

# Silmee<sup>™</sup> Bar type Lite **Instruction Manual**

Draft



- $\bullet \mbox{To}$  use the product correctly and safely, read and fully understand the instruction manual before attempting to use the product.
- •After reading the instruction manual, store it in a safe place so that whoever will later use the product can reference it at any time
- Procedures, screen shots and illustrations contained in the instruction manual may be modifi ed without prior notice.

#### ■ Trademarks

- Silmee  $^{\mbox{\tiny TM}}$  is a registered trademark of TOSHIBA Corporation.
- Android<sup>™</sup> is a registered trademark of Google Inc.
- Bluetooth® word mark and logo are owned by Bluetooth SIG, Inc. and licensed for use by TOSHIBA Corporation.
- Other product and system names described in this document may be used as registered trademarks or trademarks by the respective owners.

#### **Safety Precautions** Be sure to observe the following precautions:

This section lists important precautions which users of this product (and anyone else) should observe in order to avoid injury to human body and damage to property, and to ensure safe and correct use of the product. Please be sure that you understand the meanings of the labels and graphic symbols described below before you move on to the detailed descriptions of the precautions, and comply with the precautions stated.

# **■** Explanation of labels

Label	Description
<b>▲WARNING</b>	Indicates a potentially hazardous situation that may lead to serious injury or death if the precaution is not followed.
<b>ACAUTION</b>	Indicates a potentially hazardous situation that may lead to minor or moderate injury if the precaution is not followed.
CAUTION	Indicates a situation that could lead to property damage if the precaution is not followed.

#### **■** Explanation of graphic symbols

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Graphic symbol	Description	
Prohibited	o indicates prohibited actions. Specifi c actions to be prohibited are indicated within or near the graphic symbol using an appropriate picture or text.	
Instructions	indicates actions which must be undertaken for safety purposes. Specific actions to be undertaken are indicated within or near the graphic symbol using an appropriate picture or text.	

#### To prevent injury

# **AWARNING**



Do not insert the Silmee Bar type Lite into the dedicated cradle while wet.

Such an attempt may result in a fire, heat generation or electric shock. Ensure that the Silmee Bar type Lite is suffi ciently dry before attempting

Do not attempt to insert a wire or any other metal into the dedicated cradle.

Such an attempt may result in a fire, heat generation causing burns, or electric shock.

Do not charge the product in a state where it may accumulate heat, such as when covered with a blanket or quilt.

Such an attempt may result in a fi re or heat generation causing burns.

Do not insert the Silmee Bar type Lite into the dedicated cradle while a gel pad is still attached.

Such an attempt may result in a fi re, heat generation or electric shock. Ensure that a gel pad is removed from the Silmee Bar type Lite before attempting to charge it.

Do not look directly at any lights emitted from the pulse sensor or LEDs on the product at a short distance.

Such an attempt may cause damage to your eye.

People who use a cardiac pacemaker should not use Silmee Bar type Lite.

Radio waves emitted from the product may cause the cardiac pacemaker to malfunction.

People with allergies and/or sensitive skin should not use Silmee Bar type Lite. People who develop numbness, swelling, skin rash, or itching at the location where the Silmee Bar type Lite is attached to the body should not use this product.

Use by such people may result in physical problems and/or a worsening



If your skin feels electrical stimulation during measurement, immediately remove the product from the body and turn it off. This may result in electric shock.

If the Silmee Bar type Lite becomes hot during measurement, immediately remove it from the body and

turn it off.

This may cause burns

#### Proper operation and storage

# **AWARNING**



When affi xing the product on your body, ensure that it is located suffi ciently away from a cardiac pacemaker, if used.

Instructions

Radio waves emitted from the product may cause the cardiac pacemaker to malfunction.

# **ACAUTION**



Do not use the product in any location where the use of such devices is prohibited, such as within medical institutions or aircrafts.

Radio waves emitted from the product may affect the operation of electronic devices, possibly resulting in an accident

Do not use the product near any automatically controlled equipment, such as automatic doors and fi re alarms, or any medical equipment.

Radio waves emitted from the product may affect the operation of electronic devices, possibly resulting in an accident

Do not use or store the product in any of the following locations:

- Extremely hot location (for example, in a sauna, in a closed car, or near a heater or open fl ame) or extremely cold location (observe the operating temperature/humidity specifi cations described in "Specifi cations" on the back cover)
- Dusty location
- · Location subjected to strong vibration
- · Location subjected to strong static electricity or electromagnetic waves, or location close to a magnet or any other substance generating a magnetic fi eld
- · Location where any corrosive gas, such as sulfur dioxide, hydrogen sulfi de, gaseous chlorine or ammonia, may be generated

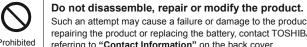
#### To prevent damage

# **ACAUTION**



Stop using this product immediately if the dedicated cradle becomes hot during charging.

This may damage the product or cause it to catch fi re.



Such an attempt may cause a failure or damage to the product. For repairing the product or replacing the battery, contact TOSHIBA by referring to "Contact Information" on the back cover.

Do not drop, step on or otherwise apply a strong shock to the product.

Such an attempt may cause the product to fail or malfunction. Such damage to equipment may also reduce its waterproofness.

Do not intentionally splash water on the product, sink it in water, or get in the water wearing it.

Such an attempt may cause a failure of the product. Although the Silmee Bar type Lite is waterproof against splashes of water occurring in daily life (such as sweat or splashes occurring when you are washing your face) as well as splashes caused by rain, it cannot be used in any situation where it may be severely splashed, such as washing the product, bathing or taking a shower wearing it. Furthermore, accessories are not waterproof.

Do not charge any product other than Silmee Bar type Lite in the dedicated cradle.

Such an attempt may cause a failure of the cradle or the device being charged. The dedicated cradle is intended for use only with Silmee Bar

Do not use the dedicated cradle or cradle USB cable if damaged

Such an attempt may cause a failure of the cradle or the device being charged.

#### Notes on use

# **ACAUTION**



Do not use test results for purpose of diagnosis or treatment

Silmee Bar type Lite is not a medical device under Japan's Act on Ensuring Quality, Effi cacy and Safety of Pharmaceuticals and Medical Devices (hereafter referred to as "medical device regulations of Japan"). As such, it is not intended for use in verification experiments or evaluation. Do not carry out diagnosis or treatment based on

measurements made with this product.

## ■ Operating precautions

- This product is not a medical device under the medical device regulations of Japan, and is not intended for use in carrying out diagnosis or treatment. Do not make any determination on the state of your health, or another person health, based on measurements made with this product. TOSHIBA Corporation bears absolutely no responsibility for damage to or impact on the state of health of users of this product if measured results are used to carry out diagnosis or
- If you become concerned about the state of your health due to using this product, consult a physician immediately to receive any necessary diagnosis and treatment based on results from existing medical
- This product is not intended for use in verifi cation experiments or evaluation. If you have any questions or concerns regarding the use of this product, please contact TOSHIBA Corporation.
- The warranty period of this product is six months. Problems occurring within the warranty period will be handled by providing a replacement product rather than by providing repair. TOSHIBA Corporation's responsibilities regarding this product are limited to those listed in this Instruction Manual
- If the person being tested has any severe arrhythmia or circulatory disease causing erratic pulses or frequently experiences extrasystole or atrial fi brillation, the product may fail to correctly measure a heart beat or pulse interval
- If pulses are weak, too frequent, or too infrequent, the product may fail to correctly measure a pulse interval.
- If the cardiac electrical signal is too weak, or if the heart rate is too high or too low, the product may fail to correctly measure the heart rate.
- If the person being tested has any precapillary circulation disorder due to diabetes or other diseases, the product may fail to correctly measure a
- If the ambient temperature is so low that the person being tested feels chilly, the product may fail to correctly measure a pulse interval due to poor circulation of the blood.

• The product may fail to correctly measure a person's cardiac electrical signal and/or pulse due to individual differences between people.

### ■ Radio wave considerations

- This product is not guaranteed to connect to all Bluetooth® devices.
- This product has been certified for compliance with relevant technical standards as radio wave equipment for a radio station as part of a

small-power data communication system based on the Radio Law. Therefore, the customer does not need to have a radio station license to use the product. The customer may, however, be punished by a law if he or she performs any of the following actions: - Disassembling or modifying the product

- Modifying this product's certifi cation label
- This product's Bluetooth® feature uses the following frequency band.

2.4: Indicates wireless equipment that uses the 2.4-GHz band. FH: Indicates that the modulation system is FH-SS. Indicates that anticipated radius of interference is 10 m or

: Indicates that all bands are used and that the

bands of other mobile devices cannot be avoided.

- The frequency band used for the product (2.4 GHz) is also used for industrial, scientific and medical equipment, such as microwave ovens, as well as in-house radio stations for identifying movable bodies on manufacturing lines in factories, which require a license, and specifi ed small-power radio stations, amateur radio stations and other radio stations which do not require a license (hereinafter collectively referred to as "other radio stations").
- 1. Before attempting to use the product, ensure that no other radio stations are operated somewhere around.
- 2. If any radio interference occurs between the product and another radio station, immediately change the location where you use the product or stop the operation of the product (stop the emission of radio wave).
- 3. If you encounter any other problem related to radio interference, contact TOSHIBA according to "Contact Information" on the back
- If you use the product near a microwave oven, television set, radio or other electronic devices, radio interference may occur, causing both devices to malfunction, degrading communication performance or causing a communication error.
- The product can communicate at a distance of about 10 m but it may vary with the operating environment or radio wave conditions.

## ■ Handling batteries

- · Replacement batteries may be purchased for a charged fee. (The customer cannot replace the battery by themselves.)
- If the battery is left uncharged for a long time, its remaining charge may decrease even when the product is not used. In such a case, charge the battery before using the product.
- The time required to charge the battery varies with the battery status, ambient temperature and other conditions.
- If the battery is used at a low temperature, its continuous operating time may be shortened.
- As the battery is used repeatedly, it is degraded with its continuous operating time shortened gradually. The continuous period of operation even after fully charging the battery may become extremely short due to degradation of the battery. Please refer to "Contact Information" on the

In particular, storing the battery in a hot (40°C or higher) place accelerates the degradation of the battery and should be avoided.

• To prevent overdischarging, the product automatically terminates measurement if the voltage of the battery falls below a specifi ed level even when measurement has not yet been completed. TOSHIBA Corporation shall not be liable for inability to measure data in such a case.

To check the remaining battery level, see "■ Checking the remaining battery charge, turning the main unit on/off, and taking measurements" on the back cover.

#### **■** Other precautions

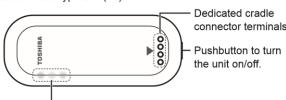
- Toshiba Corporation, and its subsidiaries and affi liates (collectively "TOSHIBA"), reserve the right to make changes to the information in this document, and related hardware, software and systems (collectively "Product") without notice.
- This document and any information herein may not be reproduced without prior written permission from TOSHIBA. Even with TOSHIBA's written permission, reproduction is permissible only if reproduction is without alteration/omission.
- Do not disassemble, analyze, reverse-engineer, alter, modify, translate or copy Product, whether in whole or in part.
- Product shall not be used for or incorporated into any products or systems whose manufacture, use, or sale is prohibited under any applicable laws or regulations.
- In no event shall TOSHIBA be liable for any damage caused by an earthquake, thunder, storm or flood, a fire caused by a reason not attributed to TOSHIBA, any action taken by a third party or any other accident; any damage intentionally or accidentally caused by the customer; or any damage caused by the misuse or use of Product under any abnormal conditions.
- In no event shall TOSHIBA be liable for any incidental damages (including, but not limited to, loss of business revenue, business interruption or the like), arising out the use of, or the inability to use,
- In no event shall TOSHIBA be liable for any damages arising out of a failure to observe the descriptions in the instruction manual.
- In no event shall TOSHIBA be liable for any damages arising out of a malfunction or other problems caused by a combination with any connected device or software with which TOSHIBA is not concerned
- TOSHIBA shall not compensate for any lost measurement data or other information stored in the storage device (internal memory) regardless of the cause of any failure or fault that may occur with Product.
- TOSHIBA bears absolutely no responsibility for measurement data divulged to others due to the loss of this product.
- TOSHIBA bears absolutely no responsibility for data erroneously retrieved while connected to this product.

#### Names of Components and Accessories

Ensure that the package contains all necessary components and that n damages are found on them.

### ■ Main unit

⊐Silmee Bar type Lite (×1)



OLight (red)

Indicates a problem during operation such as inability to take accurate measurements

OLight (green)

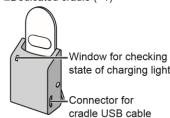
Indicates the unit can be controlled from the application.

OLight (blue)

Indicates that the power is on and the unit is functioning.

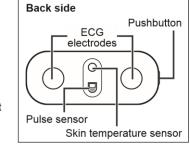
## Accessories

□Dedicated cradle (×1)



□Cradle USB cable (×1)





□Instruction manual (×1)

## **Charging the Main Unit**

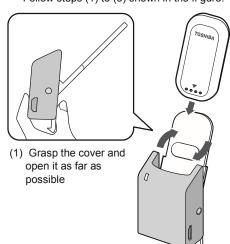
Fully charge the main unit before using the unit for the first time or when the remaining battery level is low.

Always use the supplied dedicated cradle to recharge the main unit.

# 1. Press the pushbutton until all lights light up to turn off the

#### 2. Insert the main unit into the dedicated cradle.

• Follow steps (1) to (3) shown in the fi gure.



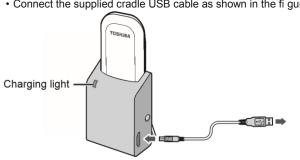
(2) With the dedicated cradle connector terminals facing downward, align the raised guide in the center of the back of the main unit with the groove in the dedicated cradle and insert.

(3)Close the cover.

- If you insert the Silmee Bar type Lite with the cover of the dedicated cradle not fully opened, it may cause damage to the charge terminals inside the dedicated cradle. Always open the cover as far as possible.
- Do not insert the main unit into the dedicated cradle while connected to an Android terminal via Bluetooth or while taking measurements.

# 3. Connect the dedicated cradle to your PC or a USB power

· Connect the supplied cradle USB cable as shown in the fi gure.



Once the main unit starts charging, the charging light goes on. If the charging light does not go on, check the contacts between the main unit and dedicated cradle terminals. If the charging light still does not go on, contact us as described in "Contact Information"

- · Once the unit is fully charged, the charging light goes off.
- If the charging light does not go out even though the unit is fully charged, contact us as described in "Contact Information".

#### ■ Checking the remaining battery charge, turning the main unit on/off, and taking measurements

For information on the topics listed above, please refer to documentation provided on the website given below

http://www.toshiba.co.jp/healthcare/Silmee

#### Cleaning

Observe the following precautions during cleaning. Otherwise, it may cause a failure

- Do not clean with water or soak in water.
- Take care that water does not get inside the main unit or dedicated
- Do not use chemicals such as thinner, benzene, polishing agents, or dish washing liquid.

#### ■ Main unit

Do not press forcefully on the ECG electrodes, pulse sensor, or skin temperature sensor

If the main unit becomes soiled, gently wipe it clean with a soft, dry cloth. In case of severe soiling, wet the soft cloth with some rubbing alcohol, and wipe gently.



#### ■ Dedicated cradle

If the dedicated cradle becomes soiled, gently wipe it clean with a soft, dry cloth. In case of severe soiling, wet the soft cloth with some rubbing alcohol, and wipe gently.

## Specifi cations

Model	S1150SL00
Wireless communication method	Conforms to Bluetooth Ver. 4.0 (Class 2) (protocol depends on the fi rmware)
Maximum wireless communication distance	Line-of-sight distance: Approx. 10 m (depends on the operating environment)
Wireless frequency band	2.4-GHz band (2.4000 GHz to 2.4835 GHz)
Wired communication method	USB 2.0 Full Speed
Power supply	Internal lithium polymer battery
Continuous operating time	Approx. 24 hours (depending on the operating conditions)
Charge time	Approx. 2 hours
Number of charges	Use this product about once per day as a rule
External dimensions	64 (width) × 28 (depth) × 9.6 (thickest part) mm (excluding protrusions)
Weight	Approx. 14.0 g (including battery)
Operating environment temperature/humidity	Ambient temperature range: 10°C to 40°C at a relative humidity of 30% to 90% (without condensation)
Waterproofness	IPX5/IPX7
Memory	Approx. 16 MB (up to 14 fi les)
Accessories	Dedicated cradle (×1) Cradle USB cable (×1) Instruction manual (×1) product may be modifi ed without prior notice.

The specifi cations of this product may be modifi ed without prior notice

### Notes on Disposal

When disposing of this product, the user should follow all laws and regulations of the locality in which it is being used.



The battery contained in the product can be recycled. You should not remove the battery by yourself but contact Toshiba by referencing **Li-ion00** "Contact Information".

#### **Contact Information**

For information on software or for questions about replacement, handling and/or cleaning, please contact us at the following email address. HC-silmee-support@ml.toshiba.co.jp Or, visit the following website. http://www.toshiba.co.jp/healthcare/Silmee

#### **FCC Statement**

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- · Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

NOTE: THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERFERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE **FQUIPMENT** 

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or