



Oral Wellness System

SillHa

LH-4912 | Operating Manual

arkray, inc.

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Intended Use

SillHa is an oral health assessment instrument, providing information to assess gum health, tooth health and oral cleanliness. The instrument uses oral rinse (saliva) samples from individuals to perform this assessment. The instrument is not intended for diagnosis. It is to be used by dental health care professionals (such as dentist, hygienist, etc.) to help with patient education on oral wellness.

Introduction

This operating manual contains important information on the functions of SillHa Oral Wellness System. Read carefully prior to using and retain for future reference.

This manual provides an overview and the proper procedures for operation and maintenance. The use of this device by a method or for a purpose other than those presented herein shall not be guaranteed.

This product conforms to the EMC Standard IEC61326-1:2012(EN61326-1:2013).
Class of emission: CISPR 11 Class A.

NOTE: This instrument has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the instrument is operated in a commercial environment. This instrument generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the operating manual, may cause harmful interference to radio communications. Operation of this instrument in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

The electromagnetic environment should be evaluated prior to operation of the device. **Do not** use this device in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

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- The information in this operating manual is subject to change without notice.

Glossary of Symbols

References obtained from:

- ISO 15223:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

Symbol	Title of Symbol	Description of Symbol	Standard Ref. No.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4
	Keep dry	Indicates a medical device that needs to be protected from moisture.	5.3.4
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	5.3.1
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	5.3.8
	Handle with care	Indicates handle with care.	N/A
	Biological risks	Indicates that there are potential biological risks associated with the medical device.	5.4.1

For optimal performance

IMPORTANT: Follow the instructions given here to obtain accurate measurement results.

NOTE: Information useful for preventing damage to the instrument or parts, and other important information you should keep in mind.

REFERENCE

Additional explanations that help you make the best use of the instrument and information on related functions.

Chapter 1: Overview of SillHa Oral Wellness Instrument

1.1 Overview

1.1.1 Features

- **Multiple items can be rapidly measured.**

With a single measurement taking as little as five minutes, seven analytes (cariogenic bacteria, acidity, buffer capacity, blood, leukocyte, protein and ammonia) can be measured simultaneously.

- **Simple operation by tapping [Test].**

Measurement is performed simply by tapping [Test] and placing the test strip on the instrument. The measurement results are automatically transmitted to the PC.

- **Easy-to-view graphic display**

The test results can be displayed on the PC through easy-to-understand tables and graphs using the SillHa software.

- **Hassle-free daily maintenance**

Daily maintenance requires only cleaning of the test strip holder, which can be removed easily without the use of any tools.

- **Equipped with the self-check function**

The light volume and driving speed are checked when the instrument starts. If the measurement cannot be successfully completed, an error message is shown to notify the user.

1.1.2 ARKRAY Customer and Technical Service

The Troubleshooting Guide is in Chapter 5 for both the instrument and the software. If you have questions or require technical assistance regarding the use of SillHa Oral Wellness Instrument and test strips, please contact ARKRAY at 844.559.0842 between the hours of 8 am to 6 pm Central Standard Time.

Return Authorization: All returns must be preapproved by ARKRAY USA before returning the instrument. Please contact Customer Service at 844.559.0842 between the hours of 8 am to 6 pm Central Standard Time.

For more information on SillHa Oral Wellness System, visit our website at: www.arkrayusa.com/oral-wellness.

1.1.3 Specifications: SillHa Oral Wellness Instrument

Item	Description
Name	SillHa Oral Wellness Instrument
Configuration	Instrument, external PC software (SillHa software), accessories
Measurement object	Oral rinse sample
Test strip type	SillHa paper
Measurement item	Cariogenic bacteria, acidity, buffer capacity, blood, leukocyte, protein and ammonia
Measurement wavelength	565 nm, 635 nm, 760 nm
Sample supply	Manual dropping
Measurement time	Approx. 5 min./measurement sample
Number of measurement samples	1 measurement sample
Warm-up time	Maximum 30 seconds
External output	USB 1 port
Measurement environment	Temperature: 50° – 86°F (10° – 30°C); Humidity: 30 – 60% RH (No condensation)
Storage environment	Temperature: 33.8° – 95°F (1° – 35°C); Humidity: 20 – 80% RH (No condensation)
Environment during transport	Temperature: 14° – 140°F (-10° – 60°C); Humidity: 20 – 80% (No condensation)
Dimensions	160 (W) x 51 (H) mm
Weight	Approx. 430 g (including a rechargeable battery)
Power supply	USB (5 VDC, rechargeable battery used)
Power input	DC 2.5 w or below
Sound pressure level	80 dB or below
Location of use	For indoor use only
Altitude	Up to 6500 ft.
Pollution degree	2
Expected life	5 years (According to company data)
The following environment is required for running the SillHa software on the PC.	
OS	• Windows® 7 or later • MAC OS X (version 10.10 or later) • May not operate correctly in some usage environments or with some settings.
Processor	Intel® Pentium 2, 266 MHz or above
Main memory	For Windows® 1 GB or above For Mac OS X: 2 GB or above
HDD/SSD available space	1 GB or above
Resolution	VGA (640 x 480) or above
USB	USB2.0 5 V 500 mA

Windows® is either a registered trademark or trademark of Microsoft Corporation in the U.S. and/or other countries.

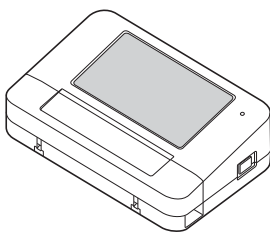
Mac OS is a trademark of Apple Inc., registered in the U.S. and other countries.

1.1.4 Measurement Principle

This instrument measures the oral rinse measurement sample using the dual-wavelength reflectance method. The change in the color of the test strip after sample application is measured by the reflectance of light with wavelengths of 565 nm, 635 nm and 760 nm. Then, results are obtained for cariogenic bacteria, acidity, buffer capacity, blood, leukocyte, protein and ammonia.

1.2 Contents of the Shipping Carton

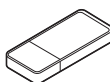
You will find the following items in the shipping carton. Make sure all of these items are present inside. If anything is missing or damaged, contact ARKRAY.



Instrument



USB cable



USB memory stick (SillHa software for Windows and Mac OS)

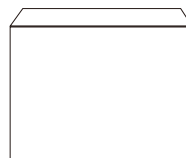


Check strips

•Operating manual (this document)

SillHa paper (test strip kit)

- 30 test strips
- 30 oral rinse solutions
- SillHa paper package insert

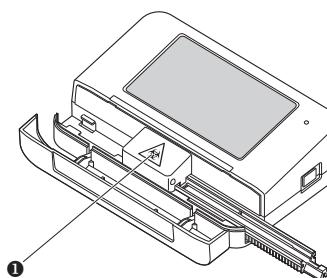


CAUTION:

❶ Inside the reading unit cover

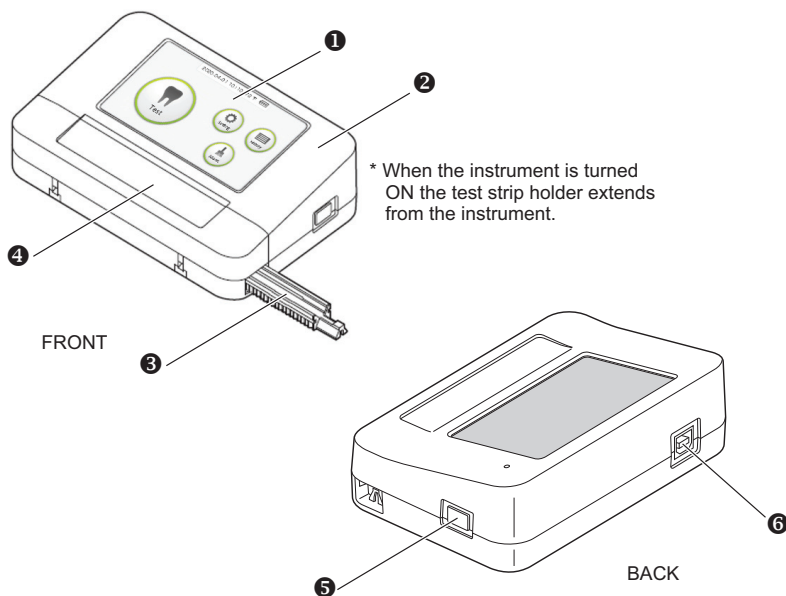


Do not touch the parts inside the reading unit cover and the test strip holder with unprotected hands. Wear personal protective equipment to prevent exposure to pathogenic microorganisms while placing the test strip, and during maintenance of these parts.



1.3 Instrument Part Names and Functions

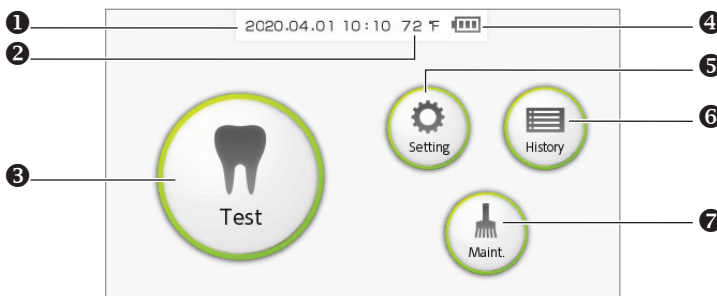
1.3.1 Instrument Parts



No.	Name	Description
①	Display/ operator panel	This is a touch panel. Tap the buttons displayed on the screen to perform operation.
②	Charge indicator light	ON (red): Charging, OFF: Not charging
③	Test strip holder	Holder for test strip with measurement sample.
④	Reading unit cover	Open this cover to place the test strip.
⑤	Power button	Press and hold for one second or longer to turn the instrument ON. Press and hold for two seconds or longer to turn the instrument OFF.
⑥	USB terminal	Connect the USB cable to this USB terminal, and connect the other end of the cable to the PC. This terminal is used for communicating with the PC and charging the instrument.

1.3.2 Instrument Touch-Screen Display

Top Menu Screen



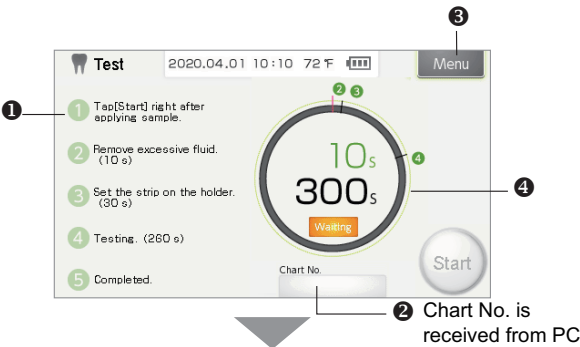
No.	Name	Description
①	Date/Time	Current date and time.
②	Temperature	Temperature of the instrument. It is displayed in the range of 32° – 104°F (0° – 40°C). When the temperature is below 32°F (0°C), LO is displayed, and when it exceeds 104°F (40°C), HI is displayed.
③	[Test] button	Complete the test of the measurement sample (see page 25).
④	Battery level indication	Indicates the battery level.  The battery is fully charged.  The battery level has been reduced, but measurement can be performed.  The battery level has been reduced. The red frame indicates that the battery is low. Measurement cannot be performed.
⑤	[Setting] button	Set the date and time, medical chart number, sound level, screen brightness and the direction of placing the test strip (see pages 43 – 46).
⑥	[History] button	Resend the most recent measurement results to the PC (see page 48).
⑦	[Maint.] button	Perform check measurement (see pages 36 – 38), clean the test strip holder, and adjust the driving speed (see pages 60 – 64).

REFERENCE

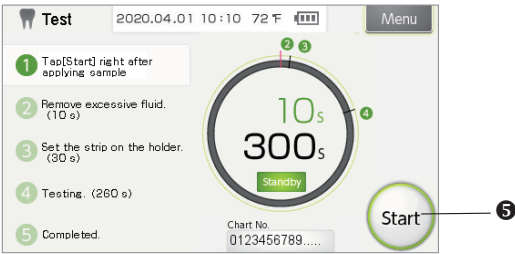
- **Operation sound:** When you tap the button, a “beep” is heard for confirmation. If the button is disabled, a different sound will be heard, notifying a problem. If an error occurs, a continuous beep will be heard.
- **The backlight turns OFF:** If no operation is performed for 5 minutes, the panel backlight turns OFF to save power. To return to ON, either tap anywhere on the panel, or press the power button. If no operation is performed for 60 minutes after the backlight turns OFF, the instrument turns OFF.

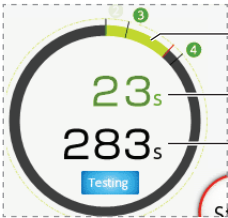
Measurement Procedure Screen (on the instrument)

Waiting for
Chart No. entry
from the PC

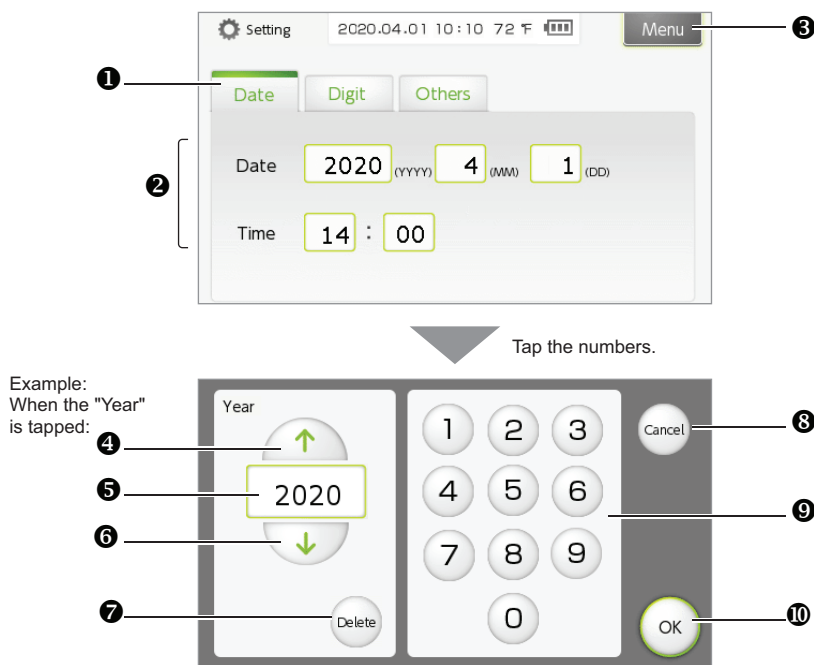


Standby Screen
while preparing
sample



No.	Name	Description
①	Procedure guide	Describes the measurement steps and the time limit.
②	Medical chart number	The medical chart number received from the PC is displayed.
③	[Menu] button	Return to the Top menu screen (see page 11).
④	Status display	Displays the progress status from the time [Test] is tapped. 
⑤	[Start] button	This button is enabled when the medical chart number is received. When disabled, it is grayed out. IMPORTANT: To obtain accurate measurement results, perform the operation according to the operation guide on the screen and the procedures in “2.3 Performing a Measurement” on page 25.

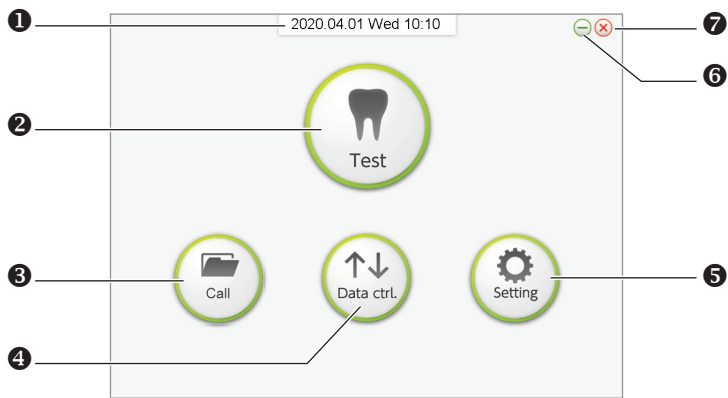
Setting Screen



No.	Name	Description
①	Tab	For selection – Date, Digit, Others
②	Setting value	Change the numeric value by tapping the entry field (yellow-green frame).
③	[Menu] button	Return to the Top menu screen (see page 11).
④	[↑] button	Increase the numeric value by 1.
⑤	Entry field	Displays numeric value.
⑥	[↓] button	Decrease the numeric value by 1.
⑦	[Delete] button	Delete the current numeric value one digit at a time.
⑧	[Cancel] button	Cancel the entered numeric value and return to the previous screen.
⑨	Numeric buttons	Enter a numeric value.
⑩	[OK] button	Confirm the entered numeric value and return to the previous screen.

1.3.3 SillHa Software Screen

Top Menu Screen



No.	Name	Description
①	Date and Time	Current date and time.
②	[Test] button	Enter the measurement mode (see pages 22 – 28).
③	[Call] button	Call the past test results (see page 49).
④	[Data ctrl.] button	Export or import the result data (see pages 51 and 52).
⑤	[Setting] button	Register a comment, enter clinic/dr. and maintenance (see pages 55 – 57).
⑥	[-]	Minimize the screen.
⑦	[X]	Exit the SillHa software.

1.4 Cautions During Instrument Installation and Relocation

1.4.1 Install the Instrument



- Where temperature and humidity can be maintained in the following ranges:
 - Temperature 68° – 86°F (20° – 30°C)
 - Humidity 30 – 60%
- This instrument can perform a measurement at 50°F (10°C) or above. However, when temperature is lower than 68°F (20°C), cariogenic bacteria and ammonia results may not be accurate at this temperature.
- In a place without condensation, direct sunlight or wind.
- On a level, vibration free, and sturdy surface.
- If the instrument is not going to be used for long periods of time, disconnect the USB cable from the instrument to the PC.
- If instrument is moved from environment with temperature variation, allow at least one hour to adjust to room temperature before a measurement is taken.
- If an abnormal noise, odor or fumes come from the instrument, disconnect the USB cable from the device. If it persists after restarting the device, contact Customer Service at 844.559.0842.



DO NOT:

- Place the instrument within 3 inches of an object on the left and right to allow for free movement of the strip holder.
- Install the instrument close to magnetic sources.
- Install near places where chemicals are stored, or near equipment that generates corrosive gas or electrical noise.
- Drop or hit instrument.
- Repair or modify the instrument to prevent damage or injury to a person.
- Allow the instrument to get wet with water as this will result in failure of the instrument.

1.4.2 Follow These Cautions for Best Results When Relocating the Instrument:



- Remove the test strip from inside the instrument to prevent pathogenic microorganisms from contaminating the areas inside the instrument.
- Press and hold the power button to turn the instrument off, and remove the USB cable from the instrument.
- **Do not** subject the instrument to shocks or vibrations during relocation to prevent damage to the instrument.

1.4.3 Disposal:

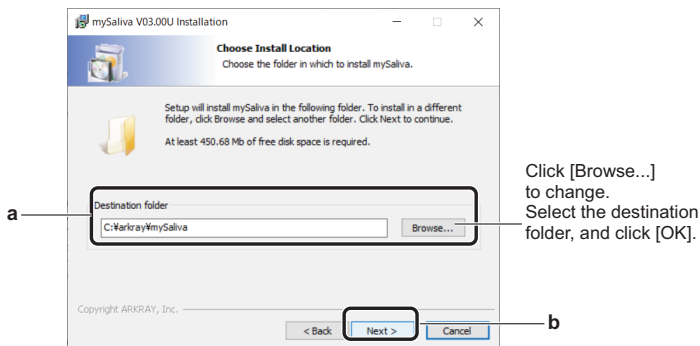
- This instrument contains a lithium ion battery that should be removed and disposed of separately from the instrument following local disposal guidelines.

1.5 Installation of Software and Connection

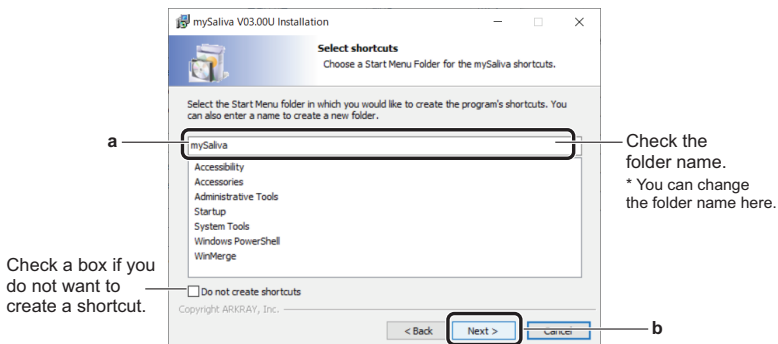
The SillHa software is for receiving measurement results from the instrument and creating a result sheet.

1.5.1 Installing the SillHa Software [Windows Edition]

- ❶ Connect the USB memory stick to the USB port of your PC.
- ❷ Double-click the “Windows_mySaliva~.exe” file in the USB memory. The Installation Wizard screen appears. Follow instructions in the Wizard to install the software.
- ❸ Click [Next].
- ❹ Read the Terms of Use, and click [I Agree].
- ❺ Check the installation destination folder name specified under [Destination folder] (a), and click [Next] (b).



- ❻ Check the folder name to be added to the Start Menu (a), and click [Next] (b).
 - A shortcut will be saved on this folder.



- 7 Select the location for the shortcut, and click [Next].
 - Creates a shortcut on desktop.
 - Creates a shortcut in Start Menu.
- 8 Check the settings on screen, and click [Install]. Click [Back] if you want to review or change any settings.
 - Installation will start.

REFERENCE

If the Microsoft .NET Framework 4 Setup Screen appears:

- a. Read the license terms. Check a box next to [I have read and accept the license terms.], and click [Install]. Installation will start.
- b. When [Installation is Complete] appears, click [Finish].

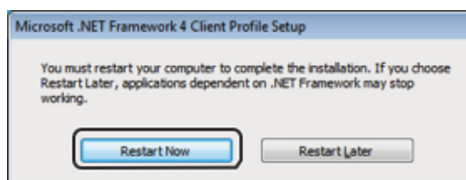
REFERENCE

If the Microsoft SQL Server Compact Setup Screen appears

- a. Click [Next].
 - b. Read the license agreement. Check a box next to [I accept the terms in the license agreement] and click [Next].
 - c. Click [Install]. Installation will start.
 - d. When [Completing the Microsoft SQL Server Compact 4.0 ENU Setup] appears, click [Finish].
- 9 When the completed screen appears, click [Finish].

REFERENCE

When the screen below appears: Click [Restart Now] to restart your PC.



- 10 Make sure the shortcut icon on the right has been created on the desktop.
 - If you have selected “Do not create shortcuts” in step 6, this icon will not be displayed.
- 11 Remove the USB memory from the PC.
 - Go to “1.5.3. Connecting the Instrument, PC and Printer” on page 19.

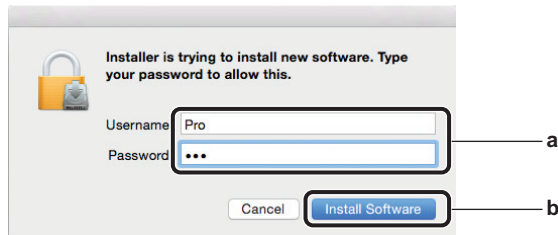


1.5.2 Installing the SiliHa Software [Mac Edition]

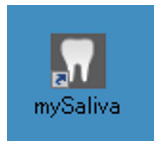
REFERENCE

If the installation has not been properly complete in the procedure below:
Save a copy of “Mac_mySaliva~.pkg” file in the USB memory on the desktop of your PC, and double-click it. When the Installation screen appears, repeat from step ③.

- ① Connect the USB memory to the USB port of your PC.
- ② Double-click the “Mac_mySaliva~.pkg” file in the USB memory.
 - The Installation screen appears.
- ③ Click [Continue].
- ④ Read the License Agreement, and click [Continue].
- ⑤ Click [Agree].
- ⑥ Click [Install] to perform a standard installation.
- ⑦ Enter the [Username] and [Password] (a), and click [Install Software] (b).
 - Installation will start.



- ⑧ When the installation complete screen appears, click [Close].
- ⑨ Make sure the shortcut icon below has been created on the desktop.

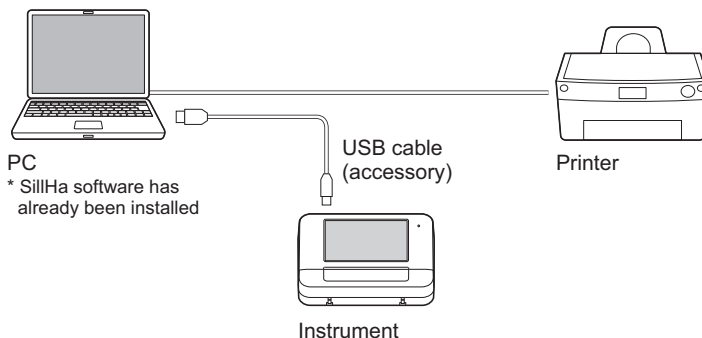


- ⑩ Remove the USB memory from the PC.
 - Go to “1.5.3. Connecting the Instrument, PC and Printer” on page 19.

1.5.3 Connecting the Instrument, PC and Printer

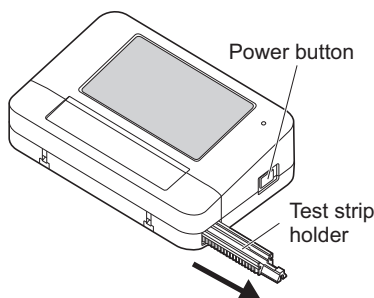
Use the USB cable provided to connect the instrument to the PC.

- For details on how to connect the printer to the PC (optional), read the appropriate printer operating manual.



1.5.4 Set Initial Settings on Instrument

- 1 Ensure the SillHa software **is not running** on the PC.
- 2 Press and hold the power button.
 - Remove your finger when a beep is heard and the screen lights up.
 - The test strip holder extends from the instrument.
 - A beep is heard again and the Top menu screen is displayed.
- 3 Press and hold the power button again, and remove your finger once the test strip holder will start moving.
 - The test strip holder will retract inside the instrument.
 - The display and instrument power will turn off.
- 4 The initial settings are now complete.



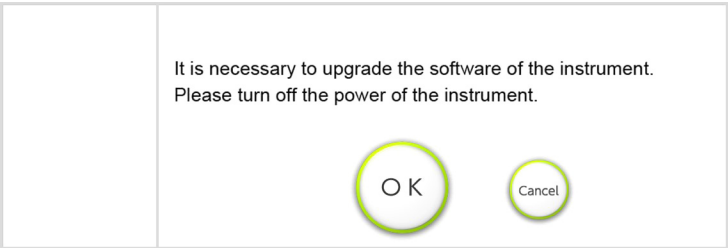
1.5.5 Automatic Upgrading of the Instrument Software

If the instrument software version requires upgrading, a message will appear in the SillHa software screen.

- ❶ Start the PC software while the PC and instrument are connected with the USB cable.
- ❷ Turn on the power of the instrument. If the following screen is displayed on the PC at this time, go to step ❸ and upgrade the software of the instrument.

REFERENCE

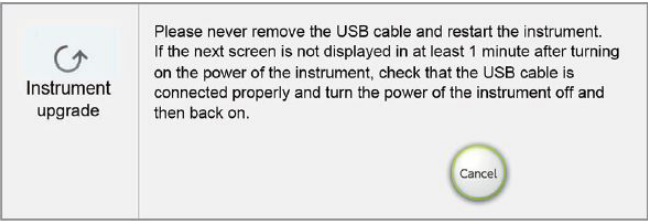
If an error or trouble occurred during the upgrade, restart the PC software and instrument and then perform the procedure again from step ❸.



- ❸ Turn off the power of the instrument and click [OK] in the PC screen of step ❷.
- ❹ When the message below is displayed, turn on the power of the instrument again.

REFERENCE

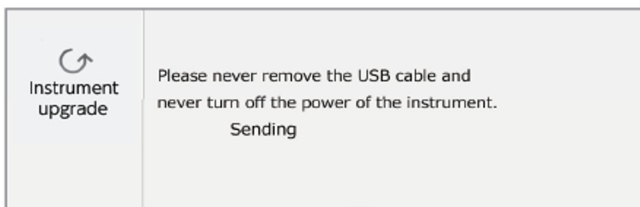
If the next screen is not displayed in at least 1 minute after turning on the power of the instrument, check that the USB cable is connected properly and turn the power of the instrument off and then back on.



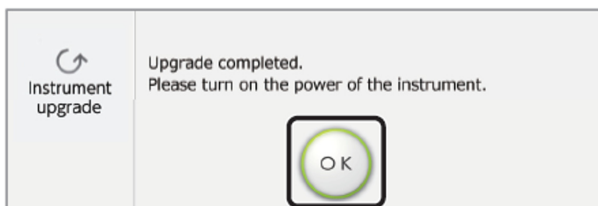
- ⑤ The message below is displayed automatically and upgrade of the software of the instrument starts.

NOTE:

- **Do not** remove the USB cable during upgrade and never turn off the power of the instrument.



- ⑥ When upgrade is completed, the message below is displayed and the power of the instrument turns off automatically.



- ⑦ After click [OK] in the PC screen of the step ⑥, turn on the power of the instrument again. Top menu screen is displayed for both PC and instrument.

This chapter describes how to measure a sample with the instrument and create a result sheet using the SillHa software. It also describes how to perform check measurement and test the software.

CAUTIONS:



- This device must only be used by dental professionals and NOT by dental patients.
- This device is for education purposes only and should NOT be used for any diagnostic purposes.

2.1 Cautions During Measurement

2.1.1 Handling the Measurement Sample

CAUTIONS:



- TAKE UTMOST CARE WHEN HANDLING MEASUREMENT SAMPLES. Oral rinse sample is used as the measurement sample in this instrument. Wear personal protective equipment to prevent exposure to pathogenic microorganisms when handling the measurement sample.
- Dispose of used test strip and oral rinse (saliva) sample per local regulations.
- If the measurement sample is spilled, wipe it off with normal disinfectant wipes, and dispose of the used cloth in accordance with local regulations for biohazardous waste.
- Be careful to avoid contact between eyes, skin or mouth and reagent or sample. If the reagent or measurement sample comes in contact with the eyes, skin or mouth, immediately wash with plenty of water, and consult a doctor.

2.1.2 Handling the SillHa paper (Test Strip)

IMPORTANT:

- Only use the SillHa paper (test strip) for use with the instrument.
Do not use any other test strips.
- Carefully read the package insert that comes with the SillHa paper before use.
- **Do not** use a test strip beyond the expiration date, or a test strip with a discolored pad even if it is within the expiration date. This may cause inaccurate results.
- Use the test strip within 10 minutes after removing it from the foil wrapper. If you remove more than the required number of test strips and leave them for a while, they may absorb moisture from air, or attract dust resulting in inaccurate measurement results.
- **Do not** touch the pad of the test strip with unprotected hands as this may leave skin oils on it, resulting in inaccurate measurement results.
- Use an oral rinse sample for measurement immediately after collection.
- All the consumables used for each test including the oral rinse solution (purified water), reagent test strips, and dropper are for single-use only.
Do NOT re-use.

NOTE:

- **Do not** dispose of the measurement sample until you have successfully completed the measurement.

2.1.3 Factors Affecting Test Results

- **Cariogenic bacteria**
 - Ascorbic acid may cause falsely high results.
 - Results obtained at a temperature lower than 68°F (20°C) may not be accurate.
- **Acidity**
 - Ascorbic acid or calcium chloride may cause falsely high results.
- **Buffer capacity**
 - Falsely high results may be obtained due to ascorbic acid or when pH is 5.8 or below.
 - Falsely low results may be obtained when pH is 7.1 or above.
- **Blood**
 - Ascorbic acid may cause falsely low results.
- **Ammonia**
 - Results obtained at a temperature lower than 68°F (20°C) may not be accurate.

2.2 Preparation for Measurement

2.2.1 Recommendations for Patients

It is important to provide this guidance to your patients before taking a measurement with SillHa Oral Wellness System.

- **Do not** drink, eat or brush your teeth for two hours before measurement for best results.
- The oral rinse solution is purified water and should not be swallowed.

NOTE:

- Perform this salivary testing only for individuals who can rinse their mouth with oral rinse solution lightly for approximately 10 seconds, and spit into a cup.

2.2.2 Items Required to Perform Test

These items are required to perform the test:

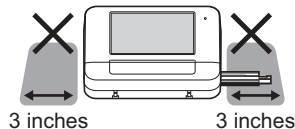
1. SillHa paper (test strip)
2. Personal protective equipment
3. Dropper
4. Cup
5. Oral rinse solution (purified water)

CAUTIONS:



Do not touch the area where the test strip holder moves to prevent personal injury.

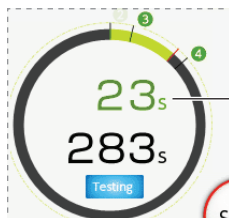
Do not place anything within 3 inches from the left and right sides of the instrument to allow the test strip holder to move properly.



2.3 Performing a Measurement

IMPORTANT:

- Observe the time limit of each procedure.
- It is recommended to read the procedure beforehand, and understand the flow of operations.
- For details on handling the test strip, read the package insert that comes with the SillHa paper.
- Use the recommended dropper for best results.
- Check the temperature on the screen of the instrument before starting measurement. When the temperature is lower than 68°F (20°C), the display appears as shown on the right. Cariogenic bacteria and ammonia results may not be accurate at this temperature.
- **Do not** remove the USB cable during measurement.

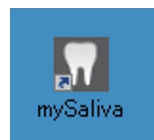
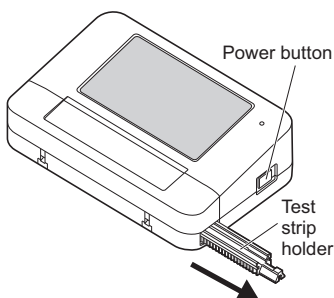


Countdown to time limit



2.3.1 Turn on Instrument and Run Software

- 1 Turn on the instrument: Hold the power button until a beep is heard.
- 2 Run the SillHa software by clicking the icon on the PC.

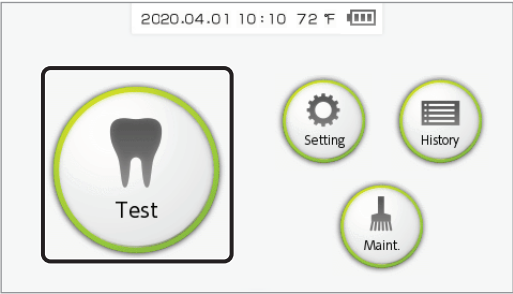


REFERENCE

When the message prompting the upgrade of the software of the instrument is displayed on the PC screen, read “1.5.5. Automatic Upgrading of the Instrument Software” and upgrade the software of the instrument.

The Top menu screen will appear on both the instrument and the PC.

Top menu screen



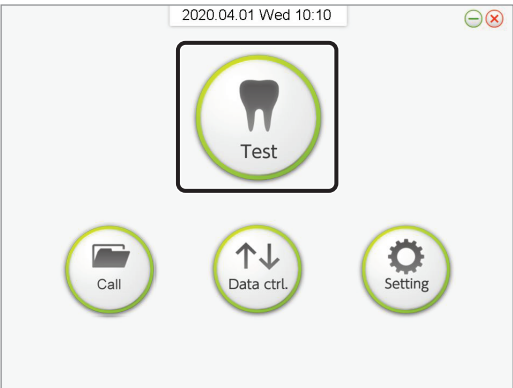
REFERENCE:

Even if you do not tap [Test] on the instrument after step ❷, the instrument display automatically switches to the measurement screen in step ❸ when the medical chart number is received from the PC.

❸ Select [Test] on either the software or the instrument.

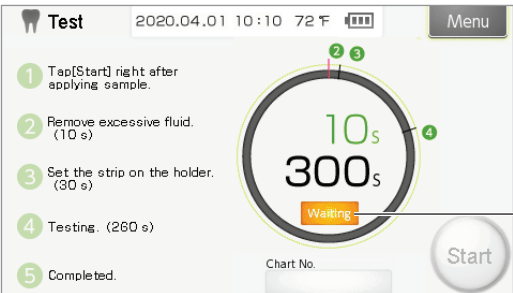
- a. When [Test] is pressed on the PC, the patient information screen appears (see page 27) on the PC.

PC Top menu screen



- b. When [Test] is pressed on the instrument, the following Waiting Test procedure screen will display on the instrument while waiting for the chart number.

Procedure screen Waiting for Chart No. from PC

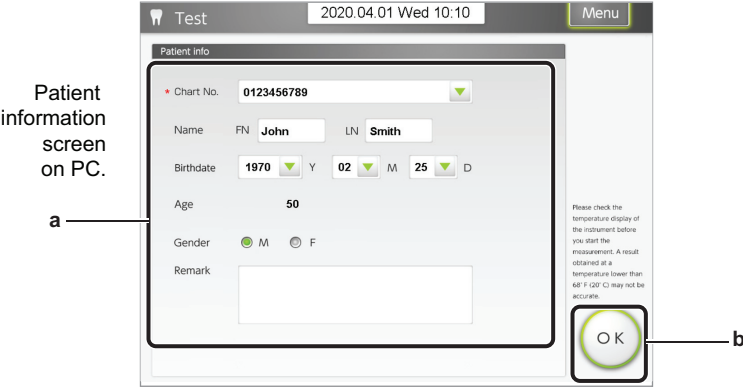


Waiting for entry

- c. The Procedure Screen provides instructions and timing to obtain and place the sample, and perform the test. Follow carefully for best results.

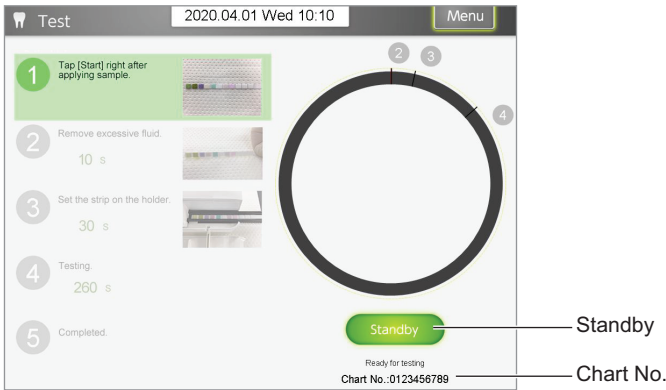
2.3.2 Enter Patient Information on the PC

- 1 Enter the patient information (a), and click [OK] (b).
 - a. Note that a unique patient chart number must be entered to keep this test for future reference.



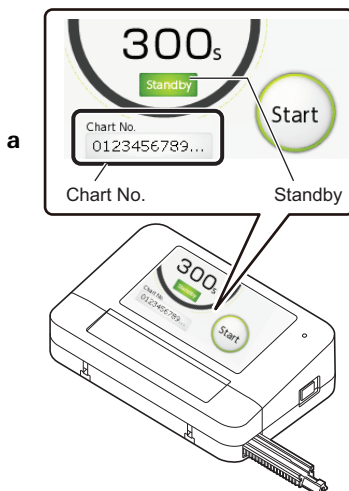
Item	Description
Chart No.* (Required field)	Enter the medical chart number (up to 30 alphanumeric characters).
Name	Enter the first name and last name of the patient (up to 10 characters).
Birthdate/Age/ Gender	Enter the patient information.
Remark	Enter a comment (up to 40 characters).
[Call] button	If you click this button after entering the [Chart No.] and [Name], the registered patient information appears automatically.

- 2 The Standby Screen appears next on the PC.



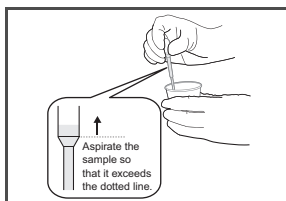
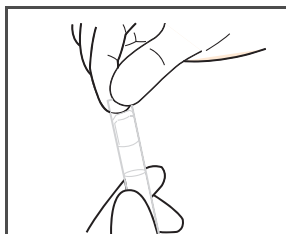
2.3.2

- a. The Chart Number appears at the bottom right of the Procedure Screen on the instrument. Check for accuracy.



2.3.3 Prepare Measurement Sample

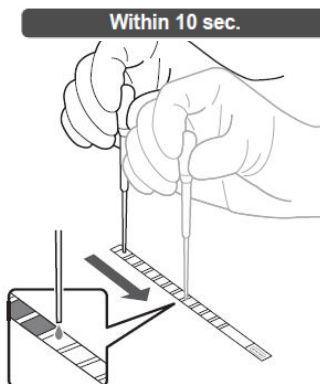
- ❶ Collect the patient sample.
 - a. Twist open the cap of the oral rinse solution and pour all of it into the cup.
 - b. Ask the patient to put the oral rinse solution in their mouth and swish gently for 10 seconds to spread throughout the mouth.
 - c. The oral rinse should be spit back into the cup after 10 seconds.
- ❷ Remove a test strip from foil wrapper and place on a flat, absorbent surface.
- ❸ Aspirate the measurement sample with the dropper.
 - a. Be careful not to aspirate air bubbles.
 - b. Fill the dropper to above the line as shown in the picture.



- ④ Apply one drop of sample to the center of each pad starting with the yellow pad and proceeding to the other end.

IMPORTANT:

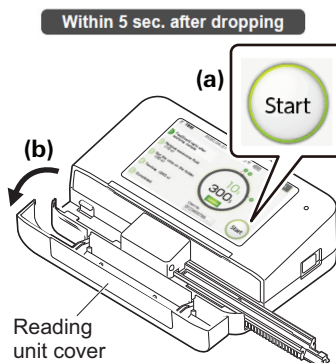
- Finish dropping the sample on all eleven pads within 10 seconds. If it is delayed, results may not be accurate.
- Apply one drop of sample, keeping the tip of the dropper away from the pad. If the dropped volume is too much or too little for measurement, results may not be accurate.
- Perform the operation in next step after completing the dropping of the sample. If there is a delay in starting measurement, results may not be accurate.



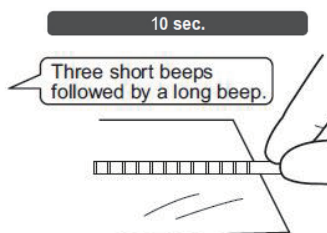
- ⑤ Start timing. Tap [Start] immediately after the dropping of the sample is complete (within 5 seconds) (a). Then, open the reading unit cover (b).
- The instrument starts counting down from 10.

REFERENCE

To stop measurement: Tap and hold [Stop].



- ⑥ During the 10-second countdown (before the beep stops sounding), tilt and blot one edge of the test strip on a clean absorbent surface to remove excess sample from all pads.



REFERENCE

When three seconds are left until the end of the countdown, a short beep starts sounding, and a long beep sounds at 0 second.

- 7 Place the test strip on the test strip holder.
- Slide the test strip along the groove in the test strip holder until it stops.

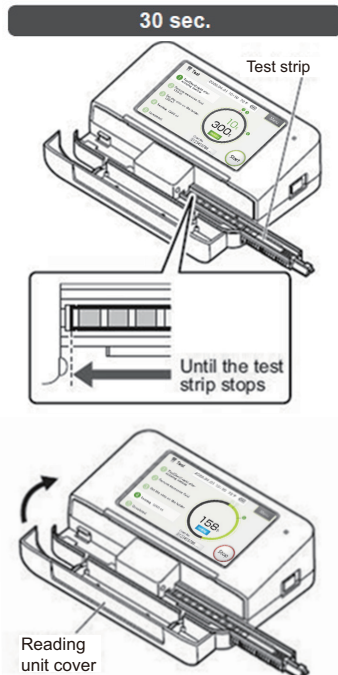
IMPORTANT:

If the test strip deviates from the groove of the test strip holder, accurate measurement results cannot be obtained.

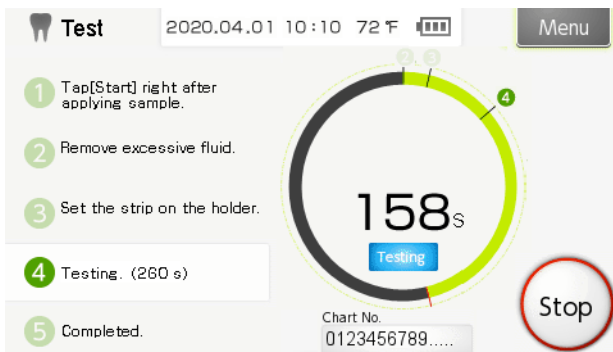
- 8 Close the reading unit cover.

REFERENCE

If the test strip has not been placed until the test strip holder starts moving: [E-100] occurs. Tap [OK] and repeat the procedure from step 1 on page 27, "2.3.2. Enter the Patient Information on the PC".



- 9 Measurement will start automatically, and the remaining time is displayed.



The test strip holder will start moving. Do not touch the instrument until measurement is complete to prevent personal injury. The test strip holder moves twice, when the remaining time is approximately 260 sec. and approximately 20 seconds.

REFERENCE

To stop measurement: Tap and hold [Stop].

⑩ When measurement is complete:

Instrument:

- A short beep sounds, and the display returns to the [Standby] screen.
- The measurement results are transmitted to the PC.

PC:

- The test results are displayed (see “2.4. Viewing the Test Results” on this page).
 - a. Open the reading unit cover of the instrument, remove the test strip, and dispose of it.
 - b. Close the reading unit cover.

2.4 Viewing the Test Results on the PC

Once the measurement is complete, the test results are displayed on the PC. The result sheet can be selected from two types: Type A and Type B.

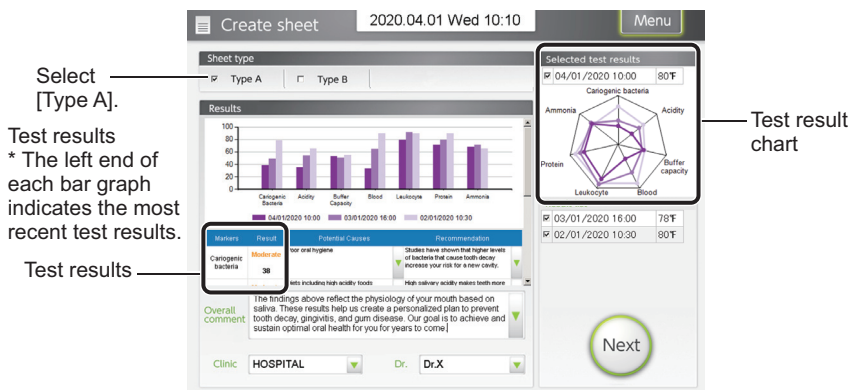
IMPORTANT:

For test results obtained at a temperature lower than 68°F (20°C), the temperature is displayed in blue. Cariogenic bacteria and ammonia results may not be accurate at this temperature.

Type A

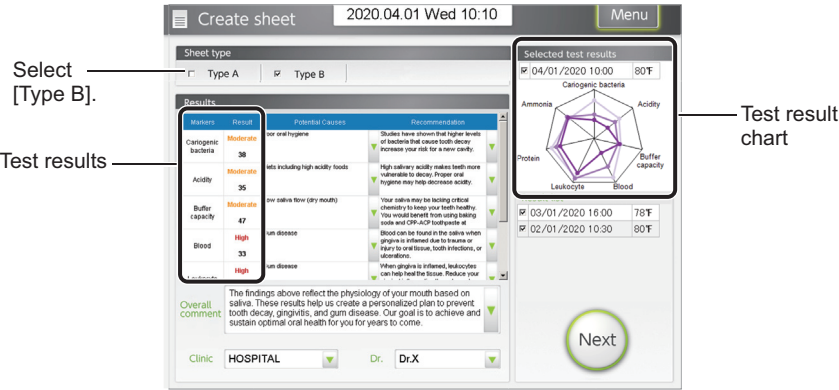
(Comparison using bar graphs)

- Comparison with past test results (up to two records) is possible.
- An overall comment can be entered.



Type B
(Comparison by superimposing one radar chart on the other)

- Comparison with past test results (up to two records) is possible.
- Seven potential causes and recommendations and an overall comment can be entered.



2.5 Creation of the Result Sheet

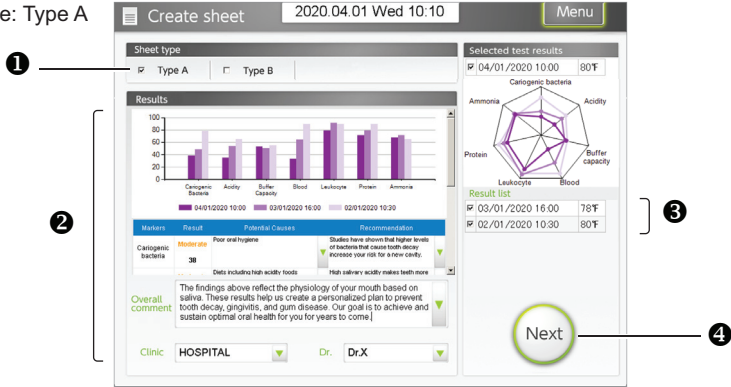
2.5.1 Format and Enter Information

- 1 Choose type of result sheet format under Sheet type.
- 2 Enter a "Potential cause" and "Recommendation", name of the clinic*, and name of the doctor* in the result sheet.

*Mandatory fields

Item	Description								
Cariogenic bacteria, acidity, buffer capacity, blood, leukocyte, protein, and ammonia	In Type A and Type B, click the [▼] to each item and select a comment that matches the test results. If you click [▼] and double-click near the center of the blank field, you can enter any comment (up to 108 characters). Example: <table><thead><tr><th>Markers</th><th>Result</th><th>Potential Causes</th><th>Recommendation</th></tr></thead><tbody><tr><td>Cariogenic bacteria</td><td>Moderate 38</td><td>Poor oral hygiene</td><td>Studies have shown that higher levels of bacteria that cause tooth decay increase your risk for a new cavity.</td></tr></tbody></table> Test result Potential Causes Recommendation Click to select the comment.	Markers	Result	Potential Causes	Recommendation	Cariogenic bacteria	Moderate 38	Poor oral hygiene	Studies have shown that higher levels of bacteria that cause tooth decay increase your risk for a new cavity.
Markers	Result	Potential Causes	Recommendation						
Cariogenic bacteria	Moderate 38	Poor oral hygiene	Studies have shown that higher levels of bacteria that cause tooth decay increase your risk for a new cavity.						
Overall comment	Click [▼] and select a comment that matches the test results. If you click [▼] and double-click near the center of the blank field you can enter any comment (up to 244 characters).								
Clinic/Dr.*	Enter the name of the clinic and doctor's name. You can also click [▼] to select an item from the list.								

Example: Type A



- 3 From the [Result list], select the date of the past test results that you want to compare.
- 4 Click [Next].

- To print the result sheet: Go to “2.5.2. Printing the Result Sheet” on page 33.

REFERENCE

- Creation of a "Potential cause" and "Recommendation": See “3.6. Setting a Comment on the PC” on page 55.
- Registration of the names of the clinic and doctor: See “3.6.1. Registering the Names of the Clinic and Doctor” on page 55.
- To stop the creation of report: Click [Menu]. The result sheets that have not been printed are saved as “Not created”.

2.5.2 Printing the Result Sheet

REFERENCE

Select 8.5" x 11" Letter paper size on your print screen.

Example: When [Type A] is selected:



- ❶ Check the preview of the result sheet.

REFERENCE

- To magnify the display, click on the sheet. To return to its original display, click [-].
 - To correct the result sheet, click [Back].
 - To correct the medical chart number and patient name, click [Edit]. On the [Name] screen, correct the medical chart number or patient name, and click [OK].
- ❷ Click [Print] to start printing.
 - Printing will start.
 - ❸ To create a PDF of the result sheet, make this choice on your print screen, and save to location of your choice.

NOTE:

You may be able to attach the PDF to your patient electronic chart.

REFERENCE

- To continue measurements, click [Menu] to return to the Top menu screen, and go to “2.3.2. Enter the Patient Information on the PC” on page 27.

2.5.3 Example of Printing a Result Sheet

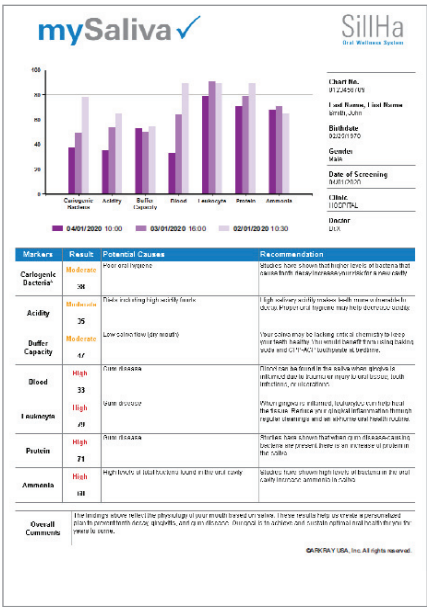
IMPORTANT:

For test results obtained at a measurement temperature below 68°F (20°C), the temperature is printed in blue. Cariogenic bacteria and ammonia results may not be accurate at this temperature.

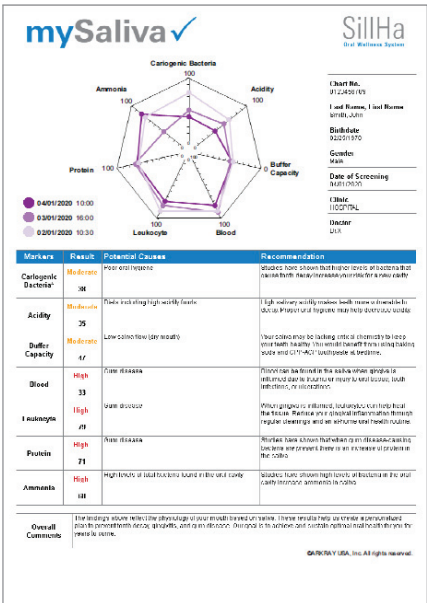
REFERENCE

All result sheets are printed on letter size paper.

Type A (Bar chart)



Type B (Radar chart)



2.6 At the End of the Day

When all daily tests and cleaning are complete, power off the instrument.

- ❶ Clean the test strip holder.
 - See 4.2.1. Cleaning the Test Strip Holder on page 61.
- ❷ Press and hold the power button of the instrument.
 - The test strip holder will retract inside the instrument.
 - The display and power will turn off.
- ❸ Exit the SillHa software.
 - Click [Menu] to return to the Top menu screen.
 - On the Top menu screen, click [X].
 - When "Close?" appears, click [OK].

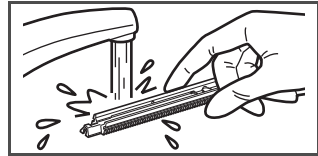
2.7 Check Measurement

If test results seem inaccurate, perform a check measurement using a check strip to check the condition of the instrument. Instructions are shown on the instrument screen.

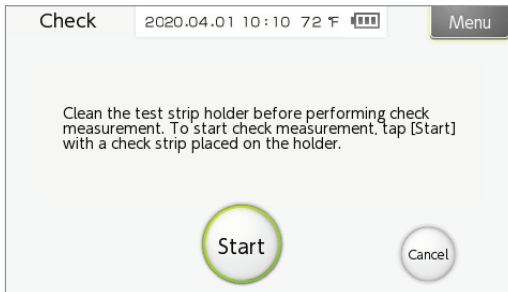
- ❶ Clean the test strip holder.
 - See "4.2.1. Cleaning the Test Strip Holder" on page 61.

NOTE:

If dirt adheres to the test strip holder, the check strip may be contaminated and lose its effectiveness.



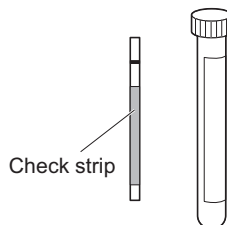
- ❷ Turn on the instrument: Hold the power button until a beep is heard.
- ❸ Run the SillHa software by clicking the icon on the PC.
- ❹ On the Top menu screen, tap [Maint.] and [Check], in that order.
 - The Check screen will appear.



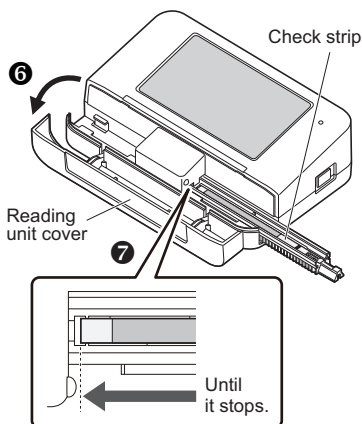
- 5 Remove one check strip from the container.
- You will find two gray check strips. Use either one of the strips.

IMPORTANT:

Do not touch the surface of the check strip.
If sebum adheres to the check strip, accurate measurement results cannot be obtained.



- 6 Open the reading unit cover.
- 7 Place the check strip on the test strip holder.
- Slide the test strip along the groove on the test strip holder until it stops.

**IMPORTANT:**

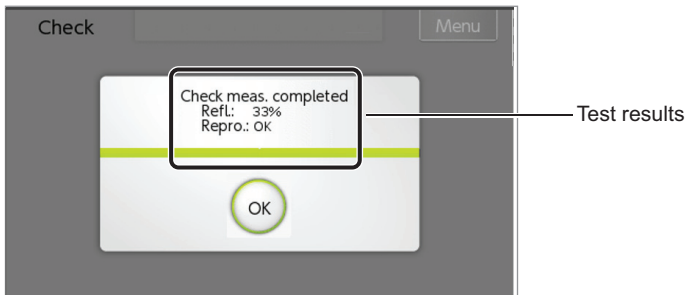
If the check strip deviates from the groove of the test strip holder, accurate measurement results cannot be obtained.

- ⑧ Close the reading unit cover.
- ⑨ Tap [Start].
 - Measurement will start and [Performing check measurement] is displayed.
 - When measurement is complete, a beep is heard, and the test results are displayed.

REFERENCE

To stop measurement: Tap [Stop].

- ⑩ Check the test results.
 - The correct range of [Refl.] is specified on the label affixed to the check strip container.



- [Refl.]: Within the range, [Repro.]: OK
The instrument is normal.
Tap [OK] to return to the Top menu screen.
The check measurement is then complete. Tap [Menu] to return to Top menu screen.
- [Refl.]: Outside the range, or [Repro.]: NG
Either the instrument or the check strip is faulty.
Tap [OK] and go to next procedure below.

Follow the procedure below if [Refl.] is outside the range or [Repro.] is NG.

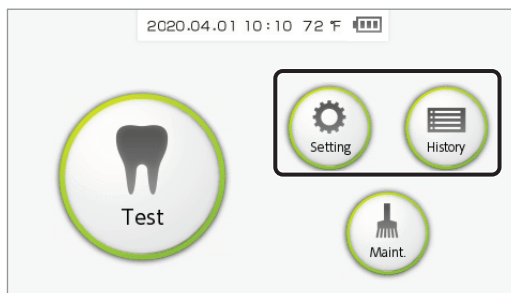
- ① Use the remaining check strip, and perform check measurement again.
 - See steps 4 to 10.

- ② Check the test results.
 - [Refl.]: Within the range, [Repro.]: OK
The instrument is normal. The check strip used for the first check measurement is faulty.
 - [Refl.]: Outside the range, or [Repro.]: NG
There is a problem with the instrument. Contact ARKRAY.
- ③ Tap [OK].
 - The display returns to the Top menu screen.

3.1 List of Auxiliary Operations

3.1.1 Auxiliary Operations of the Instrument

Top menu screen



Button	Item		Description	Reference page
Setting	Date		Set the date and time.	43
	Digit		Set the digits of the medical chart number.	44
	Others	Sound	Set the sound level of the beep.	45
		Brightness	Set the screen brightness.	45
		Strip direction	Set the direction of the test strip holder.	46
History			Re-transmit the most recent measurement results to the PC.	48

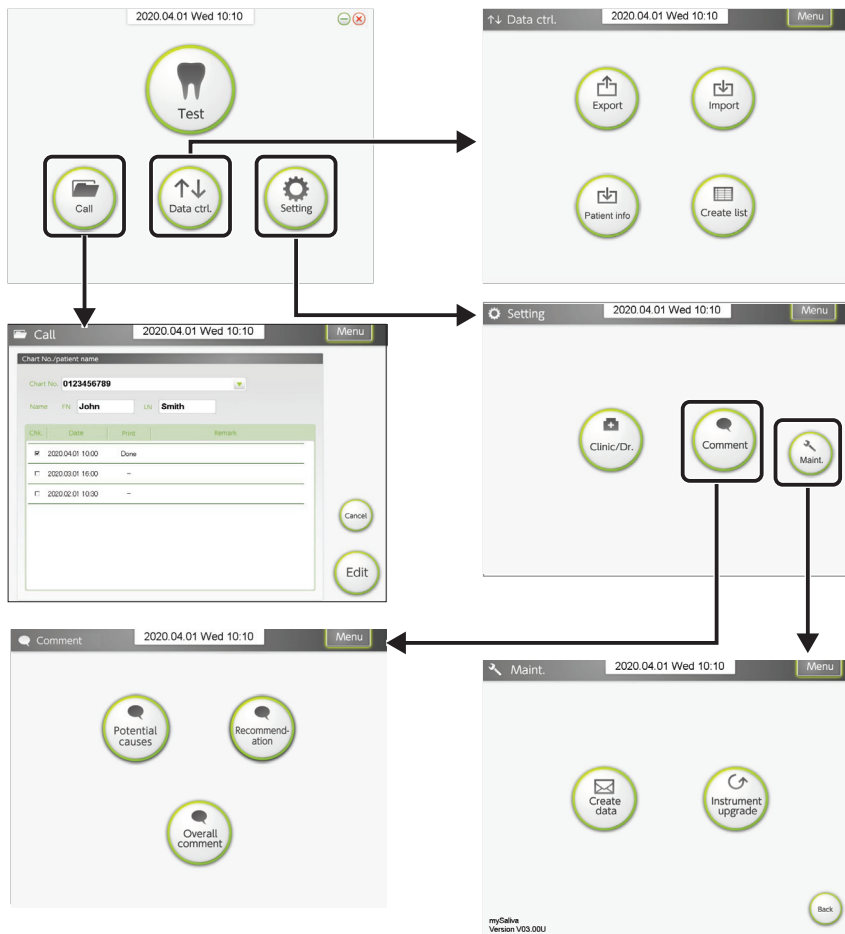
- For maintenance, see Chapter 4, page 60.

3.1.2 Auxiliary Operations of the SillHa Software

REFERENCE

The SillHa software can be operated even when the instrument is off.

Top menu screen



Button			Description	Reference page
Call			Used to search the test results of patients, and to edit the uncreated results sheet.	49
Data ctrl.	Export		Used to compile and export the saved result data.	51
	Import		Used to import the result data exported from another PC.	52
	Patient info		Used to import the patient information data in CSV format.	53
	Create list		Used to create a list of the saved result data.	54
Setting	Clinic/Dr.		Used to register the clinic and doctor's name.	55
	Comment	Potential causes	Used to create a potential cause to be added to the test results.	56
		Recommendation	Used to create a recommendation to be added to the test results.	56
		Overall comment	Used to create an overall comment to be added to the test results.	57
	Maint.	Create data	Used to transmit the measurement data.	N/A
		Instrument upgrade	Used to upgrade the instrument's software.	58

See Section 3.5 for Data Control Operations.

See Section 3.6 for Setting Comments.

3.2 Instrument Settings

3.2.1 Setting the Date and Time

REFERENCE

When the instrument is connected to a PC, the date and time settings of the PC are received automatically.

- ❶ Tap [Setting] on the Top menu screen.
- ❷ Tap the numeric value you want to change for the correct date and time.
- ❸ Enter the numeric value either through [↑]/[↓], or through the numeric buttons, and tap [OK].

REFERENCE

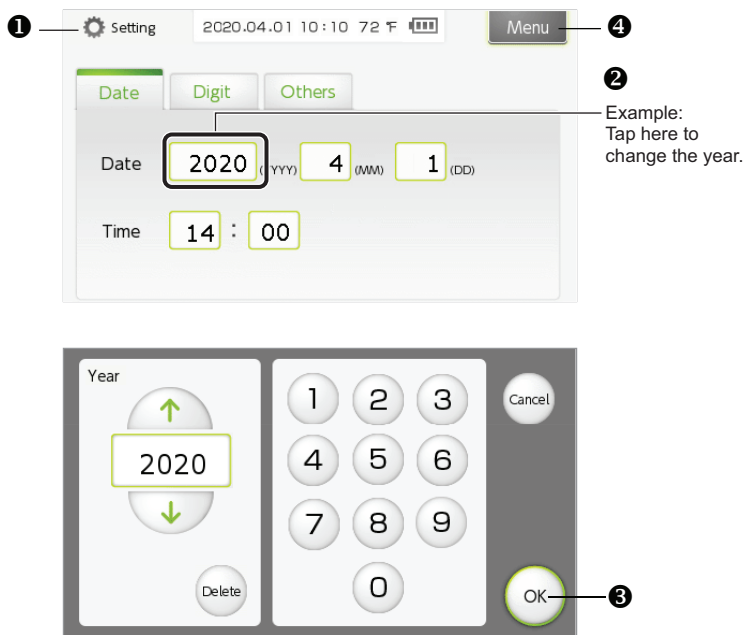
[Delete]: Delete the entered numeric value one digit at a time.

[Cancel]: Cancel the entered numeric value and return to the previous screen.

- ❹ Tap [Menu].
 - The display returns to the Top menu screen.

REFERENCE

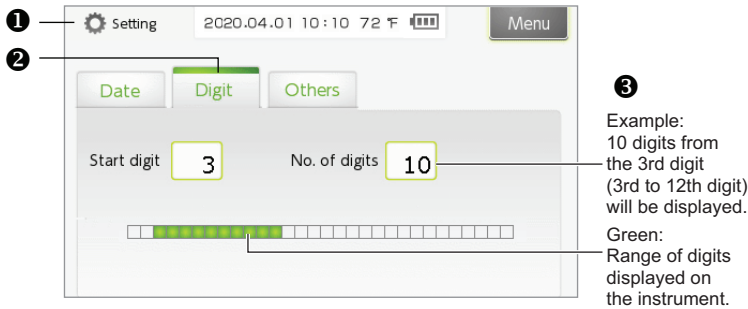
Upon returning to the Top menu screen, the settings are reflected in the date and time display.



3.2.2 Setting the Digits of the Medical Chart Number

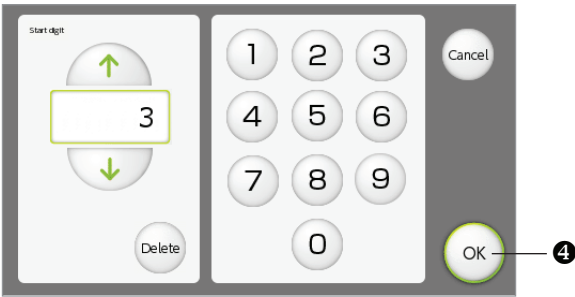
For the medical chart numbers used at the facility, set the starting digit and number of digits to be displayed on the instrument.

- 1 Tap [Setting] on the Top menu screen.
- 2 Tap the [Digit] tab.
- 3 Tap the numeric value you want to change.



Item	Description
Start digit	This is the 1st digit displayed on the instrument.
No. of digits	Number of digits from the [Start digit] (1 to 13 digits)

- 4 Enter the numeric value either through [↑]/[↓], or through the numeric buttons, and tap [OK].



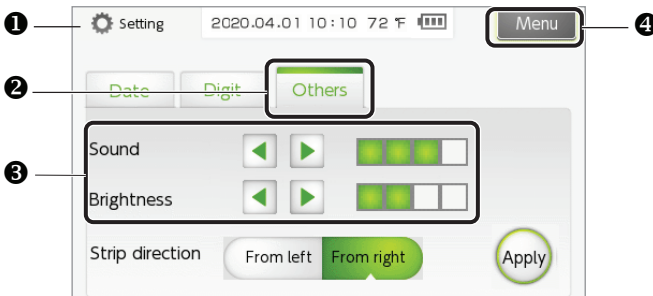
- 5 Repeat steps 3 and 4 to set the start digit and number of digits.
- 6 Tap [Menu].
 - The display returns to the Top menu screen.

3.2.3 Adjusting the Sound Level and Screen Brightness

Adjust the beep sound level and the screen brightness.

- ❶ Tap [Setting] on the Top menu screen.
- ❷ Tap the [Others] tab.
- ❸ Tap [↑]/[↓] to change the sound level and brightness.
 - The current settings are displayed on the right side.
- ❹ Tap [Menu].
 - The display returns to the Top menu screen.

Item	Description
Sound	Mute, Level 1 to 4. The beep sounds at the selected level each time this button is tapped.
Brightness	Level 0 to 4.



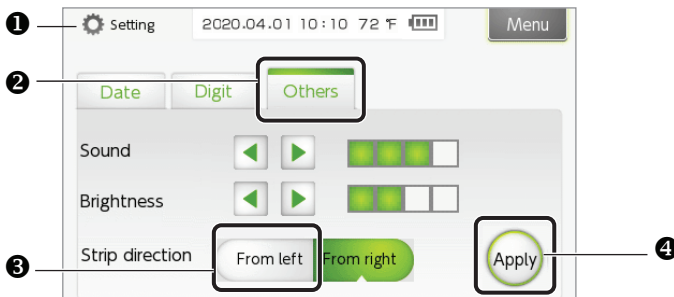
3.2.4 Changing the Test Strip Direction

This instrument has been factory-set so that you can place a test strip on the test strip holder from the right side of the instrument. Left-handed persons may find it convenient if the settings are made to enable the placing of the test strip from the left side.

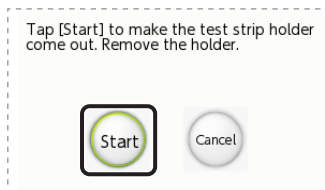


Wear personal protective equipment to prevent exposure to pathogenic microorganisms.

- ❶ Tap [Setting] on the Top menu screen.
- ❷ Tap the [Others] tab.
- ❸ Tap [From left].
- ❹ Tap [Apply].

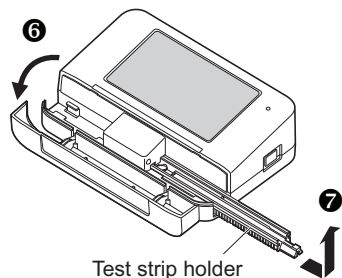


- ❺ Tap [Start].



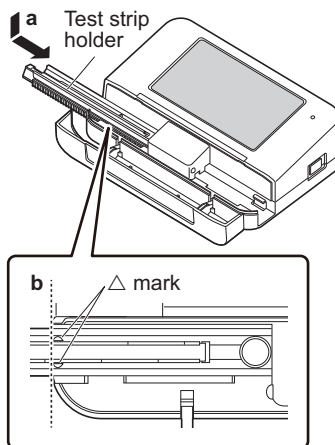
- The test strip holder extends from the instrument and unlocks.

- ❻ Open the reading unit cover.
- ❼ Slide the test strip holder to the right, and remove it.



- 8 Hold the test strip holder so that its white plate comes to the right, and attach it from the left side of the instrument.

- Insert the test strip holder along the instrument guide (a), and lightly push the test strip holder until the Δ mark comes slightly inside the outer edge of the instrument (b).



- 9 Tap [Start].

- The test strip holder retracts inside the instrument and locks.
- The display returns to the Top menu screen.

- 10 Close the reading unit cover.

Hold the test strip holder with the white plate on the right side, and attach it from the left side of the instrument. Lightly push the holder until the Δ mark on the holder comes slightly inside the outer edge of the instrument.



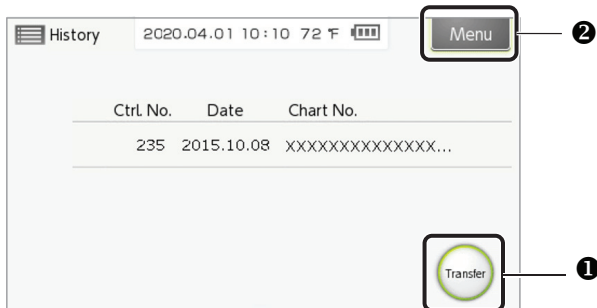
3.3 History

3.3.1 Re-transmitting the Most Recent Measurement Results to the PC

NOTE:

Before re-transmitting the test results, run the SillHa software on the PC, and establish communication with the instrument (see “2.3.1. Turn on Instrument and Run software” on page 25).

Tap [History] on the Top menu screen.



- ❶ Check the medical chart number, etc., and tap [Transfer].
 - The most recent measurement results will be transmitted.
- ❷ Tap [Menu].
 - The display returns to the Top menu screen.
- ❸ If necessary, create a result sheet for the received measurement results using the SillHa software on the PC.
 - See “3.4. Calling the Test Results” on page 49.

3.4 Calling the Test Results (Searching)

3.4.1 Searching for Test Results

You can search the test results of a specific patient and display them in a list.

Click [Call] on the Top menu screen.

The screenshot shows a software interface titled 'Call' with a date and time display '2020.04.01 Wed 10:10' and a 'Menu' button. Below the title bar, there is a section for 'Chart No./patient name'. This section contains a 'Chart No.' field with the value '0123456789' and a dropdown arrow, and a 'Name' field with sub-fields for 'FN' (John) and 'LN' (Smith). A circled '1' points to this search area. Below the search fields is a table with columns 'Chk.', 'Date', 'Print', and 'Remark'. The table contains three rows of data. A label 'List of test results' points to the table. At the bottom right of the interface are two circular buttons labeled 'Cancel' and 'Edit'.

Chk.	Date	Print	Remark
☒	2020.04.01 10:00	Done	
☐	2020.03.01 16:00	--	
☐	2020.02.01 10:30	--	

1 Specify the patient.

- Enter information in any of the fields, [Chart No.], [FN] or [LN].
- The medical chart number can also be selected from the list by clicking [▼].

REFERENCE

If “[W-304] The corresponding test history does not exist” is displayed:
Click [OK] to close the pop-up window.

3.4.2 Editing an Uncreated Result Sheet on the PC

You can select an “Uncreated” test result and edit it. The test results of “Uncreated” result sheet are saved but not printed.

- ❶ Call the test results.
 - See “3.4.1. Searching for Test Results” on page 49.
- ❷ Check a box for the result sheet you want to edit.

Chk.	Date	Print	Remark
☒	2020.04.01 10:00	Done	
☐	2020.03.01 16:00	-	
☐	2020.02.01 10:30	-	

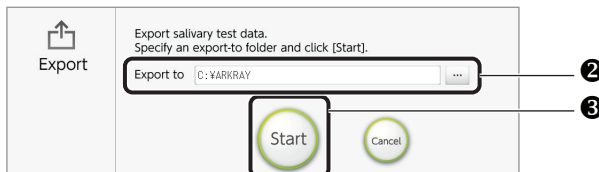
-]: The result sheet has not been created.
[Done]: Already created (printed)

- ❸ Click [Edit] at the bottom right of the screen.
 - The result sheet is displayed.
- ❹ Edit the result sheet.
 - See “2.5 Creation of the Result Sheet” on page 32.

3.5 Operations using the Result Data on the PC

3.5.1 Exporting the Result Data on the PC

Compile and export the result data saved in the PC. By importing this data to another PC, data such as the test results of the patient, name of the clinic, name of the doctor, comment, etc. can be used.



❶ On the Top menu screen, click [Data ctrl.] → [Export] in that order.

❷ In [Export to] enter the data storage destination.

REFERENCE

To select from a list of folders: Click [...]. On the [Browse For Folder] screen, select the export-to folder, and click [OK].

❸ Click [Start].

❹ When “Exported successfully.” is displayed, click [OK].

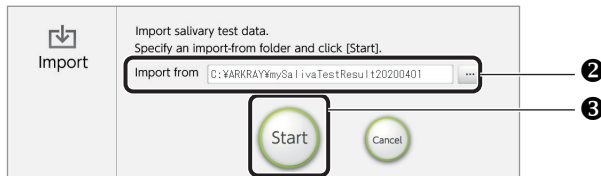
- The export process is then complete.

REFERENCE

The exported result data is saved on the [mySalivaTestResult(Date)] folder.

3.5.2 Importing the Result Data on the PC

By importing data that has been exported from another PC, the entered clinic name, doctor's name, comment, etc. can be used.



- ❶ On the Top menu screen, click [Data ctrl.] → [Import] in that order.
- ❷ In [Import from], specify the folder on which the export file is saved.
(The folder name is [mySalivaTestResult(Date)].)

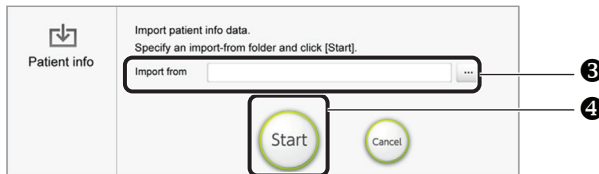
REFERENCE

To select from a list of folders: Click [...]. On the [Browse For Folder] screen, select the folder, and click [OK].

- ❸ Click [Start].
- ❹ When [Imported successfully.] is displayed, click [OK].
 - The import process is then complete.

3.5.3 Importing the Patient Information

You can import the patient information data in CSV format. This function is useful when you want to enter the information of several patients.



- ❶ Prepare the patient information file (CSV format).

REFERENCE

To create the file in a text editor, etc.

Enter the patient information as described below and save it in the CSV format.

ex)	1234	,	AAA	,	BBB	,	2020/4/1	,	F	,		[Linefeed]
	1237	,	CCC	,	DDD	,	2020/11/10	,	M	,		[Linefeed]
	(1)		(2)		(3)		(4)		(5)		(6)	

Demarcate each item ((1) to (6)) with a single-byte comma

- | | |
|--------------------------|--|
| (1) Chart No. | Up to 30 alphanumeric characters (mandatory) |
| (2) Patient's first name | Up to 15 characters |
| (3) Patient's last name | Up to 15 characters |
| (4) Date of birth | Year/Month/Day (Demarcate with a slash) |
| (5) Gender | One alphabet M (Male) or F (Female) |
| (6) Comment | Up to 40 characters |

- ❷ On the top menu screen, click [Data ctrl.] -> [Patient info] in that order.

- ❸ In [Import from], specify the patient information file (CSV format) prepared in step ❶

REFERENCE

To select from a list of files:

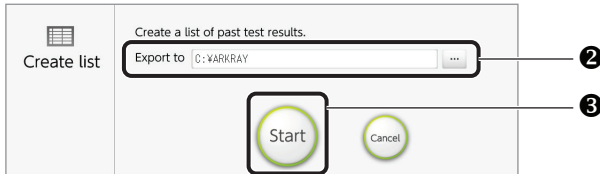
Click [...]. On the [Open] screen, select the file, and then click [OK].

- ❹ Click [Start].

- ❺ When [Imported successfully] is displayed, click [OK].
 - The import process is then complete.

3.5.4 Creating a List of Result Data

Create a list of result data saved in the PC, and save the list in the [Test Results List] file.



- ❶ On the Top menu screen, click [Data ctrl. → [Create list] in that order.
- ❷ In [Export to], specify the storage destination of the file containing the list.

REFERENCE

To select from a list of folders: Click [...]. On the [Browse For Folder] screen, select the folder, and click [OK].

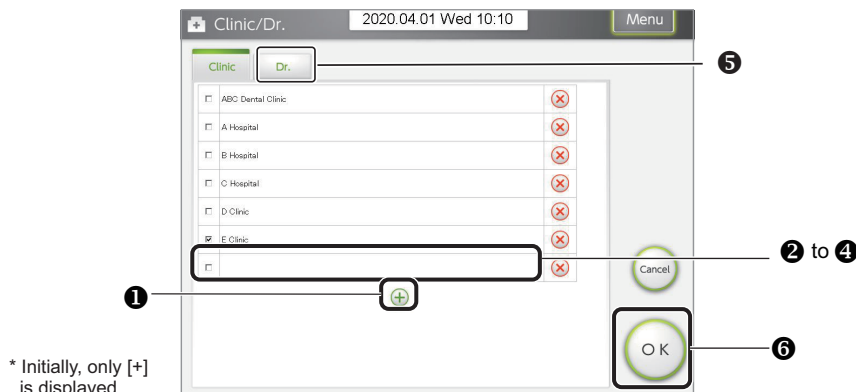
- ❸ Click [Start].
- ❹ When [Test result list data created.] is displayed, click [OK].
 - The creation of the list is then complete.

3.6 Setting a Comment on the PC

3.6.1 Registering the Names of the Clinic and Doctor

The registered name can be selected from the list when the result sheet is created, and is displayed/printed on the result sheet.

On the Top menu screen, click [Setting] → [Clinic/Dr.] in that order.



❶ Under the [Clinic] tab, click [+].

- A blank entry field appears.

REFERENCE

To edit an existing clinic name: Click the entry field you want to edit, and go to step

❸.

❷ Click the blank entry field.

❸ When a check mark appears on the left side, click the entry field again.

- A cursor appears.

❹ Enter the name of the clinic (up to 20 characters).

- Up to 10 clinic names can be entered.

REFERENCE

[✓]: Check a box next to the name of the clinic that is to be displayed as the default. If a box is not checked for any clinic name, the default is blank.

[x]: Used to delete a clinic name.

❺ Click the [Dr.] tab and enter the name of the doctor (up to 20 characters).

- See steps ❶ to ❹.

❻ Click [OK].

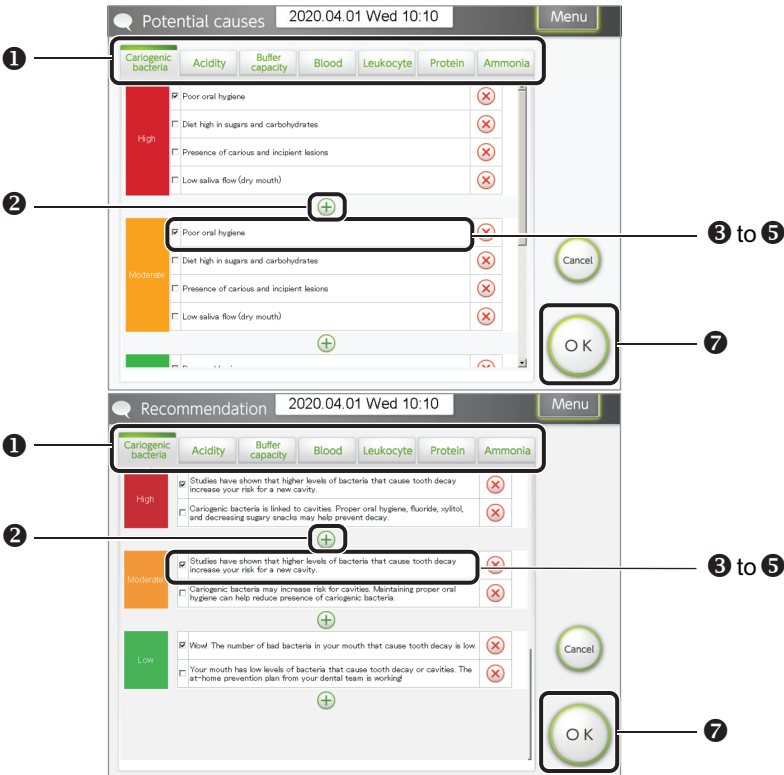
When “Updated successfully” is displayed, click [OK].

- The registration process is then complete.

3.6.2 Creating Potential Causes and Recommendation for the Result Sheet

Create a comment in each test result field of the result sheet for the Potential Causes and Recommendation. Comments can then be selected in each field to customize the result sheet for each patient. New comments can be added or existing comments can be edited.

On the Top menu screen, click [Setting] → click [Comment] → click [Potential causes] and [Recommendation].



- 1 Click the tab of the measurement item to create a comment.
- 2 Click [+] under the test result table.
 - A blank entry field appears.

REFERENCE

To edit an existing comment: Click the entry field to edit, and go to step 4.

NOTE:
If you edit a comment that is already saved, you cannot change it back to its original version.

- 3 Click the blank entry field.
- 4 When a checkmark appears on the left side, click the entry field again.
 - A cursor appears.

- ⑤ Enter a comment (up to 108 characters). Up to 10 comments can be entered.

REFERENCE

[✓]: Check a box next to the comment that is to be displayed as the default. If a box is not checked for any comment, the default is blank.

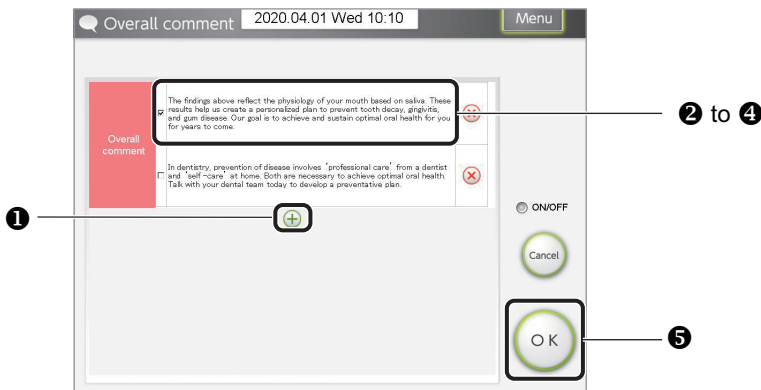
[x]: Used to delete a comment.

- ⑥ If necessary, click the tab of another measurement item, and enter a comment.
- See steps ① to ⑤.
- ⑦ Click [OK].
- ⑧ When “Updated successfully” is displayed, click [OK].
- The creation of a comment is then complete.

3.6.3 Creating an Overall Comment

Create a comment to be added to the overall comment field of the result sheet. The comments created here can be selected from the list during creation of the result sheet. New comments can be added, and comments that are already saved can be edited. Select ON/OFF to either show or hide the overall comment on the test result sheet.

On the Top menu screen, click [Setting] → click [comment] → click [Overall comment] in that order.



- ① Click [+] under the table.
- A blank entry field appears.

REFERENCE

To edit an existing comment: Click the entry field to edit, and go to step ③.

NOTE:

If you edit a comment that is already saved, you cannot change it back to its original version.

- ② Click the blank entry field.
- ③ When a check mark appears on the left side, click the entry field again.
 - A cursor appears.
- ④ Enter a comment (up to 244 characters).
 - Up to 10 comments can be entered.

REFERENCE

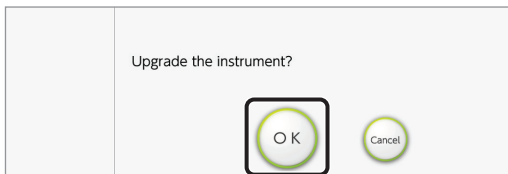
[✓]: Check a box next to the comment that is to be displayed as the default.
 If a box is not checked for any comment, the default is blank.

[x]: Used to delete a comment.

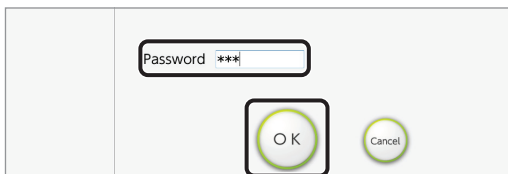
- ⑤ Click [OK].
- ⑥ When “Updated successfully” is displayed, click [OK].
 - The creation of a comment is then complete.

3.6.4 Upgrading the Instrument Software (As Necessary)

- ① Make sure the PC and instrument are connected by the USB cable, and the power supply to the instrument is OFF.
- ② On the Top menu screen of the SillHa software, click [Setting] → [Maint.].
- ③ Click [Instrument upgrade].
- ④ In the [Password], enter the password provided by ARKRAY and click [OK].



- ⑤ Click [OK].



- ⑥ When [Checking] appears, turn the instrument ON.
 - When a connection is established to the instrument, “Sending” appears, and the software upgrade will start.

REFERENCE

If “[T-504] A timeout has occurred” is displayed: The software upgrade could not be started. Click [OK], and repeat the procedure from step ③.

- ⑦ When the instrument upgrade is complete, and [Completed] appears, click [OK].
 - The upgrade is then complete.
- ⑧ Click [Menu] to return to the Top menu screen.

This chapter describes how to clean the instrument and upgrade the version.

4.1 Frequency

This section lists the parts that require maintenance and the standard frequency to perform maintenance tasks. Refer to the table below and perform maintenance at recommended intervals.

CAUTIONS:  • Wear personal protective equipment to prevent exposure to pathogenic microorganisms when performing maintenance tasks marked with biological risk symbol. • Dispose of used test strips, cleaning tools, and personal protective equipment in accordance with local regulations for biohazardous waste.			
Caution	Maintenance task	Frequency	See page
	Cleaning of the test strip holder	Every day	61
	Cleaning of the reading unit	If [E-101] or [T-203] occurs	63
	Adjustment of the driving speed	If [E-101] or [T-203] occurs even after cleaning the test strip holder and reading unit	64
	Instrument upgrade	As necessary	58

4.2 How to Perform Maintenance

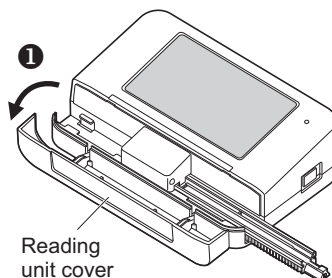
A standard disinfectant wipe may be used during the maintenance task for this instrument.

4.2.1 Cleaning the Test Strip Holder

Once all daily measurements are complete, clean the test strip holder.

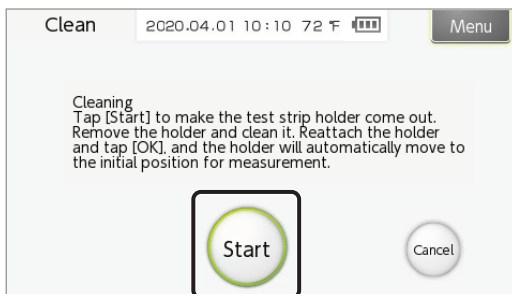
The following instruction is for the test strip holder with the direction setting, [From right] (default setting).

- ❶ Open the reading unit cover.



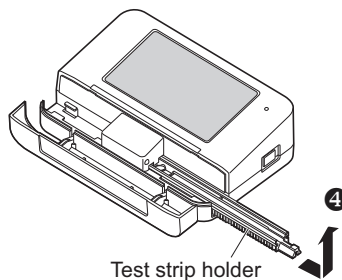
- ❷ On the Top menu screen of the instrument, tap [Maint.] → [Clean], in that order.

- ❸ Tap [Start].

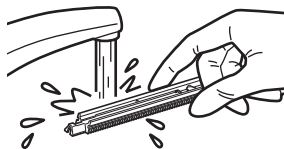


- The test strip holder extends from the instrument and unlocks.

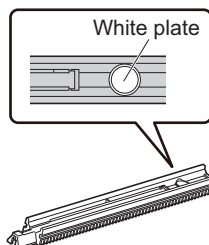
- ❹ Slide the test strip holder and remove it.



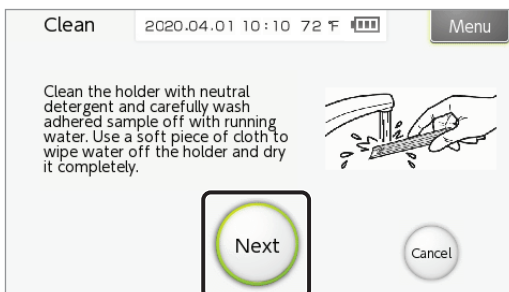
- ⑤ Clean the test strip holder.
- Use a neutral detergent for cleaning.
 - Wash off the dirt on the surface with running water.
 - Wipe off the water with a soft cloth, and dry the test strip holder thoroughly.



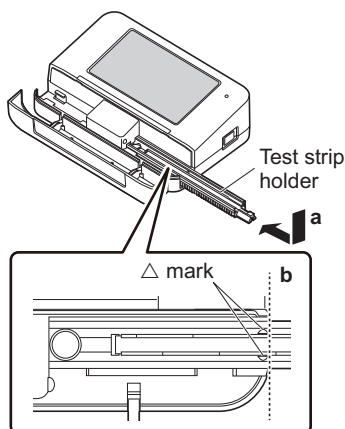
- ⑥ Clean the white plate.
- Carefully wipe off the dirt with a soft cloth moistened with water or alcohol.



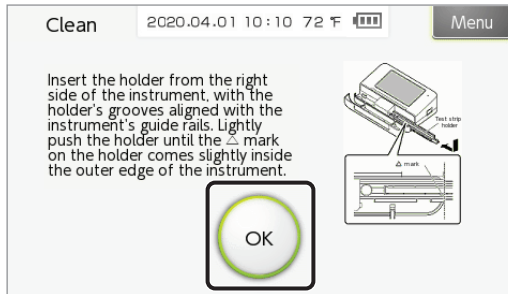
- ⑦ Tap [Next].



- ⑧ Hold the test strip holder so that its white plate is on the left, and attach it from the right side of the instrument.
- Insert the test strip holder along the instrument guide (a), and lightly push the test strip holder until the Δ mark comes slightly inside the outer edge of the instrument (b).



9 Tap [OK].



- The test strip holder retracts inside the instrument and locks.

10 Close the reading unit cover.

11 When all tests and cleaning are complete, power off the instrument.

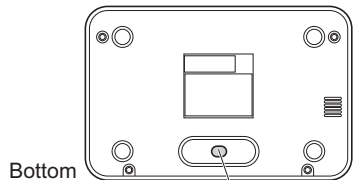
4.2.2 Cleaning the Reading Unit

Clean the reading unit if [E-101] or [T-203] occurs.

1 Remove the test strip holder.

- See step 1 in "4.2.1. Cleaning the Test Strip Holder" on page 61.

2 Check the cleaning slot on the bottom of the instrument.



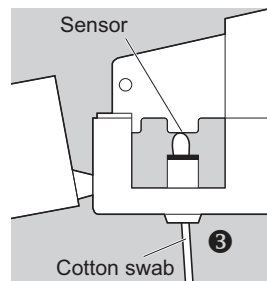
3 Clean the reading unit.

- Insert a cotton swab moistened with water or alcohol into the cleaning slot.
- Wipe off the dirt while ensuring that the tip of the cotton swab is touching the sensor.

4 Attach the test strip holder.

- See step 3 in "4.2.1. Cleaning the Test Strip Holder" on page 61.

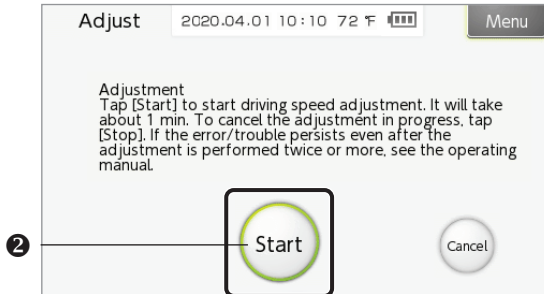
Instrument cross-sectional view



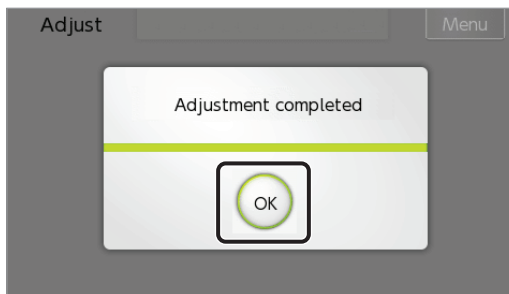
4.2.3 Adjusting the Driving Speed

If [E-101] or [T-203] continues to occur even after the white plate of the test strip holder and the reading unit have been cleaned, adjust the driving speed.

- ① On the Top menu screen, tap [Maint.] → [Adjust], in that order.
- ② Tap [Start].



- [Adjusting] is displayed, and the driving speed is adjusted (approximately one minute).
 - The test strip holder moves.
- ③ When the screen below appears, tap [OK].



- The display returns to the Top menu screen.

IMPORTANT:

If [E-101] or [T-203] continues to occur even after adjustment has been performed twice or more, contact ARKRAY.

This chapter describes the measures to be taken if a warning, error, or trouble occurs in the instrument or the SillHa software.

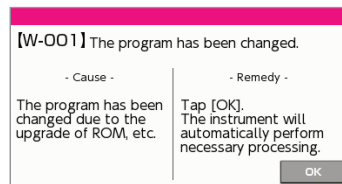


- Wear personal protective equipment to prevent exposure to pathogenic microorganisms before any operation that may expose you to measurement samples.
- Dispose of used measurement samples and personal protective equipment in accordance with local regulations for biohazardous waste.

5.1 Instrument Troubleshooting

The measures to be taken to resolve a warning, error, or trouble that may occur in the instrument are below.

- 1 The instrument notifies you of a warning, error, or trouble by:
 - Emitting short beeps
 - Displaying the warning, error, or trouble code, and a message.



- 2 Take the necessary action to remove the cause.
 - See "5.1.1. Instrument [Warning] Causes and Remedies" on page 66.
 - See "5.1.2. Instrument [Error] Causes and Remedies" on page 67.
 - See "5.1.3. Instrument [Trouble] Causes and Remedies" on page 68.
- 3 If the problem persists, turn off the instrument, and contact ARKRAY.

NOTE:

If the instrument freezes: If the instrument does not operate even after tapping the buttons on the screen, and no warning, error, or trouble is displayed, press and hold the power button for 10 seconds or longer. The instrument will turn off. Then, press and hold the power button again to make sure that the instrument starts up normally.

5.1.1 Instrument [Warning] Causes and Remedies

A warning occurs as a result of an incorrect operating procedure. You can continue measurement by following simple remedial procedures.

No.	Description	Cause	Remedy
[W-001]	The program has been changed.	The program has been changed due to the upgrade of ROM, etc.	Tap [OK]. The instrument will automatically perform necessary processing.
[W-002]	Remove the test strip.	The power cannot be turned off because the test strip is left on the test strip holder.	Remove the test strip and tap [OK].
[W-003]	The test strip holder is not attached properly.	The test strip holder is attached improperly.	Properly attach the test strip holder and tap [OK].
[W-011]	The battery level is low.	Measurement cannot be performed due to low battery level.	Tap [OK]. Start measurement when the battery has been charged.

5.1.2 Instrument [Error] Causes and Remedies

An error occurs due to improper instrument operations or measurement that may affect measurement results. You can continue measurement by following simple remedial procedures.

No.	Description	Cause	Remedy
[E-100]	The test strip is not placed properly.	• The test strip is not in place. • The test strip is not for use with the instrument. • The test strip is placed improperly.	• Use only test strips for use with the instrument. • Properly place the test strip on the test strip holder. Tap [OK] and turn on the instrument again.
[E-101]	The LED emits too much light.	• The photometric section is exposed to stray light. • There is a problem with the LED.	Tap [OK] and turn off the power. Clean the white plate on the test strip holder (see page 61) and the reading unit (see page 63). If the error persists, perform driving speed adjustment (see page 64).
[E-102]	The photometric section is exposed to strong light.	The photometric section is exposed to stray light.	Tap [OK]. Close the reading unit cover and retry measurement.
[E-103]	A communication error occurred.	An error occurred in communication between the instrument and the PC.	Tap [OK]. Disconnect the USB cable from both the ends of the instrument and the PC, and connect them again. Then, retry measurement.
[E-104]	A temperature error occurred.	• The environmental temperature is outside the range of 50° – 86°F (10° – 30°C). • The instrument has not adjusted to the environmental temperature. • There is a problem with the instrument.	Tap [OK]. Allow the instrument to adjust to the environmental temperature of 50° – 86°F (10° – 30°C), and retry measurement. If the error persists, contact ARKRAY.
[E-105]	The instrument was powered down during measurement.	• The USB cable is not connected properly to the instrument or the PC. • The battery is disconnected or deteriorated.	Tap [OK]. Make sure that the USB cable is connected properly. If the error persists, contact ARKRAY.

5.1.3 Instrument [Trouble] Causes and Remedies

Trouble occurs if there is a problem with the electrical circuits, the mechanical section, or other parts of the instrument.

No.	Description	Cause	Remedy
[T-200]	A problem occurred while the instrument was reading data from the memory.	There is a problem with data read from the Flash ROM.	Tap [OK]. Turn the power off and then on. Then, retry measurement.
[T-201]	A problem occurred while the instrument was writing data to the memory.	Data could not be written to the Flash ROM.	
[T-202]	The test strip holder does not move properly.	The test strip holder is not attached properly.	Tap [OK]. Properly attach the test strip holder and turn on the power.
[T-203]	The LED emits insufficient light.	The white plate and the reading unit are dirty.	Tap [OK] and turn off the power. Clean the white plate on the test strip holder (see page 61) and the reading unit (see page 63). If the trouble persists, perform driving speed adjustment (see page 64).
[T-204]	Calculation trouble	Calculation of the test result was not performed correctly.	Tap [OK]. Turn the power off and then on. Then, retry measurement.
[T-205]	A problem occurred during driving speed adjustment.	The driving motor or PCB may have an abnormality.	Tap [OK]. Make sure that the test strip holder was cleaned appropriately, and contact ARKRAY.
[T-999]	Software trouble	Some other trouble occurred.	Turn off the power and contact ARKRAY.

5.2 SillHa Software Troubleshooting

The measures to be taken to resolve a warning, error, or trouble that may occur in the SillHa software are below.

- ❶ If a warning, error, or trouble occurs, a code and message are displayed as shown on the right.
- ❷ Take the necessary action to remove the cause.
 - See “5.2.1. SillHa Software [Warning] Causes and Remedies” on page 70.
 - See “5.2.2. SillHa Software [Error] Causes and Remedies” on page 71.
 - See “5.2.3. SillHa Software [Trouble] Causes and Remedies” on page 72.
- ❸ If the problem persists, contact ARKRAY.

[W-306] Specify import-from folder.



5.2.1 SillHa Software [Warning] Causes and Remedies

A warning occurs as a result of an incorrect operating procedure. You can continue using the instrument by following simple remedial procedures.

No.	Description	Cause	Remedy
[W-301]	The corresponding patient information does not exist.	Data corresponding to the entered medical chart number or patient name does not exist.	Click [OK] and enter the correct medical chart number or patient name.
[W-302]	Enter the medical chart number.	The medical chart number has not been entered.	Click [OK] and enter the medical chart number.
[W-303]	The corresponding medical chart number already exists.	The same medical chart number has already been registered.	Click [OK] and confirm the correct medical chart number.
[W-304]	The corresponding test history does not exist.	Data corresponding to the entered medical chart number does not exist.	Click [OK] and enter the correct medical chart number.
[W-305]	Specify the export-to location.	The export-to location of the data has not been specified.	Click [OK] and specify the export-to location.
[W-306]	Specify the import-from location.	The location where the import-from data is saved has not been specified.	Click [OK] and specify the storage location of the data.
[W-307]	The password is incorrect.	The password is incorrect.	Click [OK] and enter the correct password.
[W-308]	Select the data.	[Edit] was clicked even when the result sheet was not called.	Call the result sheet to be edited, and click [Edit].
[W-309]	Select up to two records.	Three or more past test results have been selected for displaying in the result sheet (Type A or B).	Click [OK]. Select up to two past test results.
[W-310]	No measurement data was found.	The necessary measurement data could not be received.	Click [OK]. Tap [History] on the instrument screen, make sure the measurement results are for the corresponding medical chart number, and tap [Transfer]. If the measurement results are not for the corresponding medical chart number, or if the results cannot be transferred, retry measurement.
[W-311]	The target data does not exist.	The measurement results to be used as transmission data have not been saved.	Click [OK], perform measurement, and create the transmission data again.

5.2.2 SillHa Software [Error] Causes and Remedies

An error occurs due to incorrect operations performed as a result of faulty PC environment. You can continue using the instrument by removing the cause of the error.

No.	Description	Cause	Remedy
[E-401]	The update has failed.	An error occurred while the database was being updated.	Click [OK] and again perform the operation that was in progress before the occurrence of the error.
[E-402]	The transmission has failed.	An error occurred during communication.	Reconnect the USB cable between the PC and the instrument. Restart the SillHa software and the instrument, and repeat the operation you were performing before the error occurred.
[E-403]	Data could not be exported.	The PC memory is insufficient.	Click [OK]. Expand the PC memory.
[E-404]	Data could not be imported.	Either data does not exist in the specified import from location, or the file is corrupted.	Click [OK] and check the storage location of the data to be imported.
[E-405]	The test results list data could not be created.	The storage capacity (HDD) of the PC is insufficient.	Click [OK]. Expand the PC memory.
[E-406]	Printing could not be performed.	The printer is not connected to the PC.	Properly connect the printer to the PC.
[E-407]	The measurement data could not be received.	Data could not be received properly from the instrument at the end of measurement	Click [OK]. Properly connect the instrument to the PC. Tap [History] on the instrument, make sure the measurement results are for the corresponding medical chart number, and tap [Transfer]. If the measurement results are not for the corresponding medical chart number, or if the results cannot be transferred, retry measurement.

5.2.3 SillHa Software [Trouble] Causes and Remedies

Trouble occurs when the instrument cannot be upgraded using the SillHa software. You can continue using the instrument by removing the cause of the trouble.

No.	Description	Cause	Remedy
[T-501]	The setting file of the transfer program cannot be opened.	The setting file of the transfer program is incorrect.	Reconnect the USB cable between the PC and the instrument. Restart SillHa software and the instrument, and repeat the operation you were performing before the error occurred.
[T-502]	The file of the writing control program cannot be opened.	The file of the writing control program is incorrect.	
[T-503]	The file of the writing ROM data cannot be opened.	The file of the writing ROM data is incorrect.	
[T-504]	A timeout has occurred.	There was no response from the instrument for up to 10 seconds from the starting time of the writing process.	

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Manufactured For
ARKRAY, Inc.
Yousuien-nai, 59 Gansuin-cho
Kamigyo-ku, Kyoto 602-0008, JAPAN

U.S. Support
844-559-0842
www.arkrayusa.com

