

TAN Bead Nucleic Acid Extractor (Non-Sterile)

Maelstrom Switch 8 User Manual

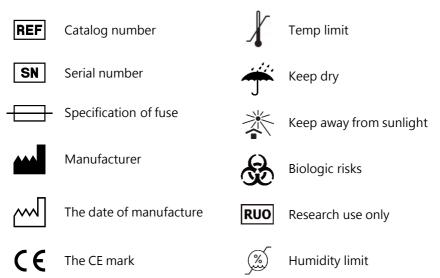
Rev V1.1

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About Manual

The label on the instrument, User Manual, and other packaging material may contain following symbols:





Instructions for Use



Non-sterile



Biologic risks



Hot surface, risk of burns



Caution



The WEEE symbol, indicating separate collection for WEEE-Waste of electrical and electronic equipment

About Instrument

Warning

- Use a power cord that meets your country's standard. In case of any questions, contact your local distributor for assistance.
- Maelstrom Switch 8 operates within the voltage range from 100 Volts to 240 Volts.
- Do not use the instrument with damaged power cord or a loose socket.
- To unplug, hold the power plug itself instead of pulling the power cord.
- Prior to performing the maintenance, make sure to unplug the power plug from the outlet.
- Do not pour any liquid on the instrument.
- Do not place any containers with liquid on the instrument. Doing so may cause a fire, an electric shock or malfunctions of the instrument.
- Do not touch the power plug or cord if there is a chance of lightning. Failure to observe this may cause electric shocks.
- If you hear a thunder or suspect an approaching lightning when in use, turn off the power switch and disconnect the power plug from the AC outlet immediately. Failure to observe this may cause a fire or malfunctions.

About Instrument

Caution

- Never attempt to remodel the instrument without the permission from the manufacturer. Doing so may lead to a fire or an electric shock.
- Do not subject the instruments to any impacts and do not knock it. Doing so may cause malfunctions.
- Any repairs to the instrument must be performed by agencies authorized by Taiwan Advanced Nanotech Inc.
- Only use the original spare parts supplied by Taiwan Advanced Nanotech Inc on the instrument.
- If the equipment is used in a manner not specified by the manufacturer, the protection given by the instrument may be impaired or invalid.
- User and/or patient the need to report any serious incident that occurred in relation to the device to the manufacturer and to the competent authority of the Member State where the user and/or patient is established.

About

Maelstrom Switch 8 is an automated nucleic acid platform designed for Flexible Applications. Specialized spin tips enable mixing efficiency of magnetic beads. With intuitive interface and compatible with Tanbead reagent kits. Maelstrom Switch 8 can boost molecular diagnostic laboratory productivity by transforming routine operations into a walk-away solution.

Operation Principle

Maelstrom Switch 8 uses patented magnetic beads, spin tips and reagent kits technologies , consisting of three major processes: isolation, purification and concentration.

Intended Purpose/Intended Use

- Maelstrom Switch 8 shall be used in combination with TANBead Nucleic Acid Extraction Kit to extract DNA/RNA from various sample types.
- Maelstrom Switch 8 can handle magnetic beads for extraction and purification of nucleic acid.
- Please note that this medical device is used by physicians or medical technologists.
- The purified nucleic acid can be used with any downstream application employing PCR-based qualitative, semi-quantitative and quantitative assays.

Sample Type

Maelstrom Switch 8 automated nucleic acid extractor is not applicable for specimen collection. It equipped with different types of TANBead Nucleic Acid Extraction kits, which can extract and purify nucleic acids from biological samples. Please refer to the following for sample type and compatible reagent kits required.

Sample	Reagent kits		
Blood	61E series	611 series	621 series
biood	622 series	91E series	
cfDNA	61C series		
Virus	615 series	635 series	665 series
VIIUS	685 series	61H series	
Bacteria	61G series	61G-SE series	6MB series
	6BG series		
Tissue	6T2 series	6K2 series	
FFPE	61P series	62P series	
Stool	6SC series		
Plant	613 series	613-SE series	6K3 series
Fungi/Yeast	61F series		
Environment sample	6EM series		
Food and	6GM		
feed	series		
Forensic	6TF series		
Plasmid	6PE series	9PE series	

Environmental Requirements

To avoid shortening the lifespan of the instrument, use Maelstrom Switch 8 in a location that meets the following criteria:

- Choose a location with good air circulation.
- Place Maelstrom Switch 8 on the table that can bear at least 20 kg.
- Do not use Maelstrom Switch 8 in a location where is with huge temperature and humidity variability.
- Operate condition: Temperature: 10-40°C Relative humidity: 40-80%
- Storage and transport condition: Temperature: 5-50°C Relative humidity: 20-85%
- Maximum operate altitude: 2000m

Safety Instructions and Guidelines

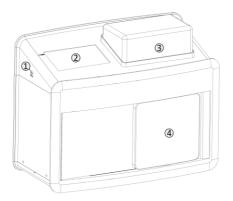
- This device can be used with potentially biohazardous materials. Use appropriate personal protective equipment (gloves, safety goggles, lab coat, etc.) for handling and disposing of biohazardous materials.
- Under a normal condition, sound pressure level from Maelstrom Switch 8 does not exceed 80dB and does not cause a hazard. Please contact technical support for assistance in case of a higher sound pressure level.
- This device can be hazardous due to the use of chemical and biohazardous substances.
- Users should adhere to their institutional guidelines for the handling and disposal of all infectious substances used with this device.
- It is important to clean the device after every use. If samples or reagents have been spilled, clean the instrument immediately to avoid damage or contamination.
- This device is to use with the compatible spin tips. Using incompatible spin tips may cause poor extraction performance.
- Read this user manual completely prior to operating the device. Failure to read, understand, and follow the instructions in the manual may result in damage to the device, injury to laboratory and operating personnel or poor performance.

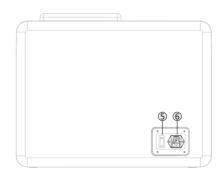
Safety Requirements

- The device has passed the tests and conformed to the standards of IEC 61010-1:2010+A1:2016 (Edition 3.1) and EN 6010-1:2010+A1:2019, "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements".
- The device has passed the tests and conformed to the standards of IEC 61010-2-101:2018 with IEC 61010-1:2010 + A1:2016 and EN 61010-2-101:2017 with EN 61010-1:2010 + A1:2019, "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment".

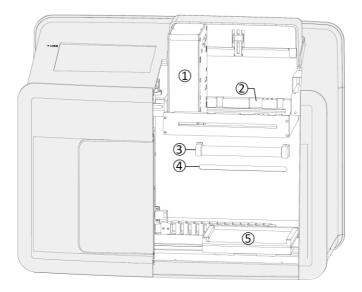
EMC Requirements

 The device has passed the tests and conformed to the standards of IEC 61326-1:2020 / EN IEC 61326-1:2021 & IEC 61326-2-6:2020 / EN IEC 61326-2-6:2021, "Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment".





- ① USB port
- 2 Touch screen
- 3 Top lid
- ④ Door lid
- (5) Power switch
- ⁽⁶⁾ Power inlet



- 1 Fixed gearbox
- 2 Guide rail
- 3 UV light
- ④ LED light
- (5) Loading position

Accessory

Following accessories may vary region-to-region.



Power cord



Magnetic separator

Accessory

Following accessories may vary region-to-region.



4 gearbox



24 heating block



8 gearbox



96 heating block



8+ gearbox

Consumables

Maelstrom Switch 8 uses specially designed for optimal processing. Use of other types of pates may damage the instrument and compromise the warranty



24 deep well holder



24 deep well



holder



24 spin tip

Consumables

Maelstrom Switch 8 uses specially designed for optimal processing. Use of other types of pates may damage the instrument and compromise the warranty



96 deep well



96 spin tip holder



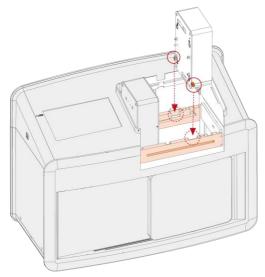
16 base B



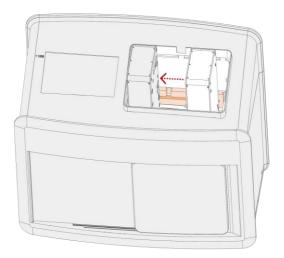
96 spin tip

16 auto tube

Please follow instruction below while change different gearboxes.

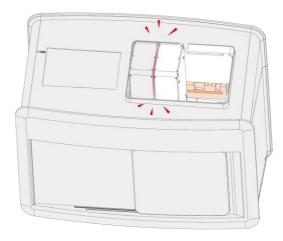


Step 1: Locate gearbox on guide rail



Step 2: Push gearbox to left side

Please follow instruction below while change different gearboxes.

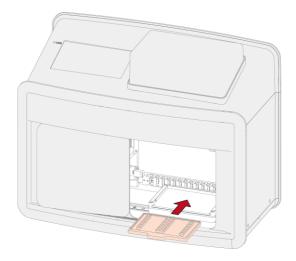


Step 3: Make sure gearbox is attached firmly

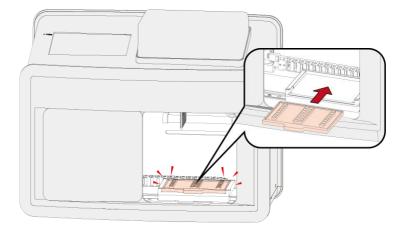


Please turn off the instrument before change gearbox.

Please follow instruction below while change different heating blocks.









The heating plate surface may be hot during operation and change. Use caution to avoid risk of burns.

3. Instrument Specification



ITEM	SPECIFICATION	
Model	Maelstrom Switch 8	
Weight	N.W. 16.5kg G.W. 23.0kg	
Dimensions	Instrument 524(W)x265(D)x412(H)mm Package 638(W)x426(D)x568(H)mm	
Power rating	100~240Vac, 2.3~1.1A, 50/60Hz	
Fuse	T5A L 250V	
Max. Throughput	Low Volume: Max 16 samples/run High Volume: Max 4 samples/run	
Process volume	Low Volume: 50~1,200μL High Volume: 100~9,000μL	
Spin speed	500~3,000rpm	
Heater	1 independent heater	
Magnetic rod	Low Volume: >3,900 gauss High Volume: >4,700 gauss	
Display	7" touch screen	
UV light	UV-C	

4. Installation & Get Started

Please note that this instrument weight is around 20kg, it is highly recommended to have 2 individuals or above to handle when taking it out from the box and be sure to work safety.

Step 1:

Take out the instrument from the box, 2 or more individuals is highly recommended.

Step 2:

Remove the cushions around the instrument.

Step 3:

Place the instrument on a flat table that bears over 20 kilograms.

Step 4:

Connect the power. Please note that this instrument is compatible with 100-240Vac power only. Using wrong power source will lead to malfunction or damage.

Step 5:

Power on the instrument and it will perform initialization.

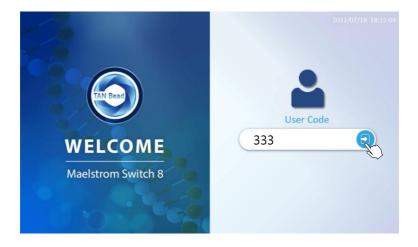
Warning: This product contains very strong permanent magnets. People wearing a pacemaker or metallic prostheses should not use this product. A pacemaker or prostheses may be affected or damage if it comes in close contact with a strong magnetic field.

5. Software Applications

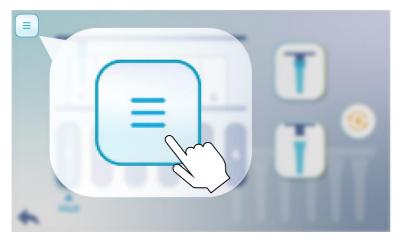
Start



It takes seconds for system ready.



Please input a User Code 333 to access the system. In case of forgotten password, contact distributor or Taiwan Advanced Nanotech Inc. for assistance.



Press Toolbar to use following function.



- ① Back to Homescreen
- ② Turn on/off LED
- ③ Get the version information
- ④ Update software and firmware

Home Screen



Home screen on the Maelstrom Switch 8 is used for following functions.

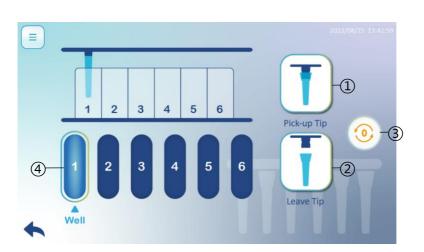
- ① Change User
- ② Current Temperature



Pick-up and leave tip(s)

U

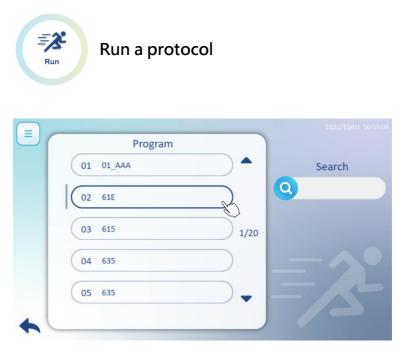
Tip



Caution: Before a run,

- ① Pick-up Tip : Press the icon to pick up tips.
- ② Leave Tip : Press the icon to leave tips.
- ③ Origin: Press the icon to initialize instrument.
- Well : Press the icon 1~6, Pick-up or Leave tips in different positions.

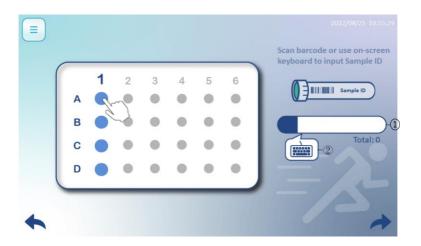




Switch 8 has an impressively large store of 100 programs. Chose a program which is preinstalled and in line with reagent kit. Type in key words in search box to look for a program sooner.

=)		
	Program 61E	
	Kit Lot.	
	Tip Lot.	52-
		- A

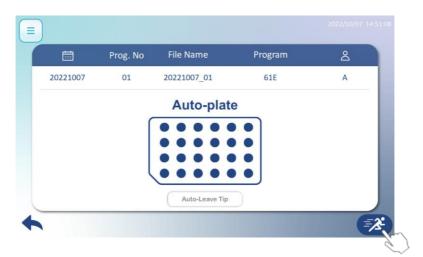
Type in Kit lot and Tip lot numbers for further tracking. Press arrow to proceed next page.



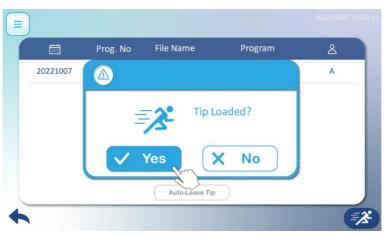
Press a circle(A1~D1) to input sample ID by using 1-D barcode (1) barcode or (2) manual type in.



A circle turns yellow when inputs sample ID successfully. Then it moves to next sample ID automatically. E.g. $A1 \rightarrow B1$, $B1 \rightarrow C1$ etc. Press arrow to proceed next page.



Please check above information is correct such as Date, Program No., File Name etc. Press run icon to execute program.



Please check Tip(s) is/are loaded. Press Yes to begin the program.

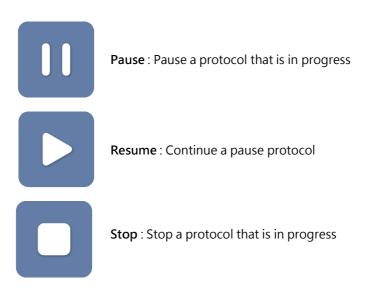


Program will be executed until temperature reaches setting value.



Realize following symbols is highly recommended. It helps you acknowledge protocol status.

- ① Current Step
- ② Star Time, Estimated Time, Pause Time
- ③ PV refers to the actual temperature. SV is really the set value.





Mix : This step is to mix beads and reagents



Collection : This step is used for collecting the magnetic beads from the wells of the plate, press Pause or Stop. Maelstrom Switch8 is not action immediately until finish collection.



Vapor : This step dries the magnetic beads above a well or tube.



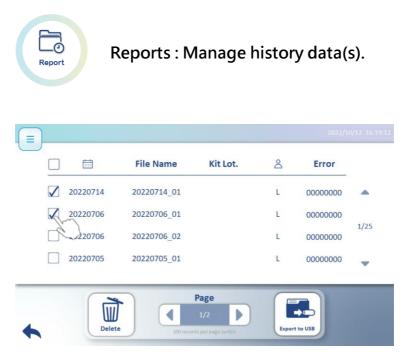
Completion : Buzzer rings up after a protocol finished.



Pause : Pause a protocol



Well 1 to 12, number of well and name of buffer varies from kits to kits.



Please press the square(s) to delete data(s) or export data(s) to USB.



UV lamp : Switch the UV lamp on/off.



Set UV light, then press bulb to star.

Please close the door before turn on the UV light, running time is recommended over 30 minutes.

Home Screen



Home screen on the Maelstrom Switch 8 is used for following functions.

- ① Change User
- ② Current Temperature



Pick-up and leave tip(s)

U

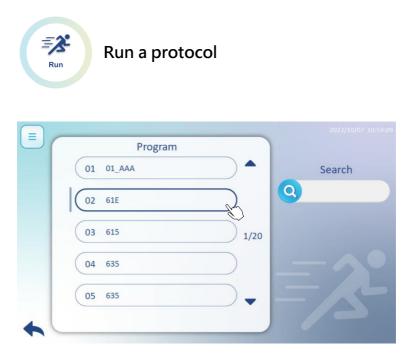
Tip



Caution: Before a run,

- ① Pick-up Tip : Press the icon to pick up tips.
- ② Leave Tip : Press the icon to leave tips.
- ③ Origin: Press the icon to initialize instrument.
- Well : Press the icon 1~6, Pick-up or Leave tips in different positions.





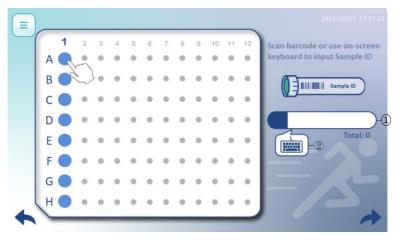
Switch 8 has an impressively large store of 100 programs. Chose a program which is preinstalled and in line with reagent kit. Type in key words in search box to look for a program sooner.

Program 61E	
Kit Lot.	
Tip Lot.	

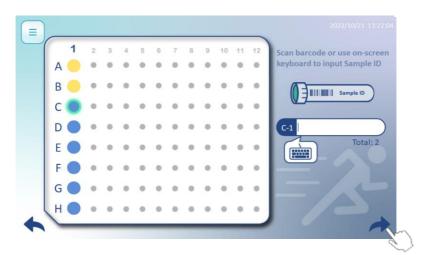
Type in Kit lot and Tip lot numbers for further tracking. Press arrow to proceed next page.



Choose a position Left or Right to run a protocol. Press arrow to proceed next pate.



Press a circle(A1~H1) to input sample ID by using 1-D barcode (1) barcode or (2) manual type in.

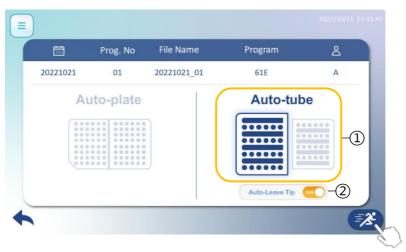


A circle turns yellow when inputs sample ID successfully. Then it moves to next sample ID automatically. E.g. A1 \rightarrow B1, B1 \rightarrow C1 etc. Press arrow to proceed next page.



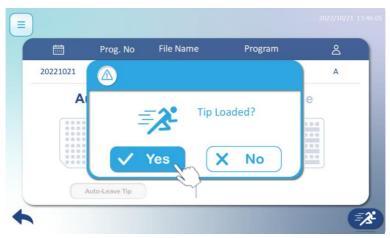
Chose Auto-Plate, Tip(s) is auto-leave after finishing a run.

Please check above information is correct such as Date, Program No., File Name etc. Press run icon to execute program.



- 1) Chose Auto-Tube
- 2 Tip(s) auto-leave can be turned on/off.

Please check above information is correct such as Date, Program No., File Name etc. Press run icon to execute program.



Please check Tip(s) is/are loaded. Press Yes to begin the program.

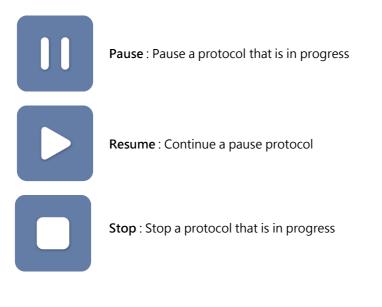


Program will be executed until temperature reaches setting value.

Run KitLot : 20220909 2 3 4 5 6 WB1 WB2 MB WB3 EB Program 01_AAA Step 1 (1)Collect 130µl / 3000rpm Mixing 00:06 Start 14:10 € PV. 0.0 °C (2)(3) End 14:13 11 Pause 00:00

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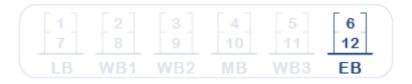
Vapor : This step dries the magnetic beads above a well or tube.



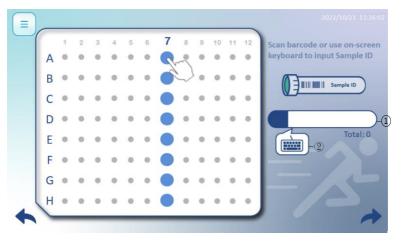
Completion : Buzzer rings up after a protocol finished.



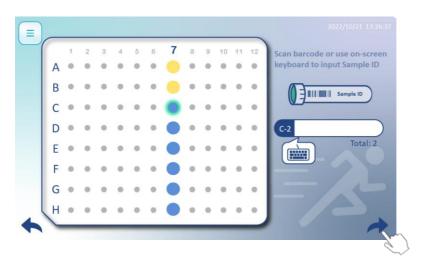
Pause : Pause a protocol



Well 1 to 12, number of well and name of buffer varies from kits to kits.



Press a circle(A7~H7) to input sample ID by using 1-D barcode ①barcode or ②manual type in.



A circle turns yellow when inputs sample ID successfully. Then it moves to next sample ID automatically. E.g. A7 \rightarrow B7, B7 \rightarrow C7 etc. Press arrow to proceed next page.



	Prog. No	File Name	Program	2
20221021	01	20221021_01	61E	А
A	uto-plate		Auto-tub	e
0000				
		:		
	Auto-Leave Tip			

Chose Auto-Plate, Tip(s) is auto-leave after finishing a run.

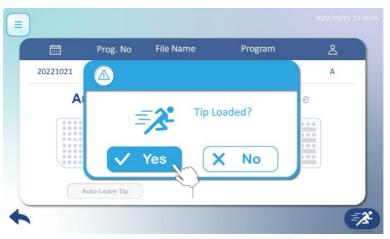
Please check above information is correct such as Date, Program No., File Name etc. Press run icon to execute program.

i	Prog. No	File Name	Program	8
20221021	01	20221021_01	61E	А
A	uto-plate		Auto-tub	e
			Auto-Leave Tip	
			Huto Leave tip	

① Chose Auto-Tube

2 Tip(s) auto-leave can be turned on/off.

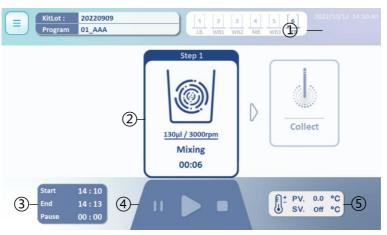
Please check above information is correct such as Date, Program No., File Name etc. Press run icon to execute program.



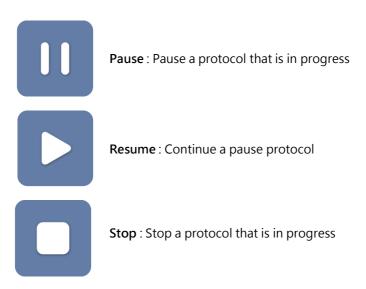
Please check Tip(s) is/are loaded. Press Yes to begin the program.



Program will be executed until temperature reaches setting value.



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Collection : This step is used for collecting the magnetic beads from the wells of the plate, press Pause or Stop. Maelstrom Switch8 is not action immediately until finish collection.



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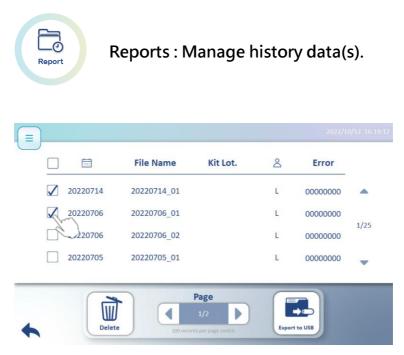
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Please press the square(s) to delete data(s) or export data(s) to USB.



UV lamp : Switch the UV lamp on/off.



Set UV light, then press bulb to star.

Please close the door before turn on the UV light, running time is recommended over 30 minutes.

Home Screen



Home screen on the Maelstrom Switch 8 is used for following functions.

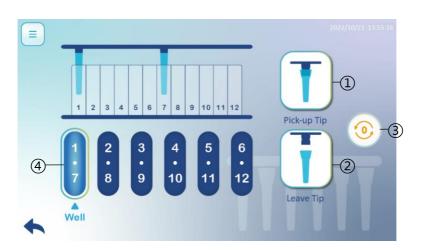
- ① Change User
- ② Current Temperature



Pick-up and leave tip(s)

J

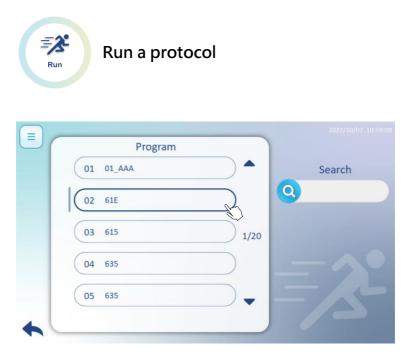
Tip



Caution: Before a run,

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- ③ Origin: Press the icon to initialize instrument.
- Well : Press the icon 1~6, Pick-up or Leave tips in different positions.

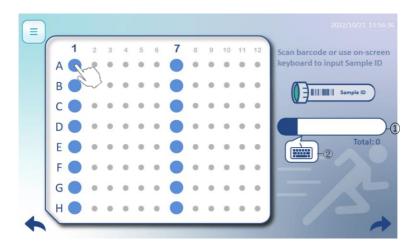




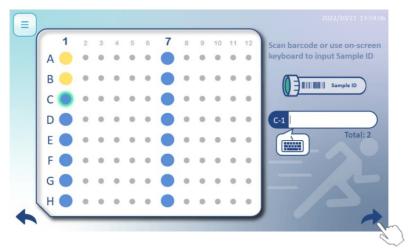
Switch 8 has an impressively large store of 100 programs. Chose a program which is preinstalled and in line with reagent kit. Type in key words in search box to look for a program sooner.



Type in Kit lot and Tip lot numbers for further tracking. Press arrow to proceed next page.



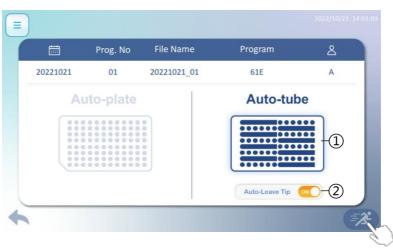
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A circle turns yellow when inputs sample ID successfully. Then it moves to next sample ID automatically. E.g. A1 \rightarrow B1, B1 \rightarrow C1 etc. Press arrow to proceed next page.

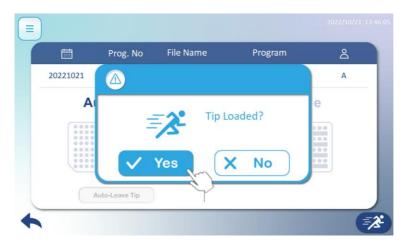


Chose Auto-Plate, Tip(s) is auto-leave after finishing a run. Please check above information is correct such as Date, Program No., File Name etc. Press run icon to execute program.



- ① Chose Auto-Tube
- ② Tip(s) auto-leave can be turned on/off.

Please check above information is correct such as Date, Program No., File Name etc. Press run icon to execute program.



Please check Tip(s) is/are loaded. Press Yes to begin the program.

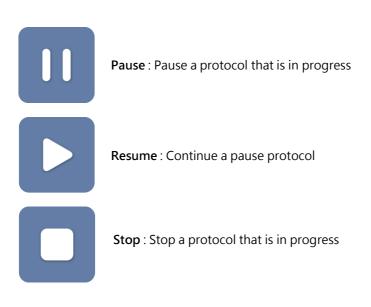


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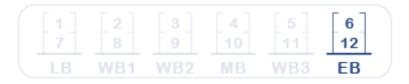
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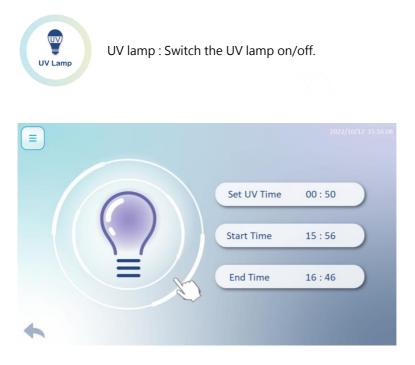
Pause : Pause a protocol



Well 1 to 12, number of well and name of buffer varies from kits to kits.

Repor	P F	Reports : N	lanage h	histor	y data(s).
					2022/1	0/12 16:19:12
		File Name	Kit Lot.	Po	Error	
	20220714	20220714_01		L	00000000	
R	20220706	20220706_01		L	00000000	
	220706	20220706_02		L	00000000	1/25
	20220705	20220705_01		L	00000000	-
•	Delet		Page 1/2	Export	t to USB	

Please press the square(s) to delete data(s) or export data(s) to USB.



Set UV light, then press bulb to star.

Please close the door before turn on the UV light, running time is recommended over 30 minutes.

6. Technical Support

In case of any questions, please try to contact our authorized distributor nearest to you. Taiwan Advance Nanotech Inc. provides post-sale services call number at +886-3-3167568 or via email: <u>service@tanbead.com</u> for assistance.

Please provide this instrument serial number when you talk to our technician, that will solve the problems efficiently and answer your questions more precisely.

7. Cleaning and Maintenance

- Clean the device after every use. When users detect samples or reagents have been spilled, clean the device immediately to avoid damage or contamination.
- Wear gloves and appropriate personal protective equipment. If the device is used with biohazardous materials, dispose of any cleaning materials used in accordance with your institutional guidelines.
- The device may go through a run with the magnetic rods unprotected. If this happens, the magnetic rod needs to be cleaned immediately.
- To clean the magnetic rods, wipe with a soft cloth dampened with pure water. Do not use alcohol solvent.
- If the magnetic rods cannot be cleaned, please contact TANBead (Tel: +886-3-3167568) for technical assistance.

8. Disposal

The decision whether or not to dispose of a potentially contaminated medical device is usually made by the owner in consultation with appropriate federal, state, and local authorities. In determining which medical devices should be discarded, the owner must assess each product's current condition and potential safety risks.

9. Patent

Patent List		
USA	US09616398B2	
EU	EP2937136	
Canada	CA2862946	
Japan	JP6151735B2	
Korea	KR101696517B1	
China	CN104971638B	
Taiwan	TWI526245B	
WIPO	WO2016127292	

10. About Manufacturer



- Manufacturer : Taiwan Advanced Nanotech Inc.
- Manufacturer Address : 4F, No. 188, Wenhe Rd. Guishan Dist., Taoyuan City 333, Taiwan (R.O.C.)
- Manufacturer Tel: +886-3-3167568

11. Appendix

Specification of Fuse:

- UL recognized component
- F5A L 250V
- 5.20 x 20mm

Precautions

Fuse Fuse

The following safety precautions will prevent injury to personnel and damage to equipment. There are the MINIMUM safety precautions for replacing fuse(s).

- 1. Turn the power off and discharge the circuit before removing a blown fuse.
- 2. Use a fuse puller (an insulated tool) when you remove a fuse from a clip-type fuseholder.
- 3. Please always replace the faulty fuse(s) with one equal in size, amperage, rating and type.
- 4. Turn the main power switch back on and see if electricity is restored.

12. Previous Generation

ITEM	SPECIFICATION
Model Name	Magnetic rotary mixer
Weight	600 g
Dimensions	112(W)x327(H)x63(D)mm
Power	5 Vac, 2 A
Battery	3.7 Vac , 2850mAh
Throughput	8 samples per run
Pro. volume	50 μl ~ 1,500 μl
Spin Speed	up to 3000 rpm
Magnetic rod	>3000 gauss
Display	2.4" LCD, 240 x 320 pixels



ITEM	SPECIFICATION
Model	Autostage
Weight	9.6 kg
Dimensions	357(W)x285(H)x190(D)mm
Power	19 Vac, 120 W
Heater	1 heating block