

ENGLISH

Product code: 66090

HM-CODIAM



Contains the Operation Manual of HM-CODIAM, HM-JACK Reaction Cell and Sample Cup

“For Professional Use Only”

The instrument is an automatic analyzer that mixes specimens or samples with reagents and quantitatively measures the target substance by measuring the absorbance of the reacting mixture. The instrument is for in vitro clinical laboratory test use only. (In vitro Diagnostic Medical Device) Intended to be used by professional users.

This instruction for use (hereinafter this instruction) describes how to handle the instrument and its accessories, HM-JACK Reaction Cell, HM-JACK Sample Cup, and the Wash Liquid (Auto Detergent H).

HM-JACK Reaction Cell (hereinafter referred to as reaction cell) is a disposable container for reacting reagents and specimen.

HM-JACK Sample Cup (hereinafter referred to as sample cup) is a disposable container for holding specimen for measurement. In addition, Wash Liquid (hereinafter referred to as detergent) is a Wash Liquid for cleaning the nozzle and stirring spatula.

Before start using the instrument, please read this instruction thoroughly, and use the instrument properly.

[Intended Use]

This product is an automatic analyzer that mixes specimens or samples with reagents and measures the target substance by measuring the absorbance of the reacting mixture.

[Measurement Principles]

Photometric measurement is performed every 18 seconds to obtain absorbance (Abs.) data. Concentration is calculated based on the calibration curve from the absorbance change (Δ Abs.) from the reaction start point to the reaction end point.

[Instrument Outline]

Measurement operation

The reagent nozzle aspirates the buffer solution and reagent from the bottles and dispenses it to a reaction cell placed on the reaction table.

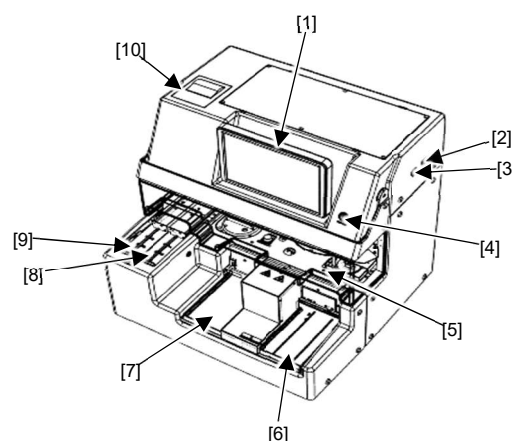
Next, after the sample nozzle aspirates the sample from MC Collection Picker and dispenses it into the reaction cell, the Sample (buffer solution, reagent, and sample) in the reaction cell is stirred with a stirring spatula. The reaction table rotates every 18 seconds and photometric measurement is performed.

Configuration of the instrument

The names of parts/accessories of the instrument are as follows.

- [1] Touch screen
- [2], [3] USB port
- [4] Power on button
- [5] Front cover
- [6] Rack loading part
- [7] Rack unloading part
- [8] Cell cassette table (right)
- [9] Cell cassette table (left)
- [10] Printer

Please refer to the “Operation Manual” for details.



Dimension

Dimension	650 mm×615 mm×700 mm (W x D x H) (Not including protrusions)
Weight	80 kg or less

Electric rating

Rated voltage	100-240V ±10%
Frequency	50/60Hz
Power consumption	300VA or less

[Installation Environment]

- (1) Condition relates to electricity and noise
 - Power supply voltage AC100-240V \pm 10%, 50/60Hz
 - Power consumption 300VA or less
- (2) Temperature and humidity conditions during use
 - Operating temperature 15-33°C (Fluctuation within \pm 2°C during analysis)
 - Operating humidity 10-85%RH (Do not condense.)

[Installation Condition]

Please secure the space to install the instrument. Leave a space of 30 cm or more on the left side to open the dust box, and a space of 15 cm or more on the back and right sides. Prepare a sturdy installation stand that takes into account the weight of the instrument.

[Fundamental Operation]

Please refer to the "Operation Manual" for details.

Preparation of measurement

- (1) Press the Power on button until its color changes to green.
- (2) Set the buffer bottle/reagent bottle on the reagent table.
- (3) Set the cell cassette on the cell cassette table. (If necessary)
- (4) Set the printer paper. (If necessary)
- (5) Tap [Reagent Check].

Preparation and measurement of calibrator

- (1) Prepare CAL rack and calibrator.
- (2) Set a sample cup on CAL rack.
- (3) Insert the CAL information card into the CAL rack with the bar code side facing the front.
- (4) Set the CAL rack to the rack loading part.
- (5) Tap [Start].
- (6) Confirm measurement results.

Preparation and measurement of control

- (1) Prepare QC rack and control.
- (2) Set a sample cup on QC rack.
- (3) Insert the CAL information card into the CAL rack.
- (4) Set the QC rack to the rack loading part.
- (5) Tap [Start].
- (6) Confirm measurement results.

Preparation and measurement of samples

- (1) Prepare Sample rack.
- (2) Set the EXTEL HEMO AUTO MC Collection Picker on the Sample rack.
- (3) Set the Sample rack to the rack loading part.
- (4) Tap [Start].
- (5) Confirm measurement results.

Procedure after measurement complete

- (1) Maintenance.
- (2) Discard the used reaction cell of cell dust box.
- (3) Discard the samples on the rack.
- (4) If buffer solution /reagents remain, cap the bottle, and keep the bottle refrigerated.
- (5) Fill deionized water tank with deionized water and detergent tank with wash liquid.
- (6) Empty the waste tank.
- (7) Tap [Shutdown].

[Warnings and Precautions]

Prevention from ignition and damages

- (1) Use the instrument correctly according to the installation environment and installation conditions described in this instruction.
- (2) Installation and adjustment of the instrument is performed only by our certified workers.
- (3) If you would like to change installation condition, contact your local distributor.
- (4) If the instrument malfunctions, stop the instrument immediately and contact your local distributor.
- (5) Never use flammable or explosive gases near the instrument because it is not explosion proof.

Precaution for operation of the instrument

- (1) It is extremely dangerous to open the front cover during measurement, so be sure to close it before use.
- (2) Opening the front cover stops sampling after a certain period of operation. Do not touch the moving parts until the sampling operation and reagent dispensing operation have completely stopped.
- (3) The tips of the sample nozzle, reagent nozzle, and stirring spatula are sharp, so be careful not to injure yourself or get infected.
- (4) Use protective equipment during operation.
Never use flammable or explosive gases near the instrument because it is not explosion proof.
- (5) Observe the following when handling the power cord.
Damage to the power cord may cause fire, electric shock, or electric leakage.
 - Do not twist.
 - Do not pinch between products, walls, etc.
 - Do not bend forcibly.
 - Do not put heavy things on the instrument.
 - Do not bundle.
 - Do not modify or replace with improperly rated cord.
 - Keep away from heating application.
 - Do not pull (When pulling out the power plug, be sure to hold the power plug without pulling the cord).
 - Do not do anything else that could damage the power cord.
- (6) Inspect regularly to remove dust from the power plug.
Accumulation of dust can cause a fire.
- (7) Make sure that the power plug is firmly inserted all the way into the outlet.
Poor contact will generate heat and cause burns or fire.
- (8) When not in use, turn off the main power switch and disconnect the power cord.
Do not leave the instrument with the power plug inserted.
- (9) Do not allow the power cord and power plug to get wet.
It may cause electric shock or electric leakage.
- (10) Do not touch the power plug with wet hands.
It may cause electric shock.
- (11) Do not pass the power cord through passages, etc.
There is a risk of short circuiting the power cord.
- (12) Use the power on button (and the breaker of the original power supply) to turn on the power.
When the power is turned on with the plug of the power cord (by unplugging and plugging the cord), the plug may generate heat.
- (13) When unplugging the power cord from the outlet, hold the plug without pulling on the cord.
- (14) Please use in an environment where electrostatic discharge does not occur.
If the instrument is used in a dry environment, harmful electrical discharges, especially in the presence of chemical fibers (synthetic fiber clothing, carpets, etc.), can cause incorrect measurement results.
- (15) Use the instrument under the conditions specified in this instruction.
- (16) Do not allow the instrument to get wet. Also do not place it in a place where it may get wet.
If the instrument gets wet, unplug the instrument's power plug before touching it.
- (17) Do not use other than the purposes described in this instruction.
- (18) Do not use if the instrument does not operate normally or is damaged.
 - Ex 1) Damaged power cord or its plug.
 - 2) Damage caused by dropping the instrument.
 - 3) Damage caused by dropping the instrument into water or getting the instrument wet.
- (19) Do not block the vent of the instrument and place the instrument on a soft surface that can block the vents.
- (20) Be careful not to let lint, hair, fluff, etc. get into the vents of the instrument.
- (21) Do not place anything on the instrument.
- (22) Do not drop or insert anything into the openings, pipes or joints of the instrument unless explicitly stated in this instruction.
- (23) Do not get on the instrument
- (24) Before cleaning, be sure to turn off the power first, and then unplug the power cord from the outlet.
- (25) When an abnormality occurred, immediately turn off the power, stop the operation, and unplug the power cord from the outlet.
Leaving the abnormality unattended may cause an accident or fire.
- (26) Do not repeat the power ON/OFF operation frequently.
It may cause a malfunction of the instrument.

Precautions regarding EXTEL HEMO AUTO MC Collection Picker, sample cup, reaction cell, and medical wastes.

- (1) Please give full consideration to prevent infection.
Specimens (EXTEL HEMO • AUTO MC Collection Picker (hereinafter referred to as EXTEL HEMO AUTO MC Collection Picker)), used reaction cells, and sample cups, may be contaminated with pathogens.
- (2) Please wear medical rubber gloves when handling.
Be careful not to touch with your bare hand and wash your hands after handling.
- (3) Please read the Instruction for Use carefully and understand the contents regarding the handling of EXTEL HEMO AUTO MC Collection Picker and reagents.
- (4) Dispose of waste properly.
For medical waste such as used sample, be careful not to damage the surrounding environment and health, and ask a professional contractor to dispose of it.
Items corresponding to medical waste
 - Waste fluid
 - Used reaction cell
 - Reagent and reagent bottle
 - Buffer solution and buffer bottle
 - Used EXTEL HEMO AUTO MC Collection Picker
 - Calibrator before/after preparation
 - Container for calibrator
 - Used sample cup
 - Container for control
- (5) Do not use anything other than the EXTEL HEMO AUTO MC Collection Picker, sample cup, and reaction cell dedicated to the instrument.

Precaution for electromagnetic compatibility

The instrument complies with the mission and immunity requirements specified in the EMC standard JIS C61326-2-6 (IEC 61326-2-6), and is designed and tested in accordance with CISPR11 Class A. Depending on the adjacent instrument, the noise from that instrument may affect the measurement results and operation of the instrument, and the noise from the instrument may affect the performance of the adjacent instrument. In addition, it may cause radio interference in the home environment etc., in which case it is necessary to take measures to reduce the interference.

Evaluate the electromagnetic environment and take countermeasures as necessary prior to the operation of the instrument.

Precaution for electromagnetic waves

- (1) Do not bring equipment that emits large electromagnetic waves close to the instrument.
- (2) Do not intentionally bring mobile phones, cordless phones, transceivers, etc., close to the instrument.

Precautions for installation environment

- (1) Please secure the following installation environment.
Indoor use only.
 - A place where does not expose the instrument to direct sunlight or overly bright lighting.
 - A place with little dust (Pollution level 2 as defined by IEC and UL standards)
 - Flat place with little slope (Slope 1/200 or less)
 - A place with little vibration
 - A place where does not exceed an altitude of 2000m.
 - A place without corrosive gas.
 - The air conditioning wind should not hit directly.
(In case there is concern about reagent concentration.)
- (2) Installation and adjustment of the instrument is performed only by certified workers.
If you would like to install or change the location, contact the local service provider.
- (3) Connect the power plug directly to a wall outlet.
The instrument should be connected directly to a wall outlet. Using an extension cord or tap may cause overheat and a fire from the cord.
- (4) Ground the power plug
Use an outlet with a ground terminal to ensure a ground connection. If the ground connection is not complete, it has a risk of electric shock.

Security

- (1) Operations related to system settings may be restricted by user authority to prevent erroneous operations.
- (2) For the data handled by the instrument, sample management is performed by ID (including barcode ID)
- (3) External memory device (USB flash drive)
Please perform virus check in advance to save the measurement results etc.
In addition, infection via the USB port is avoided by suppressing the auto play function.

[Storage]

- (1) Store in a location that is not exposed to water.
- (2) Store in a place where there is no risk of adverse effects from atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, air containing salt, and sulfur.
- (3) Pay attention to safe conditions such as tilting, vibration, and impact (including during transportation).
- (4) Do not store where chemical reagents are stored or where gas is generated.
- (5) Storage temperature: 5-50°C
- (6) Storage humidity: 10-85%RH (Do not condense.)
- (7) Service life: 7 years

[Maintenance Operation]

- (1) Maintain the following items.
Please refer to the "Operation Manual" for details.

Item	Maintenance/inspection cycle
Cleaning each tank	Monthly

- (2) Parts replacement and maintenance will be performed based on the followings by certified service personnel.

Maintenance/parts	Approximate replacement cycle
Periodical maintenance	1 year
Deionized water tank filter	
Detergent tank filter	
Pump tube	2 years
Button battery	3 years

[Bundled Items]

No.	Name	Quantity	Description/Remarks
1	Instrument	1	HM-CODIAM
2	Deionized water tank	1	5L tank
3	Detergent tank	1	2L tank
4	Waste tank	1	5L tank
5	Deionized water tube	1	Deionized water tank connector Φ5
6		1	Deionized water tank connector Φ6
7	Detergent tube	1	Detergent tank connector
8	Waste tube	1	For connecting waste fluid
9	Deionized water volume sensor (Hereinafter referred to as deionized water sensor)	1	For deionized water tank
10	Detergent volume sensor (Hereinafter referred to as detergent sensor)	1	For 2L detergent tank
11	Waste fluid volume sensor (Hereinafter referred to as waste fluid sensor)	1	For waste tank
12	Deionized water tank filter	2	Impurity filtration in tank
13	Detergent tank filter	1	Impurity filtration in tank
14	Power cable	1	Power supply
15	Sample rack (white)	8	For sample measurement
16	Dilution rack (blue)	1	For dilution measurement
17	CAL rack (yellow)	1	For CAL measurement
18	QC rack (white)	1	For QC measurement
19	Cup rack (Black)	1	For sample cup measurement
20	HM.Printer paper A	1	For printing measurement results
21	Dust bag	1	1 set for disposal cell (100 sheets)

Other

No.	Name	Quantity
1	Instruction for use	1
2	Operation Manual	1
3	Quick Reference	1
4	HM-JACK Reaction cell	1
5	HM-JACK Sample cup	1
6	50 mL bottle	1
7	Cap (Light blue)	1

[Consumables list]**(1) HM-JACK Reaction Cell**

Disposable containers for reacting reagents and specimen.

Product code 53150

Package configuration 40 cells/cassette x 25

Storage condition Store in a building avoiding from light, heat, and humidity.

Expiration date Use by the expiration date indicated on the product box label.

(2) HM-JACK Sample Cup

A disposable container to pour the sample for measurement.

Product code 53151

Package configuration 500 units

Storage condition Store in a building avoiding from light, heat, and humidity.

Expiration date Use by the expiration date indicated on the product box label.

(3) Wash Liquid (Auto Detergent H)

Product code 52404



















Package configuration 200 mL x 1













(4) HM.Printer paper A

Product code 57848

Package configuration 1 unit

[Definition of Symbols]

Symbol	Description	Symbol	Description
	Serial number		This side up
	Manufacturing date		Do not stack
	Manufacturer		Fragile, handle with care
	European Community/European Union authorized representative		Keep away from sunlight and heat.
	UK Responsible Person		Keep dry
	Professional use only		Temperature limit
	Refer to instruction for use		Caution
	In vitro diagnostic medical device		Biological risk
	CE marking		Beware of electric shock

Symbol	Description	Symbol	Description
	UKCA marking		Beware of hot part
	WEEE marking *1		Beware of light
	Power supply	I	On (power supply)
	Do not reuse	O	Off (power supply)
	Handle with care		Catalog number
	Use no hook		Batch code
	Expiration date		Contents

*1 :

Only for European Union and EEA (Norway, Iceland and Liechtenstein)



These symbols indicate that this product is not to be disposed of with your household waste, according to the WEEE Directive (2012/19/EU), the Battery Regulation((EU) 2023/1542) and/or national legislations implementing those Directive and Regulation.

If a chemical symbol is printed beneath the symbol shown above, in accordance with the Battery Regulation, this indicates that a heavy metal (Pb = Lead) is present in this battery at a concentration above an applicable threshold specified in the Battery Regulation.

This product should be handed over to a designated collection point, e.g., on an authorized one-for-one basis when you buy a new similar product or to an authorized collection site for recycling waste electrical and electronic equipment (EEE) and batteries and accumulators. Improper handling of this type of waste could have a possible impact on the environment and human health due to potentially hazardous substances that are generally associated with EEE. Your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources.

In the EU, there are separate collection and recycling schemes for batteries. To find out more about recycling schemes for batteries available in your area, please contact the local service provider.

Note

- (1) In this instruction, the unit is expressed in SI (International System of Units).
- (2) Reproduction of part or all of the contents of this instruction without permission is prohibited.
- (3) The contents of this instruction are subject to change without notice due to improvements in performance and functions.
- (4) Illustration etc. described in the text of this instruction may be partially different from actual products.
- (5) Although every effort has been made to ensure the contents of this instruction, if you have any suspicious points, errors, or notice, please contact the local service provider.
- (6) Please report any serious incident associated with the product to the below address and the competent authority of the member state.



Minaris Medical Co., Ltd.
1-8-10, Harumi, Chuo-ku, Tokyo,
104-6004 JAPAN
Tel: +81-3-6219-7600
Fax: +81-3-6219-7614



Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium



Alpha Laboratories Ltd.
Unit 40 Parham Drive Eastleigh
Hampshire SO50 4NU
United Kingdom