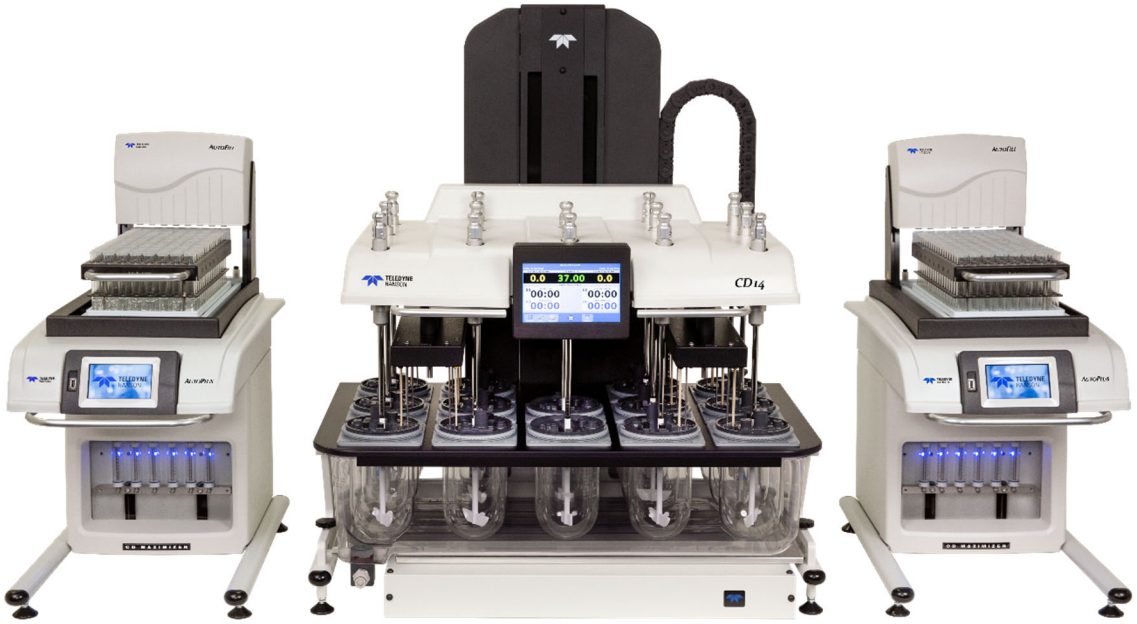
CD14 Comparative Dissolution Tester
and
CD AutoPlus Autosampler
User Guide



TELEDYNE HANSON

75-108-800-Rev. B—31 May 2021

About Teledyne Hanson

Teledyne Hanson, 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 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 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

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Sales and Support

Congratulations on your purchase of the Teledyne Hanson CD14 Comparative Dissolution tester and CD AutoPlus™ Autosampler. While we are certain you will enjoy these new products, 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

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Document Revision History

REVISION	DATE	DESCRIPTION
A	10 July 2020	Initial release.
B	31 May 2021	Added CD AutoPlus autosampler accessory information and instructions.

Note: To confirm that you have received the latest version of this user guide, contact Teledyne Hanson Technical Support.

Table of Contents

Figures and Diagrams

Section A – CD14 Tester Introduction

The Teledyne Hanson 14-vessel Comparative Dissolution Tester runs two methods simultaneously or independently—ideal for bioequivalence studies of generic vs. innovator drug formulations. The 14 stirring positions allow for 6+1 or 12+2 configurations for improved workload efficiency in R&D, formulations, QC, and stability-test labs. With digital temperature probes at 12 positions the CD14 comparative dissolution tester is able to test two different formulations with separate settings for every parameter under the same temperature conditions.

The CD14 Tester is controlled by a fast, powerful computer built into the color touchscreen display mounted to the drive head. The adjustable tilt angle accommodates operators of different heights while the Linux-based operating system with its own SQL database responds instantly to user input. The highly durable resistive touchscreen works with gloves on or off. An easy-to-use interface includes context-sensitive help; logs for events, errors, test reports, test history, and service; rapid programming of new methods; ability to search database by any combination of fields; import/export including full system backup; programmable alarms for automatic power-on and warm-up; countdown to sampling points; tools including full system diagnostics; and more.

The CD14 Tester onboard database stores up to 100 users with three-levels of security (operators, managers, and administrators) with the ability to customize permissions and profiles at each level. The CD14 Tester's biometric fingerprint reader allows rapid enrollment of one or two fingers and provides positive ID of instrument operators. A password-only option is also included. Customize your own report formats and approval systems by specifying up to three signatures per report. An extensive audit trail records all system events and logs any changes made by users. System configurations are stored on-board, and the system logs any changes to methods and configurations.

All critical components of the CD14 Tester are identified by unique serial numbers traceable to the factory level including the spin-shafts installed into the drive head, all baskets and paddles, and all dissolution vessels. The part number and serial number of each vessel are laser-engraved into the top of the vessel rim in large, easy-to-read type, such that breakage of the glass will not destroy identifying information. The on-

board database of the CD14 Tester stores the system configuration including the serial numbers of all vessels, paddles, and baskets, and the position into which each item is installed.

Each dissolution vessel installs into an adjustable bracket attached to the vessel plate. These vessel-centering brackets allow precision adjustments to the dissolution vessel's position in relation to the spin-shaft and any apparatus attached to it. The system allows fast and easy vessel centering to meet or exceed USP and/or ASTM mechanical calibration specifications.

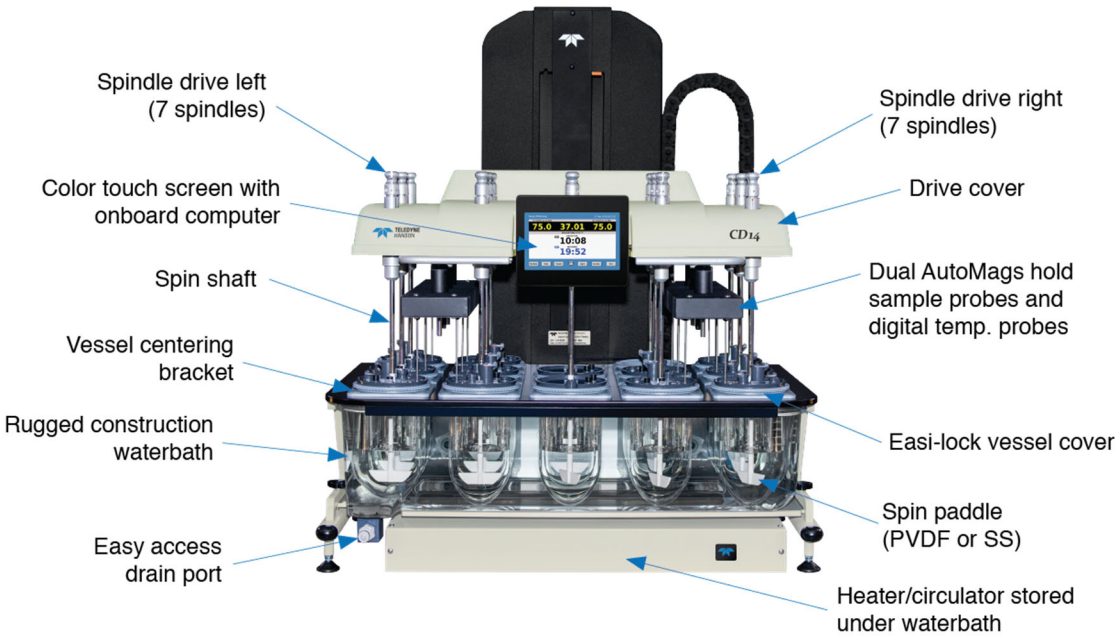
Features

The new CD14 dissolution testers take the next step in dissolution testing with a streamlined new design and increased functionality. Here are some of the new features.

Standard Features
Compact footprint
Easi-Lift™ moveable drive head with brake
14 precision drive spindles with spindle shafts
14-position vessel plate
Standard footprint, 4 across x 3 deep with 2 center positions
Automation-ready (with optional AutoMag™)
Precision control for speeds 25 - 250 rpm, temperature 25 - 51 ºC
Elegant, ergonomic design with workhorse performance
Highest quality components and engineering
Minimal user adjustments for easy setup and go
Independent heater system located under the tester
Rugged molded waterbath with fast heat-up and low-level drain port
Digital temperature probe (1) for use in bath and vessels
Full color touchscreen with intuitive menus and programming
Store hundreds of methods (create, manage, and save routines)
Upload and download programs with flash drive
Electronics and firmware include 32-bit digital technology
Print to both serial and network printers
Alarms for sampling, maintenance, and calibration
Security system supports 21 CFR Part 11 compliance
USP / FDA / ASTM / EP / JP compliant
CE / RoHS compliant, includes earth-friendly packing

CD14 Comparative Dissolution Tester Identification

Figure A-1: Identification of the CD14 Tester



Section B – CD AutoPlus Sampler Introduction

The CD AutoPlus™ is a programmable precision syringe-pump sampling instrument that handles a wide variety of dissolution applications and requirements. The basic instrument consists of 6 precision glass sampling syringes driven by a stepper motor, with internal valve interfacing, in one compact ergonomic instrument package. PTFE tubing harnesses connect to a CD14 Tester, multi-cell changers for on-line UV/VIS sample analysis, as well as collection trays for sample archive.

The CD AutoPlus can be directed to withdraw an aliquot from a dissolution tester at a pre-programmed time. The sample is measured and dispensed through a UV flow cell and/or further into a collection rack that contains vials or test tubes. The CD AutoPlus can be programmed to repeat this process multiple times.

Most other commercial dissolution sampling systems use peristaltic pump movement of samples into a collector or through a UV flow cell. The CD AutoPlus avoids the volumetric inconsistency and high maintenance of the peristaltic pump and provides an inert environment to minimize drug absorption.

The AutoFill™ is an automated sample collector designed for seamless integration with the CD AutoPlus. The AutoFill includes sample collection capability from eight sources, home port arrays for wash and waste, all-inert tubing and dispense probes, and reduced tubing lengths to minimize rinse volume and save time. Collection racks include 16 x 100 mm test tubes for UV, 13 x 100 test tubes for UV, 12 x 32 vials for HPLC.

Definitions:

AutoMag™
An automated mechanism that can be installed on the CD14 Tester to automate raising and lowering of the sample probes and digital temperature probes (DTPs).

Detect
Determine a sample's absorbance.

Dilute
To collect a solute and a solvent in the same container with the purpose of reducing its concentration.

Dispense
The pushing out of material from the syringe by the syringe plunger.

DissoScan™
The autosampler with one 3-way solenoid valve per syringe to direct fluid flow. The DissoScan provides 2 fluid lines (A and D).

Load
The drawing of material into the syringe by the syringe plunger.

Maximizer™
The autosampler with four 4-way solenoid valves per syringe to direct fluid flow. The Maximizer provides 4 fluid lines (A, B, C, and D).

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

Occurrence
The dictated time at which a function is performed.

Prime
To fill sample lines with media.

Rack
The vial/test tube holder that fits on the AutoFill.

Recurrence
The dictated time at which a function repeats.

Rinse
The clearing out of old media from tubing with the target media.

Solenoid Valve
The device that controls flow direction.

Transfer
The moving of liquid from a source to a destination.

Wash
The clearing out of old media from tubing with blank or wash media.

Figure B-1: CD AutoPlus/AutoFill Identification

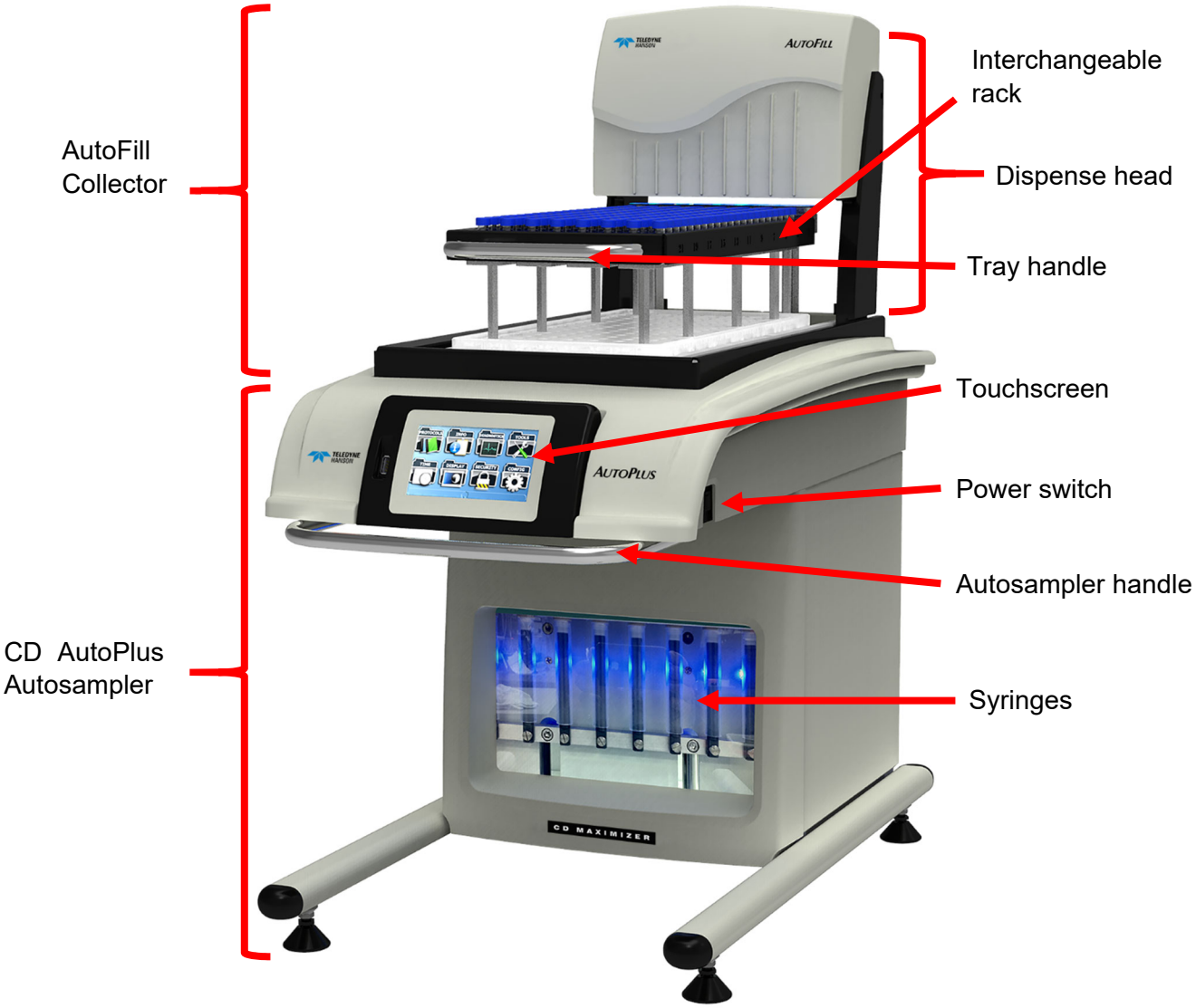
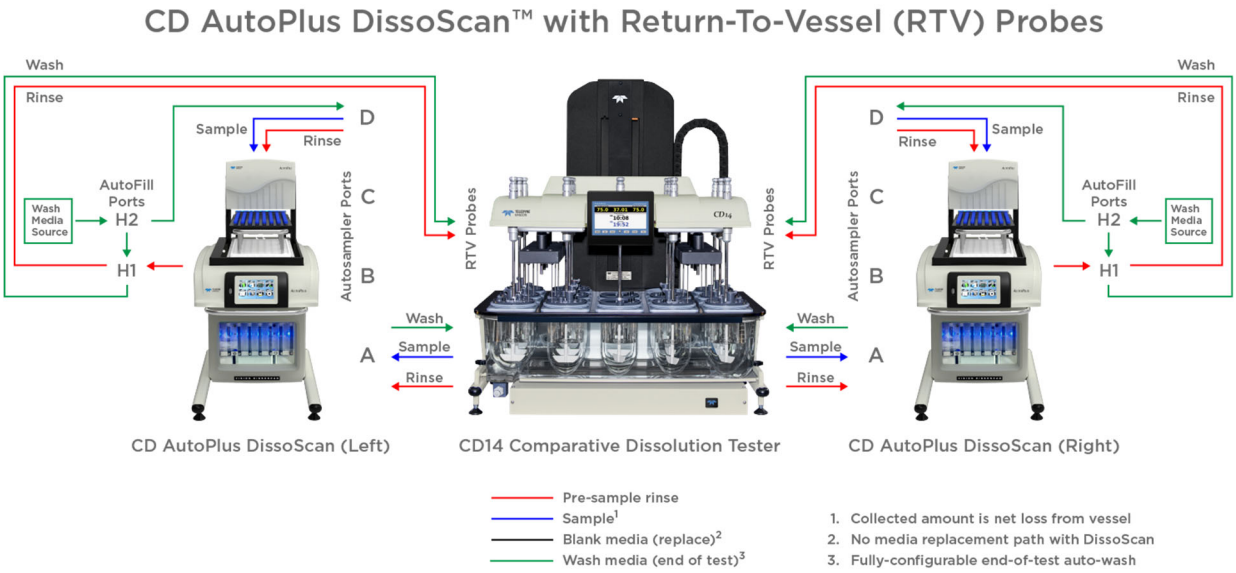
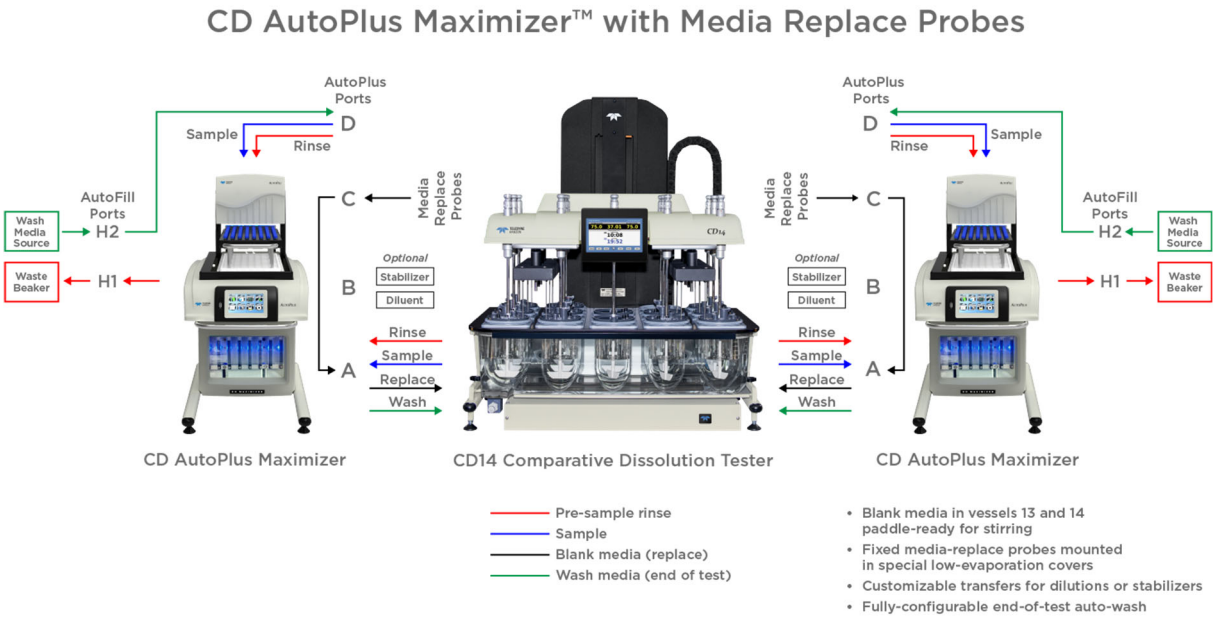


Figure B-2: Identification of the CD AutoPlus Fluidics





Section C – Regulatory and Safety

Regulatory Compliance

Teledyne Hanson, a business unit of Teledyne Instruments, Inc. hereby certifies that this product, including hardware and firmware, was designed, evaluated, validated, inspected, and tested to approved specified quality requirements of Teledyne Hanson in conformance with current USP, EP, JP, and other international standards (India and Korea).

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 réglements sur le brouillage radioélectrique édictés par le Ministère des Communications du Canada.

CD14 Tester 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.

Never insert items into openings or vent holes while the unit is connected to power.

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

CD14 Tester 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, 15 A for the heater and 1.5 A for the 24 V power supply.
- Mains supply voltage fluctuations not to exceed ± 10% of the nominal voltage
- Installation Category II (overvoltage categories)
- Pollution Degree 2
- Please note potential pinch hazards described below.
- See the installation section for lifting instructions.
- Additional hazards may exist if the equipment is not operated according to the instructions in the user guide.

Safety Symbols

The following safety symbols are used on the instruments and throughout this manual.

Symbol	Definition
	General warning of potential damage or danger from a variety of sources.
	Electric shock warning: disconnect power before servicing instrument.
	Hot surface warning: internal components may be hot after covers are removed.
	Pinch hazard: keep hands and fingers clear.
	Tip hazard: follow the Moving and Storage instructions to prevent unit from tipping.
	Heavy object warning: follow the Moving and Storage instructions to prevent injury.
	Electrical grounding connection.

CD14 Tester Warning Locations

System warnings on the mast – 

Service warnings on the heater – 

CD AutoPlus General Safety Considerations

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. If condensation forms on or inside the AutoFill collector, allow it to dry thoroughly before connecting to a power source.

Never work on the electrical components in the system while there is power to the unit.

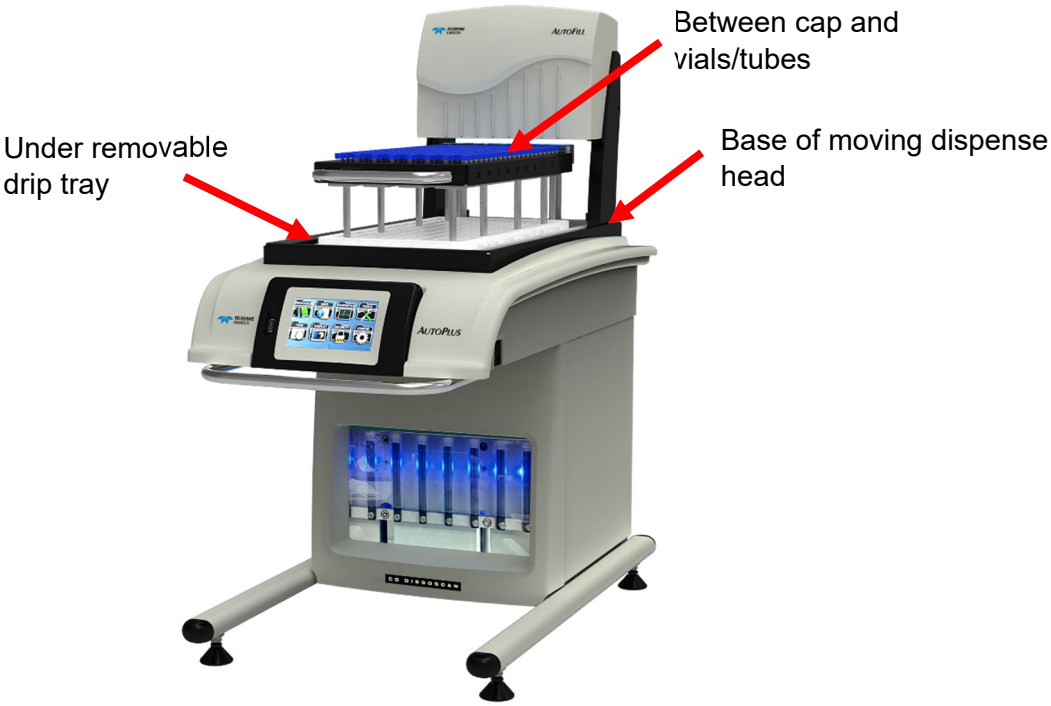
Warning: Disconnect power before servicing the instrument.

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

CD AutoPlus CSA Safety Considerations

- For indoor use only
- Maximum altitude up to 2,000 meters
- Environmental operating temperature 5 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 ±10% of the nominal voltage
- Installation Category II (overvoltage categories)
- Pollution Degree 2
- See the maintenance section (Moving and Storage) before moving the equipment.
- Please note potential pinch hazards per the diagram below (Figure C-1).
- Additional hazards may exist if the equipment is not used correctly per the user guide.

Figure C-1: CD AutoPlus/AutoFill Potential Pinch Hazards



Section D – Tester Installation

Quick Start

1. Determine location for the tester and remove packing material and accessories leaving the unit on the base of the shipping container.
2. Remove weight covers and then remove the 4 weight locking bolts. Replace covers.
3. Install handles on sides of frame and using at least 4 people lift the unit onto the bench.
4. Level tester at vessel plate.
5. Place heater control unit under bath support plate.
6. Make electrical connections. Turn unit on to see that it powers up, then turn power off.
7. Make bath tubing connections and fill bath to just above the ports on the back of the bath. Check for leaks.
8. Turn pump on and prime with priming syringe if needed. Check for leaks and that the unit is pumping bath water. Turn pump off.
9. Place temperature probe in bath and set temperature to 25 °C and see that the bath temperature goes up.
10. Set up and configure firmware, (date, time, security, etc.).

Location

This section provides information on determining if a location is suited to a CD14 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 requirements 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 stated in the specifications section.

The CD14 Tester should be placed in the center of the autosamplers, if used.

Electrical Requirements

Each CD14 dissolution tester requires two grounded outlets within 3 meters (9 ft.) of the location of the system; one for the dissolution unit and one for the heater box.

The CD14 Testers are available in one configuration, 100 V through 240 V. The voltage is automatically set by the instrument.

Power cords should meet the following specifications: IEC 320-C13 connector; SJT 18AWG3C, 2 x 0.824 mm2, 60 °C, 300 V.

Section D – Tester Installation

General Unpacking and Installation

The CD14 Tester has been shipped in a one-use, disposable shipping container. Prior to unpacking, the shipment should be located in an area that allows working room around the container. Vertical clearance will be needed to remove the mast covers up and over the unit to gain access to the counterweight lock screws. It's best to do this as close to the final installation site as possible.

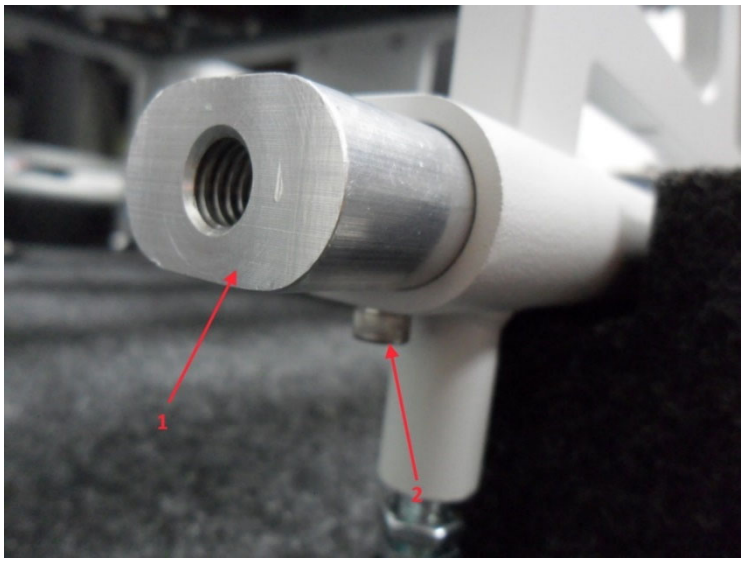
Unpacking the CD14 Tester

1. Prior to unpacking, note any damage to the container. If the container is damaged, contact the shipping company and Teledyne Hanson before proceeding.
2. Remove the straps and open the top of the cardboard box.
3. Remove any inside packaging and as many small items as can be accessed from the top opening.
4. Pull the outside cardboard box up and over the unit.
5. Remove all remaining loose items and packaging.
6. Cut the corners of the bottom cardboard tray and fold down the four sides of the tray.
7. Remove the heater enclosure out from under the unit.

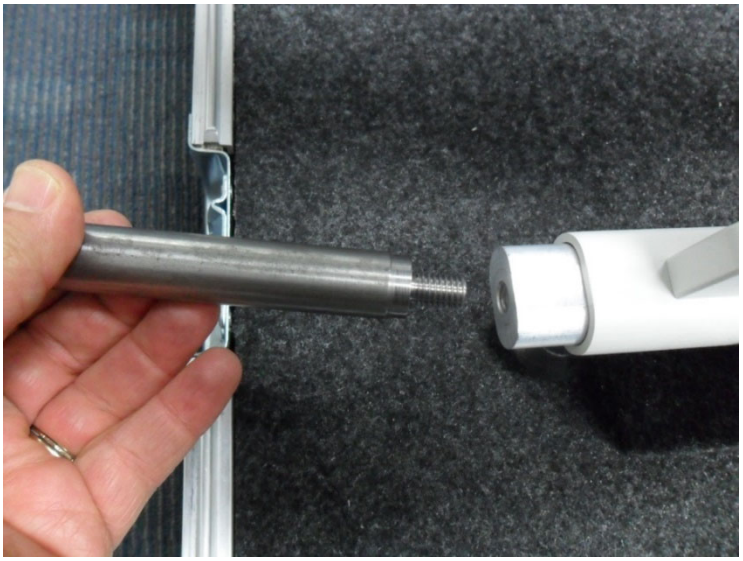
Attach Lifting Handles

1. Locate the oval handle inserts in the ends of the oval shaped openings of the bottom legs.
2. The inserts are retained in the ends of the legs with a single screw from under the legs.

   NOTE: The inserts will be removed from the legs once the CD14 Tester is located on a bench.



3. Screw the handles into the oval handle inserts.

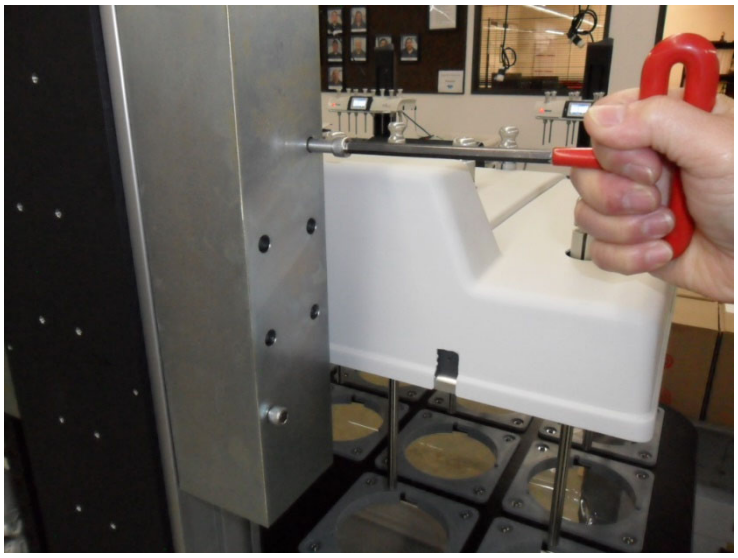


4. **Important:** Verify oval handle inserts will not pull out of the legs by pulling on the handles.

Remove Counter-Weight Shipping Bolts

While the unit is still on the plastic pallet and low to the floor, do the following:

1. Remove the 3 screws that secure the mast cover that is located next to the cable track and then carefully pull it up and away from the mast to gain access to the 2 counterweight lock screws.
2. Remove the 2 lock screws with the provided ¼” hex wrench.



3. Make sure the counterweight cable is properly seated in the groove of the pulley above. The counterweight can be lifted enough to provide slack in the cable if this is needed.
4. Replace the mast cover.
5. Remove the other mast cover on the other side of the mast, remove the 2 counterweight lock screws on that side, check that the cable is in the pulley groove above, then replace the mast cover.

Moving the Unit

There may be various ways and means of moving the unit from the point of unpacking to the final location of installation depending on available resources and equipment. The following steps assume the unit has been successfully unpacked and moved to a point directly in front of the bench onto which it will be set. It also assumes the only way to lift the unit is manually from the floor to the bench.

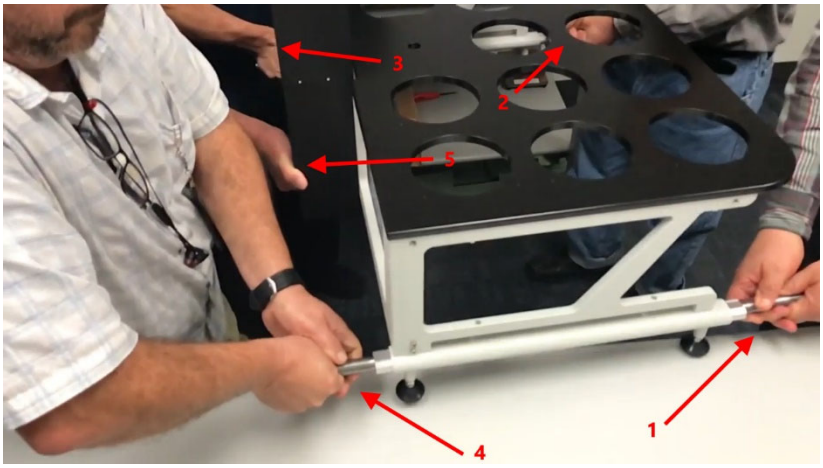
Lifting the Unit

It is recommended that at least 5 people, each able to lift 55 lbs. should be used to lift the unit from floor level to the surface of the bench. The following steps outline a process that should minimize the amount of time and effort required to lift the unit. For reference, the unit weighs approximately 260 lbs. (118 kg). Note: For illustrative purposes, the following photos contain an incomplete CD14 Tester.

Safety First

All who are lifting should lift with their legs, not their back.

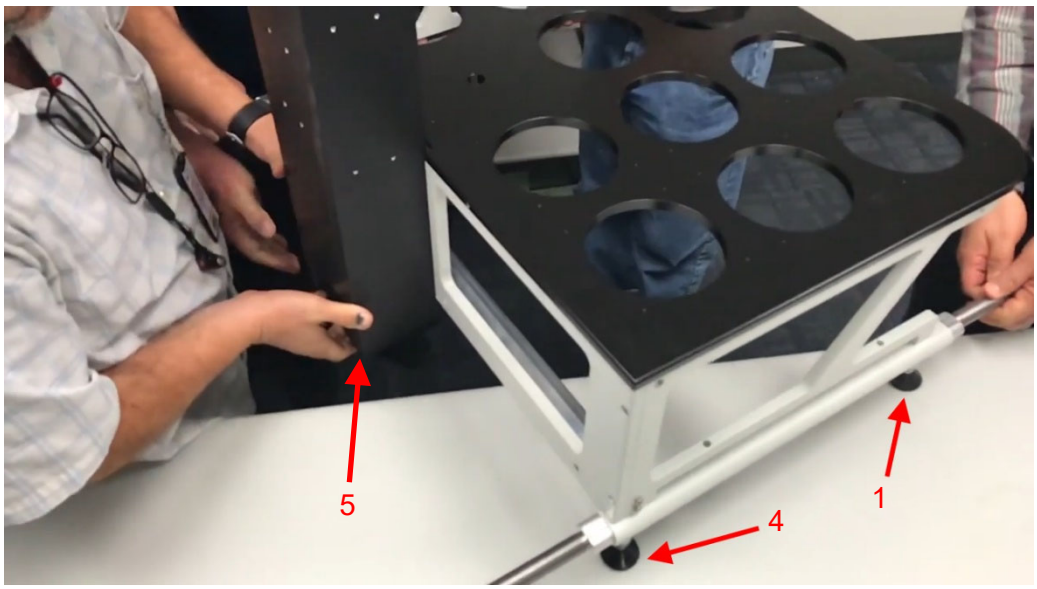
1. The unit is positioned on the floor perpendicular to the bench it will be placed on.
2. A person lifts from each of the 4 handles.



3. A fifth person stabilizing the unit at the mast.

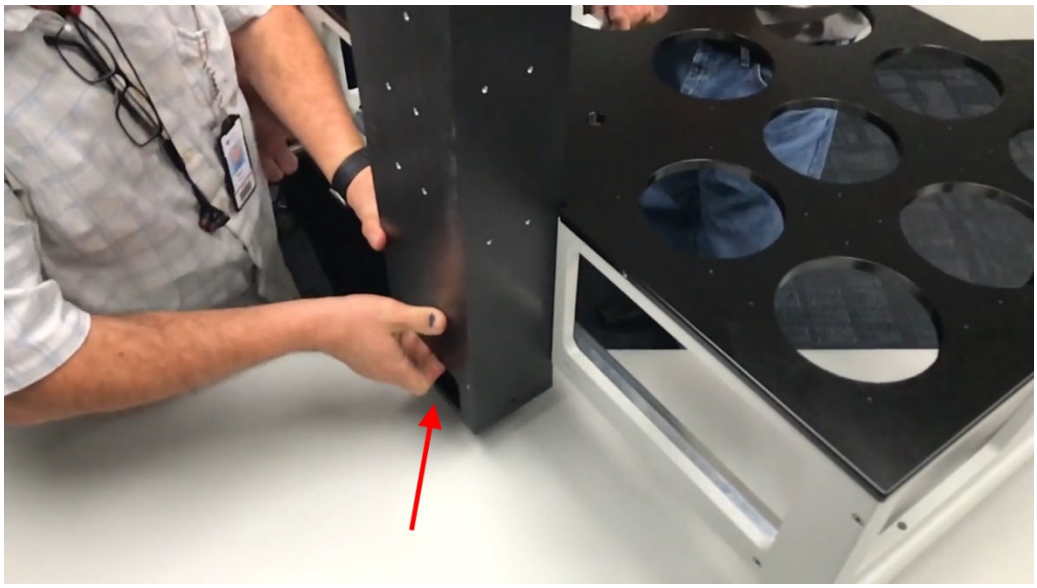
Caution: The rear side of the unit is the heavier side. Those lifting from the front should not lift faster than those on the rear to avoid shifting the weight to the rear and making the unit unstable during lifting.

4. The two side feet are placed on the bench first.

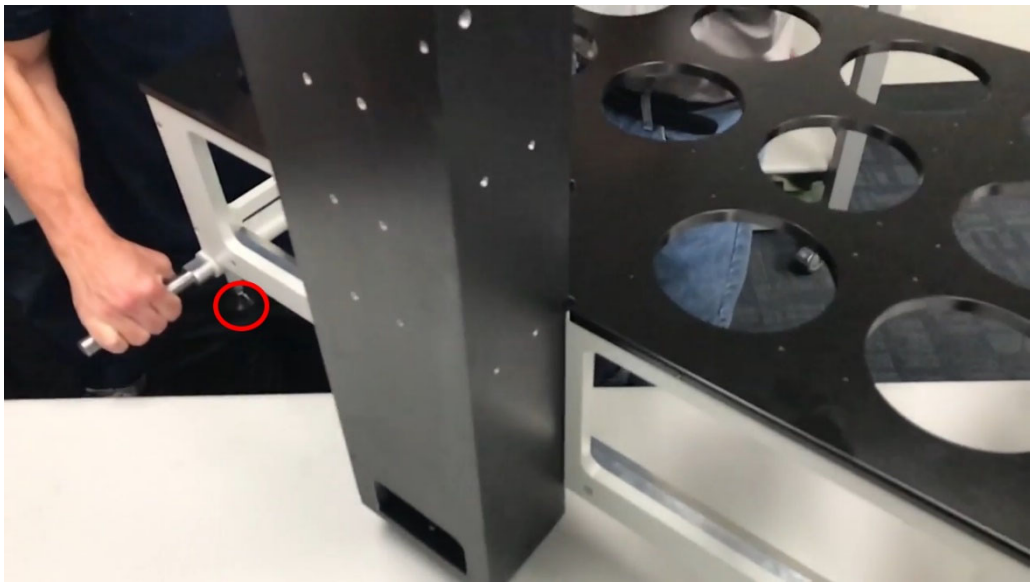


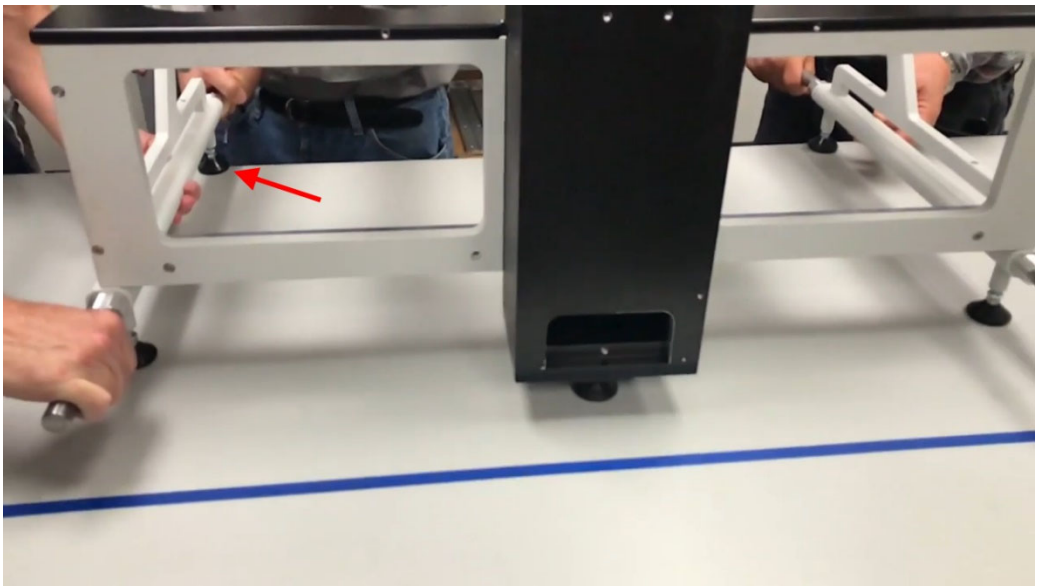
5. At this point the person at position 4 at the rear corner, where the instrument foot is now on the bench, will move to position 5 replacing that person originally there who has now backed away.

6. The foot under the mast slides onto the bench.

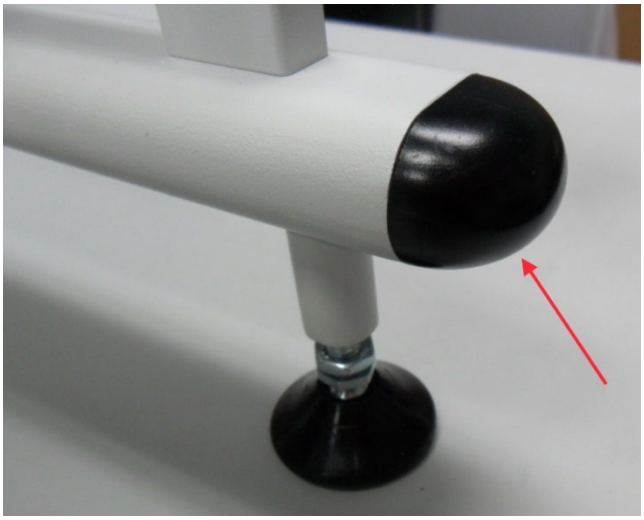


7. The unit continues to be slid onto the bench, so the last rear foot is supported by the bench. In the process the unit is turned to a forward-facing position.



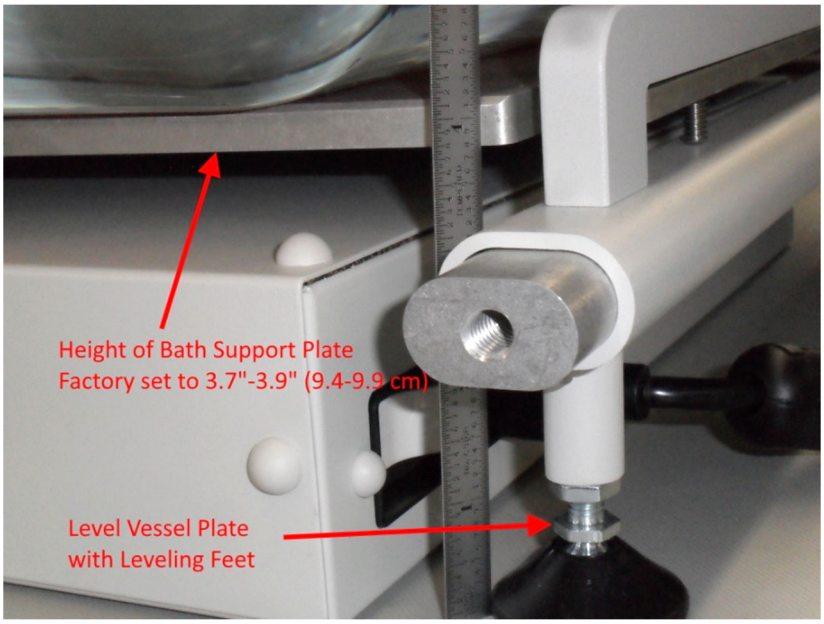


8. The people on the rear side should back away from the unit as soon as they can while the two on the front continue to position the unit with all 5 feet in contact with the bench top.
9. Remove the lift handles and oval inserts (5/32” Allen hex wrench) from the frame.
10. Install the two front frame end caps by lightly tapping them in place with a hammer.



Level the Unit

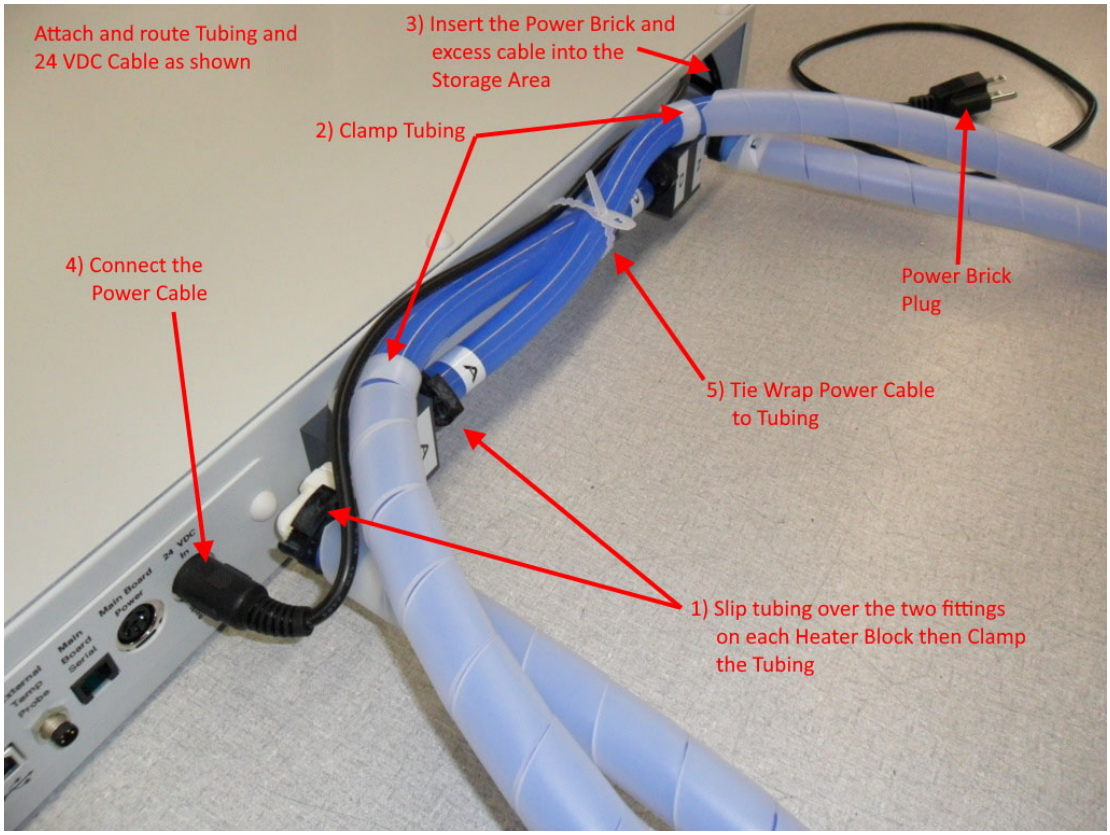
1. Position the unit on the table to allow for other equipment that may need to be installed next to it (e.g., autosamplers).
2. The height of the unit has been factory set to within 3.7 – 3.9 in. (9.4 – 9.9 cm) from the bench top to the underside of the bath support plate.
3. Level the unit via the two front feet, and the single rear foot under the mast. While doing so, maintain the height of the unit within the factory height range.



4. While leveling, place a digital level at the center of the front edge and rear edge of the vessel plate to check the X-axis (left to right), and, along the left and right outside edges of the plate to check the Y-axis (front to back) levelness.

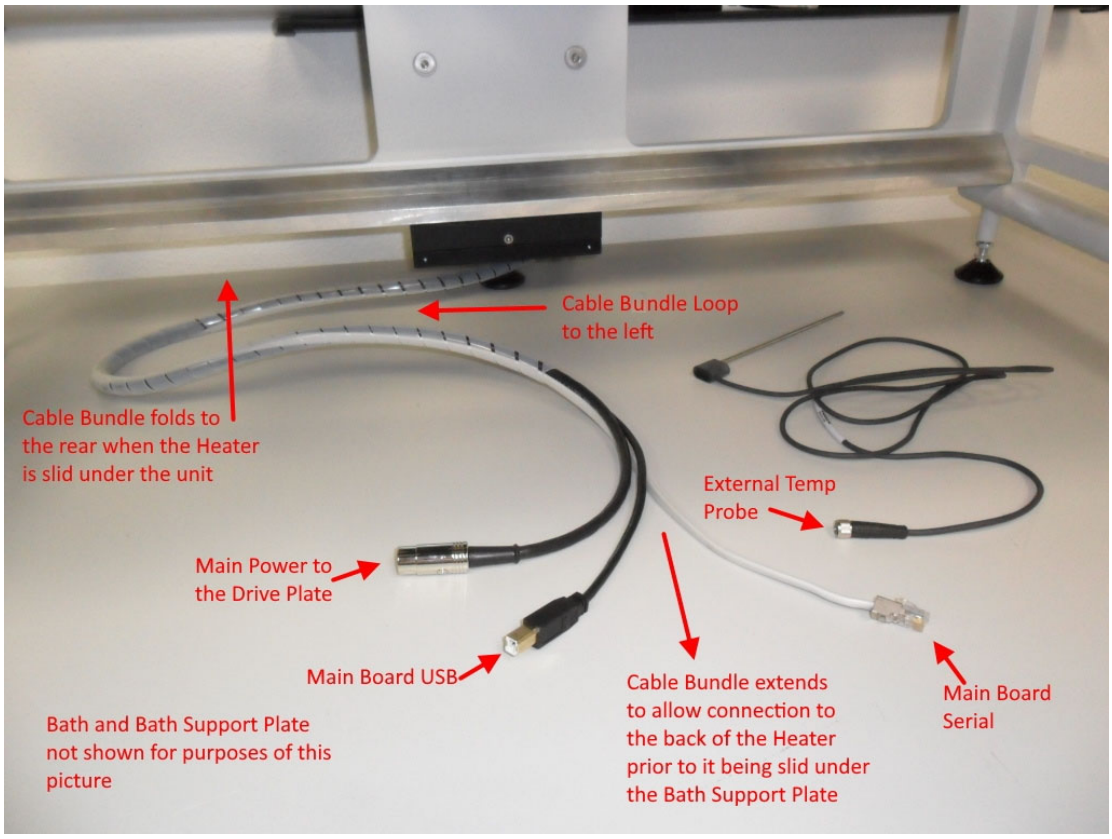
5. To level, raise the two back feet out of the way and then adjust the two front feet, and the single foot under the mast, to achieve a maximum of 0.2 degrees in both directions. Once set, lower the two back feet that were raised prior to leveling, down to where they just touch the bench top. Forcing them down further will change the levelness. Lock the upper nuts of all five feet to the frame.

Heater Assembly



1. Match the labeled ends of the tubing with the labeled locations on the back of the heater assembly.
2. Make the connections and route the tubing as shown.
3. Insert the power brick in the storage area shown.
4. Route the 24VDC power cable as shown and plug the connector into the back of the heater.
5. Tie-wrap the cable to the tubing as shown.

Heater Installation

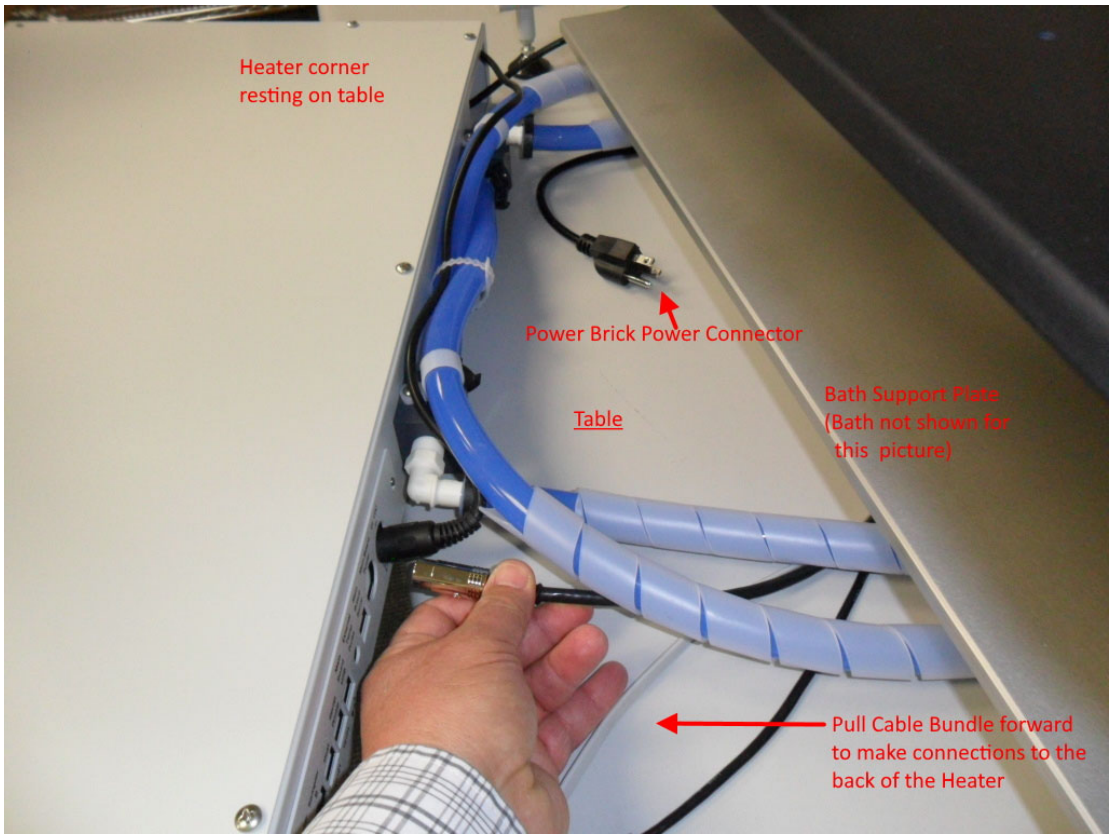


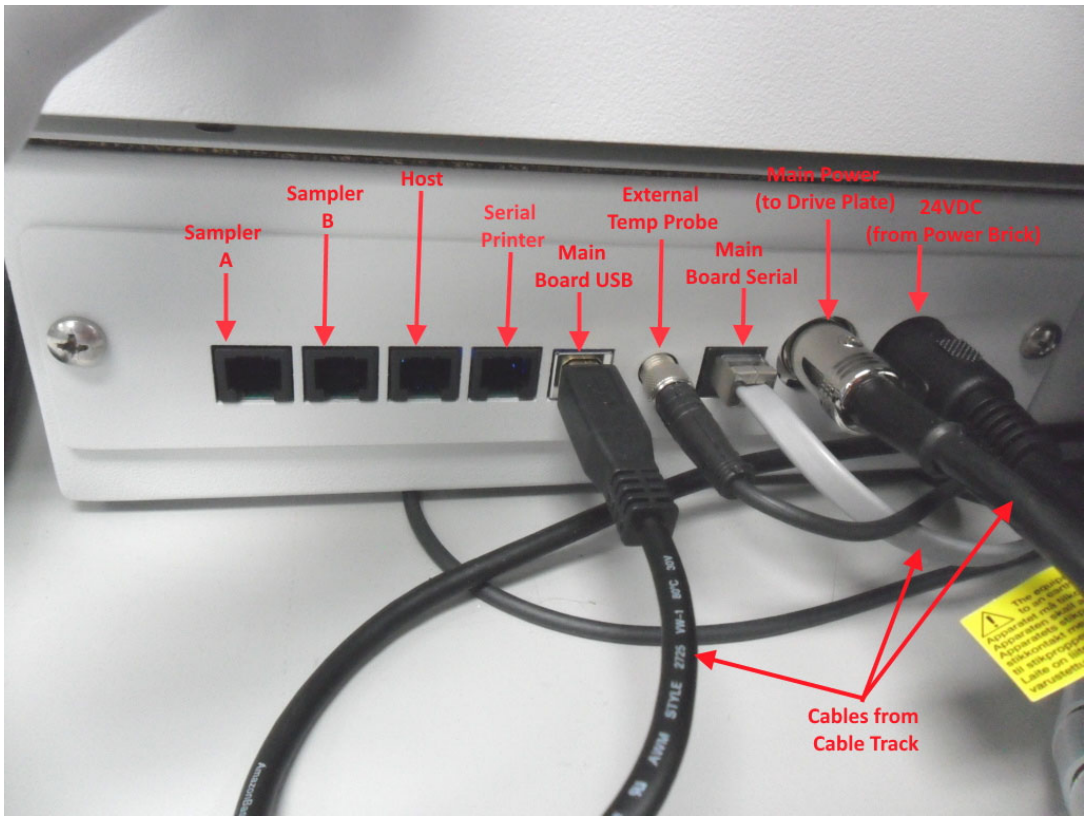
1. Prior to installing the heater, make sure the cable bundle that exits the cable track at the lower rear end of the unit is laid out on the bench, under the bath support plate, such that there is a loop to the left as viewed from the front of the unit. The cable bundle will extend out to the front of the unit when the connections are made to the heater, then fold back with the loop to the left when the heater is pushed all the way back into position.

   NOTE: If samplers, host and\or serial printer cable are intended to be part of the installation, these cables can be tie-wrapped at this time to the cable bundle to allow for an easier installation of the heater under the unit.

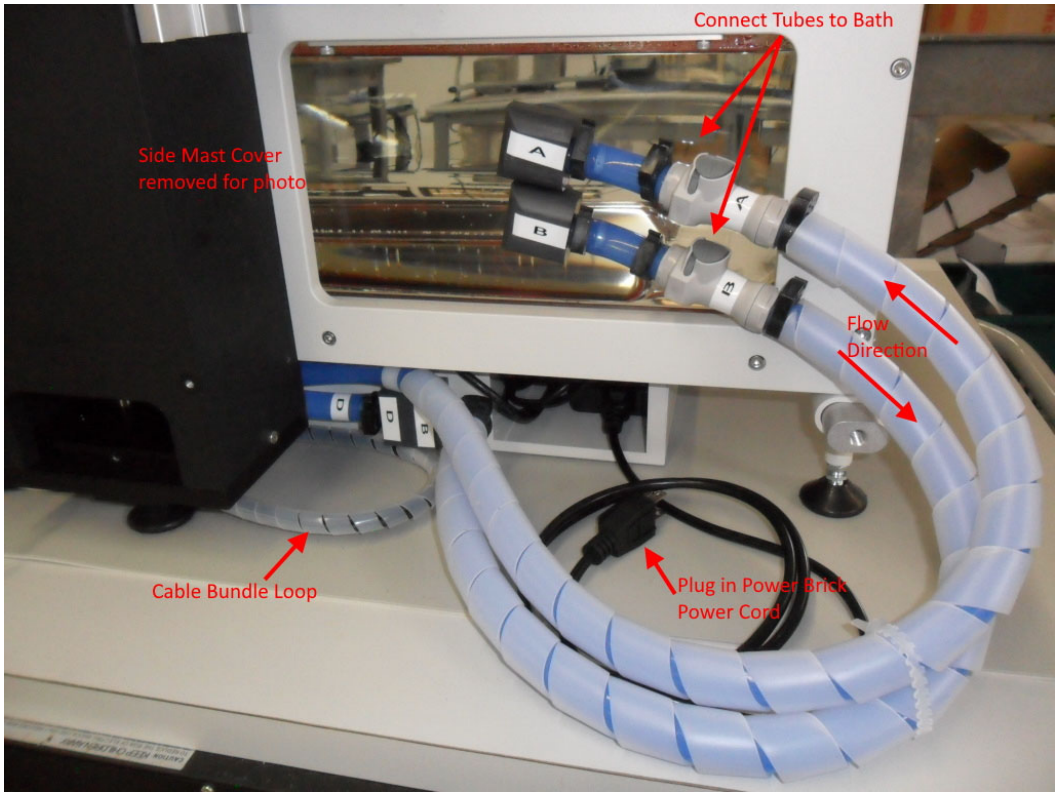
2. The power cord that feeds the power brick will need to be ‘threaded’ straight back as the heater is moved into its final position in the following steps.

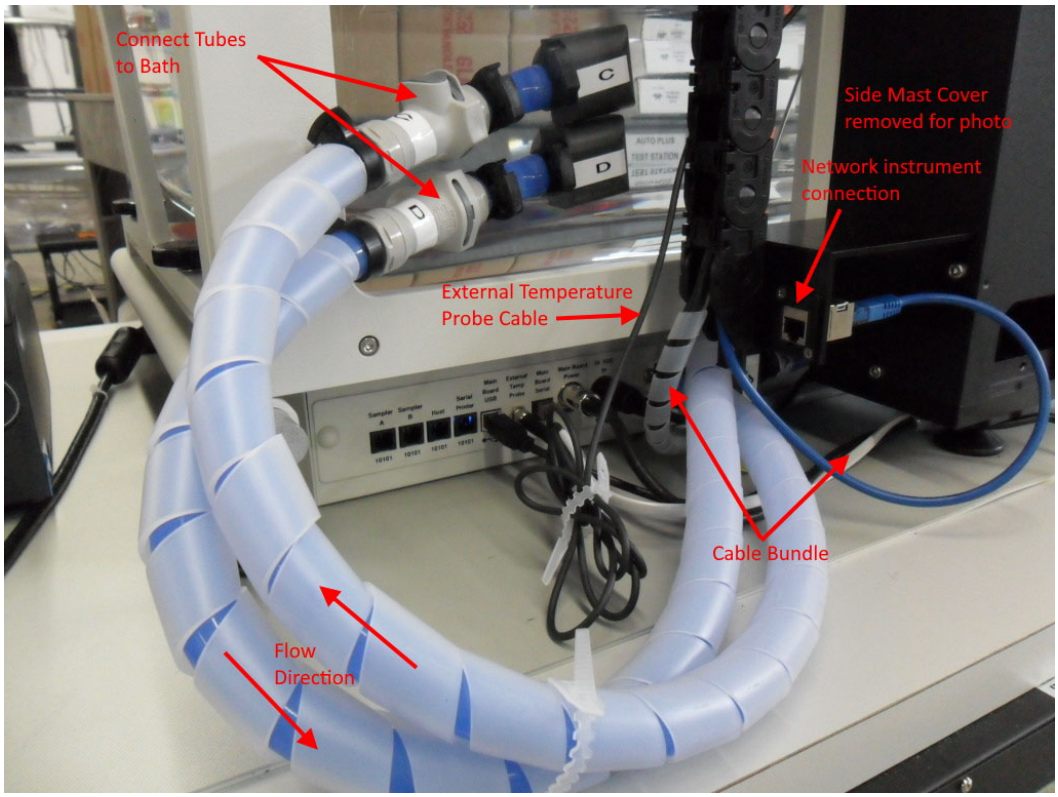
3. Holding the heater in front of the unit, guide the blue water circulation tubes and power brick power cord under the bath support plate, and on top of the cable bundle that comes from the back of the unit, and rest the back end of the heater on the bench.
4. While still supporting the front of the heater, make the cable connections from the cable bundle to the rear of the heater.



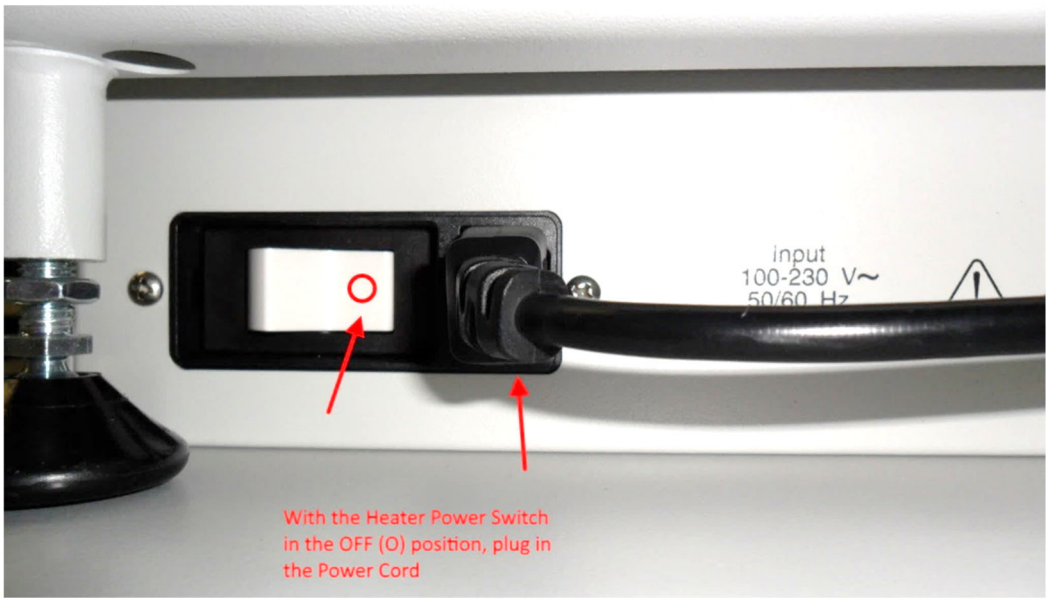


5. Insert the external temperature probe into the fitting located adjacent to the mast in the vessel plate.
6. After all connections have been made to the heater, gently slide the heater box all the way back as far as it will go. The tubes may need some guidance as this is done so they go straight back and are over the cable bundle.
7. With the drive plate assembly raised all the way up, reach over the vessel plate (if there is no clearance on the sides) to connect both sets of water circulation tubes to the quick-disconnect fittings on the back of the bath.


Connect Tubes to Bath
Side Mast Cover
removed for photo
Flow
Direction
Cable Bundle Loop
Plug in Power Brick
Power Cord


Connect Tubes
to Bath
Side Mast Cover
removed for photo
Network instrument
connection
External Temperature
Probe Cable
Cable Bundle
Flow
Direction

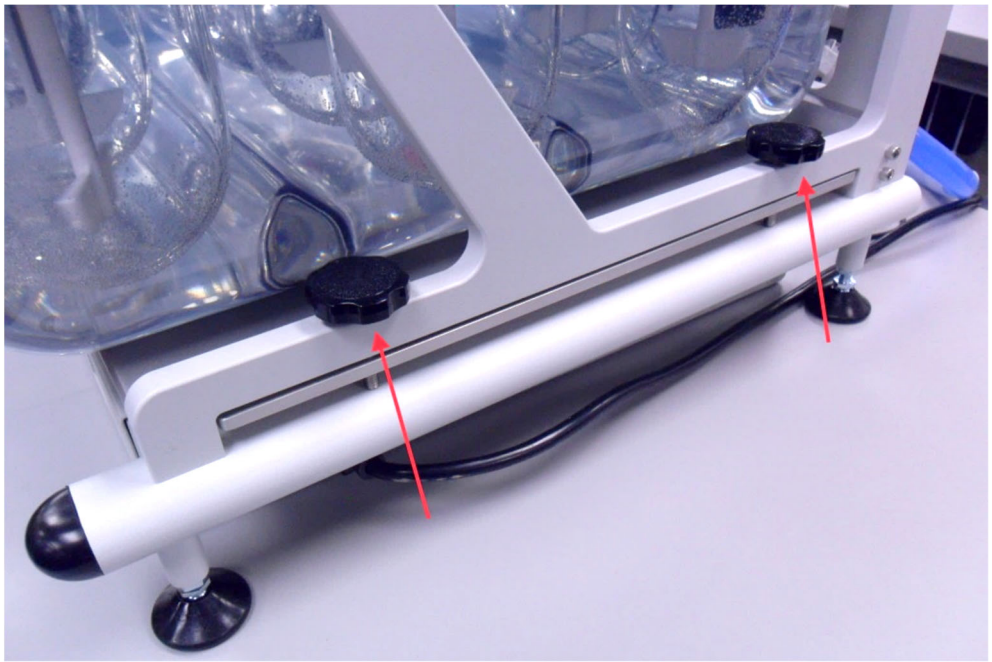
8. Plug in the network connection (if applicable) to the connector located on the lower end of the mast.
9. With the drive head power switch in the off (O) position, plug in the power brick power cord to a power source.
10. With the heater power switch in the off (O) position, plug in the heater power cord to a power source.



Filling the Bath

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

1. Verify that the waterbath is adjusted all the way up by turning the four bath support plate adjustment knobs clockwise until they can no longer be turned.

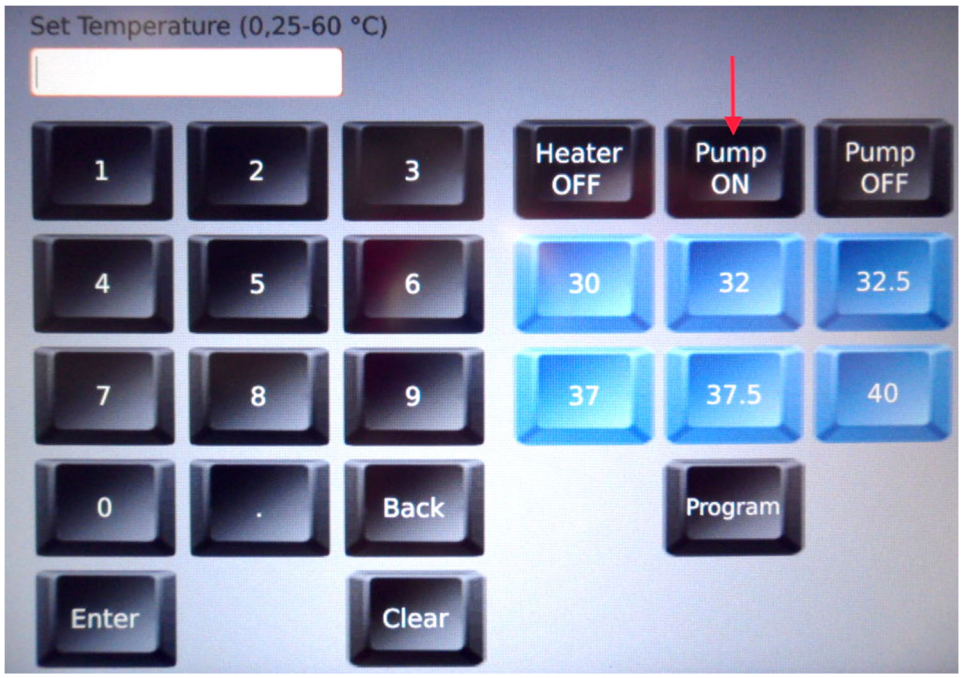


2. The use of DI (deionized) water is highly recommended for filling the bath.
3. If the vessels have not been installed, fill through a vessel hole in the vessel plate to the water level indicated on the left-front corner of the bath.
4. Check for leaks.

Start the Pump

1. Before starting the pump, the water level needs to be at least to the fill line indicated on the bath.
2. At the display, touch the center of the black ribbon. This will bring up a keypad window.

3. At the keypad window, touch the “Pump ON” button. Any additional air that blows out into the bath will stop shortly. Note: If water doesn’t start flowing when the pump is started, then shut the pump off at the displayed keypad, inject water into the two bottom (left and right) ports within the bath a couple of times with the supplied syringe. Start the pump again.



4. The bath water temperature can be set by touching any of the blue buttons, or a temperature can be entered at the keypad to the left. Touch “Enter” to start.

5. Check for leaks a second time.

Tester Installation is Complete

The CD14 dissolution tester is now ready for adding desired accessories and proceeding with normal operations.

The next section describes the installation of the accessory autosamplers. If manual sampling is going to be used, skip to the operation section.

Section E – Autosampler Installation

Location

This section provides information on determining if a location is suited to a CD AutoPlus and AutoFill.

Environmental Requirements

The CD AutoPlus samplers should be placed one on the left (Side A) and one on the right (Side B) of the CD14 Tester. The Teledyne Hanson AutoFill collectors should be placed on top of each CD AutoPlus.

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

Space Requirements

The bench should be at least 60 cm (24 in.) deep and clearance above the units of at least 82cm (32 in.).

The bench should be level and flat.

The bench should be capable of supporting weight given in the specifications section.

For additional pieces of equipment (e.g., UV/Vis spectrophotometers, etc.), see the user guides for the respective pieces of equipment.

Electrical Requirements

Each CD AutoPlus requires a single grounded outlet within 1 meter (3 ft.) of the location of the system.

Each AutoFill requires a single grounded outlet within 1 meter (3 ft.) of the location of the system.

The CD AutoPlus and AutoFill 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.

Unpacking and Inspection

This section provides instructions on unpacking and setting up each CD AutoPlus and AutoFill.

1. Unpack each CD AutoPlus individually from its shipping container.

a. Note any damage to the shipping container. If container is damaged, contact Teledyne Hanson immediately.

b. Place shipping containers near installation location.

c. Remove straps from the containers.

d. Open containers and remove any accessory boxes.

e. Carefully remove each CD AutoPlus and AutoFill from its shipping container.

2. Place each CD AutoPlus on the bench.

a. Each CD AutoPlus should be placed in a manner to allow access to the back of the autosampler until the installation is completed. Once the installation is complete, the instrument can be placed in its final position.

b. Place each AutoFill on top of its corresponding CD AutoPlus with the tray for the rack toward the front of the unit.

c. Place a collection rack on the tray of each AutoFill. The racks should sit flat on the bottom of the trays.

Electrical Connections

NOTE: The CD AutoPlus and AutoFill have ports located on the underside of the silkscreen panel. The panel illustrates port placement. (See Figures E-1 and E-2.)

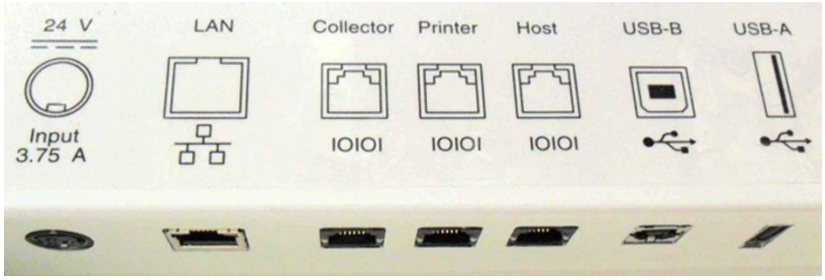


Figure E-1: CD AutoPlus Back Panel and Ports

Figure E-2: AutoFill Back Panel and Ports

This section provides instructions on making the power connections to the CD AutoPlus and AutoFill.

1. Ensure the power switch located on the right side of the CD AutoPlus is in the off (O) position.
2. Connect the power supply to the port labeled 24 V Input 3.75 A on the lower left corner of the back panel of the CD AutoPlus, flat side facing the unit (the connector is keyed so it will only fit one way). Then connect the power supply to the wall outlet.
3. Ensure the power switch located on the back of the AutoFill is in the off (O) position.
4. Connect the power supply to the port labeled 24 V Input 3.75 A on the back of the AutoFill, flat side facing the user (the connector is keyed so it will only fit one way). Then connect the power supply to the wall outlet.
5. Connect a flat RS-232 cable from the ‘Host’ port of the CD AutoPlus on the left of the CD14 Tester to the ‘Sampler A’ port of the CD14 Tester.
6. Connect a flat RS-232 cable from the ‘Host’ port of the CD AutoPlus on the right of the CD14 Tester to the ‘Sampler B’ port of the CD14 Tester.

7. Do not turn on the CD AutoPlus or AutoFill at this time.

CD AutoPlus to AutoFill Communication Connections

This section provides instructions on how to make the communication connections between the CD AutoPlus and AutoFill so that the CD AutoPlus can control the AutoFill.

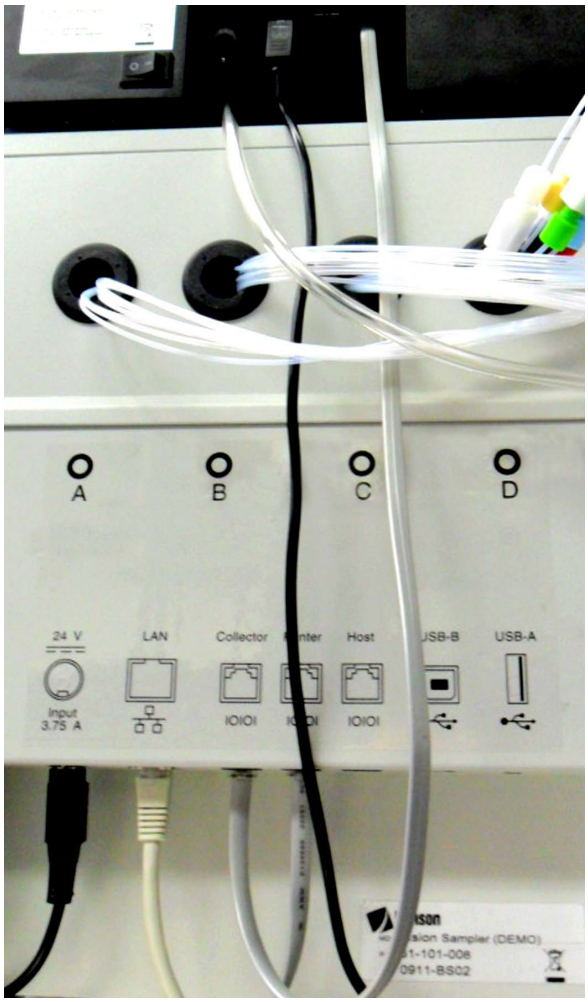


Figure E-3 CD AutoPlus/AutoFill Connections

For each sampler/collector pair:

1. Connect one end of the RS-232 cable to the port labeled Collector on the back of the CD AutoPlus.
2. Connect the other end of the RS-232 cable to the RS-232 port labeled Sampler on the back of the AutoFill.

3. Turn on (I) both AutoFill collectors. The dispense heads should move to the home position and blue lights will illuminate under the dispense heads. If either of the AutoFill collectors do not power on consult the troubleshooting section of this user guide.

4. Turn on (I) both CD AutoPlus samplers. Their syringes should move to the home position and their displays will be illuminated. The units may take as long as 30 seconds to reach the home screen. If either CD AutoPlus does not power on, consult the troubleshooting section of this user guide.

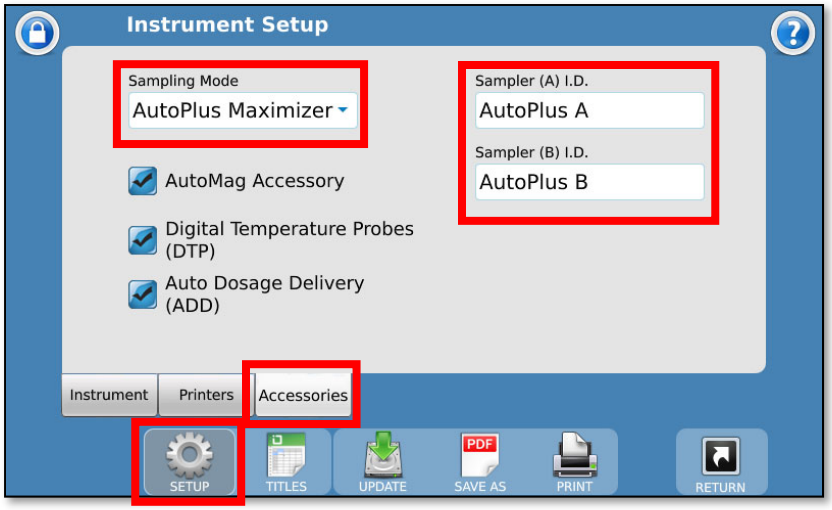
   NOTE: If the AutoPlus is turned on before its corresponding AutoFill, an error will be generated, and the user will be forced to power up the instruments in the correct order before any syringe or collector operations will work.

5. With the CD AutoPlus powered on, the home screen will appear. This is the default screen displayed when the sampler is idle.

6. Touch the screen anywhere; the menu will appear. Touch the ‘x’ button at the bottom to exit back home.

7. From the CD14 Tester main screen, touch the menu button and select the ‘Config’ option.

8. Touch the ‘Setup’ button and select the ‘Accessories’ tab.



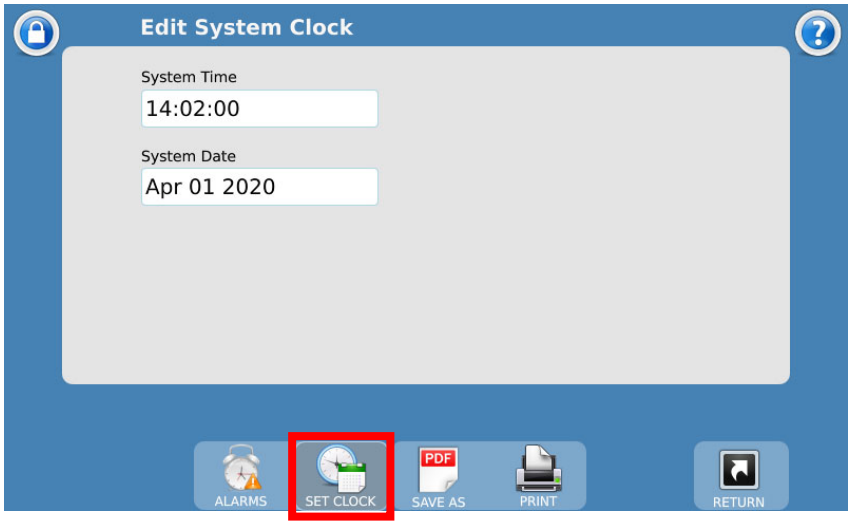
9. Depending on the autosampler type, select either the ‘AutoPlus DissoScan’ or ‘AutoPlus Maximizer’ for the ‘Sampling Mode’.

10. Enter the corresponding sampler ID’s to be associated with the samplers.

11. Press the ‘Return’ button when done.

12. From the CD14 Tester main screen, touch the menu button and select the ‘Time/Alarms’ option.

13. Touch the ‘Set Clock’ toolbar button and adjust the system time and date. Touch ‘Return’ to exit back to the main screen.



NOTE: When a CD AutoPlus is configured in the sampling mode (as was done above), the CD14 Tester will also set the clocks of both samplers.

Verifying Syringe Functions

This section provides instructions on how to verify that the syringe drive is functioning properly.

1. From the CD AutoPlus Home screen touch anywhere on the screen to enter the menu screen. Note: Access to the menu screen of the CD AutoPlus is restricted once ‘Security’ is enabled in the CD14 Tester.

2. Once in the menu screen, touch the ‘Tools’ button.

3. The Automatic Syringe Control screen will appear.
4. Touch the Manual (syringe) button located at the bottom of the screen. The Manual Syringe Control screen will appear.

5. Touch the Volume field to bring up the numeric keypad.

6. On the numeric keypad, touch 5 and then OK to enter a volume of 5.0.

The Manual Syringe Control screen will reappear.

7. Touch the green arrow button ( ) located in the center of the display to perform a transfer. Ensure that the syringes go down and then return to the home position.

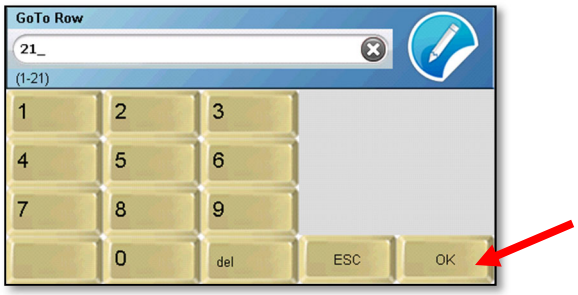
Verifying Collector Functions

This section provides instructions on how to verify that the collector is working properly.

1. Starting from the screen in the previous step 5 of “Verifying Syringe Functions”, touch the Collector button located at the bottom of the screen. The Collector Controller Menu will appear.

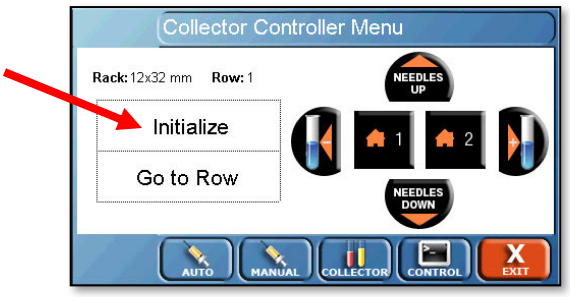
Note the type of rack installed, which appears next to the word Rack: on the screen. Touch the Go to Row button.

2. If a 12 x 32 rack is installed, enter “21” and touch the OK button. If a 13 x 100 or 16 x 100 rack is installed, enter “18” and touch the OK button. The dispense head should move to the last row of the installed rack.

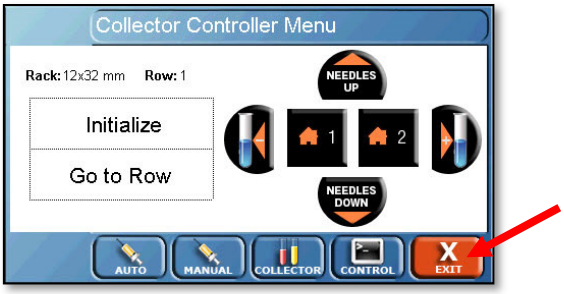


3. Touch the Needles Down button. Ensure that the needles lower properly and align with the rack.

4. Touch the Initialize button to return the dispense head to the home position.



5. Touch the Exit button to return to the menu screen.



Section F – Operation

Drive Head Movement

The CD14 Tester 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 at the desired location.

The drive head should be all the way down when running a test.

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 the need for 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.
2. Insert the threaded end of the shaft into the threaded opening at the bottom of the spindle shaft.
3. Rotate the shaft counterclockwise until the outer rim of the shaft contacts the spindle shaft. Snug the two together by hand.
4. 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.

Figure F-1: Shaft Clamp and Key in Position

Vessel Installation

1. Lower the vessel into place in the vessel bushing.
2. Rotate until the keys on the vessel slide into the groves on the vessel ring and then rotate the vessel clockwise until it stops. Note the witness marks. The vessels will only go in one way.

Configuration and Programming

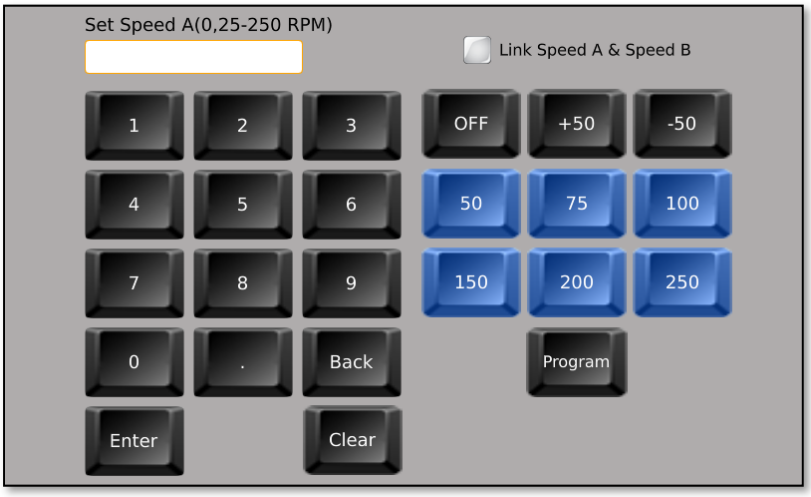
Main Screen

The main screen displays instrument status information regarding the current speeds (side A and B), current bath temperature and test status (elapsed time, next sample time, etc.).

NOTE: The left side is side A, and the right side is side B.

Manually setting speed and temperature

The speed and temperature may be set directly by touching the status speeds and temperature readings. Enter the desired speed or temperature using the keypad. Program often used values into the blue keys using the ‘Program’ button. The set points for both side A and side B speeds can be linked using the checkbox.



Main toolbar

The main toolbar gives the user access to the following:

Methods: Select/view/edit instrument methods.

Tools: Access user tools such as adjusting temperature probe readings and magazine calibration.

Run/Stop: Run/stop a dissolution method.

Vessels: View/print vessel temperatures.

Main menu

The main menu gives the user access to the following:

Config: View/edit instrument configuration, labels, accessories.

Security: View/edit instrument users and security configuration.

Diagnostics: Run instrument diagnostic tasks.

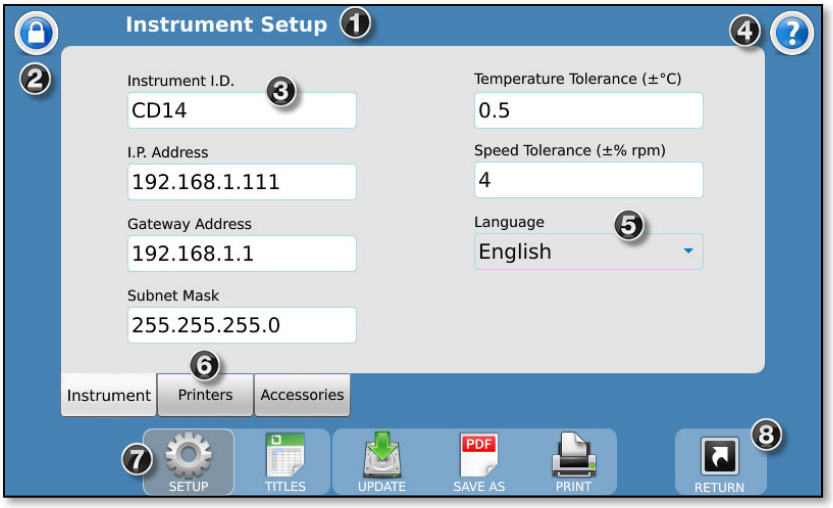
Display: Configure instrument display settings. Calibrate touchscreen.

Time/Alarms: View/edit instrument real time and alarms.

Info/Logs: View instrument information such as event logs, instrument errors, test reports, serial numbers, and service logs.

User Interface Screens

The typical user interface screen has a common look and function. The numbers below highlight these common features.



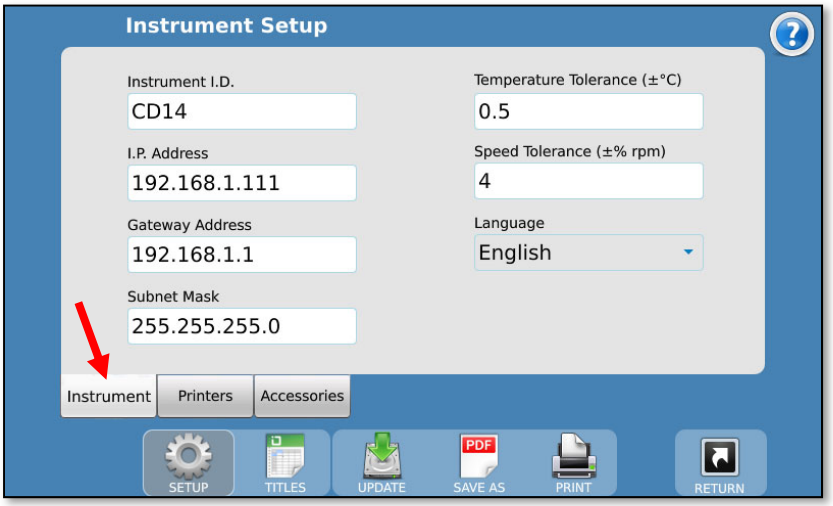
User Interface Screen Features		
#	Name	Description
1	Screen caption	Descriptive title of the main function or content of the screen.
2	Security icon	When visible, instrument security is enabled, and user activity is restricted to user security access.
3	Input field	Displays the name and value of a field. White background signifies that the user may touch the field to edit the value displayed.
4	Help icon	When touched, displays context-sensitive help for this particular screen. This may involve detailed descriptions and tips for the screen.
5	Read-only field	When grayed, user can only view the value of the field but cannot edit it. A field may not be editable by design or because of restricted user access.
6	Screen tabs	Access to additional related sections.
7	Toolbar icons	Access to tools or related screens. These icons may also be grayed out depending on security settings.
8	Exit/return	Exit/return to previous screen.

Instrument Setup

The Instrument Setup screen is accessed by touching the Setup button at the bottom of the configuration toolbar. This screen allows the user to view/edit/print the instrument configuration. This includes network settings, printers, accessories, and report titles.

Instrument tab

The Instrument tab allows for the configuration of the instrument ID and network communication settings.



Instrument ID: The instrument identification will appear on the header of various printouts. This identifies the source instrument of the information. The system ID is limited to 25 characters.

I.P. Address: The internet provider address is a numerical label assigned to each tester communicating through the network.

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.

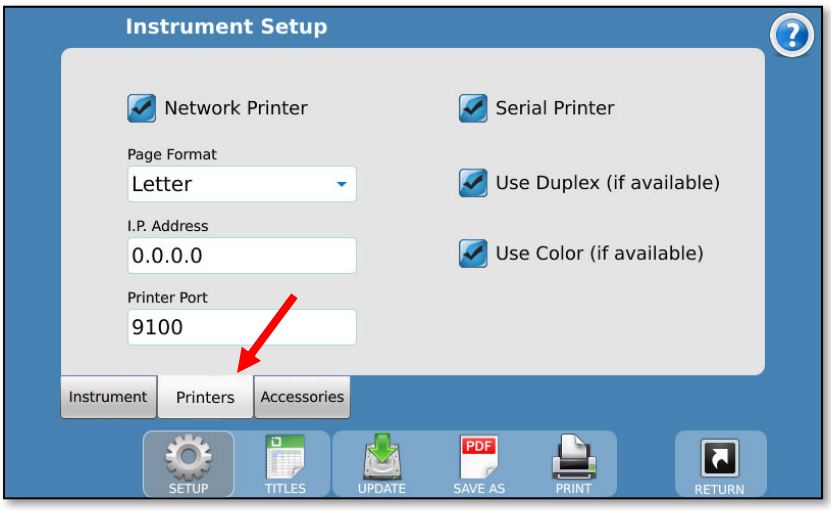
Temperature Tolerance: Temperature tolerance when a method is not running. The default value is ± 0.5 °C. The range is 0(off), 0.1 to 5.00 °C.

Speed Tolerance: Drive speed tolerance when a method is not running. The default value is ± 4% of the set point. The range is 0 (off), 1 – 10%.

Language: Primary user interface language. Currently English is the only language available.

Printers tab

The Printers tab allows the user to configure the printer(s) the CD14 Tester instrument will use.



Network Printer: Selected when a network 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 PC software drivers or do not support PostScript will not work. Only the Epson serial printer provided by Teledyne Hanson is supported. Both network and serial printers may be enabled at the same time.

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

NOTE: Setting the wrong paper size may omit lines from the printout.

I.P. Address: For use when printing to a PostScript-capable network printer. 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). The default is 9100.

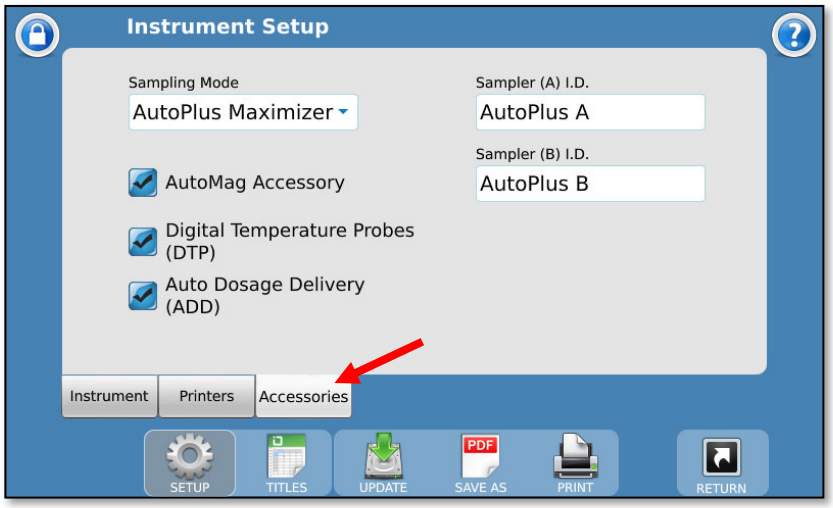
Use Duplex (if available): This allows for printing on both sides of a page if a network printer supports this option. Network printers which do not support duplex printing will print normally even if this is selected.

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 selected.

Serial Printer: Selected when the Epson serial printer provided by Teledyne Hanson is connected.

Accessories tab

The Accessories tab allows the user to define the accessories installed on the CD14 Tester and accessories connected to the system.



Sampling Mode: How sample aliquots are collected.

- Manual: if collected by hand.
- AutoPlus DissoScan or AutoPlus Maximizer: if using one of the two versions of autosamplers for the CD14 Tester.

AutoMag Accessory: Selected when the CD14 Tester magazines are connected to the instrument.

Digital Temperature Probes (DTP): Selected when digital temperature probes are connected to the instrument.

Auto Dosage Delivery (ADD™): Selected when auto dosage delivery flask covers are installed in the instrument.

Titles Button

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

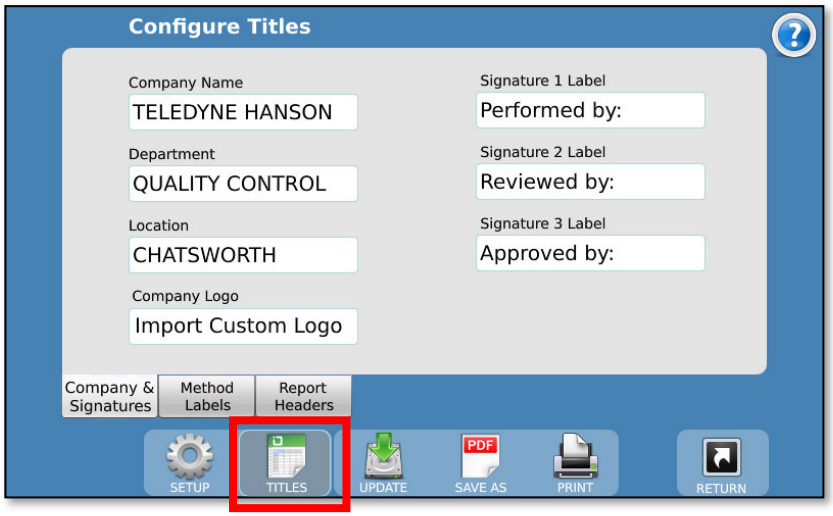
To edit any of the information, touch the field and enter the new title of the desired field. Titles are limited to 25 characters in length. For example, if instead of “Method I.D.” the user wanted the field titled “Lab Notebook”, the user would touch the field for “Method I.D” and enter the text “Lab Notebook.” This would change the field name to Lab Notebook in all methods. This works the same for the fields in report headers.

Company Name: This is the name of the company that owns the CD14 Tester.

Department: The department that controls the instrument.

Location: The location of the instrument.

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



How to import a custom logo

1. Prepare a jpeg image that meets the following requirements:
   - No more than 100 pixels wide by 50 pixels high
   - 96 dpi
   - File size 15 KB or less

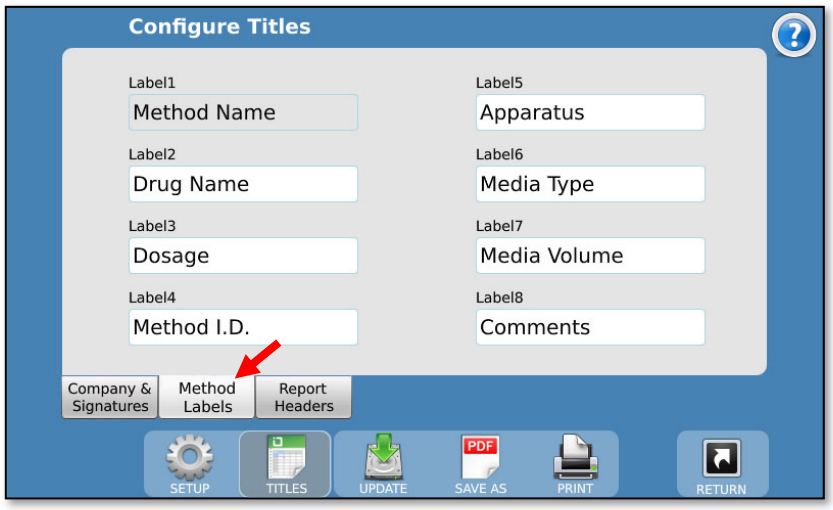
- Named ‘logo.jpg’

2. Load the image into the root directory of a USB flash drive.
3. Insert the USB flash drive into the USB port next to the fingerprint scanner of the CD14 Tester instrument.
4. Touch the Logo field to load the logo into the instrument.

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

Method Labels tab

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



The default values are:

Method Name: This field always contains the method name and cannot be changed.

Drug Name: The name of the drug the method is designated to test (e.g., Aspirin).

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

Method ID: A secondary ID for the method; this does not need to be unique.

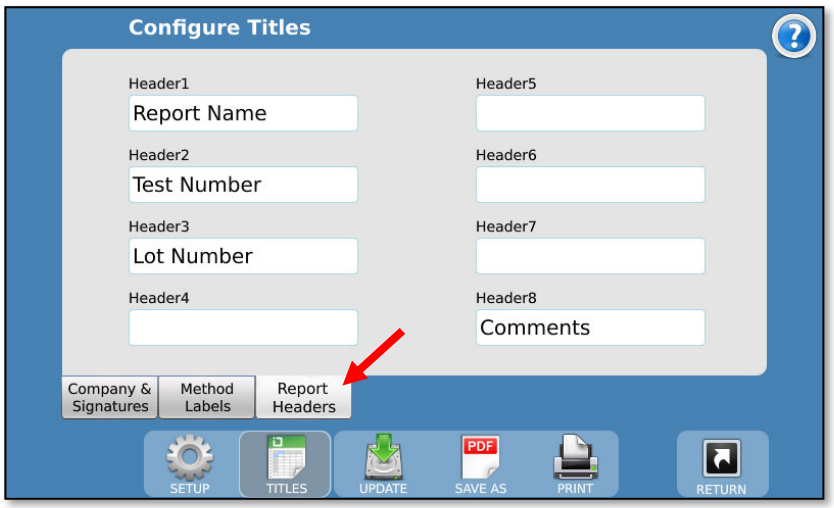
Apparatus: Lists the apparatus used for the testing (e.g., paddles, baskets, paddle over disk).

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).

Report Headers tab

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



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

Report Name: The name of the current report. This label may be changed but the report name will always be put here.

Test Number: A test number 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.

Firmware Update

The firmware update feature is accessed by touching the Update button from the toolbar at the bottom of the screen. The firmware update feature allows an operator (with the proper permission) to update the firmware of the CD14 dissolution tester.

Firmware updates are available as firmware update kits which contain update instructions as well as version release history. Please follow the instructions included with the kit.

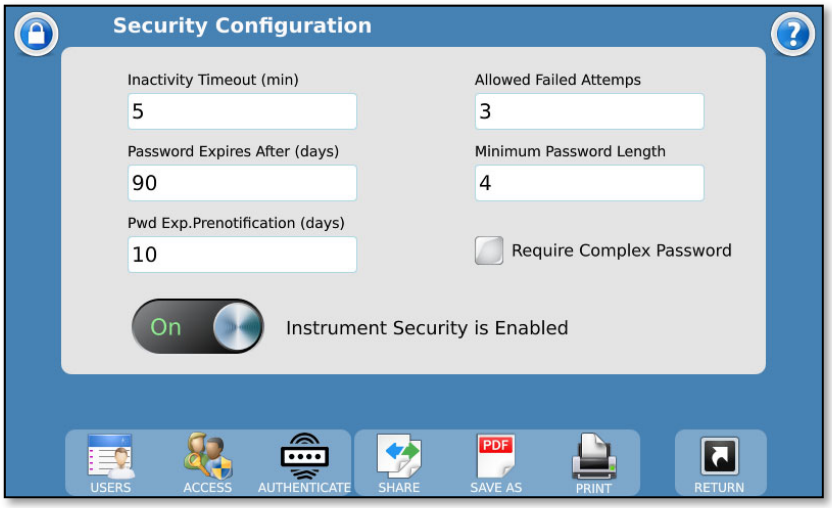
Security

The Security button on the main menu allows the user access to the Security Configuration screen.

The CD14 Tester can be configured to require users to log in and allows for tracking of any changes made to the method. The security system allows for three types of users (administrators, managers, and operators) and can accommodate up to 100 users.

User Hanson is installed as a manager from the factory. The default password for the Hanson manager is 0000.

Security On/Off Switch: Enables/disables security for the instrument if the user has security settings access. Security is disabled from the factory by default.



Inactivity Timeout: A configurable period during which a user can be idle (that is, not interact with the touchscreen) and remain logged in his/her session. After this period, a user must log back in to continue working with the instrument. The range is 0 – 60 min.

Password Expires After (days): A programmable length of time after which a user must change his/her password. The previous password will not be accepted. The range is 1 – 365 days.

Password Expiration Prenotification (days): A programmable length of time before a user's password expires that a reminder regarding the upcoming expiration will be given. The range
is 1 – 30 days.

Allowed Failed Attempts: The maximum number of tries that a wrong password can be entered consecutively before a user is locked out of the instrument. A user with security access must unlock a user that has been locked out. The range is 1 – 10.

Minimum Password Length: The minimum length of a password that will be required of the user when entering a new password or changing an existing one. The range is 4 – 25.

Require Complex Password: When selected, the instrument will require passwords that have at least an uppercase letter, a lowercase letter, a number, and a special character.

NOTE: Enabling this feature does not affect existing users until they change their existing passwords.

The security toolbar gives users with proper permissions, access to user management, user access (permissions) management and password/biometrics authentication.

Share button

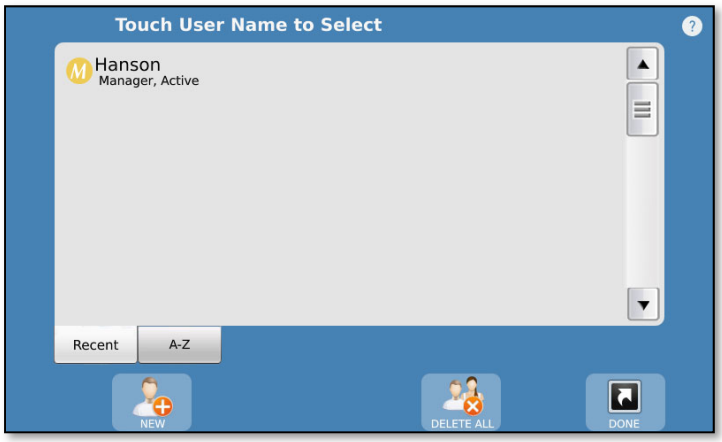
This feature allows exporting and importing the security configuration and users between CD14 instruments. Note: Importing the security data completely replaces the configuration and users in the destination instrument.

Authenticate button

This feature is used to add user authentication such as password and fingerprint detection. Once security is enabled, an existing user may use this wizard to enter or change his or her password and fingerprint scan for authentication. Passwords and fingerprint scans allow the user to log into and use the instrument when security is enabled.

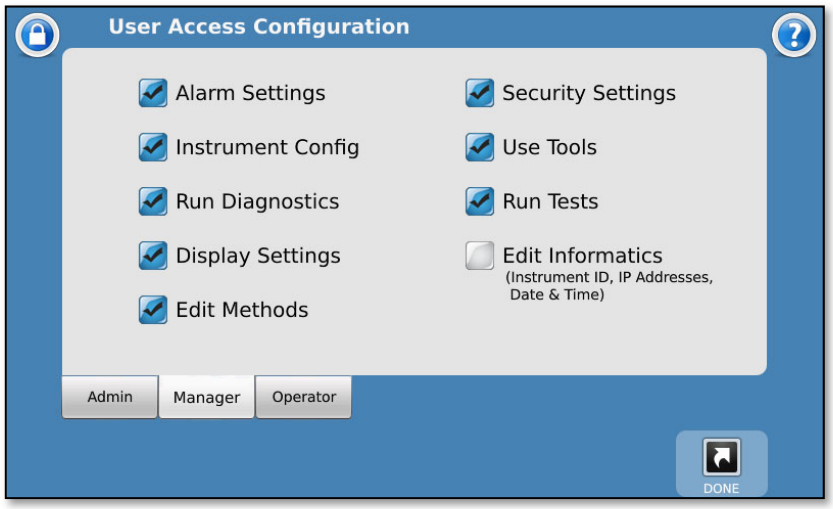
Users button

This screen allows a user with security settings access to manage instrument users. The list of users includes user type and current status (active/locked).



Access button

This button accesses the User Access Configuration screen.



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 and volume, and recalibrate the screen.

Edit Methods: Allows the ability to edit, create, import, and export methods.

Security Settings: Allows the configuration of security settings, adding/removing users, and adjusting access levels. At least one group must have this permission.

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

Run Tests: Allows the ability to run a test from a method. Methods can be viewed and printed by all active users.

Edit Informatics: Allows the editing of the system time, date, Instrument ID, and network configuration settings.

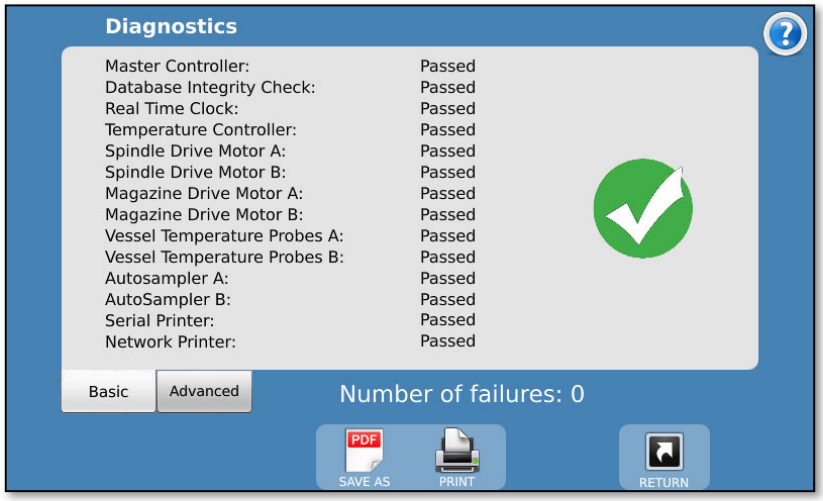
By default, these are the user access (permissions) settings:

User Access Settings			
Task/User Type	Admin	Manager	Operator
Alarm Settings		X	
Instrument Config		X	
Run Diagnostics		X	X
Display Settings		X	X
Edit Methods		X	
Security Settings		X	
Use Tools		X	X
Run Tests		X	X
Edit Informatics	X		

Diagnostics

The Diagnostics button on the main menu launches the CD14 Tester's diagnostics screen. 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/Logs screen (from the main menu).

NOTE: For a list of errors and possible causes/remedies, refer to appendix A of this user guide.

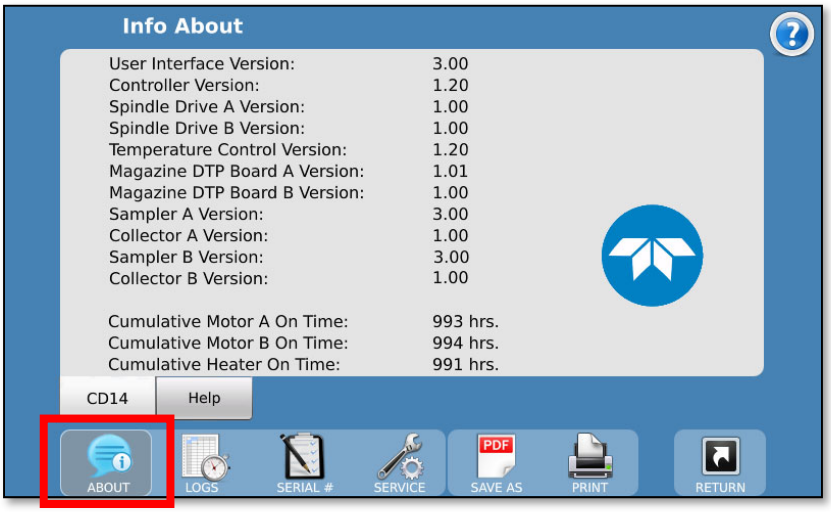


Information

The Info/Logs button on the main menu allows access to various system logs and other basic information about the CD14 Tester. Touching Info/Logs brings up the Versions screen.

Versions screen

The Versions screen provides information on the software installed on the CD14 Tester. This screen is accessed by touching the About button.



User Interface Version: User interface firmware version.

Controller Version: Main controller firmware version.

Spindle Drive (A/B) Version: Motor drive firmware versions.

Temperature Control Version: Temperature control firmware version.

Magazine Board (A/B) Version: Magazine board firmware versions.

Sampler (A/B) Version: Autosampler firmware versions.

Collector (A/B) Version: AutoFill collector firmware versions.

Cumulative Motor (A/B) On Time: Cumulative motor on time on the instrument motors.

Cumulative Heater On Time: Cumulative time on the instrument heater.

Help tab

Additional help information and links.

Instrument Logs screen

The Instrument Logs screen can be accessed by touching the Logs button from the toolbar at the bottom, and provides access to the event, test, and error logs by touching the respective tabs. All logs have up and down arrows on the right side which allow the user to scroll the log data up and down.

Events Log: This log records important instrument activity. This includes, but is not limited to, parameter changes, user logins, running diagnostics, changes to settings, or editing of methods.

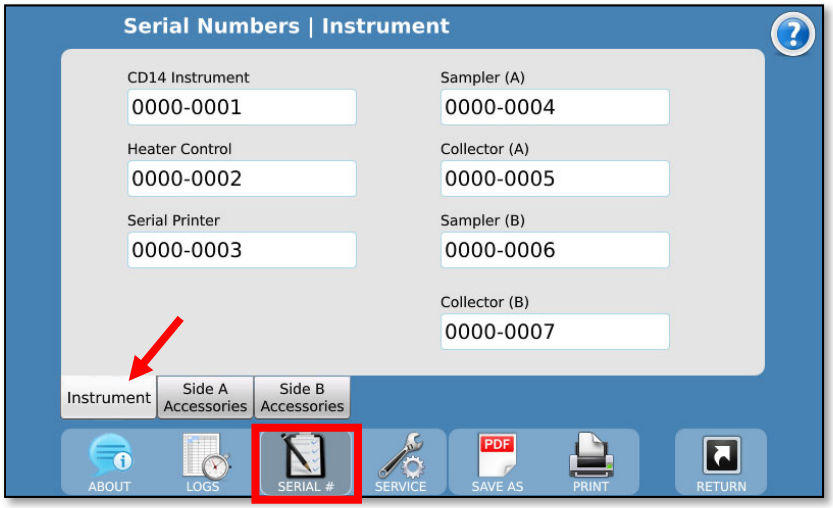
Test Report/Test Report B: This log lists all the actions that occurred during the last test. The log is transferred to the test history log when a new test starts.

Errors Log: This log lists system errors that occur on the unit. This can include communication issues, diagnostic failures, or other 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 previous instrument test reports. It allows the user to select the test based on method name, time, and date, and to reprint the report.

Serial Numbers screen

The Serial Numbers screen allows the user to enter the serial numbers of the components installed in the CD14 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 with proper permission.



Instrument tab

CD14 Instrument: This is the serial number for the CD14 Tester itself.

Heater Control: This is the serial number for the heater.

Serial Printer: This is the Epson printer serial number provided by Teledyne Hanson that is connected to the instrument.

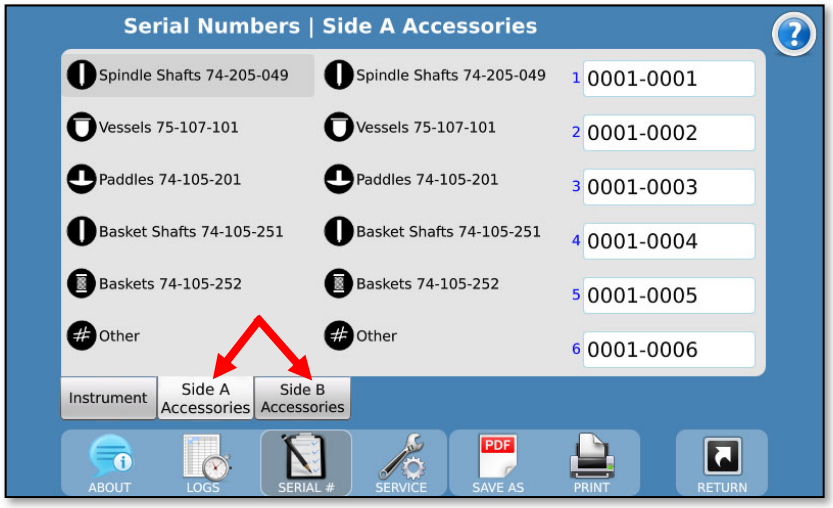
Sampler (A/B) Serial Numbers: These are the serial numbers for Sampler A (left side) and for Sampler B (right side).

Collector (A/B) Serial Numbers: These are the serial numbers for the AutoFill Collectors.

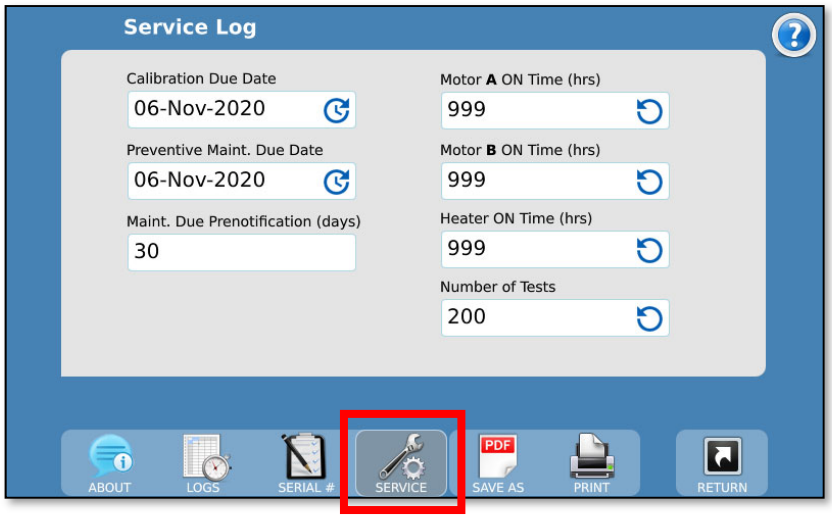
Side A/B Accessories tabs

Each of the 12 items on the tab represents a group of 6 serial numbers with their corresponding vessel positions. There are 12 groups for Side A and 12 groups for Side B.

To select a group, touch the name of the group once. The corresponding serial numbers populate the fields. To edit the serial numbers, touch the desired field. To edit the group name and icon, touch the selected group a second time.



Service Log screen



The Service Log screen is accessed by the Service button of the toolbar. Touch the appropriate field to reset the item. When resetting any of the counters, a confirmation will be requested.

Calibration Due Date: The date of the last calibration of the unit.

Preventive Maintenance Due Date: The date of the last preventive maintenance performed on the unit.

Maintenance Due Prenotification (days): The number of tests performed on the tester.

Motor A ON Time (hrs.): The number of hours on motor A and its drive belt.

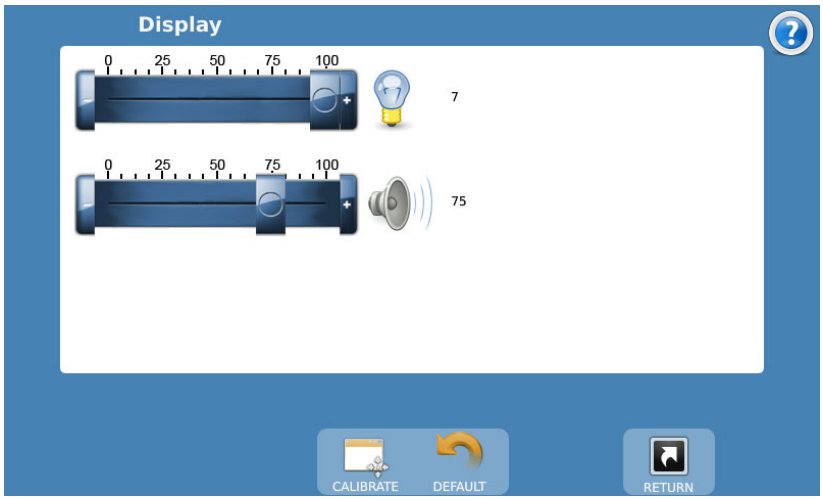
Motor B ON Time (hrs.): The number of hours on motor B and its drive belt.

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

Number of Tests: The number of tests run.

Display

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



Brightness Slider: Adjust the brightness of the screen by using the slider located next to the brightness symbol.

Volume Slider: Allows the user to increase or decrease the volume of the feedback sounds.

Calibrate Button: This button begins the touchscreen calibration procedure. It is recommended that a stylus be used for this to ensure the proper precision.

Warning: Use a stylus. Do not use sharp objects for the calibration procedure, as the screen can be seriously damaged.

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

Time/Alarms

The Time/Alarms button on the main menu provides access to the instrument notification alarms and real clock time and date.

Preheat Wakeup tab

This tab allows the user to enable a preheat wakeup alarm. When triggered, the waterbath heats to the bath temperature 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. The button brings up numeric keypad. The range is 25 – 51 °C; preset values are 32, 37, and 51 °C.

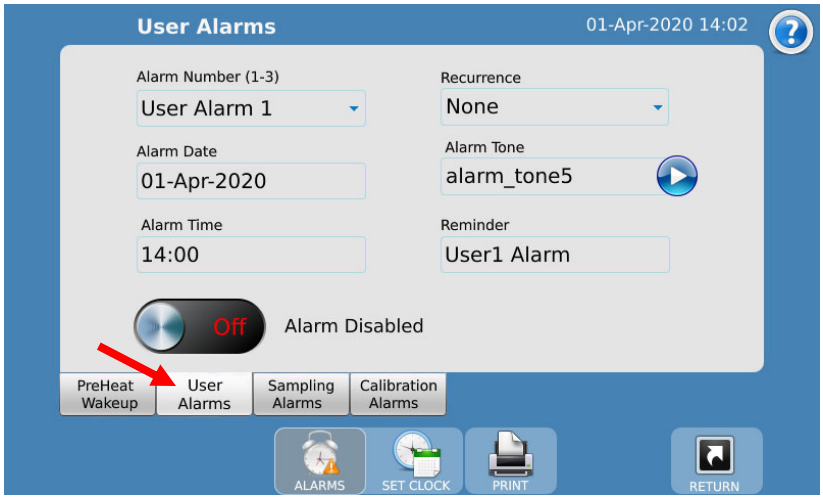
Alarm Date/Time: The date/time the alarm will begin heating the bath.

NOTE: The bath temperature is only changed if a test is NOT currently in progress.

Recurrence: The method by which the alarm repeats. Either never, at specific days of the week, or at day intervals.

User Alarms tab

User alarms are customizable alarms which can be 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 can be set to repeat.



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.

On/Off Switch: Enables/disables the user alarms.

Alarm Number: Toggles between the 3 user alarms available.

Alarm Date/Time: The date/time the alarm will trigger the reminder message.

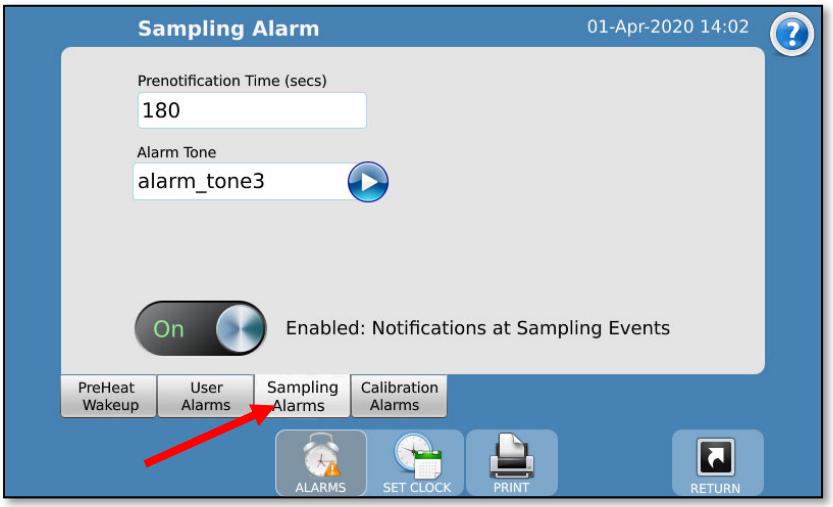
Recurrence: The method by which the alarm repeats. Either never, at specific days of the week, or at day intervals.

Alarm Tone: The tone the instrument will play when the alarm triggers. The current tone is played when the ‘Play’ icon is touched.

Reminder: The text displayed when the alarm triggers. For example, if the operator sets this to “Change Tester Bath Water” the text “Change Tester Bath Water” would be displayed when the alarm triggers.

Sampling Alarms 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 upcoming when a test is running. A message is displayed on the screen with an alarm sound.



On/Off Switch: Enables/disables notifications at sampling events.

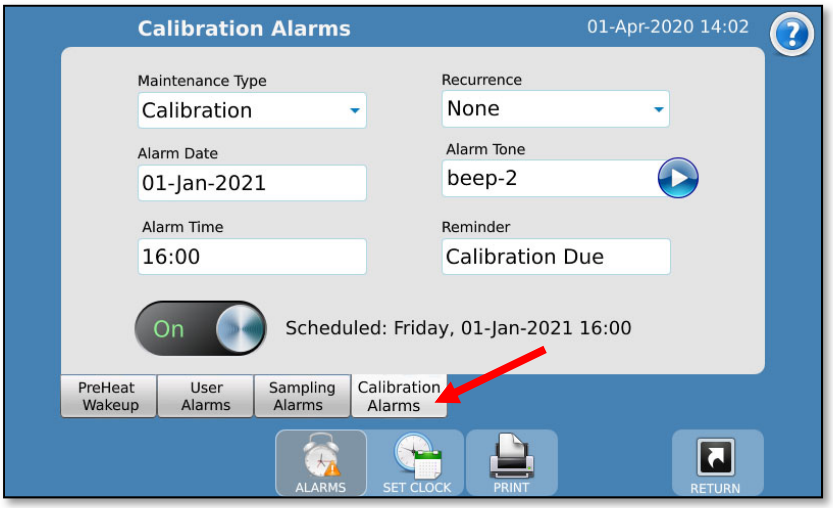
Prenotification Time: The amount of time before a sample point the alarm begins to sound. For example, if the user set the alarm to 0:01, the alarm would begin 1 minute before each sample point (0 – 9:59 in hh:mm).

NOTE: If enabled from the method, a sampling wizard appears guiding the user when to take a manual sample.

Alarm Tone: The tone the instrument will play when the alarm triggers. The current tone is played when the ‘Play’ icon is touched.

Calibration Alarms tab

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



Maintenance Type: Calibration or preventive maintenance.

Alarm Date/Time: The date/time the alarm will trigger the reminder message.

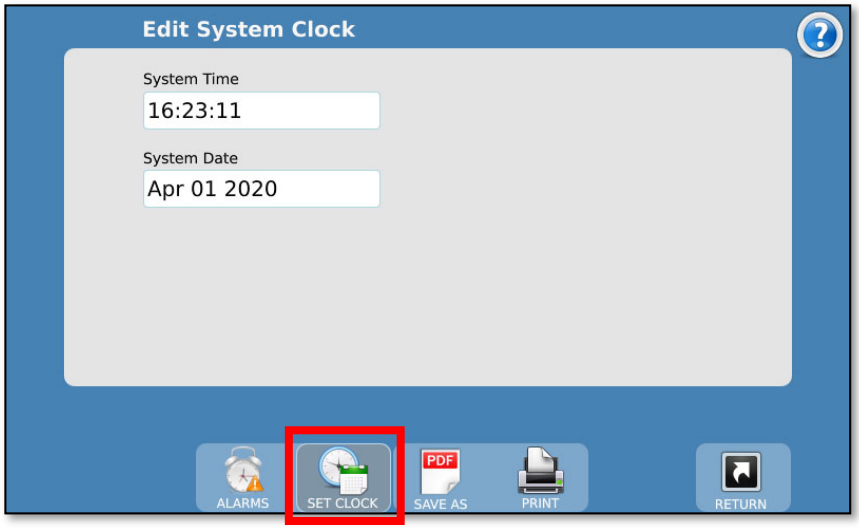
Recurrence: The method by which the alarm repeats. Either never, at specific days of the week, or at day intervals.

Alarm Tone: The tone the instrument will play when the alarm triggers. The current tone is played when the ‘Play’ icon is touched.

Reminder: The text which is displayed when the alarm triggers. The default reminders are ‘Calibration Due’ or ‘Preventive Maintenance Due’.

Edit Time/Date screen

The Edit System Clock screen is accessed by touching the Set Clock button from the toolbar. It allows the user to set the time and date on the tester.



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

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

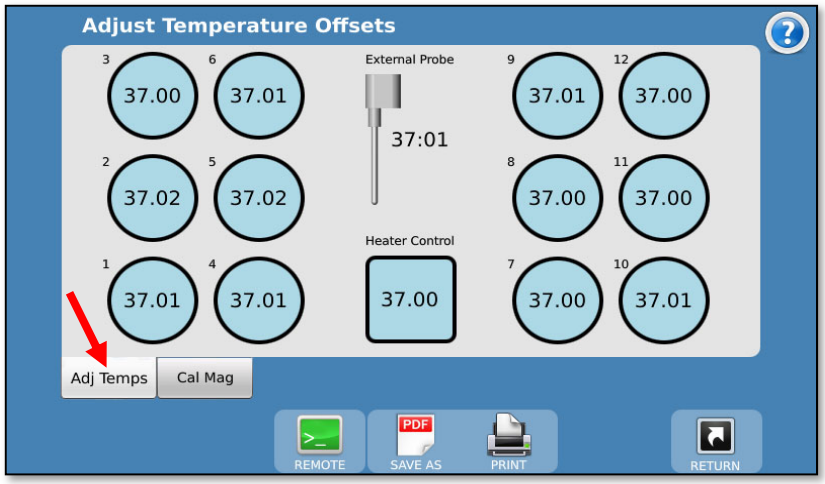
NOTE: The system clock is powered by a capacitor. If the system is left unplugged for 2 weeks, then the time and date will have to be reset. The system must be plugged in at least 5 minutes for the capacitor to reach sufficient charge to maintain the time and date when the system is powered off.

Tools Button

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

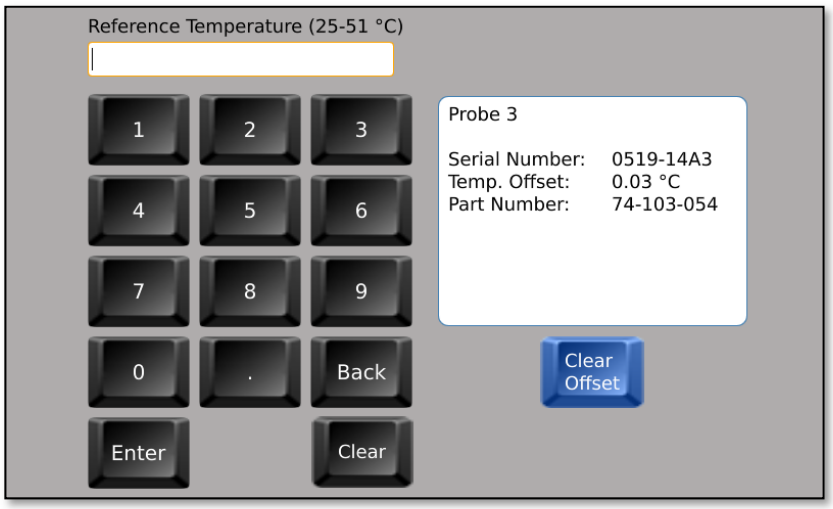
This section provides the ability to set temperature probe reading offsets and to calibrate magazine travel.

Adjust Temperatures (Adj Temps tab)



The instrument temperature probes (including those that determine the temperature control and feedback) are factory calibrated. However, each individual probe's reading may be adjusted by changing its offset value.

Touch the corresponding temperature reading and enter the corrected 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.

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

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

Calibrate Magazines (Cal Mag) tab

Touch the Cal Mag tab to access the magazine calibration screen.

NOTE: This tab only appears if magazines are selected in the configuration section.

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

Magazine ADD Travel: This field is the distance in mm from the home position to the ADD covers to implement a pill drop.

Home A/B: Homes the magazine by raising it up against the drive head then moving it down a set amount.

Up: Moves the magazine up.

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

Pill Drop: Moves the magazine down to the height to trigger Auto Dosage Delivery (ADD) covers.

Calibrate A/B: This button runs the magazine calibration procedure. The magazines are calibrated before leaving the factory and should not need to be calibrated again. However, if they do need to be recalibrated, perform the following steps from the Calibrate Magazines screen:

1. Calibrate one magazine at a time.
2. With middle vessels removed, place the calibration block across the center of the middle vessel brackets, directly beneath the magazine drive screw.
3. In the Calibrate Magazines screen, touch the Calibrate button. The magazine will move down and touch the block. The magazine is now calibrated.
4. Repeat the above steps for the other magazine.

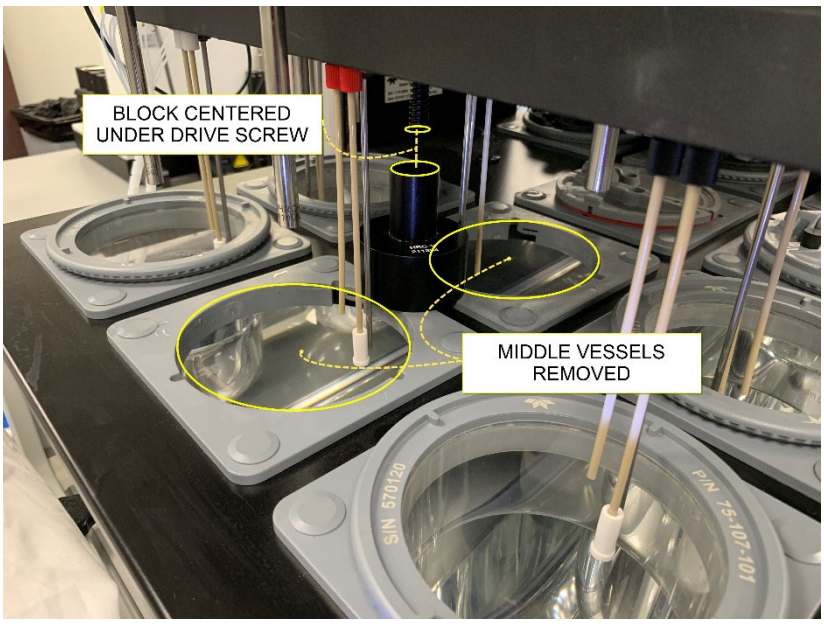


Figure F-2: AutoMag Calibration Tool in Place

Remote Command screen

The Remote Command screen is accessed by touching the Remote button from the toolbar.

This screen allows the user the ability to enter special commands used for special diagnostics and advanced features.

Warning: The Remote Command screen should only be used when instructed to by Teledyne Hanson Technical Support.

Section G – Dissolution Testing

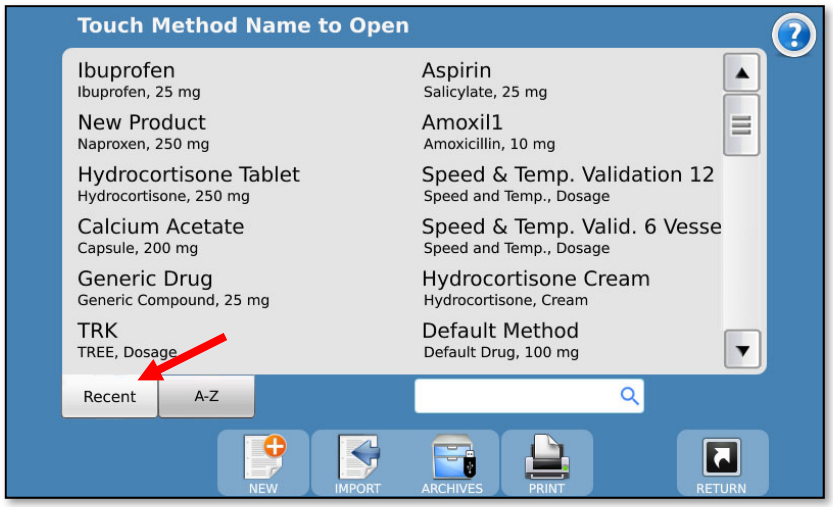
Methods

Methods can be accessed by touching the Methods button on the main screen.

Methods 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 methods can be stored.

Recent tab

The Recent tab displays the methods from the database in the order of most recently selected.



A-Z tab

The A-Z tab displays the methods in alphabetical order based on method name.

New button

Allows the user to create a new method.

Import button

Allows the user to import one or more previously exported methods.

Archives button

Allows a full backup and restore of the entire instrument database to/from a flash drive. The flash drive must be inserted in the USB port next to the touch screen. You will need to pop open the drive head cover in order to access this USB port. Backups are stored and retrieved from a folder named “Archives” in the flash drive.

NOTE: Exporting the instrument database will overwrite any existing archive in the root directory of the USB drive.

NOTE: Importing the instrument database will overwrite the existing instrument database. This task cannot be undone.

Print button

Allows the user to print the current method list.

Search/Filter box

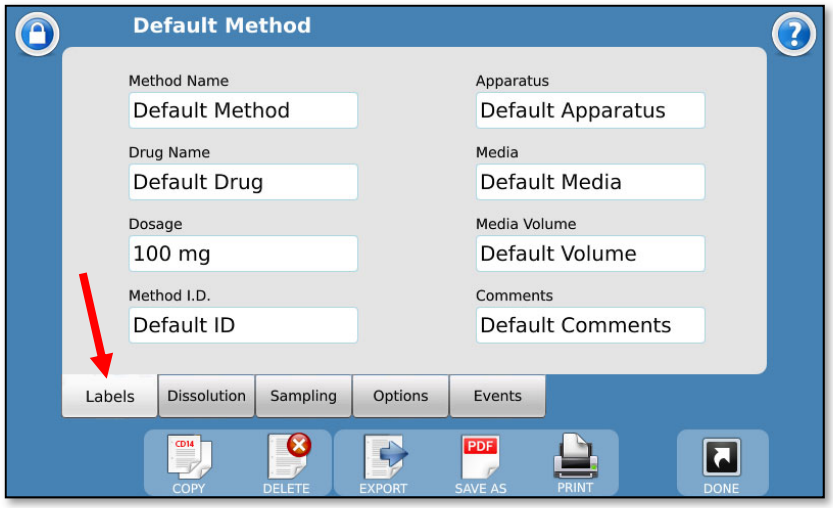
Entering a string in this field will cause the instrument to display a new screen with only the methods containing that string in the method name or in any of the fields in the Labels tab.

Method Screen

Tabs available on the Method screen are as follows:

Labels tab

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



Method Name: This is the name of the method and must be unique. The method name is how the methods are organized on the method selection screens.

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

The following field titles (e.g., Drug Name, Dosage) can also be edited by the user though the configuration settings on the title screen.

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

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

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

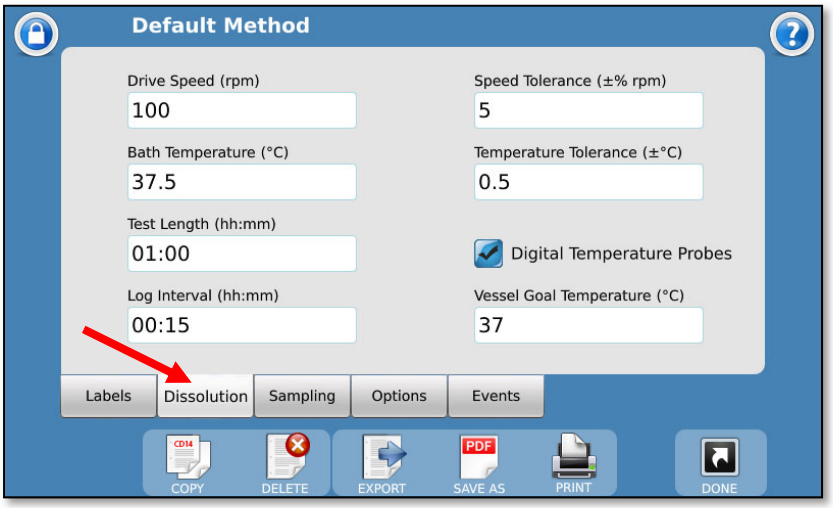
Apparatus: Lists the apparatus used for the test (i.e., paddles, baskets, paddle over disk, or apparatus number [e.g., 2]).

Media: 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

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



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

Bath Temperature: The target bath temperature of the dissolution tester. The range is 0, 25.00 - 51.00 °C.

Test Length: the total time of the dissolution test. The range is 0 – 99:00 (hh:mm).

Log Interval: The interval at which the tester status (speed, temperature, etc.) is logged to the test report. The range is 0 to 99:00 (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.

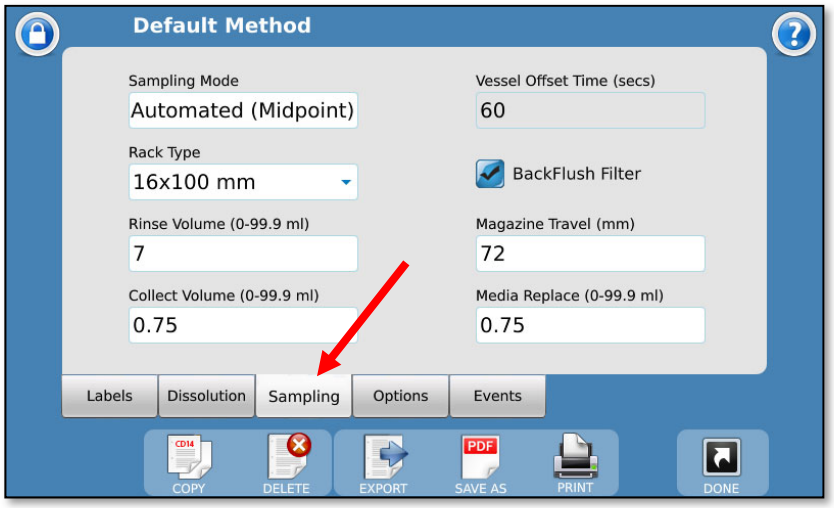
Speed Tolerance: The tolerance for the motor speed for a dissolution test. The default value is ± 4% of the set point. The range is 0 (off), 1 – 10%.

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

Digital Temperature Probes: When checked, allows vessel temperature probes mounted on the AutoMag of the CD14 Tester to be monitored during the test.

Vessel Goal Temperature: The desired temperature of the vessels. This option is only applicable when the Digital Temperature Probes field is set to Enabled. The range is 0 (off), 25.00 to 51.00 °C.

Sampling tab



Sampling Mode: determines the type of sampling procedure:

- 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 Vessel Offset Time field.
- Automated (At Point): In At Point mode, the syringe begins loading the sample volume (collect volume) within a few seconds of the programmed sampling time point. All rinse and backflush-filter operations (if any) will occur before the programmed sample time.

- Automated (Midpoint): In Midpoint mode the instrument calculates how long it will take to load the sample, and then it adjusts operations such that the midpoint of the complete sampling cycle occurs at the specified sample time point. In this mode the syringe will begin to load the sample just prior to the programmed time point such that the midpoint of the cycle will fall within a few seconds of the specified sampling time. For example, if the sample collect volume is 8 ml, and Midpoint mode is selected, then at the programmed sample time point about 4 ml of sample will already have been loaded into the syringe. If the sample (collect volume) is larger than 10 ml, the calculated duration of the complete sampling cycle will include the time needed to dispense the full syringe before the rest of the sample is loaded.

Rack Type: The type of rack used for sample collection during the test. Options are 16 x 100 or 12 x 32.

Rinse Volume: The amount of volume pumped before collection is done. The range is 0 – 99.9 mL. This volume should be large enough to ensure that old material in the sampling lines is rinsed to ensure the sample collected is representative of what is in the vessels of the tester. This parameter applies only in automated sampling mode. The default value is 7 mL.

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 parameter applies only in automated sampling mode.

NOTE: If the collect volume is larger than the capacity of the test tube or the vial, the sample will be collected into multiple rows of vials or test tubes.

Vessel Offset Time: In manual mode, the dosage is dropped and the vessels are each sampled sequentially, by this fixed interval. The vessel offset time should be long enough to allow for the user to sample a vessel and get ready for the next one. After the test length elapses, the stirring time is extended by the vessel offset time times the number of vessels (6 or 12). Vessel offset time is not used during automated sampling as the dosage is dropped and the samples are taken simultaneously.

Magazine Travel: This parameter defines magazine stroke from home to the sampling position. The range is 0 (disabled) to 105 mm.

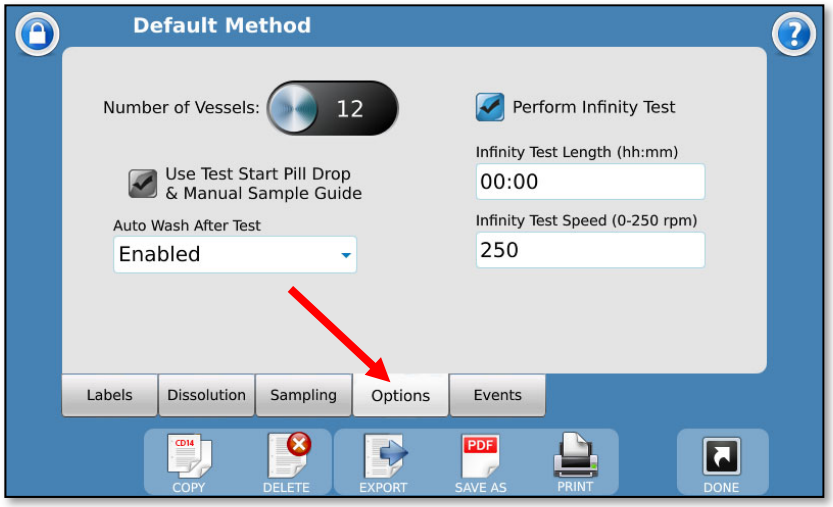
NOTE: The travel values may require fine tuning as necessary to account for additional distance that may be needed due to tip filters.

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.

Generally, the media replace volume should be set to be the same as the total of the rinse volume and the collect volume.

Options tab

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



Number of Vessels: the number of vessels that will be used during the test. The options are 6 or 12.

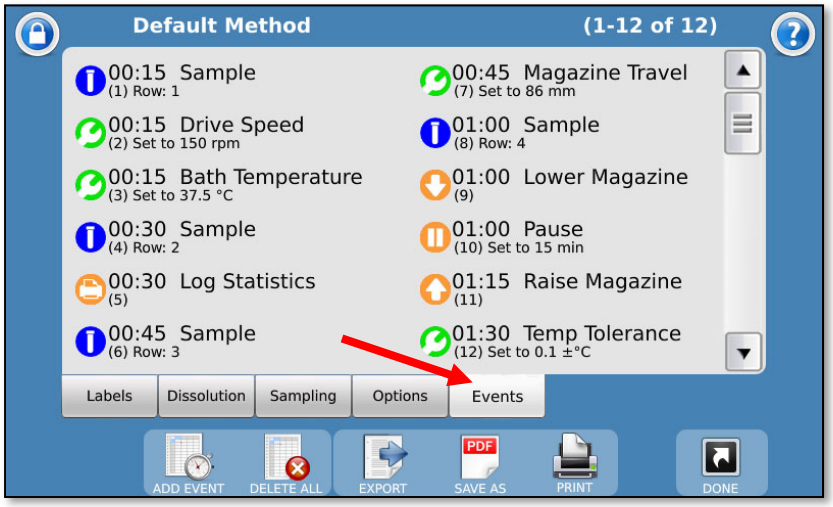
Perform Infinity Test: If checked, performs an infinity test with the designated infinity test length and infinity test speed.

Infinity Test Length: The length of the infinity test which follows the dissolution test. The range is 0:00 to 9:59 in h:mm format.

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 events that will take place at user-programmed times. There are three types of events: sampling, set parameter and action. Sampling events must have a time assigned to them. 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.

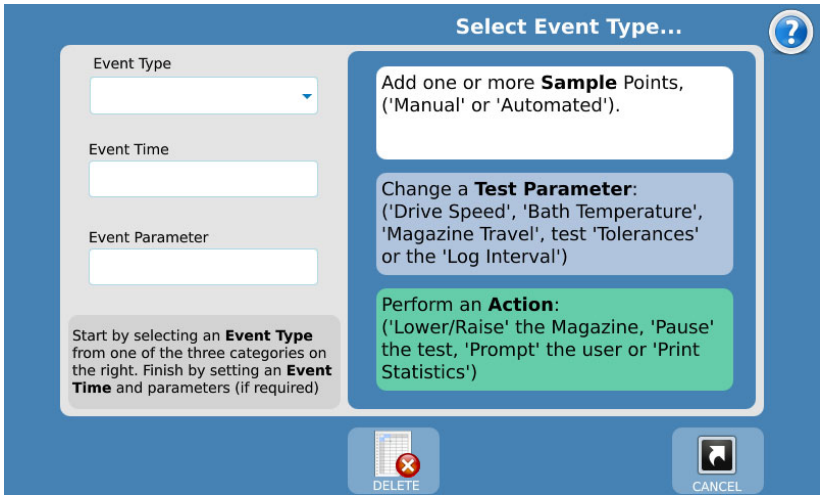
For example, an operator programs a post-run event of Bath Temperature for 40 °C. Once the test completes, the bath temperature will be set to 40 °C.

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 method, touch the Delete All button.

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

Add Event screen



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

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

How to Start a Test

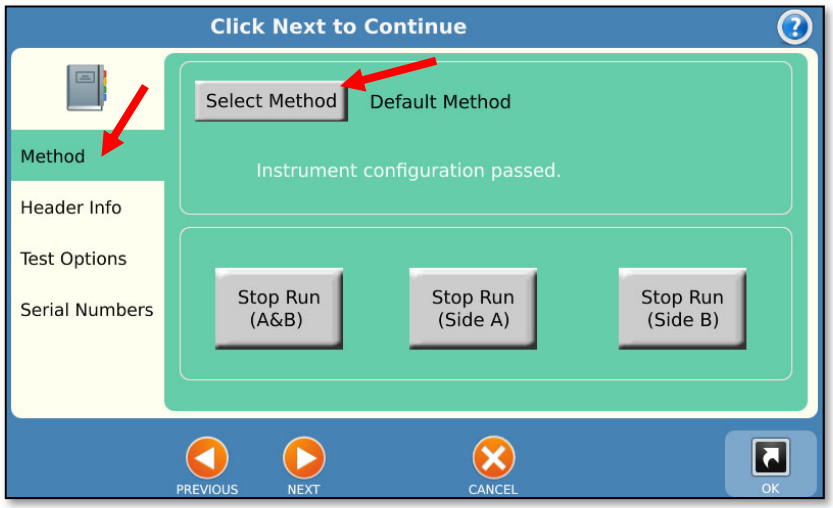
1. Run button

   To start a test, first begin at the main screen and touch the Run button on the toolbar.

2. Method tab

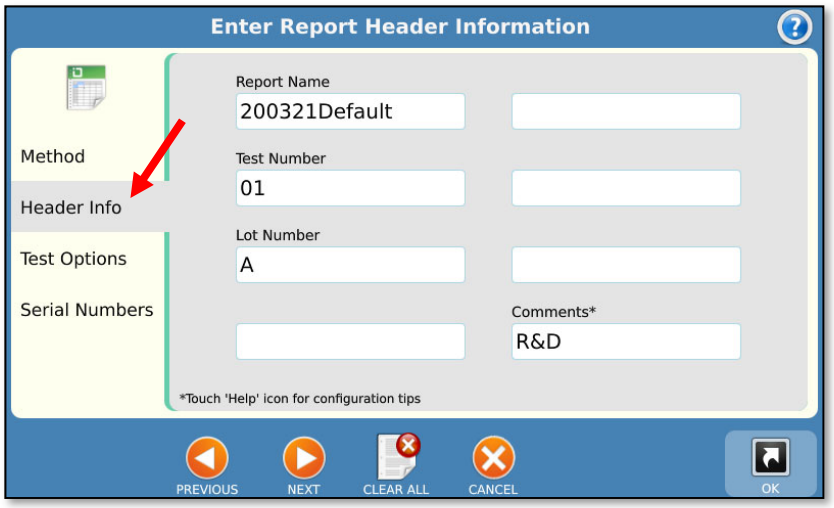
   Touch the Method tab and then the Select Method button. Select the desired method from the list. The method selected is matched against the current instrument configuration for compatibility.

   NOTE: this screen is also used to abort a test that is currently running.



3. Header Information (Header Info) tab
   a. Enter information specific to the test run in the header information screen
   b. Touch ‘Next’ to continue.

      NOTE: The labels for the headers can be changed through the configuration screens.



The default fields are:

Report Name: Allows the user to enter a final report name. By default, the report name is a timestamp plus the method name.

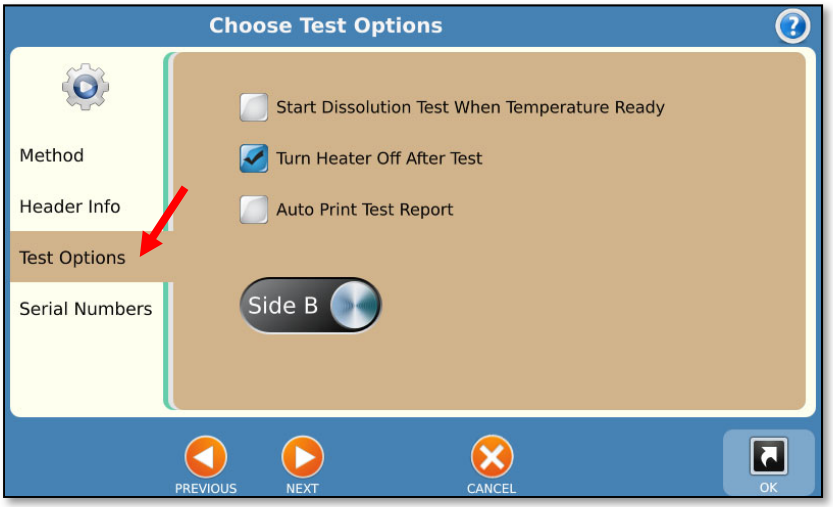
Test Number: Allows the user to input the lot number of the item being tested.

Lot Number: Lot number associated with the test run.

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

4. Test Options tab

   Select the options as appropriate for the test.



The following options are available on the Test Options screen.

Start Dissolution Test When Temperature Ready: Starts the test when the bath temperature is within specification. Requires automation.

Turn Heater Off After Test: This option causes the CD14 Tester instrument to turn off the heater at the end of the dissolution test in order to reduce power consumption.

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

Side A | Side B: This option is available to 6-vessel methods and determines which side A (left) or B (right) of the instrument will be used.

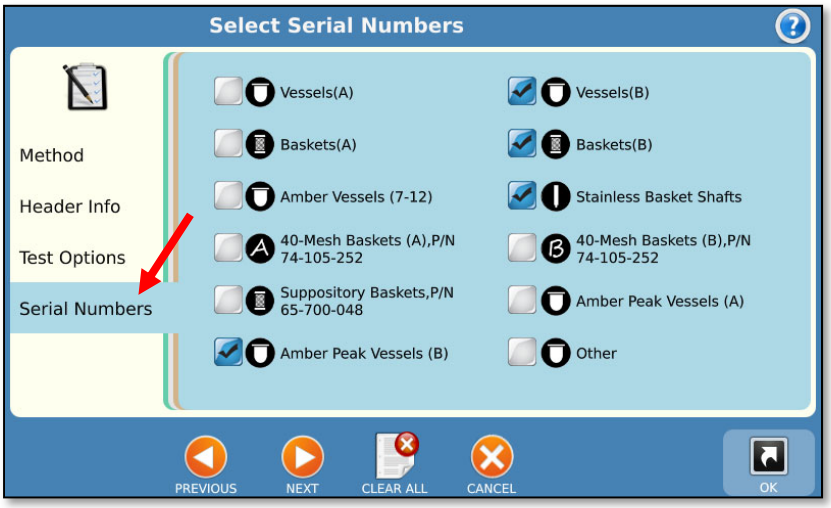
5. Serial Numbers tab

   a. Select the accessories that will be used during the test including vessels, baskets, paddles, etc.

   b. The serial numbers for side A and side B will be in separate windows.

      NOTE: The serial numbers of the items selected will be included in the final report.

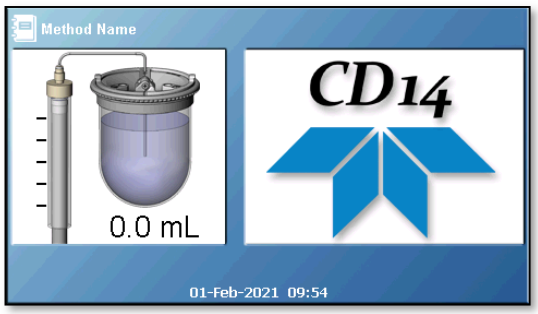
   c. Touch the ‘OK’ button to exit.



6. Start a Sequence prompt

   When the bath / vessel temperature is within tolerance, the user is prompted to start a sequence where he or she is prompted to establish time zero and drop the dosages in each vessel as per the vessel offset time established in the method.

7. If using the CD AutoPlus, the CD AutoPlus screen will switch to showing the method name and syringe position.



Manual Staggered Start with CD14 Tester

1. On the tester, touch the temperature to bring up the Temperature Setpoint screen. Enter the desired bath temperature (+ 0.10 °C of the desired vessel temperature is recommended) and touch OK.
2. Raise the drive head to its highest point.
3. Fill the vessels with media.
4. Prepare the apparatus:
   a. Baskets
      i. Raise the spindle shafts to their highest point.
      ii. 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. The CD14 Tester 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. The CD14 Tester drive head should be lowered.
      iii. Cover the vessels and allow the media to stabilize.
5. Once the media has stabilized start the method procedure described below.

6. Prepare the dosage:
   a. Baskets
      i. Place the dosage in each of the baskets and install the baskets on the basket shafts.
      ii. Lower the drive head to the testing position with all 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 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 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. 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.

Section H – CD14 Tester Maintenance

Scheduled Maintenance Overview

Spills

Immediately clean up any spills.

After Each Test

Wipe down the system with a clean damp cloth when finished. Pay close attention to the vessel plate and clean and dry any spills.

Clean baskets, basket shafts, paddles and vessels as needed. Avoid harsh or abrasive materials which may cause damage to these parts. It is best to dry these items right away, so they don't stain.

Weekly

Check bath water level and fill if needed.

Inspect bath water for algae or other contaminants. Drain and replace if necessary. If bath water develops algae in less than 3 months make sure to clean the bath very thoroughly.

Every 6 Months

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

Check the temperature and motor speed for accuracy.

Inspect the spindles for smooth rotation.

Annually

Inspect the drive belts and idler pulleys.

Inspect the O-rings, they should not be dried or cracked.

Every Two Years

Replace the drive belts.

Replace the O-rings.

O-Ring Inspection and Replacement

To replace O-rings, use the O-ring replacement tool (74-107-003).

1. 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.
2. 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.
3. 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.

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

Belt Replacement

Teledyne Hanson recommends replacing all belts at one time.

1. Grasp the drive head cover on both sides and lift straight up to remove the cover.
2. Use a 5/32 hex key to loosen the tensioners – do not remove the tensioner.
3. Loosen and remove all belts from the spindles.
4. The two small belts going to the center positions may require the pulley to be loosened and lifted from the spindle to change the belt.
5. Route the new belt around the spindles and tensioners in the same manner as the old belts.
6. Readjust tensioners. All belts should have about 6 – 10 mm of deflection before they become tight. Test this by pushing with your finger in-between pulleys.
7. Replace the cover and then press down until it pops back into place.

Draining the Waterbath

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

Insert the drain hose in the drain connector on the front left of the bath. The bath will completely drain approximately 42 L (11 gal).

Guidelines for Cleaning the Waterbath

It is recommended that the bath be cleaned in place.

With a little water in the bath use a soft cloth and wipe the inside of the bath. Rinse the bath with water and let it drain to remove foreign material. The better the bath is cleaned the longer it will stay clean.

Do not use coarse or abrasive materials. They may scratch the bath. Alcohol based products can cause the bath to crack.

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

Adjustments and Calibration

Spindle Shaft Height Adjustment

1. Install the paddle into the spindle shaft.
2. Lower the drive head and place a height set gauge in the bottom of the vessel.
3. Using a hex key, loosen the bolt on the spindle shaft clamp.
4. Gently adjust the shaft up or down so it rests on top of the height gauge.
5. Tighten the spindle clamp using the same hex key.

Heater and Temperature Probe Adjustment

1. Place an NIST traceable thermometer next to the temperature probe, or in the exit port on the left side of the bath if adjusting the bath temperature probe.
2. From the main screen, touch the Tools button on the main toolbar.

3. Touch the Adj Temps button at the bottom of the screen.
4. Touch the probe you want to calibrate.
5. Use the numeric keypad to enter the temperature displayed on the NIST traceable thermometer, then touch OK.

Moving and Storage – CD14 Tester

If the CD14 Tester will not be used for a short period of time (3 days or more), 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, the bath drained, and the tester 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.

Five people are required to lift the CD14 dissolution tester. Lifting should be done with two people situated on each side of the instrument. Lift the equipment by the base frame using the screw-in handles provided.

Warning: Lifting without assistance may cause injury.

Section I – CD AutoPlus Maintenance

Scheduled Maintenance Overview

Before Each Test

Replace sample filters if applicable.

After Each Test

The wash function should be used to clean all the liquid lines of the unit. DI or better quality water is recommended for the wash solution.

NOTE: Please contact Teledyne Hanson Technical Support before pumping organic solvents through the unit.

Weekly

Inspect syringes for leaks. Ensure that no air bubbles are entering the syringe from the side of the plunger. Syringes should be replaced when they have reached 100,000 cycles, regardless of whether or not they are leaking. For instructions on syringe replacement, refer to the syringe replacement section below.

Every 6 Months

Inspect sample lines and fittings. Ensure all fittings are tight. Sample lines should be free of debris, kinks, or breaks. For information on how to remove debris from the lines, or repair kinked or broken lines, please contact Teledyne Hanson Technical Support.

Inspect AutoFill needles for damage and replace as necessary.

Inspect AutoFill dispense head for smooth motion.

Wash Routine

About

The wash routine on the CD AutoPlus is designed to provide a thorough cleaning of all the liquid lines utilized during a test. This can be run automatically at the end of a test or run through the automatic syringe control screen located in the Tools menu.

How it Works

The wash routine requires that a wash source be connected to the CD AutoPlus. The wash source should be clean DI or better quality water. Other solvents can be used, but Teledyne Hanson Technical Support should be contacted prior to attempting washes with more aggressive solvents.

Probes on the CD14 testers are maintained in a raised position to prevent any contamination caused by media remaining in vessels that have yet to be cleaned.

The CD AutoPlus will pull from the wash source and pump the wash solution to each of the testers and the waste lines. To ensure that all lines reach their specified rinse volumes, a priming step is performed on the wash lines any time the needles return to that position. The priming step dispenses out the probes of the first CD14 Tester (A).

NOTE: It is recommended to have at least 100 mL of volume available in tester A prior to beginning a wash cycle.

The waste lines are rinsed in the same manner as the testers, then drained.

After the waste lines are washed, the CD AutoPlus will then pull from the wash source and dispense out to the dissolution testers for the specified volume. The volume is specified in multiples of the syringe capacity.

If programmed, a dry cycle will occur after the testers have been washed. The dry cycle raises the needles on the AutoFill and pulls air into the syringes. It then pumps this air out to the testers, the waste lines, and the wash port. This drying cycle ensures that no wash solution remains in the lines and that the system is now ready for another test after the vessels have been cleaned.

CD AutoPlus General Cleaning

The autosampler and collector have been designed to be a low maintenance instrument. In general, the instruments are maintained by wiping clean after each use, as well as running DI-grade water through the units after each test to clean the lines.

The exterior of the instrument should be periodically wiped down with a damp cloth. Frequency of cleaning depends on the instrument usage and operating environment. If there is spillage on the unit, clean it up as soon as possible.

Cleaning Method for Tubing, Valves and Syringes

Supply DI-grade water (or better) to the cleanest source on the autosampler. If media replace is used, supply the DI-grade water to source C. From the cleanest source, pump out to the dissolution testers and collectors. This will push any debris away from the valves and help prevent any damage or clogs from occurring.

Syringe Replacement

Replace syringe plungers when the maintenance log indicates 100,000 cycles or as needed. After replacing syringes, volume calibration should be performed. DI or better quality water should be used for this procedure.

1. Remove the front cover of the CD AutoPlus.
2. Using the autosampler controls, select the manual control option and load the syringe with 2 mL of water.
3. Remove the shoulder screw at the bottom of the syringe.
4. Using the autosampler controls, select the manual control option and load the syringe with 5 mL of water.
5. Gently unscrew the syringe by grasping the barrel and turning it clockwise.
6. Install the new syringe by screwing it in counterclockwise.

   NOTE: When the syringe contacts the manifold, turn it no more than 45 degrees in order to ensure a good seal and not damage the valve.

7. Using the autosampler controls open the valves for any lines.
8. Gently pull the syringe plunger down and align it with the drive bar.
9. Reinstall the shoulder screw.

   NOTE: The shoulder screw should be able to be installed finger tight until it is flush with the syringe plunger. If the screw cannot be turned with only your fingers, adjust the plunger and try again. Once the screw is flush with the syringe plunger, it may be tightened with a screwdriver.

Volume Calibration

Use DI-grade water at room temperature.

1. Weigh empty sample collection vials or test tubes and record the results (tare weight). Caps are required in order to ensure accuracy.
2. Program the autosampler to collect the required sample volume.
3. Weigh full sample collection vials and subtract the empty (tare) weight from the full weight. Make any necessary calculations to account for water density.

$$Volume\ (mL) = \frac{(Fill\ Weight\ (g) - Tare\ Weight\ (g))}{Density\ (\frac{g}{mL})}$$

If the volume does not fall within the specifications in the specifications section, contact Teledyne Hanson Technical Support.

Tubing Volume

Tubing volume can be calculated using the following information.

Common configuration:

- CD14 Tester, 2x CD AutoPlus, 2x AutoFill, 2x AutoMag

Tubing description	Locations	Volume (mL/inch)	Volume (mL/cm)
1/16 in. PTFE tubing	Tubing harnesses, autosampler tubing, collector tubing, sample harness located on tester	0.0176 (Note high side tolerance.)	0.00496 (Note high side tolerance.)
AutoMag probes	AutoMag	0.0503	0.01979

Common items	Tubing length (inches)	Tubing length (cm)
1/8 in. stainless steel probes	15	38.1
1/16 in. stainless steel sample return probes	17.05	43.307
CD AutoPlus tubing on source A, B, and C	36	91.44
CD AutoPlus tubing on source D	36	91.44
AutoFill (to needle)	Total mL	
CD14 Tester or extension tubing harness (3') *	36	91.44
1 L AutoMag probe	6.3	16.00
2 L AutoMag probe	7.6	19.30

* All dissolution testers manufactured after and including Vision G2 Testers have a 3 ft. harness from the magazine.

To calculate the dead volume:

(Tubing length in. or cm) x (mL/in. or mL/cm) + (Tubing length in. or cm) x (mL/in. or mL/cm) and repeat for each section.

Rinse Volume

Materials required

1. One UV/Vis spectrophotometer
2. One absorbing solution with a UV absorbance of approximately 1.00 AU.
   a. Caffeine solutions or prednisone solutions are suitable choices.
   b. An absorbance of 0.90 to 1.10 AU is strongly recommended.
3. DI or higher quality water
4. 12 test tubes
   a. Vials are not recommended due to sample size.
   b. Recommended sample size is 7 – 10 mL for UV analysis.
   c. Filters may be used at operator discretion.

Procedure

This procedure uses only line A1. There is no need to perform this procedure on other lines. See the Carryover section in this maintenance section for how to perform a carryover test, to verify the rinse volume on all the lines.

1. Prime line A1 with no less than 20 mL using DI water.
2. Use the CD AutoPlus controls to obtain two samples (blank 1, and blank 2) without removing the probe from the DI water.
3. Round the theoretical dead volume up to the next whole number.
4. Place the probe in the absorbing solution and rinse the lines with the amount determined in step 3.
5. Use the CD AutoPlus controls to obtain a sample for UV analysis.
6. Place the probe back in the DI water and prime the system with 20 mL.

7. Move the probe back to the caffeine solution and rinse by a volume 1 mL greater than the previous rinse volume.
8. Obtain a sample for UV analysis using the CD AutoPlus controls.
9. Repeat steps 6 through 8 until a total of 10 samples of the absorbing solution are obtained.
10. Run the samples on a UV/Vis spectrophotometer starting with the two blanks and working from the lowest rinse volume to highest.
11. Clean probes using DI water.
12. Use the following equation in order to determine the rinse volume.

$$A_r = \frac{(A_{100\%} - A_{0\%}) * 99\%}{100\%} + A_{0\%}$$

A_r = the minimum absorbance required

$A_{100\%}$ = the average absorbance of the 9th and 10th readings of the absorbing solution

$A_{0\%}$ = the average of the absorbance of the two blank diluent solution readings

Using the equation

1. Obtain the average of the blanks ($A_{0\%}$).
2. Obtain the average of the last two absorbing solution samples ($A_{100\%}$).
3. Subtract the value from step 1 from the value of step 2. (step 2 minus step 1)

   ($A_{100\%}$ - $A_{0\%}$)
4. Multiply the value from step 3 by 0.99 (99%)

   ($A_{100\%}$ - $A_{0\%}$) * 0.99
5. Divide the value obtained in step 4 by 1.00 (100%).

   (($A_{100\%}$ - $A_{0\%}$) * .99) / (1.00)
6. Add the values in step 5 and step 1 for the final value.

Carryover

The carryover evaluation tests the rinse volume to ensure it is true for all the lines in the system. This test is performed on all lines used, but only on source A.

Materials required

1. One UV/Vis spectrophotometer
2. One absorbing solution with a UV absorbance of approximately 1.00 AU
   a. Caffeine solutions or prednisone solutions are suitable choices.
   b. An absorbance of 0.90 to 1.10 AU is recommended.
3. DI or higher quality water
4. Test tubes
   a. Vials are not recommended due to sample size.
   b. Recommended sample size is 7 – 10 mL for UV analysis.

Procedure for obtaining the samples

1. Place all the sample lines for source A into the DI water.
2. Prime the system with no less than 20 mL of DI water.
3. Using the CD AutoPlus controls obtain a sample of the blank solution.
4. Place the sample probes in the absorbing solution.
5. Rinse with the previously determined rinse volume.
6. Using the CD AutoPlus controls obtain a sample of the absorbing solution.
7. Place the sample probes in the DI water.
8. Rinse with the determined rinse volume.
9. Using the CD AutoPlus controls obtain a sample of the blank solution.
10. Repeat steps 4 through 9 until there are 3 samples of the absorbing solution and 3 samples of the blank solution.
11. Clean probes using DI water.

Sample Order

Due to variation over time on many UV/Vis spectrophotometers, it is recommended to run the samples in the following order:

Line 1, blank sample 1

Line 1, blank sample 2

Line 1, blank sample 3

Line 2, blank sample 1

Line 2, blank sample 2

continue through

Line 8, blank sample 3

Line 1, absorbing sample 1

continue through

Line 8, absorbing sample 3

Sufficient Rinse Volume

When the absorbance values of the samples are obtained, it must be determined whether or not the rinse volume is sufficient. To do this, use the two following calculations.

For absorbing solutions:

Absorbing solution absorbance values must not be less than 0.99 x (first absorbing solution for the line).

For blanks:

Blank value must not be more than 0.01 x (first absorbing solution for the line) + (first blank sample for the line).

CD AutoPlus Moving and Storage

If the CD AutoPlus 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 CD AutoPlus will not be used for an extended period of time (30 days or more), the instrument should be cleaned, 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 CD AutoPlus and/or AutoFill. Lifting should be done with one person situated on each side of the instrument. Remove the collection rack before moving the instrument. Lift the equipment by the base (applies to both the CD AutoPlus and the AutoFill).

Warning: Lifting without assistance may cause injury.

CD AutoPlus

1. Remove all liquid sources and program the CD AutoPlus to pump 20 mL of air to clear as much liquid from the system as possible.
2. Turn the power off. Disconnect all tubing, communication, and electrical connections from the unit.

AutoFill

1. Turn the power off. Remove the rack and secure the needle arm.
2. Disconnect all tubing, communication, and electrical connections from the unit.

Section J – Troubleshooting

Contacting Teledyne Hanson 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 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.
	USB supply is not working.	Replace USB 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.
	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.
	Tester feet are not touching the bench.	Ensure all feet of the tester are secure on the bench.
	Other vibration sources.	Remove these other sources or relocate the tester.
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 the spindle shaft.
	Clamp has loosened or spindle shaft was replaced.	Perform the height adjustment.

Heater Troubleshooting

Problem	Possible Causes	Recommended Action
Tester doesn't communicate with heater	Heater not turned on.	Turn on heater.
	Heater not connected.	Connect tester to heater using cables from drive head.
	Board failure.	Contact Teledyne Hanson Technical Support.
Main Check Error when tester heats up beyond a certain temperature	Component failure.	Contact Teledyne Hanson 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 in 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 Teledyne Hanson Technical Support.

AutoMag Troubleshooting

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

Section K – Specifications

CD14 Comparative Dissolution Tester Specifications

Weight:

- Main unit, dry: 118 kg (260 lbs.)
- Main unit, bath and vessels filled with water: 174 kg (383 lbs.)

Size:

- Height: 87.6 cm (40.0 in.)
- Width: 67.3 cm (33.5 in.)
- Depth: 58.5 cm (24.0 in.)

Bath Capacity:

- With 14 vessels: 41.6 liters (11 gallons)

Power:

- Input: 100 – 230 V ± 10%, 50 – 60 Hz, 1.5 A max.
- Output: 24 VDC, 3.75 A, 90 W

Heater Specifications

Note: The heater fits under the tester.

Weight: 4.1 kg (18 lbs.)

Size:

- Height: 7.6 cm (3.0 in.)
- Width: 67.3 cm (26.5 in.)
- Depth: 43.3 cm (17.0 in.)

Power:

- Input: 100 – 230 V ± 10%, 50 – 60 Hz
- Power: 700 – 1200 W

CD14 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 51.0 °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.)

CD AutoPlus Specifications

Weight:

- Dry: 21.3 kg (47.0 lbs.)

Size:

- Height: 46.8 cm (18.4 in.)
- Width: 38.1 cm (15.0 in.)
- Depth: 66.0 cm (26.0 in.)

Power:

- Input: 24 VDC, 3.75 A, 90 W
- Only use external power supply (listed below)

AutoFill Specifications

Weight:

- Dry: 14.5 kg (32.0 lbs.)

Size:

- Height: 40.1 cm (15.8 in.)
- Width: 28.0 cm (11.0 in.)
- Depth: 47.3 cm (18.6 in.)

Power:

- Input: 24 VDC, 3.75 A, 90 W
- Only use external power supply (listed below)

CD AutoPlus/AutoFill External Power Supply

Power:

- Input: 100 - 240 V~,50 - 60 Hz, 1.5 A max
- Output: 24 VDC, 3.75 A, 90 W

CD AutoPlus/AutoFill General Specifications

Sampler Volume Accuracy:

- 0.5 to 5.0 mL: ± 0.05
- 5.1 to 10.0 mL: ± 0.10
- 10.1 to 15.0 mL: ± 0.15

Sampling:

- Minimum sample interval: 1 min (5 min is normal)
- Maximum sample interval: 999 hours, 59 min (999:59)
- Sample time points: 50 maximum
- Maximum sample volume: 90% of vial capacity

Collection:

- 13 x 100 rack: 18 x 8 test tubes, 144 total
- 16 x 100 rack: 18 x 8 test tubes, 144 total
- 12 x 32 rack: 21 x 8 vials, 168 total
- UPLC rack (12 x 32): 3 trays 6 x 8 vials, 144 total
- Septum: Pre-cut type only.

Warning: Failure to use pre-cut septa can result in damage to the AutoFill needles.

Wetted Materials

Table K-1: Wetted Materials

CD14 Tester Wetted Materials		
Part Number	Description	Material(s)
74-105-201	Spin-Paddle, PVDF, Serialized	PVDF
74-105-202	Spin-Paddle, 316 SS, Serialized	316 stainless steel
74-105-251	Spin-Basket Shaft, 316 SS, 1 L, Serialized	316 stainless steel
74-105-252	Basket, Precision, 40 Mesh, 316 SS, Serialized	316 stainless steel
74-107-022	Vessel Cover, Easi-Lock™	PVC
74-107-023	Vessel Cover, Easi-Lock™ ADD™	PVC
75-107-101	Vessel, Easi-Lock, 1 L, Glass, Clear, Serialized	Borosilicate glass
75-107-102	Vessel, Easi-Lock, 1 L, Glass, Amber, Serialized	Borosilicate glass
75-107-121	Vessel, Easi-Lock, Super Precision Vessel™, 1 L, Glass, Clear	Borosilicate glass
75-107-022	Vessel, Easi-Lock, Super Precision Vessel™, 1 L, Glass, Amber	Borosilicate glass
75-107-150	Dual AutoMag™, 12 Positions, Factory Installed	PVDF, PTFE PEEK, ETFE
75-107-151	Dual AutoMag™, 12 Positions, Field Installed	PVDF, PTFE PEEK, ETFE
75-107-160	Probe Kit, PEEK, 12 Positions, Sample and Return Probes, Factory Installed	PEEK
75-107-161	Probe Kit, PEEK, 12 Positions, Sample and Return Probes, Field Installed	PEEK
75-107-170	Probe Kit, SS, 12 Positions, Sample and Return Probes, Factory Installed	316 stainless steel
75-107-171	Probe Kit, SS, 12 Positions, Sample and Return Probes, Field Installed	316 stainless steel
75-107-180	Digital Temp Probes w/PCB, 12 Positions, Factory Installed	316 stainless steel
75-107-181	Digital Temp Probes w/PCB, 12 Positions, Field Installed	316 stainless steel

CD AutoPlus Wetted Materials		
Part Number	Description	Material(s)
-	Tubing	PTFE, ETFE
91-450-056	DissoScan Valve	PEEK, EPDM, 304SS
91-450-076	Maximizer Valve	PEEK, EPDM, PFE, 304SS
60-200-550	5 mL Syringe	PTFE, PEEK, Borosilicate Glass
AutoFill Wetted Materials		
Part Number	Description	Material(s)
61-207-717	Home Port Stand	PVDF
61-207-723	PEEK Needles	PEEK
91-030-051	16 mm x 100 mm Test Tubes	Borosilicate Glass
91-030-150	12 mm x 32 mm Vials	Borosilicate Glass, Silicone, PTFE
61-107-003	16 mm Evaporation Caps	Polyethylene
61-105-029	Syringe Barrel	Borosilicate Glass
91-425-028	Viton O-ring	Viton
91-951-004	Silicone Compound	Silicone

Section L – General Warranty

Teledyne Hanson 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. Teledyne Hanson makes no warranty, expressed or implied, for glassware, consumables, or products not manufactured by Teledyne Hanson, as evidenced by nameplate on the item or other designation. Teledyne Hanson will give reasonable assistance to buyer in obtaining from the respective manufacturer whatever adjustment is available under the manufacturer's own warranty. Teledyne Hanson 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 Teledyne Hanson. There are no other warranties, expressed or implied, and Teledyne Hanson shall not be liable under any circumstances for damages of any kind, direct, consequential, or otherwise.

Appendix A: Errors

CD14 Tester Errors

CD14 Tester Errors				
Error Code	**Error Category**	**Error Message Title**	**Fault**	**Check the Following**
2000	5	AutoMag X communication error		1. Check mag connection. 2. Wrong probe config, check system configuration.
2001	5	Vessel probe X missing		
2002	5	Vessel probe X configuration error		
2003	5	Vessel probe X 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
2004	5	Vessel probe X configuration mismatch	The method is trying to use DTPs that are not configured. Enable DTPs in configuration.	1. The vessel temperature field for method 2. System configuration of digital temperature probes
2005	5	Vessel probe X offset out of range	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
2006	5	External temperature probe (2) failure	Heater cannot communicate with external temperature probe.	1. External probe connection 2. External probe failure 3. Heater board failure
2007	5	Vessel probe X unknown calibration		
2008	5	X spindle board com error	The tester can't communicate with the spindle board	1. Check the connection 2. Spindle board failure 3. Main board failure
2009	5	Magazine X homing error	mcode=1, homing distance too long.	1. Home it again. Make sure motor is moving 2. Check lead screw and magazine coupling. 3. Spindle control board failure
2010	5	Magazine X thermal warning	mcode=4, Magazine motor driver report too hot.	1. Move it again. Make sure motor is moving 2. Check lead screw and magazine coupling 3. Spindle control board failure
2011	5	Magazine X thermal shutdown	mcode=8, Magazine motor driver report too hot.	1. Move it again. Make sure motor is moving. 2. Check lead screw and magazine coupling 3. Spindle control board failure

CD14 Tester Errors				
Error Code	Error Category	Error Message Title	Fault	Check the Following
2012	5	Magazine X over current error	mcode=16, Magazine motor driver report overcurrent.	1. Move it again. Make sure motor is moving. 2. Check lead screw and magazine coupling 3. Spindle control board failure
2013	5	Magazine X driver lost steps on winding 1	mcode=32, Magazine motor driver report overcurrent.	1. Move it again. Make sure motor is moving. 2. Check lead screw and magazine coupling 3. Spindle control board failure
2014	5	Magazine X driver lost steps on winding 2	mcode=64, Magazine motor driver report overcurrent.	1. Move it again. Make sure motor is moving. 2. Check lead screw and magazine coupling 3. Spindle control board failure
2015	5	Magazine X encoder missing steps	mcode=128, Magazine encoder and driver mismatch.	1. Move it again. Make sure motor is moving. 2. Check lead screw and magazine coupling 3. Spindle control board failure
2016	5	Magazine X calibration error	mcode=2, Calibration error.	1. Move it again. Make sure motor is moving. 2. Check lead screw and magazine coupling 3. Spindle control board failure
2017	5	Spindle X spindle board com recovery	The tester had communication problem with the spindle board	1. Check the connection 2. Spindle board failure 3. Main board failure
2018	5	Spindle X commute error	ecode=1, Spindle motor commutation error.	1. Run it again make sure motor is moving 2. Check spindle motor connection 3. Spindle control board failure
2019	5	Spindle X Hall1 sensor error	ecode=2, Spindle motor sensor 1 missing.	1. Check spindle belt tension. 2. Check spindle motor connection. 3. Spindle control board failure
2020	5	Spindle X sensor error	ecode=4, Spindle motor sensor 2 missing.	1. Check spindle belt tension. 2. Check spindle motor connection. 3. Spindle control board failure
2021	5	Spindle X sensor error	mcode=8, Spindle motor sensor 3 missing.	1. Check spindle belt tension. 2. Check spindle motor connection. 3. Spindle control board failure
2022	5	Spindle X stall error	mcode=0x40, Spindle motor driver overcurrent.	1. Check spindle belt tension. 2. Check spindle motor connection. 3. Spindle control board failure
2023	5	Spindle X driver overheat error	mcode=0x80, Spindle motor driver overheat.	1. Check spindle belt tension. 2. Check spindle motor connection. 3. Spindle control board failure

CD14 Tester Errors				
Error Code	**Error Category**	**Error Message Title**	**Fault**	**Check the Following**
2024	5	Spindle X board configuration initialize error	mcode=0x100, configuration initialization.	1. First time power up 2. I2C problem 3. Spindle control board failure
2025	5	Spindle X board EEPROM error	mcode=0x200, configuration initialization.	1. I2C problem 2. Spindle control board failure
2026	5	Spindle X board serial command overflow	mcode=0x400, serial port overflow.	1. RS232 problem 2. Spindle control board failure
2027	5	Spindle X board task overflow error	mcode=0x800, task overflow.	1. Internal problem 2. Spindle control board failure
2028	5	AutoMag X communication recovery		
2029	5	AutoMag X return home check error		
2500	5	Heater communication error	The tester and heater are not communicating.	1. Heater power 2. Heater connection
2501	5	Heater probe 1 failure (control probe)	ecode=1, Heater cannot communicate with Inlet temperature probe.	1. Inlet probe connection 2. Inlet probe failure 3. Heater board failure
2502	5	Heater input power (mains) error	ecode=0x80, heater failure	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
2503	5	Heater thermistor sensor failure	ecode=4, Heater cannot communicate with safety probe.	1. Safety probe connection 2. Safety probe failure or no water flow in heater 3. Heater board failure
2504	5	Heater watchdog timer reset	ecode=0x40, did not receive command for 15 seconds	1. Check connection to main control board. 2. Check main control board. 3. Heater board failure
2505	5	Heater configuration memory failure	mcode=0x100, configuration initialization.	1. First time power up 2. I2C problem 3. Heater board failure
2506	5	Heater fan failure	ecode=8, fan failure	1. Check fan connection. 2. Fan failure 3. Heater board failure
2507	5	Heater pump failure	ecode=0x20, fan failure	1. Check pump connection 2. Pump failure 3. Heater board failure
2508	5	Heater board I2C bus failure	mcode=0x200, configuration initialization.	1. I2C problem 2. Heater board failure
2509	5	Heater board serial port overflow	mcode=0x400, serial port overflow.	1. RS232 problem 2. Heater board failure
2510	5	Heater board background task overrun	mcode=0x800, task overflow.	1. Internal problem 2. Heater board failure

CD14 Tester Errors				
Error Code	**Error Category**	**Error Message Title**	**Fault**	**Check the Following**
2511	5	Heater communication recovered		
0060	5	Database error	Error reading or writing to the database	Try again. Contact Teledyne Hanson if the problem persists.
0061	1	Generic error	Error when accessing the USB thumb drive	Try again.
0062	1	Cannot open file	Error when accessing the USB thumb drive	Check the file is present on the USB thumb drive.
0063	1	Cannot read file data	Error when accessing the USB thumb drive	Check the file is present on the USB thumb drive.
0064	1	Corrupt data error	Error when accessing the USB thumb drive	Check the file is not corrupted on the USB thumb drive.
0065	1	Flash drive missing	Error when accessing the USB thumb drive	Insert the USB thumb drive.
0066	1	Cannot create file	Error when accessing the USB thumb drive	1. Check the USB thumb drive is not write-protected. 2. Check the USB thumb drive is not full.
0067	1	Cannot write to file	Error when accessing the USB thumb drive	1. Check the USB thumb drive is not write-protected. 2. Check the USB thumb drive is not full.
0068	1	Unhandled error	Error when accessing the USB thumb drive	Try again.
0070	1	Timeout	Fingerprint sensor error	Try again.
0071	1	Invalid serial baud rate	Internal error	Contact Teledyne Hanson.
0072	1	The specified ID is not in range	Internal error	Contact Teledyne Hanson.
0073	1	The specified ID is not used	Internal error	Contact Teledyne Hanson.
0074	1	Communication error		Check the display to fingerprint sensor connection.
0075	1	Verification failure		Try again.
0076	1	Identification failure		Try again.
0077	1	The database is full	Internal error	Contact Teledyne Hanson.
0078	1	The database is empty	Internal error	Contact Teledyne Hanson.
0079	1	Invalid order of the enrollment	Internal error	Contact Teledyne Hanson.
0080	1	Bad fingerprint		Try again.
0081	1	Enrollment failure		Try again.
0082	1	Specified command is not supported	Internal error	Contact Teledyne Hanson.
0083	1	Device error, (crypto-chip issue)		Try again, if it still doesn't work, contact Teledyne Hanson.
0084	1	Finger capture cancelled		Try again.
0085	1	Invalid parameter	Internal error	Contact Teledyne Hanson.
0086	1	Finger is not pressed		Try again.

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