

TAN Bead Nucleic Acid Extractor (Non-Sterile)

039.M1701.E01 Rev V1.0

Maelstrom Switch 8
User Manual

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About Manual

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



Catalog number



Temp limit



Serial number



Keep dry



Manufacturer



Keep away from sunlight



The date of manufacture



EC REP EU authorized representative



The CE mark



Biologic risks



In Vitro Diagnostic Medical Device



Non-sterile



Humidity limit



Biologic risks



Instructions for Use



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 a 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 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 instrument 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 most representative brands 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 applied with patented Whirl-Spin Stirring technology for transferring magnetic beads with spin tips and reagent kits. Program consisting with three major processes: isolation, purification and concentration.

Intended Purpose/Intended Use

The Maelstrom Switch 8 is classified as a general laboratory instrument designed to manipulate magnetic beads across various reagents from different application kits, performing tasks such as nucleic acid extraction, protein isolation, and cell sorting. This adaptability to different gearboxes and adjustable settings facilitates compatibility with magnetic bead-based reagent kits from leading brands.

Its efficient bead transfer capabilities enable a wide range of applications for subsequent qualitative, semi-quantitative, and quantitative PCR assays. With its fully automatic operation, it reduces human error, ensuring consistent experimental reproducibility.

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

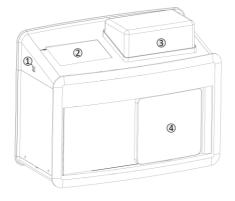
- This device can be used with potentially biohazardous materials. Use appropriate personal protective equipment (gloves, safety goggles, lab coat, etc.) for handling and disposing of biohazardous materials.
- Under a normal condition, sound pressure level from Maelstrom Switch 8 does not exceed 80dB 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.

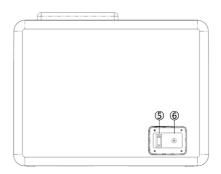
Safety Requirements

- 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".

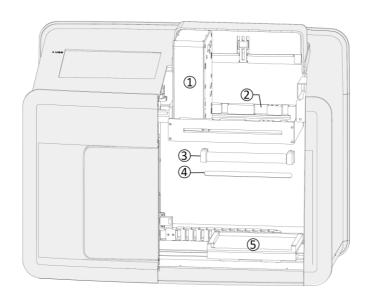
EMC Requirements

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** DC Power inlet



- 1 Fixed motor module
- ② Guide rail
- ③ UV light
- 4 LED light
- **⑤** Loading position

Accessory

Following accessories may vary region-to-region.



Power cord



Magnetic separator



Power adapter

Compatible Gearbox Sets

(A) Open Platform model (Gray)



Gearbox	Heating Plate		
CH 4 Gearbox Ø7.5(A)	24 Heating Plate F		
CH 8 Gearbox Ø3.5(A)	96 Heating Plate F		
CH16 Gearbox Ø3.5(A)			



(B) TANBead Platform model (Red)



Consumables

Maelstrom Switch 8 uses specially designed for optimal processing. Used with provided or compatible spin tip assembled box and deep well plates is a must. If applied with other types of consumables may damage the instrument and compromise the warranty. Contact us (service@tanbead.com) for further assistance if consumables other than suggested were needed.

(A) Open Platform model (Gray)





24 Spin Tips (Ø7.5) Assembled Box



96 Spin Tips (Ø3.5) Assembled Box



24 Deep Well Plate, v-bottom F



96 Deep Well Plate, v-bottom F

(B) TANBead Platform model (Red)





Spin Tips LV



96 Deep Well Plate



24 Spin Tip LV Holder



16 Base B



24 Deep Well Plate



6 Tube B



24 Deep Well Plate LV Base



Spin Tips Assembled Box

3. Instrument Specification

Maelstrom Switch 8	SPECIFICATION						
Model	Open Platform			TANBead Platform			
Weight	N.W. 16.2 kg ; G.W. 23.0 kg						
Dimensions	Instrument: 524(W) x 265(D) x 412(H) mm Package: 638(W) x 426(D) x 568(H) mm						
Power Rating	I/P: AC 100~240V, 2.8A Max, 50/60Hz O/P: DC 24V, 8.3 A						
Spin Speed	500~3,000rpm						
Display			7" touch	ouch screen			
UV Light	UV-C						
Application Reagents	Open to leading brands based on magnetic beads			TANBead: pre-filled plate, pre-filled single tube, bottle format			
Program	Customized program or assisted from TANBead			TANBead Built-In Programs			
Channels	CH 4	CH 8	CH16	CH 4	CH 8	CH16	
Gearbox							
Flux Per run	1~4	1~8	1~16	1~4	1~8	1~16	
Rod Size	Ø7.5(A)	Ø3.5(A)		Ø4.2(B)	Ø2.2(B)		
Magnetic Force (Gauss)	5,400	4,700		4,700	3,900		
Sample Volume (uL)	100~5,000 Max. 1500 rpm	50~1,200		100~9,000	50~1,600		

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: Install the System

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.

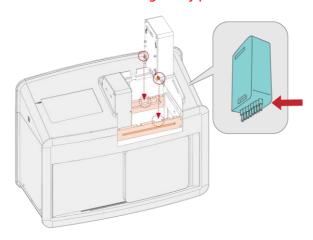
Step 4: Install Gearbox

Refer to the applying consumables to install the Gearbox module refer by following procedures.

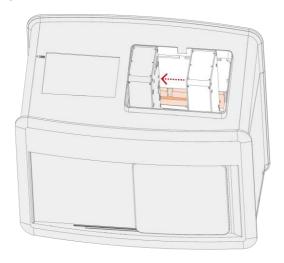
(A): Locate gearbox on guide rail



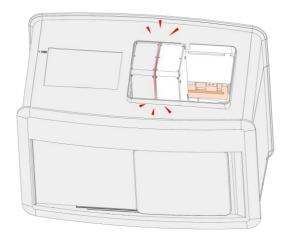
Do not "Power on" the instrument before install the gearbox. While manipulate the gearbox, please make sure the magnetic rods is safe from crushing to any parts.



(B): Push gearbox to left side



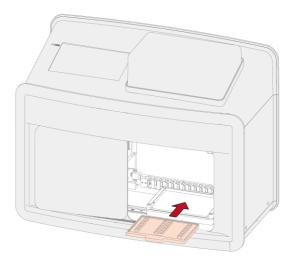
(C): Make sure gearbox is attached firmly



(D): Install the heating plate 96 or 24 wells accordingly

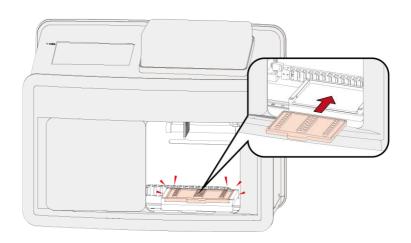


Keep heating plate horizontal during installation.





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



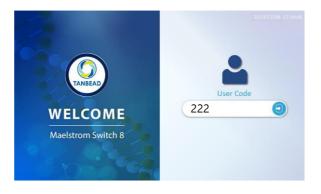
- · Step 5: Apply Power Cord
- Apply with the power cord and adapter. Please note that this instrument is compatible with AC 100-240V power only. Using wrong power source will lead to malfunction or damage.



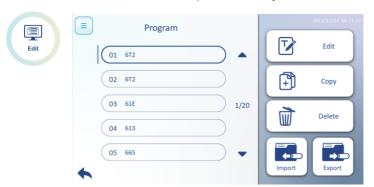
- · Step 6: Power On
- Power on the instrument and it will perform initialization.

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.

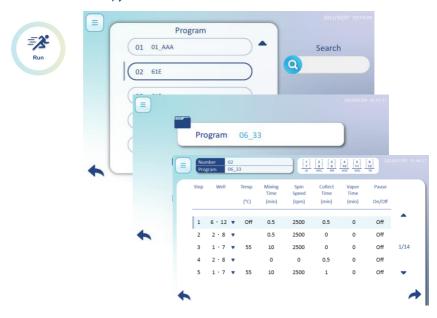
- Step 7: Enter user code
- Refer to next section for software operation to "Log-in" the system with "222" user code after the system start up.



- · Step 8: Edit Program
- Refer to section 5. to "Edit" the protocols for your reaction kits.



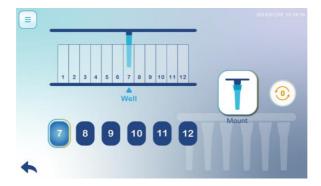
- · Step 9: Run Program
- Tap on "Run" and select present program to Run the extraction. And press on "



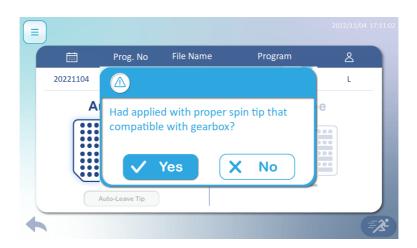
Select with "L" for left part of plate or "R" for the right. And press on " "
 to proceed. Refer to the container type to choose "Auto-plate" or "Auto Tube" and click on " to Start the run.



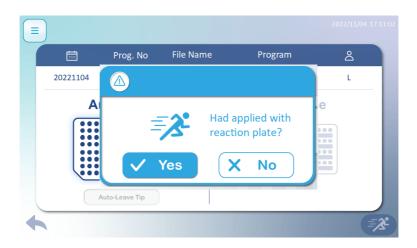
• Applied with spin tip assemble box and tap on "Mount" to pick up tip on selected lane.



 As the warning window pops, make sure to applied with correct spin tip assemble box onto the heating plate. And Press on "Yes" to pick up the tip. "No" to return previous page.



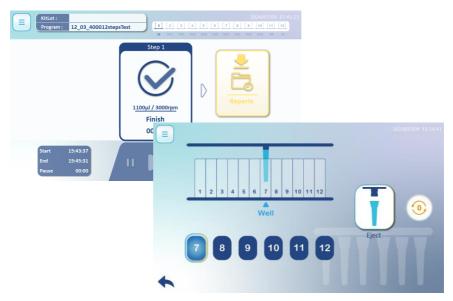
 After pick up the spin tip, warning window pops up again. Make sure to replace with prepared reaction plate into the chamber. Click on "Yes" to proceed.



· After heating up, the program will begin automatically.



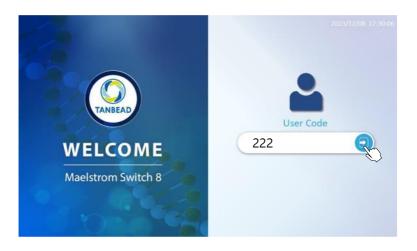
• After the program finished, press on "Report" to review the procedures. As close the report, request window pops. Select desire lane to "Eject" the spin tip before return to main menu.



Start



After power on the instrument, it takes seconds for system ready.



Please input a User Code 222 to access the system. In case of forgotten password, contact distributor or Taiwan Advanced Nanotech Inc. for assistance.

 After entering the home page, system will detect the type of gearboxes and display with different interface accordingly as followed. Also, the function of each icon will be different.

CH 4 Gearbox ø 7.5(A) for 4 channels gearbox



CH 8 Gearbox ø 3.5(A) for 8 channels gearbox



CH16 Gearbox ø 3.5(A) for 16 channels gearbox



General commends:



Press Toolbar to use following function.



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

"Home Screen" on the Maelstrom Switch 8 is used for following functions. While applying with different gearboxes, display will be different accordingly.

Home Screen (CH 8 Gearbox as Example)



- ① Change User
- ② Current Temperature
- ③ Current Gearbox type



- Edit: Edit protocols.
- **Tip**: Eject tip(s).
- Run: Enter to "Run" a protocol.
- Reports: Management of history data.
 UV lamp: Switch the UV lamp on/off.
- Setting: Adjust the parameter of the transfer platform.



Edit: Edit protocols.



Tap to enter the "Edit" function to manipulate the programs or create own protocols for relative reagent kits. In case of applying different gearboxes, programs should be created individually.

Notice: As saved with 12 step/6 step programs, program name will be recognized and renamed as "12_" or "6_". For example: As enter program name with "6T2" in 6 step program and saved, the program name will be renamed as "06_6T2".

- **O** Program: List of all programs.
- **② Edit:** Enter the selected program number to modify the protocols.
- **3 Copy:** Copy the selected program number to desire program number.
- Delete: Tap to delete selected program number
- **Import/Export:** manipulate the programs through USB drives.



Edit: Edit the running protocols.



Edit: Edit protocols.

CH 8 Gearbox as example for instruction:





- ① Number: Program number for saving
- Program: Name of the protocol.
- Meating: Activate the pre-heating function with setting temperature.
- Protocols: Preview of the protocols.
- "Previous" to go back or "Next" steps to detail protocol setting.



Edit: Edit the running protocols.



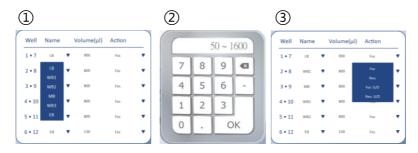
Edit: Edit protocols.

Preview of protocols



Preview of the protocols and enter with related settings.

- **1** Name: Tap to select the buffer name of each steps.
- **2** Volume: Tap to enter the volume of each sample wells.
- **Action:** Tap to select different spinning mode with "Reverse", "Forward", "Reverse with up and down mixing", and "Forward with up and down mixing".





Edit: Edit protocols.



Edit: Edit protocols.

Detail protocol setting:



Preview of the protocols and tap on displayed digits to enter with related settings as followed. Tap on "Delete" to delete the steps, "Copy" for multiplied the steps, and "Save" to store the setting of the program.

Notice: As editing the protocols, Make sure not to leave magnetic beads and eject spin tips in the same well.

- ① Step: The order of the gearbox's motion.
- Well: Processing well of each step.(May different by gearbox types.)
- **Temp.:** Heating On/Off and temperature setting of the step.
- Mixing Time: mixing time length setting of the step
- Spin Speed: speed setting of the stirring
- © Collect Time: time setting for magnetic rod to collect the beads
- Vapor Time: time setting for the evaporation of collected beads
- **Pause:** ON or OFF the pause function to temperately stop the procedure.



Edit: Edit protocols.



Copy: Copy the selected program number to the desired position.

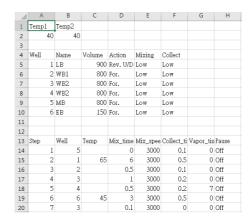




Delete: Delete the selected program number.



Import/Export: Programs can be imported or exported into CSV format through a USB drive. File format is shown as below.





Eject Tip(s)

Display different by the gearbox usage as below, but the function icon will be the same. While eject the spin tip, preferable to apply with empty reaction plate.



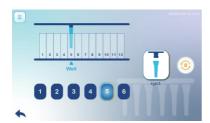
Please use correct consumables that is compatible with the installed gearbox.

CH 8 Gearbox



Caution: Before a run,

- ① Eject Tip: Press the icon to leave tips.
- ② Origin: Press the icon to initialize instrument.







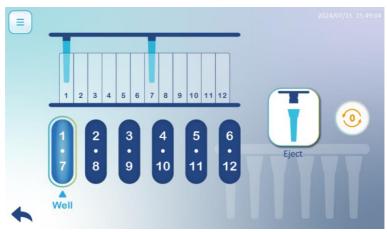


Please use correct consumables that is compatible with the installed gearbox.

CH 4 Gearbox



CH16 Gearbox





Run a protocol

Choose "Run" icon to start to run the protocols.



Switch 8 has an impressively large store of 100 programs. Choose program that in line with your reagent kit. Type in key words in search box to look for programs if needed. Number indicated with "06_" or "12_" refer to different types of program with 06 step program or 12 step program.



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

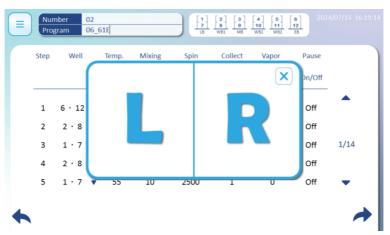


Run a protocol

Review with the setting program by scrolling up or down. And press on " \rightarrow " to proceed.



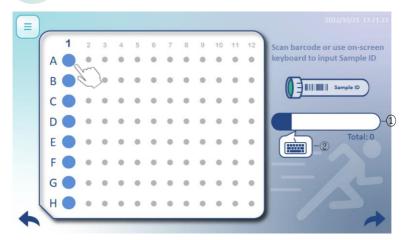
For **CH8 Gearbox with 6 steps program**, user can choose to run with "Left" or "Right" region of the deep well plate. But other types of gearbox or 12 steps program don't.



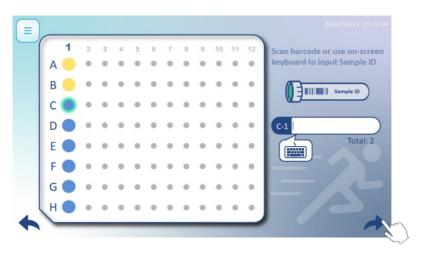
Choose a region "Left" or "Right" to run a protocol. Choose "Left" means to process from Lane 1 to Lane 6, and "Right" means from Lane 7 to Lane 12.



Run a protocol



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

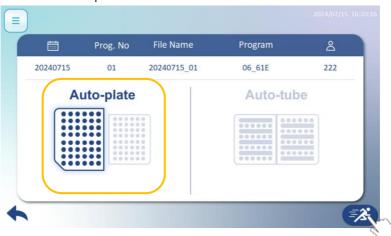


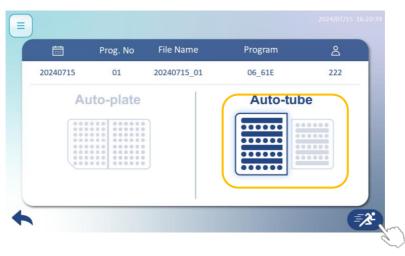
A circle turns yellow when inputs sample ID successfully. Then it moves to next sample ID automatically. E.g. A1 \rightarrow B1, B1 \rightarrow C1 etc. Press arrow to proceed next page.



Run a protocol

According to the applying plate format, choose "Auto-Plate" or "Auto-Tube" to proceed.

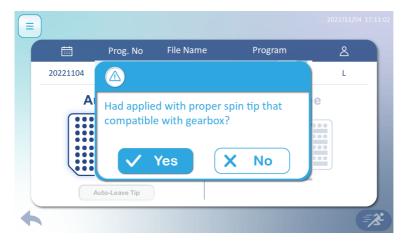




Please check above information is correct such as Date, Program No., File Name etc. Press " icon to execute the program. Or press on " " to back to previous page.

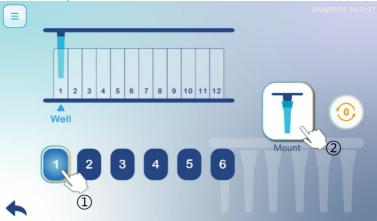


Run a protocol



After press on "
", warning windows pops. Make sure to apply with correct spin tip assemble box into the system and click on "Yes" to proceed. "No" to back to previous page.

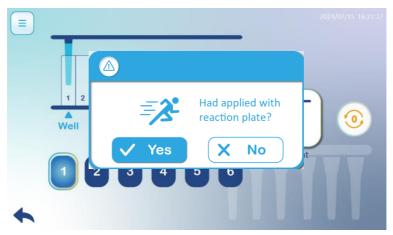
Mount Tip



Please apply with spin tip assemble box onto the heating plate inside the SW8. ① Select desire lane and ② press on "Mount" to pick up spin tips.



Run a protocol



After picking up the spin tips, make sure to replace the spin tip assemble box with prepared reaction plate. Click on "Yes" to proceed or "No" if the plate is not ready.



Program will start when the temperature reaches the set value.



Run a protocol

Running Status:



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

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



Pause: Pause a protocol that is in progress



Resume: Continue a pause protocol



Stop: Stop a protocol that is in progress



Run a protocol



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

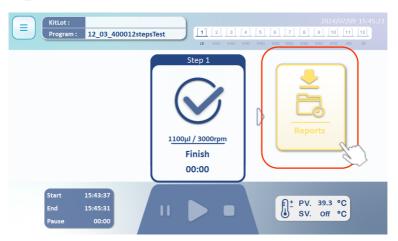


 [1]
 [2]
 [3]
 [4]
 [5]
 [6]
 [7]
 [8]
 [9]
 [10]
 [11]
 [12]

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



Run a protocol



As the program finished, press "Report" to review the result.

Spin tip should be ejected to finish the whole procedures. Select desire lane to eject the spin tip other than the lane with magnetic bead.

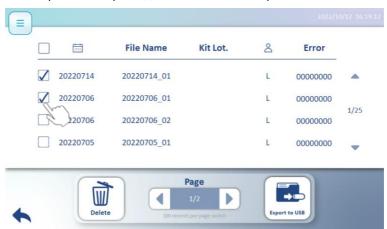
Notice: Do not leave magnetic beads and eject spin tips in the same lane.





Reports: Manage history data.

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





UV lamp: Switch the UV lamp on/off.



Set UV light, then press the light bulb to start.



Please close the door before turn on the UV light, running time is recommended over 5 minutes.



Setting: Basic Parameters can be set through setting function, including User management, Language, and Time.



- User Management: Operator authority can be set through this function.
- **② Language:** To change the UI language format
- Time: change of the time setting for the instrument.

12 Step Program

As applied with CH 8 Gearbox, there have special program allowed users to edit with freely process within 12 lanes on the reaction plate, called "12 step program". As enter the "Edit" section (refer to Page. 30), on the program list there will have two types of programs allows user to manipulate.



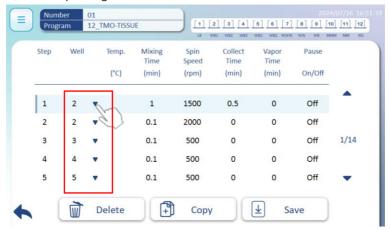
- ① 12_ : refer to 12 step program
- ② 06_ : refer to 6 step program

As edit with 12 step program, shows as following left figure.

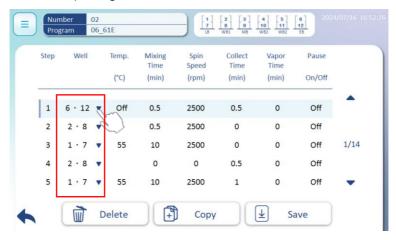


After enter the editing interface, in 12 step program (A), the "Well" lane can be chosen freely from lane 1 to 12. However, in 06 step program (B), lane 1 and 7 was bonded, and so as 2 and 8, 3 and 9...etc.

(A) 12 Steps Program



(B) 06 Steps Program



As saved with 12 step/6 step programs, program name will be recognized and renamed with "12_" or "6_" at the front. For example: As enter program name with "6T2" in 6 step program and saved, the program name will be renamed as "06_6T2".

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: service@tanbead.com 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 (service@tanbead.com) for technical assistance.

8. Disposal

The decision whether 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.
- Legal Manufacturer: 6F., No. 188, Wenhe Rd., Guishan Dist., Taoyuan City 333, Taiwan (R.O.C)
- **Production Site**: 4F., No. 188, Wenhe Rd., Guishan Dist., Taoyuan City 333, Taiwan (R.O.C)
- Manufacturer Tel: +886-3-3167568

11. TANBead Instrument Warranty Policy

This warranty sheet covers the Nucleic Acid Extractors manufactured by Taiwan Advanced Nanotech Inc. (Hereinafter referred to as TANBead).

TANBead warrants that under normal use conditions, this product will not have any material or manufacturing defects for one year from the date of purchase. If any defect is found within the warranty period, TANBead will repair or replace the product free of charge.

This warranty policy does not apply to the following situations:

- •The product is damaged due to improper use, operation, storage, maintenance, abuse, or transportation of the products.
- •The product is damaged due to accident, disaster, natural phenomenon, or other force majeure factors.
- •The product is modified, disassembled, reassembled, or repaired by unauthorized personnel.
- •The product exceeds its expiration date or is not used according to the instructions.
- Damage or loss caused by factors beyond TANBead's control, such as sample quality, experimental conditions, or user error.

To obtain the service of this warranty policy, you must register with TANBead website when purchasing the product and contact us in time when you find a defect.

To claim the warranty, please contact our customer service department with the following information:

- Proof of purchase (invoice, receipt, etc.)
- Product name (model) and serial number
- Description of the problem and evidence of defect or malfunction (photos, test results, etc.)

We will provide you with instructions on how to return the products. Please do not return the products without our authorization. TANBead will bear the shipping cost of returning the product, but not any other expenses or losses.

This warranty policy is your only remedy and replaces any other express or implied warranties or conditions. In no event shall TANBead be liable for any indirect, special, incidental, or consequential damages, including but not limited to loss of profits, business interruption, data loss or other commercial losses.

We appreciate your business and hope that you are satisfied with our products. If you have any questions or concerns, please feel free to contact us at any time. Thank you for choosing TANBead! If you have any questions about our warranty services, please email to service@tanbead.com

To register your TANBead instrument for more technical support and services, please sign up an official membership of TANBead.

