

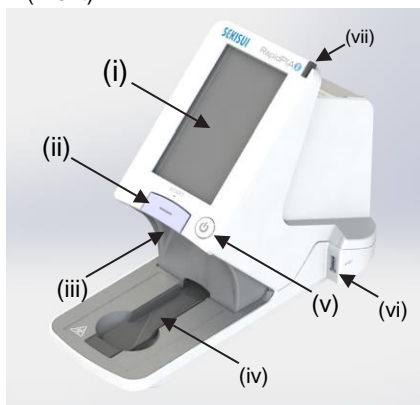
Medical Device 17 Device for blood examination
 General Medical Device, Specially-Designated Medical Device General name:
 Protein analyzer (JMDN code: 30857000)

Rapidpia II

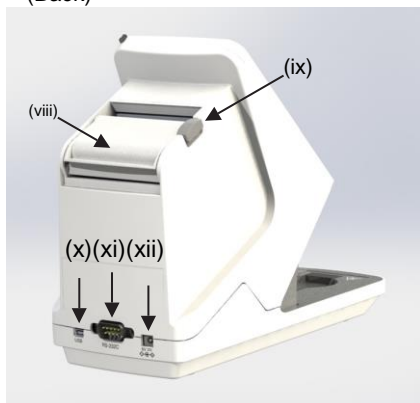
Description (form and principle)

1. Component

1) Main unit (Front)



(Back)



- (i) Touchscreen (for display and operation)
- (ii) Run start key
- (iii) Barcode scanner
- (iv) Test cassette tray
- (v) Power button
- (vi) USB port
- (vii) Touch pen storage
- (viii) Printer
- (ix) Printer cover button
- (x) miniUSB port
- (xi) RS-232C port
- (xii) DC 6V Power port

For details, see the <<System Description and Component Names>> section in Instruction Manual.

2) Standard accessories

- Designated AC adapter
- Touch pen
- Printer paper
- QC device (sold separately)

3) Optional accessories (sold separately)

- miniUSB cable
- RS-232C cable
- Mobile battery connection cable

2. Size and weight of Main unit

- External dimensions: W 106 mm, D 237 mm, H 185 mm
- Weight: Approx. 1050 g

3. Electric rating

1) Main unit

- Power voltage: DC 6 V

- Current consumption: ≤2.16 A
- 2) Designated AC adapter
- Power voltage: AC 100 V - 240 V (50 Hz or 60 Hz)
- Current consumption: ≤0.33 A

4. Operational principle

This device continuously measures the intensity of the reflection of the reagent surface. Then it determines and outputs quantitative (e.g. concentration) or qualitative results based on absorbance calculated from the reflection intensity.

5. Specifications

- Light source: LED
- Light receiving element: Photodiode
- Assay range: 5 mABS - 800 mABS
- Assay reproducibility: ≤3 CV% (as per in-house test methods)
- Number of detectable lines: 3
- Display: LCD
- Operational panel: Resistive touch panel
- Barcode scanner: Compatible to 1D and 2D
- Assay time: ≤30 s
- Compatible devices: USB, miniUSB and RS-232C

6. Usage environment

- Ambient temperature: 15°C - 30°C
- Relative humidity: ≤70% (no condensation)

Intended Use and Effectiveness

Automated or semi automated analyzer which identifies or measures the concentration of proteins produced in immune reactions including latex immune reactions.

Instructions for Use

1. Preparation before use

- (1) Make sure that the analyzer is operational.
- (2) Power-on the analyzer.
- (3) A self-check will start automatically.
- (4) With a QC device (sold separately), check that the analyzer is in a normal operating condition. This must be done after turning the power on. Refer to the <<Quality Control>> section in the Instruction Manual regarding how to check the analyzer status using a QC device.
- (5) Before measuring a new test menu, and before using a new lot of assay, register the assay specific information.

2. Operational procedure

- (1) Select "RUN" from the main menu. If appropriate, input a patient ID.
- (2) Insert a test device (test cassette) into the test cassette tray, and let the analyzer read the barcode on the cassette. The test menu will be chosen automatically.
- (3) Dispense the sample as instructed, and press the Run start key.
- (4) A countdown will start and the remaining time until the start of measurement will be displayed.
- (5) When the time is reached, the assay starts.
- (6) After calculating the measurements, the results will be displayed on the analyzer.
- (7) Touch the Print button to print the result. Via a compatible USB memory or a PC connected with a miniUSB or RS-232C cable, assay results can be sent externally.

3. Post-operational procedure

- (1) Remove the used test cassette from the test cassette tray.
- (2) Clean the tray accordingly if residues or spills were found.
- (3) Turn off the analyzer.

Operational procedures may vary depending on your

settings. Please refer to the <<Basic Operation>> and <<Other Functions and Setting>> sections in Instruction Manual for details.

Precautions for Use during use

1. Please read this Package Insert and Instruction Manual well to ensure correct usage of device.

2. Do not contact samples directly.

3. Before using the analyzer, please confirm that:

- (1) the analyzer is on a level and smooth surface.
- (2) there is no damage to the exterior of the instrument and that the cassette slot is free from foreign matter and dirt.
- (3) it operates in a safe and correct way.
- (4) the measuring unit is not contaminated especially before using QC device.
- (5) there are no heat sources around the analyzer. Heat sources may cause heat-related errors.

4. While using the analyzer, please:

- (1) confirm that a test cassette is placed correctly before starting an assay.
- (2) confirm that there are no electric wave emitting devices around the analyzer.
- (3) do not use it in a place subject to direct sun light or susceptible to ambient light, such as a place near a window because this analyzer has an optical reader.
- (4) do not move or incline the analyzer.

5. After using the analyzer, please:

- (1) store the analyzer in the similar place to that in use.
- (2) clean the analyzer so that it can be used appropriately in the next session.

Precautions for Use

General Precautions

1. In the case of malfunction, stop the operation, label the analyzer appropriately and contact the retailer.
2. Do not modify the analyzer.
3. Do not apply impacts to or drop the analyzer.
4. Do not make the analyzer wet.
5. Confirm that there are no heat sources around the analyzer.
6. During maintenance, turn off the analyzer and remove the designated AC adapter.
7. When the analyzer is not in operation for long periods of time, disconnect the designated AC adapter from the analyzer and the power outlet.
8. Take care not to have the cassette slot contaminated with dust or foreign materials.

Other Precautions

1. When installing the analyzer, please:
 - (1) place the analyzer on a level and smooth surface.
 - (2) place the analyzer away from water.
 - (3) place the analyzer in environments not susceptible to intense magnetic or electric fields.
 - (4) place the analyzer away from oil, smoke, dusts, or corrosive gas
- *2. Make sure to use a USB memory confirmed to be compatible (to function with the analyzer) and safe and not infected by malware. Take security measures for PCs which receive patient data from the USB memory.
3. This analyzer should be disposed of in accordance with relevant national and local regulations including Waste Management and Public Cleansing Act.

Storage and Shelf Life

1. Storage

Store this device under the following conditions.

- Ambient temperature: -10°C - +45°C
- Relative humidity: ≤70% (no condensation)

2. Shelf-life or life time

5 years after putting into service (after installation) with regular maintenance and inspection (Self-certification).

Note: According to the <<Maintenance, Replacement of Consumables, and Storage>> section in Instruction Manual, maintain the analyzer and replace the consumables. Please

contact the retailer to request a repair based on an inspection.

Maintenance and Inspection

1. Maintenance by user

- (1) When turning on the analyzer, perform quality control using a QC device to confirm that:
 - measurements are inside the specified interval.
 - items are displayed on the display panel.
 - items are printed on paper.
- (2) Annually (once a year), perform the following maintenance activities.
 - Cleaning of main unit
 - Calibration of time
 - Inspection of touch panel
 - Inspection of buttons
 - Inspection of printer

2. Maintenance by external party

The manufacturer requires the following regular maintenance by an external party.

- Driving unit's gear: Once every 3 years
- Motor: Once every 3 years

For further details please contact the manufacturer.

According to the <<Maintenance, Replacement of Consumables, and Storage>> section in Instruction Manual, perform the maintenance and inspection.

For details, refer to the <<Maintenance, Replacement of Consumables, and Storage>> section in Instruction Manual.

Manufacturer

SEKISUI MEDICAL CO., LTD.

1-3, Nihonbashi 2-chome, Chuo-ku, Tokyo 103-0027 JAPAN
Email: international@sekisui.com

Manufacturing site:

HAMAMATSU PHOTONICS K.K.
325-6, Sunayama-cho, Naka-ku, Hamamatsu City,
Shizuoka Pref., 430-8587, Japan

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Read the Instruction Manual as well.