

VISION[®] G2 CLASSIC 6[™] AND ELITE 8[™] DISSOLUTION TESTERS USER GUIDE



About Teledyne Hanson Research

Teledyne Hanson Research, a division of Teledyne Instruments, Inc., is a global technology company specializing in analytical test instruments for the pharmaceutical industry. Founded by the innovator of modern dissolution test technology, Teledyne Hanson Research (THR) helps ensure the world's pharmaceuticals are pure, safe, and effective by manufacturing equipment that sets the global standard for quality, innovation, and long-term value. Teledyne Hanson Research instruments are used by scientists in over 75 countries worldwide and are supported by the industry's top customer service team. For more information, visit teledynehanson.com.

Headquarters

Teledyne Hanson Research
9810 Variel Avenue
Chatsworth, CA 91311, USA
Phone: +1 818.882.7266
www.teledynehanson.com



Congratulations on your purchase of the Teledyne Hanson Research Vision G2 dissolution tester. While we are certain you will enjoy this new product, we also understand from time to time you may have a question or technical issue requiring our assistance. Please feel free to contact us at any time by any of the methods below.



Website: teledynehanson.com

Tech support request form: teledynehanson.com/tech-support-request

Email: hansontechsupport@teledyne.com

Email: hansonsales@teledyne.com



Phone: +1 818.882.7266



Teledyne Hanson Research
9810 Variel Avenue
Chatsworth, CA 91311, USA

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Introduction

Teledyne Hanson Research Vision® "G2" (second generation) dissolution instruments are designed for the 21st century, with state-of-the-art electronics, mechanics, and quality throughout. These systems are power-packed for the demands of today's pharmaceutical scientist, from research, to formulations, to quality assurance. We have applied 60 years of innovation and expertise to the design and manufacture of these quality test systems.

At Teledyne Hanson Research, we combine art with science and engineering. We apply elegant design and instrument ergonomics to the rigors and everyday challenges of scientific investigation, research, and analysis. Every dissolution test operator requirement is evaluated and simplified for ease of use and fast results. Our test systems are designed for the dissolution laboratory with a tight schedule and a heavy workload.

Definitions

ADD™ Cover

A vessel cover with a sealed chamber for the dosage. The chamber protects the dosage from environmental conditions and can be triggered by an AutoMag™ to automatically start a test.

AutoFill™

The redesigned sample collection instrument built in to the top of the Vision AutoPlus.

AutoMag™

An automated mechanism that can be installed on the Vision Elite 8 dissolution tester to automate raising and lowering of the sample probes and Digital Temperature Probes (DTPs).

Classic 6™

A rugged compact six-position dissolution test station with a unique two-across, three-deep design. The workhorse unit ideal for manual test routines, space-limited laboratories, and budget-minded programs.

Detect

Determine a sample's absorbance.

DissoScan™

The autosampler with one 3-way solenoid valve per syringe to direct fluid flow. The DissoScan provides 2 fluid lines (A and D). One tester can be connected to a DissoScan.

Easi-Lock™

The system used by Vision vessels that allows them to be locked into place. It allows for consistent centering and prevents chipping of the edges of the vessel.

Elite 8™

An eight-position high-performance machine built for automation and extended applications.

Fixed Probe

A stationary vessel mount sampling probe mounted to the vessel cover for connection to an automated sampler.

Maximizer™

The autosampler with 4-way solenoid valves per syringe to direct fluid flow. The Maximizer provides 4 fluid lines (A, B, C, and D). Up to 3 testers, or 2 testers with media replace can be connected to a Maximizer.

Occurrence

The dictated time at which a function is performed.

Protocol

The parameters that are entered into the instrument that determine the operation and steps that are to be accomplished for a given test.

Recurrence

The dictated time at which a function repeats.

Retrieval Reservoir

The Retrieval Reservoir is an optional accessory placed on the AutoFill. This accessory enables the AutoPlus to return rinse volume back to vessel(s) in multiple tester applications. This method will accommodate one or two testers with media replace or three testers without media replace.

Shaft Clamp

The knob at the top of the spindle shaft. It is used to easily manipulate or remove the spindle shaft.

Spindle Shaft

The shaft that passes through the drive head of a Vision dissolution tester. There are 6 spindle shafts on the Classic 6 and 8 on the Elite 8. Basket shafts, paddles, and other apparatus can be screwed into the spindle shafts.

SuperMag™

An automated mechanism capable of accommodating 1-liter, Small Volume (SV), and Chinese Small Volume (CSV) vessels that can be installed on the Vision Elite 8 dissolution tester to automate raising and lowering of the sample probes and Digital Temperature Probes (DTPs).

Vessel Rings

The rings that snap into the Vision dissolution tester vessel plates. The rings hold the Vision Easi-Lock vessels securely in place.

Vision® AutoFilter™

A programmable filter changing instrument which uses 25 mm in-line syringe filters.

Vision® AutoPlus™

The redesigned Teledyne Hanson autosampler series (either Maximizer or DissoScan) with stepper motor driven syringes.

Vision® G2

Teledyne Hanson Vision® “G2” dissolution instruments represent a significant upgrade from the original Vision testers introduced in 2008. Our new G2 operating platform includes full-color touchscreens for instrument programming, extensive programming menus, up to 100 operating protocols, a security configuration which supports 21CFR11-compliance, a convenient flash drive for instrument uploads and downloads, and 32-bit digital technology.

Waters Transfer Module

The Waters Transfer Module is a syringe-based sampling system connected to a Waters HPLC. It allows for full automation of dissolution systems with HPLC analysis.

Features

The new Vision G2 dissolution testers take the next step in dissolution testing with a streamlined new design and increased functionality. Here are some of the new features

| Classic 6 | Elite 8 | Standard Features |
|-----------|---------|---|
| ✓ | | Fixed drive head |
| ✓ | | 6 Precision drive spindles with spindle shafts |
| ✓ | | 6-Position Easi-Lock™ vessel plate |
| ✓ | | Compact footprint (2 across & 3 deep) |
| | ✓ | Easi-Lift™ moveable drive head with multi-lock positions |
| | ✓ | 8 Precision drive spindles with spindle shafts (use 6, 7, or 8) |
| | ✓ | 8-Position Easi-Lock™ vessel plate (use 6, 7, or 8 vessels) |
| | ✓ | Standard footprint (4 across & 2 deep) |
| | ✓ | Automation-ready (with optional AutoMag™ & SuperMag™) |
| ✓ | ✓ | Precision control for speed 25-250 rpm, temperature 25-55 °C |
| ✓ | ✓ | Elegant, ergonomic design with workhorse performance |
| ✓ | ✓ | Highest quality components and engineering |
| ✓ | ✓ | Minimal user adjustments for easy setup and go |
| ✓ | ✓ | Independent Vision® heater system |
| ✓ | ✓ | Rugged molded waterbath with fast heat-up & low level drain |
| ✓ | ✓ | Digital temperature probe (1) for use in bath and vessels |
| ✓ | ✓ | Full color touchscreen with intuitive menus and programming |
| ✓ | ✓ | Up to 100 protocols (create, manage and save routines) |
| ✓ | ✓ | Upload & download programs with flash drive |
| ✓ | ✓ | Electronics and firmware include 32-bit digital technology |
| ✓ | ✓ | Print to both serial and PostScript network printers |
| ✓ | ✓ | Alarms for sampling, maintenance and calibration |
| ✓ | ✓ | ISO 9001 quality certified |
| ✓ | ✓ | Security system supports 21 CFR Part 11 compliance |
| ✓ | ✓ | USP / FDA / ASTM / EP / JP compliant |
| ✓ | ✓ | CE / CSA / RoHS compliant, includes Earth-friendly packing |

Vision G2 Tester Identification

Figure A-1 Identification: Vision G2 Classic 6 Tester

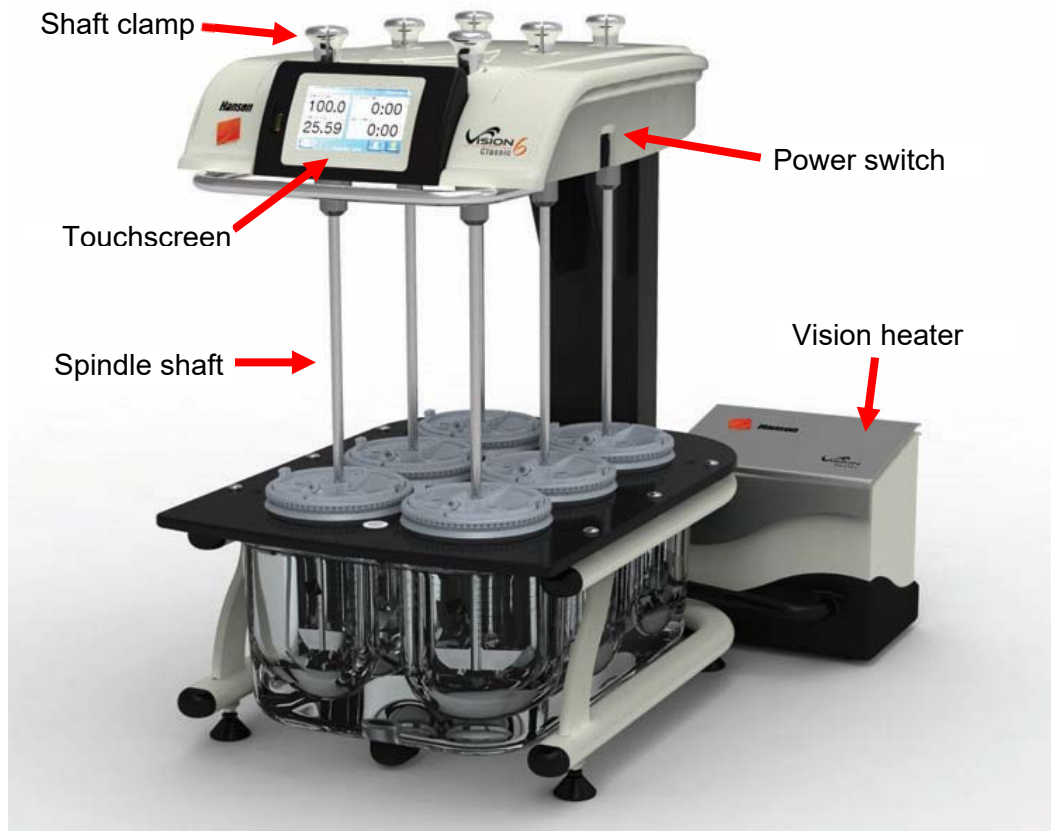
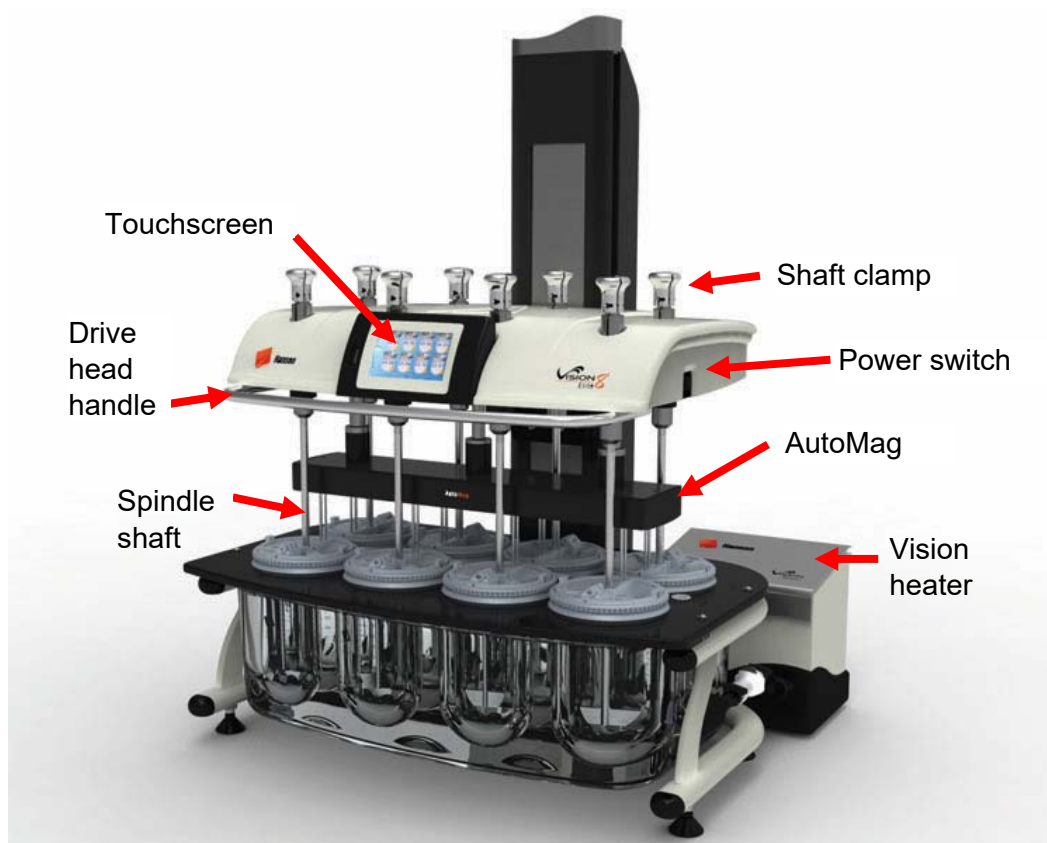


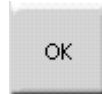
Figure A-2 Identification: Vision G2 Elite 8 Tester



Learning the Interface

The Vision G2 dissolution tester software was designed to be intuitive and easy to use. A user is able to interact and program the unit using the touchscreen interface. The touchscreen can be used with fingers or with a stylus. The interface has the following forms of input:

Buttons: In order to use a button, touch it with your finger or a stylus. Buttons may appear as having text or as icons.



Sliders: In order to use a slider, place a finger on the slider button and slide the finger right or left to place the slider in the desired position. Sliders are found for display and audio settings on the unit.



Text Keypad: Text keypads are used for text entry into the unit.

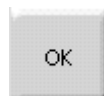
Text fields are typically restricted to 25 characters.



To enter a letter, touch the button for the letter. To delete a letter, use the del button.



To finish entering text, touch the OK button.

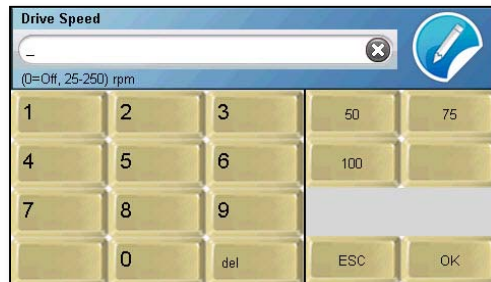


To cancel out of the screen, touch the ESC button.



NOTE: Touching the (X) in the input line clears in the whole line.

Numeric Keypad: The numeric keypads are used for numeric entry into the unit.



Unlike the text keypads, numeric keypads often have limits or specific formats which must be observed when entering information. These limits and formats are stated in the upper left corner of the screen below the field name. For example, the IP address of the Vision tester must be entered in a numerical format as follows: xxx.xxx.xxx.xxx. If the wrong format is entered, the Vision tester will produce an error sound and reset the field so the correct value can be entered.

NOTE: Some numeric keypads have preset entry buttons for commonly used values, such as the instrument's speed and temperature.

Calendar



When setting dates, a calendar screen will be displayed. Touch the arrows located at the bottom of the calendar screen to select the month. Touch the day of the date displayed to select that date.

Tab buttons



The tab buttons are located on the left side of the screen and allow access to different parts of a section of the software. For example, the Edit Alarms screen has 4 tabs that allow the editing of the Preheat Alarm, Sampling Alarms, User Alarms, and Calibration Alarms.

Fields



When touched, these will allow the user to edit the settings for that field. Depending on the field, the values will be toggled, or a data entry screen (text keypad, numeric keypad, calendar) will appear, allowing the user to edit the data accordingly.

Send button



The Send button allows the user to print the displayed logs to the printer or upload them to a USB flash drive. This is a common button on many of the screens of the Vision tester.

NOTE: For ease of reading, it is recommended to open logs in a word processor. Text editors (e.g., Windows Notepad) may place all the information on one line.

Exit button

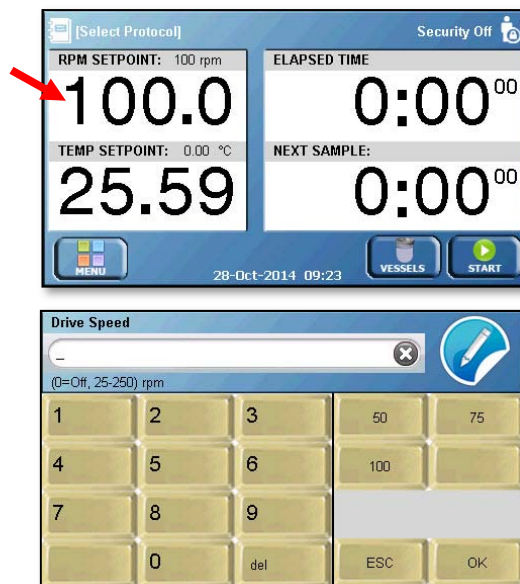


The Exit button allows the user to return to the main menu. This button is typically located in the lower right corner of the screen.

After the initialization sequence completes, the unit remains at the home screen. The home screen displays the motor speed (rpm), motor speed set point, temperature, temperature set point, elapsed test time, and a countdown until the next event. If no test is running, the times will be listed as 0:0000. The motor speed and temperature are displayed on the left side of the screen.



To adjust the motor speed, touch the RPM SETPOINT field and a numeric keypad will appear.



Enter the desired motor speed and touch OK. This will start the motor spinning at the desired speed. Preset buttons are available for 50, 75, and 100 rpm. The OFF button will stop the motor. The Quick Start button will hold the value for a quick test.

Touch the Elapsed Time field to set a test length for a Quick Start test. For starting a quick test, see "How to Use Quick Start" section.

NOTE: If a Quick Start speed is not set, the Elapsed Time field will not respond when touched.

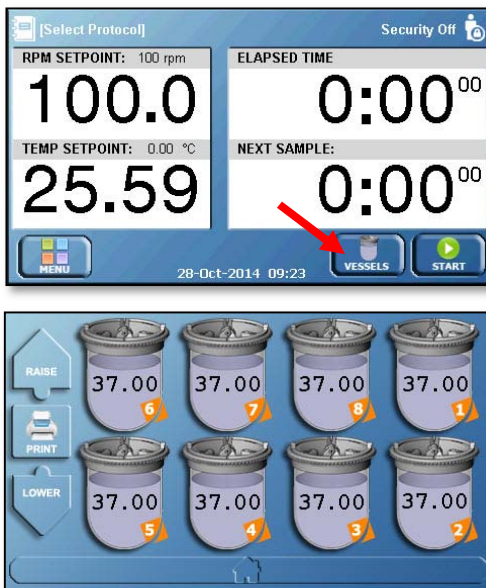
To adjust the temperature, touch the current temperature on the home screen and a numeric keypad will appear. If there is a problem with the external temperature probe, "Probe Error" will be displayed.



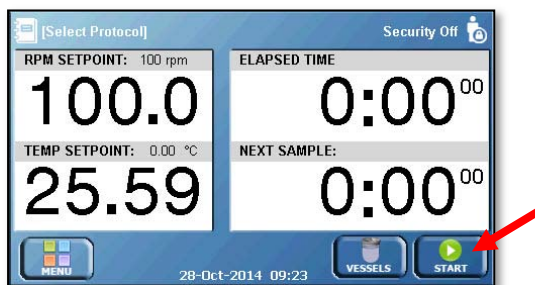
Enter the desired temperature and touch Ok. The pump will start and the temperature should begin to rise. There are preset buttons for 32 °C and 37 °C. The PUMP button starts the pump if it is off, or stops it if it is running. The temperature will automatically be set to 0 if the pump is turned off. The OFF button turns off the pump and sets the temperature to 0.

NOTE: As a safety feature, manual control of the pump is only active when the set temperature is 0.

Touching the Vessels button brings up the Vessels screen, which displays the current temperature in the vessels. On the left side of the Vessels screen, you have the option of raising or lowering the probes using the Raise or Lower arrows (if AutoMag or SuperMag is installed), and/or printing the vessel temperatures using the Print button. If there is an error with one of the vessel temperature probes, "--.--" will be displayed in place of the temperature.



The Start button is located on the bottom right of the home screen and is used for starting tests. The time and date of the system are displayed at the bottom center of the screen.



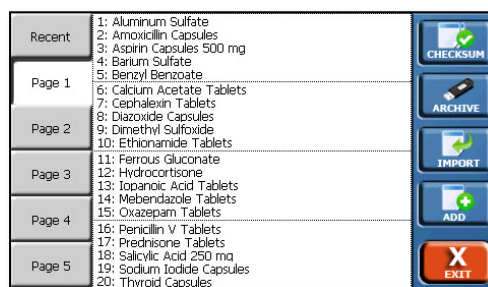
The menu is accessed by touching the Menu button located in the bottom left corner of the screen.



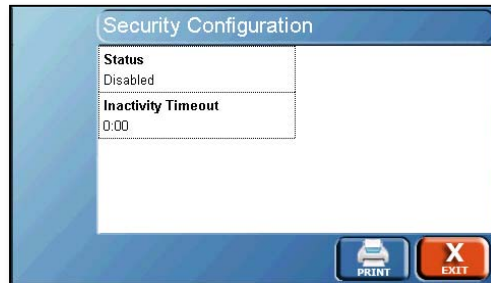
If a protocol is already loaded, the protocol name will appear in the upper left corner of the screen, and when touched it will be opened for editing. If no protocol is loaded, Select Protocol will appear in the corner; when touched, the Vision dissolution tester will allow the user to select a protocol for testing. When a Quick Start test is running, the words “Quick Start” will appear.



Protocol list screen



If security features are enabled, the current user is displayed in the upper right corner of the screen. If no user is logged on, and security features are enabled, Please Log In appears in the corner. If security features are not enabled, a user can log on by touching the same corner of the screen. Security Off appears in the corner of the screen and when the corner is touched, the Security Configuration screen appears.



The main menu provides access to all the functions of the Vision tester. To return to the home screen, touch the bar at the bottom of the menu with the house icon.



Regulatory and Safety

General Safety Considerations

This equipment contains moving parts, which have the potential to pinch or jam.

The installation category (overvoltage category) for this instrument is Level II. The Level II category pertains to equipment that receives its electrical power from a local level, such as an electrical wall outlet.

This instrument must be connected to a grounded electrical outlet.



Warning: Never work on the electrical components in the system while there is power to the unit. Disconnect power before servicing the instrument.

Review all safety and environmental precautions pertaining to any chemicals that are to be used in conjunction with this equipment.

CSA Safety Considerations

For indoor use only

Maximum altitude up to 2,000 meters

Environmental operating temperature 5 °C to 40 °C

Operating relative humidity 80% for temperatures up to 31 °C, decreasing linearly to 50% relative humidity at 40 °C

Mains supply ratings 100-240 V~, 50-60 Hz, 1.5 A

Mains supply voltage fluctuations not to exceed $\pm 10\%$ of the nominal voltage

Installation Category II (overvoltage categories)

Pollution Degree 2

See the installation section for lifting instructions.




Additional hazards may exist if the equipment is not used correctly per the user guide.

Canadian Emissions Notice

This digital apparatus does not exceed the Class A limits for radio noise emissions from digital apparatus set forth in the Radio Interference Regulations of the Canadian Department of Communications.

Le présent appareil numérique n'émet pas de bruits radioélectriques dépassant les limites applicables aux appareils numériques de la classe A prescrites dans les règlements sur le brouillage radioélectrique édictés par le Ministère des Communications du Canada.

The following safety symbols are used throughout this manual.

| Symbol | Definition |
|---|--|
|  | General warning of potential damage or danger from a variety of sources. |
|  | Electrical grounding connection. |
|  | Pinch hazard; keep hands and fingers clear. |

Installation

Location

This section provides information on determining if a location is suited to a Vision G2 dissolution tester. Consideration should be made as to the final system layout design prior to placing any equipment on the bench.

Environmental Requirements

The location should be clean and free of any issues which may influence dissolution testing. Issues which may affect dissolution results include vibration, significant heat, or significant cold.

Space Requirements

See the specifications section to determine space requirement based on the size of the equipment.

The bench should be level and flat.

The bench should be capable of supporting the full weight (including water) of each machine as laid out in the specifications section.

The first Vision G2 dissolution instrument should be placed to the left of an autosampler, if used. Additional testers should go to the right of the autosampler.

Electrical Requirements

Each Vision G2 dissolution tester requires two grounded outlets within 1 meter (3 ft.) of the location of the system; one for the dissolution unit and one for the heater.

The Vision G2 testers are available in one configuration, 100 V through 240 V. The voltage is automatically set when the voltage is supplied to the external power supply.

Power cords should meet the following specifications: IEC 320-C13 connector; SJT 18AWG3C, 2 x 0.824 mm², 60 °C, 300 V. Note that USA-style power cords are provided with the equipment. It is the responsibility of the end user to provide power cords that meet that country's electrical connection requirements. The power cords also meet or exceed the above specifications.

Unpacking and Inspection

This section provides instructions on unpacking and setting up the Vision G2 dissolution tester.

NOTE: Moving, lifting, and carrying THR dissolution testers requires 2 people to prevent damage to the instrument. Lift the instrument by the frame below the vessel plate while supporting the back of the tester to prevent it from tipping. DO NOT lift the instrument by the chrome handle.

Unpack the Vision tester from the shipping container.

- a. Note any damage to the shipping container. If container is damaged, contact Teledyne Hanson Research immediately.
- b. Place shipping container near installation location.
- c. Remove straps from the container.
- d. Open container and remove any accessory boxes.
- e. Carefully remove the Vision tester from the shipping container. Remove protective bag and cut the strap holding the support block.

Place the Vision tester on the bench.

- f. The Vision tester should be placed at a 90° angle from the desired operating position to allow access to the back of the tester during installation. Once the installation is complete, the Vision tester can be placed in its final position.

- g. If installing the Elite 8, the two locking bolts should be removed from the weight using the included hex wrench. There are no locking bolts on the Classic 6, as the drive head is fixed and not adjustable.



Fig. C-1 Remove Locking Bolts

- h. Once the locking bolts are removed, the Elite 8 drive head can be moved by pulling the lock release lever on the left underside of the drive head (behind the handle bar), then moving the drive head up or down. Releasing the lever and slightly moving the drive head up or down will allow a pin to engage in a locking position.



Fig. C-2 Elite 8 Release Lever

Level the dissolution tester.

- i. Place a bubble level in the center of the vessel plate.
- j. Adjust the feet of the dissolution tester until the bubble level indicates the vessel plate is level.



Fig. C-3 Bubble Level on a Leveled Tester

- i. For the Classic 6, adjust all 4 feet as necessary.
- ii. For the Elite 8 adjust the 2 front feet and the foot located underneath the mast. When the tester is level, adjust the 2 back feet for added support.

Place a vessel in each of the locking rings.

- k. Lower the vessel into place in the vessel ring.
- l. Rotate until the keys on the vessel slide into the holes on the vessel ring.
- m. Rotate the vessel clockwise to lock it into place.

Plug the temperature probe into the port labeled "Temp Probe" on the back of the tester. Place the probe in one of the holes located in the vessel plate.

Electrical Connections

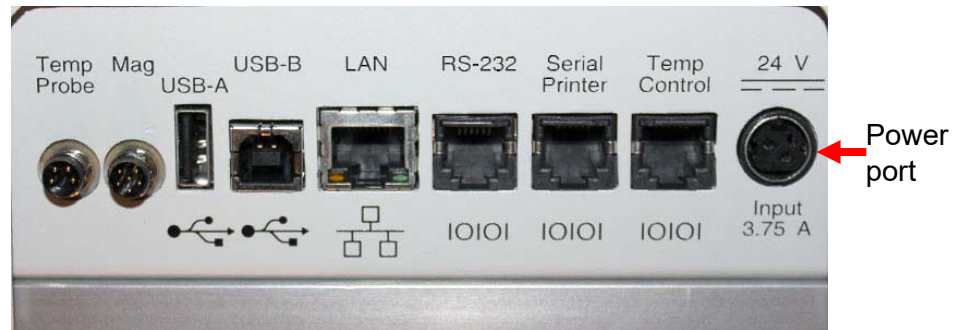


Fig. C-4 Vision G2 (Classic 6 and Elite 8) Back Panel Ports



Fig. C-5 Vision Heater Back Panel Ports

This section provides instructions on making the power connections to the Vision tester.

1. Ensure the power switch located on the right side of the Vision tester is in the off (O) position.
2. Connect the power supply to the port labeled Input on the back panel of the Vision tester, and the other end to a power source.
3. Ensure the power switch located on the back of the heater is in the off (O) position.
4. Insert the power cable into the back of the heater, and the other end to a power source.

Vision Heater Installation

1. Place the Vision heater to the right rear side of the tester.
2. Connect the tubing as shown in figure C-6 or C-7.
3. Ensure hose clamps are on straight. Tighten the clamps 3 to 5 clicks to prevent leaks.

NOTE: A pair of pliers is required for proper tightening of the hose clamps.

4. Connect the tester to the heater by plugging an RS-232 cable into the Temp Control ports on the tester and heater.

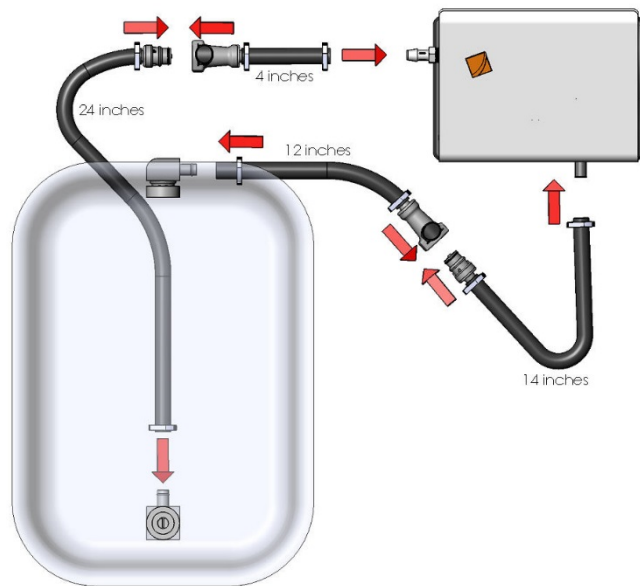


Fig. C-6 Classic 6 Bath to Heater Tubing Connection

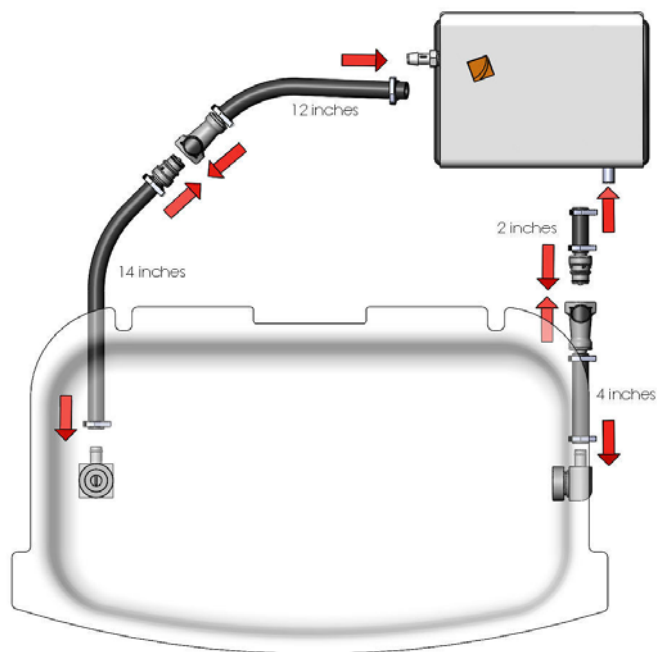


Fig. C-7 Elite 8 Bath to Heater Tubing Connection

Priming the Waterbath

Method 1



WARNING: Do not set a temperature during this procedure. Doing so may result in damage to the Vision heater.

1. Fill the waterbath to the line on the sticker located at the center front of the bath.

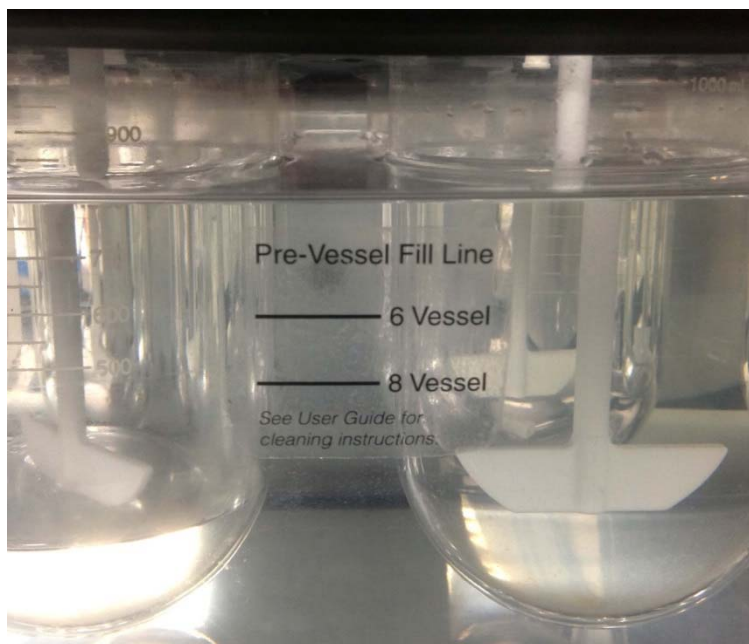


Fig. C-8 Fill waterbath to appropriate line on sticker

Go to the Temperature Setpoint screen and touch the PUMP button.



WARNING: Do not set a temperature during this procedure. Doing so may result in damage to the Vision heater.

Completely fill the syringe with bath water.

Insert the end of the syringe assembly into the bath fitting that is mounted to the bottom of the bath.

NOTE: Push the end of the syringe assembly down as far as possible. If the end of the assembly is too high, the water will not be pushed into the tubing.



Fig. C-9 Insert the tubing from the syringe into the fitting

Dispense the syringe. Watch the fitting on the side of the bath to ensure bubbles are being pushed out. If no bubbles are pushed out, push the tubing down farther into the fitting.

Repeat steps 2 through 4 until only water is pushed out.

Place your hand in front of the fitting on the side of the bath and ensure water is flowing.

Check for leaks.

Method 2

WARNING: Do not set a temperature during this procedure. Doing so may result in damage to the Vision heater.



1. Fill the waterbath to the line on the sticker located at the center front. See Fig. C-8.
2. Connect the drain hose to the Vision heater output. Ensure the other end of the drain hose is in a large container.

3. Go to the Temperature Setpoint screen and touch the PUMP button.



WARNING: Do not set a temperature during this procedure. Doing so may result in damage to the Vision heater.

Wait for consistent flow from the drain hose. When the pump has been primed, the noise from the Vision heater should decrease.

Disconnect the drain hose and reconnect the heater output to tubing that leads to the waterbath. It is not necessary to stop the pump during this step.

Place your hand in front of the fitting on the side of the bath and ensure water is flowing.

Draining the Waterbath (not required for installation)



WARNING: Do not set a temperature during this process. Doing so may result in damage to the Vision heater.

1. Remove a vessel over the bath output fitting.
2. Insert the drain plug into the bath output fitting. This will allow the bath to drain completely.

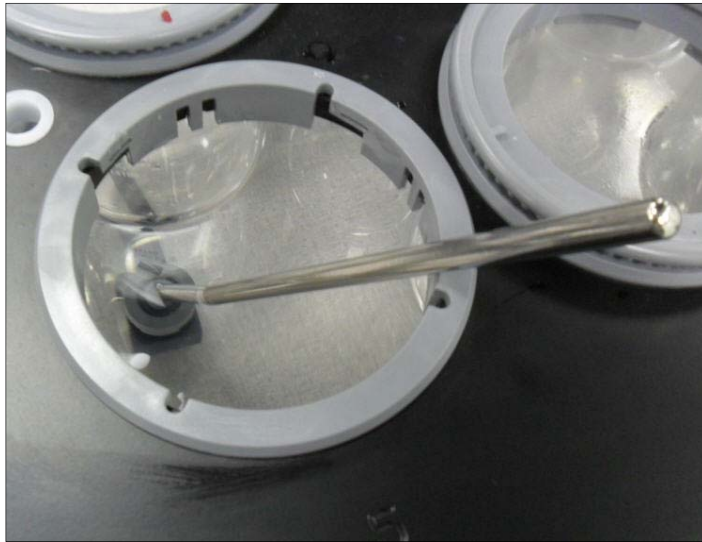


Fig. C-10 Drain plug in the bath output fitting (viewed from above)

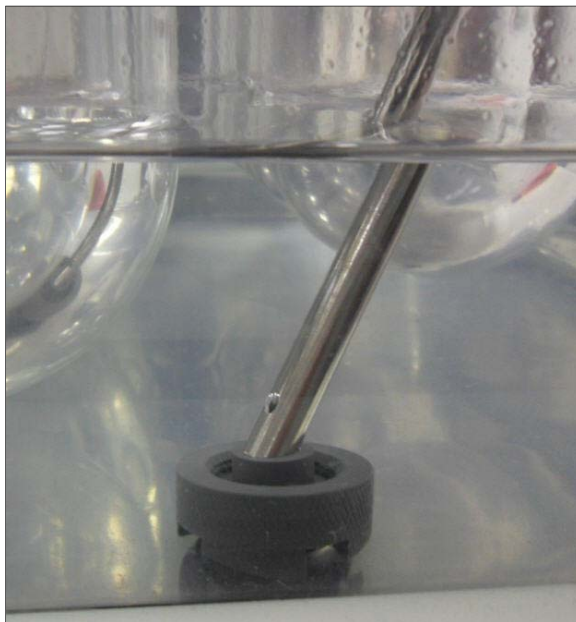


Fig. C-11 Drain plug in bath output fitting (viewed from the side)

Connect the drain hose to the heater output.

Go to the Temperature Setpoint screen and touch the PUMP button.



When the bath is completely drained, touch the PUMP button again to stop the pump.

Guidelines for Cleaning the Waterbath

This section provides only guidelines for cleaning the waterbaths of the Classic 6 and Elite 8.

1. Use only a soft cloth when wiping down the waterbath. Coarse materials may scratch the bath material.
2. Use only warm water when cleaning the bath or at any other time.



WARNING: The use of chemicals may damage the waterbath and will not be covered by the warranty. Clearbath will damage PETG.

The bath can be cleaned in place or removed for cleaning.

- a. The vessel rings should be removed when removing the bath for cleaning.
- b. For the Elite 8, the bulkhead fitting on the side of the bath must be removed in order to remove the bath.

Verification of Manual Controls

This section provides instructions on how to test the manual controls to ensure the tester can perform basic functions.

1. Turn on (I) the Vision heater with the power switch located on the back.
2. Turn on (I) the tester using the power switch on right side of the drive head.
3. Once the tester has reached the home screen, touch the current motor speed (0.0) and the motor speed screen should appear.
4. Touch the 50 button to set the motor speed to 50 rpm. Observe the spindles and ensure that they spin.
5. Touch the current temperature and the temperature set point screen should appear.
6. Touch the 37 button to set the bath temperature to 37 °C.
7. Observe the temperature on the home screen and ensure that the temperature begins to rise.

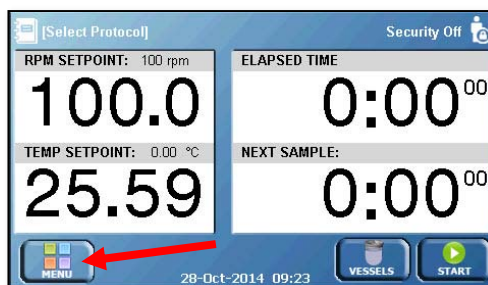
Vision Tester Communication Connections

This section provides instructions on how to make the communication connections between the Vision tester and a serial (validation) printer, an autosampler or a network (including a PostScript capable network printer, if applicable).

NOTE: For more information on TCP/IP communications, refer to appendix B. For connecting to a Waters Alliance Dissolution System, refer to appendix C.

1. Use an RS-232 cable to connect a serial (validation) printer to the Serial Printer port on the tester.
2. Use a network cable to connect the LAN port of the tester to an autosampler, a network switch, or a port of the local network, as appropriate.

3. From the home screen, touch the Menu button to bring up the tester menu screen.



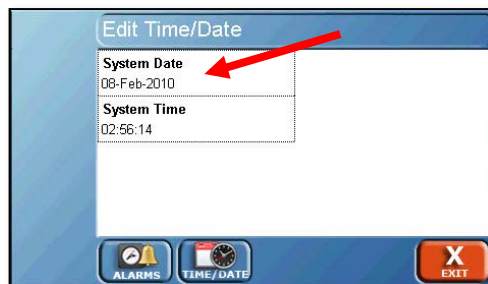
4. Touch the Time button to bring up the Edit Alarms Screen.



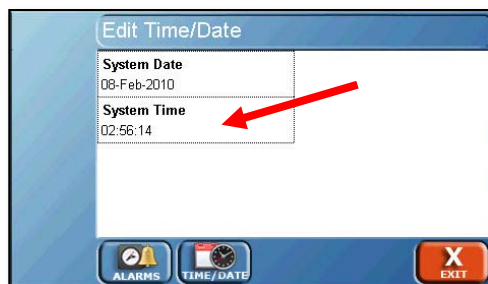
5. The Edit Alarms screen will appear. Touch the Time/Date button at the bottom of the screen.



6. The Edit Time/Date screen will appear. Touch the System Date field to set the current date. Enter the date in the DD-MM-YYYY format, and touch OK when done.



7. The Edit Time/Date screen will reappear. Touch the System Time field to enter the current time. Enter the time in 24hr format. For example, if it is 2:30 pm, enter 14:30. Touch OK to return to the Edit Time/Date screen.



8. Touch the Exit button at the bottom right corner of the screen to return to the main menu.



9. Touch the Config button to bring up the system configuration screens.



10. The first tab is Instrument. Touch the Instrument ID field to edit the instrument ID for the tester. This ID will appear on printouts and in applicable software packages. When touched, an alphanumeric keypad appears. Use the keypad to enter the appropriate system ID. Touch the OK button when complete.



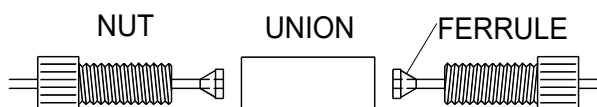
11. Touch the IP Address field to edit the IP address. A numeric keypad will appear to allow the entry. The IP address must take the form of `###.###.###.###`. To ensure proper communication, the first 3 sections of the IP address must match between the tester and sampler or printer. Touch OK when finished.

For example, if the tester has the IP Address 192.168.1.20, then the IP address of the printer must begin with 192.168.1. For more information on configuring IP addresses, refer to appendix B.

12. Touch the Gateway Address field to edit the gateway address. Once again a numeric keypad will appear and the gateway address must take the form of `###.###.###.###`.
13. Touch the Subnet Mask field to enter the subnet mask. Once again a numeric keypad will appear and the subnet mask must take the form of `###.###.###.###`. The value of 255.255.255.0 is recommended.
14. When all the fields on the Device Setup screen have been updated, touch the exit button located in the lower right corner of the screen.

Liquid Line Connections

Sample line connections are made by connecting the six or eight liquid tubes from the Vision AutoPlus/AutoFill or other autosampler to the dissolution tester. These are numbered and color-coded for easy identification. They can be connected with nuts, unions, and ferrules as shown in the figure below:



| Position | Fitting Color |
|----------|---------------|
| 1 | Black |
| 2 | Red |
| 3 | White |
| 4 | Yellow |
| 5 | Green |
| 6 | Blue |
| 7 | Clear |
| 8 | Purple |

Fig. C-12 Liquid Line Connections

Security

The Vision tester can be configured to require users to log in and allows for tracking of any changes made to the protocol. The security system allows for 25 users when using firmware versions below 2.50 and 50 users for versions 2.50 and above.

Firmware versions below 2.70 offer two levels of users (managers and operators) with fixed permissions:

- Managers are given full access to the unit and allowed to make any changes to the system as required, with all these changes being tracked by the software. All users can be configured as managers for full control of the Vision tester. One manager is required by the software. Hanson is installed as a manager from the factory. The default password for the Hanson manager is 0000.
- Operators are permitted to run tests but are not allowed to make changes to protocols or other system settings. Not all users can be configured as operators; the software requires at least one user be configured as a manager.

Firmware versions 2.70 and above offer Enhanced Security with three levels of users (administrators, managers and operators) with *configurable* permissions.

Security settings

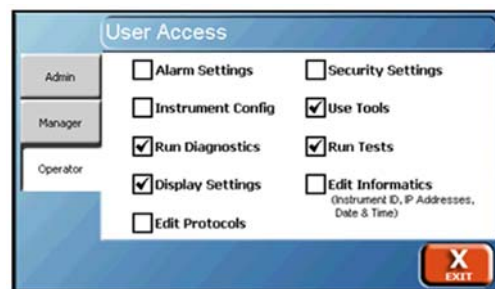
To configure security settings, begin by selecting the Security button from the main menu and the Security Configuration screen will appear.



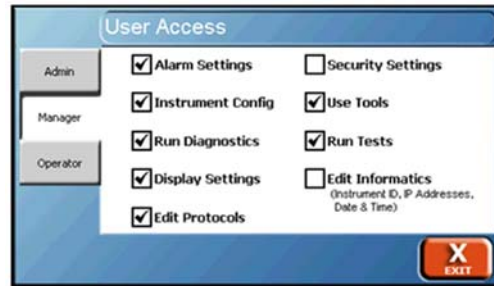
Status: Enables or disables the security feature.

Inactivity Timeout: The amount of time without user input before the system requires a user to log in. The range is 0 to 1:00 (hh:mm). Entering 0:00 disables the timeout function.

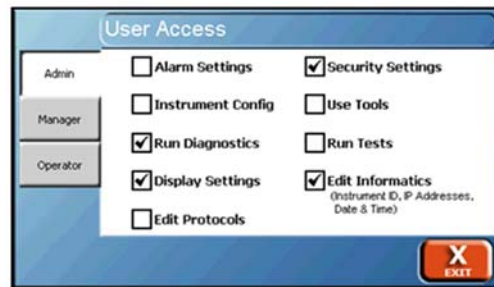
Access: (Enhanced Security Only) Allows the configuration of the different user levels (administrators, managers and operators) as dictated by the lab requirements. By default, only manager and operator are enabled. The following settings are recommended for an operator:



The following settings are recommended for a manager.



The following settings are recommended for an administrator.



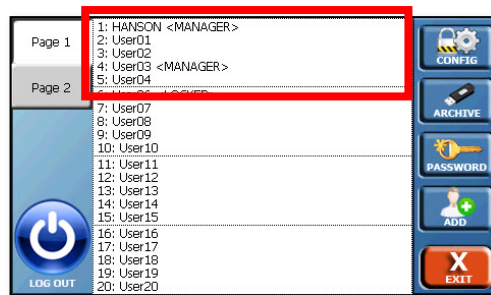
- Alarm Settings: Allows the configuration and resetting of the alarms for the instrument.
- Instrument Config: Allows adjusting the instrument configuration settings such as whether a printer is connected to the instrument.
- Run Diagnostics: Allows users in that level to run the diagnostics routine on the instrument.
- Display Settings: Allows the ability to adjust the display brightness, volume, and recalibrate the screen.
- Edit Protocols: Allows the ability to edit and create protocols. Protocols can still be run depending on the permissions provided.
- Security Settings: Allows the configuration of security settings, adding/removing users, and adjusting access levels. At least one group must have this permission.

NOTE: A user is not able to toggle the security settings of a group they belong to. For example, a manager is not able to toggle the security settings on and off for managers.

- Use Tools: Allows access to the tools menu of the instrument.

- **Run Tests:** Allows the ability to run a protocol. Protocols can still be viewed or edited depending on the permissions provided.
- **Edit Informatics:** Allows the editing of the system time, date, Instrument ID, and network configuration settings.

Only users with permission to edit security settings can display the User List. The users are listed alphabetically and displayed in groups of 5 per page (4 groups of 5) over 2 pages within the interface. Maximum 50 users.



To select a user, first select the group the user is in.
Select the user from the list that appears.



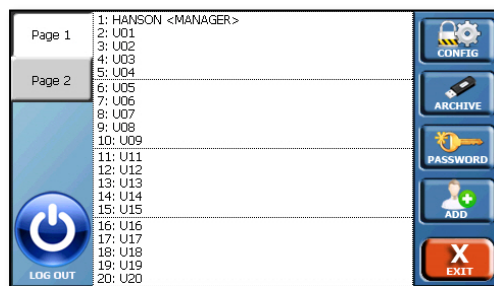
When the user is selected, the following can be changed:

- **Name:** The name of the user.

- **Type:** Toggles the type of user. The options are operator or manager; the default is operator.
- **Status:** The user's status. The options are locked or unlocked. An unlocked user has access to the system, a locked user does not and must be unlocked by a manager.

Security screen

On the Security screen the following options are available to the manager:



- **Config:** Allows access to the Security Configuration screen
- **Archive:** Allows the manager to use backup or restore functions as follows:
 - **Backup:** Allows a manager to create and send a backup of the instrument's security configuration (including the users and corresponding profiles) to a flash drive in the USB port. The security configuration is in a single file under the filename security.bak.

NOTE: The backup function will overwrite all users previously saved on the flash drive.

- **Restore:** Allows a manager to restore the instrument's security configuration (including users and corresponding profiles) from a flash drive in the USB port from the security.bak file.

NOTE: The Restore function restores only user profiles from the backup file, but clears all users' passwords. All users not in the backup file will be erased.

- **Password:** Allows the user who is currently logged in to change their password.

- **Add:** Allows a manager to create a new user. The screen that appears is identical to the Edit User Profile screen.
- **Log Out:** Logs out the current user
- **Log In:** With security enabled, a user can log on either by touching the upper right of the home screen where Please Log In or the name of the user who is logged in is displayed. Additionally, if any other input is attempted, the Vision tester will prompt the user to log in.

Drive Head Movement (Elite 8 Only)

The Vision G2 Elite 8 drive head can be moved by pulling the lock release lever on the left underside of the drive head (behind the handle bar), then moving the drive head up or down. Release the lever when the drive head is near the desired location. Move the drive head slightly up or down until it locks in place.

Paddle and Basket Installation

The spindle shaft is factory-adjusted to provide the correct height for baskets and paddles. The precision design of the Easi-Lock vessels, the shaft components, and the test unit itself are intended to reduce user adjustments and settings. It should not be necessary to adjust the position of the spindle shafts to obtain the proper height spacing between the bottom of the apparatus and the vessel. If adjustment is needed, refer to the troubleshooting section of this user guide.

To install paddles or baskets:

1. Ensure the spindle shaft is in place.

NOTE: The tension of the spindle shafts can be adjusted by the application of silicone grease. If the shafts become too loose after the application of grease, they can be tightened by wiping the shaft with ethanol.

Insert the threaded end of the paddle or basket shaft into the threaded opening at the bottom of the spindle shaft.

Rotate the paddle or basket shaft counter clockwise until the outer rim of the paddle or basket shaft contacts the spindle shaft. Turn slightly past the point of contact to ensure that the shaft will stay in place.

To release the paddle or basket shaft, grasp the shaft clamp, then rotate the paddle or basket shaft clockwise out of the spindle shaft. If the shaft releases with a slight pop it has been properly tightened.

When the tester is in operation, ensure that the key of the shaft clamp and the key on the spindle itself are at the same level so that they will lock together.



Fig. C-13 Shaft Clamp and Key in Position

Vessel Cover Installation

Easi-Lock Cover

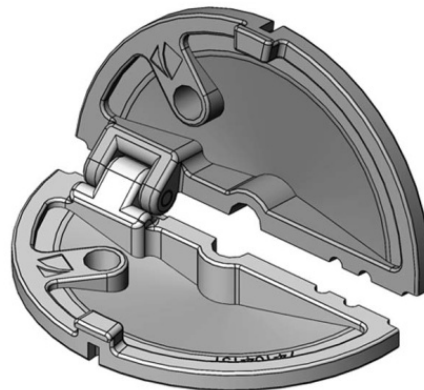


Fig. C-14 Easi-Lock Cover 74-104-151

To install the hinged Easi-Lock vessel cover, with the drive head down (Elite 8) and shafts in place:

1. Fold the cover so that a space can be created for the spindle shaft to slide through. If an AutoMag or SuperMag is installed, align the cover with the sample probes.

2. Slide the cover so that the spindle shaft is located in the center hole and unfold the cover. The cover should rest on the vessel rim such that the notches fit around the raised keys of the vessel rim.

ADD Cover for Vision

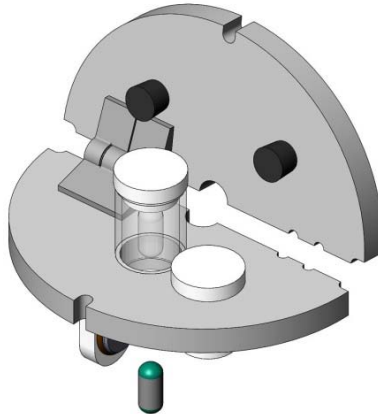


Fig. C-15 ADD Cover for Vision 74-104-152

To install the hinged ADD Cover for Vision testers, with the drive head down (Elite 8) and shafts in place:

1. Fold the cover so that a space can be created for the spindle shaft to slide through. If an AutoMag is installed, align the cover with the sample probes.

NOTE: This ADD cover is compatible with the AutoMag, but NOT the SuperMag.
2. Slide the cover so that the spindle shaft is located in the center hole and unfold the cover. The cover should rest on the vessel rim such that the notches fit around the raised keys of the vessel rim.
3. Raise the cover and ensure the door that holds the sample is closed. Once the door has been closed lower the ADD Cover for Vision into place.
4. At the appropriate time open the cap covering the sample chamber and place the sample inside.
5. Apply the cap to the sample chamber to protect the sample from moisture.
6. Ensure the push pin is installed in the cover.

Easi-Lock ADD CS Cover

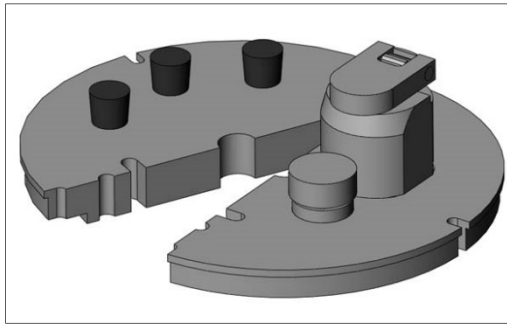


Fig. C-16 Easi-Lock ADD CS Cover 74-107-013

To install the ADD vessel cover, with the drive head down (Elite 8) and shafts in place:

1. Open the cover and slide it around the shaft so that the spindle shaft is in the center of the cover. If an AutoMag or SuperMag is installed, align the cover with the sample probes.

NOTE: This ADD cover is compatible with SuperMag or AutoMag.

2. Raise the cover and ensure the door that holds the sample is closed. Once the door has been closed, lower the ADD vessel cover back to the rim of the vessel.
3. At the appropriate time, open the cap covering the sample chamber, and place the sample inside.
4. Close the cap to ensure the sample remains sealed from moisture.

Easi-Lock CS Cover

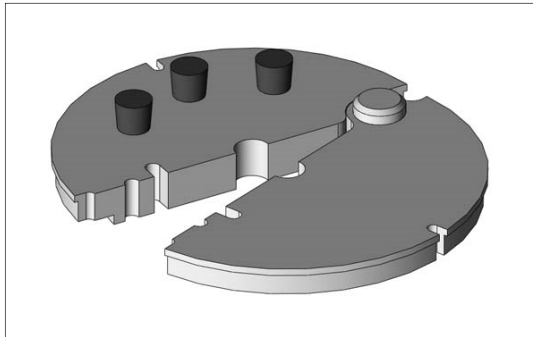


Fig. C-17 Easi-Lock CS Cover 74-107-012

To install the clam shell cover with the drive head down (Elite 8) and shafts in place:

1. Open the cover and slide it around the shaft so that the spindle shaft is in the center of the cover. If an AutoMag is installed, align the cover with the sample probes.

NOTE: This cover is compatible with AutoMag or SuperMag.

2. Close the cover around the spindle shaft and probes.

Installation is Complete

The installation of the Vision G2 dissolution tester is now complete.

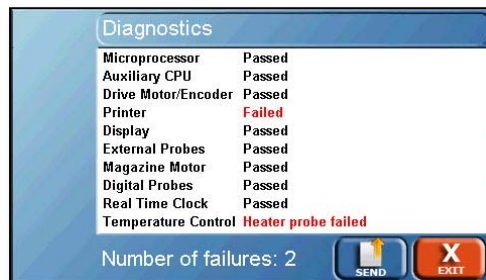
Operation

Diagnostics

The Diagnostics button on the main menu screen launches the Vision tester diagnostic procedure. When the Diagnostics button is touched, a confirmation pop-up appears asking the user if they wish to run diagnostics. If OK is touched, the diagnostics will run. If Cancel is touched, the diagnostics will not run, and the operator will be returned to the menu.



This procedure performs a self-test to check functionality and test the connections of the configured equipment. Failures are shown in red text on the screen. The failures of the diagnostics tests are also stored in the error log located in the Info screen (from main menu).



NOTE: For a list of errors, refer to appendix A of this user guide.

Information



The Info button allows access to various system logs and other basic information about the Vision tester. Touching Info brings up the Versions screen.



Versions screen

The Versions screen provides information on the software installed on the Vision tester. This screen is also accessed by touching the About button located at the bottom of the info screen.

Tester Firmware: Version number of the tester firmware.

Auxiliary CPU Firmware: Version number of the auxiliary CPU firmware.

Bootloader Firmware: Version number of the bootloader firmware used to upgrade the tester firmware.

Temp Controller Firmware: Version number of the Vision heater firmware.

Touchscreen Firmware: Indicates the firmware revision of the touchscreen.

PCB Revision: Indicates the revision of the PCB main board hardware.

PCB Identifier: Unique PCB identifier.

Magazine Firmware: Version number of the magazine firmware.

Instrument Logs screen

The Instrument Logs screen can be accessed by touching the Logs button at the bottom of the Info screen, and provides access to the event, test, and error logs by touching the respective tabs at the left side of the screen. All log screens have large, semi-transparent up and down arrows on the right side which allow the user to scroll up and down.



Event Log: This log provides information on what was done on the unit. This includes, but is not limited to, powering on, powering off, running diagnostics, changes to settings, or editing of protocols. The log will store the last 543 events.

Test Log: This log lists all the actions that occurred during the last test. It is overwritten when a new test is started.

NOTE: This function is equivalent to "Print Last Test" on legacy testers.

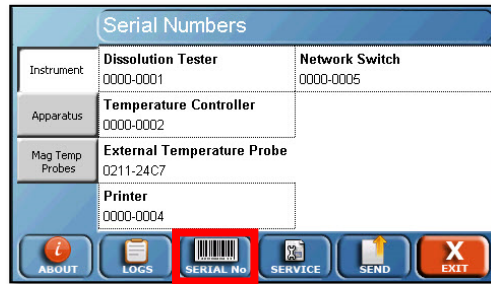
NOTE: Exporting the test log will overwrite any existing test log on the USB drive.

Error Log: This log lists system errors that occur on the unit. This can include communication issues, diagnostic failures, or other errors. The log will store the last 331 errors. Tolerance errors and other test specific errors are located in the test log. For a list of errors, refer to appendix A.

Test History Log: This tab provides access to the last 8 tests run. It allows the user to select the test based on protocol name, time, and date, and to reprint the test.

Serial Numbers screen

The Serial Numbers screen allows the user to enter the serial numbers of the components connected to the Vision tester. To change the serial number, touch the field and enter the serial number. All serial numbers are limited to 9 characters. If security features are enabled these items may only be edited by a manager.



Instrument tab

Dissolution Tester: This is the serial number for the dissolution tester itself.

Temperature Controller: This is the serial number for the Vision heater.

External Temperature Probe: The serial number of the external temperature probe. This is read by the software directly from the probe and cannot be changed.

Printer: This is the serial number of the printer connected to the Vision tester, this is generally reserved for serial (validation) printers that are directly connected to the Vision tester, not through a network.

Network Switch: This is the serial number of the communications switch used for network communications between multiple dissolution instruments and a PostScript capable network printer.

Apparatus tab

All fields on the apparatus tab open up sub-screens for the item. Each sub-screen has 8 fields for each of the corresponding vessel positions, which appear when the field is touched. The first few serial numbers are displayed for each item depending on the length of the serial numbers.

Spindle Shafts: The serial numbers of the spindle shafts

Paddles: The serial numbers of the paddles

Basket Shafts: The serial numbers of the basket shafts

Baskets: The serial numbers of the baskets

Vessels: The serial numbers of the vessels

Custom Sets [1-3]: For additional serialized accessories or apparatus which may be used on the unit. These can be changed through the Titles configuration screen. For example rotating cylinders (Apparatus 6).

Mag Temp Probes tab

Lists the serial numbers of each of the vessel temperature probes if they are installed on an AutoMag or SuperMag (Elite 8 only). These serial numbers are read directly from the probes and cannot be edited.

Service Log screen

The Service Log screen is accessed by the Service button at the bottom of the screen. To update the service logs, touch the appropriate field for the item to be updated and the current date will be entered and, if applicable, the cycles reset to 0. When resetting any of the counters, a confirmation will be requested. The date refers to the date the action last occurred.

The screenshot shows the 'Service Log' screen with a table of maintenance logs and a bottom navigation bar. The table has two columns: the left column contains labels and dates, and the right column contains numerical values. The bottom navigation bar includes buttons for ABOUT, LOGS, SERIAL No, SERVICE (highlighted with a red box), SEND, and EXIT.

| Service Log | |
|------------------------|--------------------|
| Last Calibrated: | Motor Time (hrs): |
| 05Feb2010 | 05Feb2010 7821 |
| Last Preventive Maint: | Heater Time (hrs): |
| 05Feb2010 | 05Feb2010 7821 |
| Number of Tests: | Pump Time (hrs): |
| 05Feb2010 85 | 05Feb2010 7821 |
| Belt Time (hrs): | Magazine (cycles): |
| 05Feb2010 7821 | 05Feb2010 21 |

Last Calibrated: The date of the last calibration of the unit.

Last Preventive Maint: The date of the last preventive maintenance performed on the unit.

Number of Tests: The number of tests performed on the tester.

Belt Time (hrs.): The number of hours on the belt and time since they were last replaced.

Motor Time (hrs.): The number of hours on the motor and time since it was last replaced.

Heater Time (hrs.): The number of hours on the heater element, and the time since it was last replaced.

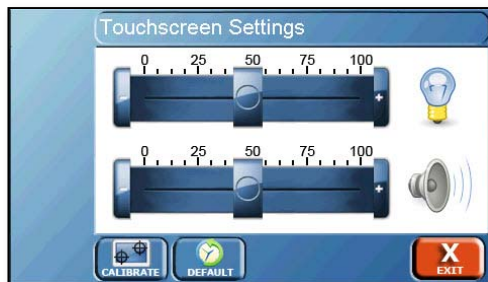
Pump Time (hrs.): The number of hours on the water pump, and the hours since it was last replaced.


Magazine (cycles): The number of times the magazine has moved up and down and the date since the motor was last replaced.


Display




The Display button allows the user to access the Touchscreen Settings screen.




Brightness (): This screen allows the user to adjust the brightness of the screen by using the slider under located next to the brightness symbol.

Volume (): The volume slider located next to the speaker symbol allows the user to increase or decrease the volume of the feedback sounds.

Calibrate (): This button begins the screen calibration procedure; it is recommended that a stylus be used for this to ensure the proper precision.

NOTE: Do not use sharp objects for the calibration procedure, as the screen can be seriously damaged.

Default (): This button returns the touchscreen back to the factory default settings for brightness and volume.

Configuration

Touch the Config button on the menu to bring up the Device Setup screen.



Device Setup screen

The Device Setup screens allow the user to configure the Vision tester for communication and use with accessories. It can also be accessed by touching the Setup button at the bottom of the Device Setup screen.



Instrument tab

The Instrument tab allows for the configuration of the instrument ID and network communication settings. For more information on TCP/IP configuration, refer to appendix B.

Instrument ID: The instrument identification which will be displayed on printouts and applicable software packages. The system ID is limited to 25 characters.

IP Address: The internet protocol address is a numerical label assigned to each instrument (sampler, tester, network printer) participating in a computer network that uses the Internet Protocol for communication.

Gateway Address: The gateway address of the unit when connecting to a network.

Subnet Mask: The subnet mask of the unit when connecting to a network.

Printer tab

The Printer tab allows the user to configure the printer the Vision tester will use.



Printer Type: When touched, toggles the type of printer connected to the instrument.

Network: Used when the printer is connected via a TCP/IP network and supports PostScript.

NOTE: Network printers must support PostScript in their firmware. Printers that support PostScript through software drivers or do not support PostScript will not work.

RS-232: Used when an RS-232 printer is connected.

None: Used when no printer is installed.

Page Format: Toggles the paper size between Letter and A4 when using a PostScript-capable network printer.

NOTE: Wrong paper size may omit lines from printout.

IP Address: For use when printing to PostScript-capable network printers. Allows the user to enter the IP address of the target printer.

Printer Port: For use when printing to PostScript-capable network printers. Allows the user to enter the appropriate port of the target printer (0-65535).

Add Signature Line to Footer: This adds a line for a signature and date to the bottom of printed reports (Yes or No).

Use Duplex (if available): This allows for printing on both sides of a page if a network printer supports this option. Network printers which do not support duplex printing will print normally even if this is set to Yes (Yes or No).

Use Color (if available): This allows for color printing if a network printer supports this option. Network printers which do not support color printing will print normally in black and white even if this is set to Yes (Yes or No).

Accessories tab



The Accessories tab allows the user to define the accessories installed on the Vision tester and accessories connected to the system.

Sampler: Configures the system for different autosamplers.

Vision: Refers to the Vision AutoPlus.

Transfer Module: Refers to a Waters Transfer Module as part of a Waters Alliance Dissolution System. For more information on configuring the tester for a Waters Alliance Dissolution System, refer to appendix C.

None: No autosampling system is used.

Sampling Probe: Toggles which type of sampling probe is connected to a system when touched. Options are 1L on a 1L Magazine, 1L on a 2L Magazine, or 2L on a 2L Magazine (for use with the Vision Elite 8 AutoMag or SuperMag), or Fixed (when no magazine is installed).

Digital Temperature Probes: Toggles the Digital Temperature Probes (DTPs) installed between 0, 6, 7, and 8. This option is only visible if Magazine is selected as the sampling probe.

Automatic Dosage Delivery: Toggles whether or not Automatic Dosage Delivery (ADD) covers are used on the unit.

Titles

The Titles configuration is accessed by touching the Titles button at the bottom of the Device Setup screen. The titles configuration screen allows the user to set the desired titles for the test headers, protocols headers, and company information.



To edit any of the information, touch the field and enter the new title of the desired field. Titles are limited to 25 characters in length. For example, if instead of “Test Name” the user wanted the field titled “Lab Notebook” the user would touch the field for “Test Name” and enter the text “Lab Notebook,” which would change the field name to Lab Notebook.



Company: This is the name of the company that owns the Vision tester.

Department: The department that controls the Vision tester.

Logo: Touch this field to load a custom logo that will appear at the top of the report.

How to Load a Custom Logo

1. Prepare a jpeg image that meets the following requirements:
 - a. No more than 100 pixels wide by 50 pixels high
 - b. 96 dpi
 - c. File size 15 KB or less.
 - d. Named logo.jpg
2. Load the image into the root directory of a USB flash drive.
3. Insert the USB flash drive into the USB port of the Vision instrument.
4. Touch the Logo field to load the logo into the Vision instrument.

NOTE: The previous logo will be overwritten by the new logo. Only one logo can be present in the instrument at a time.

Header tab

Headers are information which applies to each individual test run, rather than a protocol. This tab allows for editing the header field names. Up to 8 header fields are available, each having a maximum length of 25 characters.

| Edit Titles | | |
|-------------|-------------------------|----------|
| Company | Header 1 User Name | Header 5 |
| Header | Header 2 Test Number | Header 6 |
| Protocol | Header 3 Lot Number | Header 7 |
| Apparatus | Header 4 Comments | Header 8 |

SETUP TITLES UPDATE SEND EXIT

The default values for headers 1, 2, 3, and 8, respectively, are:

User Name: Allows the user to enter their name or if security is enabled the name of the user logged in is automatically displayed. This label cannot be changed.

Test Name: A test name if applicable.

Lot Number: The lot number of the item being tested.

Comments: Allows the user to add any comments which should be noted related to this test run.

Protocol tab:

The Protocol tab allows for editing the field of the protocol labels section. Up to 8 label fields are available, each having a maximum length of 25 characters.

| Edit Titles | | |
|-------------|------------------------|-------------------------|
| Company | Label 1 Drug Name | Label 5 Media Type |
| Header | Label 2 Dosage | Label 6 Media Volume |
| Protocol | Label 3 Protocol ID | Label 7 |
| Apparatus | Label 4 Apparatus | Label 8 |

SETUP TITLES UPDATE SEND EXIT

The default values are:

Drug Name: The name of the drug the protocol is designated to test (i.e. Aspirin).

Dosage: The dosage size of the drug to be tested (i.e. 300 mg).

Protocol ID: A secondary ID for the protocol; this does not need to be unique.

Apparatus: lists the apparatus used for the testing (i.e. Paddles, Baskets, Paddle over Disk).

Media Type: Lists the media type used for the dissolution test (i.e. Water, pH 7.4 Phosphate Buffer).

Media Volume: Lists the media volume used for the dissolution test (i.e. 900 mL).

Apparatus tab

The Apparatus tab allows for editing the field of the apparatus labels section. Up to 8 label fields are available, each having a maximum length of 25 characters.



The default values are:

Spindle Shafts: The serial numbers of the spindle shafts.

Paddles: The serial numbers of the paddles.

Basket Shafts: The serial numbers of the basket shafts.

Baskets: The serial numbers of the baskets.

Vessels: The serial numbers of the vessels.

Custom Sets [1-3]: For additional serialized accessories or apparatus which may be used on the unit. For example, rotating cylinders (Apparatus 6).

Firmware Update

The firmware update feature is accessed by touching the Update button at the bottom of the screen. The firmware update feature allows an operator to update the firmware of the Vision dissolution tester.



The firmware update feature uploads the file “timage.hru” from the root of the USB flash drive. The firmware update process is automated and takes up to 5 minutes to complete. Protocols, system settings, security settings, and users are not overwritten when a firmware update is performed.

Time

The time and alarm settings are accessed by touching the Time button on the menu. The Edit Alarms screen appears. This screen provides access to the alarms of the Vision tester and setting the system time and date.



The Alarms button at the bottom also brings up the Edit Alarms screen. There is a tab available for each alarm; the function of each alarm is listed below.



The Reset button at the bottom of the screen will clear or turn off the selected alarm.



Preheat Alarm screen

This screen allows the user to enable a preheat wakeup alarm. The waterbath heats to the set point at the specified time and date. This allows the tester to be ready for the start of a workday while saving power overnight.

Bath Temperature: This is the temperature that the tester will heat up to. Brings up numeric keypad. Range 25-55 °C; preset values are 32, 37, and 55 °C.

Alarm Time: The time the alarm will begin the bath heating.

Alarm Date: The date that the alarm will begin the tester heating (or Disabled).

Recurrence: Toggles between the following values:

Disabled: The alarm will occur only once at the time and date set and will not reoccur.

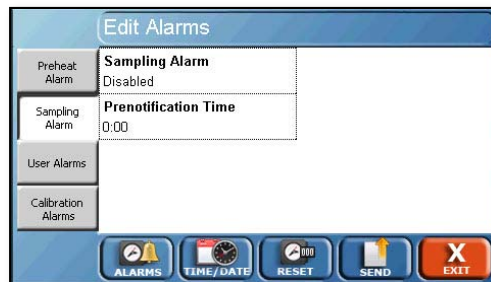
Every Day: The alarm occurs every day.

Every 0 days: This option brings up an Edit button, which allows the user to enter the number of days between when the alarm occurs. For example, if the user entered 30 days, the alarm would occur every 30 days. The range is 2-1827 days.

Mon -> Fri: The alarm will occur every Monday through Friday.

Mon -> Sat: The alarm will occur every Monday through Saturday.

Sampling Alarm tab



This screen provides the user with the ability to enable a sampling alarm. The sampling alarm notifies the user when a sample point is eminent when running a protocol. A message is displayed on the screen with an alarm sound. The alarm will disappear after the sampling point has passed.

Sampling Alarm: Toggles the alarm between enabled or disabled.

Prenotification Time: The amount of time before a sample point the alarm begins to sound. For example, if the user set the alarm to 0:01, the alarm would begin 1 minute before each sample point (0-9:59 in hh:mm).

User Alarms tab

| Edit Alarms | | |
|--------------------|------------------------|----------|
| Preheat Alarm | Alarm Number 1 | Reminder |
| Sampling Alarm | Alarm Time 0:00 | |
| User Alarms | Alarm Date Disabled | |
| Calibration Alarms | Recurrence Disabled | |

ALARMS TIME/DATE RESET SEND EXIT

User alarms are customizable alarms which the user can set up to display a specific message. The alarms can be used to notify users when to change the bath water, or any other routine task. The user alarms can be set for a specific time and date, and also can be set to recur.

The alarm displays a reminder message on the screen with an alarm sound. The alarm will stop when the user touches OK on the alarm notification pop-up.

Alarm Number: Toggles between the 3 user alarms available.

Alarm Time: The time the alarm will begin.

Alarm Date: The date the alarm will begin (or Disabled).

Recurrence: Toggles between the following values:

Disabled: The alarm will occur only once at the time and date set and will not recur.

Every day: The alarm occurs every day.

Every 0 days: This option brings up an Edit button, which allows the user to enter the number of days between when the alarm occurs. For example, if the user entered 30 days, the alarm would occur every 30 days. The range is 2-1827 days.

Mon -> Fri: The alarm will occur every Monday through Friday.

Mon -> Sat: The alarm will occur every Monday through Saturday.

Reminder: The text which is displayed when the alarm goes off. For example, if the operator set this to "Change Tester Bath Water" the text "Change Tester Bath Water" would be displayed when the alarm went off. This message is not erased if the reset button is touched to reset the alarm.

Calibration Alarms tab

The Calibration Alarm notifies the user that the calibration or preventive maintenance on the instrument is due.



Alarm Type: The type of alarm that is displayed. The options are:

Calibration: Displays a calibration due pop-up on the screen

Preventive Maintenance: Displays a Preventive Maintenance due pop-up on the screen.

Alarm Time: The time the alarm will begin.

Alarm Date: The date the alarm will begin (or Disabled).

Recurrence: Toggles between the following values:

Disabled: The alarm will occur only once at the time and date set and will not recur.

Every day: The alarm occurs every day.

Every 0 days: This option brings up an Edit button, which allows the user to enter the number of days between when the alarm occurs. For example if the user entered 30 days, the alarm would occur every 30 days. The range is 2-1827 days.

Mon -> Fri: The alarm will occur every Monday through Friday.

Mon -> Sat: The alarm will occur every Monday through Saturday.

Edit Time/Date screen

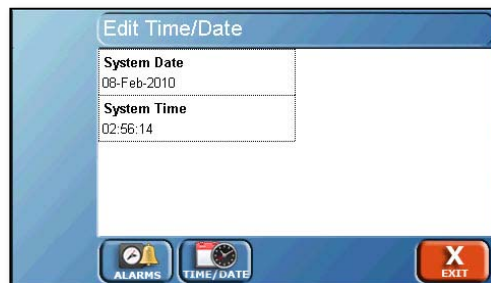
The Edit Time/Date screen is accessed by touching the Time/Date button located along the bottom of the Edit Alarms screen. It allows the user to set the time and date on the tester.



The System Date format is displayed as DD-MMM-YYYY where DD is the day (01-31), MMM is the current month (Jan – Dec), and YYYY is the year in the long format (2009-2999). The entry of the format is numerical having the format DD-MM-YYYY.

The System Time format is 24-hour time (military time) as HH:MM where HH is the current hour (00-24) and MM is the current minute (00-59).

NOTE: The system clock is powered by a capacitor. If the system is left unplugged for 2 weeks, then the time and date will have to be reset. The system must be plugged in at least 5 minutes for the capacitor to reach sufficient charge to maintain the time and date when the system is powered off.



Tools

Tools button

Touching the Tools button on the main menu displays the Tools screen.



This provides access to the Magazine Calibration screen first (only available when an AutoMag or SuperMag is installed and Auto-Probes are configured in the Config menu). This screen allows the user to calibrate the AutoMag or SuperMag and provides access to basic control for movement of the magazine.



Magazine Calibration screen

The Magazine Calibration screen is also accessed by touching the Cal Mag button at the bottom of the screen.

Mag Sample Travel: This field is the depth at which the Magazine will travel to when the sample button is touched.

Up: Moves the Magazine up.

ADD: Moves the Magazine down to the height to trigger Auto Dosage Delivery covers.

Home: Homes the Magazine by raising it up against the drive head then moving it down a set amount.

Sample: Moves the Magazine to the sample position specified in the Mag Sample Travel field.

Calibrate: This button runs the magazine calibration procedure. The AutoMag is calibrated before it leaves the factory. However, if it needs to be recalibrated, use the following procedure from the Magazine Calibration screen:

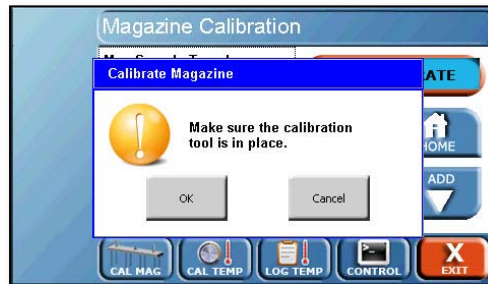
1. Place the AutoMag calibration tool in the center of the vessel plate. (See Fig. D-1 for placement.)

NOTE: Before touching the Calibrate button, ensure that the magazine calibration tool is in place on the vessel plate below the drive screw.



Fig. D-1 AutoMag Calibration Tool in Place

2. Touch the Calibrate button. This will bring up a pop-up screen that asks if the calibration tool is in place. Select OK to confirm.



3. The AutoMag or SuperMag will lower, then stall on the calibration tool, then return to the home position. Once this cycle completes, the magazine is calibrated.

Adjust Temp Probe Offset screen

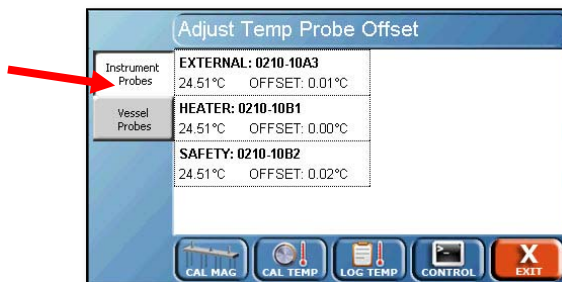
Touch the Cal Temp button at the bottom of the screen for the Adjust Temp Probe Offset screen. This screen allows the user to adjust the offsets to each of the temperature probes installed on the tester and within the Vision heater.



There are two tabs, Instrument Probes and Vessel Probes. To adjust the offset of a probe, touch the field in which it is listed and a numeric keypad will appear. Enter the correct temperature as measured by an NIST traceable thermometer to make the correction.

NOTE: If "--.--" is displayed in any of the fields, that indicates there is an issue with that temperature probe. Contact Technical Support for assistance.

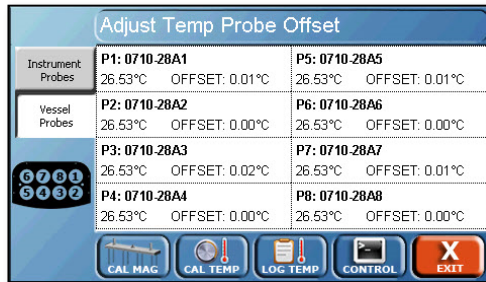
Instrument Probes tab



External: The external temperature probe installed on the dissolution tester.

Heater: The temperature probe located in the heater which controls the rate at which the heater is heating the bath water.

Safety: This is for reference and technical support only. The offset cannot be adjusted.

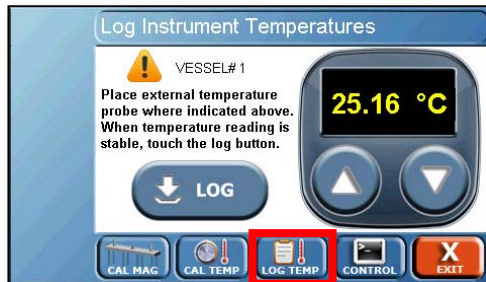


Vessel Probes tab

Each of the vessel probes are listed and can be adjusted independently.

Log Instrument Temperatures screen

Log Instrument Temperatures screen is accessed by touching the Log Temp button at the bottom of the screen.



This screen allows users with only an external temperature probe to log bath and vessel temperatures to the printer.

NOTE: If “Probe Error” is displayed there is an issue with the temperature probe. Contact Technical Support for assistance.

Up (▲) and Down (▼) Arrows: These buttons cycle through the vessels (1 through 8) and the bath.

Log: This button will print the temperature of the selected position. If a serial validation printer is installed, the temperatures will print each time the Log button is pressed. If a PostScript network printer is installed, the temperatures will print when the operator leaves the Log Instrument Temperatures screen.

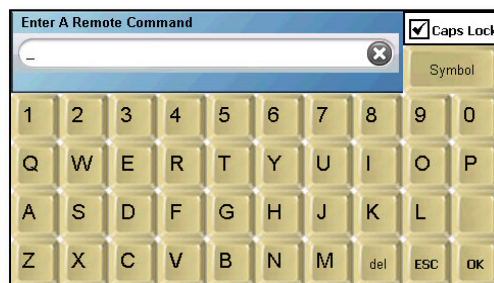
If a test is running, the elapsed time will replace the buttons at the bottom of the screen. A Log button will appear on the pop-up when starting or ending a test. This allows the user to log temperatures before, during, and after a test and ensure those temperatures will appear in the test log.

Remote Command Screen

Remote Command screen is accessed by touching the Control button at the bottom of the screen.



This screen provides access to the Vision tester service and support functions. The button for this screen does not appear to operators if security features are enabled.



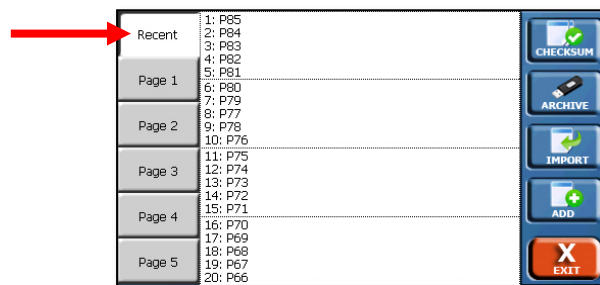
NOTE: The Remote Command screen should only be used when instructed by THR Technical Support.

Protocols

Protocols can be accessed by touching the Protocols button on the main menu, or from the home screen by touching the [Select Protocol] or protocol name displayed in the upper left corner of the home screen.



Protocols are a list of parameters and events that are required to perform a dissolution test. These parameters can be modified to accommodate the user needs. Up to 100 different protocols can be stored.



Recent tab

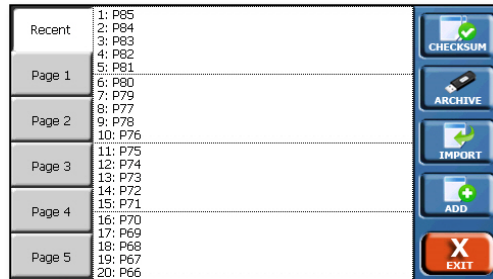
The Recent tab displays the 20 protocols which were used most recently.

Page # tabs

The Page # tabs display the protocols in alphabetical order based on protocol name.

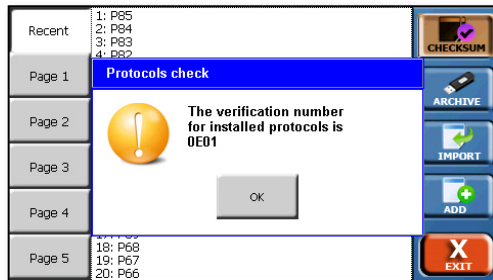


The protocols are listed alphabetically by protocol name in groups of 5 over 5 pages within the interface. The options available for protocols are shown on the buttons on the right side of the screen when all protocols are displayed:



Checksum button

This button generates a unique checksum for the protocols. This can be used to ensure a restored set of protocols is identical to the original set. When touched, the Protocols check pop-up is displayed, which first informs the user the value is being calculated, then displays the calculated value.

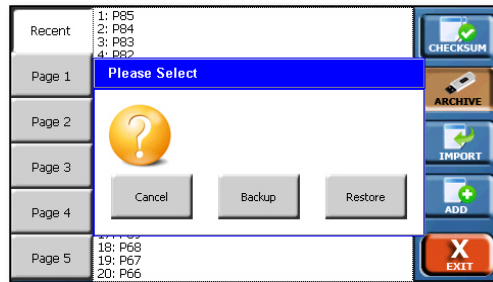


For example, an operator touches the Checksum button and obtains a value of 0EA4. The operator then changes a protocol label by 1 character. When the operator touches the Checksum button again, it will generate a different value.

This feature can be used to ensure that backups and restorations of protocols are identical to the originals. The feature can also be used by managers to ensure that protocols have not been changed without authorization.

Archive button

Allows Backup and Restore functions.



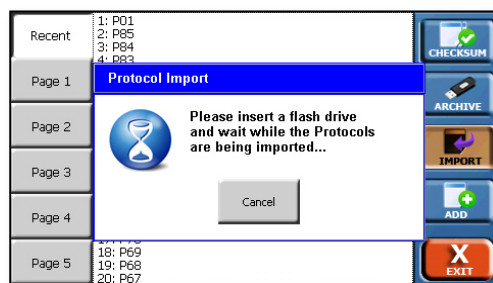
Backup: This button saves all existing protocols on a USB flash drive. When this button is touched, the protocol backup pop-up is displayed. The pop-up prompts the user to insert a flash drive into the USB slot if it is not inserted. If the flash drive is already inserted, the protocols are written to the drive and the pop-up disappears. The protocols are saved in a single file named dproto.bak.

NOTE: Exporting the test log will overwrite any existing test log on the USB drive.

Restore: This button allows protocols to be restored from the flash drive inserted into the USB port. All protocols will be restored from the dproto.bak file.

NOTE: The restore function will produce an exact copy of the protocols on the flash drive. All existing protocols will be overwritten.

If the dproto.bak file does not exist, then a pop-up error message is displayed and the message is also written to the error log. The message asks the user to confirm protocol restoration. If the user touches No, then the protocols will not be restored. If the user touches Yes, all the protocols will be overwritten.



Import button

This button allows the user to import all previously exported protocols from a flash drive inserted into the USB port. Protocols must have been previously exported to the flash drive in order to import them. Only protocols with differing protocol names will be added. Existing protocols may be overwritten if the user confirms an overwrite; otherwise, the existing protocol will remain.

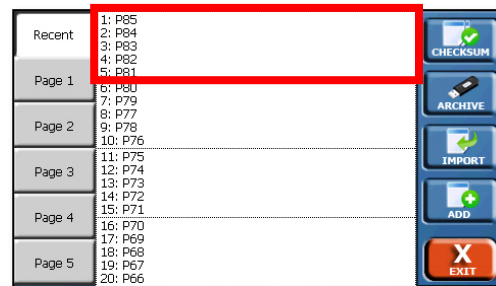
| Term | 2.14 file name | 2.20 file name | Used for | Existing protocols/ users | Data sent |
|---------|----------------|----------------|------------------------|---------------------------|-----------------------|
| Backup | proto.bak | dproto.bak | All protocols or users | Overwritten | Writes to USB drive |
| Restore | proto.bak | dproto.bak | All protocols or users | Overwritten | Copies from USB drive |
| Export | *.hpf | *.hpd | Single protocols | Kept | Writes to USB drive |
| Import | *.hpf | *.hpd | Single protocols | Kept | Copies from USB drive |

Fig. D-2 Summary of USB Transfer Functions

Add button

Allows the user to create a new protocol.

To select an existing protocol, first select the group it is in.



Select the individual protocol on the following screen. The revision date of each protocol is displayed and cannot be directly edited. If security features are enabled, the last user to edit the protocol is displayed.

| | |
|--------|---|
| 1: P01 | Revised on 25-Jul-2011 14:50:00 by HANSON |
| 2: P02 | Revised on 01-Feb-2010 10:00:00 by HANSON |
| 3: P03 | Revised on 01-Feb-2010 15:07:51 by HANSON |
| 4: P04 | Revised on 01-Feb-2010 12:19:29 |
| 5: P05 | Revised on 01-Feb-2010 12:19:37 |



Protocol screen

The following options are available once a protocol is selected, beginning with the tabs along the bottom of the screen:

Event Library: Touching this will convert the protocol into an event library, which is used with the Call event. For more information, see appendix E.

Export: Exports the open protocol to a USB flash drive. The exported protocols are saved with an .hdp extension.






Copy: Creates a copy of the open protocol for the user to work on. The copy is immediately opened for editing and the protocol name has (Copy) added to the end. If the protocol name is too long, part of it may be overwritten.

Delete: Deletes the open protocol.

Print: Prints the selected protocol.

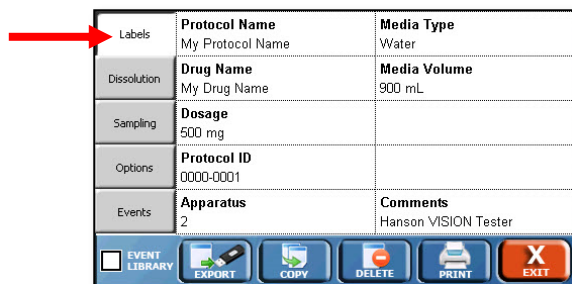
| | | |
|-------------|--|---|
| Labels | Protocol Name My Protocol Name | Media Type Water |
| Dissolution | Drug Name My Drug Name | Media Volume 900 mL |
| Sampling | Dosage 500 mg | |
| Options | Protocol ID 0000-0001 | |
| Events | Apparatus 2 | Comments Hanson VISION Tester |

☐ EVENT LIBRARY

Tabs available on the Protocol screen are as follows:

Labels tab:



| | | |
|-------------|--|---|
| Labels | Protocol Name My Protocol Name | Media Type Water |
| Dissolution | Drug Name My Drug Name | Media Volume 900 mL |
| Sampling | Dosage 500 mg | |
| Options | Protocol ID 0000-0001 | |
| Events | Apparatus 2 | Comments Hanson VISION Tester |

☐ EVENT LIBRARY

The Labels tab provides the user a place to list the protocol name, as well as other information on the protocol:

Protocol Name: This is the name of the protocol and must be unique. The Protocol Name is how the protocols are organized on the protocol selection screens.

NOTE: Do not use a comma (,) in the Protocol Name field. Doing so will cause communication issues with the dissolution tester.

Comments: Allows the user to add any notes specific to the protocol.

The following field names can also be edited by the user though the configuration settings on the title screen.

Drug Name: The name of the drug the protocol is designated to test (e.g. prednisone).

Dosage: The dosage size of the drug to be tested (e.g., 300 mg).

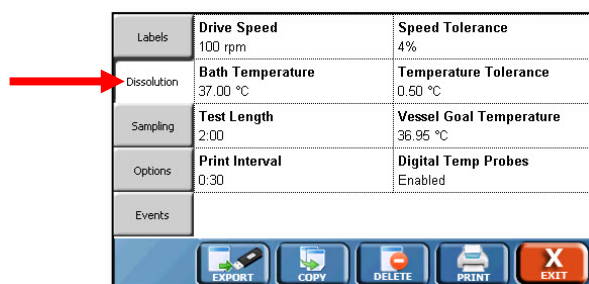
Apparatus: Lists the apparatus used for the testing (i.e. Paddles, Baskets, Paddle over Disk, or apparatus number [e.g., 2]).

Protocol ID: A secondary identifier for the protocol. This does not need to be unique like the Protocol Name.

Media Type: Lists the media type used for the dissolution test (e.g., Water, pH 7.4 Phosphate Buffer).

Media Volume: Lists the media volume used for the dissolution test (e.g., 900 mL).

Dissolution tab



| | | |
|-------------|-------------------------------------|--|
| Labels | Drive Speed 100 rpm | Speed Tolerance 4% |
| Dissolution | Bath Temperature 37.00 °C | Temperature Tolerance 0.50 °C |
| Sampling | Test Length 2:00 | Vessel Goal Temperature 36.95 °C |
| Options | Print Interval 0:30 | Digital Temp Probes Enabled |
| Events | | |

EXPORT COPY DELETE PRINT EXIT

The Dissolution tab provides information and settings for the dissolution test.

Drive Speed: The target drive speed for the dissolution test. Range is 0, 25-250 rpm.

Speed Tolerance: The tolerance for the motor speed for a dissolution test. The default value is $\pm 4\%$ of the set point. Range is 0 (off), 1-10%.

Tester Temperature: The target tester temperature of the dissolution tester. Range is 0, 25.00 - 55.00°C.

Temperature Tolerance: The tolerance for the primary temperature probe on the dissolution tester. The default value is ± 0.5 °C. Range is 0 (off), 0.10 to 5.00 °C.

Test Length: the total time of the dissolution test. The range is 0-999:00 (hh:mm).

Digital Temp Probes: Allows vessel temperature probes mounted on the AutoMag or SuperMag of the Vision Elite 8 to be monitored during the test. The options are Enabled or Disabled.

Print Interval: The interval at which the tester status (speed, temperature, etc.) will be printed. The range is 0 to 999:00 (hh:mm). If the user does not wish the status to print the Print Interval should be set to 00:00.

NOTE: The tester status is printed by default at all sample points, even if the print interval is set to 00:00.

Vessel Goal Temperature: The desired temperature of the vessels. This is option is only applicable when Digital Temp Probes field is set to Enabled. The range is 0 (off), 25.00 to 55.00 °C.

Sampling tab

| | | |
|-----------------|-----------------------------------|---------------------------------|
| Labels | Sampling Mode Manual | Magazine Travel 72 mm |
| Dissolution | Stagger Extension 8 min | |
| Sampling | | |
| Options | | |
| Events | | |

EXPORT COPY DELETE PRINT EXIT

If the Vision (G2) AutoPlus is being used, the protocol can be exported to it and these settings will be used for the automated sampling.

NOTE: A stand-alone tester will only run protocols with the sampling mode set to Manual.

| | | |
|-------------|--|--------------------------------------|
| Labels | Sampling Mode Collect And Detect | Rack Type 13x100 mm |
| Dissolution | Rinse Volume 7.0 mL | Tester Offset Time 0:00:00 |
| Sampling | Collect Volume 2.0 mL | Magazine Travel 72 mm |
| Options | Detect Volume 2.0 mL | |
| Events | Read Delay 5 | |

EXPORT COPY DELETE PRINT EXIT

Sampling Mode: determines the type of sampling procedure:

Collect Only: The AutoPlus collects a sample.

Manual: For manual sampling. When manual sampling is selected, the user has the option of defining how long the paddles remain spinning after a test has ended, to allow for collection of the last sample. This time is entered in the Stagger Extension field.

Collect and Detect: A sample is collected and the system pauses for the Read Delay for detection by UV/Vis spectrophotometric analysis.

Rack Type: The type of rack used for sample collection during the test. 16 x 100 (default), 12 x 32, UPLC 12 x 32, T 12 x 32, and SA 12 x 32. If the wrong rack is installed, the test will not start.

Rinse Volume: The amount of volume pumped before detection or collection is done. The range is 0-99.9 mL. This volume should be large enough to ensure that old material in the lines is rinsed past the needles of the collector and/or UV cells to ensure the sample collected or detected is representative of what is in the vessels of the tester. The default value is 7 mL.

NOTE: If a Vision AutoFilter is installed, this volume is pumped without a filter in place.

Rinse Volume with filter: This field is only visible if a Vision AutoFilter is installed. This is the sample rinse volume pumped with a filter in place. The range is 0-99.9 mL. A minimum of 3 mL is recommended. This option is not visible if the AutoFilter option in the protocol is set to No. A filter icon is present to indicate this volume is pumped with a filter in place.

Collect Volume: The volume collected into test tubes or vials during a sampling cycle. The range is 0-99.9 mL. The maximum for 16 x 100 test tubes is recommended to be no more than 15 mL; for 12 x 32 vials, no more than 1.5 mL. This function only applies to Collect Only and Collect and Detect modes.

Media Replace: Volume from the media replace source (typically Source C if configured) to be transferred to the current source after sampling. The range is 0-99.9 mL.

If the AutoFilter is configured for pull-through, an option is available to select whether or not the AutoFilter will keep a filter in place for the Media Replace step. If enabled an icon of a filter will appear in the Media Replace field.

Generally, the Media Replace volume should be set to be the same as the total of the Rinse Volume and the Collect Volume. For systems that use a Retrieval Reservoir, the media replace volume should be same as the Collect Volume.

Detect Volume: The volume pumped after detection by a UV spectrophotometer. Only applicable with Collect and Detect mode. The range is 0-99.9 mL. This volume must be less than the Collect Volume.

Read Delay: This is the time required to hold the flow cell full for detection, and should be programmed to the time required to analyze all the flow cells used. It is the length of the pause that occurs between the collection volume and detect volume. This option is only applicable with Collect and Detect mode. The range is 0 to 12,000 seconds.

Magazine Travel: This parameter defines magazine stroke from home to the sampling position. The range is 0 (disabled) to 100 mm (for 1 L vessels) or 140 mm (for 2 L vessels). The default value is 60 mm. Preset options for magazine travel are Baskets 500, Baskets 900, Paddles 500, Paddles 900, Small Vol, and Chinese Small Vol for selecting predetermined sampling height based on apparatus and commonly used media volume in the vessels.

For example, Baskets 500 would be a preset value for the proper magazine travel in a test involving 500 mL of media in each vessel.

The travel values are approximate and fine tuning may be necessary. The suggested travel values do not account for additional distance that may be needed due to tip filters.

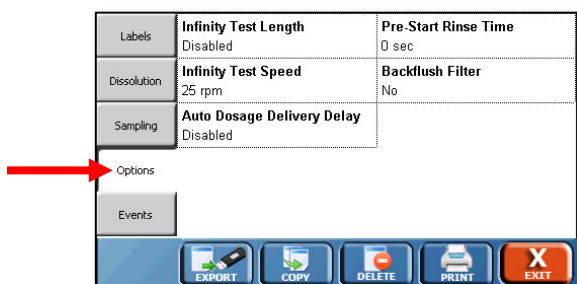


Auto Dosage Delivery Delay: If Auto Dosage Delivery (ADD) covers are installed on the Vision Elite 8, this value is the delay between when the ADD covers are triggered, and the time the test starts. The recommended value for this is 5 seconds. The range is 0 (disabled) to 99 seconds.

Tester Offset Time: This determines the offset between the testers when running multiple testers. The minimum recommended value is 0:05 minutes. The range is 0:00 – 1:30 (hh:mm).

Options tab

The Options tab allows for testing options to be set outside of sampling and dissolution tester settings.



Auto-Start Test: This option is only available if Auto Dosage Delivery Delay is set to Enabled. Auto-Start Test allows the user to determine if the test will automatically start. For the types of auto-starts, see the testing section. The options available are:

Enabled: The protocol will automatically start once the conditions are reached.

Disabled: The protocol will not automatically start once the conditions are reached and it must be started manually.

Prompt: When the protocol is set up to run, the user will be prompted if they want to automatically start the test or not.

Pre-Start Rinse Time: Allows the user to set the Vision G2 AutoPlus to start the pumping ahead of the scheduled sampling time to allow for fine tuning sample points. The range is 0-3600 seconds.

Backflush Filter: When enabled, the system will withdraw 1 mL of sample and return it to the source before the sampling cycle begins in order to clean material out of any installed filters. The options are Yes or No.

NOTE: The pumping for the Backflush Filter option begins on the second sample point.

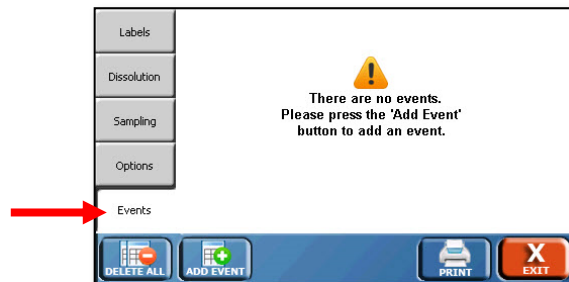
Infinity Test Length: The length of the infinity test which follows the dissolution test. If no infinity test is desired set this value to 0:00. The range is 0:00 to 9:59 in h:mm format.

NOTE: The infinity test begins after the dissolution test is over. For example, if a dissolution test was 2 hours, with a 30-minute infinity test, the user would need to set a sample point at 2:30 (h:mm) to collect an infinity test sample.

Infinity Test Speed: Sets the speed of the infinity test that follows the normal test. The range is 0, 25 to 250 rpm.

Events tab:

The Events tab allows the user to add events or modify the Event Table.



The Event Table is a sequence of up to 50 events that will take place at user-programmed times. There are two types of events, sampling and remote commands. Sampling events must have a time assigned to it. Remote command events may occur during the test, pre-run (before the test), or post-run (after the test).

NOTE: Pre-run and post-run events cannot be sampling events.

Pre-Run: Events programmed as a pre-run event will occur before the test begins.

For example, an operator programs a pre-run event of Drive Speed for 25 rpm. Prior to the test starting the motor will spin at 25 rpm. When the test begins, the motor will go to the speed programmed on the Dissolution tab.

Post-Run: Events programmed as post-run will occur after the test has completed.

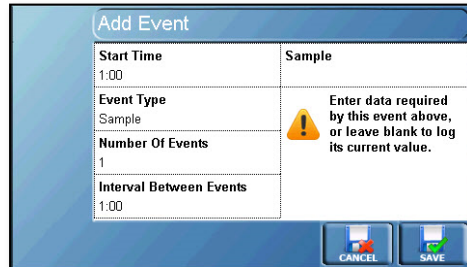
For example, an operator programs a post-run event of Bath Temp for 40 °C. Once the test completes, the bath temperature will be set to 40 °C.

| | | |
|-------------|------------------------------|------------------------------|
| Labels | PRE-RUN Rinse Volume=4.00 | 4:00:00 Sample |
| Dissolution | 1:00:00 Sample | 5:00:00 Sample |
| Sampling | 2:00:00 Sample | 6:00:00 Sample |
| Options | 3:00:00 Sample | 7:00:00 Sample |
| Events | 3:00:00 Drive Speed=100 | POST-RUN Print Statistics |

To edit or delete an event, touch the field in which it appears; this will open the Edit Event screen.

To delete all the events in a protocol, touch the Delete All button.

To add a new event, touch the Add Event button; the following screen is displayed:



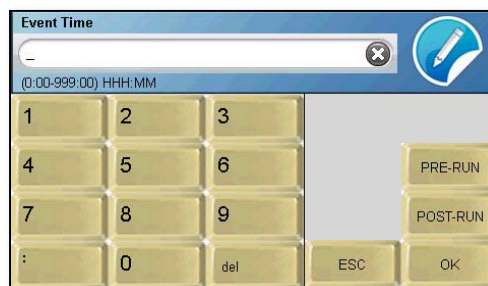
The 'Add Event' screen is a form with a blue header. It contains several input fields: 'Start Time' with the value '1:00', 'Event Type' with the value 'Sample', 'Number Of Events' with the value '1', and 'Interval Between Events' with the value '1:00'. To the right of these fields is a larger area labeled 'Sample' which contains a yellow warning triangle icon and the text: 'Enter data required by this event above, or leave blank to log its current value.' At the bottom right of the screen are two buttons: 'CANCEL' and 'SAVE'.

Add Event screen

The Add Event screen allows the user to add an event or events to the event table.

Start Time: This defines the start of the first event. The range is 0:00 to 999:00 (hh:mm). Preset buttons are Pre-Run and Post-Run.

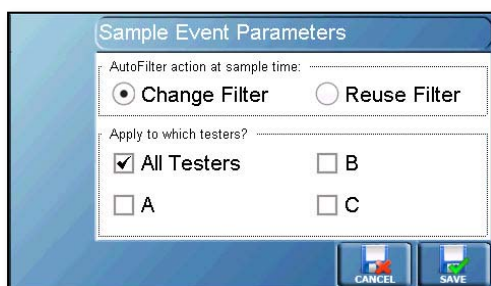
NOTE: A warning will appear if sample points may overlap due to the protocol settings. This warning is based on the total volume pumped by the AutoPlus at each sample point, testers configured, tester offset time, and AutoFilter use. The warning will appear when the user attempts to save the protocol. The warning will not appear if the user views the protocol without making any changes.



The 'Event Time' screen features a blue header with the title 'Event Time'. Below the header is a large input field for time, currently showing a dash '-' and a small 'x' icon. Below the input field is the text '(0:00-999:00) HHH.MM'. The screen contains a numeric keypad with buttons for digits 1-9, 0, and a 'del' button. To the right of the keypad are two buttons labeled 'PRE-RUN' and 'POST-RUN'. At the bottom right are 'ESC' and 'OK' buttons. A blue circular icon with a pencil is located in the top right corner.

Event Type: This defines the type of event that is to occur. By default, all events are sampling events. An (S) before the event indicates that it is performed by the Sampler. A (T) before the event indicates it is performed by the Tester. A (B) before the event indicates it is performed by either or Both the autosampler and dissolution tester. An (F) indicates the command is performed by the Filter Changer:

(S) Sample: Collects a sample. If an AutoFilter is installed, the following options will appear to modify the sampling process.



Change Filter: Instructs the AutoFilter to change the filter on the specified tester(s). Cannot be selected together with the “Reuse Filter” option for the same sample point.

Reuse Filter: Instructs the AutoFilter to reuse the filter for the specified tester(s). Cannot be selected with “Change Filter” option for the same sample point.

All Testers: Apply the option (reuse or change filters) to all testers at the sample point.

A, B, or C: Select tester(s) A, B, and/or C individually to reuse or change filters at the sample point.

For example:

- Reuse Filter/All Testers: The filters will be reused for all testers on this sample point.
- Change Filter/B: The filters will be changed on tester B. Tester A will reuse the filter from the previous sample point.

(S) Backflush Filter: The options are Enabled or Disabled. This draws 1 mL of media from the vessels on the dissolution tester, then pumps the media out back to the vessels, before a sampling cycle begins. This removes any particles that might clog the tip filter.

(T) Bath Temp: The parameter is a temperature value. It allows the user to set a new dissolution tester bath temperature.

(F) Change Filter: Instructs the Vision AutoFilter to change a filter. The parameters are the testers (A, B, or C) for which the filter is changed.

For example, if B was entered, the AutoFilter would change a filter for the sample on tester B, but would not change the filter for tester A.

(S) Collect Volume: This allows the user to set a new collection volume for the test.

(B) Delay: This allows the user to set a delay for the start of the test. The delay waits for the specified amount of time. Range 1 to 12,000 sec. It is valid for Pre-Run only.

NOTE: To stop paddle rotation temporarily during a dissolution test, use the Pause event.

(S) Detect Volume: The parameter is the detection volume. It allows the user to set a new Detect Volume for the test.

(S) Dilute: The options are (dilution) Volume, Rinse (volume), Source, StartRow, and RowCount. It allows the user to perform a dilution at the time of the event rather than after each sample (dilution event). The range is 0 to 99.9 mL.

NOTE: The Dilute event is only compatible with port B or port C set as a media source. It will not function with Home Port 2 set as a media source.

For example, if the user programmed a Dilute event at 2 hours with 5, 7, C, 3, 10, the AutoPlus would first rinse from C to D with 7 mL, then pump 5 mL from source C in to rows 3 through 13.

(S) Dilution: The options are Volume, Rinse, and Source. It allows the user to perform a dilution during the test only after each sample. The range is 0 to 99.9 mL. Set volumes to 0.0 to turn off.

For example, for a dilution volume of 5 mL, a rinse of 7 mL, and a source C, the parameter would read: 5,7,C.

(F) Discard Filter: The AutoFilter discards the current filter. The parameters are the tester.

For example, if an operator entered A, the filter would be discarded for tester A sample points.

(S) Dispense Flow Rate: The parameter is speed of the syringes while dispensing. This changes the speed at which the Vision G2 AutoPlus syringes dispense material. The range is 0.6 to 23.8 mL/min. The default setting is 19.0 mL/min.

NOTE: 19.0 mL/min. should not be exceeded, or the Vision G2 AutoPlus could be damaged.

(T) Drive Speed: The parameter is the tester drive speed. It allows the user to set a new motor speed for the dissolution tester. The range is 0 for off, or 25 to 250 rpm.

(F) Filtered Media Replace: Toggles whether or not the media replace is done with a filter in place. The options are yes and no.

(F) Filtered Retrieval: Toggles whether or not the retrieval volume is pumped with a filter in place. The options are yes and no.

(S) Load Flow Rate: The parameter is speed of the syringes while loading. This changes the speed at which the Vision G2 AutoPlus syringes load material. The range is 0.6 to 23.8 mL/min. The default setting is 19.0 mL/min.

NOTE: 19.0 mL/min. should not be exceeded, or the Vision G2 AutoPlus could be damaged.

(B) Mag Home Offset: (Version 2.64 and above only) Allows the mag home offset position to be set as a pre-run event. The offset remains active for the duration of the test but user interaction such as printing the test report or acknowledging the test over prompt clears the offset position. The range is 0-30 mm.

(T) Magazine Travel: This parameter defines magazine stroke from home to the sampling position. The range is 0 (disabled) to 100 mm (for 1 L vessels) or 140 mm (for 2 L vessels). The default value is 60 mm. Preset options for magazine travel are Baskets 500, Baskets 900, Paddles 500, Paddles 900, Small Vol, and Chinese Small Vol for selecting predetermined sampling height based on apparatus and commonly used media volume in the vessels.

For example, Baskets 500 would be a preset value for the proper magazine travel in a test involving 500 mL of media in each vessel.

(S) Media Replace: The parameter is volume, and the range is 0 to 99.9 mL. This changes the media replace volume pumped during the test.

(T) Pause: The parameter is time in minutes from 1 to 999. This stops the spindles on the testers from spinning for the specified amount of time. The tester will then count up for the duration of the pause, while the total elapsed time is held constant. If pause is set to 0, the pause is indefinite, so the user must resume the tester manually.

For example, if a pause was programmed for 2 minutes, the paddles would stop spinning for 2 minutes, then resume spinning after the 2 minutes had expired.

(T) Print Interval: The parameter is the interval between printing. This changes the print interval for printing the status of the dissolution testers.

(B) Print Statistics: This prints the current statistics for the test. There are no parameters for this command.

(T) ProbeDown: Moves the AutoMag down.

(T) ProbeUp: Moves the AutoMag up.

(B) Prompt: This creates a pop-up message box with a message. The message may be up to 11 characters in length.

(S) Read Delay: This changes the read delay when working with collect and detect protocols. The parameter is time; the range is 0 to 12,000 sec.

(S) Retrieval Volume: This changes the volume pulled when operating the Retrieval Reservoir; the range is 0 to 99.9 mL.

(F) Reuse Filter: This instructs the AutoFilter to reuse a filter. If a filter is not coupled, but is in the hold position, the filter will be reused for the sample point. If a filter is already in the filter coupled position, then the filter will be kept in place. If there is not a filter in the filter coupled position or on the shuttle assembly, then a new filter is loaded. The parameters are the testers that the filter will be reused for.

For example, if a A,B were entered, the filter would be reused for tester A and B at the next sample point.

(S) Rinse Volume: This allows the user to set a new sample rinse volume (0 to 99.9 mL) during the test.

(S) Rinse Volume with Filter: This allows the user to set a new sample rinse volume with a filter (0 to 99.9 mL) during the test.

(A) Send to Serial: The options are PortNum and Text. Text is the string that is sent to the port. PortNum refers to the port number of the Vision instrument.

1 – Host port

2 – Printer

3 – Collector (for AutoPlus) or Vision heater (for tester). This port is not applicable to the AutoFilter.

(T) Speed Tolerance: This changes the dissolution tester motor speed tolerance for the protocol. The options are 0 (disabled), or 1 to 10%.

(T) Status: This allows the user to get an automatic status at the specified time. The speed and temperature is reported.

(T) Temperature Tolerance: This changes the dissolution tester temperature tolerance for the protocol. The options are 0 (disabled), or 0.1 to 5.00 °C.

(S) Transfer: The options are Volume, Source, Destination. It allows the user to transfer a specified volume of solution from a specified source to a specified destination.

For example, if a transfer of 5 mL from source C to source A is desired, the parameter would read: 5,C,A.

The following sources/targets are available when using a Transfer command in the event table of a protocol.

U: This source/target keeps the needles up. It is useful as a source to pull air into the syringes to dry out the lines. It can also be used to push any remaining media back to the vessel.

W: This source/target lowers the needles into Home Port 2 of the AutoFill.

H: This lowers the needles into the Home Port 1 (or waste port) of the AutoFill.

1-25: This can be used as a target only. This target will lower the needles into the corresponding row of the rack.

For example, if “10” was entered, the needles would lower in the 10th row of the installed rack.

D: Keep the collector in the current position when the transfer will occur. Using D will not lower the needles of the collector when performing transfers!

X: Current tester.

P: Previous row, or the row the last sample was collected in.

N: Next row, or the row the next sample will be collected in.

(F) Uncouple and Hold Filter: This instructs the AutoFilter to uncouple and move the filter to the load position. The parameters are the testers.

For example, if the user put in A,B, the filter would be uncoupled and put in the load position for testers A and B.

(S) Valve Delay: This changes the dispense valve delay when an AutoPlus is working in conjunction with an AutoFilter. The delay allows extra pressure caused by the filter to bleed off, allowing for more accurate transfer volumes. The delay is changed only when a filter is coupled in the AutoFilter. The parameter is the time in seconds. The default value for this is 7 seconds. A minimum of 5 seconds is recommended.

(B) Vessel Goal Temperature: The parameter is the temperature value. It allows the user to change the desired vessel temperature when used with Digital Temperature Probes (DTPs) on the Vision Elite 8 AutoMag. The options are 0 (for disabled), or 25 to 55 °C.

(B) Call: Executes an event library starting at the time of a call event. For more information, see appendix E.

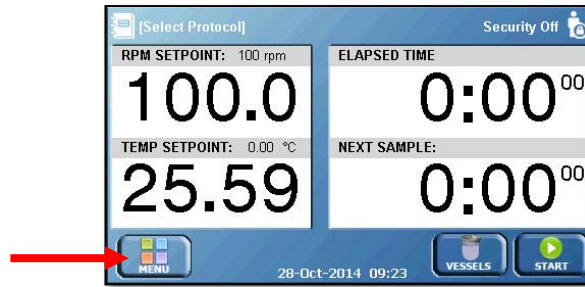
Number of Events: This allows the user to set the number of times this event will occur. By default, only one occurrence of the event is created. For multiple occurrences, the first event begins at the start time.

Interval Between Events: This allows the user to set the interval between the events occurring when multiple events are being added to the event table, in the format hh:mm, where hh is hours and mm is minutes. The range varies depending on the number of events and the sampling times.

How to Program a Protocol

Below are the instructions on how to program a basic protocol.

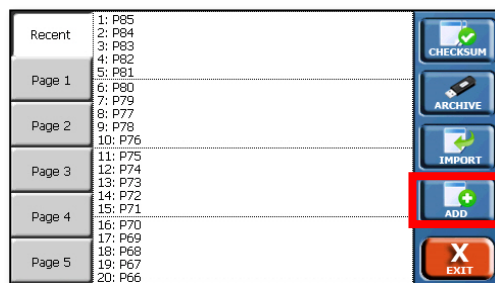
1. Touch the Menu button on the home screen to bring up the menu.



2. Touch the Protocols button on the menu to bring up the protocol screen.



3. Touch the Add button to create a new protocol.



- The Labels tab of the protocol will appear. Begin by editing the protocol name. Protocol names must be unique and be set before the protocol can be saved. To change the protocol name, touch the Protocol Name field and enter an appropriate protocol name.

NOTE: Do not use a comma (",") in the Protocol Name field. Doing so will cause communication issues with the dissolution tester.

| | | |
|-------------|----------------------------------|---|
| Labels | Protocol Name | Media Type Water |
| Dissolution | Drug Name My Drug Name | Media Volume 900 mL |
| Sampling | Dosage 500 mg | |
| Options | Protocol ID 0000-0001 | |
| Events | Apparatus 2 | Comments Hanson VISION Tester |

EVENT LIBRARY
EXPORT
COPY
DELETE
PRINT
EXIT

- Touch the other fields to enter the appropriate information for each of those fields. When finished, touch the Dissolution tab on the left side of the screen.

| | | |
|-------------|-------------------------------------|--|
| Labels | Drive Speed 100 rpm | Speed Tolerance 4% |
| Dissolution | Bath Temperature 37.00 °C | Temperature Tolerance 0.50 °C |
| Sampling | Test Length 2.00 | Vessel Goal Temperature 36.95 °C |
| Options | Print Interval 0.30 | Digital Temp Probes Enabled |
| Events | | |

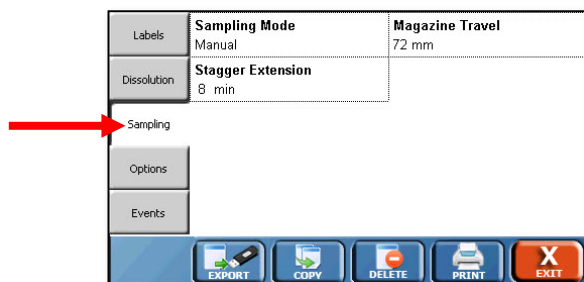
EXPORT
COPY
DELETE
PRINT
EXIT

- Begin by entering the drive speed for the dissolution testers by touching the Drive Speed field.

| | | |
|-------------|-------------------------------------|--|
| Labels | Drive Speed 100 rpm | Speed Tolerance 4% |
| Dissolution | Bath Temperature 37.00 °C | Temperature Tolerance 0.50 °C |
| Sampling | Test Length 2.00 | Vessel Goal Temperature 36.95 °C |
| Options | Print Interval 0.30 | Digital Temp Probes Enabled |
| Events | | |

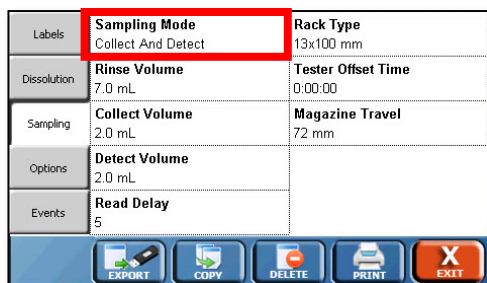
EXPORT
COPY
DELETE
PRINT
EXIT

- Once the drive speed is entered, touch the other fields to enter the appropriate information. When finished, touch the Sampling tab.



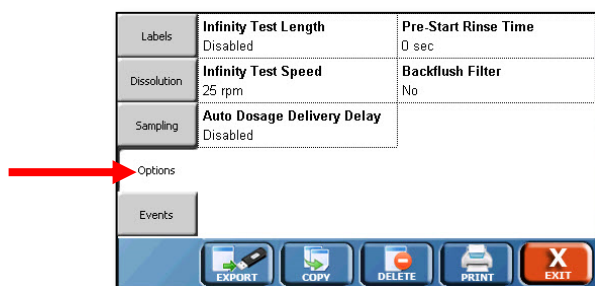
A screenshot of the 'Sampling Mode' screen. The left sidebar shows tabs: Labels, Dissolution, Sampling (selected with a red arrow), Options, and Events. The main area displays 'Sampling Mode' with 'Manual' and 'Magazine Travel' with '72 mm'. Below this is 'Stagger Extension' with '8 min'. At the bottom are buttons: EXPORT, COPY, DELETE, PRINT, and EXIT.

- Touch the Sampling Mode field to set the appropriate sampling mode.



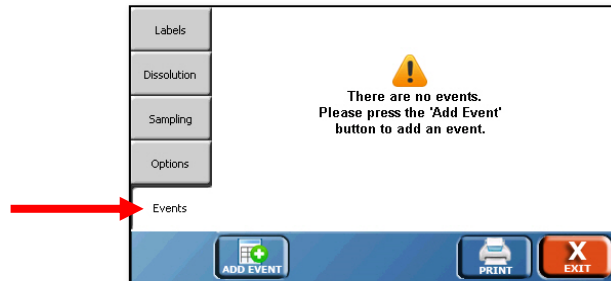
A screenshot of the 'Sampling Mode' screen. The left sidebar shows tabs: Labels, Dissolution, Sampling, Options, and Events. The main area displays 'Sampling Mode' with 'Collect And Detect' (highlighted with a red box), 'Rack Type' with '13x100 mm', 'Rinse Volume' with '7.0 mL', 'Tester Offset Time' with '0:00:00', 'Collect Volume' with '2.0 mL', 'Magazine Travel' with '72 mm', 'Detect Volume' with '2.0 mL', and 'Read Delay' with '5'. At the bottom are buttons: EXPORT, COPY, DELETE, PRINT, and EXIT.

- With the correct sampling mode entered, proceed to enter the rest of the information by touching the appropriate fields. When finished entering the information, touch the Options tab on the left.

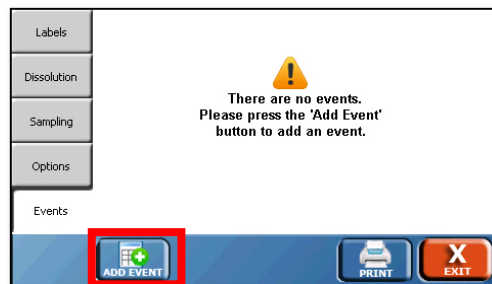


A screenshot of the 'Sampling Mode' screen. The left sidebar shows tabs: Labels, Dissolution, Sampling, Options (selected with a red arrow), and Events. The main area displays 'Infinity Test Length' with 'Disabled', 'Pre-Start Rinse Time' with '0 sec', 'Infinity Test Speed' with '25 rpm', 'Backflush Filter' with 'No', and 'Auto Dosage Delivery Delay' with 'Disabled'. At the bottom are buttons: EXPORT, COPY, DELETE, PRINT, and EXIT.

10. Configure the options as appropriate for the protocol by touching on the fields. When finished, touch the Events tab on the left.



11. Touch the Add Event button on the bottom to add a new event.



12. Select the Start Time of the first event, then the Event Type by touching the respective fields. If there is more than one of the event, as with sampling, touch the number of events field to set the total number of events (for example, sample points). Finally touch the Interval Between Events field to set the time that occurs between the events.
13. When the event is configured, touch the Save button on the bottom right to add the event to the events table.

| Add Event | |
|-----------------------------------|--|
| Start Time 1:00 | <div>Sample</div> <div>Enter data required by this event above, or leave blank to log its current value.</div> |
| Event Type Sample | |
| Number Of Events 1 | |
| Interval Between Events 1:00 | |
| <div>CANCEL</div> <div>SAVE</div> | |

14. If an event is not desired (for example, an extra sample point), touch the field the event appears in.

| | | |
|-------------|------------------------------|------------------------------|
| Labels | PRE-RUN Rinse Volume=4.00 | 4:00:00 Sample |
| Dissolution | 1:00:00 Sample | 5:00:00 Sample |
| Sampling | 2:00:00 Sample | 6:00:00 Sample |
| Options | 3:00:00 Sample | 7:00:00 Sample |
| Events | 3:00:00 Drive Speed=100 | POST-RUN Print Statistics |

DELETE ALL ADD EVENT PRINT EXIT

15. On the Edit Event screen touch the Delete button to remove the event.

Edit Event

| | |
|----------------------|---|
| Event Time 1:00 | Sample |
| Event Type Sample | <div> <div></div> <div>Enter data required by this event above, or leave blank to log its current value.</div> </div> |

DELETE

EXIT

16. If no changes are needed, touch the Exit button in the bottom right of the screen to save the protocol.

Edit Event

| | |
|----------------------|---|
| Event Time 1:00 | Sample |
| Event Type Sample | <div> <div></div> <div>Enter data required by this event above, or leave blank to log its current value.</div> </div> |





DELETE

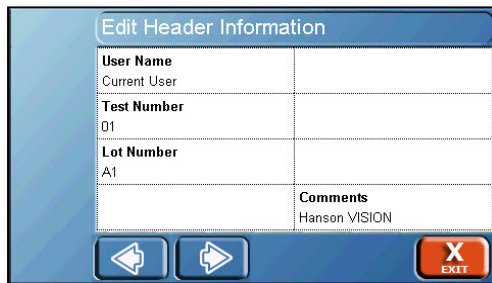
EXIT

Dissolution Testing

Test Menu

When starting a test on the Vision tester, a number of screens appear that are unique to the process. These options appear once Start is touched on the home screen.

The Prev () and Next () buttons are common to each screen. Next () advances the user to the next screen in the process of starting a test. The Prev () button allows the user to return to the previous screen.



| Edit Header Information | |
|---------------------------|--------------|
| User Name | Current User |
| Test Number | 01 |
| Lot Number | A1 |
| Comments Hanson VISION | |


Header Information screen

The header information screen allows the user to enter information specific to that test run. The labels for the headers can be changed through the configuration screens. The fields are:

User Name: Allows the user to enter a name, or if security is enabled, the name of the user logged in is automatically displayed.

Test Name: Allows the user to enter a test name, if applicable.

Lot Number: Allows the user to input the lot number of the item being tested.

Comments: Allows the user to add any comments related to the test run. 

Test Options screen:

The screenshot shows a 'Test Options' window with a blue header and a white content area. The content area is divided into two columns. The left column contains 'Auto Print Test Report' (set to 'Print Full Report') and 'Heater Off At End Of Test' (set to 'No'). The right column contains 'Auto Start' (set to 'At Set Time'), 'Start Date' (set to 'Wednesday, Jan 22, 2014'), and 'Start Time' (set to '0:00'). At the bottom of the window are three buttons: a back arrow, a 'RUN TEST' button with a green play icon, and an 'EXIT' button with a red 'X' icon.

| Test Options | |
|----------------------------------|-------------------------|
| Auto Print Test Report | Auto Start |
| Print Full Report | At Set Time |
| Heater Off At End Of Test | Start Date |
| No | Wednesday, Jan 22, 2014 |
| | Start Time |
| | 0:00 |

Select the options as appropriate for the test. The following options are available on the Test Options screen.

Auto Print Test Report: Determines if the test report will automatically print at the end of the test. The options are:

No: the user must command the instrument to print the test report at the end of the test.

Print Summary: This prints just the summary report, which is identical to the first page of the full report.

Print Full Report: This prints the full test report. It includes the summary page and test log for the dissolution tester.

Heater Off At End Of Test: This option causes the Vision tester to turn off the heater at the end of the dissolution test in order to reduce power consumption.

Auto Start: Displays if the protocol will automatically start when conditions are met. If Auto Start is disabled in the protocol, this field is locked as "No." If Auto Start within the protocol is set to Prompt or Yes, the field can be changed to the following Auto Start options:

When Temp Ready: Starts the test when the bath temperature is within specification.

At Set Time: Starts the test at a specific date and time regardless of temperature. This adds date and time fields which allow the user to set the time and date the test will start.

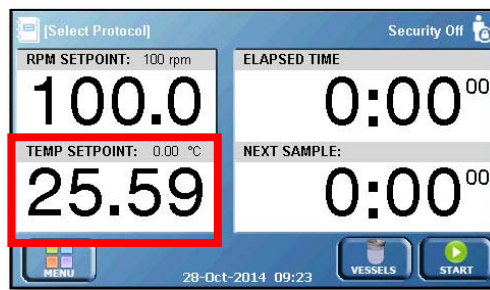
Temp and Time: Starts the test when both the temperature and time are met. If the tester temperature is not within specification at the programmed time, the test will start when the temperature is within specification. If the tester is at the correct temperature before the programmed time, the test will start at the programmed time.

Start Date: The date the test is scheduled to begin.

Start Time: The time the test is scheduled to begin.

How to Use the Quick Start

1. Begin at the home screen and ensure the temperature is correct for running the test.



2. Touch the RPM SETPOINT field (0.0 unless a test is running). Enter the speed of the test and touch the Quick Start button in the bottom right.

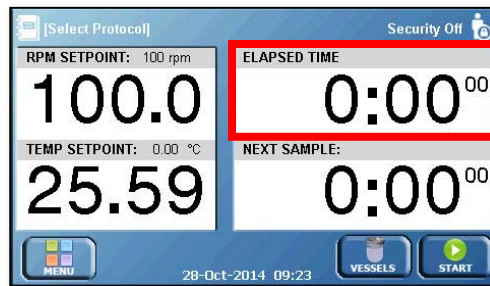
NOTE: Do not use the preset buttons if a test length has not been set, as this will start the spindles moving immediately.



Dissolution Testing

3. Touch the Elapsed Time field and set a test length, if desired. If no test length is set, the test will run until the user touches the **Stop button** in the lower right corner of the home screen.

NOTE: If Quick Start is not selected, the Elapsed Time field will not respond when touched.



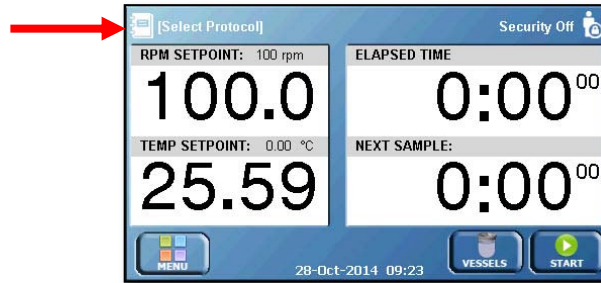
4. Touch the Start button in the bottom right corner.



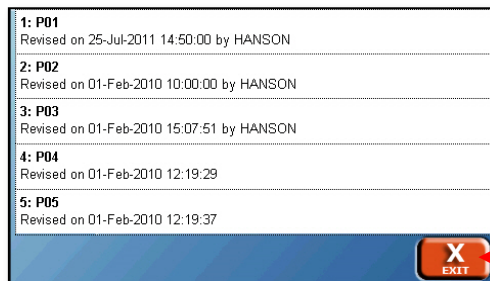
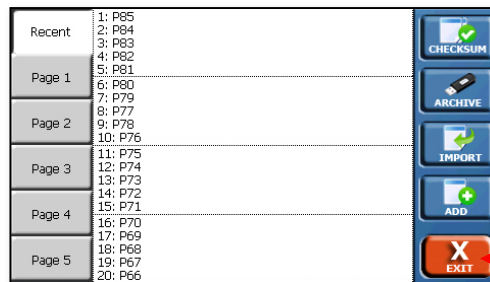
5. A pop-up will appear, asking the user to Run, Abort, or Log.
 - a. To start the test touch Run.
 - b. To abort the test, touch Abort.
 - c. To log temperatures prior to dropping a tablet, touch Log.
6. When Run is touched, the spindles will begin to turn at the set point. The test will continue until the user touches the Stop button located in the lower right corner of the home screen, or until the test length set in step 3 has elapsed.

How to Start a Test

1. To start a test, first begin at the home screen and touch protocol name or [Select Protocol] text in the upper left-hand corner of the screen.



2. Review the loaded protocol and touch the Exit button if ok. Otherwise, select the correct protocol from the list, then touch Exit, then Exit again to return to the home screen.



Dissolution Testing

3. Press the Start button located on the lower right corner of the home screen.



4. Enter the appropriate information in the Header screen. This is for information only and will appear on printed reports. When finished press the Next button at the bottom of the screen.

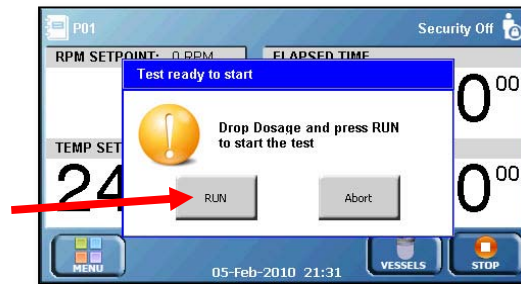
The screenshot shows the "Edit Header Information" screen. It has a table with the following fields: "User Name" (Current User), "Test Number" (01), "Lot Number" (A1), and "Comments" (Hanson VISION). At the bottom, there are three buttons: a left arrow, a right arrow (indicated by a red arrow), and an "EXIT" button with a red X.

5. Select the options as appropriate for the test. The following options are available on the test option screen. Once the options are set press the Run Test button.

The screenshot shows the "Test Options" screen. It has a table with the following fields: "Auto Print Test Report" (Print Full Report), "Auto Start" (At Set Time), "Heater Off At End Of Test" (No), "Start Date" (Wednesday, Jan 22, 2014), and "Start Time" (0:00). At the bottom, there are three buttons: a left arrow, a "RUN TEST" button (indicated by a red arrow), and an "EXIT" button with a red X.


Dissolution Testing

6. The Vision tester will return to the home screen. If Auto Start is not enabled, the tester will prompt the user to drop the dosage and press the Run button, starting the test (or Abort to cancel).



Manual Staggered Start with Vision G2 Tester(s)

1. Confirm the vessels, paddles, or baskets and basket shafts are clean and in good condition. Install them in their designated positions.
2. Confirm the heights of apparatus from the vessel bottom using a height gauge.
3. On the tester, touch the temperature to bring up the Temp Setpoint screen. Enter the desired temperature (+0.10 °C of the desired vessel temperature is recommended) and touch OK.
4. Raise the apparatus out of the vessels by pulling up on the spindle shafts, or in the case of a Vision Elite 8, raising the drive head.
5. Fill the vessels with media.
6. Prepare the apparatus:
 - a. Baskets
 - i. Raise the spindle shafts to their highest point.
 - ii. If using a Vision Elite 8, lower the drive head to the testing position.
 - iii. Cover the vessels
 - iv. Allow the media to stabilize.
 - b. Paddles
 - i. Lower the paddles into the media to about 1 cm above the testing height. If using a Vision Elite 8 the drive head should be lowered.
 - ii. Cover the vessels and allow the media to stabilize.
 - c. Paddles with ADD Cover
 - i. Close the chamber of the ADD cover by pressing the hinged portion on the bottom of the cover closed.

- ii. Lower the paddles into the media to the testing height. If using a Vision Elite 8, the drive head should be lowered.
 - iii. Cover the vessels and allow the media to stabilize.
 7. Once the media has stabilized, ensure the protocol is loaded by checking the upper left corner of the screen. If the correct protocol is loaded, do nothing. If it is not, touch the upper left corner of the screen, then touch Exit and select the protocol to be used for testing.
 8. Touch the Start button in the lower right corner of the screen. Enter the header information as appropriate, then touch Next ().
 9. Prepare the apparatus:
 - a. Baskets
 - i. Place the dosage in each of the baskets and install the baskets on the basket shafts.
 - ii. In the case of the Vision Elite 8, lower the drive head to the testing position with all 8 spindle shafts pulled up, taking care that the baskets do not come into contact with the vessel covers.
 - iii. Remove the cover over position 1.
 - iv. Lower the basket on position 1 to the testing position and touch Run to start the test.
 - v. Replace the vessel cover over position 1.
 - vi. Repeat the previous steps for the remaining positions in turn, based on the desired stagger time.

b. Paddles


- i. Drop the dosage into vessel 1 by lifting up the side of the vessel cover and inserting the dosage through the opening into the vessel while grasping the spindle clamp so the paddle does not spin.
- ii. Push the paddle down into the testing position and touch Run to start the test.
- iii. Replace the vessel cover over position 1.
- iv. Repeat the previous steps for each of the remaining positions in turn, based on the desired stagger time.

c. Paddles with ADD cover

- i. Place the dosage in each of the dose tubes located on the ADD cover for all positions.
- ii. Place the dose caps on top of the dose tubes for all positions.
- iii. Drop the dosage into position 1 by depressing the push pin.
- iv. Touch Run to start the test.
- v. Replace the vessel cover over position 1.
- vi. Repeat the previous steps for each of the remaining positions in turn based on the desired stagger time.

Manual Simultaneous Start with Vision G2 Tester(s)

1. Confirm the vessels, paddles, or baskets and baskets shafts are clean and in good condition. Install them into their designated positions
2. Confirm the heights of apparatus from the vessel bottom using a height gauge.
3. On the tester, touch the temperature to bring up the set temperature screen. Enter the desired temperature (+ 0.10 °C of the desired vessel temperature is recommended) and touch OK.
4. Raise the apparatus out of the vessels by pulling up on the spindle shafts to their highest point, or in the case of a Vision Elite 8, raising the drive head to its highest point.
5. Fill the vessels with media.
6. Prepare the apparatus:
 - a. Baskets
 - i. Cover the vessels.
 - ii. Allow the media to stabilize.
 - b. Paddles
 - i. Lower the paddles into the testing position. If using a Vision Elite 8, lower the drive head.
 - ii. Cover the vessels and allow the media to stabilize.
 - c. Paddles with ADD Cover
 - i. Lower the paddles into the testing position. If using a Vision Elite 8, lower the drive head.
 - ii. Close the chamber of the ADD cover by pressing the hinged portion on the bottom of the cover closed.
 - iii. Cover the vessels and allow the media to stabilize.

7. Once the media is stabilized, ensure the protocol is loaded by checking the upper left corner of the screen. If the correct protocol is loaded, do nothing. If it is not, touch the upper left corner of the screen, then touch Exit and select the protocol to be used for testing.
8. Touch the Start button in the lower right corner of the screen. Enter the header information as appropriate, then touch Next ().
9. Prepare the apparatus:
 - a. Baskets - Classic 6
 - i. Place the dosage in each basket and install the baskets on the basket shafts.
 - ii. Remove the vessel cover over each of the positions.
 - iii. Lower the baskets on all positions rapidly.
 - iv. Touch Run to start the test.
 - v. Replace the vessel covers over each of the positions.
 - b. Baskets - Elite 8
 - i. Place the dosage in each basket and install the baskets on the basket shafts.
 - ii. Remove the vessel cover over each of the positions.
 - iii. Lower the drive head to the testing position.
 - iv. Touch Run to start the test.
 - v. Replace the vessel covers over each of the positions.

c. Paddles

- i. Remove the vessel cover over each of the positions.
- ii. Rapidly drop a dosage in each position.
- iii. Touch Run to start the test.
- iv. Replace the vessel covers over each position.


d. Paddles with ADD cover

- i. Place the dosage in each of the dose tubes located on the ADD cover for all positions.
- ii. Place the dose caps on top of the dose tubes for all positions.
- iii. Drop the dosage into all positions by depressing the push pins on each cover.
- iv. Touch Run to start the test.

Manual (or 3rd Party Autosampling) Using AutoMag with Digital Temperature Probes (DTPs)

1. Confirm the vessels, paddles, or baskets and basket shafts are clean and in good condition. Install them in their designated positions.
2. Confirm the heights of apparatus from the vessel bottom using a height gauge.
3. On the tester, touch the temperature to bring up the set temperature screen. Enter the desired temperature (+ 0.10 °C of the desired vessel temperature is recommended) and touch OK.
4. Raise the apparatus out of the vessels by raising the drive head.
5. Fill the vessels with media.
6. Prepare the apparatus:
 - a. Baskets - Elite 8
 - i. Lower the spindles so they are at their lowest point; do not move the drive head.
 - ii. Cover the vessels
 - iii. Allow the media to stabilize.
 - b. Paddles
 - i. Lower the drive head to the testing position.
 - ii. Cover the vessels and allow the media to stabilize.
 - c. Paddles with ADD Cover
 - i. Lower the drive head to the testing position.
 - ii. Close the chamber of the ADD cover by pressing the hinged portion on the bottom of the cover closed.
 - iii. Cover the vessels and allow the media to stabilize.

Once the media has stabilized, ensure the protocol is loaded by checking the upper left corner of the screen. If the correct protocol is loaded, do nothing. If it is not, touch the upper left corner of the screen, then touch Exit and select the protocol to be used for testing.

Touch the Start button in the lower right corner of the screen. Enter the header information as appropriate, then touch Next ().

Prepare the apparatus as instructed below. Once the test is running, the AutoMag will lower and begin monitoring the vessel temperatures if configured to do so.

a. Baskets - Elite 8


- i. Place the dosage in each basket and install the baskets on the basket shafts.
- ii. Remove the vessel cover over each of the positions.
- iii. Lower the drive head to the testing position.
- iv. Touch Run to start the test.
- v. Replace the vessel covers over each of the positions.

b. Paddles


- i. Remove the vessel cover over each of the positions.
- ii. Rapidly drop a dosage in each position.
- iii. Touch Run to start the test.
- iv. Replace the vessel covers over each position.

- c. Paddles with ADD cover
 - i. Place the dosage in each of the dose tubes located on the ADD cover for all positions.
 - ii. Place the dose caps on top of the dose tubes for all positions.
 - iii. Drop the dosage into all positions by depressing the push pins on each cover.
 - iv. Touch Run to start the test.

Small Volume Vessels

1. Confirm the small volume vessels and mini paddles are clean and in good condition. Install them in their designated positions.
2. On the tester, touch the temperature to bring up the set temperature screen. Enter the desired temperature (+ 0.10 °C of the desired vessel temperature is recommended) and touch OK.
3. Fill vessels with media. Pull the spindles up to the highest level. Lower drive head if using an Elite 8.
4. Place covers on vessel.
5. Once the media has stabilized, ensure the protocol is loaded by checking the upper left corner of the screen. If the correct protocol is loaded, do nothing. If it is not, touch the upper left corner of the screen, then touch Exit and select the protocol to be used for testing.
6. Touch the Start button in the lower right corner of the screen. Enter the header information as appropriate, then touch Next ().
7. Lift the cover and drop the dosage into the first position.
8. Touch Run.
9. Once the appropriate offset has passed, drop the next dosage into position 2, and so on. Recommended offset time between positions is 2 minutes.

Immersion Cell

1. Confirm the small volume vessels and mini paddles are clean and in good condition. Install them in their designated positions.
2. On the tester, touch the temperature to bring up the set temperature screen. Enter the desired temperature (+ 0.10 °C of the desired vessel temperature is recommended) and touch OK.
3. Fill vessels with media. Pull the spindles up to the highest level. Lower drive head if using an Elite 8.
4. Place covers on vessel.
5. Once the media has stabilized, ensure the protocol is loaded by checking the upper left corner of the screen. If the correct protocol is loaded, do nothing. If it is not, touch the upper left corner of the screen, then touch Exit and select the protocol to be used for testing.
6. Touch the Start button in the lower right corner of the screen. Enter the header information as appropriate, then touch Next ().
7. Use the installation rod to place the first cell into position 1.
8. Touch Run.
9. Once the appropriate offset has passed, place the next cell into position 2, and so on. Recommended offset time between positions is 2 minutes.

Maintenance

Scheduled Maintenance Overview

After Each Test

Clean up any spills or dissolution media wherever it was spilled on the system. Wipe down the system with a clean damp cloth when finished.

Rinse baskets, basket shafts, paddles, and/or vessels with DI or better quality water. Avoid harsh detergents which may damage the materials.

Weekly

Inspect bath water for algae or other contaminants. Drain and replace if necessary.

Monthly

Replace bath water, regardless of condition, to prevent algae growth.

Every 6 Months

Check the temperature and motor speed calibration.
Inspect the spindles for smooth rotation.

Inspect the o-rings to ensure that the spindle shafts are held securely.

Annually

Inspect the drive belts and idler pulleys.

Every Two Years

Replace drive belts.

O-Ring Inspection and Replacement

1. To inspect o-rings, raise the spindle shaft up so that the end of the spindle shaft is flush with the bottom of the spindle. Release any grip on the clamps and observe the spindle shaft.
2. If the spindle shaft slips, the o-rings are in need of replacement. If the spindle shaft remains where it is, then the o-rings are fine.
3. To replace o-rings use the o-ring replacement tool (74-107-003).
4. The top o-ring can be removed using the hook end of the tool and sliding it to the o-ring through the slot in the spindle.
5. The bottom o-ring requires that the o-ring first be pushed out, using the small dowel pin. With the o-ring pushed out slightly toward the center of the spindle, it can be hooked using the tool.
6. When replacing the o-rings, use the tool to guide each o-ring into place; the spindle shaft can be used to help roll it into place.

Belt Replacement

1. Remove the spindle shafts from the tester.
2. Grasp the drive head cover on both sides and lift straight up to remove the cover.
3. Locate the tensioner(s) for the drive belts. The Classic 6 has one tensioner located near the center of the drive head. The Elite 8 has two tensioners, one near the drive motor at the rear center of the instrument, and one near the monument toward the front center of the instrument.
4. Use a 5/32 hex key to loosen the tensioner – do not remove the tensioner.
5. Loosen and remove the belt from the spindles.
6. Route the new belt around the spindles and tensioners in the same manner as the old belt.

7. Slide the tensioner to add tension to the drive belt. Proper tension will be when the belt can be gently deflected 6-10 mm between spindles 5 and 6 on the Elite 8, or spindles 2 and 3 on the Classic 6.
8. Replace the cover by aligning it over the spindles and monument and then pressing down until it pops back into place.
9. Reinstall the spindle shafts.

Heater and Temperature Probe Adjustment

1. Place an NIST traceable thermometer next to the temperature probe.
2. From the home screen, touch the Menu button followed by the Tools button.
3. Touch the Cal Temp button at the bottom of the screen.
4. Locate the probe on the Instrument or Vessel Probes tab and touch that field.
5. Use the numeric keypad to enter the temperature on the NIST traceable thermometer, then touch OK.

Spindle Shaft Height Adjustment

1. Install either the paddle or basket shaft with basket into the spindle shaft.
2. Place a height set gauge (from the Height Set and Check kit) in the bottom of the vessel of the affected position.
3. Gently lower the paddle or basket so it rests on top of the height gauge.
4. Using a hex key, loosen the bolt on the spindle shaft clamp.
5. Adjust the spindle clamp so that it is properly engaged to the spindle. Make sure that the paddle or basket is still resting on top of the height gauge.
6. Tighten the spindle clamp using the same hex key.
7. Confirm the height of any apparatus used in that spindle position. If not all apparatuses meet the necessary height requirements, contact THR Technical Support.

Moving and Storage

If the Vision tester will not be used for a short period of time (3 days or more), the instrument should be cleaned and the power should be turned off. If the tester will not be used for an extended period of time (30 days or more), the instrument should be cleaned, drained, covered, and unplugged from the power source.

The instrument is heavy and great care should be taken when moving it. If the instrument is moved to a new location, revalidation should be considered.

Two people are required to lift the Classic 6 and/or the Elite 8 dissolution tester. Lifting should be done with one person situated on each side of the instrument. Lift the equipment by the base frame.



Warning: Lifting without assistance may cause injury.

Troubleshooting

Contacting Teledyne Hanson Research for Technical Support

For technical support, please submit a TSR form located at:

<http://www.teledynehanson.com/tech-support-request>

or e-mail hansontechsupport@teledyne.com

If you require phone support, please call 818.882.7266 and select the option for Technical Support. Please have the following information available:

1. Instrument Type
2. Serial Number
3. Firmware Version
4. What is the system configuration? How is the Vision tester connected to other equipment?
5. How long did the equipment work before the problem occurred?
6. How old is the equipment?
7. Were there any recent repairs or maintenance on the unit?
8. How is the system being used? What is the application?
9. Detailed information about the problem. What is working and what is not?
10. The troubleshooting steps that have already been taken.

Electrical Troubleshooting

| Problem | Possible Causes | Recommended Action |
|---|-----------------------------------|---|
| Display is dark | Tester is not turned on. | Use power switch to turn tester on. |
| | Tester is not plugged in. | Ensure tester is plugged into an outlet that is delivering power. |
| USB functions not working | USB Drive is not formatted. | The Teledyne Hanson USB drive has already been formatted. If using another USB drive, format using a PC. |
| | USB drive is damaged. | Use another USB drive. |
| | Monument board is damaged. | Replace monument board. |
| System does not make noise | Speaker volume set to 0. | Use Display screen to raise speaker volume. |
| | Display board is damaged. | Replace display board. |
| Screen is illuminated but system not responsive | System has frozen. | Note last action, reboot system. Report issue to THR Technical Support. |
| | Touchscreen requires calibration. | If possible, recalibrate through display screen. If display screen cannot be reached, reboot system and touch the screen during the logo splash screen. |

Mechanical Troubleshooting

| Problem | Possible Causes | Recommended Action |
|-----------------------------------|--|---|
| Excessive vibration in system | Belts are too tight or too loose. | Replace or adjust belts according to maintenance procedure in this manual. |
| | Tester is not level. | Ensure all feet of tester are secure on bench. |
| | Alignment nut of high stand tester may be loose. | Tighten alignment nut. |
| Paddle/Basket heights not correct | Improper operation | Confirm that spindle clamp and spindle are properly engaged. Confirm that paddle or basket shaft is properly tightened in spindle shaft. |
| | Clamp has loosened or spindle shaft replaced. | Perform the spindle height adjustment procedure listed in the maintenance section. |

Heater Troubleshooting

| Problem | Possible Causes | Recommended Action |
|--|---|--|
| Tester doesn't communicate with heater | Heater not turned on. | Turn on heater. |
| | Heater not connected. | Connect heater to tester using RS-232 cable to Temp Control ports. |
| | Board failure. | Contact THR Technical Support. |
| Main Check Error when tester heats up beyond a certain temperature | Component failure. | Contact THR Technical Support. |
| Tester heats up to different temperature than set point | Set point has changed due to test starting. | Confirm set point on main screen. |
| | Offset for heater probe is incorrect. | Correct heater probe offset on probe calibration screen. |
| | Heater probe has failed | Replace heater probe. |
| | External temperature probe offset is incorrect. | Correct external probe offset on probe calibration screen. |
| | External temperature probe has failed. | Replace external temperature probe. |
| When measuring temperature, Probe Error or --.-- is displayed | Probe is disconnected. | Reconnect temperature probe. |
| | Probe is damaged. | Contact THR Technical Support. |

AutoMag/SuperMag Troubleshooting

| Problem | Possible Causes | Recommended Action |
|---|---|---|
| Magazine is not moving the proper distance | Magazine may not be calibrated. | Perform magazine calibration. |
| | Protocol not set up for proper sample distance. | Change Magazine Travel in protocol. |
| Magazine is not moving at all. | Magazine not configured. | Ensure protocol makes use of magazine. |
| | | Ensure magazine is set up in Device Setup. |
| | Component failure. | Contact THR Technical Support. |
| Vessel temperature probes not working. | Vessel temperature probes not configured. | Ensure probes are configured for 6, 7 or 8 probes as appropriate in device setup. |
| | Vessel temperature probes not connected. | Ensure that probes are connected to tester main board. |
| | Component failure. | Contact THR Technical Support. |
| When measuring temperature, Probe Error or --.-- is displayed | Probe is disconnected. | Reconnect temperature probe. |
| | Probe is damaged. | Contact THR Technical Support. |

Serial (Validation) Printer Troubleshooting

| Problem | Possible Causes | Recommended Action |
|---------------------------------------|------------------------------|---|
| Light always blinks | No paper. | Replace paper roll. |
| | Paper incorrectly installed. | Check paper to see that it is installed correctly and that the paper indicator button is not stuck. Consult printer operation manual. |
| Prints a little and then light blinks | Paper incorrectly installed. | Check paper to see that it is installed correctly and that the paper indicator button is not stuck. Consult printer operation manual. |
| Will not print | No paper. | Replace paper roll. |
| | Paper incorrectly installed. | Check paper to see that it is installed correctly and that the paper indicator button is not stuck. Consult printer operation manual. |
| | Printer not connected. | Connect printer. |

Serial (Validation) Printer Self-Test

Turn power off, hold down the LF button, and turn power back on. When unit begins to print, release button.

Network Printer Troubleshooting

| Problem | Possible Causes | Recommended Action |
|-----------------------|-----------------------------|--|
| Tester will not print | IP address incorrect. | Set the IP address of tester to work with printer. |
| | No PostScript support. | Switch to a printer with PostScript supported by the printer firmware. |
| | Printer settings incorrect. | Ensure printer settings are correct for printer in system configuration. |

Specifications

Vision G2 Classic 6 Specifications

Weight:

Main unit, dry: 29.5 kg (65 lbs.)

Main unit, bath and vessels filled with water: 49 kg (108 lbs.)

Size:

Height: 67.3 cm (26.5 in.)

Width: 39.4 cm (15.5 in.)

Depth: 58.4 cm (23.0 in.)

Bath Capacity:

With 6 vessels: 13.3 liters (3.5 gallons)

Power:

Input: 24 VDC, 3.75 A, 90 W

Only use external power supply (listed below)

Vision G2 Elite 8 Specifications

Weight:

Main unit, dry: 63.5 kg (140 lbs.)

Main unit, bath and vessels filled with water: 90.8 kg (200 lbs.)

Size:

Height: 87.6 cm (34.5 in.)

Width: 67.3 cm (26.5 in.)

Depth: 58.5 cm (23.0 in.)

Bath Capacity:

With 8 vessels: 19 liters (5 gallons)

Power:

Input: 100 - 230 V \pm 10%, 50-60 Hz, 1.5 A max.

Output: 24 VDC, 3.75 A, 90 W

Vision G2 Heater Specifications

Weight: 4.1 kg (9 lbs.)

Size:

Height: 22.9 cm (9.0 in.)

Width: 24.1 cm (9.5 in.)

Depth: 16.5 cm (6.5 in.)

Power:

Input: 100 - 230 V \pm 10%, 50-60 Hz

Power: 700-1200 W

Vision G2 Dissolution Tester General Specifications

Spindle Speed:

Range: 25 to 250 rpm

Accuracy: ± 1 rpm

Displayed resolution: 0.1 rpm

Temperature:

Programmable temperature range: 25.0 to 55.0 °C

Accuracy: ± 0.5 °C

Control: ± 0.1 °C

Digital Temperature Probes (all probes):

Range: 10 to 60 °C

Accuracy: ± 0.1 °C from 30 - 55 °C

Displayed resolution: 0.01 °C

Minimum submersion depth: 25 mm

Response time: < 45 seconds (normally 30 sec.)

Wetted Materials

| Part Number | Description | Material(s) |
|-------------------------------|--|---|
| Paddles | | |
| 74-105-201 | Spin-Paddle PVDF | PVDF |
| 74-105-202 | Spin-Paddle 316 SS | 316 Stainless Steel |
| 74-105-351 | Spin-Paddle PVDF 2L | PVDF |
| 74-105-361 | Spin-Paddle 316 SS 2L | 316 Stainless Steel |
| 74-105-203 | Mini Spin-Paddle PTFE | PVDF |
| 74-105-204 | Mini Spin-Paddle 316 SS | 316 Stainless Steel |
| 74-105-290 | Mini Spin-Paddle 316 SS CSV | 316 Stainless Steel |
| Assemblies | | |
| | Tubing Harness | PTFE, ETFE, PVDF |
| | AutoMag | PVDF, PTFE, PEEK, ETFE |
| | Digital Temperature Probes | 316 Stainless Steel |
| Baskets | | |
| 74-105-252 | Basket 40 mesh USP | 316 Stainless Steel |
| 74-105-251 | Spin-Basket 316 SS | 316 Stainless Steel |
| 74-105-371 | Spin-Basket 316 SS 2L | 316 Stainless Steel |
| 74-105-221 | Mini Spin-Basket Shaft 316 SS | 316 Stainless Steel, Viton |
| 74-105-240 | App. 6 Rotating Cylinder | 316 Stainless Steel |
| 74-105-241 | App. 6 Rotating Cylinder with extension | 316 Stainless Steel |
| 74-105-220 | Mini Basket 40 Mesh 316 SS | 316 Stainless Steel |
| Vessels | | |
| 74-104-101 | Vessel Easi-Lock Glass 1 Liter | Borosilicate Glass, CPVC (rim) |
| 74-104-102 | Vessel Easi-Lock Glass Amber 1 Liter | Borosilicate Glass, CPVC (rim) |
| 74-104-111 | Vessel Easi-Lock Glass 2 Liter | Borosilicate Glass, CPVC (rim) |
| 74-104-112 | Vessel Easi-Lock Glass Amber 2 Liter | Borosilicate Glass, CPVC (rim) |
| 74-105-280 | 250 mL Clear Glass Vessel Round Bottom CSV | Borosilicate Glass |
| 74-105-281 | 250 mL AmberGlass Vessel Round Bottom CSV | Borosilicate Glass |
| Vessel Covers | | |
| 74-104-151 | Easi-Lock Vessel Cover | CPVC |
| 74-105-131 | Vision ADD Cover | PVC, Silicone |
| 74-107-012 | Vision G2 Easi-Lock Cover | PVC |
| 74-107-013 | Vision G2 ADD Cover | PVC, Silicone |
| 74-104-163 | Small Volume Vessel Cover | PVC |
| 74-104-173 | CSV Vessel Cover | PVC |
| 91-430-026 | Tapered Stopper | EPDM |
| Probes and Probe Parts | | |
| 74-104-201 | Manual Sampling Canula 1/8" Probe | PEEK |
| 74-105-307 | Auto-Probe PEEK 1/8" | PEEK |
| 74-104-204 | 1/16" 316 Stainless Steel Probe | 316 Stainless Steel |
| (Varies) | Fixed-Vessel Mount Probe, 316 SS | 316 Stainless Steel |
| 74-104-205 | Return Port Fitting | PVC |
| Cannulae | | |
| 74-105-360 | Manual Sampling Cannula 2L | PEEK |
| 95-590-001 | Manual Sampling Cannula 500mL 7.75" 316 SS | 316 Stainless Steel |
| 95-590-002 | Manual Sampling Cannula 900mL 4.75" 316 SS | 316 Stainless Steel |
| 95-590-005 | Manual Sampling Canula 900mL 4.75" PEEK | PEEK |
| Filters | | |
| 27-101-087 | Sample Tip Filters | Polyethelene |
| 27-101-101 | 1/8" Sample Filter 10 Micron PVDF | PVDF |
| 91-450-062 | 5 Micron In Line Filter | Hydrophilic Acrylic |
| 74-104-301 | Cartridge Filters | Polyethelene |
| 61-105-030 | Sample Block | PVC |
| Disposable Syringe | | |
| 91-030-132 | Syringe 10 mL | Polypropylene, Latex-Free Elastomer, Silicone |

Table H-1 Wetted Materials

General Warranty

Teledyne Hanson Research (THR) is a division of Teledyne Instruments, Inc. Teledyne Hanson products are warranted for one full year including parts and labor. Service contracts and preventive maintenance contracts are available for post-warranty support. International dealer warranties may vary. THR makes no warranty, expressed or implied, for glassware, consumables, or products not manufactured by THR, as evidenced by nameplate on the item or other designation. THR will give reasonable assistance to buyer in obtaining from the respective manufacturer whatever adjustment is available under the manufacturer's own warranty. THR shall be released from any and all obligations under any warranty, either expressed or implied, if the product covered is repaired or modified by other than its own personnel, or without written authorization from THR. There are no other warranties, expressed or implied, and THR shall not be liable under any circumstances for damages of any kind, direct, consequential, or otherwise.

Appendix A: Errors

Vision Errors

| Error Code | Error Category | Title | Message | Fault | Check the Following |
|------------|----------------|-------------------------|---|---|---|
| 0001 | 2 | Backup Error | Corrupted data encountered during backup. Contact Tech Support. | Cannot open one of the protocols on the monument board when backing up the protocols. | 1. Try a new USB drive. 2. Try a new copy of the backup file. 3. Contact Technical Support if problem persists. |
| 0002 | 2 | USB Drive Backup Error | Error accessing the protocol backup file on the USB drive. Make sure the USB drive has enough space or try a different USB drive. | Cannot read or write the protocols backup file from the USB flash drive when restoring protocols from backup. | 1. Try a new USB drive. 2. Try a new copy of the backup file. 3. Contact Technical Support if problem persists. |
| 0003 | 2 | Restore Error | Error restoring the protocols from a protocol backup file. Data in the instrument memory might be corrupted. Contact Tech Support. | When restoring protocols from a backup, the checksum of the backup file was checked one more time at the end of the restore, and it failed. The protocol data that was copied to the monument board memory might be corrupted. Corrupted protocols backup file or the backup file contains protocols of an unknown version. | 1. Try a new USB drive. 2. Try a new copy of the backup file. 3. Contact Technical Support if problem persists. |
| 0004 | 2 | USB Drive Restore Error | Error accessing the protocol backup file on the USB drive. The protocol backup file on the USB drive might be missing or corrupted. | Corrupted protocols backup file or the backup file contains protocols of an unknown version. | 1. Try a new USB drive. 2. Try a new copy of the backup file. 3. Contact Technical Support if problem persists. |
| 0005 | 2 | USB Drive Write Error | Error occurred while writing data to the USB drive. Make sure the USB drive has enough space or try a different USB drive. | Information could not be sent to USB flash drive. | 1. Unsupported USB flash drive 2. Monument board failure 3. Main board failure |
| 0006 | 1 | Could Not Import Logo | Make sure the logo.jpg file being imported has the correct format as described in the User Guide. | Logo.jpg does not meet system requirements. | Logo.jpg requirements in User Guide |
| 0007 | 4 | Missing Report Template | Report template missing. Contact Tech Support. | Printing templates data is not found in main board memory. Could be that memory went bad, or cannot communicate with memory or that data was not written there during the firmware update, which means corrupted firmware update image. | 1. Bad image file for firmware update 2. Main board failure |
| 0008 | 4 | Corrupt Report Template | Report template corrupted. Contact Tech Support. | Corrupted or invalid data in the printing templates memory. | 1. Bad image file for firmware update 2. Main board failure |
| 0009 | 2 | Instrument Memory Error | Error occurred while accessing instrument memory. Contact Tech Support. | Error Reading or Writing information to the instrument memory located on the monument board. | 1. Normal after a firmware update - should not persist after first reboot 2. Monument board failure 3. Main board failure |
| 0010 | 6 | Instrument Memory Error | | Error Reading data from the instrument memory or corrupted data in the instrument memory. | Contact Technical Support |
| 0011 | 4 | I2C Bus Error | I2C Bus Error detected. Restart the instrument. If the problem persists, contact Tech Support. | The system detected I2C bus error. | 1. Monument board failure 2. Main board failure 3. Display failure |
| 0012 | 4 | SPI Bus Error | SPI Bus Error detected. Restart the instrument. If the problem persists, contact Tech Support. | The system detected SPI bus error. SPI bus error was detected when reading printing templates from memory during printing. | Main board failure |
| 0013 | 4 | Checksum Error | Error occurred while calculating the protocols checksum. Contact Tech Support. | System is unable to calculate a checksum for the protocols. | 1. Monument board failure 2. Main board failure or corrupted memory or unknown version of protocol data |

Appendix A: Errors

| Error Code | Error Category | Title | Message | Fault | Check the Following |
|------------|----------------|---------------------------------|--|--|---|
| 0014 | 2 | Firmware Update Failed | Firmware update failed. Contact Tech Support. | Part of the firmware update process failed to work. | 1. Firmware file may be corrupted 2. Monument board failure 3. Main board failure 4. Display failure |
| 0015 | 2 | Display Image Version Mismatch | Display image version mismatch. Contact Tech Support. | Firmware image does not match display firmware, or unexpected display image version returned by the display. | 1. Display firmware is compatible with system firmware 2. Display failure |
| 0016 | 1 | Version Compatibility Error | The firmware versions of the instruments in the system are not compatible. Contact Tech Support. | Mismatched firmware between different instruments. | Compatibility of firmware between instruments |
| 0017 | 3 | Test Log Full | Test log is full. Update the protocol so it generates less test log data. | The test has generated more data than is capable of fitting in the instruments memory. | Occurrence of print status messages |
| 0018 | 1 | Auto-Start Can't Be in Past | Check current time and set Auto-Start time in the future. | User set Auto-Start in the past. | Auto-Start date set in the future |
| 0019 | 7 | Temp Tolerance Error X °C | | Temperature reached an out of tolerance value during a test. | 1. Pump flow 2. Temperature probe accuracy |
| 0020 | 3 | Speed Tolerance Error X rpm | The drive speed is outside of the tolerance. Contact Tech Support. | Motor speed reached an out of tolerance value during the test. | Contact Technical Support. |
| 0021 | 7 | Vessel X Tolerance Error: X | | Temperature reached an out of tolerance value during a test. | 1. Pump flow 2. Temperature probe accuracy |
| 0022 | 1 | Printer Comm. Error | The printer is not communicating. Make sure the printer is online and connected. | The printer is off or not configured correctly. | 1. Printer connection 2. Printer tab in system configuration 3. Printer status |
| 0023 | 1 | Protocol Has No Name | Protocol has no name. Assign a name for the protocol or delete the protocol. | Protocol name field is blank. | Protocol name filed in protocol |
| 0024 | 1 | Protocol Name Already in Use | Protocol name already in use. Choose a different name for the protocol. | Protocol name is in use by another protocol. | Protocol name filed in protocol |
| 0025 | 1 | Protocols at Maximum | Maximum number of protocols reached (100). Cannot continue. | Action would create more than 100 protocols. | Unused protocols should be removed. |
| 0026 | 1 | Events Beyond Max Number | This selection creates more than the allowed number of individual events. Check the User Guide. | The number of programmed events has exceeded 50. | 1. Occurrence field of events 2. Total events number 50 or less |
| 0027 | 1 | Events Beyond Max Time | One or more event times are beyond the max test length. Check the User Guide. | Events cannot occur past 999:00 (hhh:mm). | 1. Occurrence field of events 2. Time between events field |
| 0028 | 1 | AutoMag Configuration Mismatch | AutoMag configuration and the protocol do not match. | Magazine travel in protocol exceeds that of configured AutoMag. | 1. Magazine travel field for protocol 2. System configuration of AutoMag |
| 0029 | 1 | Not Configured for AutoMag | Tester not configured for AutoMag required by the protocol. | A protocol has a magazine travel set to something besides 0 when no AutoMag is present in the configuration. | 1. Magazine travel field for protocol 2. System configuration of AutoMag |
| 0030 | 1 | Need DTP for Vessel Goal Temp | DTPs need to be enabled for non-zero Vessel Goal Temperature. | Protocol parameter conflict; enable DTPs in protocol. | 1. The vessel temperature field for protocol 2. System configuration of Digital Temperature Probes (DTPs) |
| 0031 | 1 | AutoDosage Delay for AutoStart | Need AutoDosage delay value for using Auto-Start. 5 seconds is recommended. | Protocol parameter conflict; specify AutoDosage delay. | 1. Auto Dosage Delivery covers configuration 2. Auto Dosage Delivery delay setting |
| 0032 | 1 | ADD Configuration Mismatch | ADD configuration and the protocol do not match. | The protocol specifies use of Auto-Start, but Auto Dosage Delivery covers are not configured. | 1. Auto Dosage Delivery covers configuration 2. Auto Dosage Delivery delay setting |
| 0033 | 3 | Delay Only for Pre- or Post-Run | Delay events are only valid for Pre-run or Post-run events. | User tried to set delay event during test. | Pause event in User Guide |

Appendix A: Errors

| Error Code | Error Category | Title | Message | Fault | Check the Following |
|------------|----------------|--------------------------------|---|--|---|
| 0034 | 3 | Illegal Parameter at Event X | Event X has illegal parameter value. Update the protocol and use a valid parameter. | One of the parameters of the specified event is incorrect. | Event and User Guide for proper syntax |
| 0035 | 1 | Illegal Parameter | The parameter value specified is invalid. Use a valid parameter. | One of the parameters of the specified event is incorrect. | Event and User Guide for proper syntax |
| 0036 | 1 | No Pre- or Post-Run Samples | Pre-run or Post-run time sampling not supported. Set sample event during test. | User tried to sample in pre-run or post-run. | Sampling events occur during testing. |
| 0037 | 1 | 1 Pre/Post-Run Event at a Time | Pre- and Post-run events can only be made one at a time. Change Number of Events to 1. | The occurrence was greater than 1 when creating a pre- or post-run event. | The occurrence field when creating an event |
| 0038 | 4 | Real Time Clock Error | Set the date and time of the instrument. If the problem persists, contact Tech Support. | Time or date not set or corrupted, reported when the instrument is powered on. | 1. Time and date set 2. Instrument powered on for 5 minutes 3. Main board failure |
| 0039 | 1 | Incorrect Alarm Date/Time | The alarm cannot be set in the past. Check current time. | User attempted to set alarm in the past. | Alarm set for the future |
| 0040 | 1 | System Date Not Set | System date needs to be set before setting alarm date. | System date has not been set. | System date |
| 0041 | 1 | System Date Not Set | System date needs to be set before setting alarm time. | System date has not been set. | System date |
| 0042 | 1 | System Date Not Set | System date needs to be set before setting start date. | System date has not been set or has been corrupted. | System date |
| 0043 | 1 | System Date Not Set | System date needs to be set before setting start time. | System date has not been set or has been corrupted. | System date |
| 0044 | 1 | Password Change Failed | Re-entered password didn't match the new password. | The re-entered password didn't match the first password entered. | Password and verification should match. |
| 0045 | 1 | Collect Must Be > Detect Vol | The collect volume can't be lower than the detect volume. Increase Collect volume or lower Detect volume. | The detect volume is the same as or greater than the collect volume. | Collect volume is greater than the detect volume. |
| 0046 | 3 | Call X Late X min X s | Call X was late X min X s due to a timing conflict. Check event times. | The Call event occurred later than programmed because another event was taking place. | Time between events |
| 0047 | 1 | Possible Timing Conflict | The event at time X might cause a timing conflict. | One or more of the events may overlap causing a delay. | Time between events |
| 0048 | 3 | Sample X Late X min X s | Sample X was late X min X s due to a timing conflict. Check event times. | The sample collection was delayed because one or more events were still being executed. | Time between events |
| 0049 | 1 | No Pre- or Post-Run events | Pre-run or Post-run time events not supported in events libraries. | Pre run or post run events can only be executed at the protocol level. | Review user guide. |
| 0050 | 1 | Call Event Not Supported | Calling an event library from an event library is not supported. | Call events can only be used in protocols | Review user guide. |
| 0051 | 1 | Event Library Name Too Long | Event Library name cannot be more than 11 characters long. | Event library name is too long. Shorten the event library name. | Review user guide. |
| 0052 | 1 | Cannot Load the Library | Library X could not be loaded. Check that it exists. | The event library may have been deleted after the protocol was created. | Review existing protocols and event libraries. |
| 0053 | 1 | No Pre- or Post-Run Samples | Library X has a sample event. It cannot be called at Pre-run or Post-run. | Sample events are not permitted in pre or post run. This includes event libraries called in the pre or post run. | Review user guide. |

Appendix A: Errors

Vision Tester Errors

| Error Code | Error Category | Title | Message | Fault | Check the Following |
|------------|----------------|------------------------------------|---|--|---|
| 1000 | 4 | AutoMag Error | AutoMag misaligned or jammed. Check for obstructions. | The tester detected the AutoMag did not move, or did not move as expected at the event. | 1. AutoMag misaligned or jammed 2. AutoMag motor connection 3. AutoMag motor failure 4. Main board failure |
| 1001 | 4 | AutoMag Error | AutoMag not homed. Home the AutoMag. | The AutoMag was not homed properly. Home the AutoMag before running the test. | 1. AutoMag misaligned or jammed 2. AutoMag motor connection 3. AutoMag motor failure 4. Main board failure |
| 1002 | 4 | AutoMag Homing Error | AutoMag is unable to home against drive plate. Contact Tech Support. | AutoMag did not detect upper home position. | 1. AutoMag is able to home against drive plate 2. The AutoMag motor failure |
| 1003 | 4 | AutoMag Comm Error | Cannot communicate with AutoMag or wrong probe configuration. Check system configuration. | | |
| 1004 | 6 | DTP X Missing | | | |
| 1005 | 6 | DTP Configuration Error | | | |
| 1006 | 6 | DTP Communication Error | | The tester is unable to communicate with <probe number>. | 1. Digital Temperature Probe cable connection 2. Digital Temperature probes configuration 3. Digital Temperature Probes connection to AutoMag board 4. Digital temperature probes failure 5. Main board failure |
| 1007 | 1 | DTP Configuration Mismatch | DTP configuration and protocol do not match. | The protocol is trying to use DTPs that are not configured. Enable DTPs in configuration. | 1. The vessel temperature field for protocol 2. System configuration of Digital Temperature Probes |
| 1008 | 1 | Probe Offset Out of Range | Desired offset is outside the range of -9.99 through 9.99. Check offset. If the problem persists, contact Tech Support. | User tried to apply an offset greater than 9.99 or less than -9.99. | 1. Probe offset is entered correctly 2. Temperature probe failure |
| 1009 | 4 | External Probe Error | Cannot communicate with the external temperature probe. Make sure the probe is connected. | The tester can't communicate with the external temperature probe. | 1. External temperature probe connection 2. External temperature probe failure 3. Main board failure |
| 1010 | 6 | External Probe Comm. Error | | The tester can't communicate with the external temperature probe. | |
| 1011 | 6 | External Probe Bad Temp Read | | Temperature value read was outside expected range | |
| 1012 | 6 | Auxiliary CPU Error | | Either second CPU is not programmed with firmware or has the wrong firmware or there is temporary or permanent board failure that causes communication problems between the two CPUs on the main board. The error could only be reported during diagnostics. | Main board failure |
| 1013 | 6 | Speed Tolerance Error | | During diagnostics the paddle speed was outside 4% tolerance of 50 rpm. | 1. Check the motor 2. Check the belt 3. Check the main board |
| 1014 | 1 | Set Sampling to Manual | Collect or Collect and Detect protocols must be run on the AutoPlus. Set Sampling to Manual. | User has tried to run a protocol with automation on a tester. | Sampling Mode field for protocol. |
| 1015 | 6 | DTP X Unknown Calibration | | | |
| 1016 | 6 | External Probe Unknown Calibration | | | |

Appendix A: Errors

Vision Heater Errors

| Error Code | Error Category | Title | Message | Fault | Check the Following |
|------------|----------------|------------------------------|---|---|---|
| 1500 | 4 | Heater Comm. Error | The Vision Heater is not communicating. Make sure the Vision Heater is online and connected. | The tester and heater are not communicating. | 1. Vision Heater power 2. Vision Heater connection |
| 1501 | 6 | Heater Control Test Error | | The tester external temperature probe did not record a rise in temperature during a heating test. | 1. External probe in bath water 2. Bath is full 3. Heater is heating |
| 1502 | 4 | Heater Probe Error | Vision Heater cannot communicate with Inlet temperature probe. Contact Tech Support. | Vision Heater cannot communicate with Inlet temperature probe. | 1. Inlet probe connection 2. Inlet probe failure 3. Heater board failure |
| 1503 | 4 | Heater Power Error | Vision Heater coil is not receiving power. Turn off the heater for 10 min. If the problem persists, contact Tech Support. | Heater coil is not receiving power. | 1. Emergency thermo-switch has tripped breaking the connection between the heater and power source. 2. Heater coil connection 3. Heater coil failure 4. Heater board failure |
| 1504 | 4 | Safety Probe Error | Vision Heater cannot communicate with safety probe. Contact Tech Support. | Heater cannot communicate with safety probe. | 1. Safety probe connection 2. Safety probe failure 3. Heater board failure |
| 1505 | 6 | Heater Comm. Shutdown | | | |
| 1506 | 4 | Heater Temp Rise Error | Vision Heater is heating up too quickly. Make sure the Vision Heater is primed. | Heater is heating up too quickly. The safety probe has been triggered. | 1. Priming of the pump 2. Safety probe accuracy 3. Heater board failure |
| 1507 | 6 | Heater Probe Bad Reading | | | |
| 1508 | 6 | Safety Probe Bad Reading | | | |
| 1509 | 4 | Heater High-Temp Error | Vision Heater High-Temp Error | | |
| 1510 | 4 | Heater High-Current Error | Vision Heater High-Current Error | | |
| 1511 | 4 | Heater Maintenance Log Error | Vision Heater Maintenance Log Error | | |
| 1512 | 4 | Heater Probe Memory Error | Vision Heater Inlet temperature probe memory corruption. Contact Tech Support. | | 1. Inlet probe memory bad 2. Inlet probe failure 3. Heater board failure |
| 1513 | 4 | Safety Probe Memory Error | Vision Heater safety probe memory corruption. Contact Tech Support. | | 1. Safety probe memory bad 2. Safety probe failure 3. Heater board failure |

Appendix B: Networking

Networks

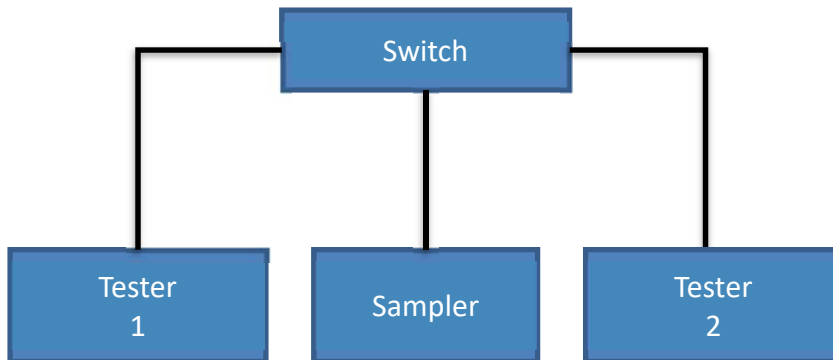
A network is a series of devices that are connected together and able to communicate with each other. The Vision G2 dissolution testers and samplers communicate with each other as a network using TCP/IP protocols.

In order for the Vision G2 AutoPlus to communicate with the Vision dissolution testers, it must be connected through a network switch. The AutoPlus and testers each communicate through a TCP/IP protocol which requires a unique IP address, default gateway address, and subnet mask.

A network PostScript capable printer may be connected directly to the switch if the operator wants to use this printer while keeping the system isolated from the larger corporate network.

Isolated Networks

If the operator wishes to have an isolated system, then the switch does not need to be connected to anything else, other than the AutoPlus and testers.



An isolated THR Vision G2 system should be set up as follows:

Vision G2 AutoPlus

IP Address: 192.168.1.10

Default Gateway: 192.168.1.1

Subnet Mask: 255.255.255.0

Vision Dissolution Tester 1

IP Address: 192.168.1.20

Default Gateway: 192.168.1.1

Subnet Mask: 255.255.255.0

Appendix B: Networking

Vision Dissolution Tester 2

IP Address: 192.168.1.21

Default Gateway: 192.168.1.1

Subnet Mask: 255.255.255.0

Vision Dissolution Tester 3

IP Address: 192.168.1.22

Default Gateway: 192.168.1.1

Subnet Mask: 255.255.255.0

Network Printer (if applicable)

IP Address: 192.168.1.30

Default Gateway: 192.168.1.1

Subnet Mask: 255.255.255.0

Connecting to Agilent ChemStation systems

When connecting Vision G2 instruments to an Agilent ChemStation system it is required that the PC with the ChemStation software and the 8453 be configured with correct IP addresses. The following settings are recommended:

Agilent ChemStation Computer

IP Address: 192.168.1.1

Default Gateway: 192.168.1.1

Subnet Mask: 255.255.255.0

8453 UV/Vis Spectrophotometer (configured through bootp)

IP Address: 192.168.1.2

Default Gateway: 192.168.1.1

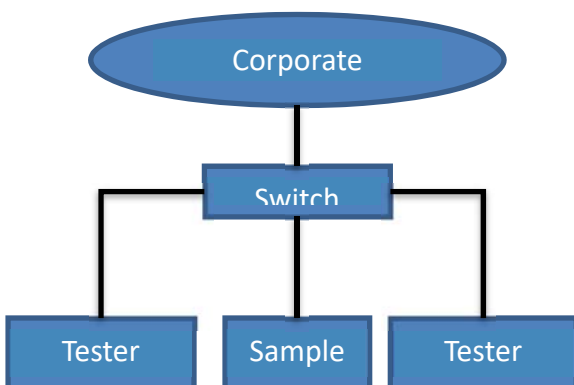
Subnet Mask: 255.255.255.0

NOTE: Teledyne Hanson Research Dissolution System Drivers version 5.0 are required for communication with Vision G2 instruments. Vision G2 instruments require firmware 2.1 or higher.

Corporate Networks

It is also possible to connect the Vision G2 AutoPlus, and Vision dissolution testers to a corporate network. However, when doing so, the operator should contact the IT department to obtain unique IP address settings for the AutoPlus and each of the installed dissolution testers.

For connections to corporate networks, contact the IT department and request the information for each dissolution tester, sampler, or printer to be added. If the IT department requires more information regarding the THR equipment, contact Teledyne Hanson Research Technical Support.



Appendix C: Working with a Waters Alliance Dissolution System

The Vision G2 dissolution testers are capable of interfacing with the Waters Alliance Dissolution System with Empower software for on-line HPLC testing. The Vision G2 dissolution testers function in a similar manner to the SR8-Plus dissolution testers when run in this configuration.

Firmware Requirements

Vision G2 dissolution testers require firmware version 2.11 or higher in order to be compatible with the Waters Alliance Dissolution System.

Installation and Configuration

1. Connect an RS-232 cable to Port #2 on the Waters Transfer Module.
2. Connect the other end of the RS-232 cable to the RS-232 port on the Vision G2 dissolution tester which will be "Bath A".
3. If a second tester is present, connect Bath A and Bath B via a TCP/IP connection. This can be through a network switch or connected directly.
4. Configure Bath A and Bath B with sequential IP addresses.
For example, if Bath A has an IP address 192.168.1.20, Bath B must be 192.168.1.21.
5. In the Device Setup screen of each tester, set the Sampler to Transfer Module.

Operating the System

The system can be operated from the Alliance 2690D/2695D interface or from Empower. For more information on operating either system in dissolution mode, refer to the appropriate Waters documentation.

To use Digital Temperature Probes (DTPs), adjust magazine travel, or set a vessel goal temperature, a protocol named WTM must be added to the dissolution tester. When starting a test, the transfer module will use the DTP settings, vessel goal temperature, and magazine travel from the WTM protocol.

NOTE: Vessel temperatures will not be recorded by Empower.

To have the tester use a specific magazine travel for tests using the Transfer Module, do the following:

1. Add a new protocol.
2. Set the protocol name to WTM. The WTM must be in all capital letters.
3. Touch the Sampling tab.

Appendix C: Waters Alliance Diss. System

4. Touch the Magazine Travel field and set the value to what is desired for the test.
5. Exit the protocol to save it.
6. Start a test using the 2690D/2695D or Empower, and the tester will move the AutoMag (or SuperMag) appropriately when collecting a sample.

Limitations

The system has the following limitations when running a test using the 2690D/2695D and Transfer Module.

The event table will be ignored in the WTM protocol.

The sampling events, temperature, infinity test speed, and auto print interval range are all restricted by Empower.

The maximum label length is 20 characters instead of 25.

The speed tolerance is either off or USP $\pm 4\%$ instead of programmable from 1 to 10%.

The temperature tolerance is either off or USP ± 0.5 °C instead of programmable from 0.1 °C to 5.00 °C.

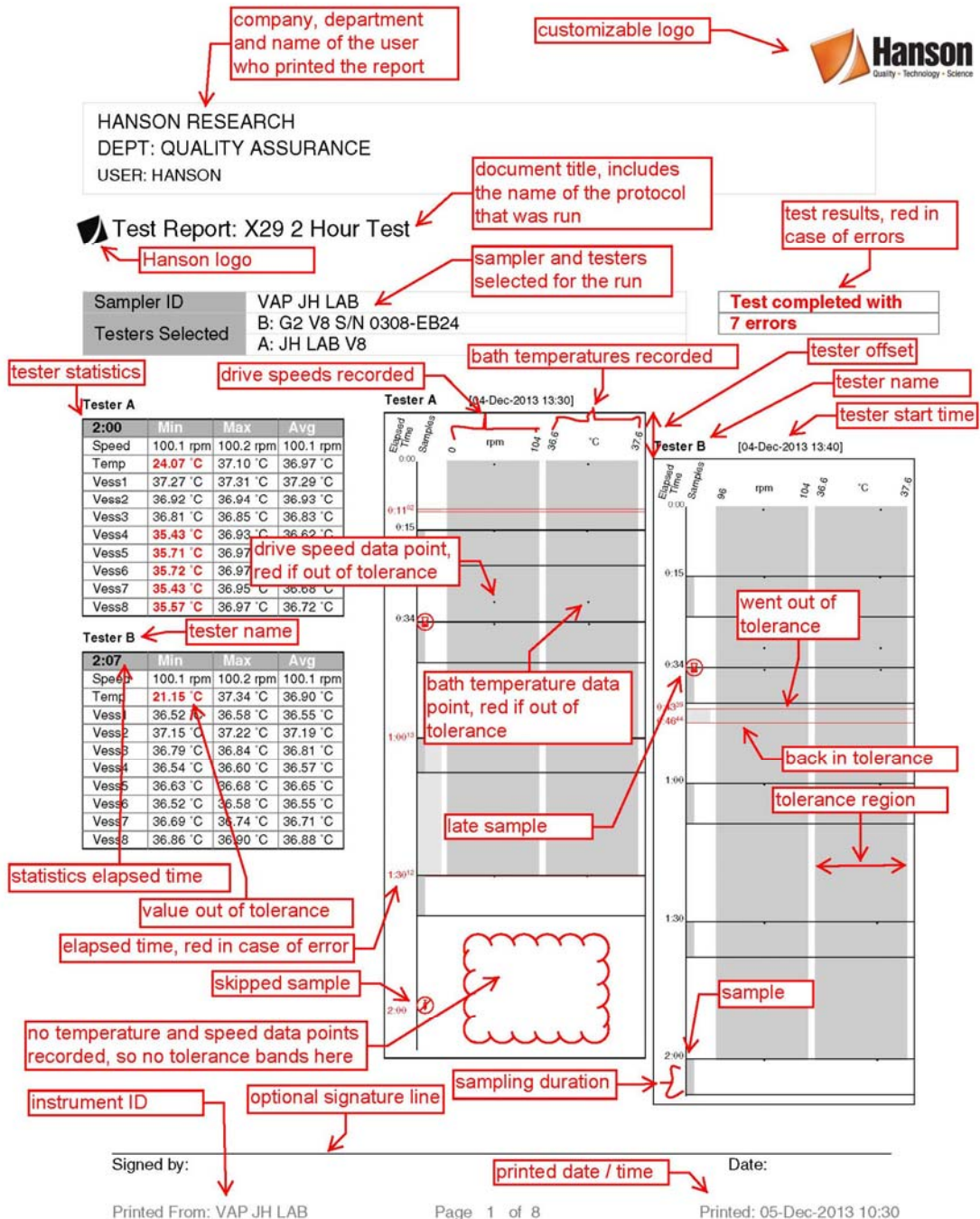
The IP address of the second Vision G2 tester must be sequential with the first tester.

If a Waters Transfer Module protocol is not present, the protocol ID "Protocol" will be used when a test is running.

Waters Empower will not record the vessel temperatures. A separate printer for the tester is required.

If ADD covers are used, the tester will delay the start of the test by 3 seconds plus the Auto Dosage Delivery Delay in the protocol. For example, if the Auto Dosage Delivery Delay was set to 5 seconds, the tester would start the test 8 seconds after the HPLC. Users can correct this by adjusting their sample points accordingly.

Appendix D: Reports



Appendix D: Reports

HANSON RESEARCH
DEPT: QUALITY ASSURANCE
USER: HANSON

Test Report: X29 2 Hour Test



Test Log

| | |
|-------------------|-----------------|
| Test | X29 2 Hour Test |
| Comments | N/A |
| Lot Number | ST4HGVY |
| Test Number | 12BF |
| User Name | John Heaney |
| Autostart | When Temp Ready |
| Heater off at end | No |
| Starting row | 1 |

| | | | |
|-------------------|--|--|---------|
| VAP JH LAB | | Test start 04-Dec-2013 13:30:05 | |
| Tester A | | Test start 04-Dec-2013 13:30:07 | |
| Tester A | | 0:00:36 Speed 100.1 rpm Temperature 37.06 °C | |
| | | Vessels (°C) | |
| | | 1 36.94 | 2 36.93 |
| | | 3 36.93 | 4 36.94 |
| | | 5 36.64 | 6 36.81 |
| | | 7 36.92 | 8 37.27 |
| | | Status | |
| Tester B | | 0:00:00 Test start 04-Dec-2013 13:40:07 | |
| Tester A | | 0:10:26 Temp tolerance error 25.96 °C | |
| Tester B | | 0:00:36 Speed 100.1 rpm Temperature 37.32 °C | |
| | | Vessels (°C) | |
| | | 1 36.86 | 2 36.69 |
| | | 3 36.52 | 4 36.63 |
| | | 5 36.54 | 6 36.79 |
| | | 7 37.18 | 8 36.52 |
| | | Status | |
| Tester A | | 0:11:02 Temp within tolerance 36.64 °C | |
| Tester A | | 0:15:01 Sample Rinse, 7.0 ml | |
| Tester A | | 0:15:12 Speed 100.1 rpm Temperature 37.05 °C | |
| | | Vessels (°C) | |
| | | 1 36.96 | 2 36.95 |
| | | 3 36.97 | 4 36.96 |
| | | 5 36.90 | 6 36.84 |
| | | 7 36.93 | 8 37.29 |
| | | Status | |
| Tester A | | 0:17:05 AutoFilter Filter changed | |

Signed by:

Date:

Printed From: VAP JH LAB

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Printed: 05-Dec-2013 10:30

Appendix D: Reports

HANSON RESEARCH
DEPT: QUALITY ASSURANCE
USER: HANSON

Test Report: X29 2 Hour Test



USER: HANSON

| | | | | |
|-----------------|----------------------|---|----------------------------------|--------------|
| Tester A | | sampling steps messages, that are right after one another, are grouped together | | |
| 0:17:05 | Sample 1 | 0:17:05 | Sample Rinse with Filter, 3.0 ml | Sample Row 1 |
| | | 0:18:07 | Collect with Filter, 5.0 ml | |
| | | 0:19:12 | Media Replace, 5.0 ml | |
| | | 0:20:33 | Rinse Retrieval, 15.0 ml | |
| | | 0:22:42 | Sample Done | |
| Tester B | | elapsed time of each sampling step | | |
| 0:15:01 | Sample Rinse, 7.0 ml | | | |
| Tester B | | row number where the sample is collected | | |
| 0:15:13 | Speed | 100.2 rpm | Temperature | 37.31 °C |
| | Vessels (°C) | 1 36.89 | 2 36.72 | 3 |
| | | 5 36.59 | 6 36.83 | 7 37.21 |
| | | | | 8 36.56 |
| Tester B | | 0:17:05 AutoFilter Filter changed | | |
| Tester B | | | | |
| 0:17:05 | Sample 1 | 0:17:05 | Sample Rinse with Filter, 3.0 ml | Sample Row 2 |
| | | 0:18:07 | Collect with Filter, 5.0 ml | |
| | | 0:19:12 | Media Replace, 5.0 ml | |
| | | 0:20:33 | Rinse Retrieval, 15.0 ml | |
| Tester A | | error icon | | |
| 0:30:34 | Speed | 100.1 rpm | Temperature | 37.06 °C |
| | Vessels (°C) | 1 36.97 | 2 36.94 | 3 36.96 |
| | | 5 36.93 | 6 36.84 | 7 36.94 |
| | | | | 8 37.31 |
| Tester B | | 0:23:47 Sample Done | | |
| Tester A | | ✖ 0:34:52 Sample late 4 min 52 s | | |
| Tester A | | 0:34:53 Sample Rinse, 7.0 ml | | |
| Tester A | | | | |
| 0:35:22 | Speed | 100.1 rpm | Temperature | 37.07 °C |
| | Vessels (°C) | 1 36.97 | 2 36.93 | 3 36.96 |
| | | 5 36.93 | 6 36.84 | 7 36.94 |
| | | | | 8 37.28 |
| Tester A | | 0:36:58 AutoFilter Filter reused | | |

Signed by:

Date:

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Appendix D: Reports

HANSON RESEARCH
DEPT: QUALITY ASSURANCE
USER: HANSON

Test Report: X29 2 Hour Test



USER: LAXON

Signed by:

Date:

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Appendix D: Reports

HANSON RESEARCH
DEPT: QUALITY ASSURANCE
USER: HANSON

Test Report: X29 2 Hour Test



statistics message

Tester A

2:00:03

| | Min | Max | Avg |
|-------------|-----------|-----------|-----------|
| Speed | 100.1 rpm | 100.2 rpm | 100.1 rpm |
| Temperature | 24.07 °C | 37.10 °C | 36.97 °C |
| Vess1 | 35.57 °C | 36.97 °C | 36.72 °C |
| Vess2 | 35.43 °C | 36.95 °C | 36.68 °C |
| Vess3 | 35.72 °C | 36.97 °C | 36.75 °C |
| Vess4 | 35.71 °C | 36.97 °C | 36.74 °C |
| Vess5 | 35.43 °C | 36.93 °C | 36.62 °C |
| Vess6 | 36.81 °C | 36.85 °C | 36.83 °C |
| Vess7 | 36.92 °C | 36.94 °C | 36.93 °C |
| Vess8 | 37.27 °C | 37.31 °C | 37.29 °C |

Statistics

value out of tolerance

Tester A

2:00:03 Test finish 04-Dec-2013 15:30:25

Tester B

2:00:01 Sample Rinse, 7.0 ml

Tester B

| | | | | | | | | | | | |
|---------|--------------|-----------|-------------|---|-------|---|----------|---|-------|--|--------|
| 2:00:13 | Speed | 100.2 rpm | Temperature | | | | 37.28 °C | | | | Status |
| | Vessels (°C) | 1 | 36.86 | 2 | 36.71 | 3 | 36.54 | 4 | 36.64 | | |
| | | 5 | 36.56 | 6 | 36.79 | 7 | 37.19 | 8 | 36.54 | | |

Tester B

2:02:05 AutoFilter filter set discarded

Tester B

2:02:05 AutoFilter Filter changed

Tester B

| | | | |
|----------|---------|----------------------------------|------------------|
| 2:02:05 | | | Sample Row 10 |
| Sample 5 | 2:02:05 | Sample Rinse with Filter, 3.0 ml | |
| | 2:03:08 | Collect with Filter, 5.0 ml | |
| | 2:04:15 | Media Replace, 5.0 ml | |
| | 2:05:36 | Rinse Retrieval, 15.0 ml | |
| | 2:07:45 | Sample Done | |

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Date:

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Appendix D: Reports

HANSON RESEARCH
DEPT: QUALITY ASSURANCE
USER: HANSON

Test Report: X29 2 Hour Test



Tester B

2:07:48

| | Min | Max | Avg |
|-------------|-----------|-----------|-----------|
| Speed | 100.1 rpm | 100.2 rpm | 100.1 rpm |
| Temperature | 21.15 °C | 37.34 °C | 36.90 °C |
| Vess1 | 36.86 °C | 36.90 °C | 36.88 °C |
| Vess2 | 36.69 °C | 36.74 °C | 36.71 °C |
| Vess3 | 36.52 °C | 36.58 °C | 36.55 °C |
| Vess4 | 36.63 °C | 36.68 °C | 36.65 °C |
| Vess5 | 36.54 °C | 36.60 °C | 36.57 °C |
| Vess6 | 36.79 °C | 36.84 °C | 36.81 °C |
| Vess7 | 37.15 °C | 37.22 °C | 37.19 °C |
| Vess8 | 36.52 °C | 36.58 °C | 36.55 °C |

Statistics

Tester B

2:07:48 Test finish 04-Dec-2013 15:48:10

VAP JH LAB

2:17:55 Test finish 04-Dec-2013 15:48:16

Signed by:

Date:

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Appendix E: Event Libraries

Event Libraries are a new feature introduced in Vision (G2) AutoPlus autosampler and Vision (G2) dissolution tester firmware version 2.3. Event libraries allow users to create a sequence of events, which can be called from a protocol. When called, the event library executes the events during the dissolution test. This allows for a larger number of events to be reserved for things that may occur only once during the dissolution test.

NOTE: This feature is intended for experienced users. All protocols and event libraries should be verified to work properly before running live product.

How Event Libraries Work

1. The call event used during a protocol will execute an event library. The event library will be executed during the test beginning at the time the call event is used. The test will continue to execute until the event library has completed, this is the same behavior as a sample event at the end of the test. If the event library is executed in the middle of a test, no time is added to the dissolution test.

Example 1:

A protocol calls an event library at 1 hour into the test.

The event library has a sample point at 0:00:00.

The sampling process will begin at the same time as the call event, 1 hour into the test.

Example 2:

A protocol calls an event library at 1 hour into the test.

The event library has a sample point at 10 minutes.

The sampling process will begin at 1 hour and 10 minutes.

2. It is the responsibility of the user to ensure that the behaviors of the protocol and event library are properly matched. Some features of the AutoPlus may interfere with the intended execution of an event library if they are not fully understood. Some examples are:
 - a. Backflush Filter: This is typically executed 30 seconds prior to a sample point. If events are programmed before a sample event in the event library, the sample point may be delayed. If backflush filter is necessary but does not work when enabled in the protocol, consider adding a transfer of 1.0 from X,X to the event library to replicate the behavior.
 - b. Filter Changes: Loading of a new filter will typically occur 2 minutes before a sample point. If this interferes with the intent of the event library, consider adding more time before the sample point, or performing filter changes using the change filter event.

Creating a Basic Event Library

1. Create a new protocol.
2. On the Labels tab, touch the check box in the lower left corner that says “Event Library”. The tabs for Dissolution, Sampling, and Options will disappear.
3. Ensure event library name is no more than 11 characters long. Fill out the other labels as appropriate.
4. Touch the Events tab.
5. Add events to the event library the same way as for a protocol. It is important to be aware of the following:
 - a. If all the event times in the event library are set to 00:00:00, then the events will be executed as quickly as possible without notification of timing conflicts.
 - b. For events that may take place before a sampling event, it is recommended to add times that allow for the operations prior to the sample point.
 - c. The delay event is still restricted to pre- and post-run. It may not be used in an event library.
 - d. Sample events may not be in an event library which is executed during the pre-run or post-run.
6. When finished, touch the Exit button to save the library.

Using an Event Library

The Call event is used to execute an event library during a protocol.

1. Go to the Events tab of the protocol.
2. Add a new event.
3. Touch the Event Type field and select the Call event located at the bottom of the event list.
4. Touch the Parameter field.
5. A list of the existing event libraries will appear. Touch the event library to select it.
6. Set the start time, number of events, and interval between events as appropriate.
7. Touch the Save button when finished.
8. When the protocol is executed, the event library will be called automatically during the test.

Examples of How to Use an Event Library

1. Using an Elite 8 with a third party autosampler. Create an event library with the following:

- a. 0:00:00 Probe Down
- b. 0:01:30 Probe Up

The time can be adjusted as appropriate to ensure the AutoMag stays down for the duration of the sampling. A sample event can be added at 0:00:00 so that the sampling alarm goes off when samples are going to be collected.

2. Split a sample between 2 rows on the Vision AutoPlus. Note: This assumes the total time to pump the rinse and collect the sample is 2 minutes.

- a. 0:00:00 Probe Down
- b. 0:00:00 Sample
- c. 0:02:00 Rinse Volume = 0
- d. 0:02:00 Rinse Volume with Filter = 0
- e. 0:02:00 Sample
- f. 0:02:00 Probe Up
- g. 0:02:02 Rinse Volume = 8 mL
- h. 0:02:02 Rinse Volume with Filter = 3 mL

3. Add a stabilizer to samples after they are collected. For this example, the system configuration is:

Port A: Tester

Port B: Stabilizer

Port C: Media Replace

Port D: AutoFill

- a. 0:00:00 Sample
- b. 0:00:00 Transfer 1.0,B,X – This step adds the stabilizer to the current row.
- c. 0:00:00 Transfer 5.0,U,B – This empties the D/Collector lines of stabilizer.



Teledyne Hanson Research

9810 Variel Avenue

Chatsworth, CA 91311, USA

Phone: +1 818.882.7266

www.teledynehanson.com

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