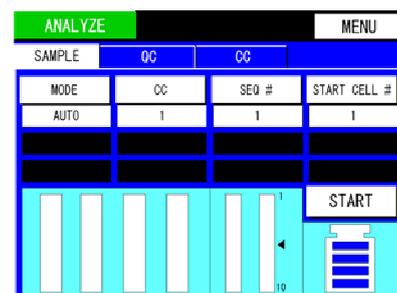


OC-SENSOR **io**

Simple Operation Manual

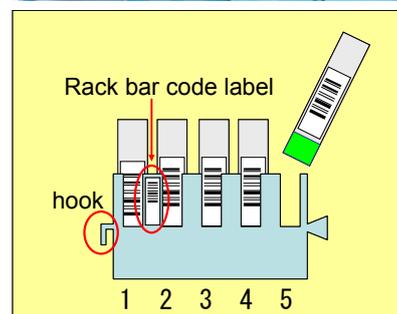
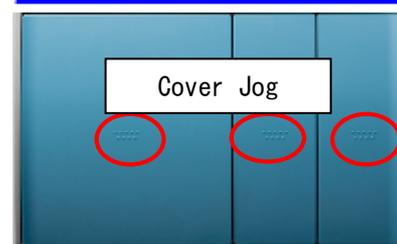
SET UP

- (1) Check the level of buffer, purified water and wash solution
 - ※ Left: Buffer Center: Wash solution Right: Purified water
 - ※ Change buffer or refill them (W.S. and P.W.) if needed.
 - ※ See P.6 for how to set W.S. and P.W.
- (2) Check the drain tank is not full
 - ※ Empty the tank if needed.
- (3) Remove the 'DISPO-10' and Sample rack if needed.
- (4) Check the thermo-sensitive paper (Printer paper)
 - ※ Set the paper if needed.
- (5) Turn on the system power switch (on the left side).
 - ※ After initialize and heat-up, "SAMPLE" screen in the "ANALYZE" will be displayed.



SET

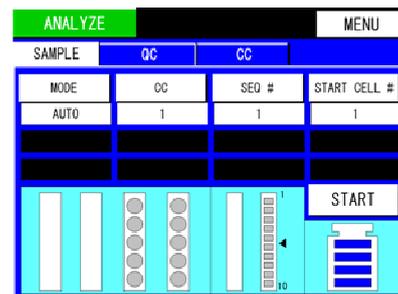
- (1) Set 'OC-Auto 3 Latex Reagent'
 1. Open the reagents cover. (Right side)
 - ※ Press the reagent cover jog to open it.
 2. Set Latex reagent on the reagent cradle.
 - ※ Mix it three times gently. Open the cap and set the bottle.
 - (Make sure there are no bubbles)**
 3. Close the reagent cover.
- (2) Set 'DISPO-10' (Cell)
 1. Open the cell cover. (Middle one)
 - ※ Press the cell cover job to open it.
 2. Set the cells from the right side.
 - ※ Up to 2 cells can be set
 - ※ See P.3 Check / Edit analysis setting (4) Setting the start cell for the details.
 3. Close the cell cover.
- (3) Set sampling bottles /sample cups
 1. Set the sampling bottles from the hook side of sample rack.
 - < **Sampling bottles** > Check the sampling bottle caps are completely closed. The barcode label side needs to face the left with the green cap facing down.
 - < **Sample cups** > Dead volume is 100uL. Pour at least 150uL of sample.
 - ※ Rack barcode and sampling bottles barcode need to face the same direction.(Left)
 - ※ Racks can hold sampling bottles and sample cups in any order.
 - ※ 5 sampling bottles or sample cups can be loaded on 1 rack.
- (4) Load sample racks on the sample rack cradle.
 1. Open the sample cover. (Left)
 - ※ Press the sample cover jog to open it.
 2. Load the sample rack from the right side of the sample rack cradle with the hook facing the back side.
 - ※ 4 sample racks (20 samples) can set in the sample rack cradle.
 3. Close the sample cover.



ANALYZE

(1) Start analysis

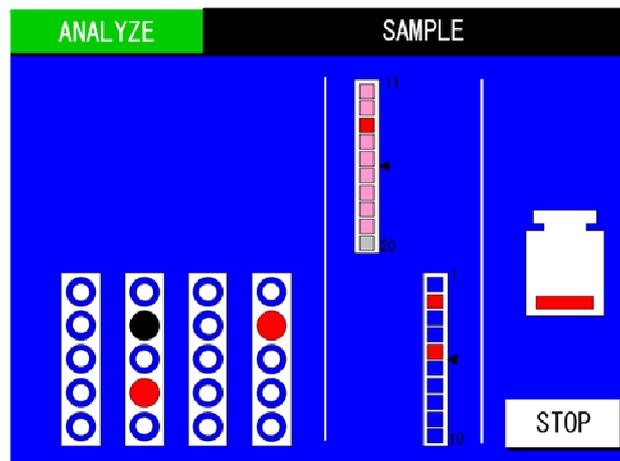
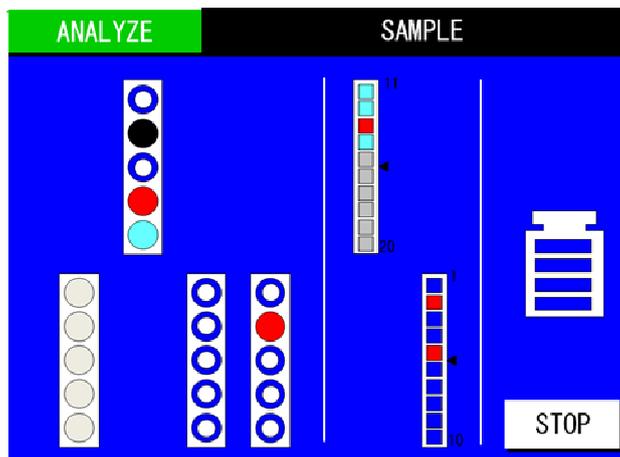
1. Check the analysis setting is correct.
 ※See P.3[Check / Edit analysis setting] for details.
2. Check the racks and cells on the screen
 ※After pressing START, the remaining latex quantity will be displayed.
3. Press [START] on the screen
 - Analysis will start.



| Display of sample rack status | |
|-------------------------------|-----------------------|
| No rack | : Box only |
| Unanalyzed sample rack | : Gray |
| Sample under sampling | : Light Blue |
| Sample without sample liquid | : Red |
| Sample being sampled | : Blue + White |
| No sample | : Black |
| Sample error | : Red |

| Display of cell status | |
|-------------------------|---------------------|
| No cell | : Box only |
| Unused cell | : Gray |
| Sample Under dispensing | : Light Blue |
| Reagent being dispensed | : Pink |
| Cell used for analysis | : Blue |

| Display of Latex volume | |
|--|--|
| Full reagents: All 4-level scales are displayed in Blue | |
| Small quantity is Low Reagent: The lower scales are displayed in red | |



4. Result will be printed after the analysis.

| | |
|--------------------|----------------------------|
| OC-io 2011. 02. 24 | ← Current Date |
| ***** | ← Calibration Curve No. |
| CC No. 1 | ← SEQ No. (001-999) |
| 001 001-01 | ← Sample Bar code No. |
| AEHF9Z | ← Sample Rack No. |
| - 0ng/mL | ← Position No. in the rack |
| 002 001-02 | ← Concentration |
| AEHG9F | ← Flag (-/+) |
| + 258ng/mL | ← Over Range (1001 over) |
| 003 001-03 | ← Error Code |
| AEHN8E | |
| +OR2223ng/mL | |
| 004 001-04 | |
| READ ERR | |
| - 89ng/mL | |

Check / Edit the analysis setting

(1) Mode setting

Press [MODE] tab to display mode selection.

AUTO :When analyze automatically (routines)
MANUAL :When analyze cells dispensed manually.
RETEST :When re-analyze the sample once punctured.

※ Retest mode will not puncture sampling bottle again.

(To prevent contamination)

※ After the analysis, change the [MODE] back to [AUTO].

(2) Setting the Calibration curve number

Press [CC] tab and select Calibration curve number

※ 3 Calibration curves will be displayed.

※ Created Date and Lot No will be displayed on the screen.

※ See P5 Calibration curve creation for the details.

(3) Setting the sample number

Press [SEQ#] tab

Number input dialog will be displayed.

Input number and press [Enter]

※ You can set sample No. from 1~999

※ When turn on the system switch, the SEQ # will become 1.

(4) Setting the start cell number

Press [START CELL #] tab

Number Input dialog will be displayed.

Input number and press [Enter]

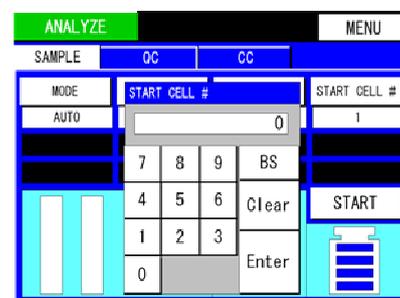
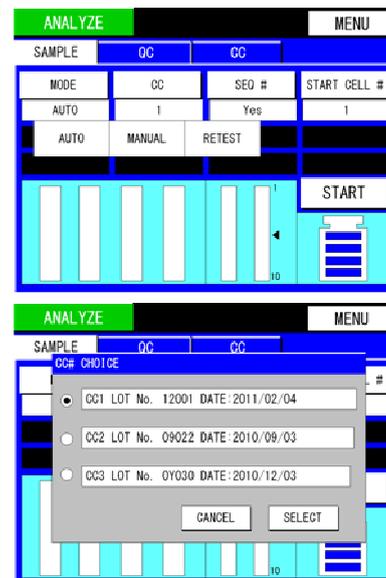
※ You can set cell No. from 1~20

※ When all cells are used, [NONE]

※ When turn on the system switch, the Start cell # will become 1.

※ When using half used cell, need to change this number.

※ To re-enter the start cell number, cell needs to be loaded again.



[BS] :The last one input will be deleted
[Clear] :All input will be deleted
[Enter] :Fix the input figures

Closing process

(1) Remove reagent, cells and racks

※ As soon as analysis is completed, close the latex reagent cap and put it back in a fridge.

※ If sample racks and cells are still in the equipment, error message will be displayed when restarted.

(2) Closing

- Press [MENU]→[CLOSE]→[START]

※ [MENU] button will be upper right of the screen.

(3) Turn off the system power switch (on the left side)

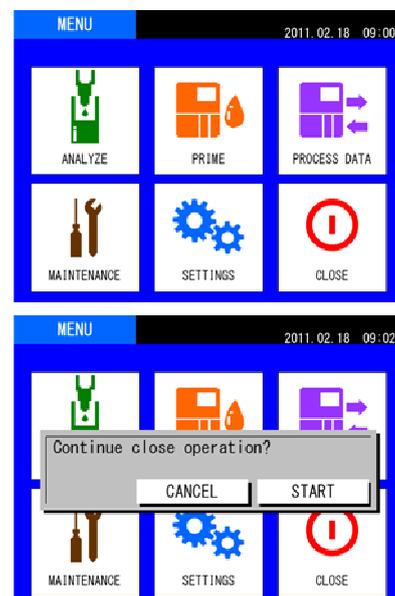
※ Do not turn off the main power switch on the back.

※ If the equipment will not be used more than 1 week, read Operation manual.

(4) Check the level of Buffer

※ Replace it to new bottle if needed.

(5) Empty the drain tank



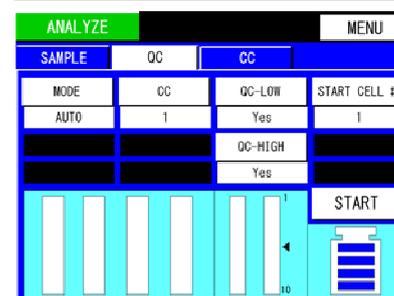
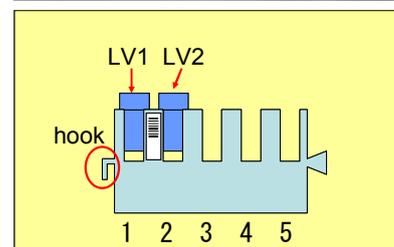
Quality Control

(1) Set controls

1. Add OC-Control LV1 & LV2 into the sample cups.
 - ※ 200 μ L(at least 4 drops)
 - ※ Do not make bubbles.
2. Set OC-Control LV1 cup at the position 1. (hook side)
3. Set OC-Control LV2 cup at the position 2.
4. Load the control racks to the rack cradle.
 - ※ The hook side facing the back side.

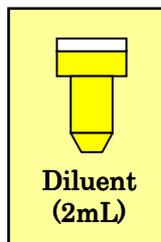
(2) Run controls

1. Press [QC] tab
 - ※ The measuring control screen will be displayed.
2. Select control to measure.
 - ※ Select either "Yes" or "No" for each control to run/not run.
3. Press [START]
4. Result will be printed and go back to [ANALYZE] screen.

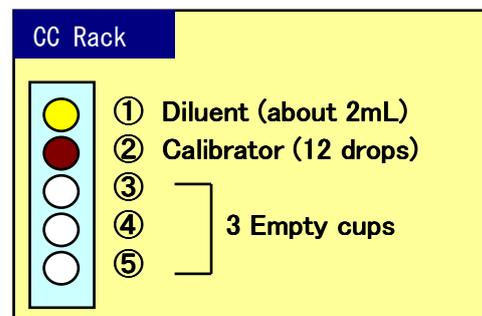


Calibration curve creation

- (1) Dispense 'Diluent' to a sample cup
 ※ Dispense about 2mL
- (2) 12 drops of the Calibrator in a sample cup
 ※ Do not make bubbles.

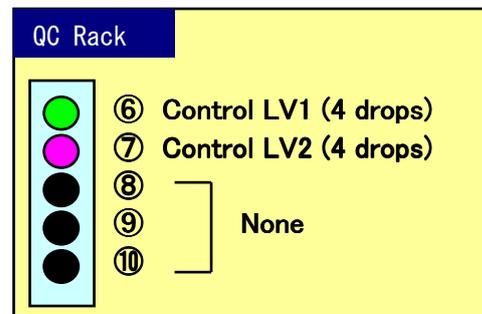


- (3) Set cups on the rack
 1. Set Diluent cup, Calibrator cup and Empty Cups like picture on the right.
 2. If control will be measured at the same time, set control cups like the picture on the right.

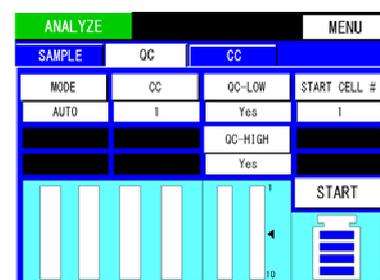


- (4) Load the Racks
 ※ First, set the CC Rack on the right and QC rack next to it.

- (5) Set new 'DISPO-10'
 1. Set the DISPO-10 on the right side.
 ※ It needs to be new 'DISPO-10'(cell)



- (6) Calibration curve creation
 1. Press [CC] tab
 ※ The calibration curve creation screen will be displayed.
 2. Select calibration curve number
 ※ You can set calibration No. 1, 2, or 3 for the calibration curve creation.
 3. Select with / without Controls
 ※ For QC-Low(LV1) / QC-High(LV2), select either "Yes" or "No"
 4. Enter Latex Reagent Lot No.
 5. Press [START]
 ※ Calibration curve creation will start.
 6. Result will be printed like the picture on the right.



- (7) Check and set of Calibration curve and control data
 1. Check the printed data.
 - Upper conc. : Theoretical value (Concentration of the Calibrator)
 - Lower conc. : Application value (The concentration recalculated based on OS value using specified calibration curve formula)
 - OS value : Electrical value of the optical system

Judgment

- STD2 Lower conc. should be $\pm 10\%$ difference from the upper conc.
- STD3~5 Lower conc. should be $\pm 5\%$ difference from the upper conc.
2. If everything is ok, press [Yes] to memorize the data.

- (8) Check the control result
 Check the control result is within the acceptable range.
 (See the package inserts)

```

OC-io 2011. 02. 04
*****
      CC DATA
*****
LotNo. 12001
  CC No. 1
STD NUMBER   =5
STD          OS
1   0ng/mL   0
      (0ng/mL)
2   50ng/mL  38
      (49ng/mL)
3   200ng/mL 216
      (200ng/mL)
4   500ng/mL 715
      (499ng/mL)
5  1000ng/mL 1510
      (1000ng/mL)

CONTROL 1
      135ng/mL
CONTROL
      433ng/mL

CC TYPE      =2
CC DEGREE   =3
CC FORMULA
F (0) = 1. 1406e+01
F (1) = 1. 0002e+00
F (2) = -6. 3780e-04
F (3) = 2. 7089e-07
PRC =553
    
```

NOTE

Adding samples during analysis

- While cover open/close indicator (Blue LED light) is off, add sampling bottles, cells, or latex reagent, if needed.
 - ※ cannot add another sample rack during sampling
 - ※ cannot add another cell during latex being dispensed
 - ※ cannot change another latex reagent bottle during reagent being dispensed
 - ※ When there are not enough cells during analysis, the message will be displayed. Select [CONTINUE] or [STOP]
 - [CONTINUE]: add new cells or replace cells and press [CONTINUE]
 - [STOP]: analysis will be ended and go back to [ANALYZE] screen.
 - ※ If cell is removed and press [STOP], error message will be displayed



Setting the number of replicates

- (1) Input number of replicates for sample
[MENU]→[SETTINGS]→[REPLICATE # (SAMPLE)]
※ Set the number of samplings from the same sample cup.
- (2) Input number of replicates for QC
[MENU]→[Settings]→[REPRICATE # (QC)]
※ Set the number of samplings from the same control cup.

Setting the cut off value

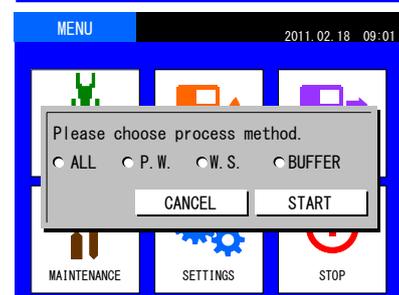
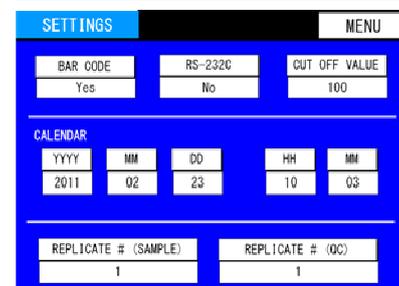
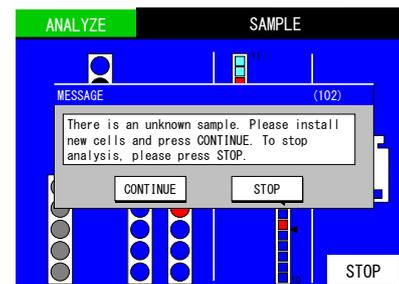
- Input cut off value
[MENU]→[SETTINGS]→[CUT OFF VALUE]
※ Result below the cut off value will be negative(-)
Ex) if cut off value was set 100ng/mL
0~100ng/mL is negative(-), 101ng/mL or above is positive(+)

Replacement of Buffer/Wash Solution/Purified Water

- (1) Remove the empty bottle. Insert the tube into the new bottle and plug it.
※ Be careful not to spill liquid on the equipment.
- (2) Prime processing
[MENU]→[PRIME]→(select)→[START]
※ Select the replaced bottle and press [START].
※ Prime will fill tubes with solution and push out the air in the tubes.

Prepare 'Wash solution'

- Make about 3% original of Sodium Hypochlorite solution by purified water.
 - Sodium Hypochlorite solution: 15mL
 - Purified water: about 485mL



PREPARATION OF REAGENTS

1. OC-Auto3 Latex Reagent (V-PH18)

Take the reagent bottle out of refrigerator and bring to room temperature. Gently invert several times to assure uniform suspension.

After opening, reagent stability:

- In refrigerator (2-10° C), stable for 14 days.
- Stored onboard for 7 days (Latex reagent cap needs to be closed when not testing)

Do not mix reagent with another bottle.

2. OC-Auto3 Buffer (V-PH46)

Incubate for 30 min in the buffer bottle cradle before use.

After opening, buffer stability:

- Stored 'onboard' for 1 month
- In refrigerator (2-10° C), buffer will be stable for 2 months.

Do not mix buffer with another lot.

Do not pour more buffer solution into the bottle.

Do not use precipitated buffer, precipitant of the buffer may cause the troubles.

3. OC-Calibrator 2 Kit (V-PH52)

OC-Calibrator 2 Kit is supplied ready to use. Calibrator should be stored at 2-8°C and is stable until the expiry date, even when opened.

OC-SENSOR io stores up to 3 calibration curves in the memory. The calibration curve is stable without time limitations and only requires changing under the following conditions:

- When the lot of latex reagent is changed.
- When the value of OC-Control (LV1, LV2) doesn't come up to the indicated range.
- When opened latex reagent bottle is stored at 2-10°C for over 2 weeks or is stored in the reagent bottle cradle for over 7 days.
- Following some maintenance support procedures

4. OC-Control LV1 & LV2. (V-PH53, V-PH54)

OC-Control LV1 & LV2 are supplied ready to use. Controls should be stored at 2-8°C and is stable until the expiry date, even when opened.

Minimum requirements are to analyse the both controls before analysis on a daily basis.

5. Preparation of the wash solution.

Make 0,15% NaClO of the 3% stock solution with deionised water (15 mL + 485 mL).

6. Preparation of the purified water.

Refresh the purified water every day.