



# Genie<sup>®</sup> HT

## User Manual

v1.01

(Instrument Software Version v4.00)





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## SAFETY NOTICES

Please read the following section carefully before using Genie® HT.

The Genie® HT is specifically designed to run any isothermal amplification method that employs target detection by fluorescence measurement. Genie® HT will detect all dyes that can be excited from a blue light source and with an emission between 510 and 560 nm and all dyes excited by a yellow light source with an emission above 620 nm. Further uses include enzyme kinetic analysis and protein denaturation analysis using fluorescent dyes.

The equipment supplied has been designed to be completely safe to use. However to avoid any risk to the safety of the equipment, operator, or anybody in the vicinity of the equipment, please read this chapter before unpacking and using the instrument. If there is any doubt as to the correct use of the equipment contact the vendor.

### Notices



Using the instrument in a manner not specified by OptiGene may result in personal injury or damage to the instrument and the protection provided by the equipment may be impaired.



Always ensure that the surface on which the instrument is placed is level and stable and will not cause the instrument to topple over. Ensure that the surface is suitable for the weight and size of the instrument. If the instrument is dropped it may be damaged.



The instrument should never be lifted by its covers. Always ensure that the base or sides are used as the lifting point.





The instrument is electrically powered. Please ensure that the correct voltage settings have been applied before applying power to the instrument. If in doubt consult a qualified electrician. The instrument has a rating label affixed to the rear. Please consult this if needed.



Always disconnect the equipment before moving or removing any guards or covers. Switch off at the mains, remove the mains plug from the wall socket and remove the cable from the inlet socket on the rear.



While every effort has been made to protect the inside of the instrument against splashes, the instrument carries no IP rating. If fluids are spilt on the instrument they may cause damage and cause an electrical hazard.



If a spill occurs, remove power from the instrument. Do not touch the instrument or any fluid flowing from it while it is connected to the mains supply. Always follow local health and safety guidelines.



The instrument is not intended for use with flammable substances.



It is not advised to open the lids whilst the instrument is running as it could cause measurement errors leading to incorrect results.



It is advised to run the 'Self-Test' function at the start of every session. This is located in Settings.



OptiGene Limited recommends that every two years the instrument's performance is checked for degradation. This can be done by requesting and purchasing ready-made strips from OptiGene that will perform an amplification and anneal run on the instrument which can then be assessed to check for optical or thermal performance issues.

Normal safe local operating standards should be applied at all times. The warnings above are for guidance only. Please consult the instrument supplier if there is any doubt.

## Disconnection Method



Genie® HT is disconnected by removal of incoming mains power source to the unit. Following disconnection the unit should be left for a period of at least 5 minutes before any internal assemblies are removed or examined.



When in use the heating block and heated lid are hot, so allow to cool before touching the surfaces.



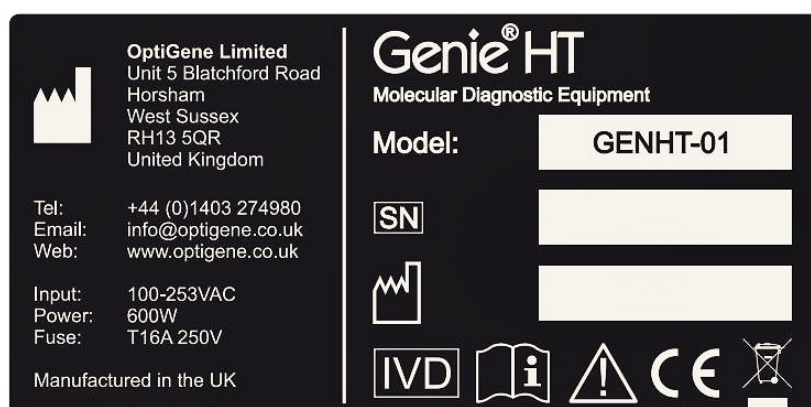
Safe removal of fluids from Genie® HT will depend on the chemistry used. This will also require knowledge of the fluids used in the system to adhere with local health and safety and COSHH regulations. If in doubt, consult the person responsible for the equipment in the laboratory.

## Cleaning Method













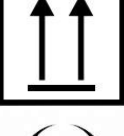


The Genie® HT can be disinfected using the following procedure which can be used as a safety measure if this equipment is routinely exposed to bio-hazardous materials and it is recommended that it should be performed prior to moving or shipping the instrument.

1. Remove all strips from the instrument and dispose of appropriately.
2. Wipe all outside surfaces of the Genie® HT with a 10% bleach solution.
3. After 10 minutes wipe all the same surfaces with a 70% ethanol solution.

**CAUTION:** Do not allow any of the liquid solutions to enter the wells as this can cause damage.



## Explanation of Symbols

	<i>In vitro</i> diagnostics	
	Serial number	
	Batch code	
	Catalogue number	
	Manufacturer	 Date of Manufacture
	Use by date	
	Consult electronic instructions for use	
	Store at (temperature range)	
	Keep away from sunlight	
	Handle with care	
	Keep dry	
	This way up	
	Biohazard	
	WEEE: waste electrical and electronic equipment should not be disposed of in your dustbin or wheelie bin. OptiGene Limited must be consulted regarding end-of-life disposal.	

## Background Information

OptiGene Limited was formed in 2008 to develop and deliver advanced molecular diagnostics solutions for applications across a range of market sectors, with the primary goal of providing the highest quality instrumentation and performance-leading reagents to support isothermal amplification of DNA and RNA. The market pull for this venture came from the growing demands around the world for field testing, rapid results and point-of-care diagnostics.

OptiGene has developed innovative products that support sensitive and specific detection of bacteria and viruses, for use in the fields of plant health, food safety, veterinary medicine, environmental monitoring and human healthcare. Bio-defence and forensics are also key markets that OptiGene addresses, either directly or through its growing network of international distributors. The company has exploited its expertise in both instrument design and enzymology to develop a sophisticated open platform that will support all isothermal amplification methods that employ target detection by fluorescence measurement. Ultra-sensitive molecular detection that has previously been constrained to laboratory use by highly-qualified personnel and taking hours to complete can now be deployed to point of application and run with very little training, producing results in single minutes. A continuous programme of development is maintained at OptiGene to satisfy the evolving demands of its customers and the wider market, in both instrumentation and enzymes and assays.

## The Genie® platform

OptiGene Genie® instruments are essentially highly sophisticated temperature-controlled fluorimeters. They are almost exclusively applied to running molecular diagnostic assays employing isothermal amplification of DNA and RNA, enabling sensitive detection of bacteria and viruses at a molecular level by fluorescence measurement. Genie® HT is the flagship high-throughput instrument; it was released to market in spring 2020, joining Genie® II (released 2011) and Genie® III instruments, many of which are to be found in a variety of diagnostic settings around the world. This powerful and extremely flexible platform allows isothermal amplification of DNA and RNA to take place in a compact device.

All Genie® instruments operate with the OptiGene strip-of-8 reaction tubes (catalogue number Genie® strips OP-0008-50 [50 strips] and OP-0008-500 [500 strips]). This proprietary consumable incorporates attached, locking caps which allow for a closed tube assay to prevent cross-contamination. Enzymes are available in the form of several master mixes that feature combinations of high-speed operation, inherent RT activity and thermostability, together with separate primers, specific to the target bacterial or virus RNA/DNA.

Specific instructions for the preparation and use of the Genie® strips are to be found in the appropriate OptiGene assay Instructions for Use (e.g. COVID-19\_RNA RT-LAMP KIT-500\_IFU V1.0 10/07/2020 and COVID-19\_Direct RT-LAMP KIT-500\_IFU V1.0 10/07/2020 for SARS-CoV-2 RNA).

To perform a test, the instrument is switched on and the software allowed to initialise. Dry and disinfected loaded strips are placed in the instrument's heater block (Genie® III – single block;

Genie® II – independent dual blocks; Genie® HT – 1 to 12 independent blocks), and the lid closed.

An appropriate protocol is selected from the start-up menu on the display (see Chapter 5 for details) and the run started. The protocol defines the operation sequence of instrument, setting the heated block temperature vs time profile. Custom profiles can be created by the user.

The Genie® II, III & HT devices detect amplified product in real-time using fluorescence measurement. The Genie® platforms automatically run an anneal curve at the end of amplification, where the reaction is heated to 98°C and slowly cooled and the peak of the resulting fluorescence detected. This acts as a secondary confirmatory check - ensuring LAMP amplicons are specific to the particular target. The result is interpreted and reported automatically from both the amplification and the anneal temperature. Genie® instruments can generate results according to detected amplification times, anneal peaks and other features (Result Calling). Due to the varying requirements of differing applications, setting up the parameters is highly flexible. This is described in detail in Chapter 6.

Genie® HT is of modular design, employing up to 12 autonomous modules, each accepting a Genie® micro-tube plastic reaction strip of 8 wells. The modules use the core ceramic heated block technology of the Genie® platform, incorporating integrated optics and photodetectors, dedicated controller and data acquisition electronics. The user interface is via a 10.1” projective capacitive touch panel; connectivity is via USB (2 x USB-A and 1 x USB-B ports) and RJ45 ethernet.

## Intended Use

The Genie® HT is specifically designed to run any isothermal amplification method that employs target detection by fluorescence measurement. Genie® HT will detect all dyes that can be excited from a blue light source and with an emission between 510 and 560 nm and all dyes excited by a yellow light source with an emission above 620 nm. Further uses include enzyme kinetic analysis and protein denaturation analysis using fluorescent dyes. The Genie® HT is intended to be used in an appropriately equipped facility, e.g. a hospital microbiology laboratory, or mobile laboratory such as the Hampshire Hospitals NHS Trust “Lab in motion”, or similar environment, by a trained non-specialist healthcare professional for molecular diagnostic purposes.

In particular, Genie® HT can perform rapid detection of SARS-CoV-2 virus (COVID-19) within nasopharyngeal and oropharyngeal swabs, using the CE-IVD registered OptiGene COVID-19\_Direct and COV-19\_RNA RT-LAMP kits.

### General Precautions for Molecular Diagnostic usage

- **Molecular Diagnostic assays are intended for use by professional users only, such as laboratory or health professionals and technicians, trained in molecular biological techniques.**
- **National guidelines on biosafety should be followed in all circumstances.**

- All samples should be handled as if they are infectious, following conventional biosafety precautions.
- Material Safety Data Sheets (MSDS) for OptiGene reagents are available from OptiGene Limited. In particular, MSDS for the COVID-19 RT-LAMP kits and COV-19-Direct LAMP kits are available from the OptiGene Limited website (<http://www.optigene.co.uk/human-diagnostics/>)
- Dispose of used strips as contaminated laboratory waste

## Storage and Handling

The Genie HT is a heavy instrument and weighs 18kg. Lift from the front and back of the instrument, never from the lids. Keep the lids closed when not in use to prevent the ingress of dust or contaminants to the optics.

Handle the instrument and its accessories with care and wear appropriate personal protective equipment when preparing and handling Genie® strips. See the specific instructions for the preparation and use of the Genie® strips, supplied with the assay. OptiGene assay Instructions for Use (e.g. COVID-19\_RNA RT-LAMP KIT-500\_IFU V1.0 10/07/2020 and COVID-19\_Direct RT-LAMP KIT-500\_IFU V1.0 10/07/2020 for SARS-CoV-2 RNA) are supplied with the reagent kits.

## Serious Incidents

Any serious incidents encountered during the use of this device must be reported in the first incidence to OptiGene Ltd.

## Technical Specification

Sample Number	12 x 8 wells
Sample Volume	10 µl to 150 µl
Touchscreen	10.1" High-brightness LCD with multi-touch projective capacitive touch panel (1280 x 800)
Heater technology	Ceramic substrate with resistive coating
Cooling method	Forced convection
Temperature sensors	High-precision thermistor
Temperature control type	Multi-zone independent digital PID
Temperature control range	ambient - 100°C
Temperature accuracy	±0.1°C
Temperature uniformity across block	±0.2°C
Temperature gradient	Programmable up to 8°C
Optics source	470 nm & 590nm dual colour LED with high-quality interference filter 40 nm band pass
Detection optics	Photodiodes with high-quality interference filters 510-560 nm band pass & 620 nm long pass
Operating temperature	0°C - 40°C
Storage Temperature	20°C - 70°C
Approvals	CE
Dimensions	635mm (L) X 434mm (W) X 153mm (H)
Weight	18kg / 40lbs
Connections	1 x USB 'B' 2 x USB 'A' 1 x Power in 1 x RJ45 – Network connection 1 x USB 'A' – diagnostic port
Environmental protection	IP20
Wireless Connections	Bluetooth & WiFi
Power supply	Input: 100-240V AC, 50/60Hz

### RoHS Compliance

OptiGene Limited declares that, to the best of our knowledge, all electrical and electronic equipment (EEE) sold by the company are in compliance with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (also known as "RoHS2").

### REACH Statement

OptiGene Limited also declares that no products sold by the company are known to contain any of the substances of very high concern (SVHC) as intentionally added components with regards to the European Regulation No. 1907/2006 (Registration, Evaluation, Authorisation & restriction of Chemicals).

# SUPPORT

## TROUBLESHOOTING AND MAINTENANCE

### HOW TO OBTAIN SUPPORT

For the latest services and support information go to <http://www.optigene.co.uk/support.htm> for frequently asked questions, software and firmware downloads, to request Troubleshooting Assistance, and to report any bugs.

**IMPORTANT!** When directed to do so, contact OptiGene Ltd. to schedule maintenance or calibration of a Genie® HT instrument.

OptiGene Limited suggests that every two years the instrument's performance is checked for degradation. This can be done by requesting ready-made strips from OptiGene that will perform an amplification and anneal run on the instrument which can then be assessed to check for optical or thermal performance issues.

### SUPPORTED CONSUMABLES

**IMPORTANT!** Genie® HT uses a proprietary tube strip that maximises optical and thermal efficiencies. **Other tubes and strips will not fit.**

**IMPORTANT!** Forcing non-supported consumables will cause damage to the instrument and invalidate the warranty.

**IMPORTANT!** The shape of the tubes is such that they will only fit in one way round. The locating pins on the block have corresponding holes in the strips.

**IMPORTANT!** The strips are single use only and have been designed with a locking cap and should never be opened after a run has ended.



## BOX CONTENTS

The following is a list of contents in the box for Genie® HT:

- Genie® HT instrument
- Barcode scanner
- Stylus
- Power lead
- USB connection lead
- USB memory stick containing this manual as a '.PDF' file

## UNPACKING THE INSTRUMENT



The Genie HT is a heavy instrument and weighs 18kg. Lift from the front and back of the instrument out of the box.

**NEVER LIFT THE INSTRUMENT FROM THE LIDS**

Please retain packaging for future use. **If repacking the instrument for transport, make sure to safely dispose of any used strips in any of the blocks prior to packing.**

Allow 10 minutes to unpack and set up the instrument. Choose a location with sufficient space to be able to see the screen and load strips into the instrument.

1. Cut the tape on the flaps on the box to open the shipping box.
2. Open the flaps and remove the top layer of foam and then lift out the accessories (shown below). Then lift out the foam layer.



3. Remove the triangular foam piece from on top of the screen. Carefully lift the instrument from the box lifting from the front and back of the machine. A second person may be required.



4. Place the instrument on a flat stable surface.

## SITE PREPARATION

### HOW TO SET UP GENIE® HT

Genie® HT has been designed to be used in a laboratory. When it is being used, the instrument should be placed on a level and stable surface and the surfaces surrounding the instrument must be clear of obstructions at all times.

Care must be taken not to unduly restrict the air at the outlet vents at the sides. Restricting airflow may impede operation and could affect performance.

Electrical points should be close to the instrument to avoid injury from trailing wires.

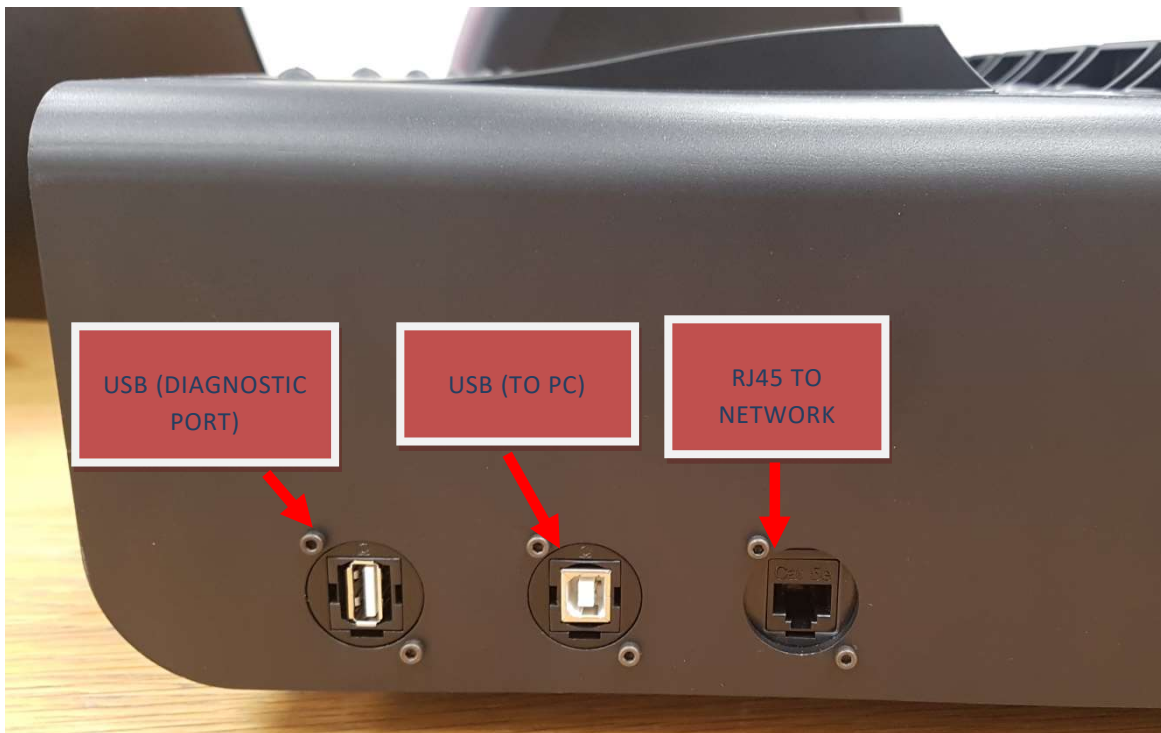
It is recommended that the instrument is kept away from sinks and other wet areas when running.

## CONNECTIONS

Genie® HT is ready to use straight out of the box with only a single power connection. It can be operated standalone and does not require a computer to be connected. Genie® HT can be connected to multiple peripherals (barcode scanner, printer, USB pendrive) via the front USB A sockets and connected to a computer via the rear USB B socket or to a network via the rear RJ45 socket.

Located at the rear is the on/off power switch and power cable connector. Connect the power cable into the back of the instrument and when the switch is in the on position Genie® HT will power up and progress through its checks.





## OPENING & CLOSING THE LIDS

Gently lift the lids upwards. Close the lids by lowering gently.



Care must be taken to ensure that objects are not obstructing the lids when trying to close it and under no circumstances should the lids be forced open or closed.

## INSERTING TUBES

**IMPORTANT!** Genie® HT uses a proprietary tube strip that maximises optical and thermal efficiencies. Other tubes and strips will not fit.

**IMPORTANT!** The shape of the tubes is such that they will only fit in one way round. The locating pins on the block have corresponding holes in the strips.

Genie® HT can be shut down using the power button in the bottom left corner. At this point Genie® HT can be switched off using the switch on the rear.



Note: If this button is pressed during a run, Genie® HT will not enter standby.

When in standby, normal operation can be resumed by pressing anywhere on the screen.

## USER INTERFACE

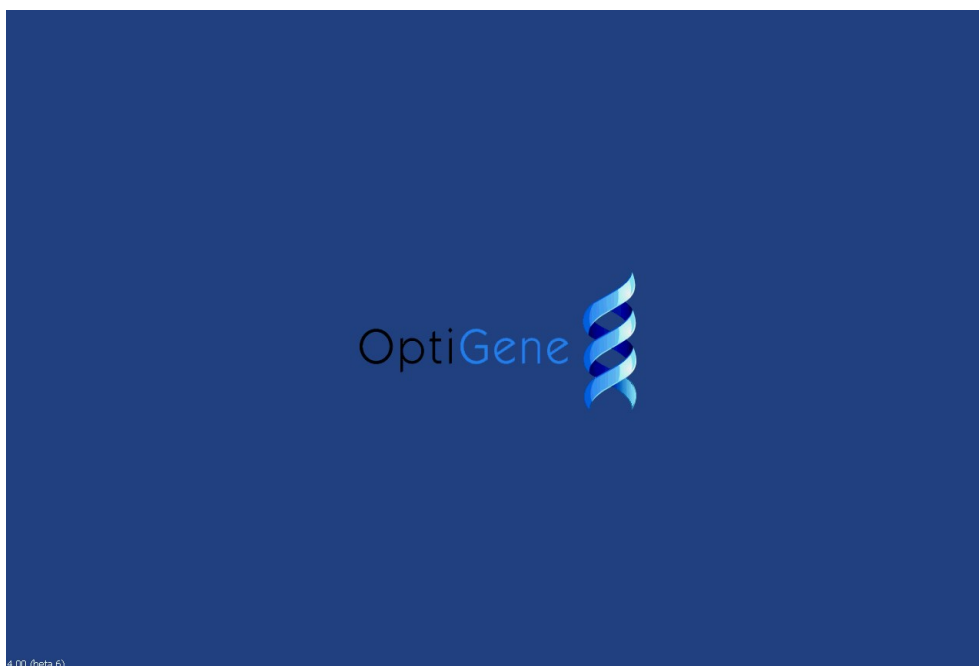
Genie® HT uses a touchscreen for viewing and inputting data.

Touch the screen gently and press the appropriate keys when required. The touch screen can be operated while wearing protective gloves or by using the stylus included with the instrument.

**IMPORTANT!** Do not use a pen or any other sharp implements to touch the screen.

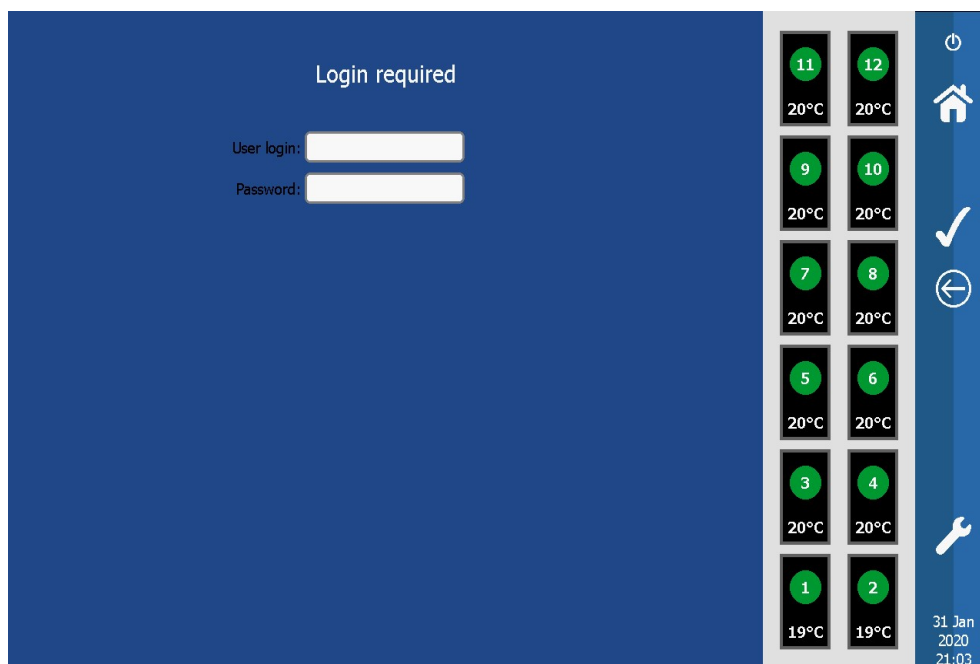
### GENIE® HT WELCOME SCREEN

When switching on, the LED above the screen will be **amber** in colour. Wait for the light to change to **green**, then touch the screen to access the login screen or home screen.



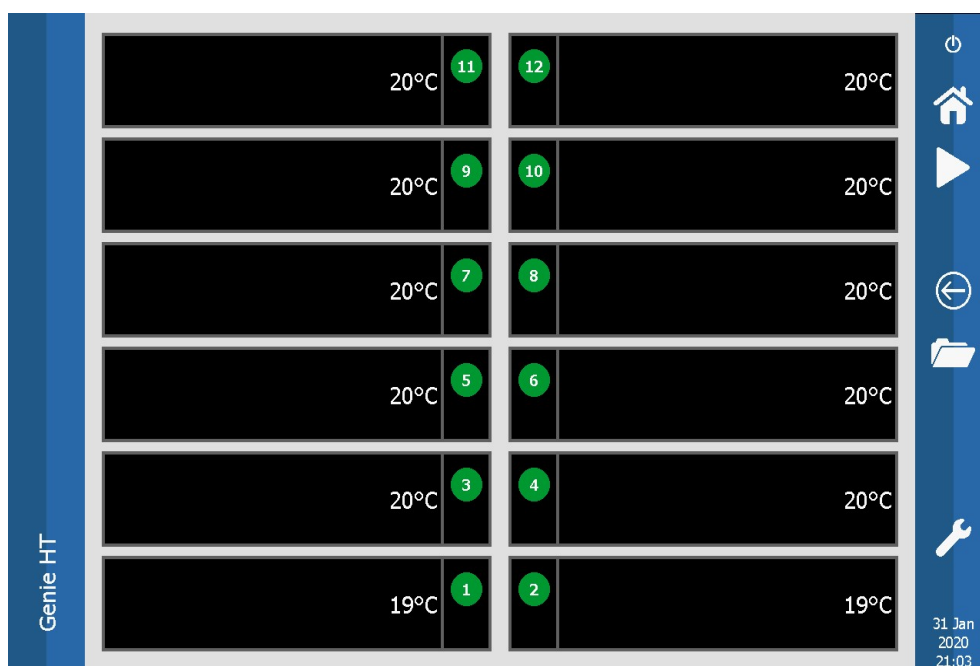
# GENIE® HT LOGIN SCREEN

If users are set up on the instrument and a log in is required, the next screen will be a login screen. Log in using your user login and password.



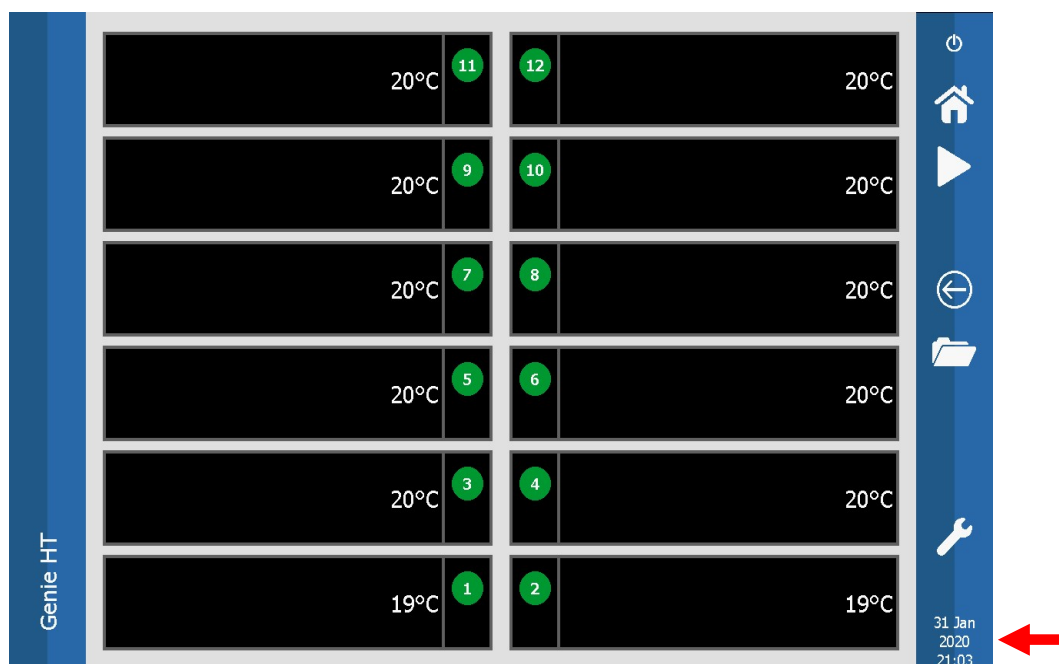
## HOME SCREEN

The next screen will be the home screen. This gives an overview of the status and temperature of all of the blocks, and their current position in their runs. The menu to the right gives access to the soft power switch, starting a run, accessing and viewing old log files, settings and the data and time.





**IMPORTANT!** When running for the first time check that the time and date on the status bar are correct. These can be changed from the Settings menu, which is accessed by tapping the spanner icon.

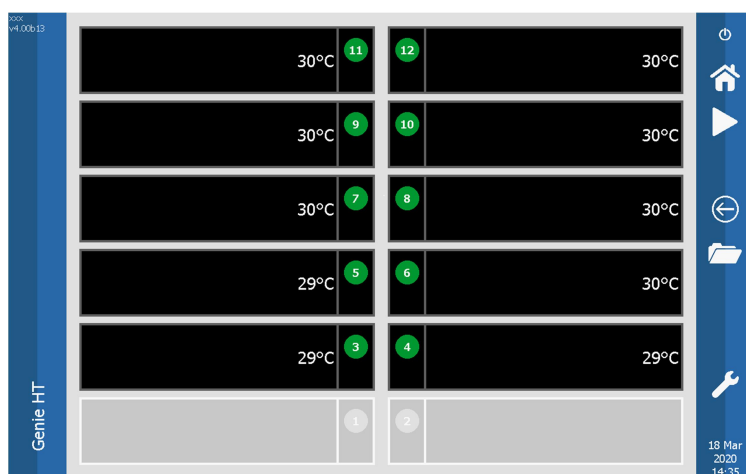


## BLOCKS

The blocks are listed in the order they are in the unit. Pressing on a block will do different things depending on what its status is.

### ENABLED/DISABLED BLOCKS

When a block is enabled it will be shown as a black box with a colour indicator to show its number and status. If a block is disabled or not installed, then the block will show as grey.



If this has happened unexpectedly please contact OptiGene.

## BLOCK STATUS

The block status will be shown using one of three colours. Each block has an LED indicator next to its lid which also corresponds to these colours, allowing the user to glance at the instrument and know the status of the blocks:



Green: The block is at a free to use and is below 40°C.



Red: The block is currently in use and cannot be used to start a run. Opening a lid that is red will result in the warning alarm sounding.



Orange: The block is available to use, but is still cooling down to 40°C. It is advised to wait until the status goes green again before starting a new run.

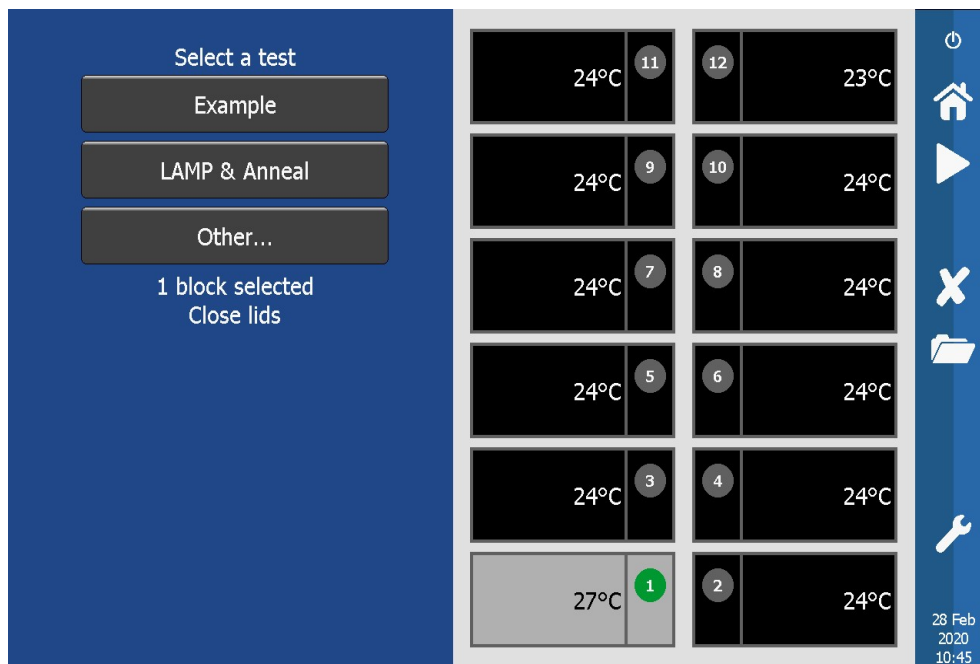
***TIP!*** When files are open or have finished running on a block, use a two finger swipe down on the block to close the file.

## STARTING A RUN

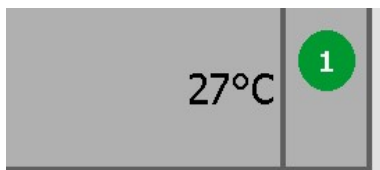
In order to start a run, there are several ways to do this:

1. Opening the lid of a free block.
2. Pressing on a block that is not being used
3. Pressing the Start run button on the right hand side of the menu.

Doing any of these actions will show the next screen.



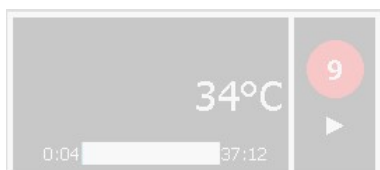
**TIP!** By opening a lid or by pressing a block will result in the block automatically being selected.



Selected blocks will look like this, and be highlighted and show the status.

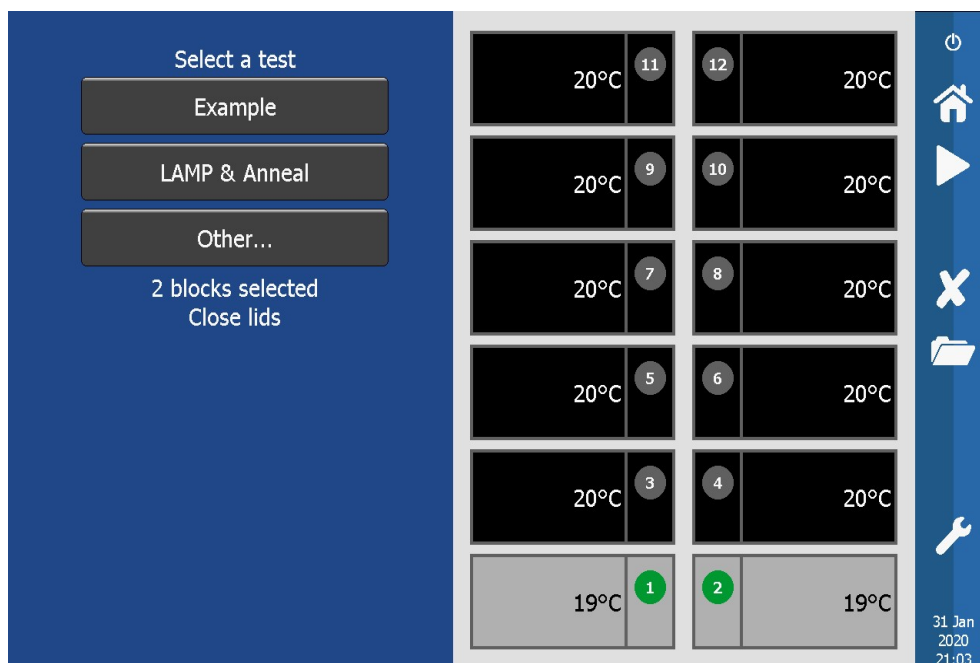


Unselected blocks will look like this and the status symbol will be grey.

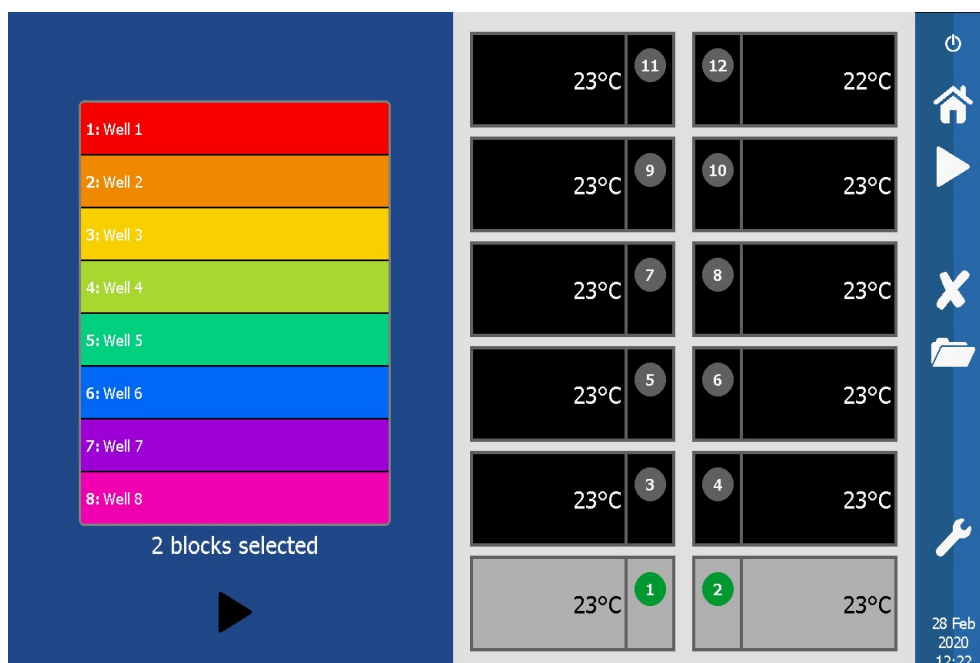


Blocks that are already in use will be unable to be selected and will show like this.

To de-select a block press the block again. To add more blocks to the run, press on the blocks to select them or open the lids.



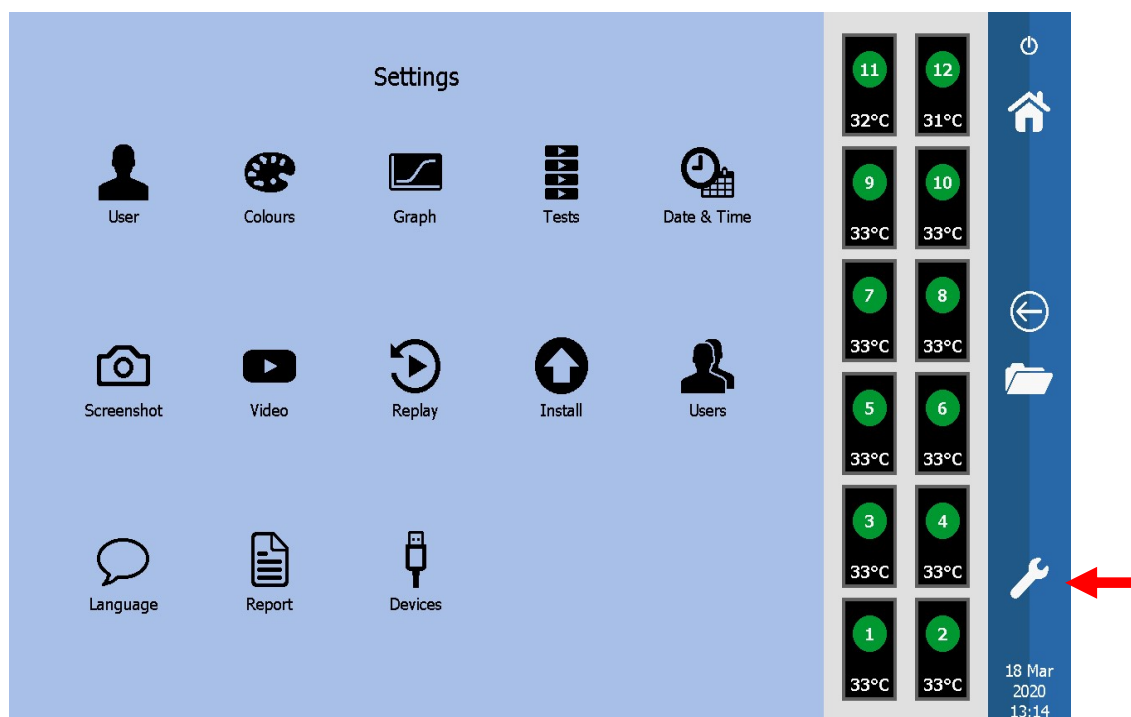
Once all the blocks are selected the next step is to select a test. Buttons can be assigned (in the Settings menu) to profiles and are shown on the left. Alternatively, touch 'Other...' to create a new profile, or open another saved profile. The numbers of blocks selected are listed, along with the reminder to close the lids. **A run cannot be started until all the lids are closed.**



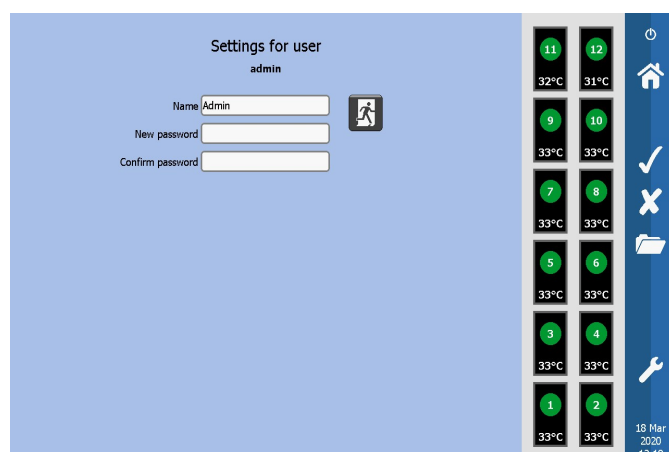
Once a test is selected, the well names are shown along with the number of blocks selected and, once the lids are closed, a play button. Pressing this will start the run. Touching on the well names will allow editing of the profile, which is explained later.

# SETTINGS

Pressing the spanner icon in the taskbar will load the Settings.



## USER

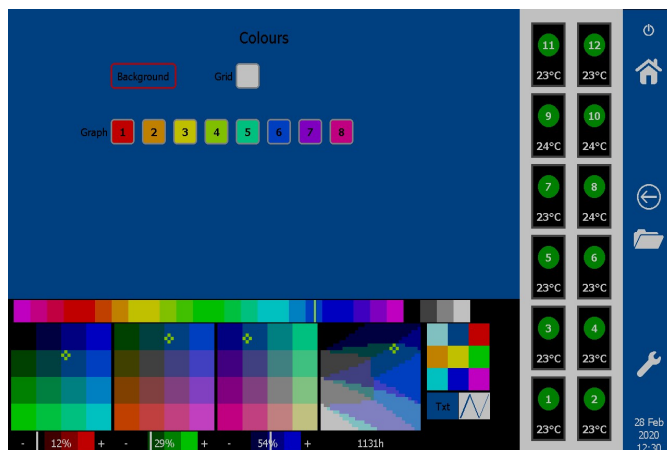


Changes to the logged in user's name and password can be changed here.

Type the new password, and then confirm this by typing it in again and press the tick in the menu to confirm or the cross to cancel and return to the settings page.

Pressing the log-out button will log the user out.

## COLOURS

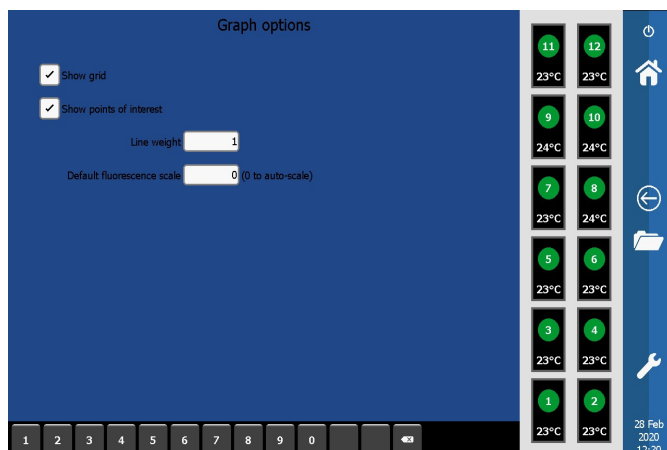


The background colour and the default colours of the lines on graphs can be changed here.

Click the background button or a graph number and then drag the cursor on the colour chart to select a colour.

The small table of coloured boxes on the right show the colour that is currently set, the default colour and the previous colours that have been used. Pressing on any of them will set the colour.

## GRAPH OPTIONS



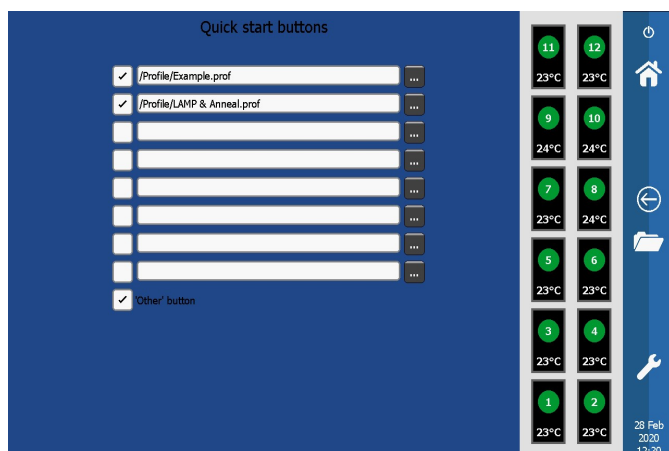
Show grid: This will enable/disable the grid behind graph plots

Show points of interest: Enable/disable any dots on the plots that have been generated by the result calling.

Line weight: set the line weight of all plots (default 1)

Default fluorescence scale: Set the Y axis upper scale on the graph. Set this value to 0 to auto-scale.

## TESTS



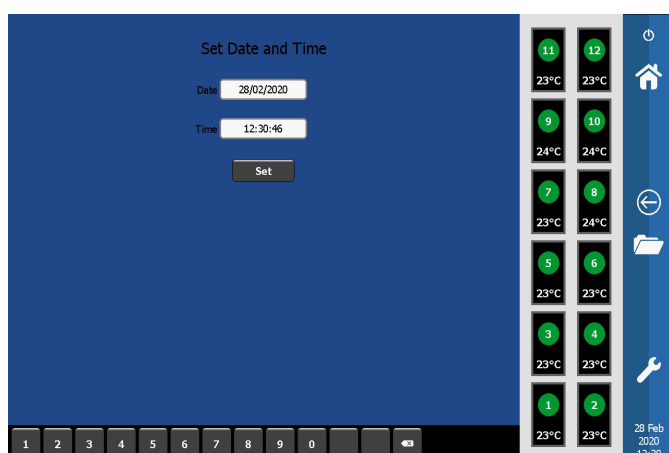
Set up the quick start buttons on the test selection screen.

Up to 8 profiles can be stored as a quick start button.

Touching '...' will allow the user to browse the saved profiles on the instrument and assign that profile to the corresponding quick start button on the test selection screen.

To remove the buttons, untick the box next to the profile name.

## DATE AND TIME



Date: click in the white box for date and enter in the format DD/MM/YY.

Time: click in the white box for time and enter in the format HH:MM:SS.

Press 'Set' to save or click the back button to cancel.

## SCREENSHOT

Screenshot: A small yellow, moveable icon will appear on the right hand menu, which, when pressed, will take a screenshot of the current screen. This will be saved into the CAPTURE directory on the instrument's internal memory.



## VIDEO

Pressing the 'Video' button will start a pre-loaded demo video.

Additional features will be added to this in the future.

When the video is playing, there are several gestures which control the playback:

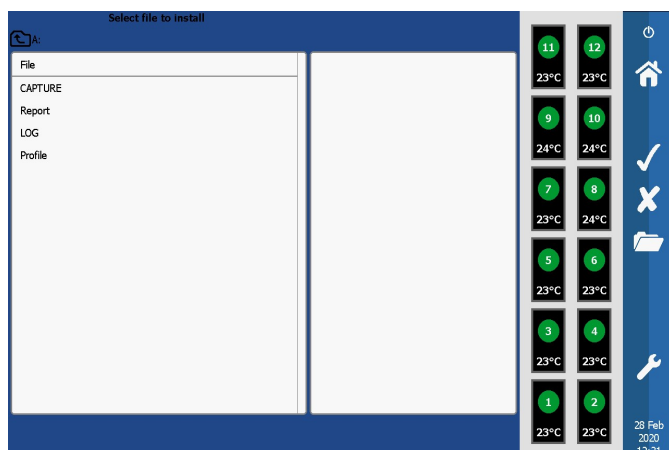
- 1 finger tap: Pause / resume
- 1 finger swipe up/down: Increase / decrease volume
- 2 finger swipe left/right: Skip +/- 30s
- 3 finger swipe down: Stop & exit



## REPLAY

Replay: This will replay a run file as if it were running in real-time. Select the file and press play.

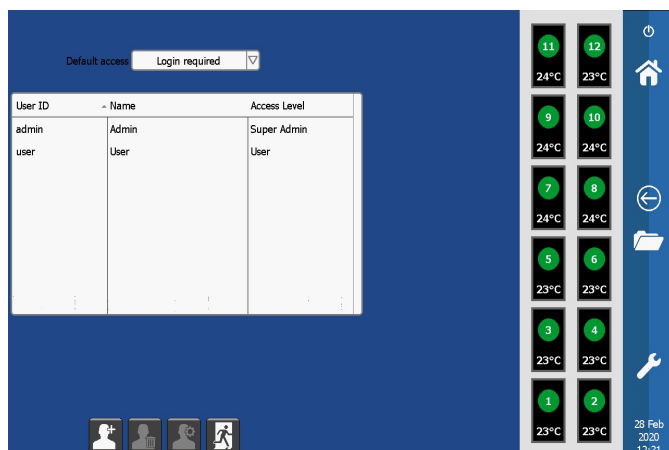
## INSTALL



Pressing 'Install' will allow updating of the instrument software (See Chapter 7).



## USERS



On the Users screen, users can be added or removed with different levels of access.

**Default access:** This sets the default access when the instrument is turned on. By default the instrument will be in Admin mode. In this mode all features are fully available. When Login Required is selected, the instrument will not be able to be used until a user has logged in.

If any level is selected and the instrument is restarted. This is the level that the instrument will default to on start-up.



To create a new user, click on the Add User button (shown), and then enter the details for the user and select an access level. Press the tick to save, or the cross to cancel (in the menu bar).

The levels of access are as follows:

- No access:** The user is disabled (can be used to temporarily revoke access to a user).
- User:** Can run any profiles on the instrument, and can change colours, power settings and the screen capture functionality.
- Expert:** The user will have access to editing profiles and viewing and editing result

calling and can change the buttons

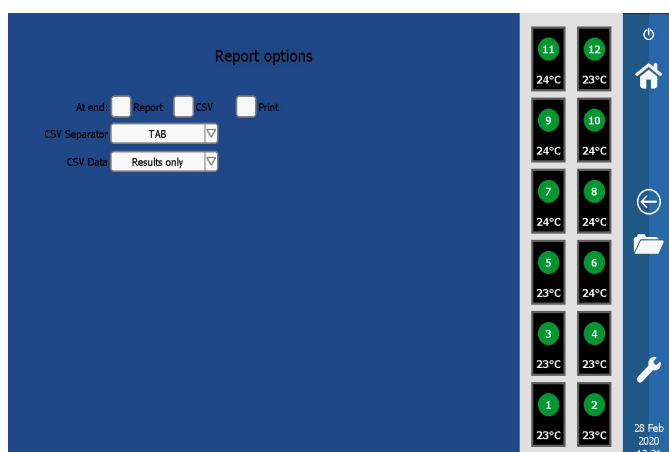
Administrator: The user will have full unrestricted access to all the instruments settings and can add users and set language.

## LANGUAGE



Default language: This sets the default language of the instrument.

## REPORT



These options can be used to adjust reports of runs.

At end: At the end of a run, if the boxes are ticked, the Genie will automatically create a PDF report, a CSV (comma separated value) file, and print the result table to the connected printer (accessory).

The separator of the CSV file can be set between a tab and a comma, depending on what is required.

The CSV data can be the results table only, the raw data, all data (including all signal processing steps) and data with the evaluation of results.

## USB DEVICES



USB devices that are connected will be listed here.

## WIRELESS\*

COMING SOON.

## NETWORK CONNECTION\*

COMING SOON.

## SELF-TEST

This will run a diagnostics on the instrument to see if there are any problems and report back if there is.

If the instrument reports a problem, please contact OptiGene Limited for assistance.

**It is advised to run the Self-Test at the start of each session.**

*\* Features are currently in development.*

## COPY & PASTE

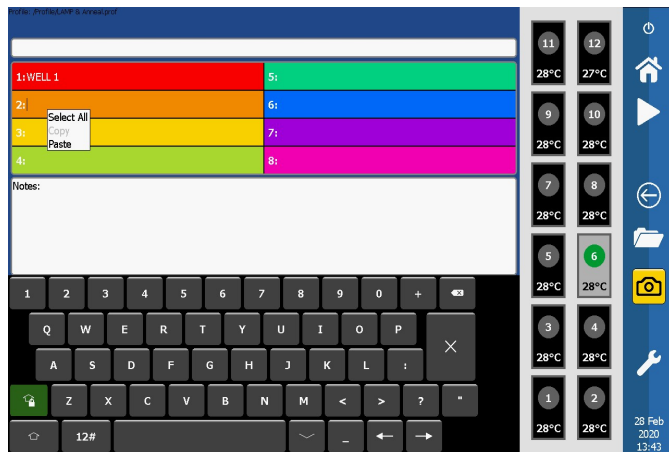
Users are able to copy and paste in any text box which can save time in entering well names or run names.



To copy:

In a text box, if text is not highlighted, highlight the text by holding down on the text box until a pop-up appears, and select 'Select All' and then hold down again and select 'Copy'.





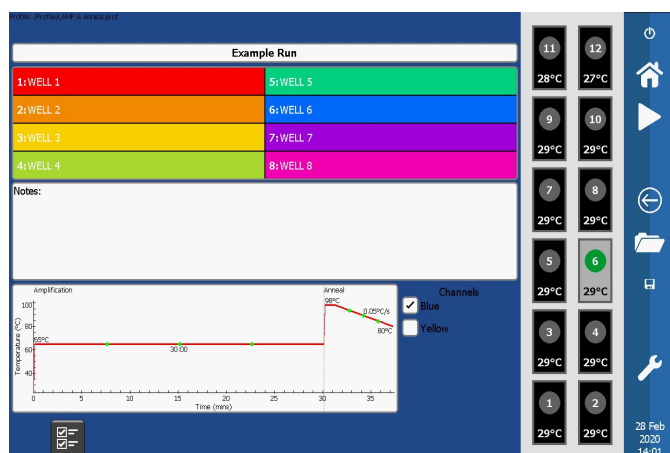
To paste:

Touch the text box you wish to paste into, and then hold down on the box until a pop-up appears and select 'Paste'.



# PROFILES

## PROFILE SCREEN OVERVIEW



This screen shows the overview of the profile.

To start the run, press the play icon.

If multiple blocks are selected when starting a run, the same profile will be used on all selected blocks, including all well names and result calling.

Example Run

The top text box is for the run name.

1: WELL 1	5: WELL 5
2: WELL 2	6: WELL 6
3: WELL 3	7: WELL 7
4: WELL 4	8: WELL 8

The wells are colour coded for identifying individual plots on the temperature, amplification and anneal graphs. These can be changed in Settings.

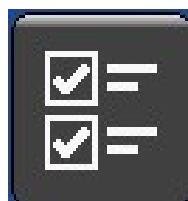
The well names can be edited by pressing on the particular well and typing using the on screen keyboard.

Notes:

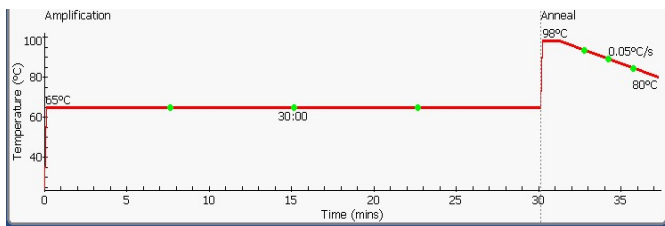
The large notes box is a text box which can be used for adding notes about the run.



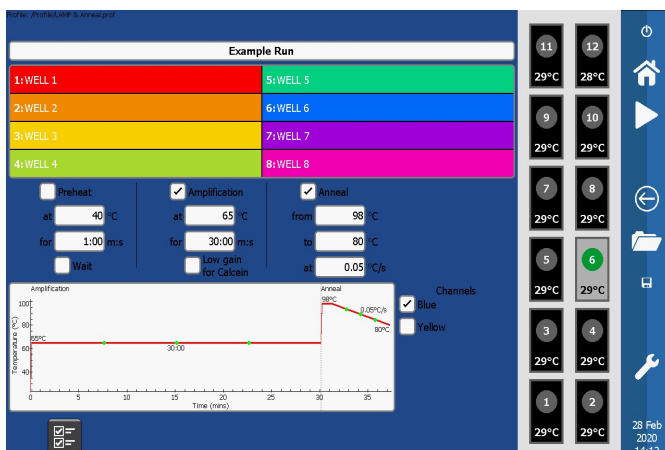
The 'Channels' area allows selection of the channels to be used.



This button accesses the result calling options (explained in later section).



The graph shows the temperature profile of the run. Touch the graph to adjust the profile by touching the appropriate temperature or time box.



The notes section will change to show the temperatures and times of the different phases of the run.

Pressing the graph again will toggle the notes back.

When changes are made to these values, the graph will automatically update to show the new temperature profile.

The temperatures and times for the pre-heat, amplification and anneal phases can be adjusted. The phases can be enabled or disabled using the tick box next to their name.

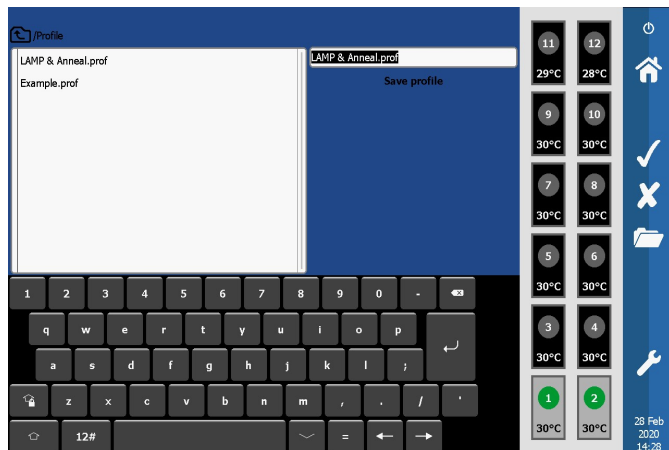
<input type="checkbox"/> Preheat	<input checked="" type="checkbox"/> Amplification	<input checked="" type="checkbox"/> Anneal
at 40 °C	at 65 °C	from 98 °C
for 1:00 m:s	for 30:00 m:s	to 80 °C
<input type="checkbox"/> Wait	<input type="checkbox"/> Low gain for Calcein	at 0.05 °C/s

<input checked="" type="checkbox"/> Amplification
at 60-67 °C
for 30:00 m:s
<input type="checkbox"/> Low gain for Calcein

To set a thermal gradient (maximum of 7 degrees) across a block, enter a range of temperatures in the 'Amplification' temperature box. The range of temperatures should be entered separated by a hyphen, as shown below.

The 'Wait' button on the pre-heat stage will cause the device to set the block(s) to the pre-heat temperature for the time, and then wait for user-input before continuing onto the next phase.

Low gain for Calcein: This option is mainly for use if the user is running experiments with Calcein.



Pressing the save icon will save the profile. Name the profile, press the tick button and it will be saved within the 'PROFILE' directory in the on-board memory allowing it to be loaded for future runs.

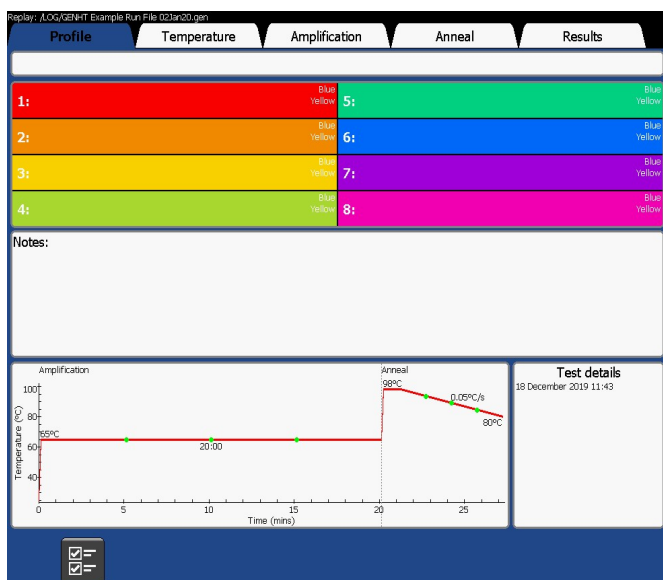
Press the cross to cancel.

If the profile is saved at this point the well names, abbreviations and all result calling will also be saved as part of the profile.



# ACTIVE

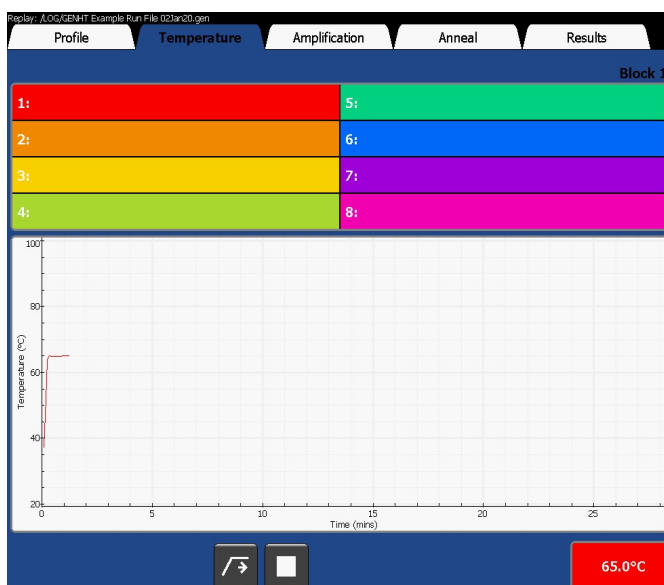
Once a run is started, the software will go back to the 'Home' screen. To view the graphs of a block, touch the block. The 'Temperature' graph screen will be shown initially. The other screens can be accessed using the tabs.



## PROFILE

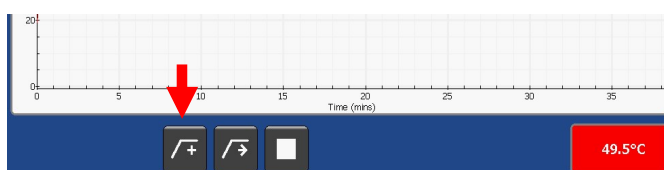
This shows the temperature profile that is running.

At the top of this screen, there is a text box to edit the run name, edit the well names, and add notes.



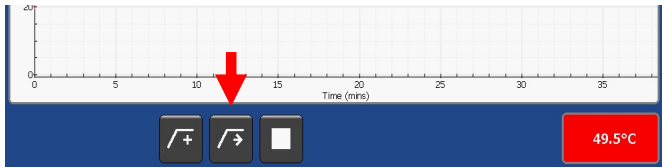
## TEMPERATURE

This shows the current temperature of the block as the experiment is progressing.



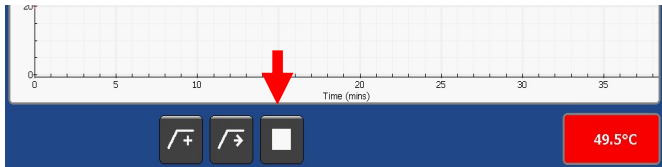
## EXTEND

This adds 10 minutes to the current phase of the run.



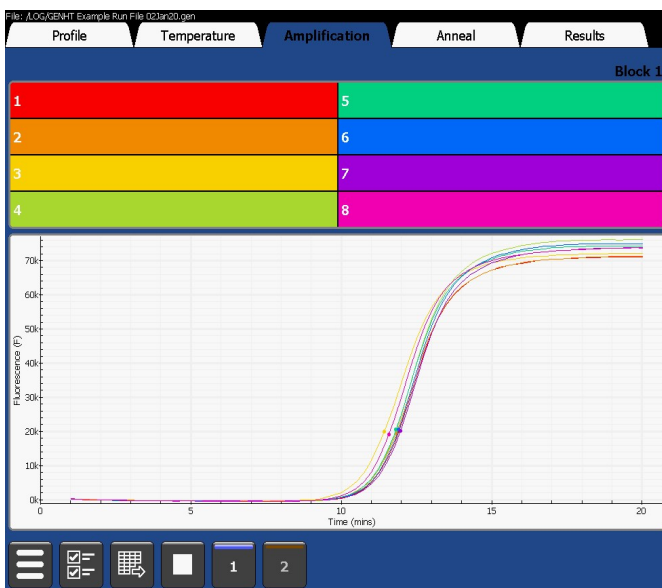
## ADVANCE

Advances to the next phase of the run (Preheat to Amplification or Amplification to Anneal).



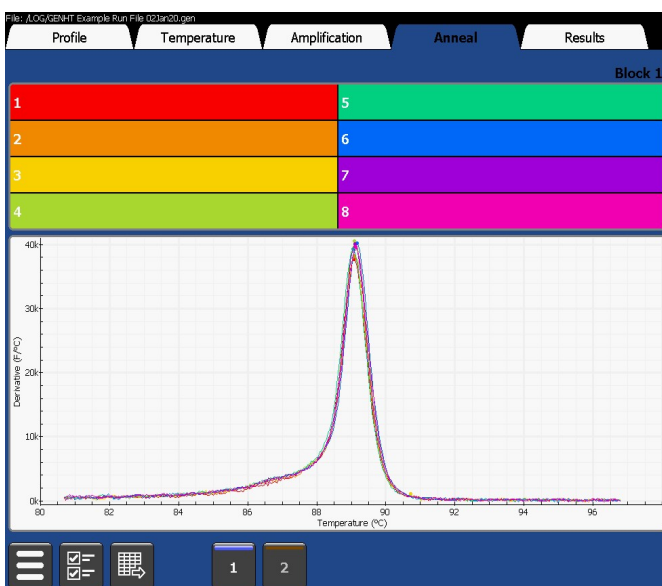
## STOP

The 'Stop' button will abort a run in progress. A confirmation pop up box will prompt 'Yes' or 'No'.



## AMPLIFICATION

This shows the fluorescence data that is being acquired during the amplification phase of the experiment.



## ANNEAL

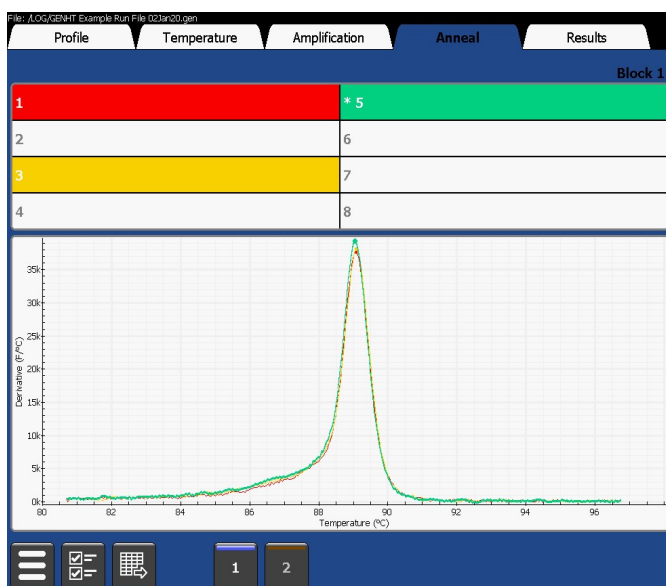
This shows the fluorescence derivative data that is being acquired during the anneal phase of the experiment.



## MULTIPLE CHANNEL OPTIONS

Genie® HT uses two different channels depending on the profile being run.

These buttons allow either the first or second channel to be selected. The graphs will update by pressing the relevant button on the 'Amplification' and 'Anneal' pages.



## SELECTION OF GRAPHS

Pressing the well name on either the 'Amplification' or the 'Anneal' page cycles the state of the related curve on the graph between normal, highlighted and off.

File: A00-GENHT Example Run File 02Jan20.gen

Tested: 18 December 2019 11:43

	Well	Type	Result	Peak Ratio	Anneal peak
1		Blue	POSITIVE	11:55	89.08°C
2		Blue	POSITIVE	11:49	89.09°C
3		Blue	POSITIVE	11:26	89.09°C
4		Blue	POSITIVE	11:50	89.10°C
5		Blue	POSITIVE	11:49	89.05°C
6		Blue	POSITIVE	11:54	89.17°C
7		Blue	POSITIVE	11:58	89.10°C
8		Blue	POSITIVE	11:35	89.14°C

At the bottom of the interface, there are icons for a document, a list, and two buttons labeled 1 and 2.

## RESULTS

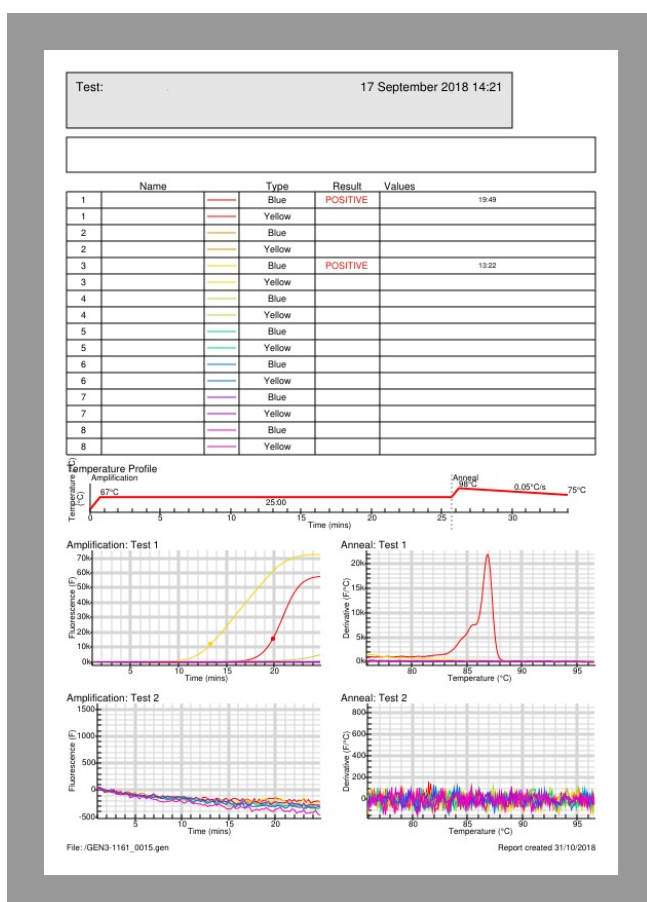
This shows the results of the experiment. Each sample name is shown as well as amplification time and annealing temperature and any result that has been defined using the result calling.

## REPORT GENERATION

6		Blue	POSITIVE	11:54	89.17°C
7		Blue	POSITIVE	11:58	89.10°C
8		Blue	POSITIVE	11:35	89.14°C



Pressing the button shown on the results page will generate an A4 PDF report. This will be a single page report showing the amplification graph, the anneal graph and the results table. These reports will be saved into a 'Reports' directory on the internal storage.



An example of a generated report file.

## EXPORT TO CSV

6		Blue	POSITIVE	11:54	89.17°C
7		Blue	POSITIVE	11:58	89.10°C
8		Blue	POSITIVE	11:35	89.14°C



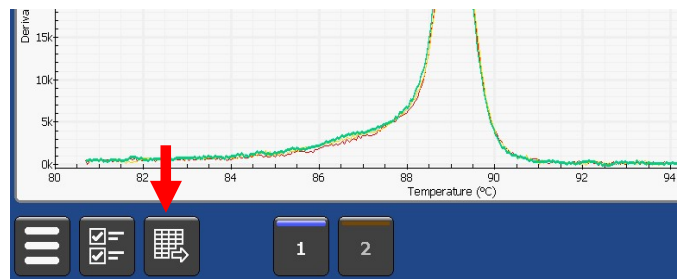
Pressing the button shown on the results page will generate a CSV (comma separated values) file with the results in and save it in the 'Reports' directory on the Genie® instrument.

The formatting can be switched between tab or comma separated using the setting in 'Admin' in Settings along with what data

is put into the CSV.

	A	B	C	D	E	F
1	Report created from	GEN3-1144	/GEN3-1161_0015.gen			
2	Experiment:	arco-genus				
3	Time:	17-09-18 14:21				
4	User:					
5	Kit:					
6						
7		Well	Type	Result	Values	
8						
9		1	Blue	POSITIVE	19:49	
10		1	Yellow			
11		2	Blue			
12		2	Yellow			
13		3	Blue	POSITIVE	13:22	
14		3	Yellow			
15		4	Blue			
16		4	Yellow			
17		5	Blue			
18		5	Yellow			
19		6	Blue			
20		6	Yellow			
21		7	Blue			
22		7	Yellow			
23		8	Blue			
24		8	Yellow			
25						
26	Notes:					
27						

An example of a generated CSV file opening in Microsoft Excel.



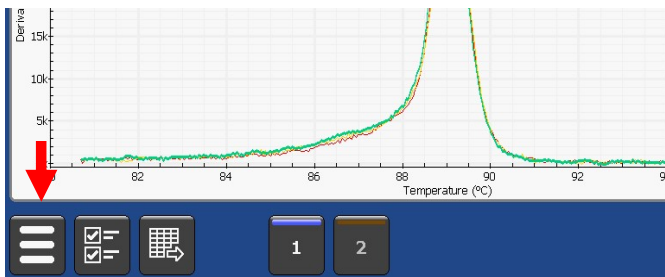
**Any graph** can have its data exported to a CSV file also by clicking on Export data in the Graph Options menu.

PRINT RESULTS TABLE

7		Blue	
8		Blue	

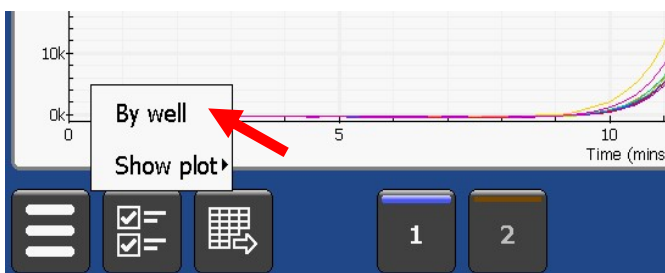
Pressing the button shown on the results table will print the table onto a label if the correct printer is attached to the Genie® instrument via the USB ports on the front of the instrument.

## ADDITIONAL OPTIONS

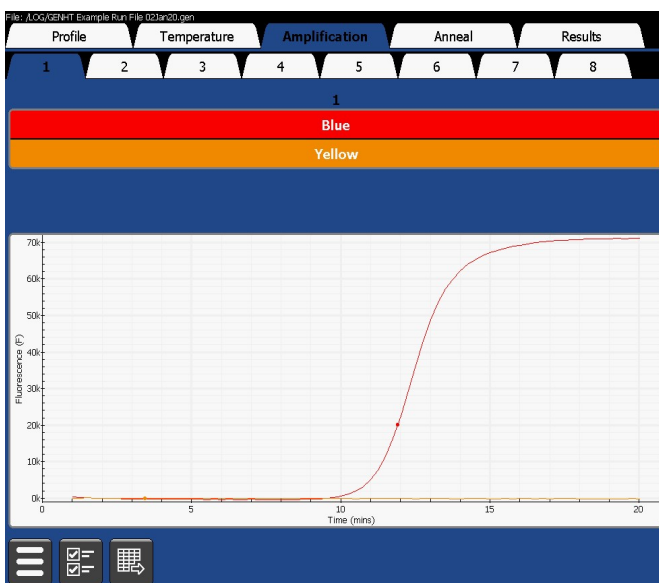


Touching the button shown on the amplification or anneal plots will show a drop down menu with some additional options.

## BY WELL

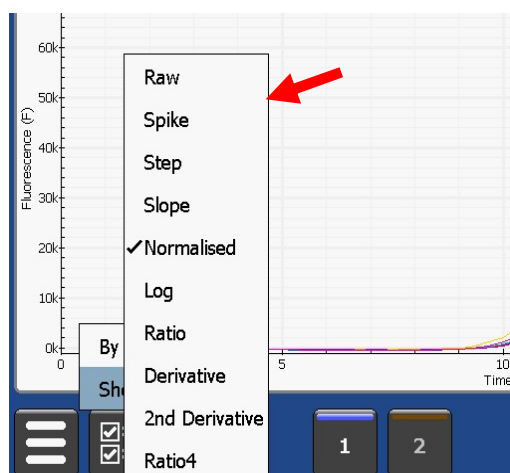


Selecting 'By well' will show all fluorescence plots by well rather than by fluorescence channel.



This allows comparison of both channels at the same time. This can be reversed by the same process.

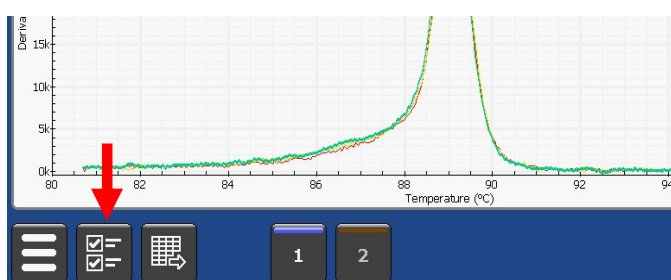
## SHOW PLOT



Selecting 'Show plot' will produce a second menu to select which plot to display on the screen depending on which signal processing step is wanting to be viewed. These are explained below and further in Chapter 6.

<b>Raw</b>	Raw unprocessed fluorescence
<b>Spike</b>	The data after spike removal
<b>Step</b>	The data after step removal
<b>Slope</b>	The data after slope correction
<b>Normalised</b>	The data after normalisation
<b>Log</b>	The log of the normalised data.
<b>Ratio</b>	The ratio ( $dF/F$ ) of adjacent points (after step removal). This plot is smoothed with an averaging filter.
<b>Derivative</b>	The gradient of the data (generated with a differentiating filter)
<b>2nd Derivative</b>	The gradient of the derivative (a second application of the same filter)
<b>Ratio4</b>	An alternative ratio ( $(F-1-F1)/F0^2$ ) that gives an earlier indication of amplification.

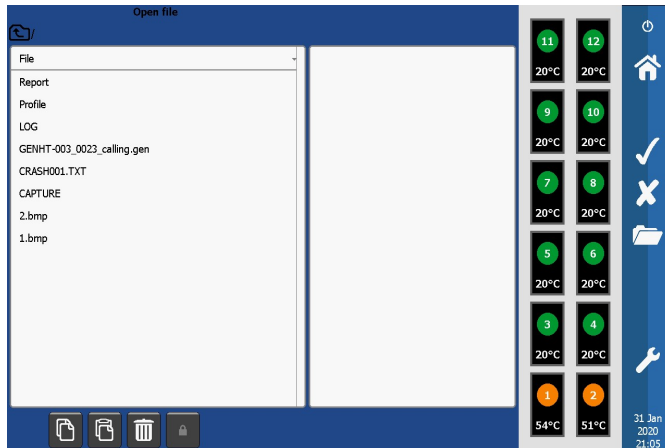
## RESULT CALLING



Result calling is explained in further detail in Chapter 6.

# VIEW

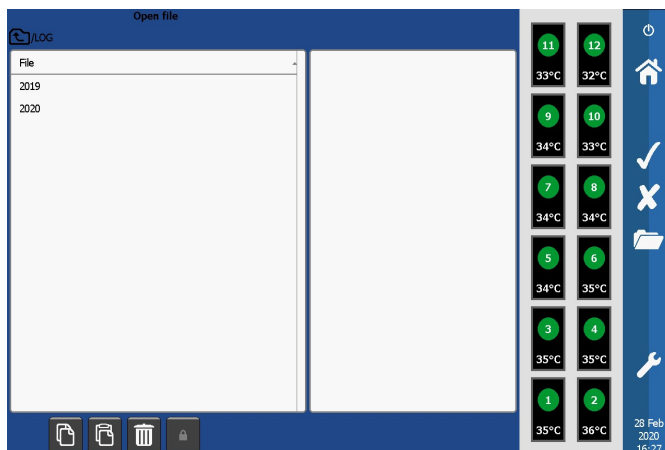
To view previous runs press the folder icon on the status bar.



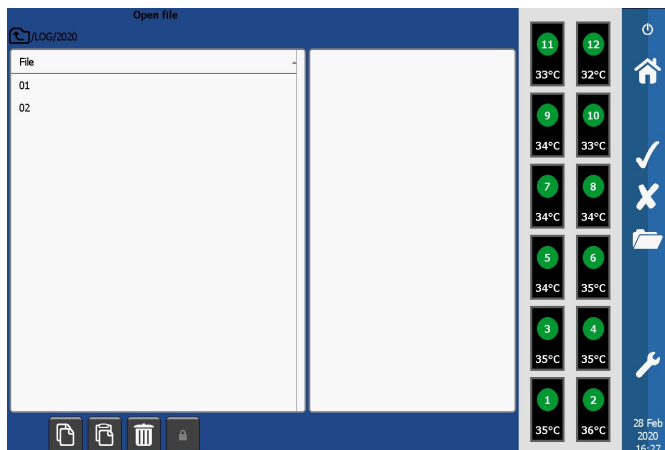
This will display a file browser window.

All Genie® HT runs are saved in the 'LOG' folder.

To open, click on 'LOG' and then tick icon, or double press on the folder name.

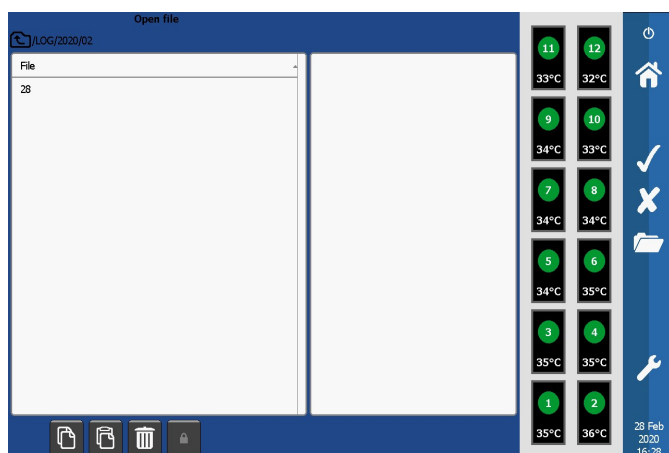


Each run is stored in a folder by date order:  
**Year**/Month/Day.

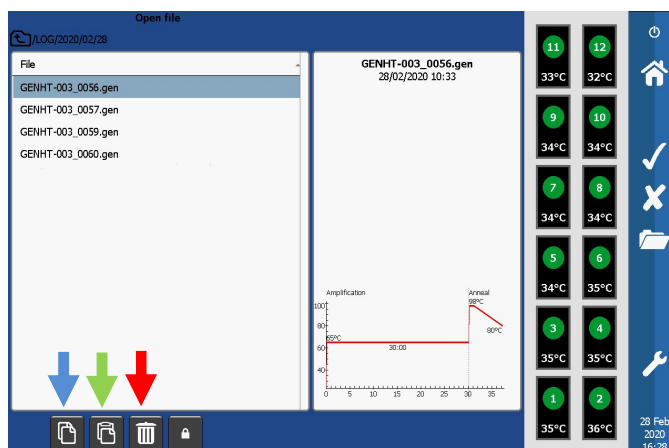


Each run is stored in a folder by date order:  
Year/**Month**/Day.





Each run is stored in a folder by date order:  
Year/Month/**Day**.



The default filename for the each run is the instrument serial number followed by a sequential number.

Select a file, then touch the tick button to load the file.

To copy a file, touch the copy icon, shown with the blue arrow.

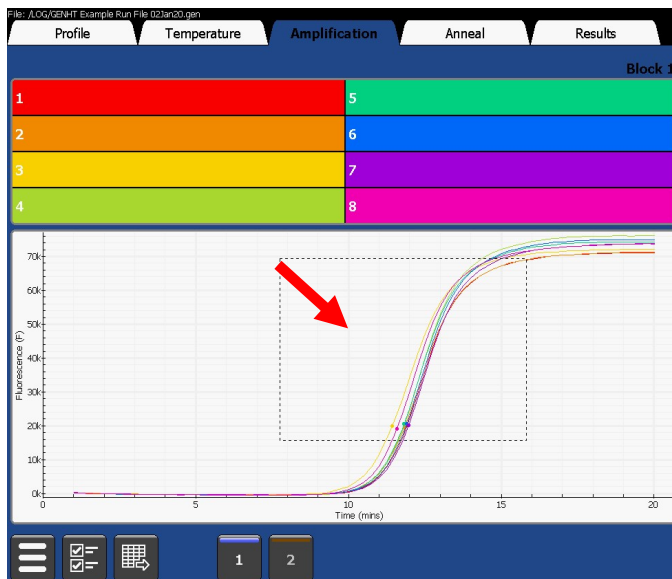
To paste a file, touch the paste icon, shown with a green arrow.

To delete a file, touch the trash can icon, shown with a red arrow.

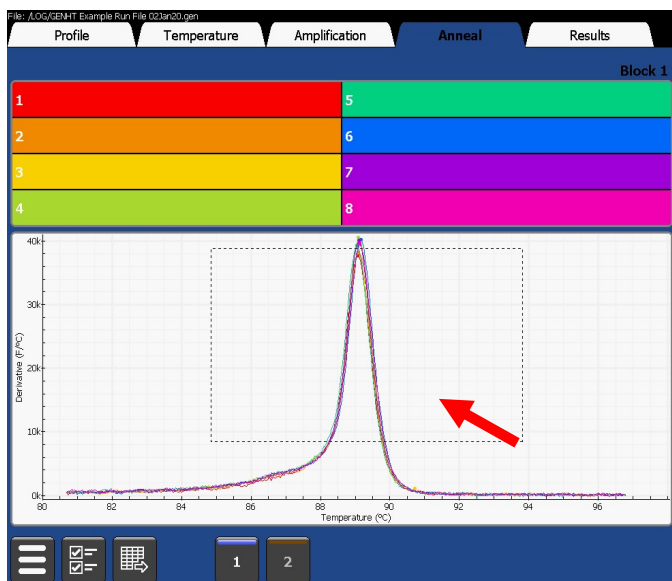
When the file has opened, Genie® HT will display the profile that was run, the temperature log, amplification data, anneal data and the results table. Up to 12 runs can be open at once.

## ZOOMING FUNCTION

Zooming is available on temperature, fluorescence and anneal graphs.



To zoom in on the area of interest, touch the plot area and drag to the right and/or down.



To zoom out, touch on the plot area and drag to the left and/or up.

A double press on the screen will zoom out to the full extent of the graphs.

# Chapter

# 6

## GENIE RESULT CALLING

### OVERVIEW

Genie® instruments can generate results according to detected amplification times, anneal peaks and other features. Due to the varying requirements of differing applications, setting up the parameters is highly flexible.

Analysis is based on **targets**, where each target has its own set of parameters and possible results. Each well can have up to three targets assigned for multiplex applications.

The target parameters specify the fluorescence channel, target type and various signal processing options.

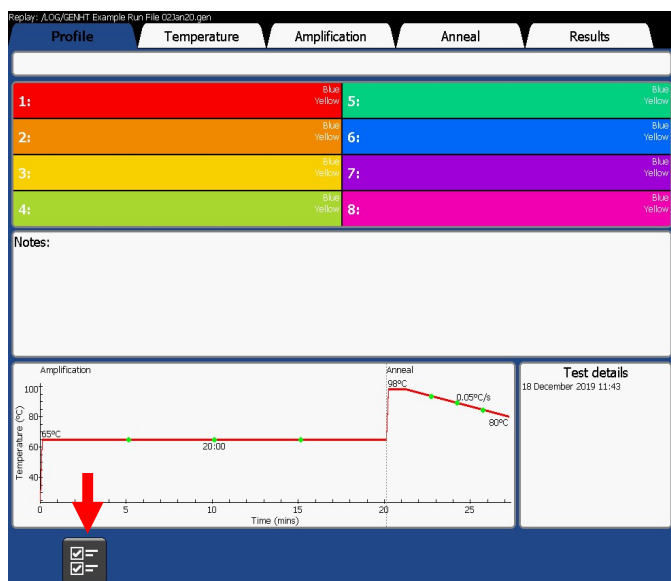
Detection starts with examining **regions** of interest on various graphs for required **features**.

The presence or absence of features in the regions determine which **result** is displayed for the well. The presence or absence of control targets in other wells can also be included in the determination.

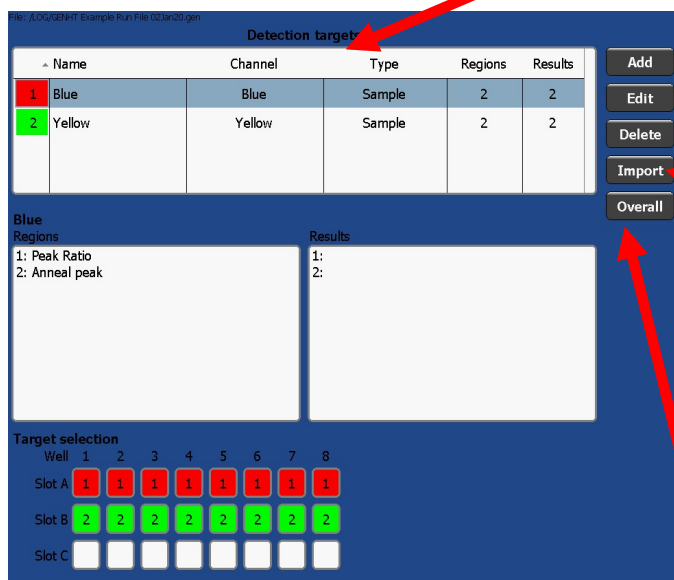
Advanced features allow regions to be defined relative to other regions or the results of other targets.

For multi-well assays, that may use the whole strip and where more than positive & negative controls are needed, an overall result can be determined.

# RESULT CALLING INTERFACE



Pressing this button on the profile screen will allow the user to change the parameters for result calling for the profile. All the parameters are stored within the profile and the run file.



This screen shows an overview of the 'Detection targets', showing the number of regions of interest, the number of results, and which targets are assigned to which well. From here new targets can be added, imported from other runs or profiles, edited or deleted.

If you wish to import targets from another profile or run file, touch 'Import' and then select the file you wish to import from, you can then select which target from that file you wish to import.

The 'Overall' button allows the user to create an overall result based on the results of multiple wells.

## TARGET PARAMETERS

Target 1

Name: Blue Type: Sample

Channel: Blue Quenching: ☐

☐ Spike removal Spike threshold: 0.03

☐ Step removal Step threshold: 0.05

☒ Slope correction ☒ Normalisation Norm/Slope time: 0 180 s

Control scope: Strip Smoothing: 0

Regions Results

This screen shows the Target parameters. The explanation of the different options is below.

**Name** The name of the target is displayed in the results table and various reports.

**Type** The target type determines the purpose of the target:

- Sample** A normal sample for analysis
- Pos control** A positive control that is expected to amplify.
- Neg control** A negative control that should not amplify.
- Reference** Some other secondary target

**Chan** The fluorescence channel / colour to examine. All regions for a target use the same channel.

**Quenching** Indicates that amplification causes a decrease in signal. Ratios and derivatives are inverted for quenching.

**Spike removal** Enable/disable spike removal. Spike removal identifies single-point spikes in fluorescence and replaces them with the average of the two adjacent points.

Spike removal analyses the data to remove rogue spikes from the fluorescence data. Spikes can be caused by particles or bubbles in the well and by external environmental factors.

**Spike threshold** Spike detection finds points in fluorescence that are proportionately higher or lower than the points on either side. The threshold should exclude normal noise in the signal. Peak noise in the unsmoothed ratio plot with spike and step removal turned off gives a good indication of the minimum threshold.

The spike removal threshold is target-dependant and is affected by noise:signal ratio of the assay.

**Step removal** Enable step removal. Step removal identifies sudden steps in fluorescence and subtracts the step height from all subsequent fluorescence values. Steps can be caused by particles, bubbles, drips and settling of well contents. Step removal occurs after spike removal.

**Step threshold** Step detection is approximately based on detecting single point spikes in the ratio (unsmoothed, with step removal turned off) exceeding the threshold on both sides. Set the threshold to clearly exceed the peak-to-peak noise.

Excessive step removal will cause flat areas and shifted amplification.

The step removal threshold is target-dependant and is affected by noise:signal ratio of the assay.

<b>Slope</b>	Slope correction adjusts for drift by examining the initial fluorescence and removing the slope from subsequent fluorescence data after a given time period ( <b>Time</b> ). Slope correction occurs after spike and step removal.										
<b>Normalisation</b>	Normalisation removes the average initial fluorescence from all fluorescence data after a given time period ( <b>S/N time</b> ). Slope correction and normalisation both use the same time.										
<b>Control Scope</b>	<p>When the target type is 'Pos Control' or 'Neg Control', this indicates which group of wells the control is related to.</p> <table><tr><td><b>None</b></td><td>The control is stand-alone and does not contribute to the result of other targets</td></tr><tr><td><b>Well</b></td><td>The control only applies to other targets in the same well</td></tr><tr><td><b>Pair</b></td><td>Applies to targets in the same pair (1-2, 3-4, 5-6, 7-8)</td></tr><tr><td><b>Half</b></td><td>Applies to targets in the same half-strip (1-4, 5-8)</td></tr><tr><td><b>Strip</b></td><td>Applies to all targets in the same strip (1-8).</td></tr></table>	<b>None</b>	The control is stand-alone and does not contribute to the result of other targets	<b>Well</b>	The control only applies to other targets in the same well	<b>Pair</b>	Applies to targets in the same pair (1-2, 3-4, 5-6, 7-8)	<b>Half</b>	Applies to targets in the same half-strip (1-4, 5-8)	<b>Strip</b>	Applies to all targets in the same strip (1-8).
<b>None</b>	The control is stand-alone and does not contribute to the result of other targets										
<b>Well</b>	The control only applies to other targets in the same well										
<b>Pair</b>	Applies to targets in the same pair (1-2, 3-4, 5-6, 7-8)										
<b>Half</b>	Applies to targets in the same half-strip (1-4, 5-8)										
<b>Strip</b>	Applies to all targets in the same strip (1-8).										

Running controls in a different strip is of dubious validity, so is not directly supported.

<b>Smoothing</b>	This setting adjusts the amount of smoothing applied to anneal derivative plots. If this value is set to 0, the default smoothing settings in the instrument is used. If this is set to a value between 1 and 8, the instrument uses an alternative smoothing function which increases the amount of smoothing as the number is increased.
------------------	--

## CONTROL TARGETS

Control targets allow easy configuration of two control types (positive & negative).

A control has a scope which indicates which other targets / wells can be affected. Control scope is relative to the part of the strip that the sample well is in.

The state of the control is determined by the final result call.

For each well, controls within scope are collected and tested with the required / prohibited options.

Positive and negative controls are treated identically – just collected separately. It is therefore possible to reverse the meaning or use two positive controls that are handled differently.

Advanced users can create additional controls using references.

## REGIONS OF INTEREST

**Blue Regions**

Name	Type	Phase	Plot	Used
1 Peak Ratio	Peak	Isothermal	Ratio	+1/-0
2 Anneal peak	Peak	Anneal	Derivative	+1/-0

Buttons: Add, Edit, Delete

**Region 1 Details**

Peak Ratio  
 Peak Isothermal Ratio  
 X: 180 - 1200  
 Y: 0.01 - 0.01

This screen shows an overview of all the regions of interest for the selected target.

The type of region, as well as which phase of the assay and plot is summarised as well as the more specific details in the box below.

The regions can be edited and deleted from this screen.

**Blue: Add region 3**

Buttons: Max amplification ratio, Amplification threshold, Amplification rate, Anneal peak, Other

Touching 'Add' will display the screen shown. These are some generic preset regions to help get the user set up quicker. Alternatively touching 'Other' will allow the user to create something custom.

**Blue, Region 1**

Name: Peak Ratio Type: Peak  
 Phase: Isothermal Plot: Ratio  
 Peak: 25 %  
 Range X: 180 to 1200 s Absolute  
 Range Y: 0.01 to 0.01 dF/F Absolute  
☒ Show X in results ☐ Show Y in results ☒ Graph dot Result column: 1  
☐ Use as reference

This is the set up screen for the region. The explanation of the different parameters is below.

Regions of interest define which features to examine to generate a result.

<b>Name</b>	The region name appears in the results set-up.
<b>Type</b>	Selects the <i>feature type</i> to examine (explained further below in the section titled Features).
<b>Phase</b>	Selects the measurement phase to examine.
<b>Plot</b>	The graph to examine. Any step of the signal processing can be examined.
<b>Raw</b>	Raw unprocessed fluorescence
<b>Spike</b>	The data after spike removal
<b>Step</b>	The data after step removal

<b>Slope</b>	The data after slope correction
<b>Normalised</b>	The data after normalisation
<b>Limited</b>	The data after limiting (value set in the Target parameter screen)
<b>Ratio</b>	The ratio (dF/F) of adjacent points (after step removal). This plot is smoothed with an averaging filter.
<b>Derivative</b>	The gradient of the data (generated with a differentiating filter)
<b>2nd Derivative</b>	The gradient of the derivative (a second application of the same filter)
<b>Ratio4</b>	An alternative ratio $((F-1-F1)/F0^2)$ that gives an earlier indication of amplification.

Amplification phases use the steps Raw, Spike, Step, Slope, Normalised, Ratio, Derivative, Ratio4.

Anneal / melt phases use the steps Raw, Spike, Step, Derivative, 2nd Derivative.

**Range X/Y to** Specify the 'window' to examine. If the limits are the same, it is treated as a threshold. Units vary according to phase and plot selected. The meaning can vary according to type. Limits are inclusive.

**Relative to** Adjusts the range 'window' relative to the value found by another region.  
**BE AWARE:** Compatibility of units is not checked – it is possible to make nonsensical selections (e.g. by making a time range (in seconds) on an amplification plot relative to an anneal temperature in °C).

**Result X/Y** Displays the X and/or Y value found on the results table, provided the region is detected and used in the result.

**Result column** Specifies which column(s) of the results table to put the X/Y value in (default 1). If both X & Y are selected the X value is in the column specified and Y is in the following column.

**Graph** Show the point found on the graphs, provided the region is detected and used in the result.

**Use as reference** Advanced feature. Allows the point found to be referenced by another target, provided the region is detected and required by the result.

Additional parameters will be displayed depending on the feature type selected. These are explained further later.

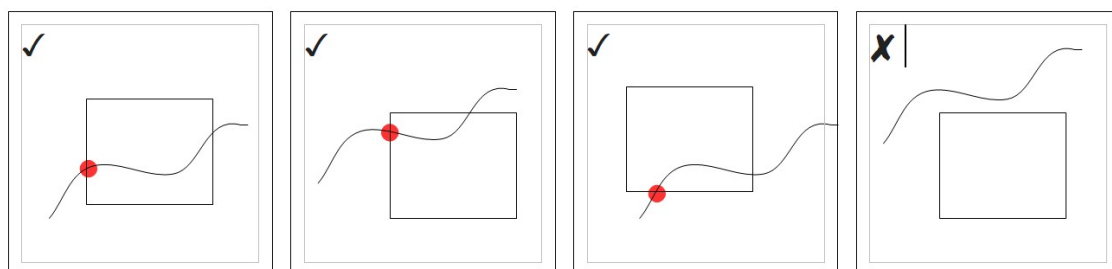
Regions (other than Threshold type) are independent unless they explicitly use relative ranges; in which case the region is undefined until the region(s) it is dependent on is/are fully determined. Be careful not to create circular references as all regions will remain undefined.



## FEATURES

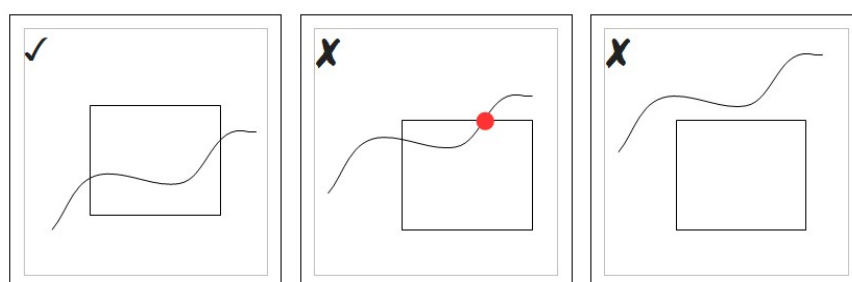
### Feature type: Any

Positive if:	Any point on the graph is within the window.
Negative if:	All points in X range are outside Y range.
Complete when:	X position passes the window or a point in range is found
Point identified:	The first point that falls in the window (without interpolation)
Additional parameters:	None
Uses:	Crossing threshold, Progress check.



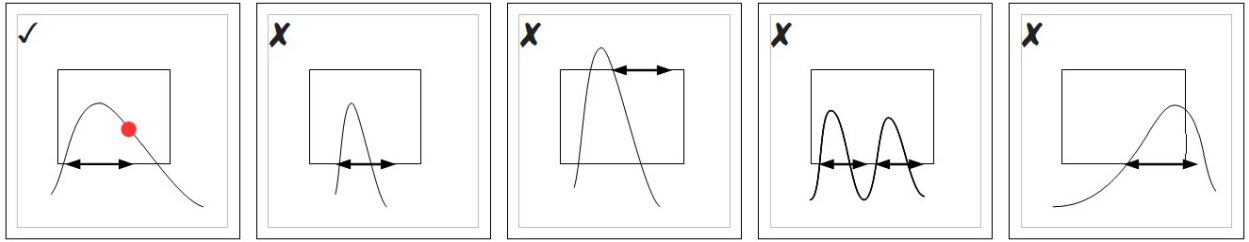
### Feature type: All

Positive if:	All points in the X range fall within the Y range
Negative if:	Any point in the X range falls outside the Y range
Complete when:	X position passes the window or a point in X range falls outside Y range
Point identified:	The first point in X range that falls outside Y range (if any)
Additional parameters:	None
Uses:	Range check



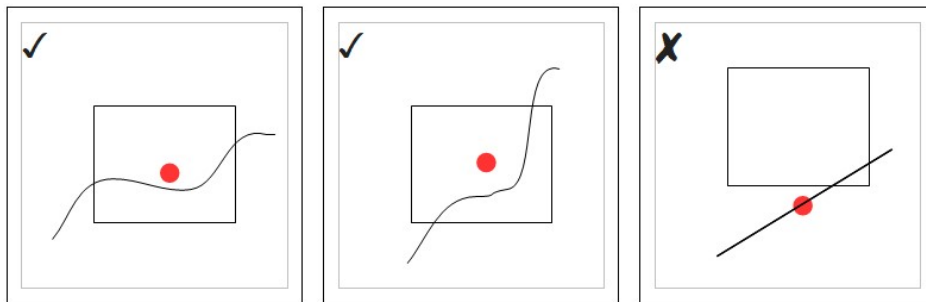
### Feature type: Min

Positive if:	A minimum width in X range falls within Y range
Negative if:	No group of points in window cover width.
Complete when:	Minimum width found or X position passes window.
Point identified:	The point where the minimum width is satisfied (i.e. width after crossing point)
Additional parameters:	<i>Width</i> : in the same units as the X axis
Uses:	Amplification rate check, anneal peak width, noise rejection.



## Feature type: Average

Positive if:	The average of all points in X range falls within Y range
Negative if:	The average of all points in X range falls outside Y range
Invalid if:	There are no points in X range
Complete when:	X position passes window
Point identified:	Y: Average Y value within X range X: Midpoint of X range
Additional parameters:	None
Uses:	Level check

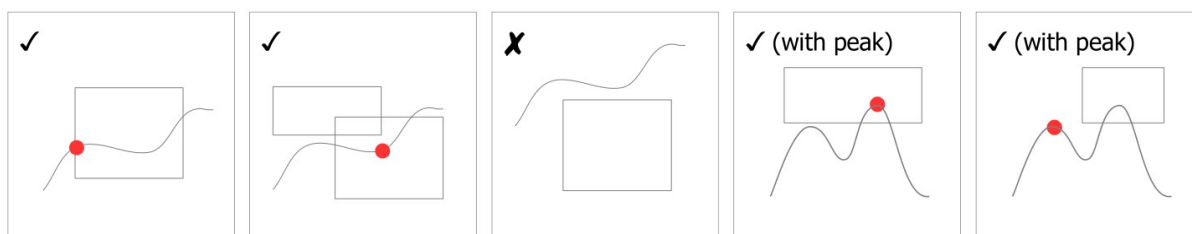


## Feature type: Threshold

All thresholds required or prohibited by a result are considered together. A threshold that is *prohibited* has its Y range inverted.

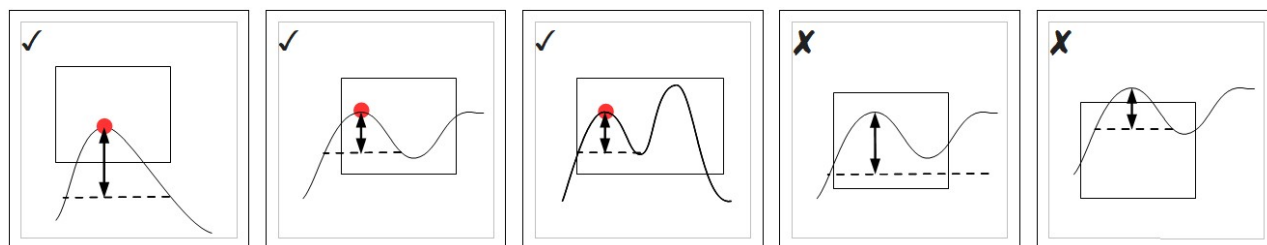
If peaks (or dips) are required, each peak is checked against all required thresholds.

Positive if:	There is a point/peak where all thresholds that are in X range are also in Y range or there is a peak where no thresholds are in X range.
Negative if:	There are no points/peaks where all thresholds are in Y range
Complete when:	A point/peak is found or X position passes window
Point identified:	The first point/peak that satisfies all thresholds
Additional parameters:	None
Uses:	Crossing threshold with multiple conditions or regions Additional peak detection criteria (e.g. minimum fluorescence)



## Feature type: Peak

Positive if:	A peak is detected in X range, with peak point in Y range (before interpolation) All required thresholds that are in X range must also be satisfied.
Negative if:	No peak detected or all peaks out of Y range or thresholds are not satisfied
Complete when:	Peak found or peak tracking point passes window (hysteresis threshold can be outside X range)
Point identified:	Peak position, if found, interpolated with 3-point quadratic fit.
Additional parameters:	<i>Peak %</i> : Detection hysteresis – signal must drop specified amount on both sides for a peak to be detected. Lower values are more sensitive to local maxima.
Uses:	Amplification time, Anneal temperature.



## Feature type: Dip

Identical to Peak type, except minima are identified instead of maxima.

## Feature type: Reference

This is an advanced calling feature to allow results from one well to affect others.

Positive if: The referenced target result is positive  
Negative if: The referenced target result is negative  
Invalid if: The referenced target result is invalid  
Complete when: The referenced target produces a result  
Point identified: The point identified by a target region that matches all the following criteria:

- Is *required* by the result of the target
- Has a valid point
- Uses matching Phase and Plot
- Has the Reference option set.

Additional parameters:

<i>Well:</i>	Well number reference.
<i>In:</i>	Relative location of reference well
<i>Same:</i>	in the same well as the current target
<i>Adjacent:</i>	in the well adjacent to the current well (other well of pair)
<i>Pair:</i>	Well 1 or 2 in the current pair
<i>Half:</i>	Well 1-4 in the current half-strip
<i>Strip:</i>	Well 1-8 in the current strip
<i>Target:</i>	Target slot to examine

Unused parameters: Window range parameters.

Uses: Comparison of amplification times, anneal temperatures, SNP target alignment, extra controls.

File: AOC\_GEN-HT Example Run File 023a033.gen

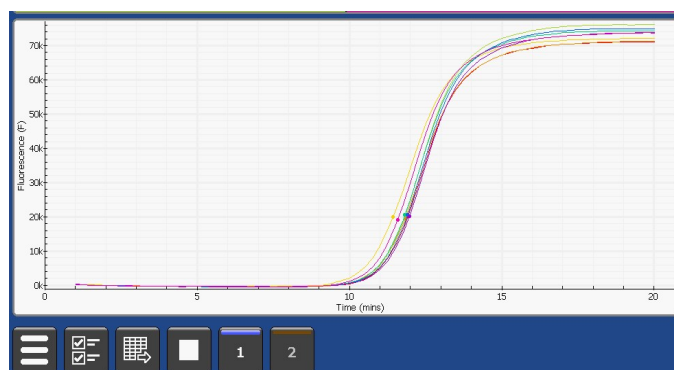
Blue, Region 1

Name	Peak Ratio	Type	Peak
Phase	Isothermal	Plot	Ratio
Peak	25 %		
Range X	180 to 1200 s	Absolute	
Range Y	0.01 to 0.01 dF/F	Absolute	

☒ Show X in results   ☐ Show Y in results   ☒ Graph dot   Result column 1

☐ Use as reference

The points at which the criteria are met are marked by a dot on the graph line.



## RELATIVE REGIONS

Relative regions allow features to be aligned to other features.

Example 1: Find the first peak ratio after normalised fluorescence has passed a threshold.

1. Create an 'any' region, testing normalised fluorescence
2. Create a 'peak' region, testing smoothed ratio; X range 0-0, relative to region 1

Example 2: Test the fluorescence at a peak ratio location.

1. Create a 'peak' region, testing smoothed ratio
2. Create an 'average' region, testing normalised fluorescence; X range -30 to +30, relative to region 1.

Regions can be relative to the values found by other targets, by using references.

## RESULT DEFINITIONS

File: /LOG/GENHT-1007\_Example Run File Block 12.gen

**Blue Results**

	Text	Type	Requires	Prohibits
1	POSITIVE	Positive	2	0
2	NEGATIVE	Negative	0	0

Result 1  
Details  
POSITIVE  
Positive

Buttons: Add, Edit, Up, Down, Delete

This screen shows an overview of the target results. The type and how many regions required/prohibited are shown.

The order of which the results are called is important. This can be changed by selecting a result and using the up and down arrows. The first matching result will be displayed in the result table.

New results can be added and results can be deleted from this screen.

File: /LOG/GENHT-1007\_Example Run File Block 12.gen

**Blue, Result 1**

Text: POSITIVE      Foreground: ■      Background: POSITIVE

Result: Positive ▼

Required: ☐ Positive controls ☐ Negative controls ☒ 1: Peak ratio ☒ 2: Arneal peak

Prohibited: ☐ ☐ ☐ ☐

Adding or editing a result will show this screen. The explanation of the different parameters is below.

Result definitions specify which features are required or prohibited for each possible result. Result definitions are tested in order. The first matching result is displayed in the result overview table.

Result checking waits for all dependant regions to complete, or until no pending regions can affect the result (e.g. if a prohibited region is positive, the state of other regions is irrelevant).

**Text** This is the result message seen by the user on the results table and recorded in reports.

**Colour/ on** These are the foreground and background colour of the displayed result.

**Result** The type of the result

None: An unused result that will block later results until determined.  
Provisional: An intermediate result that will be shown until/unless overridden.  
Invalid: A final result that cannot be determined  
Positive: A final result determined as positive  
Negative: A final result determined as negative

**Required** Select all regions and controls that must be positive to satisfy this result.

**Prohibited** Select all regions and controls that must be negative to satisfy this result.

Unselected regions and controls have no effect on the result. Regions that are both required and prohibited should be avoided – this combination may be given a special meaning in the future.

All positive control targets whose scope includes a particular well are collected together in one pair of required/prohibited tick boxes (likewise for negative control targets). Fine-grained use of controls can be achieved by advanced users by using reference regions.

File: AOCUGENHT Example Run File (02Jan20).qm

Profile Temperature Amplification Anneal Results

Tested: 18 December 2019 11:43

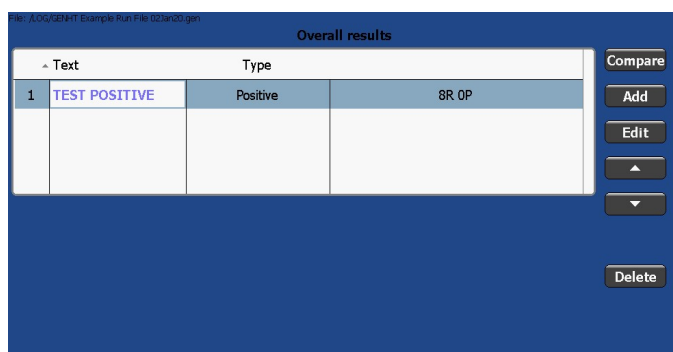
	Well	Type	Result	Peak Ratio	Anneal peak
1		Blue	POSITIVE	11:55	89.08°C
2		Blue	POSITIVE	11:49	89.09°C
3		Blue	POSITIVE	11:26	89.09°C
4		Blue	POSITIVE	11:50	89.10°C
5		Blue	POSITIVE	11:49	89.05°C
6		Blue	POSITIVE	11:54	89.17°C
7		Blue	POSITIVE	11:58	89.10°C
8		Blue	POSITIVE	11:35	89.14°C

1 2

This shows the result table showing the called result.

## OVERALL RESULT

Overall result calling takes the results for each well and combines then to give a result for the whole strip.



This screen shows the defined overall results. Result definitions are tested in order. The first matching result is displayed. This order can be changed using the up and down arrow buttons.

The Compare feature is explained below.

## OVERALL RESULT DEFINITIONS

The result definition set up screen. The explanation of the different parameters is below.

Overall result definitions specify which wells are required or prohibited for each possible result.

Result checking waits for all dependant wells to complete, or until no pending wells can affect the result (e.g. if a prohibited well is positive, the state of other wells is irrelevant).

**Text** This is the result message seen by the user and recorded in reports.

**Colour/ on** The foreground and background colour of the displayed result.

**Required** Select all wells and comparisons that must be positive to satisfy this result

**Prohibited** Select all wells and comparisons that must be negative to satisfy this result

Unselected wells have no effect on the result. Wells that are both required and prohibited should be avoided – this combination may be given a special meaning in the future.

A well is positive if any target produces a **positive** result type.

A well is negative if any target produces a **negative** result type.


File: /LOG/GEN-HT Example Run File 02Jan20.gen

Profile   Temperature   Amplification   Anneal   Results

Tested: 18 December 2019 11:43

**TEST POSITIVE**

	Well	Type	Result	Peak Ratio	Anneal peak
1		Blue	POSITIVE	11:55	89.08°C
2		Blue	POSITIVE	11:49	89.09°C
3		Blue	POSITIVE	11:26	89.09°C
4		Blue	POSITIVE	11:50	89.10°C
5		Blue	POSITIVE	11:49	89.05°C
6		Blue	POSITIVE	11:54	89.17°C
7		Blue	POSITIVE	11:58	89.10°C
8		Blue	POSITIVE	11:35	89.14°C



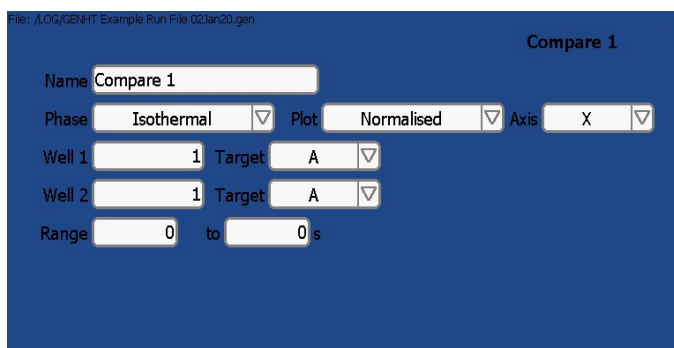
1 2

An overall result is displayed at the top of the results table, as shown in the screenshot.



## WELL COMPARE

Values calculated for wells can be compared and included in the overall result.



The compare set up screen. The explanation of the different parameters is below.

<b>Name</b>	The compare name appears in the results set-up.
<b>Phase</b>	Select the phase to compare (e.g. isothermal or anneal)
<b>Plot</b>	Select which data step to compare (e.g. normalised fluorescence)
<b>Axis</b>	Select which axis to compare (X or Y)
<b>Well 1/2</b>	Set which wells to compare
<b>Target</b>	The targets to compare
<b>Range</b>	The comparison is positive if the difference between well values is in the specified range. (Well 2 value - Well 1 value)

A region that is set to 'Use as reference', tests the selected phase and plot, and is required by the well target result, is needed before the comparison is made.

## CONNECTING TO EXTERNAL DEVICES

Genie® HT is a standalone instrument; however, it can be connected to external devices for software updates, data upload and further analysis. Files can be transferred to a PC running Microsoft Windows (XP, Vista, 7, 10) via the USB connection on the back of the instrument or via WiFi to a phone/mobile device with a network connection or via a pendrive to the USB socket on the rear of the instrument. Genie® can also be connected to a barcode scanner for text input.

### PENDRIVE

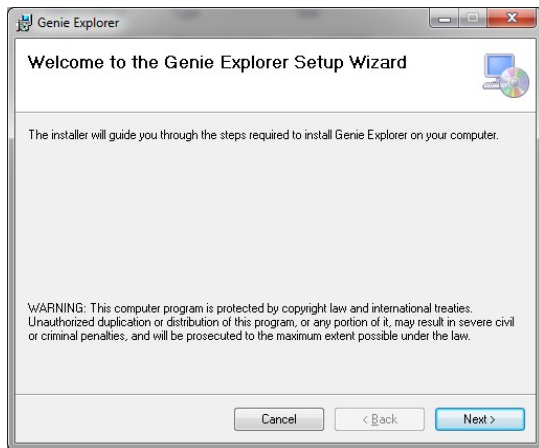
A pendrive can be plugged into the USB A sockets on the front of the unit. This allows files and software updates to be transferred to and from the unit without it needing to be connected to a PC. The pendrive can be accessed via any file manager screens, including the software update screen, allowing updates to be performed at a site without needing a computer.

### WIRED CONNECTION

***Disclaimer: Genie® Explorer is an additional tool and should not be used for patient care or clinical analysis.***

***\*GENIE EXPLORER CAN ONLY BE USED TO VIEW FILES FROM GENIE® HT.***

***IMPORTANT!*** Do not plug any Genie® instrument into the computer before installing Genie® Explorer. Genie® Explorer can be installed from the USB drive included with any Genie® Instrument.



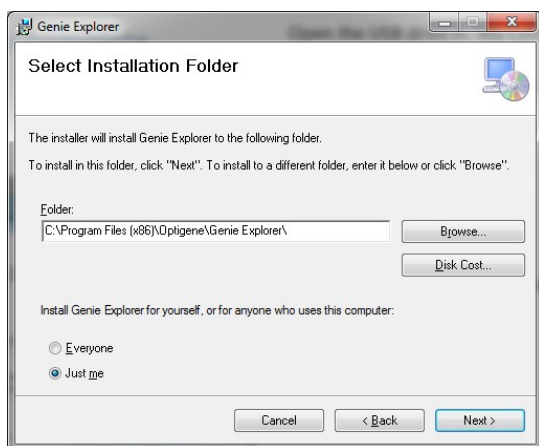
Open the USB drive in 'My Computer'.

Run the file 'GenieInstall.msi'.

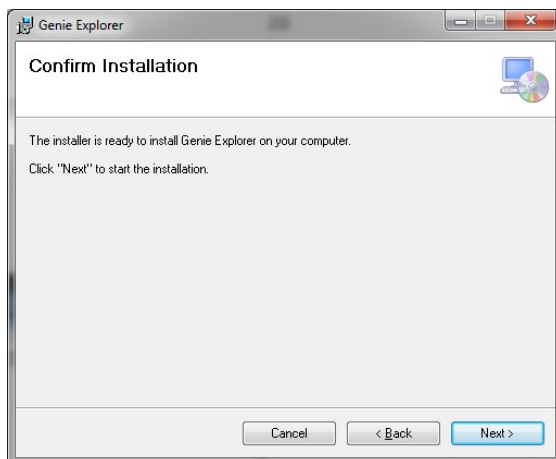
Follow the onscreen instructions.

\*A prompt may appear requesting installation of .NET Framework 4.0. This must be installed prior to installation. Follow the link to the Microsoft download page.

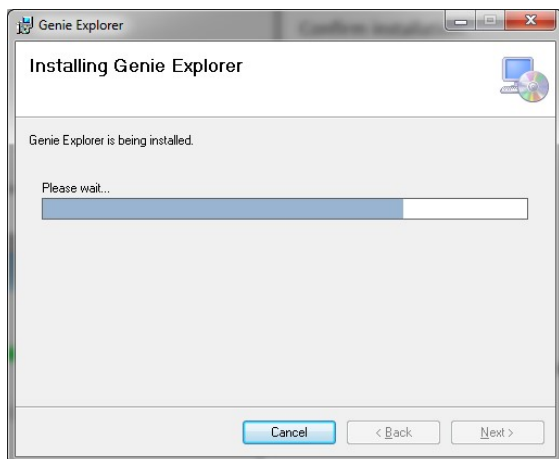
<http://www.microsoft.com/en-gb/download/details.aspx?id=17718>



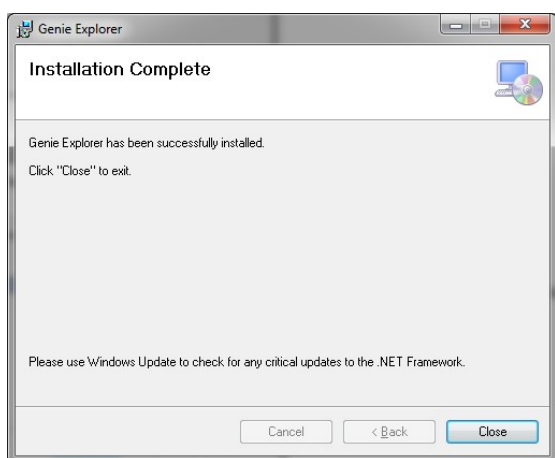
Choose a location for the installed program.



Confirm to start the installation.



The installer will copy all necessary files to the computer.



Once the installation is complete, exit by clicking 'Close'.

A Genie® instrument can now be connected to the computer. When connected via USB and switched on, the Genie® instrument will appear as a USB drive and files can be viewed from Genie® Explorer.

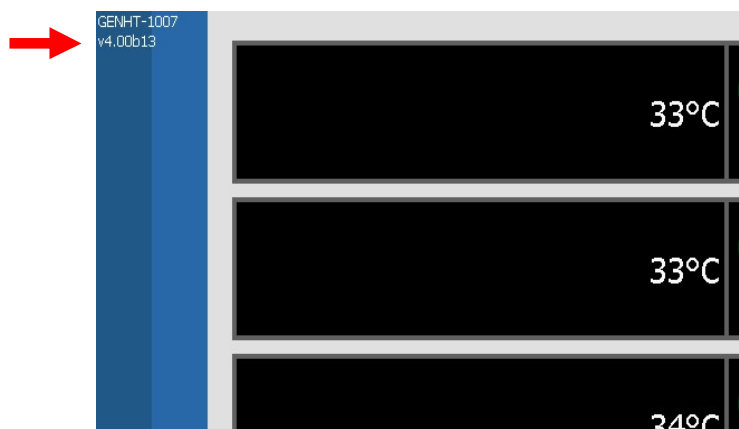
## WIRELESS CONNECTION\*

\*Currently in development.

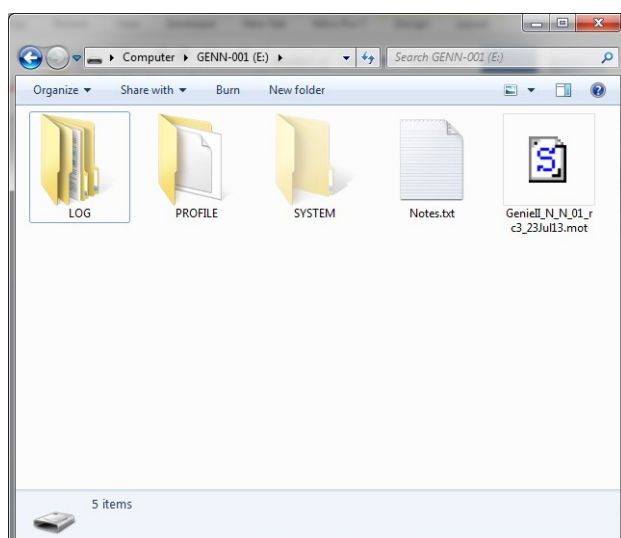
# GENIE® HT SOFTWARE UPDATES

It is recommended to keep the software on Genie® HT up-to-date. Upgrading may improve performance and add new features to Genie® HT.

The current version of firmware that is installed on Genie® HT is displayed in the top left corner of the home screen.

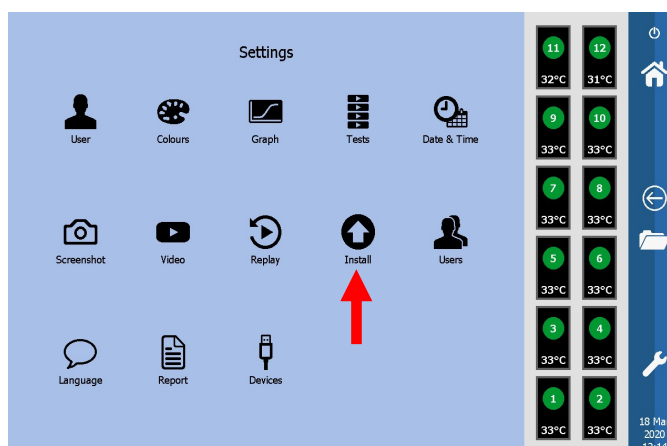


- To download the latest firmware, visit the OptiGene website (<http://www.optigene.co.uk>). Click on 'Support' and click on the appropriate link on the right hand side of the page and download the '.zip' file.
- Open the '.zip' file and extract the contents to a new folder. The contents of the folder will include the latest firmware as two '.mot' files.



To install the updates, connect Genie® HT to a computer. Navigate to 'My Computer' and open the Genie® HT drive. The drive is named with the instrument serial number, e.g. GEN3-1001. Copy and paste (or drag) the firmware or FPGA software files onto the Genie® HT drive.

The files can also be loaded to a pendrive which can be plugged into the instrument to install updates.



Now on Genie® HT touch Settings, and then touch 'Install'. Genie® HT will prompt for a file to use for the update.



Touch on the file, and touch the tick button. The Genie® HT will then install the updated software and restart the instrument. Please wait for it to finish before trying to do anything else.

Repeat this action for both files.

If the update was a firmware update, Genie® HT will restart when completed.

Genie® HT will automatically delete the files if they are on the internal file system when the update has completed.

# Chapter

# 8

## GENIE® HT TECHNICAL SPECIFICATION

Sample Number	12 x 8 wells
Sample Volume	10 µl to 150 µl
Touchscreen	10.1" High-brightness LCD with multi-touch projective capacitive touch panel (1280 x 800)
Heater technology	Ceramic substrate with resistive coating
Cooling method	Forced convection
Temperature sensor	High-precision thermistor
Temperature control type	Multi-zone independent digital PID
Temperature control range	ambient - 100°C
Temperature accuracy	±0.1°C
Temperature uniformity across block	±0.2°C
Temperature gradient	Programmable up to 8°C
Optics source	470 nm & 590nm dual colour LED with high-quality interference filter 40 nm band pass
Detection optics	Photodiodes with high-quality interference filters 510-560 nm band pass & 620 nm long pass
Operating temperature	0°C - 40°C
Storage Temperature	20°C - 70°C
Approvals	CE
Dimensions	635mm (L) X 434mm (W) X 153mm (H)
Weight	18kg / 40lbs
Connections	1 x USB 'B' 2 x USB 'A' 1 x Power in 1 x RJ45 – Network connection 1 x USB 'A' – diagnostic port
Environmental protection	IP20
Wireless Connections	Bluetooth & WiFi
Power supply	Input: 100-240V AC



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If you have any feedback or comments about the instrument please email:

[feedback@optigene.co.uk](mailto:feedback@optigene.co.uk)

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Version	Date	Changes	Approved
V1.00	18/3/2020	Initial Release	SUL
V1.01	24/06/2020	Updates for IVD	THW