MESSIAH Gamma Counter

User Manual

IVD

This product is medical device

SHINJIN MEDICS INC.

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I Label

1. Classification: GAMMA COUNTER
2. Name of Product: MESSIAH Gamma Counter
3. Manufacturer

   Manufacturer: ShinJin Medics Inc.

   Address: 302-2, 401-2, 401-3, Ilsan Techno Town, 138, Ilsan-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, 10442 Republic of KOREA

   Tel +82-31-909-8855, Fax: +82-31-908-0982
4. Intended use and Product license No.

   Intended Use: Device to count radioactive gamma-ray

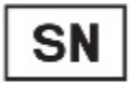
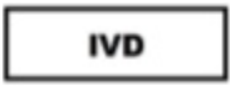
   Product license No.: IVD-10-1062 (MFDS)
5. Weight: 220 kg
6. Instruction & Caution: Refer to User manual
7. Others

   1) Rated voltage, Frequency: 220V~, 50/60Hz

   2) Power consumption: 140 VA

   3) Protection type & Grade against electronic shock: First rated

* This product is In vitro Diagnostic Medical Device

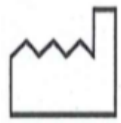
UDI-DI (GTIN-13, GS1 DataMatrix, 08806120500435) & UDI-PI (manufactured date, Serial No.)	 	 

- The description is on the back side of Product

II CONTENTS

1. Symbols and terms

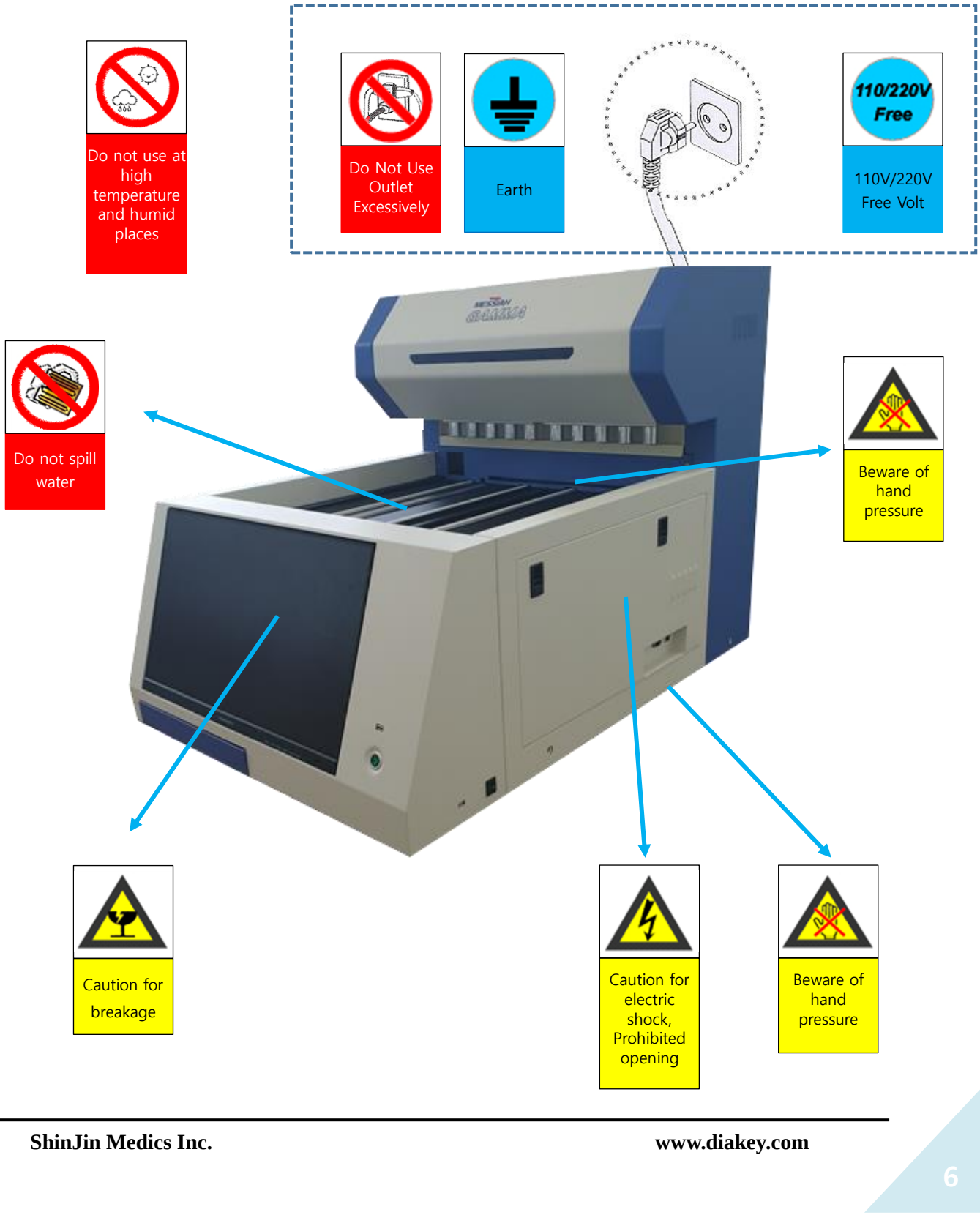
1.1. Symbols

Symbol	Meaning
IVD	In Vitro Diagnostic Device
	Date of Manufacture
	Manufacturer
	Refer to user manual
	Caution
	Caution; risk of electric shock

기호	정의
	Warning; Crushing of hands
	handle with care
	This way up
	Fragile
	Keep away from rain
	Do not actuate during operation

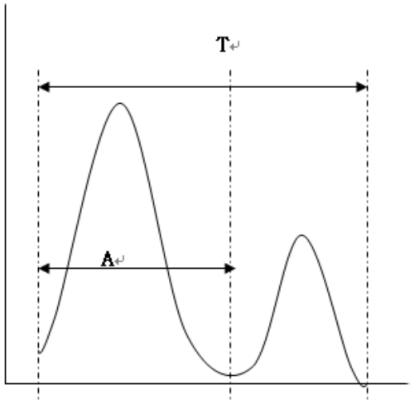
1.2 Caution sign

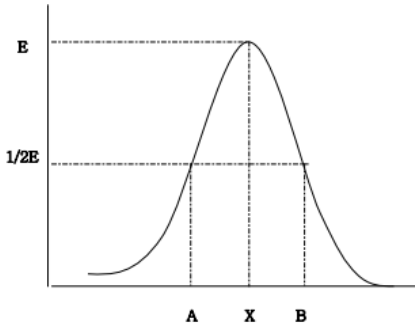
Prohibition Danger/Caution Indication

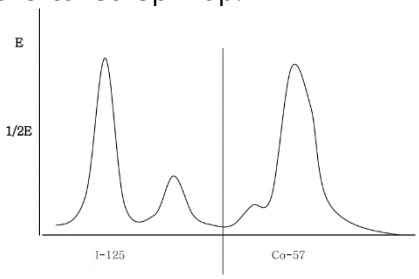
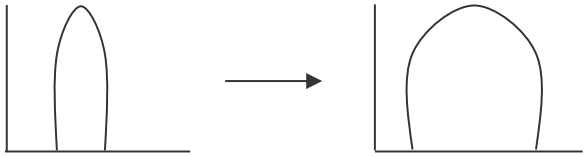
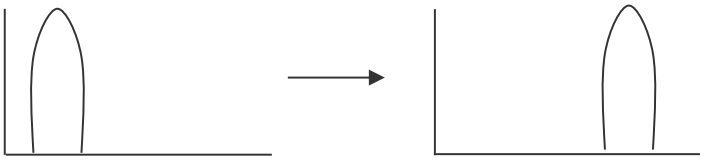


1.3 Definition of Terms

Term	Description
Radionuclide	A radionuclide (radioactive nuclide, radioisotope or radioactive isotope) is an atom that has excess nuclear energy, making it unstable. This excess energy can be used in one of three ways: emitted from the nucleus as gamma radiation; transferred to one of its electrons to release it as a conversion electron; or used to create and emit a new particle (alpha particle or beta particle) from the nucleus. During those processes, the radionuclide is said to undergo radioactive decay. These emissions are considered ionizing radiation because they are powerful enough to liberate an electron from another atom. The radioactive decay can produce a stable nuclide or will sometimes produce a new unstable radionuclide which may undergo further decay. Radioactive decay is a random process at the level of single atoms: it is impossible to predict when one particular atom will decay. However, for a collection of atoms of a single element the decay rate, and thus the half-life (t1/2) for that collection, can be calculated from their measured decay constants. The range of the half-lives of radioactive atoms has no known limits and spans a time range of over 55 orders of magnitude.
Radioactive decay	Radioactive decay (also known as nuclear decay, radioactivity, radioactive disintegration or nuclear disintegration) is the process by which an unstable atomic nucleus loses energy by radiation. A material containing unstable nuclei is considered radioactive. Three of the most common types of decay are alpha decay, beta decay, and gamma decay, all of which involve emitting one or more particles or photons. The weak force is the mechanism that is responsible for beta decay.
Radioactivity	Property exhibited by certain types of matter of emitting energy and subatomic particles spontaneously. It is, in essence, an attribute of individual atomic nuclei. 1Ci = $3.7 \times 10^{10} Bq$ (1g of ^{226}Ra radioactivity)
Mean	Sum of given numbers divided by the number of numbers. $$Mean = \frac{A_1 + A_2 + A_3 + \cdots + A_n}{n}$$
Standard Deviation, SD	In statistics, the standard deviation is a measure of the amount of variation or dispersion of a set of values. A low standard deviation indicates that the values tend to be close to the mean (also called the expected value) of the set, while a high standard deviation indicates that the values are spread out over a wider range. $$S.D. = \sqrt{\frac{\sum(x_i - Mean)^2}{(n-1)}}$$
Coefficient of Variation, CV	In probability theory and statistics, the coefficient of variation (CV), also known as relative standard deviation (RSD), is a standardized measure of dispersion of a probability distribution or frequency distribution. $$C.V = \frac{S.D.}{Mean} \times 100$$

Term	Description
Logit (Logistic)	In statistics, the logit function or the log-odds is the logarithm of the odds *p/(1-p)* where *p* is a probability. It is a type of function that creates a map of probability values from (0,1) to (-∞,+∞). It is the inverse of the sigmoidal "logistic" function or logistic transform used in mathematics, especially in statistics. $$Logit(p) = \log(\frac{p}{1-p})$$
ED 20, 50, 80	Concentration value at 20, 50, 80% Bound 0.2(0.5, 0.8) X CPM of Reference. * If the Reference Tube is set, it is used as 100% Binding. If there is no reference tube, the STANDARD with the highest CPM among the STANDARDs is used as 100% Binding.
Multi-Channel Analyzer, MCA	A multichannel analyzer (MCA) is an instrument used in laboratory and field applications, so to analyze an input signal consisting of pulses. MCAs are used extensively in digitizing various spectroscopy experiments, especially those related to nuclear physics, including various types of spectroscopy (alpha-, beta-, and gamma spectroscopy). MCAs are typically interfaced with via USB, RS-232 or Ethernet, but can use PCI also.
Count Per Minute (CPM)	Number of radiation counted in 1 minute (1 CPM = 60 CPS)
Disintegration Per Minute (DPM)	Radiation decay per minute (1 DPM = 60 DPS)
Efficiency	In the measurement of ionising radiation the counting efficiency is the ratio between the number of particles or photons counted with a radiation counter and the number of particles or photons of the same type and energy emitted by the radiation source. $$\mathrm{E}ff(\%) = \frac{CPM}{DPM} \times 100$$
I-125 Measurement efficiency	I-125 measurement efficiency was calculated using Horrocks efficiency (I-125 Efficiency), and the equation is as follows. $$I-125\ Eff(\%) = \frac{4(1-\frac{A}{T})}{(2-\frac{A}{T})^2} \times 100$$ 

Term	Description
Full width at half maximum, FWHM	Energy interval at 1/2 of the highest count value $$FWHM(\%) = \frac{B-A}{X}$$ 
Energy Resolution	Energy Resolution is the ability of the Detector to accurately determine the Energy of the Incoming Radiation. Since no system is perfect, no system is capable of determining precisely what energy photon struck the crystal. Instead, the system can only determine within a range of values, what energy radiation it is detecting. The energy resolution is expressed as a percent of the energy of the incoming photons. If the energy resolution of a detector is 10%, and only 29 keV photons are striking the crystal, the system will "see" photons ranging from 15 keV to 75 keV. That is, it can only determine to within 14 keV, what the actual incoming energy really is. Energy resolution is a very important parameter in determining the overall performance of a gamma camera, because it is the parameter, which allows a camera to differentiate between primary photons and Compton scattered photons. This ultimately determines the spatial resolution of the system. An important measurement to assess the efficiency of the scintillation counting equipment in a Nuclear Medicine department is the Full Width at Half Maximum (FWHM), which should typically be less than 10%. The formula for determining the percent energy resolution for a particular radionuclide is: $$Resolution(\%) = \frac{FWHM}{E} \times 100$$
Crosstalk	Crosstalk is when an isotope whose energy is >200 keV is measured and the source affects the surrounding detector. When checking the measurement deviation between detectors (VERIFY), measure using one I-125 source. This device is designed to simultaneously display the effects of the surrounding detectors.

Term	Description
Spill Up/Down	Spill Up/Down means that when a substance containing two or more radioactive isotopes is counted, one element affects the counting values of other elements. When counting I-125, the energy range measured by I-125 is set to 15~75 keV (or 15~80 keV), but a certain part of the radioactivity is also counted outside the area. This phenomenon affects the counts of other isotopes when measuring complex isotopes, so it is important to find and measure the correct energy spectrum. High energy measured in a low channel is called Spill down, and the opposite is called Spill up. 
Gain	The allowable value is 0~255 as the amplification factor of the signal. If you increase the value, the scale of the spectrum also increases. (example)  GAIN 100 GAIN 200
Zero Point	By adjusting the zero point of the spectrum, increasing the value causes the spectrum to move toward the higher channel.  Zero Point 100 Zero Point : 200

1.4 Isotope Energy

The gamma ray is a line spectrum, but due to the limitation of the measurement method of the Scintillation Detector, it is observed like a continuous spectrum, and LLD and ULD depend on the resolution of the detector.

The following for High-Energy and Low-Energy are the recommended values for the device.

Isotope	Name	Energy (keV)	Half-Life	Low-E	High-E
I-125	Iodine	29	60.14 day	15	75
Co-57	Cobalt	122	270 day	75	160
I-129	Iodine	31	15,700,000 yr.	19	55

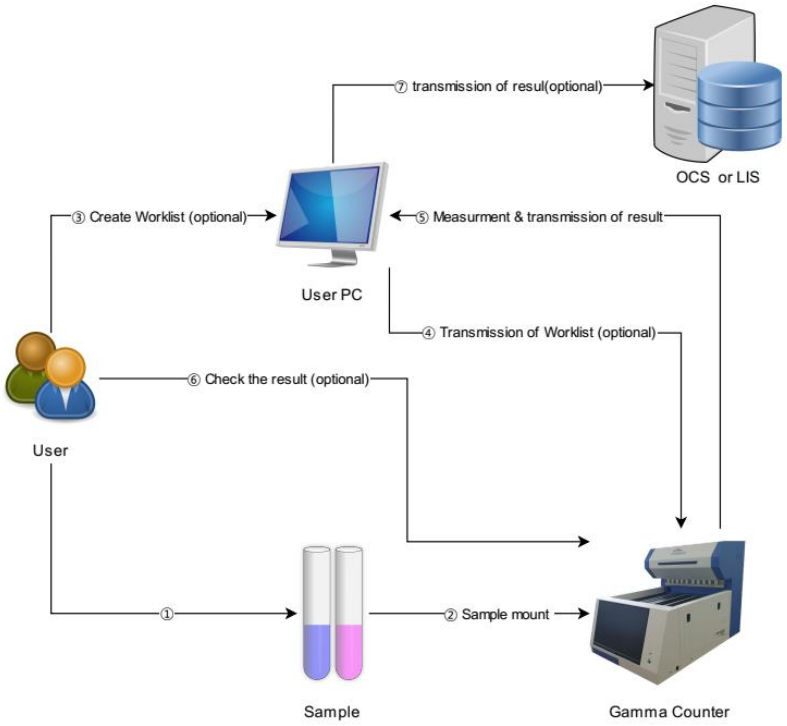
2. Product configuration and specification

2.1 Product overview

This equipment is an all-in-one device with a computer and a monitor built into it, and there is a space on the upper deck to mount a rack equipped with a tube. The detector for measurement is located at the top of the rear. A touch screen monitor and a keyboard are located on the front of the device, and a computer is located inside the right side of the device.

2.2 Principle of operation

This device is designed in a radioimmunoassay to measure the amount of radioactivity in tubes with an isotope–labeled tracer of antigen or antibody in, and calculate automatically the results of qualitative, quantitative and semi-quantitative tests.



It has the capacity to count 10(or 5) tubes with 10(or 5) detectors at the same time, and also carry out qualitative, quantitative, semi-quantitative tests and Dual Label Assay etc.

For quantitative tests, various graphs are available such as Point to Point, Linear Regression, Second Order Polynomial Regression, Cubic Spline, Smoothing Cubic Spline, Pour Parameter Logistic etc., and scales including Linear, Log and Logic are also available.

The User Interface using a touch screen contributes to operating the machine more easily. The dedicated software run by Multi Thread is to carry out what users want to do even when the machine is working.

The Magnetic Sensor that automatically checks the absence of the reagents can remove empty tubes so that it makes the automatic process through Network Interface more convenient.

This device is also the part of the four machines that are used in the total automatic laboratory system, RALS (RIA Automatic Laboratory System). In this case, the whole RIA assay system becomes automatic.

The electrical stability of the counter has already been inspected through the electrical stability test by CE, and recently obtained the certificate of ISO-13485 for quality stability.

2.3 Product composition

After receiving the product, check the components of this unit before installation.

No.	Component	Quantity	Image
1	Gamma Counter	1 EA	
2	Target Rack	30 EA	
3	Shield Tube	10 EA or 5 EA	
4	Power Cable	1 EA	

No.	Component	Quantity	Image
5	RF Clip Box	1 EA	
6	RF Clip	50 EA	

2.4 Product specification

Specification	Description
Dimension	730 x 994 x 723 (mm)
Weight	220 kg
Human Interface	Mouse, Touch Screen, Keyboard
Detector Type	Scintillation Detector - NaI(Tl) Through-hole type
Detector Efficiency	> 70% (I-125)
Countable Energy	2~10 Channels / keV
Background	< 150 CPM (I-125, C-57)
Detector Difference	Within ± 3%
Detector Resolution	≤ 34%
Detector Crosstalk	≤ 3%
Detector SPILL-UP/DOWN	≤ 3%
O.S.	Microsoft Windows

3. MESSIAH Gamma Counter Installation

3.1 Product installation and transport requirements

 **Caution**
This device has a built-in Scintillation Detector that is mainly composed of NaI(Tl) and is sensitive to temperature and humidity, so do not use it in that place. ▸ The instrument may not operate normally. ▸ Do not use in places where the indoor temperature is below 15℃, above 32℃, or above 80% humidity.
Avoid exposure to direct sunlight. ▸ This can cause machine damage and failure.
Maintain an interval of 30cm from the wall and install horizontally in a place without vibration. ▸ This can cause machine damage and failure.
Be sure to check the maximum load when installing the machine in a work desk, etc., rather than in a workbench. ▸ This can cause machine damage and failure. ▸ The device weighs 220kg.
For safety, avoid inflammable substances and places with risk of explosion. ▸ It may cause fire, failure or explosion.

 **Electric shock hazard**
When installing the product, install the power cord in a location that is easy to remove, and when not in use, remove the power plug. ▸ It may cause electric shock or fire due to short circuit.
For safety, be sure to use a grounded outlet. ▸ It may cause electric shock, fire, breakdown, or explosion.
Make sure to check the rated voltage and connect the power according to the capacity. ▸ It may cause electric shock, fire or breakdown.
The instrument should be installed in a place where stable voltage can be supplied (Allowable voltage variation rate: ±10%). If not, connect it to a Automatic Voltage Regulation (AVR) or a Uninterruptible Power System (UPS). ▸ It may cause electric shock, fire or breakdown.
Do not use the power plug with wet hands. ▸ It may cause electric shock.

Caution of hand pressed

Since the product is heavy, at least four people must unpack or transport it.

▸ Falling or bumping may damage the product or cause injury.

Handling precautions

Breakage caution

When unpacking, be careful not to scratch the outer surface of the device with sharp objects such as blades.

▸ This may damage the product.

When transporting device, be careful not to throw device or subject it to strong impacts.

▸ This may damage the product.

Carrying caution

Always treat the bottom of the package and device with the bottom facing down.

▸ This may damage the product.

Caution in rainy weather

Avoid the rain to prevent the outer packaging from getting wet and keep it dry.

(Temperature: -20℃ ~ 70℃ / Humidity: 95% R.H. under)

▸ This may damage the product.

3.2 MESSIAH Gamma Counter Installation

1) Remove the packaging material and place the product body where you will use it. It should be installed in a horizontal place with flat surface and no vibration.
2) Check the appearance of the product and connect the power cord to the power connector on the rear.
3) Connect the power cord to a power outlet of 275 VA or more of power consumption.
4) Connect the LAN cable.

3.3 Execution

1) Check the power connection status of the product, and turn on the main power by pressing the power button located at the bottom right.
2) The device operates initially and remains in standby.
3) Turn on the power of the PC on the front and check if the device and software are properly connected.

3.4 Turn off

1) It proceeds in reverse order of execution.
2) Close the software and select Shut Down in the operating system.
3) After confirming that the power of the PC is off, turn off the main power at the bottom right.

4. How to use

4.1 Precautions for use

 **Caution**
Do not leave the measured tube on the deck. ▸ There is a possibility of problems such as background rise due to device contamination.
When handling samples or reagent components, be sure to wear protective gear before working. ▸ There is a risk of infection or radiation exposure

 **Do not tamper during operation**
While the device is in operation, you can place the rack on the deck or remove the rack that has been measured, but care must be taken not to approach the area to be measured. ▸ It may cause injury due to malfunction.
Do not forcefully remove the rack while measurement is in progress. If it is unavoidable to remove it, take it out after finishing. ▸ It may cause injury due to malfunction.

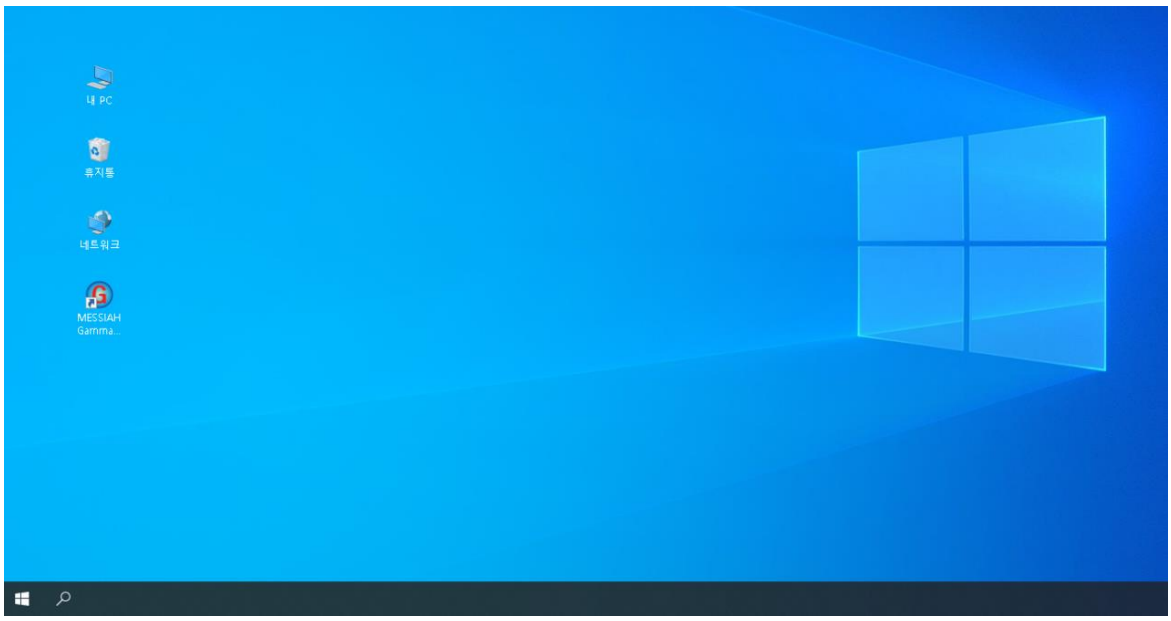
 **Electric shock hazard**
If a strange sound, smell, or smoke occurs from the product, turn off the main power supply and ventilate immediately without touching the product and power supply. ▸ It may cause electric shock or fire, so please contact the person in charge for action.

4.2 START

1) Preparation before use

- Clean the top of the deck.
- Ensure that no tubes are placed inside the device and remove them if present.
- After turning on the power of the device, check the initialization status and determine if there is any abnormality.
- Check around the device for contaminated sources such as tubes, etc., and remove them if present.
- Check the background value before using the device.

2) Execution



- When the device is started for the first time by executing the installed program icon, the device is connected and initialized. If all initial check-ups are completed normally, the program is executed and the [Main View] screen is displayed.

2) In case of connection failure

- An error message of '[ERROR] Network Connection Fail' is displayed.

3) In case of device initialization test failure

- The cause of the device failure is displayed on the screen, and the [Test Mode] and [Exit] buttons are displayed.

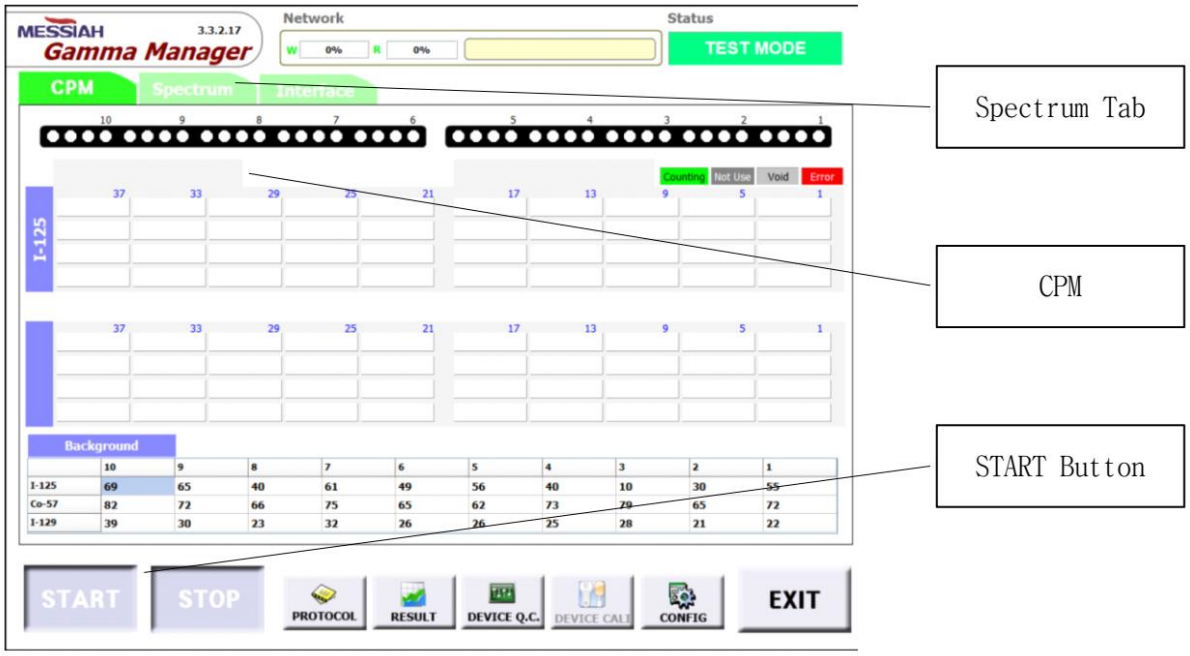
4.3 Operation sequence

① After switching on the device, run the program.

② Mount the tube to be measured on the rack, and insert the RF-Clip of the test into the side of the rack.

③ Place the rack on the deck of the device in the correct direction in the order to be measured, and click START to automatically move to the position where RF-Clip is recognized, and then designate the intended inspection protocol.

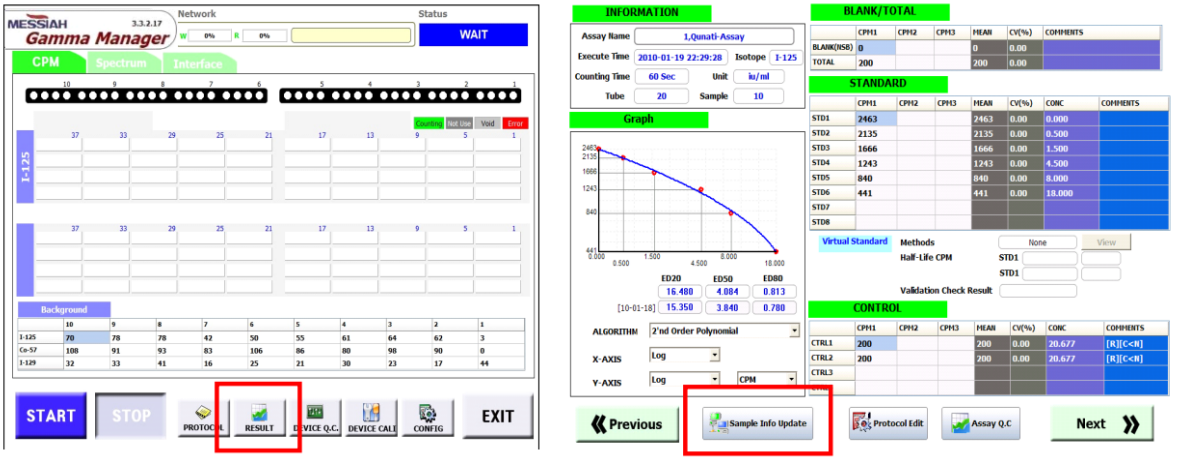
④ When the measurement starts, the radiation level of the tube is displayed on the screen with unit of CPM. If you want to stop the measurement, click STOP.



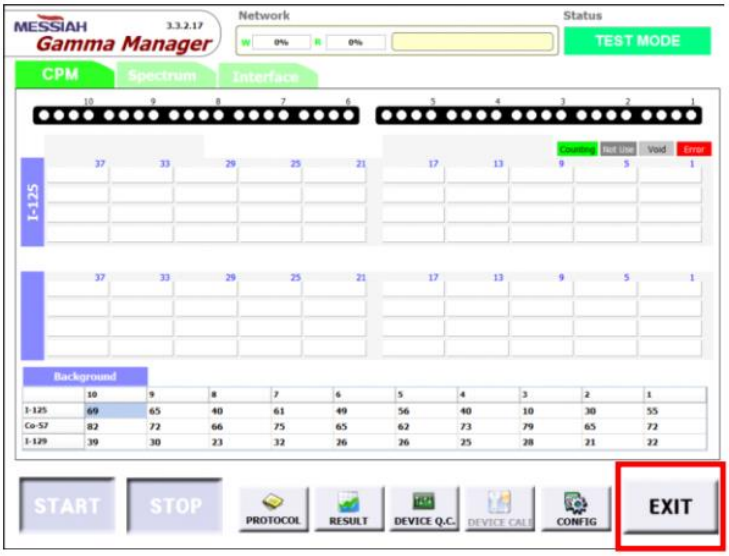
⑤ Select Spectrum Tab to view the Spectrum information of entire detector.

⑥ After measurement, check if the tube and rack come out normally.

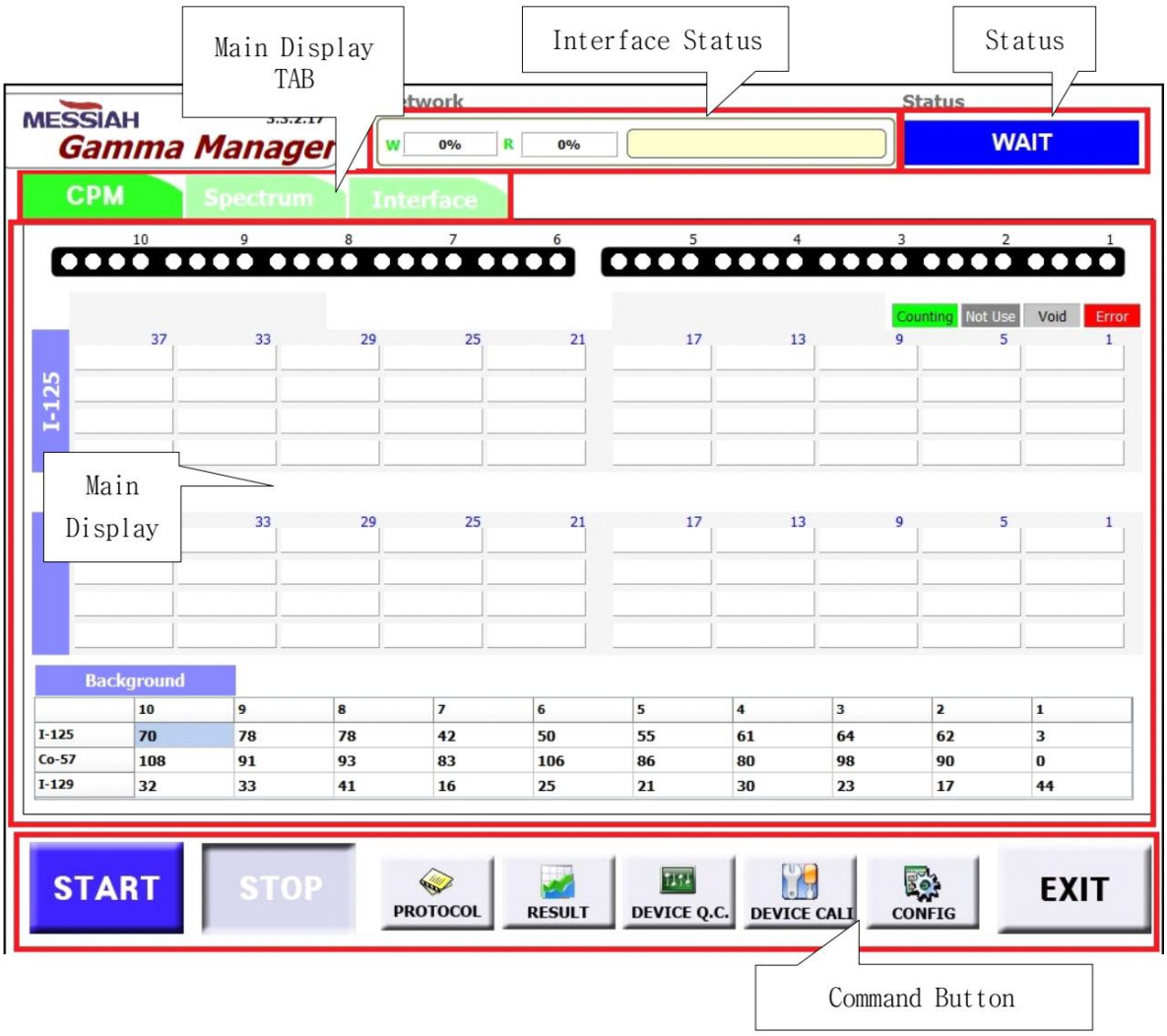
⑦ Click the Result Button on the main screen to check the measurement result and, if necessary, send it to the server through the Network Interface.



⑧ When finished using the device, close programs and operating software, and turn off the device.



4.4 Main View



	10	9	8	7	6	5	4	3	2	1
I-125	70	78	78	42	50	55	61	64	62	3
Co-57	108	91	93	83	106	86	80	98	90	0
I-129	32	33	41	16	25	21	30	23	17	44

① Interface Status

Interface Status displays the worklist transmission status and result transmission status.

② Status

Status displays the device's operating status and counting time.

③ Main Display Tab

Main Display Tab can display CPM, Spectrum, Interface information.

④ Main Display

Main Display displays the item information selected in the Main Display Tab.

⑤ Command Button

START: start the device.

STOP: stop the device.

PROTOCOL: create/modify/delete protocol.

RESULT: check the test results.

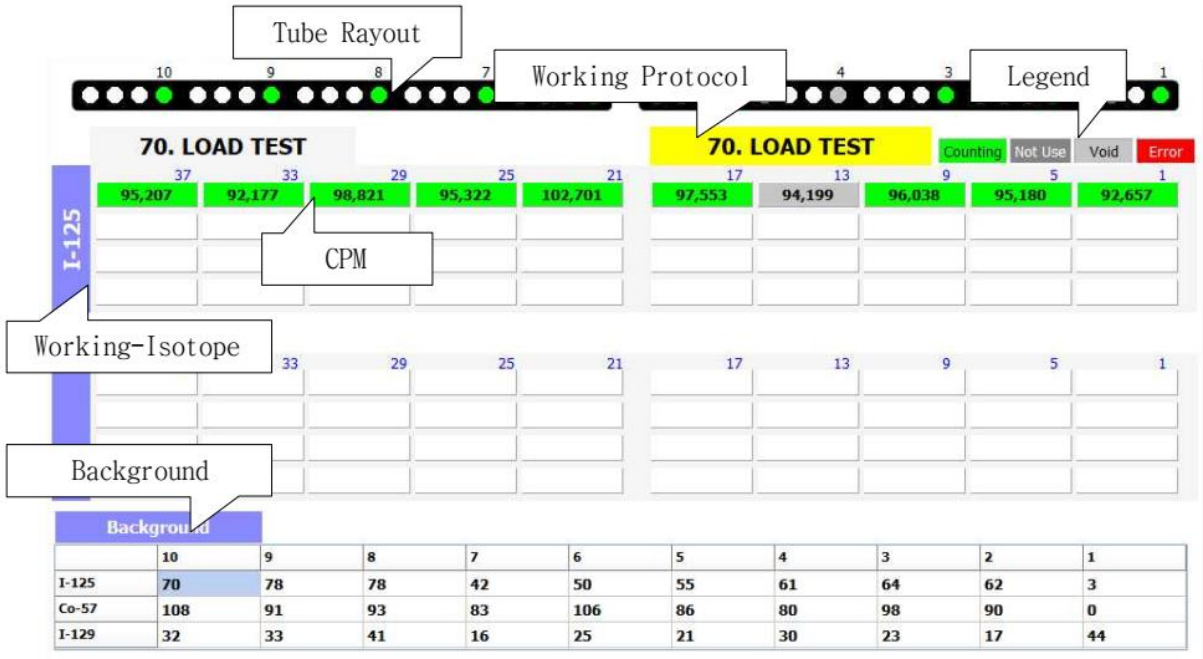
DEVICE Q.C.: check the QC history of the device.

DEVICE CALI: device operation test and operation setting.

CONFIG: configuration

EXIT: exit the program.

4.4.1 CPM



	10	9	8	7	6	5	4	3	2	1
I-125	70	78	78	42	50	55	61	64	62	3
Co-57	108	91	93	83	106	86	80	98	90	0
I-129	32	33	41	16	25	21	30	23	17	44

① Tube Layout

Tube Layout makes it easy to check the mounting status of the tube on the Cassette Rack, and the tube being measured is displayed in green.

② Working Protocol

Working Protocol is displayed on the left and right tabs. Displays the protocol of the Cassette Rack in operation.

③ CPM

Displays the counted CPM value. The same color as Tube Layout is applied. CPM information starts from the right, and the 4 panels on the far right are CPM information counted by Detector 1. This matches the layout of the Cassette Rack when the equipment is viewed from the front.

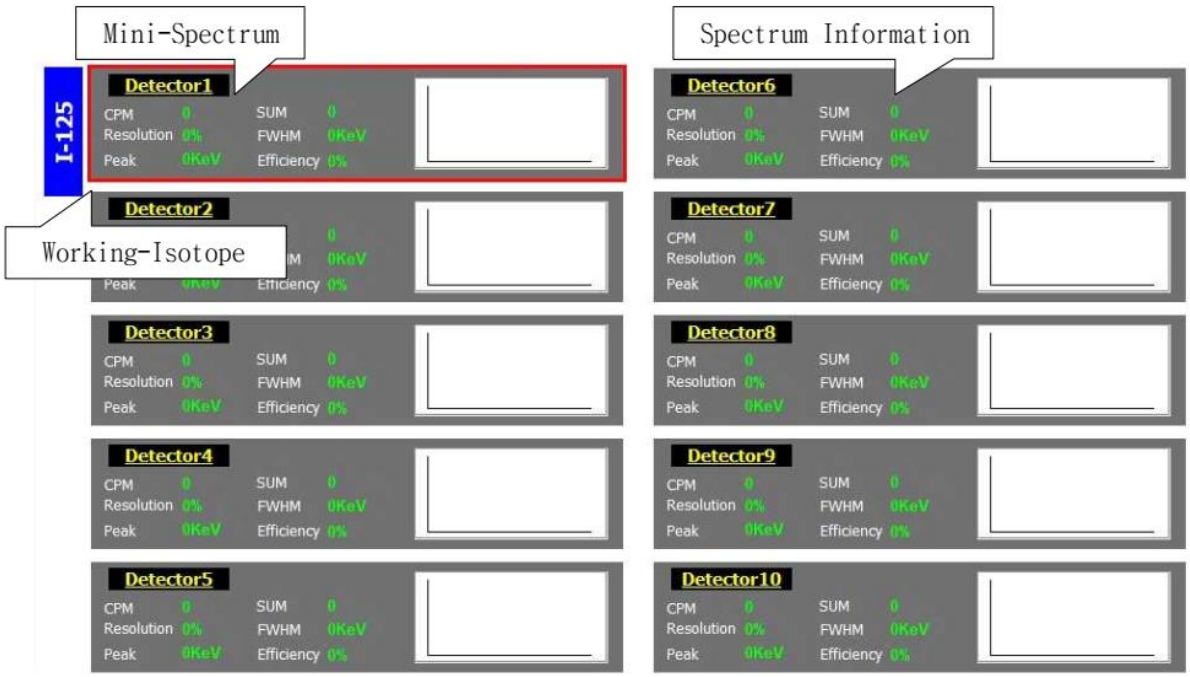
④ Working Isotope

The measured isotope of the counting tube is displayed.

⑤ Background

Displays background information of I-125, Co-57, I-129.

4.4.2 Spectrum: Brief



① Working Isotope

Isotope spectrum currently being displayed

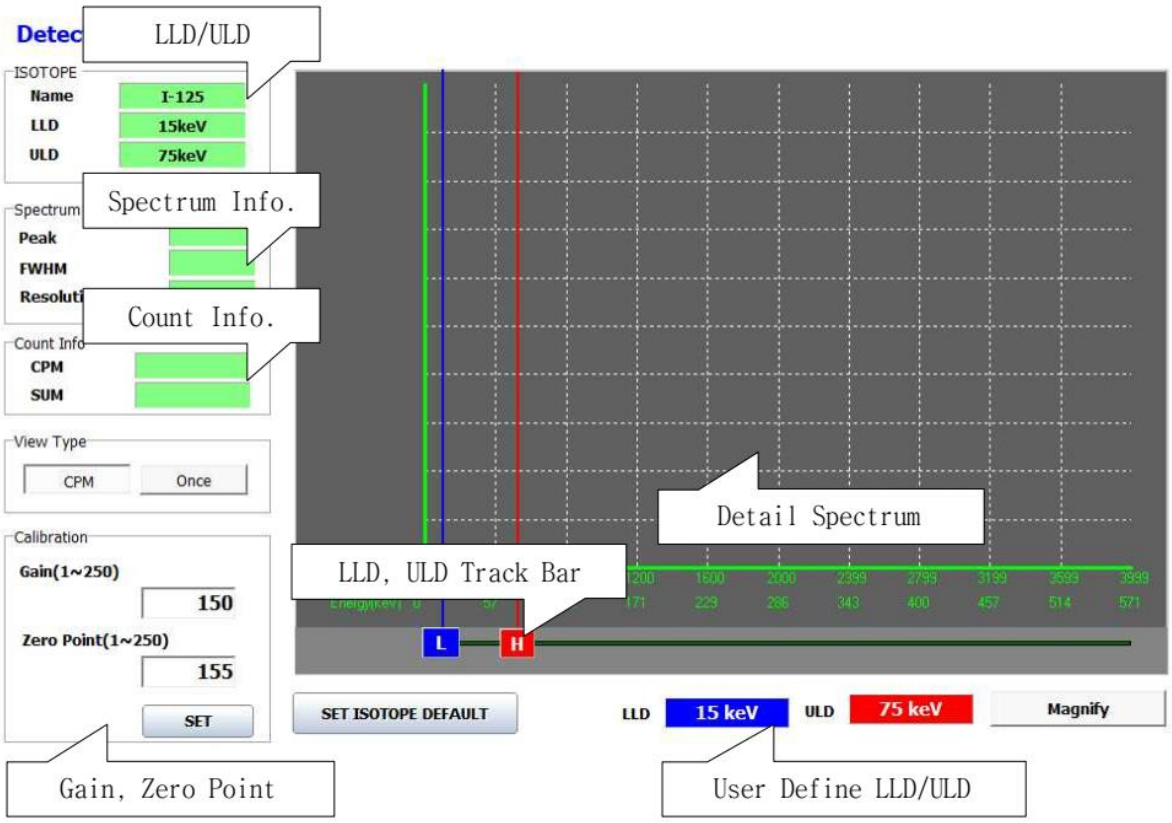
② Mini Spectrum

Mini Spectrum can check the Spectrum Shape, and if you want to check more detailed Spectrum, press and hold Mini Spectrum for 1 second to display Detail Spectrum information.

③ Spectrum Information

Check CPM, SUM, Resolution, FWHM, Peak, Efficiency(only I-125) at the same time.

4.4.3 Spectrum: Detail



① LLD/ULD

LLD/ULD of the isotope currently being measured

② Spectrum Info.

Display FWHM, Peak, Resolution, Efficiency (only I-125). Upon changing LLD and ULD, the changed part of spectrum information is displayed.

③ Count Info.

Displays the measurement CPM and the sum of the radioactivity during the measurement time. If the user has modified the LLD or ULD, the information of the corresponding range is displayed.

④ User Define LLD/ULD

Displays the LLD and ULD currently being measured. If the user wants to change, the desired range can be set by dragging the LLD or ULD Track Bar.

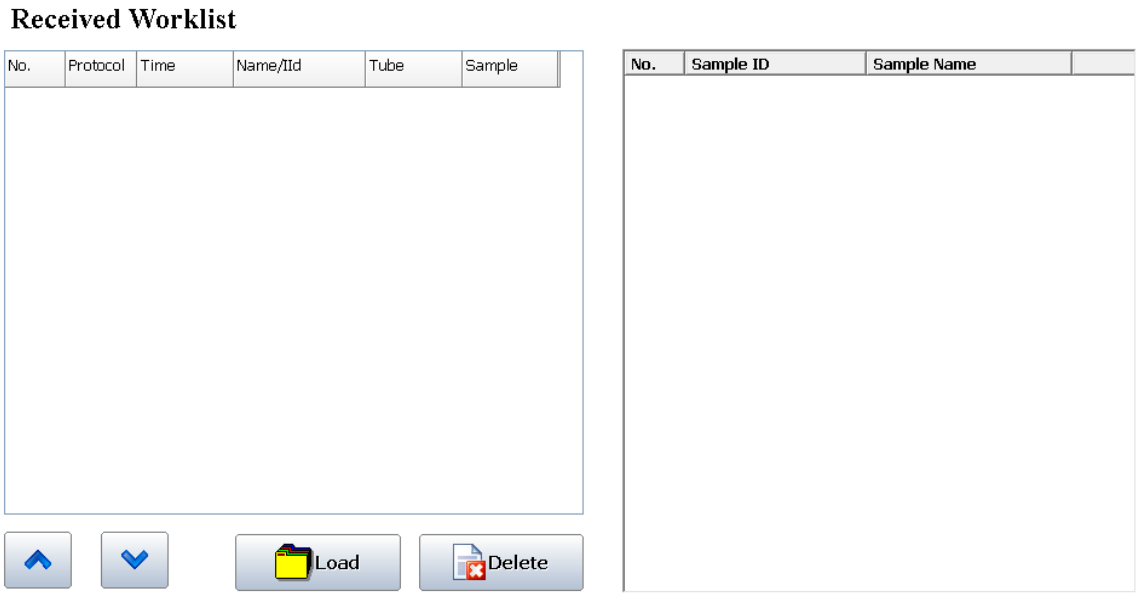
⑤ Gain, Zero Point

Gain and Zero Point can be changed by selecting after input values while viewing the spectrum information.

⑥ Detail Spectrum

Displays more extensive spectrum information.

4.4.4 Interface



① Received Worklist

Protocol, time, name/ID, number of tubes, number of samples are displayed.

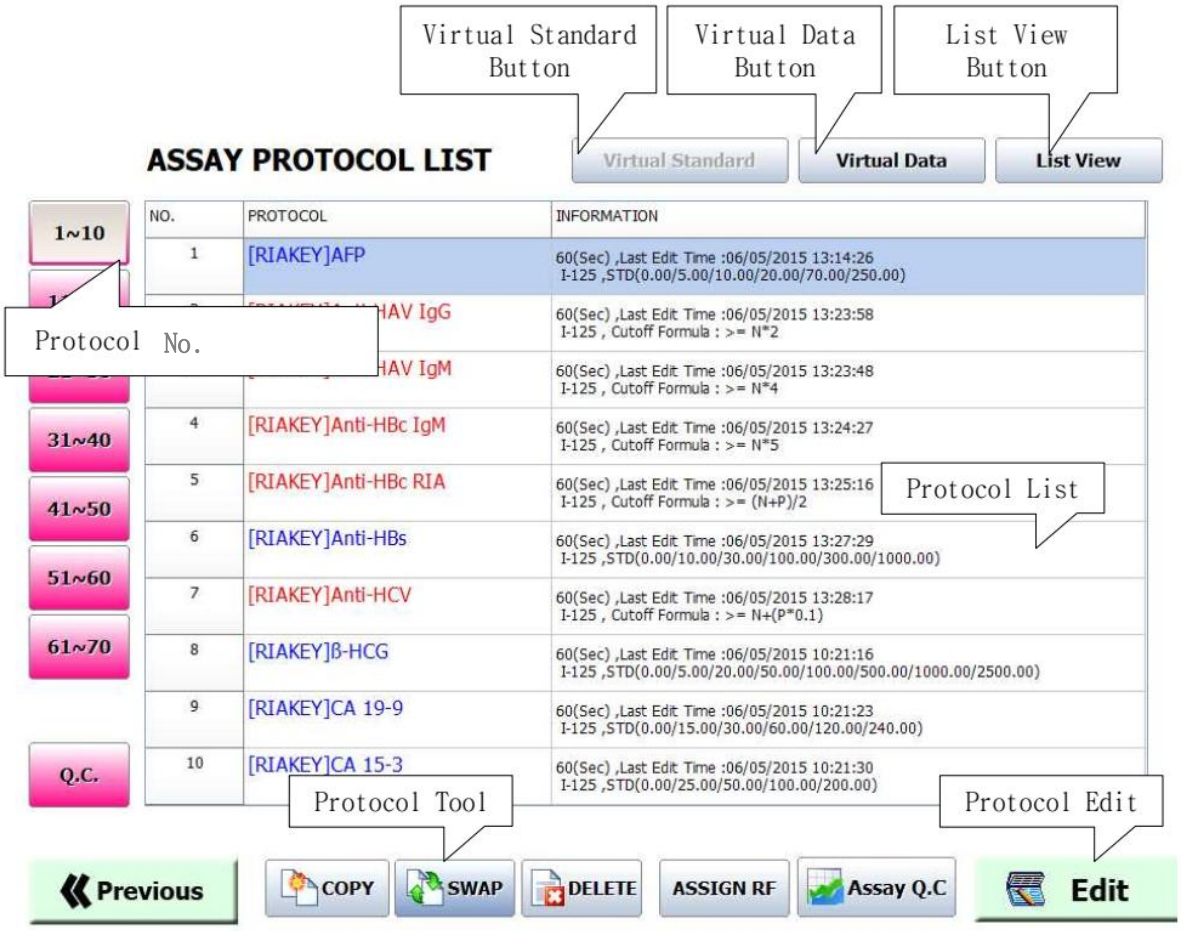
② Load

Load previously saved interface history.

③ Delete

Deletes previously saved interface.

4.5 PROTOCOL



① Protocol Number

Press the Protocol band by 10 units.

② Protocol List

Simple information of each protocol is displayed, and you can edit or delete it by selecting EDIT.

③ Virtual Standard Button

It is used when you want to apply the standard information of the previous test to a new test.

④ Virtual Data Button

Virtual Data Button allows you to check the result value by virtually input.

⑤ List View Button

List View Button allows you to view the entire list of protocols at once.

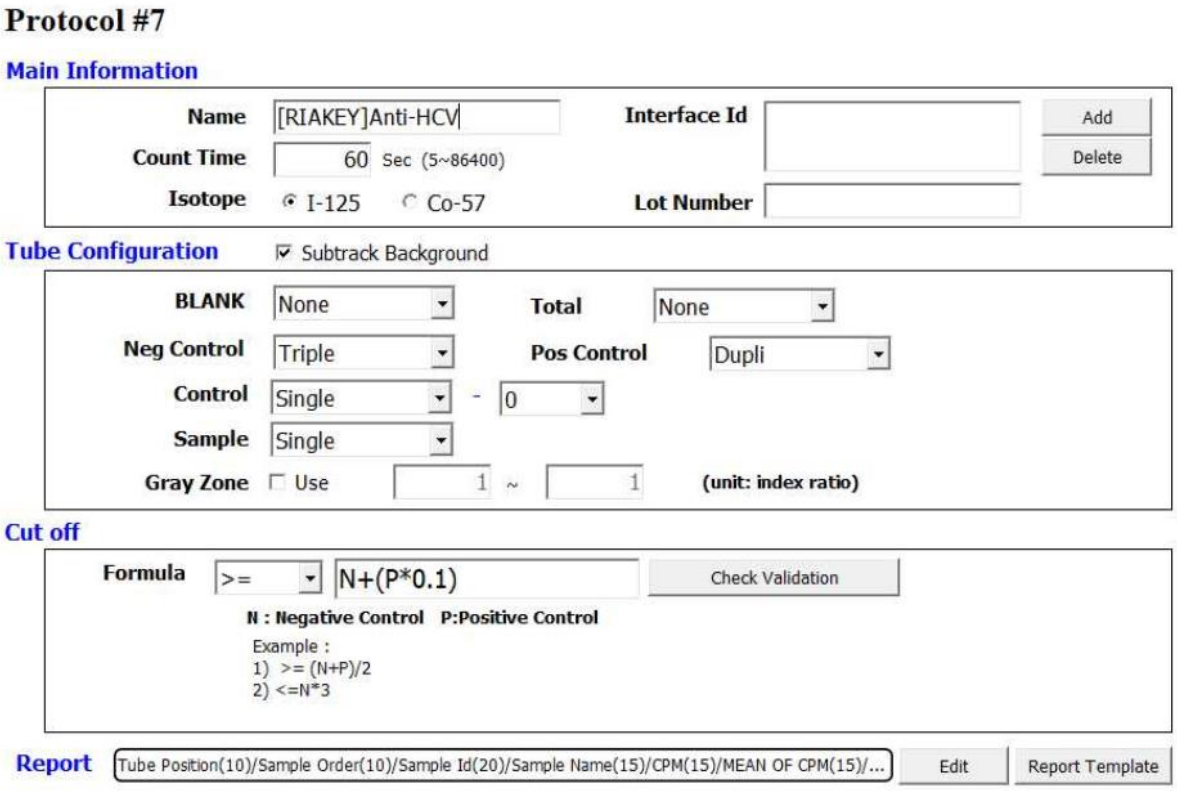
⑥ Protocol Tool Button

Protocol copy, move, and delete functions are provided.

⑦ Protocol Edit Button

Protocol can be modified or created if not specified.

4.5.1 Qualitative Assay Protocol



4.5.1.1 Main Information

① Name

Protocol name

② Count Time

Input in seconds

③ Isotope

④ Interface Id

Protocol Id used in Network Interface communication

⑤ Lot Number

Reagent Lot Number (if Q.C. for each lot is required)

4.5.1.2 Tube Configuration

① Subtract Background

Display after subtracting the recently measured background value for each detector.

② BLANK

For tests using BLANK Tubes, input the number of blank tubes used. If used, contamination

that occurred during the test can be detected.

③ Total

It means 100% Binding Tube and input the number of Total Tube to be used.

④ Neg control / Pos Control

Input the number of negative and positive controls used in the qualitative test.

⑤ Control

Input the number of control samples and the number of repeat measurements.

⑥ Sample

Input the number of repeat measurements of the patient's sample.

⑦ Gray Zone

The cut off value calculated by the formula is converted to an index and is assumed to be 1, and if the measured value of the patient sample is converted into the ratio of the cut off and is within the input range, this is alerted when reporting the result.

4.5.1.3 Cut off

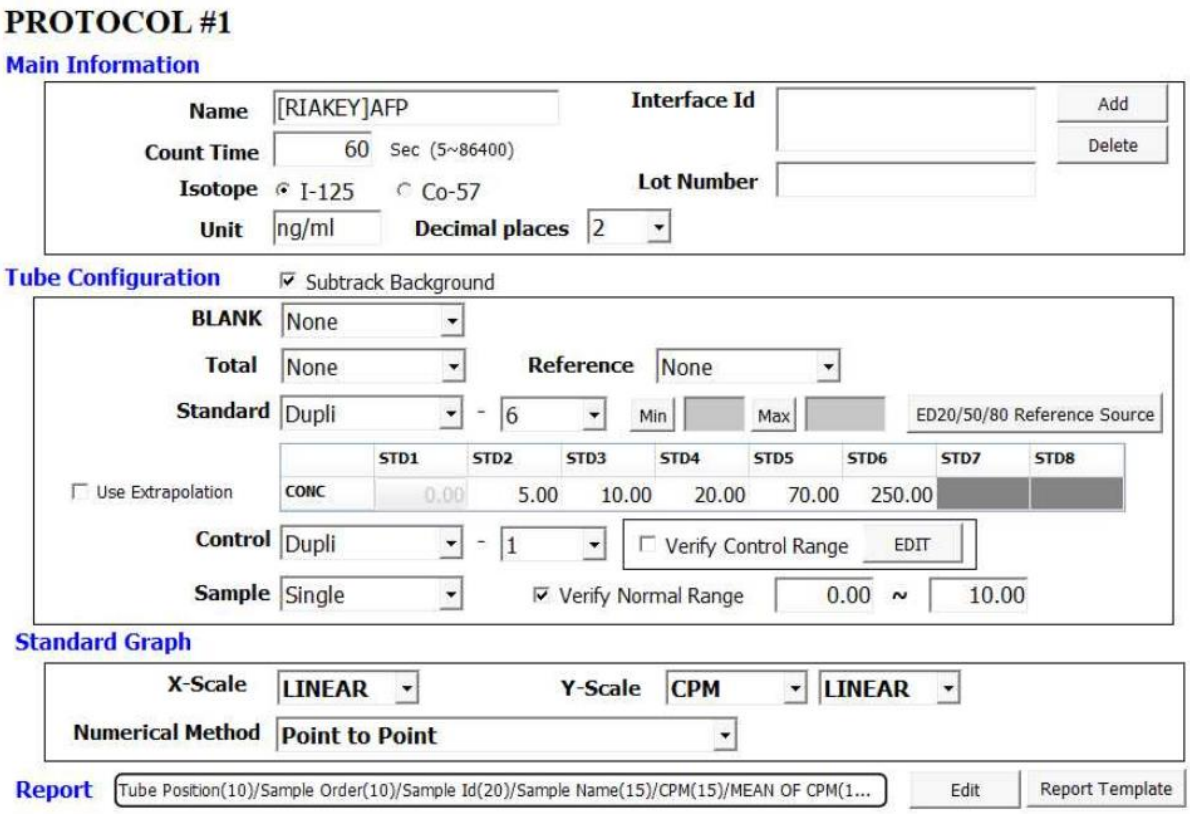
① Formula

In the qualitative test, input the calculation formula required for setting cut off. You can check whether the calculation formula is correct by selecting Check Validation.

4.5.1.4 Report

① Set the output format of the test result. To Use the previous format, click 'Report Template'.

4.5.2 Quantitative Assay Protocol



4.5.2.1 Main Information

① Name

Protocol name

② Count Time

Input in seconds

③ Isotope

④ Interface Id

Protocol Id used in Network Interface communication

⑤ Lot Number

Reagent Lot Number (if Q.C. for each lot is required)

⑥ Unit

Unit of concentration (does not participate in calculation)

⑦ Decimal Places

Specify the number of decimal places. For example, if you specify 2, the density is expressed as 2.11.

4.5.2.2 Tube Configuration

① Subtract Background

Display after subtracting the recently measured background value for each detector.

② BLANK

For tests using BLANK Tubes, input the number of blank tubes used. If used, contamination that occurred during the test can be detected.

③ Total

It means 100% Binding Tube and input the number of Total Tube to be used.

④ Reference

When inspecting with a zero concentration tube, it divides the standard CPM, which can generate a logit-log graph.

⑤ Standard

Input the number and concentration of standard tubes.

⑥ Use Extrapolation

Set whether to calculate the sample CPM by extrapolation when it is out of the range of Standard. If not used, the result outside the standard range is displayed with an inequality sign in front of the result.

⑦ Control

Input the number of control samples and the number of repeat measurements.

When the range of the control concentration is set by selecting Verify Control Range, a result outside the range is warned.

⑧ Sample

Input the number of repeat measurements of the patient's sample.

If input Verify Normal Range, the software warns you when the test result exceeds the range.

4.5.2.3 Standard Graph

① X-Scale

Scale of linear, log type concentration value.

② Y-Scale

Specify the scale of the CPM or other measurement results.

Linear / Log / Logit can be selected, and the displayed items are as follows.

1. CPM
2. B/Bmax: The ratio divided by the highest CPM among standards
3. B/T: B / Total Tube

③ Numerical Method

Select Algorithm to draw graph.

4.5.2.4 Report

① Set the output format of the test result. To Use the previous format, click 'Report Template'.

4.5.3 Semi-Quantitative Assay

① Almost similar to the qualitative test, however, the semi-quantitative test can be calculated using the control and patient sample measurements for cut off calculations.

② The variables used are:
N: Negative Control
P: Positive Control
T: Total
A: Control A
B: Control B
X: Sample

4.5.4 Dual Label Assay

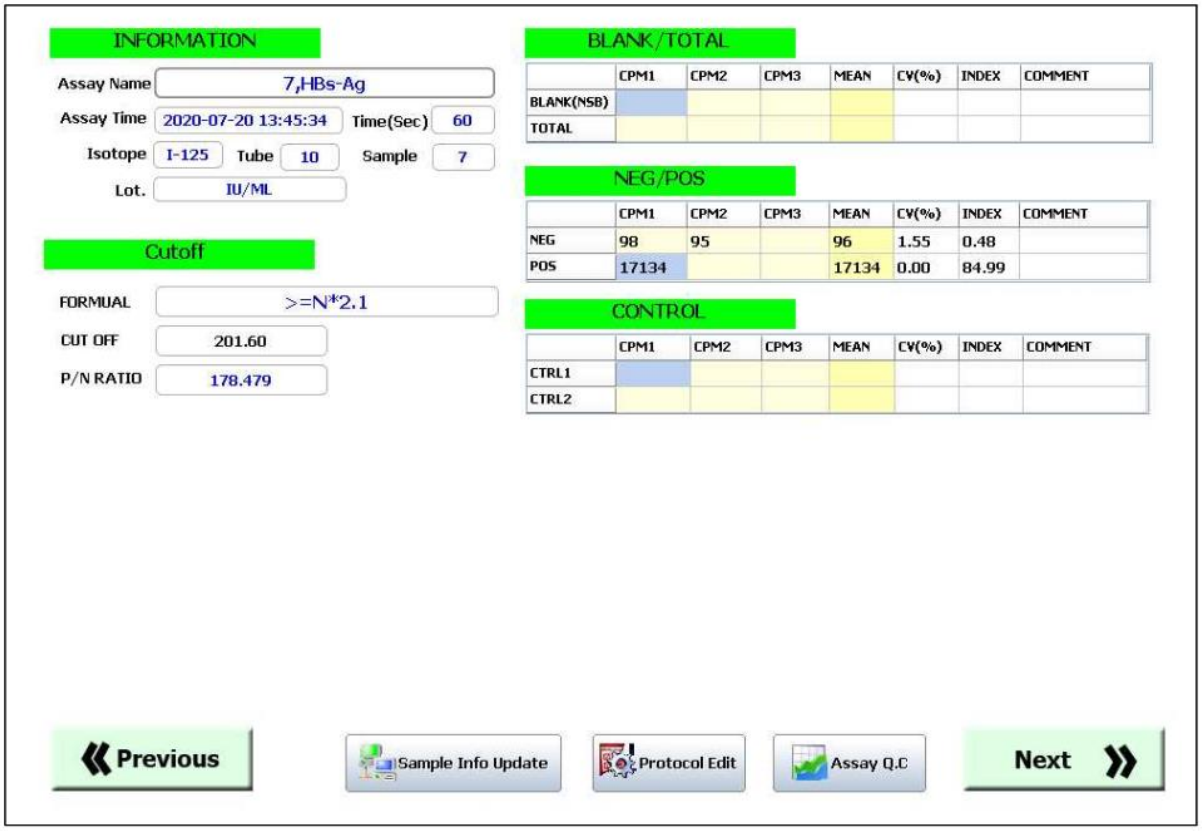
① Input the same as for quantitative test, but this test method is used when I-125 and Co-57 are labeled on one tube like Vitamin B12/Folate.

② For Dual Label Assay, first out the information on I-125 in, click the Save button, and then type Co-57 information in.

4.5.5 CPM

① It is used to measure only the CPM of the selected nuclide.

4.6 Qualitative Assay Result



① INFORMATION

To show Assay Name, Assay Time, Counting Time, Nuclide, lot and the number of tubes and samples. The number of sample tubes are determined by the number of samples alone so that tubes for other reagent tubes such as Standard, Control, Total and Blank are not included in the number of sample tubes regardless of Single, Double, and Triple etc.

② BLANK/TOTAL

The measured CPM and calculated concentration are displayed, and the concentration is automatically calculated when CPM is modified.

③ Cutoff

The cut off value of the qualitative test calculated by the formula set in Protocol Formula and P/N Ratio information used for Q.C. is displayed.

④ NEG/POS

The measured Negative and Positive Control values are displayed.

⑤ CONTROL

The measurement result of the used control is displayed.

⑥ Sample Info Update

This is used when you want to apply Network Interface information after completion of the

test. If there is OCS or LIS information corresponding to the protocol after the test is finished, a list that can match the received data is displayed.

⑦ Protocol Edit

After the test is completed, tube information or other test information can be modified. The modified protocol information is only applied to this test result.

⑧ Assay Q.C.

Checking the Q.C. information of the test.

For Q.C. information, you can check the history and lot information of ED20, ED50, ED80, and Control for each test.

4.7 Quantitative Assay Result

① INFORMATION

To show Assay Name, Assay Time, Counting Time, Nuclide, lot and the number of tubes and samples. The number of sample tubes are determined by the number of samples alone so that tubes for other reagent tubes such as Standard, Control, Total and Blank are not included in the number of sample tubes regardless of Single, Double, and Triple etc.

② GRAPH

It shows the graph calculated by the designated method, and when data is changed, it is automatically applied to the graph and re-drawn. The validity of the test can be evaluated by showing the values of ED20, ED50, and ED80 calculated in the same protocol test

performed just before.

③ Reagent

Information of Blank, Standard and Control Tube is displayed.

The measured CPM and calculated concentration are displayed, and the concentration is automatically calculated when CPM is modified.

- Virtual Standard

When the test is performed in virtual standard mode, it shows the Method, Half-Life CPM (CPM calculated with only half-life), and Validation Check Result (valid evaluation result).

④ CONTROL

The measurement result of the used control is displayed. If the Verify Control Range is set in Protocol, if the result out of the range is displayed, it is displayed in Comment.

⑤ Sample Info Update

This is used when you want to apply Network Interface information after completion of the test. If there is OCS or LIS information corresponding to the protocol after the test is finished, a list that can match the received data is displayed.

⑥ Protocol Edit

After the test is completed, tube information or other test information can be modified. The modified protocol information is only applied to this test result.

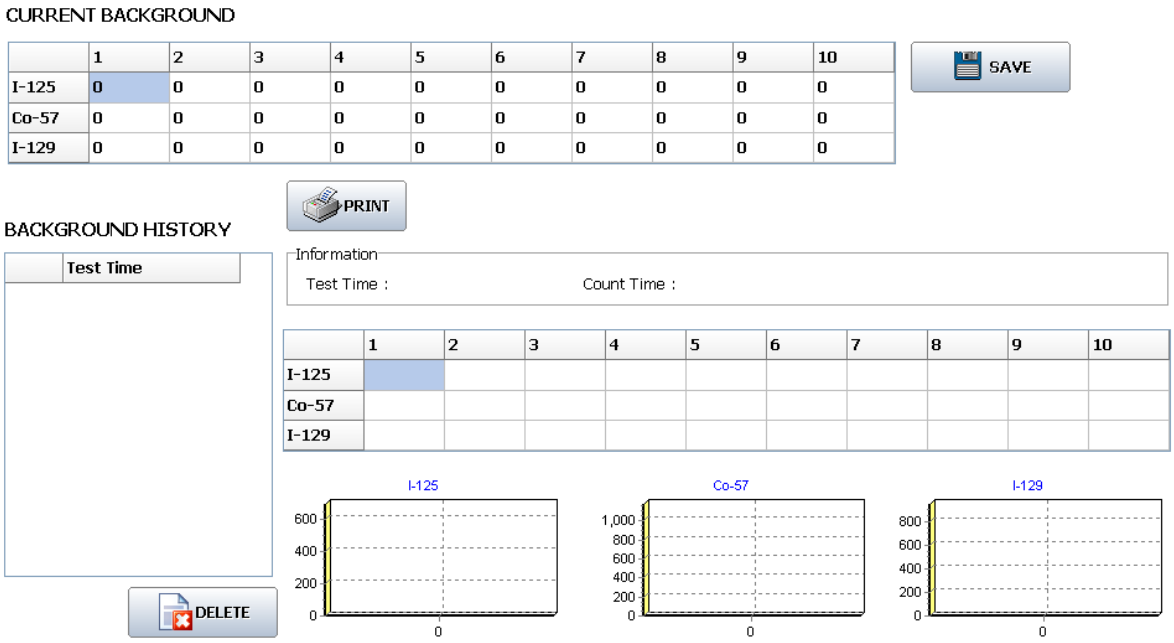
⑦ Assay Q.C.

Checking the Q.C. information of the test.

For Q.C. information, you can check the history and lot information of ED20, ED50, ED80, and Control for each test.

4.8 Device Q.C.

4.8.1 BACKGROUND



① Measure ambient radioactivity before test and before instrument operation and check for unconfirmed contamination.

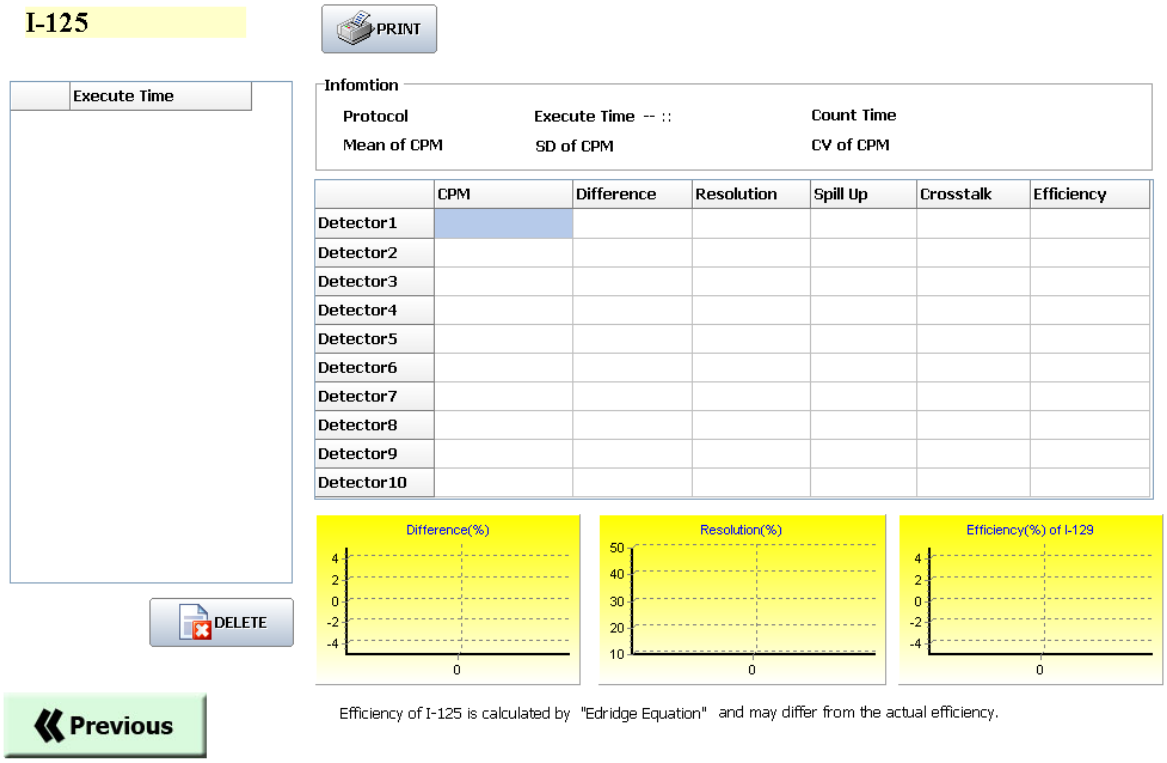
② The measured background radioactivity is accumulated by date, by measurement time, and by nuclide and can be verified.

③ Current Background Information

As the last counted background information, it indicates the currently applied value. Modification is possible, and the changed value is applied by saving after modification.

④ It should be used after checking the measurement period and test items as specified in user maintenance.

4.8.2 VERIFY I-125



① Check whether the Detector is operating normally.

② Check counting efficiency between detectors and crosstalk, spill over/down and resolution.

③ It should be used after checking the measurement period and test items as specified in user maintenance.

4.8.3 VERIFY Co-57

① It checks whether the Detector is working properly and proceeds in the same process as I-125.

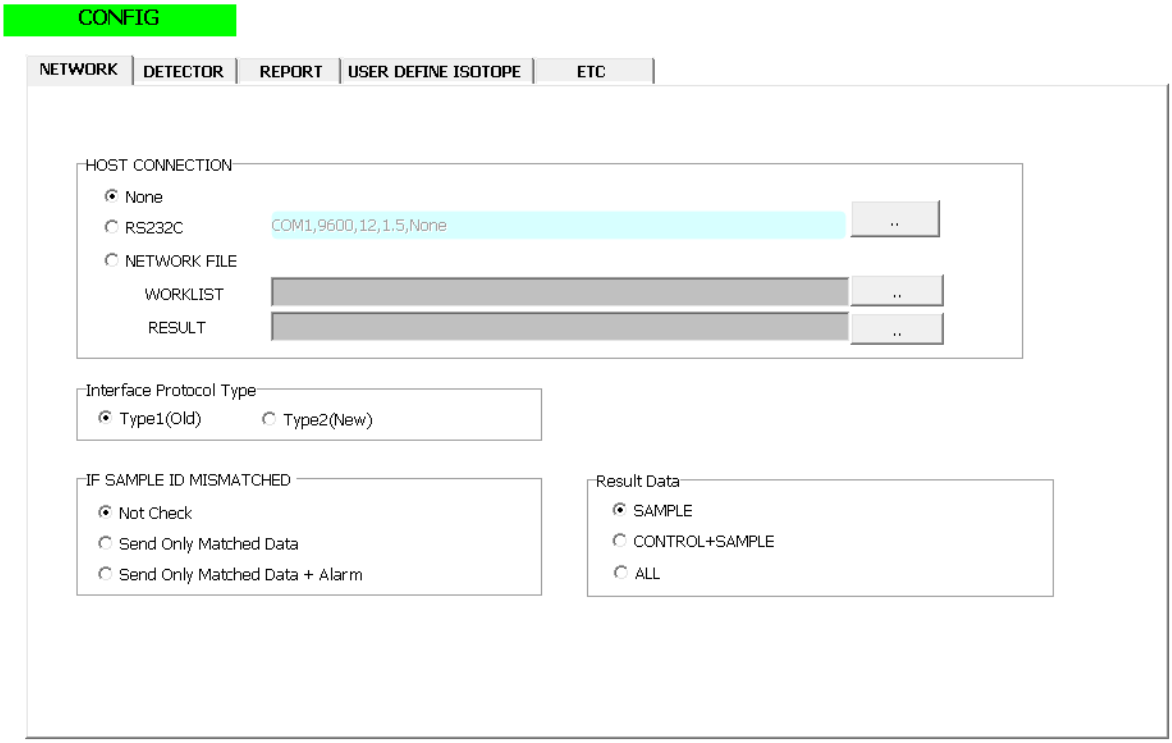
4.8.4 VERIFY I-129

① It checks whether the Detector is working properly and proceeds in the same process as I-125.

4.9 DEVICE CALI

① It is used for initial setting of device when installing and moving device, and must be operated by device installers or service technicians who have received prescribed training.

4.10 CONFIG



4.10.1 NETWORK

① Select the host connection method and file transmission/reception method.

② If there is data omission, set the alarm method.

③ It sets the data level included in the transmission/reception result.

4.10.2 DETECTOR

① Set the Channel and Energy values.

② If an abnormal value is found as a result of verifying, input the corresponding value to reduce the deviation between detectors.

③ It sets whether tube check, data reception period, whether to automatically correct Spill Up/Down, and whether to automatically correct Crosstalk.

4.10.3 REPORT

① Set the size of the report paper. It supports A4 size and LETTER size.

② Specifies the form that is entered in the report with default settings.

③ Select the report form and register it as a list.

4.10.4 USER DEFINE ISOTOPE

① Modify the value set by Isotope Energy in Section 1.4.

② Add a nuclide and set the measurement lower and upper limit energy.

③ It sets the data level included in the transmission/reception result.

4.10.5 ETC

① Select whether to automatically print or send to the network after measurement is finished.

② Designate the type of year-month-day-time used in the report.

③ Designate whether to generate sound when an error occurs.

5. User maintenance

5.1 Storage and management after use

① After the measurement is finished, the measured tube should not be left in the instrument.

② The device should be installed away from confined spaces and hot and humid environments.

③ The device should be installed in a stable place with a working voltage of ±10%, and should be used by connecting to a Auto Voltage Regulator (AVR) or Uninterruptible Power Supply (UPS).

④ Do not place heavy objects on top of the machine.

⑤ Periodically, background and verify counting of device should be performed to check the performance.

⑥ If the device is contaminated by radioactive isotopes during or after use, remove it according to the decontamination procedure. In case of contamination outside the device except for radioisotope contamination, remove it with a neutral detergent. If contaminated with infectious substances such as blood, wipe with alcohol on gauze and dry thoroughly before use.

5.2 Precautions for use

① There is a possibility that problems such as background rise may occur, so do not leave the measured tube on the deck during or after use.

② When handling a tube with adsorbed radioactive material, there is a risk of infection and radiation exposure. Therefore, you must wear appropriate protective equipment such as gloves before working.

③ Heavy objects must not be placed on top of the equipment.

④ Except for appropriately qualified service technicians, do not open the equipment at your discretion. When opening the equipment, be careful of contact with DC-DC Converter for High Voltage.

Mark	Position	Description
	Attached to the high voltage DC-DC converter case inside the device	Be careful not to touch it as there is a risk of high voltage

⑤ Be careful not to spill liquids such as reagents on the equipment during use.

5.3 Maintenance

5.3.1 Verify

Purpose	Adjust the values among Detectors with the one same source.
Interval	Once a week
Checking list	1) Difference: within ±3% Check whether the difference between each detector is within ±3%. If it exceeds the allowable range, perform verification once more. 2) Resolution: ≤34% Check if it is within the allowable range. If it exceeds 34%, contact a service technician to take appropriate action, and if it exceeds 36%, consider replacing the detector. 3) Crosstalk: ≤3% When crosstalk of I-125 exceeds the allowable range of 3%, it should be set to use crosstalk correction in CONFIG. If it exceeds 10%, appropriate measures must be taken, such as contacting a service technician. 4) Spill-Up: ≤3% If it exceeds the allowable range of 3%, appropriate measures must be taken, such as contacting a service technician.

5.3.2 Background

Purpose	Measure the natural radiation and the radiation caused by contamination around the detector. The measured value is automatically subtracted for subsequent test.
Interval	1) After verify 2) Immediately before measuring the protocol of a new item * Measuring at least once a day.
Checking list	If the background of I-125 exceeds 150, use it after removing contamination if possible. And if it exceeds 200, it must be used after removing contamination.

5.4 Other cautions

① If radioisotope contamination occurs, remove it according to the decontamination procedure. If external contamination of the device excluding radioisotope contamination occurs, use a neutral detergent to remove it.

② Except for appropriately qualified service technicians, parts should not be replaced, repaired or modified.

5.5 Storage, transport and operating environment

5.5.1 Storage

- Temperature: 0℃ ~ 40℃
- Humidity: 95% R.H. under
- Barometric pressure: 50 ~ 106 kPa

5.5.2 Transport conditions

- Temperature: -20℃ ~ 70℃
- Humidity: 95% R.H. under
- Barometric pressure: 50 ~ 106 kPa

5.5.3 Operating conditions

- Temperature: 15℃ ~ 32℃
- Humidity: 20 ~ 80% R.H.

6. Trouble shooting

6.1 General

Problems	Solutions
Power does not turn on.	1. Check if the power cord is connected to external power. 2. Check if the power cord is connected to the device. 3. Make sure the device's power switch is off. 4. If the power does not come on even though you have checked all of the above, please request technical support.
Power is on, but mechanical fricatives or loud noises are heard.	1. After disconnecting the power supply, check if any debris is trapped in the moving part of the device. 2. If you do not find any foreign substances, or if the problem occurs even though you remove them, please request technical support.
Sudden stop while operating.	1. Check if the power is connected properly. 2. Check if the power switch is pressed incorrectly. 3. Check if accidentally pressed the ‘pause’ or ‘stop’ button. 4. If you have checked all of the above and it still does not work, please request technical support.
The system smells of burning.	1. Disconnect the power cord and immediately cut off the external power. 2. Please request technical support.
‘Network connection fail’ error message appears when running the PC program.	1. Check if the power is connected properly. 2. Check if the LAN cable is connected to the device. 3. If it does not work properly even though you have checked all of the above, please request technical support.

6.2 Software

If you have identified the following software warning messages during use of the equipment, you should remove the cause of the error and contact service technician for appropriate action if necessary.

Error message	Description
[ERROR] GetProcedureInfo	RF-CLIP insertion without protocol setting
[ERROR] SAVE CPM FAIL	Failed to save CPM information due to connection error in database
[ERROR] MakePoint ERROR	Equipment fails to set initial point
[ERROR] TRAY IN ERROR	RACK movement failure

Error message	Description
[ERROR] RF-READER ERROR	Communication failure with RF-READ
[ERROR] INVALID RF ORDER	Invalid RACK sequence
[ERROR] MOVE AB FAIL	Failure to move RACK to position A and B
[ERROR] DECK IS FULL	DESK is full and unable to move rack
[ERROR] Invalid Order. Background Rack cannot located as Second Rack	When the first RACK is for BACKGROUND and the second RACK is RF TAB RACK
[ERROR] Invalid Order. VERIFY Rack cannot located as second rack	If the second RACK is VERIFY
[ERROR] AD END. DETECTOR=1	AD-END, which is a count stop command, was transmitted to AD-BOARD, but there is no response
[ERROR] LIFT TIME OUT ERROR	Obstacle jammed during LIFT UP
[ERROR] LIFT ERROR	Received response from LIFT command that the operation is not possible
[ERR] Detector Count Req Error. Detector=1	REQ_COUNT command sent to AD BOARD, but no response
[ERR] CPM Receive Error. Detector=1	Sending measurement result to AD BOARD but failed
[ERROR] VERTICAL MOVE TIME OUT ERROR	LIFT UP/DOWN ERROR
[ERROR] TRAY OUT ERROR	TRAY OUT SENSOR is pressed and cannot move RACK
[ERROR] Create Worklist	WORKLIST creation failed, DATABASE damage check is required
[ERR] Start Count Error. Detector=1	Sending REQ_START command to AD-BOARD but no response
[ERROR] RIGHT MOVE ERROR	RACK fails to move to the right due to an obstacle
[ERROR] DATBASE CONNECT FAIL	Cannot connect to DATABASE
[ERROR] NETWORK INTERFACE DEVICE NAME ERROR	Invalid SERIAL PORT

Error message	Description
[ERROR] NETWORK INTERFACE DEVICE OPEN ERROR	SERIAL PORT OPEN FAIL
[ERROR] PRINT ERROR	Cannot print
[ERROR] READ ACK	HOST not responding
[ERROR] READ INTERFACE ACK	Data is transmitted, but HOST does not transmit ACK command
[ERROR] PARSING ERROR.	Invalid data transmitted from HOST

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