogenic microorganisms.
- Always use a new lancet. Lancets are for single-use only. Do not reuse a lancet that you have already used.
- When puncturing a thin part of the body such as an earlobe, etc., do not directly support the rear of such part with your finger. (There is a risk of puncturing your finger with the needle penetrating the part of the body. This may cause an infection via blood. When there is a possibility of penetrating through to the other side, consider puncturing a thicker part of the body.)

### 3.2 Blood Sampling Method

For accurate test results, perform blood sampling as described below.

1. Disinfect the puncture site with alcohol cotton pads, etc.

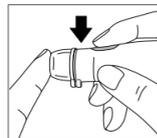


2. Let the alcohol dry thoroughly.

### NOTE

Make sure the puncture site is dry. Otherwise it may lead to hemolysis.

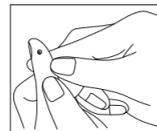
3. Puncture with the lancing device.



### NOTE

The method for using a lancing device is different for each one. Please read the manual that comes with the device.

4. Press lightly around the puncture site to obtain a small drop of blood.



5. Use clean gauze, etc. to wipe off the blood once.

6. Press lightly around the puncture site again to obtain a small drop of blood.

#### ⚠ WARNING

- Always disinfect the puncture site to avoid the risk of infection. After sampling blood, stop bleeding and protect the puncture site.

## Chapter 9 Technical Information

### 9.1 Specifications

Product	Lactate Pro™ 2
Model	LT-1730
Test item	Blood lactate level
Sample	Fresh capillary whole blood
Sample size	0.3µL
Test strips	Lactate Pro™ 2 Test Strip
Test range	0.5 to 25.0 mmol/L (5 to 225 mg/dL)
Test time	15 seconds from blood detection
Battery	3 V lithium battery (CR2032) × 1
Battery life	2000 tests or more*1 (Actual number of tests may be less under some conditions of use.)
Power consumption	0.02 W (MAX.)
Memory capacity	330 test results (A maximum of 330 test results for all three measurer codes combined.)
Beeper	Yes (volume setting possible in 4 levels)
Communication function	Yes*2
Communication speed	19200 bps
Operating environment	Temperature: 5 to 40°C (41 to 104°F) Humidity: 20 to 80% RH (No condensation)
Storage temperature	0 to 50°C (32 to 122°F)
Expected life	3 years (according to company data)
Dimensions	50 mm (W) × 100 mm (H) × 12 mm (D)

\*1 The meter is shipped with the battery loaded. So, the battery may not satisfy the "Battery life".

\*2 The data can be stored on a personal computer using software for this meter. Please contact your distributor for details.

Product specifications and appearance are subject to change for improvements without notice.

### 9.2 Product Safety Information

#### Electromagnetic Interference (EMI)

This meter complies with CISPR 11: 2003, Class B (Radiated Only). It emits low levels of energy that are not likely to interfere with nearby electronic equipment.

#### Static Electricity and Radiated Magnetic Field Immunity

This meter clears immunity requirements for Level 3 electrostatic discharge set forth in IEC 61000-4-2. This meter clears immunity requirements for radio frequency interference in the 80 MHz to 2.5 GHz range (3 V/m) set forth in IEC 61000-4-3.

### 9.3 Disposing of Your Meter

The meter qualifies as biohazardous waste once used to test blood lactate. When no longer needed, remove the battery and dispose of the meter according to your local regulations on biohazardous waste. This meter is not subject to requirements of European Directive 2002/96/EC (Directive on Waste Electrical and Electronic Equipment (WEEE)).

## 9.4 Symbols

Symbol	Description	Symbol	Description
	Storage temperature limitation		Lactate Pro™ 2 conforms to the Directive 98/79/EC
	In Vitro Diagnostic Medical Device		Suitable for self testing
	Manufacturer		Authorized Representative in the European Community
	Biological risks		Serial number
	Caution, consult accompanying documents		Consult instructions for use
	Batch code		Catalogue number
	Use by		

## 9.5 Warranty

ARKRAY shall repair or replace the Lactate Pro™ 2 free-of-charge in the event that there are defects in material and workmanship for a period of one year from the date of purchase. However, this warranty does not apply to the following:

1. Trouble or damage due to careless use.
2. Trouble or damage due to unforeseen circumstances such as natural disasters.
3. Trouble or damage due to unauthorized repairs or remodeling.
4. Trouble or damage for which ARKRAY is not responsible.

**ARKRAY Factory, Inc.**  
1480 Koji, Konan-cho, Koka-shi,  
Shiga 520-3306, Japan

IVD Directive (98 / 79 / EC)  
0 1 2 3

**ARKRAY Europe, B.V.**  
Prof. J.H. Bavincklaan 5 1183 AT  
Amstelveen, the Netherlands

Issued: 2012.11

## Chapter 7 Maintenance

### 7.1 Storage

Store your meter, test strips, lancing device, lancets and manuals in your carrying case.

**Do not** freeze. Avoid heat, humidity and direct sunlight.

Storage temperatures:

- Meter: 0 to 50 °C (32 to 122°F)
- Test strips: 1 to 30 °C (34 to 86°F)

### 7.2 Cleaning Your Meter

This product does not need special cleaning.

If your meter gets dirty, wipe it with a soft piece of cloth moistened with water.

To disinfect the meter after cleaning, wipe with a soft cloth moistened with 70% ethanol, 70% isopropanol or diluted household bleach (0.05% sodium hypochlorite solution).

### 7.3 Changing the Battery

When the battery symbol appears on the screen, the battery is getting low. Before using your meter, change the battery. Past results remain in the memory even when the battery is changed. 

#### NOTE

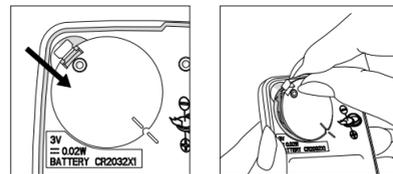
Your meter uses one CR2032 3V lithium battery. This type of battery is available in many stores. Keep a spare battery handy at all times.

You do not need to set the date and time if you insert a new battery within 2 minutes after removing the old battery. Even if you change the battery within 2 minutes, your meter's clock may be reset if:

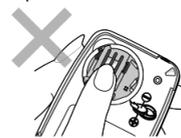
- You do not replace the battery soon after the battery symbol appears.
- You insert the battery upside down.
- You touch the metal parts inside the meter with hands or metal.

When the time has been reset during battery replacement, "12:00" or "0:00" will flash on the screen the next time you insert a Test Strip. In this case, set the correct date and time (see chapter 6 "Meter Setup").

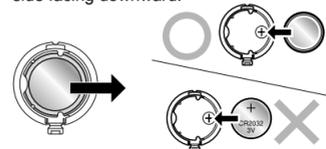
1. Make sure the meter is off.
2. Open the battery cover by lifting the tab with your finger or fingernail.



Do not touch the metal parts inside the meter with your hands or metal.



3. Remove the old battery. Slide the new battery into the battery cover with the "+" side facing downward.



#### NOTE

- If the battery is inserted upside down, the meter will not operate.

4. Match the lines on the battery cover and the meter. Close the battery cover.



Dispose of old batteries according to your local environmental regulations.



## Chapter 8 If a Message Appears

If a problem occurs with the meter or test strips, the beeper sounds and the following error codes or symbols appear on the screen.

Error message	What's the problem	What to do
E-1	There is a problem with the inside of the meter.	Contact your distributor.
E-2	The surrounding temperature is too low or too high.	Leave the meter and test strips in a place where the temperature is 5 to 40°C (41 to 104°F) and humidity is 20 to 80% RH for at least 20 minutes. Test your blood only after the error code disappears. If the error remains on the screen, contact your distributor.
E-3	Communication error	Data could not be sent or received during communication. Try again. If the error still appears, contact your distributor.
E-5	There is a problem with the inside of the meter.	Contact your distributor.
E-6	<ul style="list-style-type: none"> <li>• The insertion portion (electrode) of the Test Strip is dirty.</li> <li>• A used Test Strip is inserted into the meter.</li> </ul>	Repeat the test with a new test strip.
	A different type of test strip is inserted into the meter.	Use a Lactate Pro™ 2 Test Strip to repeat the test.
E-7	<ul style="list-style-type: none"> <li>• The test strip touched blood again after the test started.</li> <li>• The test strip inside the meter moved during testing.</li> </ul>	Use a new test strip to repeat the test with the correct method.

Symbol	What's the problem	What to do
	The battery is getting low.	Change the battery. See chapter 7.3.
	The surrounding temperature is too low or too high.	Leave the meter and test strips in a place where the temperature is 5 to 40°C (41 to 104°F) and humidity is 20 to 80% RH for at least 20 minutes. Test your blood only after the thermometer symbol disappears. Your meter can test your blood even when the thermometer symbol is displayed, but this may produce inaccurate test results.

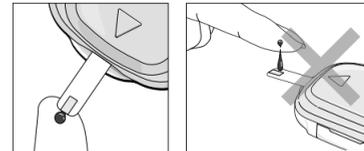
## Chapter 4 Testing Your Blood Lactate

1. Make sure that the flashing blood symbol and the date/time appear on the screen (see chapter 2.7 "Inserting Test Strips into the Meter").

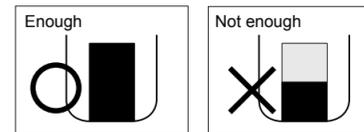
2. Touch the tip of the test strip at a 90 degree angle to the drop of blood. Let the test strip draw up blood until the check window is filled with blood.

#### NOTE

- **Do not** apply blood when a full display appears on the screen.
- **Do not** add any extra blood even immediately after the first draw. It may cause inaccurate test results.



Accurate test results will not be obtained if you apply your blood to the check window directly.



#### NOTE

- For accurate test results, touch the test strip to your blood immediately after puncturing.
- **Do not** test blood that runs or spreads out from the puncture site.
- **Do not** smear blood on the test strip.
- **Do not** press the test strip into your puncture site with force.
- Keep your hands away from the test strip until the test result appears.

3. You will hear a beep when the countdown starts from 15 to 1.

4. Read your test result.



When "Hi" or "Lo" appears as the test result, it means that the result is outside the test range.

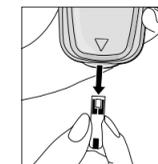
- "Hi": The blood lactate level is above 25.0 mmol/L (225 mg/dL).
- "Lo": The blood lactate level is below 0.5 mmol/L (5 mg/dL).

#### NOTE

When the test result is not what you expect, check that:

- The thermometer symbol is not on,
- The meter and the test strip adjusted to the specified temperature and humidity before the test,
- The test strip was not exposed for a long time after being removed from the aluminum pack,
- The test strip is not expired,
- The test strip is not reused,
- Sweat is not mixed with blood,
- The test strip is filled with enough blood.

5. Pull the test strip straight out of the meter. The meter stores the test result into the memory and turns itself off.



#### NOTE

- Even if the test strip is not pulled out, the meter will store the test result in the memory after 3 minutes and turns itself off.
- New results beyond the 330th result overwrite previously stored results in the order of the oldest first, regardless of the measurer code.

## Disposal of Infectious Waste

The test strips, lancets, and alcohol cotton pads qualify as infectious waste once used to test the blood lactate level. Dispose of them according to your local regulations on biohazardous waste.

## Chapter 5 Managing Your Test Results

### 5.1 Measurer Code

A measurer code makes it possible to display or delete the test results by measurer and to manage the data efficiently.

You can add a measurer code before or after test.

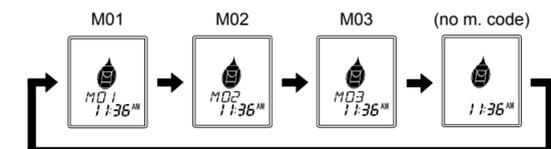
#### ■ Adding a measurer code before test

1. Insert the test strip into the meter. Make sure that the blood symbol, date and time appear.

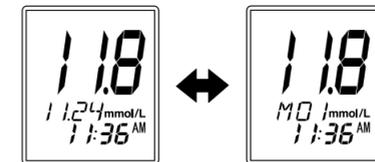
2. Press button 1. The measurer code "M01" appears.



To select a different measurer code, press button 1 again. The measurer code changes in the following order every time you press the button:



3. Select a measurer code and test your blood. After the test, the test date and the measurer code appear alternately.



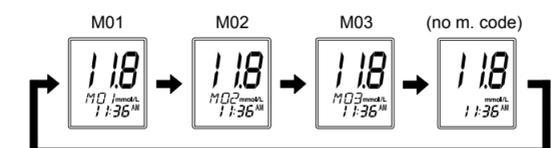
4. Pull the test strip straight out of the meter.

#### ■ Adding a measurer code after test

1. When the test result appears, press button 1 without removing the test strip. The measurer code "M01" appears.



To set a different measurer code, press button 1 again. The measurer code changes in the following order every time you press the button:



2. To save the setting and turn off the meter, pull the test strip straight out of the meter.

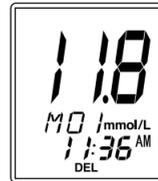
#### NOTE

- You cannot add/change the measurer code once the meter turns off.
- The meter turns off when you remove the test strip or after 3 minutes from testing.

## 5.2 Adding a Delete Flag

Add a delete flag to inaccurate test results. The meter stores the test results regardless of this flag. A delete flag indicates unnecessary data when reviewing past results.

- When the test result appears on the screen, leave the test strip in the meter and press button 2. The delete flag "DEL" appears.



To remove the flag, press the button again.

- To save the setting and turn off the meter, pull the test strip straight out of the meter.

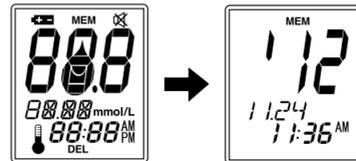
### NOTE

- You cannot add/change the delete flag once the meter turns off.
- The meter turns off when you remove the test strip or after 3 minutes from testing.

## 5.3 Reviewing Past Results

This system can store up to 330 test results. You can review the stored test results in the order of the newest to the oldest.

- Make sure the meter is off and test strip is not in the meter.
- Hold down button 1 for 2 seconds. A full display appears, followed by the present date and time. The memory symbol appears at the top of the screen.

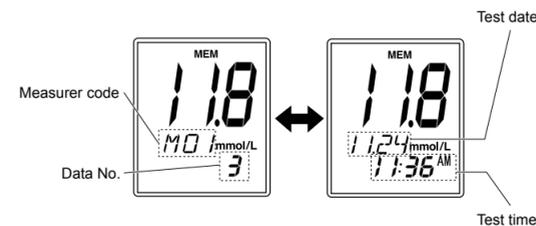


- Press button 1 to select the measurer code you want to display. The measurer code changes in the following order every time you press the button:



The measurer code appears with the total number of test results for that measurer code.

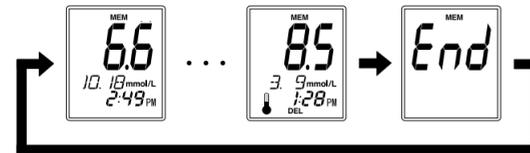
- Press button 2. The most recent test result for the selected measurer code appears. Below the result, two sets of related information appear alternately as shown below.



### NOTE

- When no test data is stored, "ALL" appears with "0". In this case, the measurer code will not change even if you press button 1. Also, test data will not appear even if you press button 2.
- To cancel call-up of test data, press button 2 for 2 seconds to turn off the meter.

- The test result appears from the newest to the oldest every time you press button 1.



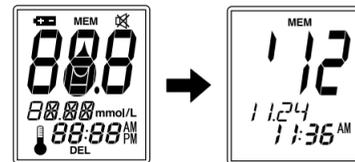
"End" appears after the oldest data in the memory. After "End", the screen returns to the newest data. To scroll through results, hold down button 1. The data No. does not appear when scrolling through. "END" appears at the end of the scroll. Every time you press button 2, the test result appears in reverse order from the oldest to the newest.

- To end this mode and turn off the meter, hold down button 2 for 2 seconds or leave the meter for 3 minutes.

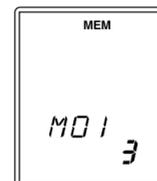
## 5.4 Deleting Test Results

You can delete all the test results in the memory or results with specific measurer code.

- Make sure the meter is off and test strip is not in the meter.
- Hold down button 1 for 2 seconds. You will hear a beep when the meter turns on. A full display appears, followed by the present date and time. The memory symbol appears at the top of the screen.



- Press button 1. Select the measurer code of the test results you want to delete. Select "ALL" to delete all the test results from the memory.



- Hold down both buttons 1 and 2 for 5 seconds. Release the buttons after "dEL" flashes.



- Hold down button 2 for 5 seconds. The meter deletes the test results. Date and time appear again.

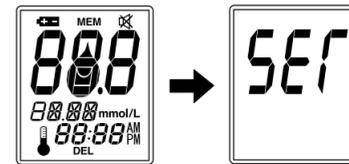
### NOTE

- "dEL" stays on while the meter is deleting the test results. This may take several minutes.

## Chapter 6 Meter Setup

Set up the beeper volume and the date and time.

- Make sure the meter is off and test strip is not in the meter.
- Hold down both buttons 1 and 2 for at least 5 seconds. A full display appears, followed by "SET".

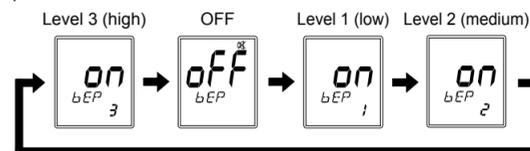


### ■ Beeper volume setting

- Press button 1. The present setting for the beeper volume appears.



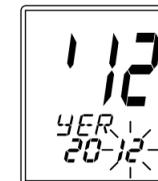
- Press button 2. The beeper volume changes in the following order every time you press the button:



The mute symbol appears when the beeper is set to OFF.

### ■ Date/Time setting

- Press button 1. The "Year" setting screen appears.



- Press button 2 to select the "Year".



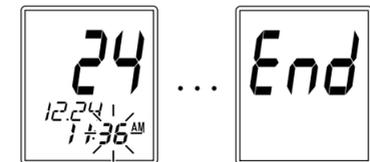
To scroll through the years, hold down button 2.

- Press button 1 to set the "Year" and go to "Month" setting.



- In the same way, set "Month", "Day", "Hour" and "Minute" in this order.

When "Minute" is set, "END" appears.



- To end the setup and turn off the meter, press button 1. To return to the beeper volume setting, press button 2.