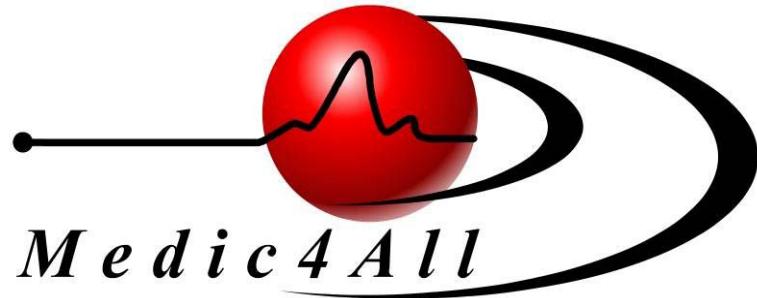


FCC submission

Product Manual



October 21, 2004

**Medic4All Ltd.
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Israel 49000**



Operation Manual

WristClinic™ - AIO67

The all-in-one wireless remote medical monitoring revolution

August 2004



⚠ Caution: Federal law restricts this device to sale by or on the order of a physician.

Ref: OM-110v1

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User Assistance Information

For assistance, contact Medic4All at:
info@medic4all.com

Local Provider Details:

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General Warnings and Cautions

- Use of this device is not intended as a substitute for consulting with your physician. Self-diagnosis can be dangerous, and may worsen the problem. Always follow your doctor's instructions.
- Do not use the Medic4All WristClinic™ for an infant or a person who cannot express their intention.
- Do not disassemble or modify the Medic4All WristClinic™. Any modifications made to the equipment void warranty and service contract obligations.
- Only authorized service personnel can disassemble or modify the Medic4All WristClinic™ device.
- Consult your local provider, concerning any operational problems. Do not attempt to carry out any repairs by yourself.
- Please take the batteries out if the Medic4All WristClinic™ is not used for a long period (app. 2 months or more)
- Do not use the Medic4All WristClinic™ for anything other than the functions described in this user guide.
- The performance of Medic4All WristClinic™ may be degraded should one of the following occur:

{A.1.1} Operating outside the manufacturer's stated temperature and humidity range

{A.1.2} Storage outside the manufacturer's stated temperature and humidity range

{A.1.3} Mechanical shock (such as harsh drop)

{A.1.4} Patient temperature below ambient temperature

- Set your Medic4All WristClinic™ to work in multi-user mode if the device is to be used by more than one user. Always use the same user number when taking measurements. Do not use a user number that is being used by someone else.
- Keep the Medic4All WristClinic™ away from electro-magnetic emitting devices, such as portable phones.
- Do not store the Medic4All WristClinic™ in direct sunlight, at a high temperature, or at excessive humidity.
- To make medical decisions, additional measurements beyond those supplied by the Medic4All WristClinic™ may be necessary.

1.  Make sure to read this entire instruction manual before trying to operate the WristClinic™.

Disposal of this product and used batteries should be carried out in accordance with the national regulations for the disposal of electronic product.

Conventions

The following are conventions that are used throughout this guide:

Icon	Description
	Note. Information that describes important features or instructions.
	Caution. Information that instructs you to be cautious.

Introducing WristClinic™

Medic4All WristClinic™ is a revolutionary all-in-one wireless remote medical monitoring device for telemedicine and homecare applications. It enables timely intervention, disease and chronic care management, improved patient compliance, and better patient care.

WristClinic™ enables you to perform and transmit a wide range of medical measurements, including:

- Blood pressure
- One lead ECG
- Heart rate
- Respiratory rate
- Pulse Oximeter (SpO₂)
- Heart rhythm regularity
- Body temperature

WristClinic™ measures, stores, displays measurement results, and wirelessly transmits physiological data to a telemedicine call center through MedicGate™ or MiniGate™.

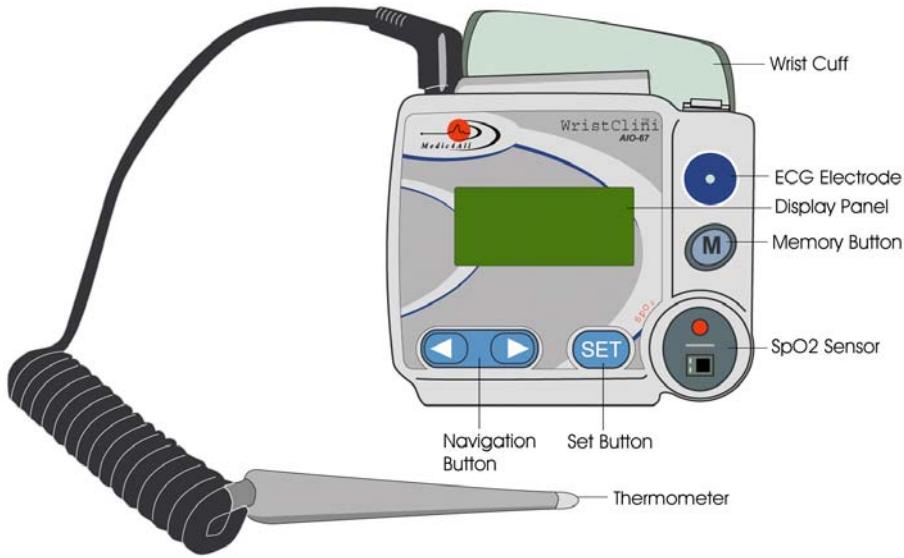
These gateways forward the data by telephone or the Internet to a telemedicine call center or to an automated web databank, where the patient's medical record is accessible via the Internet. Optionally, measurements can be taken continuously and recorded on a continuous loop system. If transmission is disrupted, WristClinic™ stores up to 200 readings for transmission at a later time.

WristClinic™ allows you to maintain your daily routine without disruption, providing monitoring at home, at the office, or while outdoors.

WristClinic™ works with up to four users. Measurements are stored for each of the users separately.

Description of the WristClinic™

The following are the various parts of the WristClinic™.



Following are various accessories included with the WristClinic™:

- Thermometer probe
- Replaceable ECG electrodes
- Two 1.5V AAA Batteries
- Storage case
- Medic4All WristClinic™ AIO-67 User Guide (this guide)

Getting Started

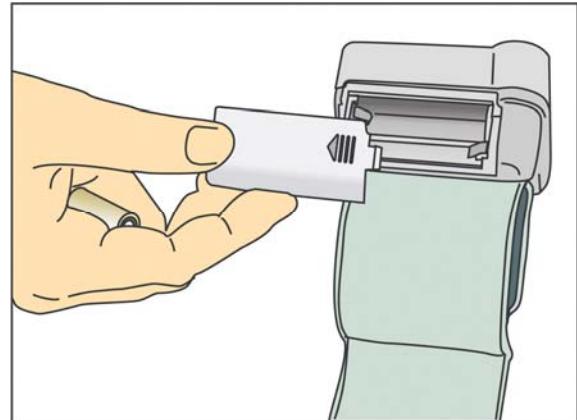
Before you begin taking measurements using the WristClinic™, do the following:

- Insert the batteries in the WristClinic™. For more information, refer to *Inserting the Batteries* on page 8.
- Familiarize yourself with the various options available. For more information, refer to *Working with the WristClinic™ Display and Buttons* on page 8.
- Set the date and time, temperature units, language, and number of users of the WristClinic™. For more information, refer to *Setting Up the WristClinic* on page 10.

Inserting the Batteries

To insert batteries in the WristClinic™ device:

Slide the door of the battery compartment on the bottom of the WristClinic™ to the right in order to open the compartment.



2. Insert two AAA-size batteries (1.5V each), as shown in the figure inside the battery compartment. The WristClinic™ turns on, **SELF TEST** appears, then **CHECK MEMORY**, then **TEST PASSED/ FAILED** and then **COMM CHECK** appears on the display for a few seconds, after which the WristClinic™ turns off automatically.



3. Ensure that the polarity (+/-) of the batteries is correct.

2. Close the WristClinic™ battery cover.

Under normal conditions, you can perform approximately 200 measurements with one set of new long life AAA alkaline batteries.

The number of measurements increases dramatically when the number of blood pressure measurements decreases.

It is preferable to turn off the WristClinic™ after using it.



4. The WristClinic™ automatically turns itself off after 60 seconds of inactivity.

Remove the batteries from the WristClinic™ if you are not using it for an extended period of time (two months or more). However, each time you remove the batteries, the clock inside the WristClinic™ ceases to work, requiring it to be set to the correct time after the batteries are reinserted. For instructions on how to set the WristClinic™ clock, refer to *Setting the Date and Time* on page 11.

Working with the WristClinic™ Display and Buttons

This section describes how to turn on the WristClinic™ and use its display panel and buttons.

Turning on the WristClinic™

To turn on the WristClinic™:

- Press   key or the  key.

5. The WristClinic™ turns on and **COMM CHECK** may appear in the display. This indicates that the communication between the WristClinic™ and the gateway is being checked. If there is a communication failure, such as when the gateway is shut down, **COMM FAILED** appears on the display, after which the first item in the WristClinic™ main menu, **BLOOD PRESS.**, appears.

6.  If you are working in multi-user mode, you are first prompted for the user number. For instructions on how to change users, refer to Selecting and Changing Users on page 14.

Main Menu Options

The following options are available in the main menu:

Option	Description	For more information...
BLOOD PRESS.	Enables you to measure blood pressure and heart rate.	<i>Measuring your Blood Pressure and Heart Rate</i> on page 17
ECG	Enables you to measure ECG.	<i>Measuring your ECG</i> on page 18
ECG and BREATH	Enables you to measure ECG and breath rate.	<i>Measuring your ECG and Breath Rate</i> on page 19
SpO₂	Enables you to measure oxygen saturation in the blood and heart rate.	<i>Measuring your SpO₂ and Heart Rate</i> on page 21
TEMP	Enables you to measure body temperature.	<i>Measuring your Temperature</i> on page 24
SETTINGS	Enables you to set the date and time, number of users, display language, and other parameters of your WristClinic™.	<i>Setting Up the WristClinic</i> on page 10
OFF	Turns off your WristClinic™.	

WristClinic™ Buttons

The following buttons are available on your WristClinic™:

Button	Description
	Press the right and left arrows to navigate among the various options in the display.

Button	Description
	Press to confirm selection of the current option in the display, or to abort a measurement in progress.
	Press to access measurements stored in memory. For more information, refer to <i>Using the Memory Function</i> on page 14.

Setting Up the WristClinic™

To access the SETTINGS menu:

- Press  to navigate to **SETTINGS** and press .

The following options are available in the SETTINGS menu:

Option	Description	For more information...
LANG-UAGE	Enables you to set the language of the WristClinic™ display.	<i>Setting the Display Language</i> on page 13
ERASE MEMORY	Enables you to erase all the measurements in memory.	<i>Clearing Memory</i> on page 15
SET DATE & TIME	Enables you to set the date and time of the WristClinic™.	<i>Setting the Date and Time</i> on page 11
1 OR 4 USERS	Enables you to set the WristClinic™ to handle a single user or multiple users.	<i>Setting the User Mode</i> on page 12
SERIAL NUMBER	Enables you to view the serial number and hardware and software version numbers for the WristClinic™.	<i>Viewing the WristClinic™ Serial Numbers</i> on page 12
SET TEMP UNITS	Enables you to set the units used for measuring temperature.	<i>Setting the Temperature Units</i> on page 11
TECH MODE	Enables a technician to access the WristClinic™ for technical purposes.	<i>Tech Mode</i> on page 14

Option	Description	For more information...
EXIT SETTING-S	Enables you to exit the SETTINGS menu and return to the main menu	Exiting SETTINGS on page 14

Setting the Temperature Units

WristClinic™ enables you to set the units in which your temperature is measured, either °C (Celsius) by default or °F (Fahrenheit).

To set the temperature units:

1. From the SETTINGS menu, press   to navigate to **SET TEMP UNITS** and press .
2. Press   to select the temperature units (**TEMP IN °C** or **TEMP IN °F**) and press .
3. The temperature units are set to the selected value.

Setting the Date and Time

In order for your measurements to be recorded in correct chronological order, you should initially set your WristClinic™ to the correct date and time.

Every time your WristClinic™ communicates with a gateway, it receives the date and time as it appears on the PC or Call Center clock. **No further action is needed.**

9.  If a change of location includes a change in date and time, make sure to set your WristClinic™ to the correct date and time.

Perform the following steps if your WristClinic™ is not communicating with any gateway:

To set the date and time:

3. From the SETTINGS menu, press   to navigate to **SET DATE & TIME** and press .
4. The date appears (**MMM DD YYYY**), with the month flashing.
5. Press   to navigate to the correct month and press .
6. The month is set to the selected value and the day flashes.
7. Press   to navigate to the correct day and press .
8. The day is set to the selected value and the year flashes.
9. Press   to navigate to the correct year and press .
10. The year is set to the selected value and the time appears (**hh:mm**), with the hours flashing.
11. Press   to navigate to the correct hour and press .

14. The hour is set to the selected value and the minutes flashes.
8. Press   to navigate to the correct minute and press .
15. The minutes are set to the selected value and you are returned to the **SET DATE & TIME** option in the SETTINGS menu.

Setting the User Mode

WristClinic™ enables you to define if you want to work in single mode or multi-user mode.

16.  When switching from multi-user mode to single mode, all measurements in memory are erased.

To set the user mode:

9. From the SETTINGS menu, press   to navigate to **1 OR 4 USERS** and press .
17. The current user mode appears.
10. Press   to select the user mode (**SINGLE USER** or **MULTIPLE USERS**) and press .
18. **PUSH SET TO ALTER** appears.
11. Press .
19. **CHANGING USERS NO** appears and the number of users is set according to the selected mode.

When set to multi-user mode, the user number appears on the lower right of the display. When the WristClinic™ is turned on, if it is in multi-user mode, you are prompted to select the user to work with. For more information, refer to *Selecting and Changing Users* on page 14.

Viewing the WristClinic™ Serial Numbers

Using the WristClinic™, you can view the serial number of your device and its hardware and software version numbers.

To view your serial numbers:

12. From the SETTINGS menu, press   to navigate to **SERIAL NUMBER** and press .
20. The device serial number appears (e.g., **SER NO. 000000B7**).
13. Press   to view the hardware version number (e.g., **HW 2003\A1-14-A1**) and software version number (e.g., **SW VER. 01.28**).

Setting the Display Language

™ enables you to set the language in which you view the information WristClinic displayed.

To set the display language:

14. From the SETTINGS menu, press   to navigate to **LANGUAGE** and press .
21. *The current language appears.*
15. Press   to select the desired language for the display and press .
16. Press  again to confirm altering the language.
22. *The display language is now set to the selected value.*

Tech Mode

23.  The Tech Mode is for Medic4All technicians only.

Exiting SETTINGS

To exit the SETTINGS menu:

- From the SETTINGS menu, press  to navigate to **EXIT SETTINGS** and press .
- 24. You are returned to the **SETTINGS** option in the main menu.

Selecting and Changing Users

When working with multiple users, the measurements you take are automatically associated with the user that appears on the lower right of the display.

To select a user number:

17. Press  to turn on the WristClinic™.
25. **SELECT USER X** appears, where **X** is the current user number.
18. Press  to change the number to the user for which you want to perform measurements and press .
26. The user number appears highlighted on the lower right of the display.

To change to a different user:

19. Press  to navigate to **OFF** and press .
27. The WristClinic™ turns itself off.
20. Press any key to turn on the WristClinic™.
28. **SELECT USER X** appears, where **X** is the current user number.
21. Press  to change the number to the user for which you want to perform measurements and press .
29. The user number appears highlighted on the lower right of the display.

Using the Memory Function

The memory function enables you to view previous measurements that are stored in the WristClinic™. In addition, you can clear all previous measurements from memory when they are not needed.

Browsing Through Current User Measurements

To browse through user measurements:

22. Press .
30. The first measurement in the memory appears, followed by the date and time for that measurement.
31.  If there are no measurements stored in memory, **MEMORY EMPTY** appears.
23. Press  to navigate through the measurements in the memory for the current user.
24. Press  to exit the memory.

Clearing Memory

To erase all measurements stored in memory:

25. Press  to navigate to **SETTINGS** and press .
26. Press  to navigate to **ERASE MEMORY** and press .
32. **PUSH SET TO ERASE** appears.
27. Press .
33. **ERASE DONE** appears and the measurements stored in the memory are erased.

Operating Instructions

Before you begin using the WristClinic™, you need to position the WristClinic™ cuff correctly. After the WristClinic™ is positioned correctly on your wrist, you can then take the following measurements:

- Blood pressure and Heart Rate
- ECG
- ECG and Breath Rate
- SpO₂ and Heart Rate
- Temperature

Wrapping the WristClinic

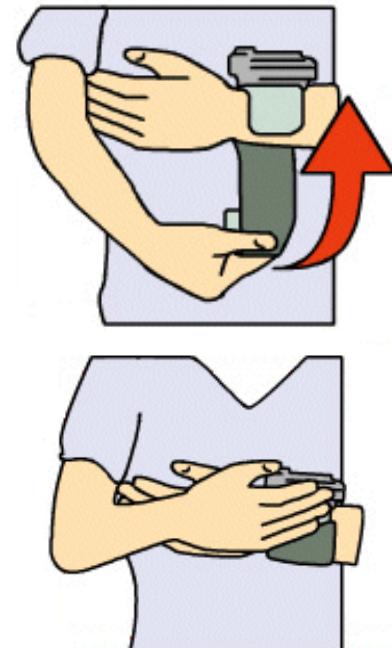
In order to take accurate measurements using the WristClinic™, it is necessary to wrap the cuff around your wrist correctly.

34.  If you have a very small (circumference of under 13.5 cm) or large wrist (circumference of over 21 cm), contact your service representative about obtaining a smaller/larger wrist cuff.

35.  Place the WristClinic™ cuff directly on your skin. Make sure that your clothing is not constricting your blood flow and that the electrodes on the inside of the cuff are touching your skin.

To place the WristClinic™ on your wrist:

28. Remove all objects around your left wrist, leaving it bare.
29. Place the cuff over your left wrist with your thumb facing upwards. Leave approximately 1-2 cm between the edge of the wrist cuff and the bottom of the palm.
30. Pull the wrist cuff upwards and fasten the Velcro strap firmly on your wrist.



36.  The display of the WristClinic™ should be facing towards you.

37.  Do not fasten the Velcro strap tightly on your wrist as it might restrict your blood flow.

Unwrapping the WristClinic™ Cuff

To unwrap the WristClinic™ cuff:

- Unwrap the Velcro strap from around your wrist and remove the WristClinic™ cuff.



Measuring your Blood Pressure and Heart Rate

Before measuring your blood pressure:

- Avoid eating, smoking, and exercising 30 minutes before taking your blood pressure.
- Sit in a relaxed position.
- Remain still and do not talk while you are taking your blood pressure.

38.  To measure your blood pressure correctly, make sure to wrap the cuff around your wrist correctly (refer to *Wrapping the WristClinic* on page 15).

Obtaining the Correct Posture

39.  An incorrect posture might cause the WristClinic™ to measure your blood pressure incorrectly.

To obtain the correct posture:

31. Sit down and stretch your back.
32. Relax your body by relieving the stress from your shoulders and arms.
33. Breathe deeply several times.



34. Make sure the WristClinic™ is in your heart level. Position your arms as illustrated in the picture.



Taking your Blood Pressure and Heart Rate

40.  If you are working with more than one user, verify that the WristClinic™ is set to the correct user before taking a measurement. The user number appears on the lower right of the display.

To take your blood pressure and heart rate:

- Press   to navigate to **BLOOD PRESS** and press .

41. --- / ---

HR --- appears on the display and a few seconds later the cuff begins to inflate. The measurement lasts about 30 seconds, after which the cuff deflates.

Aborting the Measurement

To abort the measurement:

- Press  before the measurement is complete.

42. The measurement stops after a few seconds, and **CHECK ABORTED** appears on the display.

Viewing your Blood Pressure and Heart Rate Results

To view the results:

After approximately 30 seconds, the cuff deflates, the WristClinic™ transmits the measurements, and **SENDING DATA** appears on the display.

If **SENDING FAILED** appears, refer to

Troubleshooting on page 28.

After sending the measurements, the WristClinic™ beeps three times and the measurements automatically appear on the WristClinic™ display. The measurement results (e.g., **129 / 89 HR 65**) and **CHECK DONE** are displayed alternatively.

To return to the main menu:

- Press any key to return to the menu.

43.  After 60 seconds of inactivity, the WristClinic™ turns itself off.

Measuring your ECG

44.  To measure your ECG correctly, make sure to wrap the cuff around your wrist such that the 4 inner electrodes located on your inner cuff will firmly touch your bare skin.

45.  If you are working with more than one user, verify that the WristClinic™ is set to the correct user before taking a measurement. The user number appears on the lower right of the display.

To take your ECG measurement:

35. Press   to navigate to **ECG** and press .

46. **PLACE FINGER** appears on the display.

36. Place the index finger of your right hand on the ECG electrode located above (M).



47. The WristClinic™ detects your finger and the measurement begins. The timer counts down from 45 seconds.

48.  Avoid moving your finger, and do not use excessive pressure when placing your finger on the ECG electrode.

Moistening your index finger, which is in contact with the ECG electrode, with a wet cloth will help to improve the quality of the ECG measurement.

If your finger or your 4 inner electrodes located on your inner cuff are not detected within 20 seconds, **CHECK FAILED** appears on the display. Refer to Troubleshooting on page 28 for instructions.

Aborting the Measurement

To abort the measurement:

- Press  before the measurement is complete.

49. **CHECK ABORTED** appears on the display.

Viewing your ECG Results

Your ECG measurement is automatically transmitted to the gateway. The results are not displayed on the WristClinic™ when the measurement is complete. You can view your ECG measurement on the MiniGate or Call Center application.

CHECK DONE appears on the display and the WristClinic™ beeps three times.

To return to the main menu:

- Press any key to return to the menu.

50.  After 60 seconds of inactivity, the WristClinic™ turns itself off.

Measuring your ECG and Breath Rate

51.  To measure your ECG correctly, make sure to wrap the cuff around your wrist such that the 4 inner electrodes located on your inner cuff will firmly touch your bare skin.

52.  If you are working with more than one user, verify that the WristClinic™ is set to the correct user before taking a measurement. The user number appears on the lower right of the display.

To take your ECG and Breath Rate measurement:

37. Press  to navigate to **ECG AND BREATH** and press .

53. **PLACE FINGER** appears on the display.

38. Place the WristClinic™ on your upper abdomen.



39. Place the index finger of your right hand on the ECG electrode located above .



54. The WristClinic™ detects your finger and the measurement begins. The timer counts down from 50 seconds.

55.

 Avoid moving your finger, and do not use excessive pressure when placing your finger on the ECG electrode.

Moistening your index finger, which is in contact with the ECG electrode, with a wet cloth will help to improve the quality of the ECG measurement.

If your finger or your 4 inner electrodes located on your inner cuff are not detected within 20 seconds, **CHECK FAILED** appears on the display. Refer to Troubleshooting on page 28 for instructions.

Aborting the Measurement

To abort the measurement:

- Press  before the measurement is complete.

56. **CHECK ABORTED** appears on the display.

Viewing your ECG and Breath Rate Results

Your ECG and breath rate measurements are automatically transmitted to the gateway. The results are not displayed on the WristClinic™ when the measurement is complete. You can view your ECG and breath rate measurement on the MiniGate or Call Center application.

CHECK DONE appears on the display and the WristClinic™ beeps three times.

To return to the main menu:

- Press any key to return to the menu.

57.  After 60 seconds of inactivity, the WristClinic™ turns itself off.

Measuring your SpO₂ and Heart Rate

There are two options to perform a SpO₂ and heart rate measurement:

1. Using the external SpO₂ finger clip
2. Using the internal SpO₂ sensor

58.  Avoid taking your SpO₂ measurement when exposed to very strong ambient light. Avoid motion while performing a SpO₂ measurement.

59.  If you are working in multi-user mode, verify that the WristClinic™ is set to the correct user before taking a measurement. The user number appears on the lower right of the display.

60.  Do not immerse the SpO₂ finger clip in liquid. Do not use caustic or abrasive cleaning agents.

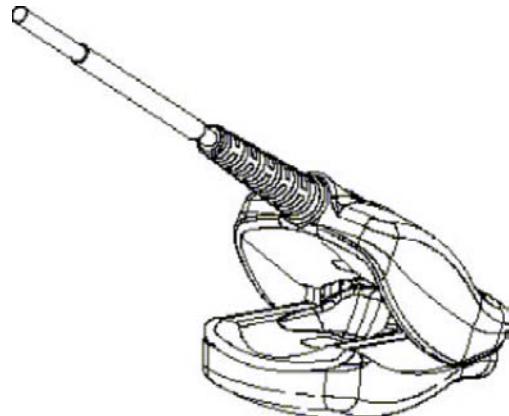
61.  The SpO₂ finger clip is designed for use on the fingers of patients weighing more than 30 kilograms, where the finger tissue is between 5 and 21 millimeters.

To take your SpO₂ measurement with the finger clip:

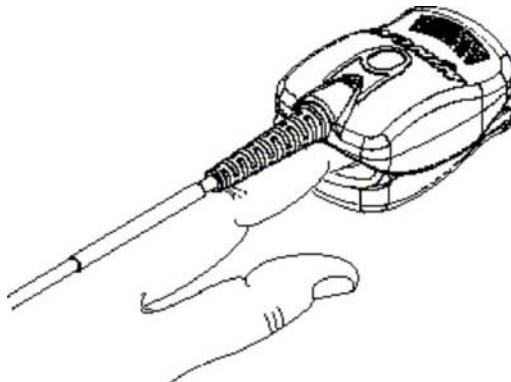
40. Attach the external SpO₂ finger clip to the connector marked SpO₂ on the side of the WristClinic™.

41. Press  to navigate to **SpO₂** and press .

Insert a finger (preferably the index, middle, or ring finger) into the SpO₂ finger clip until the end of the finger reaches the finger stop.



Keep the fingernail facing the sensor top, and ensure that long fingernails do not interfere with proper sensor position.



62. **SpO₂--- % HR ---** appears on the display. After a few seconds, SpO₂ and HR data appear. The measurement data is refreshed every 5 seconds. The measurements last about 30 seconds. Only the last measurement is stored and transmitted to the gateway.

63.  Avoid moving your finger, and do not use excessive pressure when placing your finger on the SpO₂ sensor.

To clean the SpO₂ finger clip:

Clean the SpO₂ finger clip with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids on the SpO₂ finger clip, and allow it to dry thoroughly before reusing. Do not use caustic or abrasive cleaning agents.

64.  The thumb is not recommended for use with the SpO₂ finger clip. The SpO₂ finger clip does not contain natural rubber latex.

To take your SpO₂ measurement with the internal sensor:

43. Press  to navigate to **SpO₂** and press .

65. **PLACE FINGER** appears on the display.

Place the index finger of your right hand on the SpO₂ sensor. Make sure to cover the SpO₂ sensor completely with your finger



66. **SpO₂--- % HR ---** appears on the display. After a few seconds, SpO₂ and HR data appear. The measurement data is refreshed every 6 seconds. The measurements last about 30 seconds. Only the last measurement is stored and transmitted to the gateway.

67.  Avoid moving your finger, and do not use excessive pressure when placing your finger on the SpO₂ sensor.

If the SpO₂ is not detected, **SpO₂--- %** remains on the display until the measurement ends, after which **MEASUREMENT FAILED** appears.

Aborting the Measurement

- Press  before the measurement is complete.

68. **CHECK ABORTED** appears on the display.

Viewing SpO₂ and Heart Rate Results

After 6 seconds, the oxygen saturation percent (SpO₂) and heart rate (HR) are displayed. The display is updated every 6 seconds.

When the measurement is complete, the last successful measurement data is transmitted and **SENDING DATA** appears.

After sending the measurements, the WristClinic™ beeps three times and the measurements automatically appear on the WristClinic™ display. The last successful measurements results (e.g., **SpO₂ 97% HR 67**) and **CHECK DONE** are displayed alternatively.

Measuring your Temperature

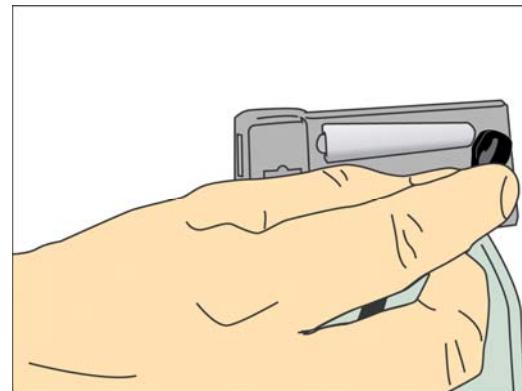
To measure your temperature, perform the following steps described below:

- Connect the thermometer to the WristClinic™.
- You may place a thermal sheath on the thermometer.
- Position the thermometer.
- Take your temperature.

69. You can set the temperature display to Celsius or Fahrenheit (refer to Setting the Temperature Units on page 11).

Connecting the Thermometer to the WristClinic™

- Plug the thermometer into the TEMP connector on the top of the WristClinic™.



70.  Make sure the thermometer is firmly plugged into the connector.

71.  The thermometer is suitable exclusively for measurements of body temperature

72.  Never boil the thermometer tip

Putting on the Thermal Sheath

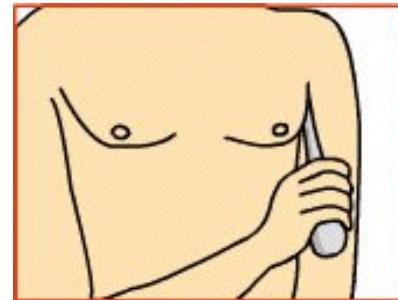
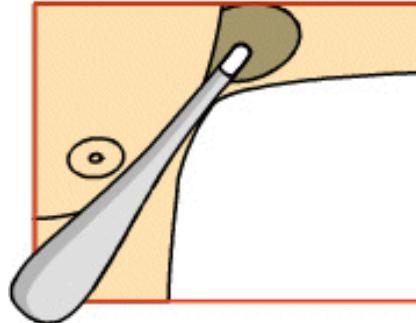
- Place the thermal sheath over the thermometer. Put away the protective plastic that covers of the thermal sheath
- When you are done, discard the thermal sheath and the plastic cover.

Placing the Thermometer

You can place the thermometer under your armpit or in your mouth.

Placing the Thermometer under your Armpit

- Place the tip of the thermometer at the center of your armpit. The tip of the thermometer must be parallel to your body, as much as possible.

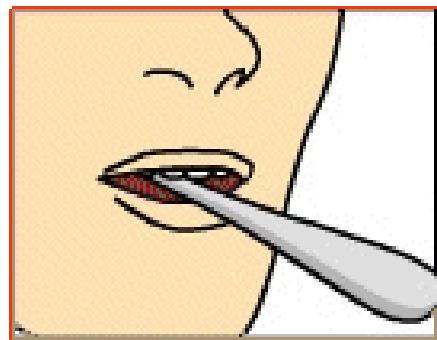


73.

 For the most accurate measurement, make sure the temperature tip is in good contact with your armpit. Press the tip slightly against your armpit to obtain the best results.

Placing the Thermometer in your Mouth

- Position the tip of the thermometer in one of the two pockets under your tongue. The tip must be in good contact with the tissue. Close your mouth and breath through the nose.



Taking your Temperature

74.  If you are working with more than one user, verify that the WristClinic™ is set to the correct user before taking a measurement. The user number appears on the lower right of the display.

- Press  to navigate to **TEMP** and press .

75. *The initial temperature appears on the display.*

Aborting the Measurement

- Press  before the measurement is complete.

76. **CHECK ABORTED** appears on the display.

Viewing your Temperature

During a measurement, the current temperature is displayed every second.

77.  If the temperature is below 35 °C (95 °F), **LOW TEMP** appears on the display. If the temperature is above 43 °C (109.4 °F), **HIGH TEMP** appears on the display.

The measurement takes about 60 seconds.

When the measurement is completed, the data is transmitted and **SENDING DATA** appears on the display.

After sending the measurements, the WristClinic™ beeps three times and the temperature automatically appears on the WristClinic™ display. The temperature and **CHECK DONE** are displayed alternatively.

Cleaning the Device

To clean the WristClinic™ monitor, use only a soft, lightly moistened cloth.

78.  Do not use petroleum spirits, thinners, or other solvents when cleaning the WristClinic™.

To clean the WristClinic™ thermometer tip wash the area extending about 2" from the tip of the thermometer with warm (not hot) soapy water before and after each use; be sure to dry thermometer thoroughly. You may also wipe the area described above with 70% isopropyl alcohol before and after each use. Even if you use a thermal sheath, follow either of the above two cleaning procedures as an extra precaution.

To clean any stains on the WristClinic™ cuff, use a moistened cloth and soapy water.

79.  Do not wash the cuff or make it wet. No water should enter the WristClinic™ main unit.

Low Battery Indication

The **REPLACE BATTERY** indication appears when the batteries run low. When **REPLACE BATTERY** first appears replace the batteries as soon as possible with two new fresh LR03 (AAA) batteries.

However, you can still run a few full cycle measurements. When **REPLACE BATTERY** is followed a **BYE**, the WristClinic™ will automatically shut down.

80.  **REPLACE BATTERY** usually appears after a Blood Pressure measurement. However, you can continue taking some measurements before replacing the batteries.

Refer to *Inserting the Batteries* on page 8 for instructions on how to change the WristClinic™ batteries.

Maintenance

81.  Do not perform any repairs yourself on the WristClinic™. Only authorized service personnel should handle the WristClinic™.

Replacing the Electrodes

The electrodes on the inside of the cuff and the electrode on the front panel of the WristClinic™ should be changed approximately every one-year. The replacement frequency depends on your usage of the WristClinic™. The time to replace the electrodes is either when they appear to be worn out, or when measurements are not easily obtainable.

82.  Note that there are two types of electrodes: one electrode on the front panel of the WristClinic™ and four electrodes on the cuff's inner side. Replace each electrode with the correct electrode type.

83.  Replace the electrodes one at a time. Do not remove all the old electrodes at once.

To replace an electrode on the WristClinic™:

45. Using a flat screwdriver, remove the electrode from the device or cuff.

46. Place the new electrode in the location of the old electrode and press down until it fits firmly into place.

Disposal of WristClinic™ Accessories

Disposal of the WristClinic™ and any used batteries must be done in accordance with the national regulations for the disposal of electronic products.

Storage

Follow the guidelines below for storing your WristClinic™:

- Keep the WristClinic™ device in the storage case, protected from extreme temperatures and humidity.
- Remove the batteries from the WristClinic™ if you are not using it for an extended period of time (two months or more).
- Keep the WristClinic™ away from electro-magnetic emitting devices, such as portable phones.

Troubleshooting

The following are possible error indications:

Error Message	Description	What to do
CHECK ABORTE D	The check was aborted in the middle of the measurement.	Redo the check to obtain an accurate measurement
CHECK FAILED	The finger was not detected on the ECG electrode.	Restart the check and place your finger firmly on the ECG electrode.
HIGH TEMP	The temperature measurement was above 43 °C (109.4 °F).	Take another temperature reading in the mouth. If a high temperature is indicated again, contact your physician.

Error Message	Description	What to do
LOW TEMP	The temperature measurement was below 35 °C (95 °F).	<p>Verify that the tip is inserted fully into its socket.</p> <p>Make sure to position the tip correctly (refer to <i>Placing the Thermometer</i> on page 24.)</p>
NO FINGER	The finger was not detected during ECG and ECG and breath measurement checks.	<p>Verify that the device is firmly attached to your wrist. Place your index finger firmly on the electrode.</p> <p>If the error message keeps reappearing, wet your finger with tap water.</p>
REPLACE BATTERY	Indicates low battery.	<p>Replace batteries with new 1.5 V AAA batteries</p>

Error Message	Description	What to do
SENDING FAILED	<p>The measurements were not sent to the gateway.</p> <p>If you are not connected to a gateway, ignore this message.</p> <p>If you are connected to a call center, contact the call center.</p> <p>If you are connected to a MiniGate, verify that your device is allocated to your gateway, as described in the <i>MiniGate User Guide</i>. If you allocated your device and you are still receiving this message, contact your service provider.</p>	
TEST FAILED	<p>When powered up, WristClinic™ performs a self test.</p> <p>Contact your service provider.</p>	
USER EMPTY	<p>There are no measurements for the user in memory.</p>	

Spare Parts and Accessories

The following accessories are available for the WristClinic™:

- Batteries
- Thermometer probe
- Hygienic sheaths for use with the thermometer
- Electrodes
- External finger pulse oximeter

Specifications

Medical Measurements

1 lead ECG Measurement

Pulse 40-200 beat/min

Bandwidth 0.05-40 Hz

Heart rhythm regularity detection Irregular / Regular / Not available

Measurement time 45 sec.

ECG Measurement time 30 sec.

Measurement time

Input dynamic range ± 5 mV

1 lead ECG and Breath Measurement

Breathing 5-35 inhale-exhale/min

Pulse 40-200 beat/min

Heart rhythm regularity detection Irregular / Regular / Not available

Measurement time 50 sec.

ECG Bandwidth 0.05-40 Hz

ECG Measurement time 30 sec. (simultaneous with breath)

Input dynamic range ± 5 mV

Measuring Accuracy

Pulse ± 3.5 beats/min for 67%

± 7.0 beats/min for 95%

Breathing	± 3 cycles/min for 67% ± 6 cycles/min for 95%
Thermometer	
Temperature range	35.0 °C -43.0 °C, Temp<35.0 °C display "LOW TEMP" Temp>43.0 °C display "HIGH TEMP"
Temperature accuracy	± 0.1 °C between 35.5 and 42.0 °C ambient temperature 18°C to 28°C. The manufacturer recommends verifying the accuracy by an authorized laboratory every 2 years.
Standard	prEN12470-3: 1997, and ASTM-112E
Measurement time	App. 60 sec.
<i>Blood Pressure</i>	
Measurement method	Fully automatic Oscillometric measurement for measurement on the wrist.
Measurement range	Pressure: 0 – 299 mmHg Pulse: 40 – 180 /minute
Accuracy	Pressure: +/- 3 mmHg or 2%, whichever is greater Pulse: +/- 5%
Measurable circumference of wrist	13.5 – 21.5 cm

<i>External Pulse Oximeter</i>	
Measureme nt range	SpO ₂ : 0 – 100% Pulse: 18 - 300 pulses/min
Accuracy (± 1 Standard Deviation)	SpO ₂ : 70 -100% \pm 2 digits for adults Pulse: $\pm 3\%$ \pm 1 digit
Measureme nt time	30 seconds, reading every 5 second cycles
<i>Internal Pulse Oximeter</i>	
Measureme nt range	SpO ₂ : 70 – 99% Pulse: 40-250 beat/min
Accuracy	SpO ₂ : +/- 3 digits Pulse: +/- 3%
Measureme nt time	30 seconds, reading every 6 second cycles

<i>Electronics</i>	
Processor	TI MSP430 micro controller
RF communicat ion	
Frequency	433.92 MHz/ 868.3 MHz/ 915 MHz Depends on domestic regulation

Max transmission power	+10 dBm @ 433.92 MHz (E.R.P) +8 dBm @ 868.3 MHz (E.R.P) -1 dBm @ 915 MHz (E.I.R.P)
Bandwidth	60 kHz
Transmission range	App. 200 m (free space)
<i>Mechanical & Environmental</i>	
Operating Temperature and humidity	+10°C to +40°C, 30 to 85% RH
Storage Temperature and humidity	-10°C to +55°C, 10 to 95% RH
<i>Power Supply/bat</i>	
Power	Two LR03 batteries (AAA)
Maximum Internal Voltage	4.5V

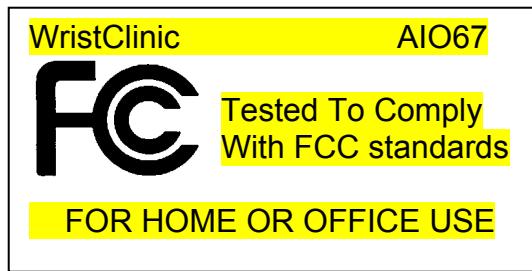
FCC Part 15 Information

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 Federal Communication Commission (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 to 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.



Warranty

This product is warranted against defects in material and workmanship beginning from the date of shipment for a period of one year (the "Term").

Under the Term, the obligation of Telcomed Advanced Industries Ltd (the "Company") will be limited to repair or replacement of the product (not including batteries, cables and spendable parts), according to the Company's discretion. Such repair or replacement will be made only after the Company's examination determines that said product is defective in material and/or workmanship.

This product warranty is void if the product has been repaired or altered in any way as to affect its use and operation as determined by the Company. This warranty is

also void if the product has been subjected to abuse, misuse, negligence or accident.

No warranties, whether expressed or implied, shall exist beyond the Term.

Under no circumstances shall the Company be responsible for any loss of data or income or any special, incidental, consequential or indirect damages, arising from the product or its operation, howsoever caused.

Under no circumstances the Company will be liable for any claim arising from the product or its operation in excess of the total price paid for this product.

The Company reserves the right to make changes and improvements to the product without prior notice.