

# PHOENIX™ DB-6 DIFFUSION TESTER USER GUIDE



## **About Teledyne Hanson Research**

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

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## Sales and Support

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Congratulations on your purchase of the Teledyne Hanson Research Phoenix DB-6 Diffusion Tester. While we are certain you will enjoy this new product, we also understand from time to time you may have a question or technical issue requiring our assistance. Please feel free to contact us at any time by any of the methods below.



Website: [teledynehanson.com](http://teledynehanson.com)

Tech support request form: [teledynehanson.com/support](http://teledynehanson.com/support)

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# Revision History

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## Document Revision History

<u>Revision</u>	<u>Date Revised</u>	<u>Description of Change</u>
A	30 April 2018	Original issue

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

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## A. Introduction

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### Phoenix DB-6 Diffusion Tester Overview

The Phoenix DB-6 diffusion instrument is designed to facilitate testing of semi-solid dosage forms, patches, and other topical or transdermal products. The DB-6 was designed to meet the standards listed in USP chapter <1724> and other harmonized standards. The unit consists of a display assembly and a combined heater block and stirring device which holds the vertical diffusion cells.

The stirring is driven by electric motors which can be set to speeds from 200 RPM to 1000 RPM. Heating (25 °C to 40 °C) is achieved by using a dry heat block which eliminates the need for water circulation systems.



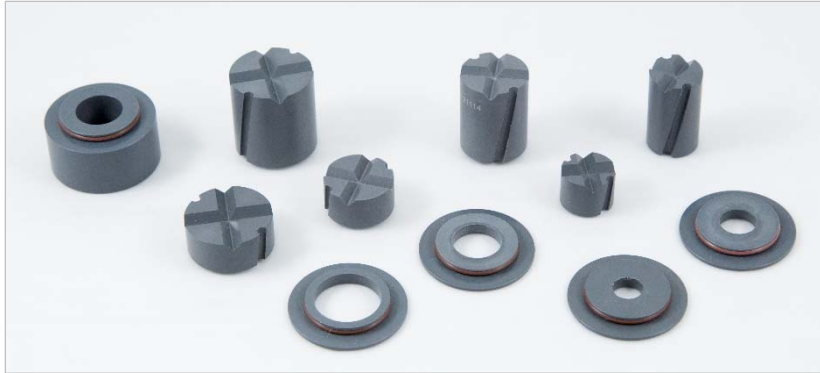
The diffusion cells are similar to Model B of USP Chapter <1724> with notable innovations which allow for different sized orifices and volumes while using the same glass cell.



## A. Introduction

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Orifice sizes can be adjusted by using different cell cap assemblies. Orifice sizes range from 9 mm up to 20 mm diameters.



Custom sizes are available upon request. The precision-machined caps snap into each other, which provide a more consistent dosage area from cell to cell. This can help reduce variability in diffusion testing results.

Cell volumes are adjusted by using different stirrers. Volumes can range from approximately 10 mL up to 30 mL depending on the combination of cell size and stirrer used. All the cells are manufactured from high precision syringe barrel tubing. When combined with the precision-machined stirrers this can reduce variation in the receptor media volume.

The arm has a larger diameter than traditional Franz cells, which allows for easy sampling using a syringe or micro-pipette. The larger arm diameter also ensures the entire receptor media is a uniform concentration.

### **Power Requirements**

The power supply of the DB-6 automatically switches to accommodate either 120VAC/60Hz or 240VAC/50Hz. All systems come with a detachable power cable suitable for any region the instrument will be installed in.

### **User Interface**

The user interface of the DB-6 consists of a touch screen display which is connected by a cable to the DB-6 heater/stirring unit. The touch screen interface allows the user to select and activate all of the DB-6 settings.

For a record of the tests run, a validation printer is available. The printer can be used to print system settings, protocols, and test reports.

The display assembly holds most of the data for the system which includes, users, protocols, and system settings. The heater block stores only the serial number and cumulative motor and heater time. The back of the display is magnetized for convenient positioning on the front or sides of the block.

### Phoenix DB-6 Operation Overview

Once the DB-6 has been unpacked, installed and qualified, routine operation consists of 4 steps: power on the system; set up the test; run the test; and cleanup. The instrument has the ability to run in a timer mode allowing the user to only set speed and temperature as well using protocols mode, which will monitor test time, inform the user of sample points, and print complete reports of the test run. A quick-start overview of the operational procedure is as follows:

1. Power up the DB-6.
2. Set the temperature of the DB-6 to ensure the cells can be maintained at the correct testing temperature. For example, if the desired cell temperature was 32.0 °C; the DB-6 may need to be set to 32.5 °C.
3. Insert the desired stirrer into the diffusion cell.
4. Install the membranes in the cell caps.
5. Install the assembled cell caps on top of the diffusion cell.
6. Fill the diffusion cell so that no bubbles are trapped under the membrane.
7. Place the diffusion cells, with sleeves if necessary, into the DB-6 and allow them to heat. About a 30-minute heat-up time is recommended for most applications.
8. Set the stirrer speed to the desired rpm.
9. Start the test by applying the dosage to the top of the membrane and starting a timer or protocol.
10. Sample at the appropriate time points.
11. After the last sample is collected perform the clean-up.

The above steps are described in greater detail in the Operation section of this user guide.



## **Recommendations for Using this Manual**

Teledyne Hanson Research recommends the following steps for making best use of this user guide:

1. Review the Introduction section for an overview of the instrument.
2. Carefully review and follow all safety instructions.
3. Unpack, inspect, and install the instrument according to instructions in the Installation section.
4. Conduct an initial test of the system using the procedures outlined in the Operation section.
5. Review the Maintenance and Troubleshooting sections to become familiar with keeping the instrument in good working order.
6. Immediately contact Teledyne Hanson Research Technical Support with any questions on how to properly operate and maintain the DB-6 diffusion system.

## B. Regulatory and Safety

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### Regulatory Compliance

Teledyne Hanson Research hereby certifies that this product, including hardware and firmware, was designed, evaluated, validated, inspected, and tested to approved specified quality requirements of Teledyne Hanson Research in conformance with current USP, EP, JP, and other international standards (India & 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 règlements sur le brouillage radioélectrique édictés par le Ministère des Communications du Canada.

### 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 source such as an electric wall outlet.
- This instrument must be connected to a grounded electrical outlet.
- Never work on the electrical components in the system while there is power to the unit. DISCONNECT POWER BEFORE SERVICING THE INSTRUMENT.
- Review all safety and environmental precautions pertaining to any chemicals that are to be used in conjunction with this equipment.

## B. Regulatory and Safety

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### Safety Considerations

- For indoor use only
- Maximum altitude 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
- Mains supply voltage fluctuations not to exceed  $\pm 10\%$  of the nominal voltage
- Installation Category II (overvoltage categories)
- Pollution Degree 2
- Please note potential pinch hazards described below.
- Additional hazards may exist if the equipment is not operated according to the instructions in the user guide.

### **Phoenix DB-6 Diffusion Tester Installation**

Review all safety instructions before proceeding with installation of the DB-6 diffusion tester.

The installation process consists of three steps:

1. Selecting an appropriate location, which includes confirming environmental and space requirements.
2. Reviewing and conforming to electrical requirements.
3. Unpacking and installing the tester into the confirmed location.

Proceed by following the instructions below.

### **Environmental Requirements**

The installation location should be clean and free of factors that may affect the integrity of disintegration testing results, such as excessive vibration and significant variations in temperature.

### **Space Requirements**

Please refer to the Specifications section for space requirements based on the physical dimensions of the tester.

The bench should be level and flat. It must be capable of supporting the full weight of the instrument.

### **Electrical Requirements**

Each system requires a grounded electrical outlet within 2 meters (6 feet) of the system. See power requirements in previous section.

Power cords must meet the following specifications: IEC 210-C13 connector; SJT 18AWG, 3C, 60 °C, 300 V.

### **Unpacking and Inspection**

While unpacking the instrument, first make note of any damage to the shipping container. If the container is damaged, contact the shipper immediately.

1. Open the main container which holds all the components of the DB-6.
2. Remove any accessory boxes.
3. Remove box containing the DB-6 from the main container.
4. Place DB-6 heater/stirrer on the bench.

### Assemble the System

1. Connect the display to the display port located on one end of the DB-6.
2. Connect the power supply to the power connector located on the end of the DB-6.
3. Connect the other end of the power supply to the wall outlet.
4. If purchased, connect the validation printer to the printer port.

### Install the Cells

1. If small or medium cells are to be used, install the appropriate sleeves in the heater block.
2. Install the cells into the heater block. The arm should line up with the arm guide on the heater block.



3. Slide the cell assembly into the heater block so that the arm is resting in the cell restraint plate.

### Best Practices for Diffusion Testing

In-vitro diffusion testing is divided into two broad categories. The first is In-Vitro Permeation Testing (IVPT). Permeation testing is used by research and development teams to determine if a product is penetrating the skin. Depending on the product, penetration may be desired or may not be. For example, a product used to treat a skin condition should penetrate the skin. But a product such as sun-screen should remain on top of the skin and not penetrate.

The second category of testing is In-Vitro Release Testing (IVRT). Release testing is used primarily by quality control teams to determine if a batch of a product is suitable for release. Release testing is designed to ensure product uniformity and discriminate bad product from good product.

Each type of testing has a different approach and different requirements.

### In-Vitro Permeation Testing

Since the purpose of permeation testing is to determine if the product will work, the following points are often considered when designing a method:

- Receptor media is often bio-relevant and set to match the chemistry of the area of application. Receptor media may have additional ingredients to improve solubility of the active pharmaceutical ingredient (API) (e.g. albumin) or antibiotics to ensure natural membranes are maintained for the duration of the test.
- Membranes are typically natural, such as animal or cadaver skin. In some cases, a synthetic or artificial substitute can be used. Artificial substitutes can be in the form of fully synthetic membranes designed to work like skin, or cell cultures which are grown specifically to be used for simulating skin during testing. However artificial substitutes may have different performance characteristics with the API. This difference in performance needs to be taken into account when determining the effectiveness of the API.

## D. Best Practices

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- Test length is typically 24 hours or the intended duration of the product. If the product is intended to last longer than 24 hours some consideration must be given to how a natural membrane may degrade. This can be slowed by the use of antibiotics in the media or by switching to a suitable artificial substitute.
- Results typically focus on the rate of release, or flux, at each time point. Typically, concentrations are near the pico-gram level.

### In-Vitro Release Testing

The purpose of release testing is to determine if a product is suitable for release. Release testing methods are designed to ensure the product meets manufacturing requirements rather than a direct measurement on the product to determine its efficacy. Consequently, IVRT methods may not have much bio-relevance. The focus of release testing is to ensure the drug diffusing into the receptor media is the only thing being measured. Nothing in the media, membrane, or any other part of the test method should contribute to affecting the diffusion rate.

- Receptor media is typically a mixture of organic and aquatic solutions. In some cases, fully organic solvents must be used due to solubility issues. The media should maintain sink conditions where up to 10x the anticipated amount released should be soluble in the media. Media should be selected by testing multiple candidates and selecting the media which gives the best results.
- Membranes in an IVRT test are strictly to hold the dosage in place and separate it from the receptor media. This helps to keep the surface area constant and allows for comparisons of the diffusion rates relative to area. Membranes should not absorb the drug, nor elute anything into the receptor media that will skew or bias the analysis. Ideally, membranes should not restrict the amount of diffusion from the product at all; however, a minimal amount of resistance is expected.

## D. Best Practices

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- Test length is typically 4 to 8 hours with a minimum of 5 sample points. The test length and sample points should be determined by a methodical process. Sampling should begin after the membrane has had time to completely saturate. In many cases 30 minutes to 1 hour is sufficient. Sampling should end before 30% of the API has been released. Though in some cases having not more than 10% of the product released is preferable. This is due to needing an infinite dosage, in which there is always a sufficient amount of drug to drive the diffusion process at the highest speed for the conditions.
- Results are typically evaluated as the slope obtained by graphing the amount released at each time point (y-axis) against the square root of time (x-axis). The time can be in minutes or hours so long as it is kept consistent for the data set (e.g. 30 min or 0.5 hr.). If testing is for evaluating a change in a product against an existing lot, then the slopes of the new lots will be compared against the slopes of the old lot run at the same time. If the new lot passes a 90% confidence interval it is thought to be identical to the old lot. For more information on this see the FDA Scale Up and Post Approval Change (SUPAC) guidance for semi-solids.



### Operation

Please review and follow all safety and installation instructions before operating the DB-6 diffusion tester.

### Turn on the System

To turn on the system ensure it is plugged in and touch the screen.

### The Home Screen

The Home screen is the first screen shown when the system powers up. The following items are accessible from the Home screen:



*Manual Speed Setting:* To set the speed, touch the number shown below the words *SET SPEED*. From the following screen select a preset speed or enter the desired value manually. When completed touch the Done button and you will return to the main screen.



A preset can be stored by entering a desired number into the text box, touching the Program button, then touching one of the red buttons. The button will change to the new speed and will be available as a preset.

## E. Operation

Restart Motors will briefly stop the motors and then return to the previous setpoint. This is to ensure the stirrers are in sync with the motors.

On the Home screen, if the value is displayed in green it means that the speed is within the tolerance (default 5%). If the value is yellow, it indicates the value is approaching or outside the tolerance value.

**NOTE:** Speeds over 900 rpm will be within the USP <1724> tolerance but may not reach the exact setpoint.

**NOTE:** Viscous receptor media may require lower speed setpoints for adequate rotation of the stirrer.

**Manual Temperature Setting:** To set the temperature touch the number shown below the words *SET TEMP*. From the following screen select a preset temperature or enter the desired value manually. When completed touch the Done button and you will return to the main screen.

Set Temperature (0,25-50 °C)

1	2	3	OFF	+0.1	-0.1
4	5	6	30	32	35
7	8	9	37	40	50
0	.	Back	Program		
Done		Clear			

**NOTE:** It is recommended to set the heater block to 32.5 °C for a cell temperature of 32.0 °C.

A preset can be stored by entering a desired number into the text box, touching the Program button, entering a temperature into the text box, then touching one of the red buttons. The button will change to the new speed, and will be available as a preset.

If the value is displayed in green, it means that the temperature is within the tolerance (default 0.5 °C). If the value is yellow, it indicates the value is approaching or outside the tolerance value. If the value is red, check the error log.

## E. Operation

**ELAPSED TIME:** If a protocol is running, the elapsed time will be displayed under *ELAPSED TIME*. This indicates the total amount of time since the test was started. The time is displayed in HH:MM:SS. If only 00:00 is present, it is shown in minutes and seconds.



Touching the elapsed time will bring up the following buttons.

- **START:** If a protocol is not running, touching the START button starts a timer. This is intended to be used when performing a manual test without the use of a protocol.

If a user has started to launch a protocol, the START button still start the test.

- **STOP:** The STOP button will only appear if the timer is running. Touching the STOP button will stop the timer, but it will not reset it.
- **RESET:** Touching the RESET button can only occur when the timer has been stopped. It will reset the timer to 00:00 (mm:ss).

**NEXT SAMPLE:** If a protocol is running, the time displayed will be a countdown until the next sample for the listed cell. If a protocol is not running, buttons will be displayed.

**Status:** The status is located in the lower left corner of the Home screen. It indicates what the instrument is doing.

**Date and Time:** The date and time are located in the lower right corner of the screen. It indicates the time and date the instrument is set to.

**Security / User:** The person who is logged onto the system is indicated in the upper right corner of the Home screen. If security is disabled, it will read *Security Off*.

## E. Operation

*Protocol / Timer Mode:* If a protocol is loaded, the protocol name will appear in the upper left-hand corner of the screen. If the timer mode is in use, *Timer Mode* will appear in the upper left corner of the Home screen.

*Toolbar:* The Toolbar button is located at the top center of the Home screen. Touching this button will bring up the PRINT button and OFF button.



**MOTORS:** Touching the MOTORS button will toggle the speed display between motor 1, or all 6 motors. If a single motor is out of specification all 6 motors will be displayed so the faulty motor is visible.

**PRINT:** Touching this button will print the status to the printer if installed, or the test log if a protocol is running.

The PRINT button located on other screens will print information relative to that screen. If a protocol is open, it will print the protocol. If the service log is being viewed, the PRINT button will print the service log.

**OFF:** Touching this button will put the instrument to sleep. It will dim the display, turn off the stirrers and heater, and log out any users. Touching the display again will wake the instrument up.

*Menu:* The Menu button is located at the bottom of the Home screen. Touching this button will bring up the Menu screen. The Menu screen allows access to protocols, settings, and other options within the software.

### The Main Menu

The Main menu is reached by touching the Menu button on the bottom center of the Home screen. The Main menu gives access to the following screens by touching the associated buttons.



- **PROTOCOLS:** Allows for the creating, editing, and archiving of protocols for the instrument.
- **INFO:** Allows access to firmware versions, test logs, serial number logs, and service logs.
- **DIAGNOSTICS:** Runs a short diagnostic routine to ensure the instrument is in good operating condition.
- **TOOLS:** Allows for adjustment of the temperature offset and access to the remote command prompt.
- **TIME:** Allows access to set the time and date as well as alarms.
- **DISPLAY:** Allows the user to set brightness, volume, and recalibrate the display.
- **SECURITY:** Allows the user to enable or disable security and manage users. Security features help ensure compliance with 21 CFR Part 11 and require users within the instrument to enter a password.
- **CONFIG:** The CONFIG button allows the user to assign an instrument ID, and set tolerances; as well as configure the printer and other accessories. The user can set titles which appear in test printouts or within protocols. Firmware updates for the heater block can also be performed through this screen.

### Protocols

Protocols are saved test methods which allow a user to run repeated tests using the same conditions. Protocols store the speed and temperature set points, information about the protocol, and events which occur during a test. The following buttons are present at the bottom of the Protocol screen.

- **NEW:** This button creates a new protocol with nothing entered.
- **COPY:** This button creates a copy of the open protocol. The protocol name is copied and the word *COPY* is appended to the end of the protocol name. If the protocol name is at or near the character limit, the last 6 characters will be overwritten with the word *COPY*.
- **DELETE:** This button deletes the protocol. Confirmation is requested prior to deleting the file.

**Labels Tab:** The Labels tab holds information regarding the protocol itself. This information is to provide users with a means of identifying the protocol from printouts or when viewing protocols.

Default Protocol ?		
Labels	<b>Protocol Name</b> Default Protocol	<b>Membrane</b> Membrane2
Diffusion	<b>Drug Name</b> Drug Name2	<b>Media Type</b> Media Type2
Events	<b>Dosage</b> Dosage2	<b>Media Volume</b> Media Volume2
	<b>Protocol I.D.</b> Protocol ID2	<b>Comment</b> Comment2

NEW COPY DELETE PRINT OK

**Protocol Name:** This is the name of the protocol. It must be unique within the instrument. When loading a protocol, or selecting a protocol to edit, this is the name that will appear in the lists.

## E. Operation

**NOTE:** The following items on the Labels tab can be edited through the CONFIG screen.

- Drug Name: The name of the drug or product being tested.
- Dosage: The type of dosage being tested. For example, cream, gel, or ointment.
- Protocol I.D.: An additional reference for the protocol name. It can be associated to document or method numbers from other instruments or systems.
- Membrane: The type of membrane being used. For example, polysulfone, cadaver skin, or Teflon.
- Media Type: The type of media being used for the test. For example, 30% ethanol, Tetrahydrofuran, pH 4.0 acetate buffer.
- Media Volume: The nominal volume of the diffusion cells with installed mixers.

**NOTE:** It is strongly recommended that the determined volume for each cell be used for calculating results. Using the nominal volume for calculations may result in inaccuracies and additional variation.

- Comment: Any additional comments relevant to the protocol.

**Diffusion Tab:** The Diffusion tab allows the user to program how the instrument will behave during the test run. This includes speeds, temperatures, and tolerances among other things.

The screenshot shows a software interface titled "Default Protocol" with a question mark icon in the top right corner. On the left, there is a vertical menu with three tabs: "Labels", "Diffusion", and "Events". The "Diffusion" tab is currently selected. The main area of the screen displays a table of settings for the Diffusion tab. The table has two columns and four rows. The first row shows "Temperature" set to "32.5 °C" and "Temperature Tolerance" set to "±0.5 °C". The second row shows "Stirring Speed" set to "400 RPM" and "Speed Tolerance" set to "±5% RPM". The third row shows "Test Length" set to "006:00" and "Cell Offset Time" set to "30 sec". The fourth row shows "Log Interval" set to "01:00". At the bottom of the screen, there is a toolbar with icons for "NEW", "COPY", "DELETE", "PRINT", and an "OK" button.

	Temperature	Temperature Tolerance
Labels	32.5 °C	±0.5 °C
Diffusion	Stirring Speed 400 RPM	Speed Tolerance ±5% RPM
Events	Test Length 006:00	Cell Offset Time 30 sec
	Log Interval 01:00	

- Temperature: This is the temperature set point for the protocol. It is recommended to set the set point above the desired cell temperature to obtain the desired membrane/media temperature.

## E. Operation

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- **Stirring Speed:** This is the stirring speed for the protocol. For a uniform mixture 400 rpm will be sufficient. The range is 200 to 1000 rpm.

**NOTE:** *Speeds over 900 rpm should be within the USP <1724> specification but may not reach the exact setpoint.*

- **Test Length:** This is the total length of the test for a single cell. The test will automatically be extended for all six cells to be sampled according to the offset time.
- **Log Interval:** This is how often the instrument will log, or print, the status of the instrument in the test log. The status will include the current stirring speed as well as the current temperature.

**NOTE:** *The status of the instrument will be logged automatically at time zero and at every sample time point regardless of the log interval.*

- **Temperature Tolerance:** This is the temperature tolerance for the protocol. If the temperature is read outside of the tolerance, an error will be displayed and added to the test report.
- **Speed Tolerance:** This is the speed tolerance for the protocol. If the speed is read outside of the tolerance, an error will be displayed and added to the test report.
- **Cell Offset Time:** This is the time between applying the dosage to each of the diffusion cells. It will extend the test length by 6 times to allow for identical sampling from each diffusion cell.

For example. If a user sets a test length of 6 hours, and a cell offset time of 30 seconds. When the user started the test, they would apply the dosage to each cell 30 seconds apart. At the end of the test, the second cell would be sampled at 6:00:30, and the last cell would be sampled at 6:03:00 (6 x 30 seconds).



## E. Operation

Events Tab: The Events tab allows the user to set sample points for when the protocol is run. Eight events can be shown at one time. If more events are present, they will be displayed on additional pages. A maximum of 50 events can be added per protocol.

	Sample	Sample
Labels	01:00	06:00
Diffusion	02:00	
Events	04:00	
	05:00	

- **ADD:** The ADD button allows the user to add a new sample event to the protocol.

Add Sampling Event (0,999:59 hhh:mm)

: |

1 2 3 OFF +0.1 -0.1

4 5 6 00:15 00:30 00:45

7 8 9 01:00 01:15 01:30

0 . Back Program

Done Clear

- **PREV:** The PREV button allows the user to move to the previous page of the event table.
- **NEXT:** The NEXT button allows the user to move to the next page of the event table.
- **PRINT:** The PRINT button allows the user to print the protocol to the installed printer.

### Info

The INFO button allows access to test logs, and general information about the instrument. The user can switch what information is displayed by touching the buttons at the bottom of the screen.

ABOUT: The ABOUT screen shows the firmware version, control firmware and PCB revision. This information is used for technical support if there is ever a problem with the instrument.



The following items are listed on the ABOUT screen:

- User Interface: This is the firmware version of the user interface. This is the main firmware for the instrument.
- Controller Firmware: This is the firmware used by the heater block for the temperature and speed control.
- Serial Number: This is the serial number of the instrument. It is entered at the factory and cannot be edited.
- Cumulative Motor Time: The total time the motor has been running. This cannot be reset except by the factory.
- Cumulative Heater Time: The total time the heater has been running. This cannot be reset except by the factory.
- PCB Revision: This is the revision of the board located within the heater block.
- PCB Identifier: This is a unique identifier for the board located within the heater block.

## E. Operation

LOGS: The LOGS screen has the following tabs.

- Events Tab: This a list of general events on the system such as power on, protocols being edited, and who logged in or logged off.

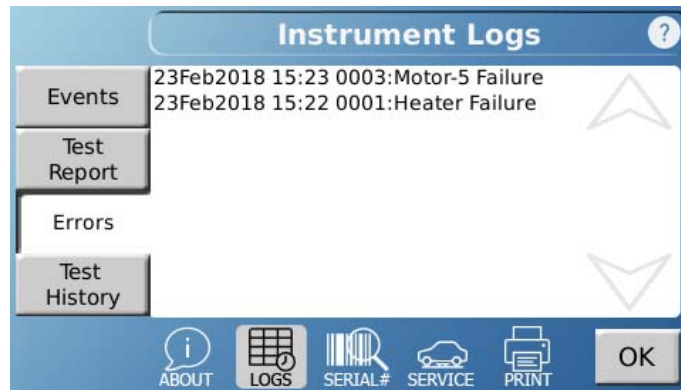


- Test Report Tab: This tab shows the report for the last test run. This is updated every time a protocol is started.

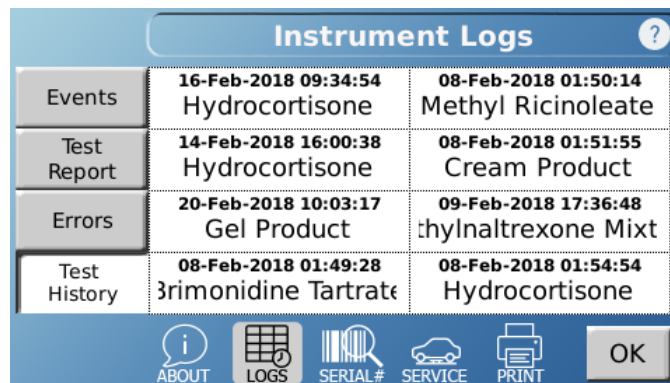


## E. Operation

- **Errors Tab:** This tab shows a list of the errors that have occurred on the system. Each error has a code associated with it which can be provided to tech support for additional assistance.



- **Test History Tab:** The Test History tab allows the user to view the past 8 tests on the instrument. Each time a new test is added to the test history, the oldest test is removed.



## E. Operation

**SERIAL# (Serial Numbers):** This screen has the serial numbers for the system.

**Instrument Tab:** This displays serial numbers for the instrument itself and the printer.

The screenshot shows the 'Serial Numbers' screen with two tabs: 'Instrument' and 'Apparatus'. The 'Instrument' tab is selected, displaying the following data:

	Phoenix DB-6
Instrument	0000-0001
Apparatus	Serial Printer 0000-0000

The bottom navigation bar includes icons for ABOUT, LOGS, SERIAL#, SERVICE, and PRINT, along with an OK button.

- **Phoenix DB-6:** This is the serial number for the instrument. It is set at the factory and cannot be changed.
- **Serial Printer:** This is the serial number for the serial validation printer. This field can be changed by touching it.

**Apparatus Tab:** This screen is for logging the serial numbers of the cells and other serialized items. To edit an apparatus touch the apparatus type from the main screen, then enter the serial numbers for each position in the new fields.

The screenshot shows the 'Serial Numbers' screen with the 'Apparatus' tab selected. It displays a table with serial numbers for various apparatus types:

	Cells	Default Title 5
Instrument	000-0011,0000-001	000-0051,0000-005
Apparatus	Cell Tops	Default Title 6
	000-0021,0000-002	000-0061,0000-006
	Mixers	Default Title 7
	000-0031,0000-003	000-0071,0000-007
	Default Title 4	Default Title 8
	000-0041,0000-004	000-0081,0000-008

The bottom navigation bar includes icons for ABOUT, LOGS, SERIAL#, SERVICE, and PRINT, along with an OK button.

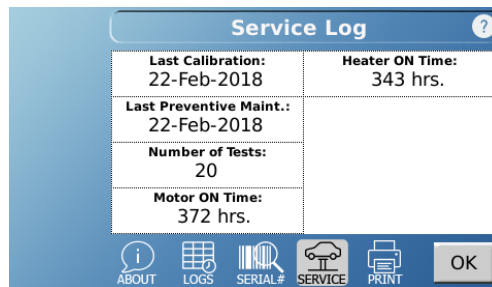
The screenshot shows the 'Cells' SN screen, which displays a table of serial numbers for different positions:

Position 1	Position 4
0000-0011	0000-0014
Position 2	Position 5
0000-0012	0000-0015
Position 3	Position 6
0000-0013	0000-0016

The bottom navigation bar includes icons for ABOUT, LOGS, SERIAL#, SERVICE, and PRINT, along with a Back button.

## E. Operation

SERVICE: The Service Log has only the Instrument tab. It displays the following:



The screenshot shows a 'Service Log' window with a blue header and a white body. The body contains a table with the following data:

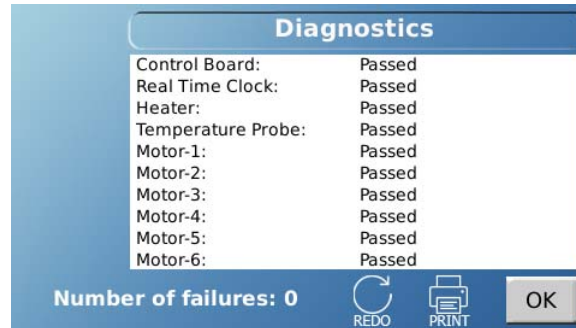
Service Log	
Last Calibration: 22-Feb-2018	Heater ON Time: 343 hrs.
Last Preventive Maint.: 22-Feb-2018	
Number of Tests: 20	
Motor ON Time: 372 hrs.	

At the bottom of the window is a navigation bar with icons for ABOUT, LOGS, SERIAL, SERVICE (highlighted), and PRINT, along with an OK button.

- Last Calibration: The date the instrument was last calibrated. This can be reset by touching the field.
- Last Preventive Maint.: The date the instrument last had a preventive maintenance. This can be reset by touching the field.
- Number of Tests: The count of how many tests have been run on the instrument. This can be reset by touching the field.
- Motor ON Time: The time the motor has been running. This field can be reset by touching it and may be different then the cumulative motor time found on the ABOUT screen.
- Heater ON Time: The time the heater has been running. This field can be reset by touching it and may be different then the cumulative heater time found on the ABOUT screen.

### Diagnostics

Touching the DIAGNOSTICS button allows the user to run a short series of tests to ensure the DB-6 is in operating condition. The following items are tested:

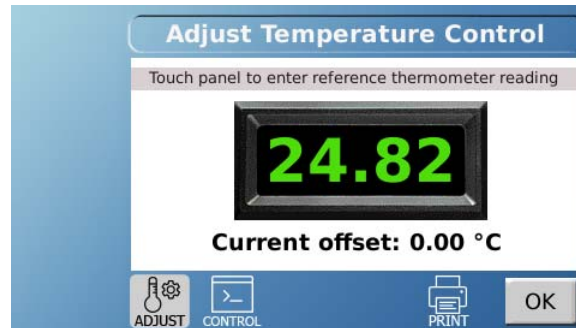


- Controller Board: Controller input and output.
- Real-Time Clock: The real-time clock which is responsible for keeping time on the instrument.
- Heater: The heater to ensure current is passing through it properly.
- Temperature Probe: Communication and suitability of the temperature probe connected.
- Motors 1 through 6: Ensure each motor is responding properly to commands.
- REDO: The REDO button will start the diagnostics again.
- If a test fails, the instrument will refer the user to view the error log for additional information and possible resolution of the issue.

### Tools

The TOOLS screen allows for adjustment of offsets and use of the command prompt interface.

ADJUST: This screen allows for adjustment of the temperature probe within the heater block.



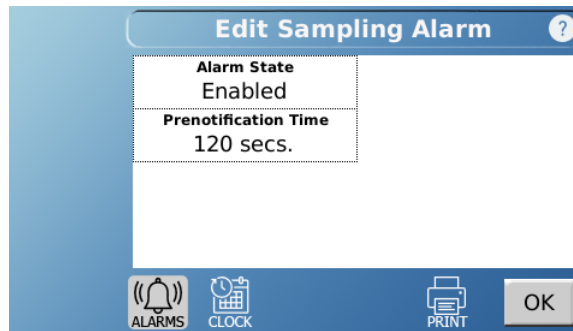
1. Clear the previous offset.
2. Set the heater block to a non-zero temperature and allow it to stabilize at least 30 minutes.
3. Place a traceable thermometer probe in the hole located between cells 3 and 4.
4. Allow the probe to stabilize for 1 to 2 minutes.
5. Turn off the heater to prevent the temperature from changing during the reading.
6. When the reading is stable, touch the screen display and enter the reading from the traceable thermometer.

CONTROL: Remote commands are used by service personnel only to resolve technical issues with the equipment. Instructions will be given from tech support on how to use the remote commands if there is a problem.



### Time

The TIME button opens up the sampling alarm and clock for the system.



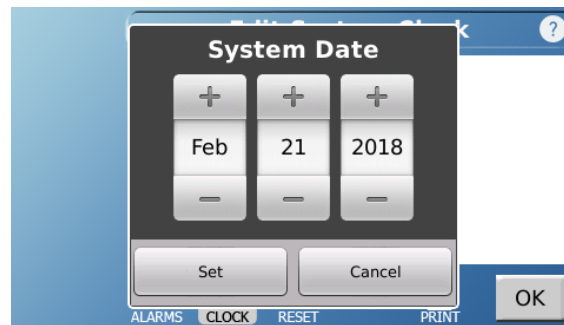
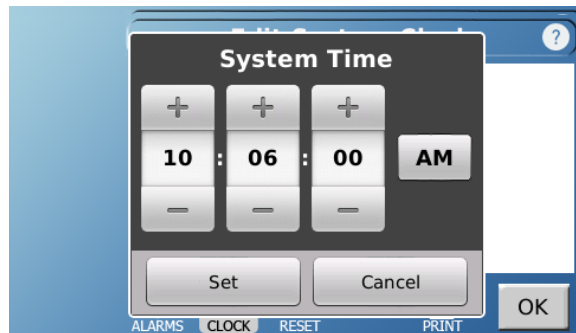
**ALARMS:** The sampling alarm will notify the user when a sample point is imminent.

- **Alarm State:** This enables or disables the alarm.
- **Prenotification Time:** This is the amount of time before a sample point the alarm sounds, set in seconds. If a user sets the alarm for 15 seconds, then 15 seconds prior to the sample point a notification would appear on the screen with a countdown to the sample.

## E. Operation

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**CLOCK:** The CLOCK screen allows the user to set the time and date of the instrument.

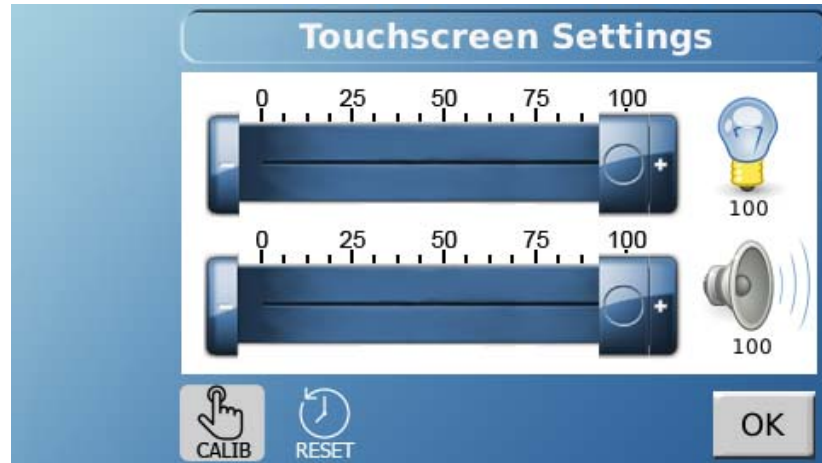


**PRINT:** The PRINT button will print all the alarm settings to the attached printer.

## E. Operation

### Display

The DISPLAY button allows access to the touch screen settings. There are two sliders present.



- Brightness (Light Bulb): Adjusts the brightness of the screen.
- Volume (Speaker): Adjusts how loud the system is when it beeps.

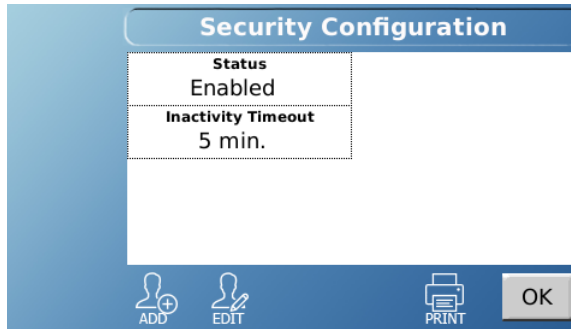
**CALIB (Calibration):** This launches the touch screen calibration. Touching it will bring up a confirmation box. If the user then touches *Calibrate*, the system will reboot into a calibration mode. The process takes about 30 seconds. The user is then instructed to touch 5 points on the screen. A stylus is highly recommended for this procedure.

**NOTE:** Do not use sharp objects for calibration as they can damage the screen.

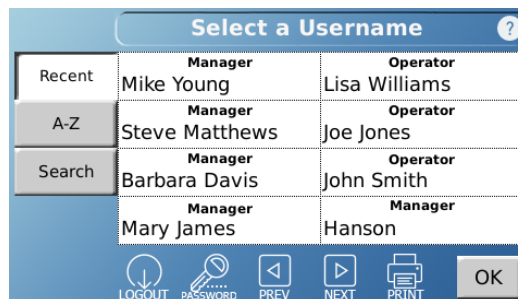


### Security

The SECURITY button opens up the security settings and users for the instrument.



- Status: The Status button switches the security between Enabled and Disabled.
- Inactivity Timeout: The amount of time it takes for the instrument to lock out the current user after not sensing any input.
- When a user sets the security status to Enabled and touches OK, they will be presented with a list of the available users and must log into the instrument. Users are divided into 2 categories.



Manager: A manager has the ability to modify anything present on the DB-6. Any change will be tracked in the event log.

**NOTE:** By default, a **Hanson** user is present as a manager. The default password for **Hanson** is 0000 (four zeros).

Operator: An operator can view any setting in the DB-6, but is only allowed to run protocols, operate the manual controls, and change their own password. A lock icon will appear next to a screen title to show that the data shown cannot be edited as security is enabled and the current user has operator privileges.

## E. Operation

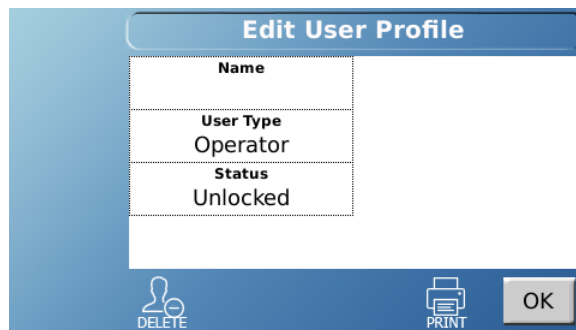
---

The following buttons are available to all users

- LOGOUT: Logs the current user out of the instrument. Any new activity will require a user to log in with a password.
- PASSWORD: Allows the current user to change their password.

When a manager logs into security they have the following buttons available:

- ADD: The ADD button allows the manager to add a new user.
- EDIT: The EDIT button allows the manager to edit a current user.



Edit User Profile	
Name	
User Type	Operator
Status	Unlocked

DELETE PRINT OK

When adding or editing a user the following items are available:

- Name: The name of the user. This must be unique on the system. Two users cannot have the same name.
- User Type: This field determines if the user is an operator with limited access, or a manager with complete access.
- Status: This is a toggle that determines if a user is locked or not. If a user is locked, they will be unable to log into the instrument.

**NOTE:** A user will be locked out after 5 failed attempts to log in. To unlock the user a manager must log in and unlock the user through the security screens.

## E. Operation

### Config

The CONFIG button opens up the system configuration options for the instrument.

SETUP: The SETUP screens are for configuring the instrument settings which may affect operation.

Instrument Tab: The Instrument tab allows the user to set tolerances and the instrument ID.

The screenshot shows the 'Device Setup' screen with a blue header and a white background. On the left, there is a vertical navigation bar with two tabs: 'Instrument' (selected) and 'Printer'. The main area displays the following settings:

<b>Instrument I.D.</b>	DB-6
<b>Temperature Tolerance</b>	$\pm 0.5$ °C
<b>Speed Tolerance</b>	$\pm 5\%$ RPM

At the bottom, there is a blue bar with five icons: a gear for 'SETUP', a tag for 'TITLES', a lightning bolt for 'UPDATE', a printer for 'PRINT', and an 'OK' button.

- **Instrument I.D.:** The instrument ID is what appears on printouts when a test is run and allows an identification of the instrument beyond the serial number. To change the ID, touch the field.
- **Temperature Tolerance:** This is the temperature tolerance used for the instrument when a protocol is not running. If a protocol is being used, the tolerance for the protocol will be used until the protocol is complete. This tolerance applies to manual settings only.
- **Speed Tolerance:** This is the speed tolerance used for the instrument when a protocol is not running. If a protocol is being used, the tolerance for the protocol will be used until the protocol is complete. This tolerance applies to manual settings only.

## E. Operation

Printer Tab: The Printer tab allows the user to configure the printer.

The screenshot shows the 'Device Setup' window with the 'Printer' tab selected. The window has a blue header with the title 'Device Setup' and a help icon. On the left, there is a vertical menu with 'Instrument' and 'Printer' tabs. The 'Printer' tab is active, showing a table with two rows: 'Printer Type' with the value 'RS-232 Epson' and 'Add Signature Line Footer' with the value 'Yes'. At the bottom, there is a navigation bar with icons for 'SETUP' (gear), 'TITLES' (tag), 'UPDATE' (lightning bolt), 'PRINT' (printer), and an 'OK' button.

Device Setup	
Instrument	Printer Type RS-232 Epson
Printer	Add Signature Line Footer Yes

SETUP TITLES UPDATE PRINT OK

- **Printer Type:** The options for printer type are *None* for no printer, and *RS-232 Epson*. As support for additional printers is added, more options may become available.
- **Add Signature Line Footer:** When set to *Yes*, this option will print a line for a signature at the bottom of every printout.

**TITLES:** The TITLES screens allow the user to configure the titles used for different parts of the reports and protocols.

**Company Tab:** The Company tab allows customization of the company and department the instrument belongs to.

The screenshot shows the 'Configure Titles' window with the 'Company' tab selected. The window has a blue header with the title 'Configure Titles' and a help icon. On the left, there is a vertical menu with 'Company', 'Report Headers', 'Protocol Labels', and 'Apparatus' tabs. The 'Company' tab is active, showing a table with two rows: 'Company Name' with the value 'TELEDYNE HANSON' and 'Department' with the value 'QUALITY CONTROL'. At the bottom, there is a navigation bar with icons for 'SETUP' (gear), 'TITLES' (tag), 'UPDATE' (lightning bolt), 'PRINT' (printer), and an 'OK' button.

Configure Titles	
Company	Company Name TELEDYNE HANSON
Report Headers	Department QUALITY CONTROL
Protocol Labels	
Apparatus	






SETUP TITLES UPDATE PRINT OK

## E. Operation

- **Company Name:** The name of the company the instrument belongs to.
- **Department:** The department that uses the instrument.





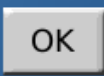
**Report Headers Tab:** Report headers are the labels which are used for each test run. They appear in the screens prior to starting a protocol, as well as the printed reports. With the exception of user name, all the fields can be changed by touching the field and entering the desired text. For information on what the default values mean refer to the subsection on Protocols earlier in Section E (Operation).

Configure Titles ?		
Company	<b>Header 1</b> User Name	<b>Header 5</b>
Report Headers	<b>Header 2</b> Test Number	<b>Header 6</b>
Protocol Labels	<b>Header 3</b> Lot Number	<b>Header 7</b>
Apparatus	<b>Header 4</b>	<b>Header 8</b> Comment

**Protocol Labels Tab:** Protocol labels are the labels that appear in the protocol on the Labels tab. With the exception of the protocol name, all the fields can be changed by touching the field and entering the desired text. For information on what the default values mean, refer to the subsection on Protocols earlier in Section E (Operation).

Configure Titles ?		
Company	<b>Label #1</b> Protocol Name	<b>Label #5</b> Membrane
Report Headers	<b>Label #2</b> Drug Name	<b>Label #6</b> Media Type
Protocol Labels	<b>Label #3</b> Dosage	<b>Label #7</b> Media Volume
Apparatus	<b>Label #4</b> Protocol I.D.	<b>Label #8</b> Comment



## E. Operation

Apparatus Tab: All Apparatus Titles can be entered or changed by touching the field and entering the desired text. These values will appear in the serial number log. For information on what the default values mean, refer to the INFO screens.

The screenshot shows a screen titled "Configure Titles" with a table of titles and a bottom navigation bar. The table has four rows, each with a category on the left and two title fields on the right. The bottom bar contains icons for SETUP, TITLES, UPDATE, PRINT, and an OK button.

	<b>Apparatus Title#1</b>	<b>Apparatus Title#5</b>
Company	Cells	Default Title 5
Report Headers	<b>Apparatus Title#2</b> Cell Tops	<b>Apparatus Title#6</b> Default Title 6
Protocol Labels	<b>Apparatus Title#3</b> Mixers	<b>Apparatus Title#7</b> Default Title 7
Apparatus	<b>Apparatus Title#4</b> Default Title 4	<b>Apparatus Title#8</b> Default Title 8

Bottom Bar: SETUP (gear icon), TITLES (tag icon), UPDATE (lightning bolt icon), PRINT (printer icon), OK (button).

UPDATE: The UPDATE button launches a firmware update procedure to update the DB-6 firmware.

### Testing Screens

There are a number of screens unique to running a test.

**Edit Report Header:** The Report Headers screen allows a user to enter information into the test report that is unique to each test run. This could be things such as a notebook entry, lot number, or test number.

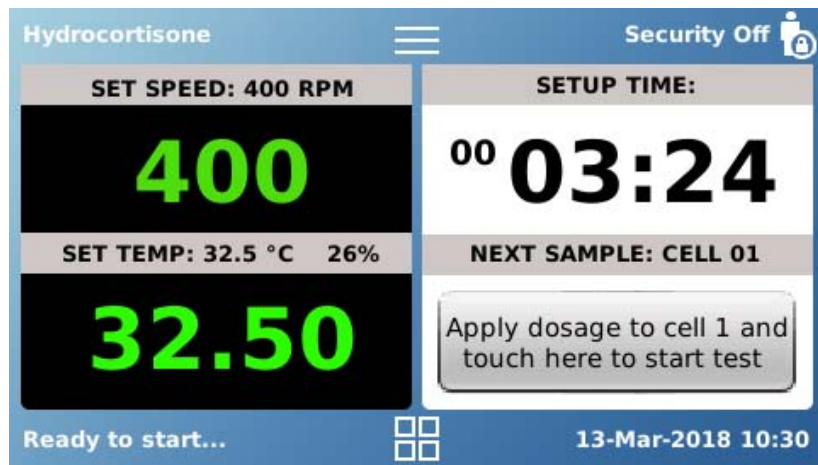
Edit Report Header	
User Name	John Smith
Test Number	02
Lot Number	A
	Comment New Product

CLEAR OK

- User Name is auto-populated from security if enabled. Otherwise the user can enter their name.
- Other fields present are configurable through the TITLES screens of the Configuration menu.
- The CLEAR button will remove all data from the fields. Data is retained from the previous test run to reduce user entry with sequential tests.
- The OK button will advance to the main screen where the test is started.

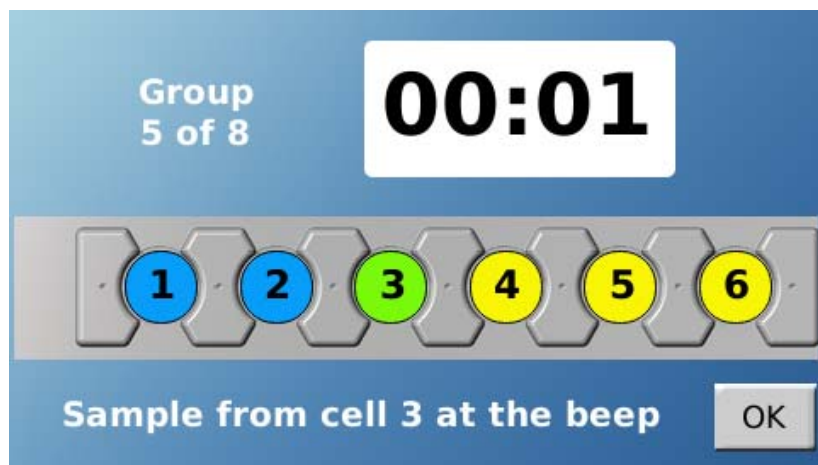
When the DB-6 is heated and stirring at the correct speed, the following screen will be displayed.

## E. Operation



To start the test the user needs to touch the button located in the NEXT SAMPLE field.

Sampling Position Screen: This screen indicates which cell should be sampled based on the cell offset in the protocol.



- Group: Indicates which of the total sample points is happening.
- Countdown: A countdown occurs for each individual cell based on the offset from the protocol.
- Cell Color: Based on the stage of the sampling process the cells will change color:
  - Blue: Already sampled
  - Green: Currently being sampled
  - Yellow: Will be sampled
- OK: Closes the screen and returns to the main screen.

## F. Diffusion Testing

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### Cells and Test Preparation

Before running a diffusion test, the cells will need to be assembled and prepared, the heater stirrer block should be turned on and allowed to heat up, and the cells allowed to reach the testing temperature.

### Turning on the Heater

The heater block takes roughly 30 minutes to heat and stabilize. It is recommended that prior to placing the cells in the heater block, that it is heated to the desired testing temperature. Typically, an offset of about 0.5 °C is necessary to get cells and membranes to the desired testing temperature. However, this may vary based on environmental conditions.

1. From the main screen touch the temperature.
2. Enter a temperature on the numeric keypad and touch Done or select one of the programmable preset temperatures.
3. The screen will return to the Home screen and the block will begin heating. Note that the *SET TEMP* value changed to the desired set point.

### Preparing the Diffusion Cells

Preparing the diffusion cells involves a few key points. The membrane must be allowed to soak prior to the test. The cell must be assembled, filled, and all air bubbles need to be removed.

1. If a membrane needs to be soaked in something different than the receptor media, then soak the membrane. Otherwise, go to step 2.
2. Place the desired stirrer inside the diffusion cell.
3. Install the cell cap onto the top of the diffusion cell.
4. Place the membrane on top of the cell cap.

## F. Diffusion Testing

---

6. Install the dosage lid on top of the membrane. Give the dosage lid a quarter turn while pressing firmly down to ensure it seats properly on top of the membrane.

**NOTE:** *Selection of the proper dosage lid should be based on the product type. Creams and ointments which do not change during the test can be used with the standard 4 mm thick tops. Gels, which may swell during testing, and liquids may perform better with 20 mm deep cell tops.*

7. Fill the cell with deaerated receptor media through the arm. Use of a syringe is recommended.

**NOTE:** *Do not fill the cell too quickly as doing so may re-aerate the media which will cause bubbles to appear and block the membrane during the test.*

8. Place the cell on a stir plate or in the DB-6 with the stirrers activated and allow any bubbles trapped along the stirrer to move to the top of the cell.
9. Remove the cell from the stir plate or DB-6. Tip the cell to dislodge any bubbles.
10. Adjust the volume so that the meniscus of the media is in line with the volume mark on the diffusion cell.
11. Place the dosage lid cover on top of the cell.
12. Place the assembled cell in the DB-6 and allow the media to heat up to the desired temperature. A heat-up time of 30 minutes is recommended.
13. Repeat for each diffusion cell used in the test.
14. Ensure the stirrer is rotating at proper speed within the cells.

## F. Diffusion Testing

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### Starting the Test

1. Use manual controls to set the desired block temperature and allow the block to heat up.
2. If desired, use the manual controls to set the motor speed for the test.

**NOTE:** *Setting the motor speed prior to the test allows the receptor media to be circulated and reach a testing temperature more quickly. If using a protocol, the speed will remain 0 until the user touches the START button which will start the stirrers.*

3. Select the protocol by touching the upper left corner of the Home screen, then using the tabs to navigate all the protocols. Touch the field of the desired protocol to load it. The DB-6 will return to the Main screen and the START and RESET buttons will appear.
4. Ensure the cell temperatures are within range to begin the test. An IR thermometer used to measure the membrane is recommended.

**NOTE:** *Ensure the sensor of the IR thermometer is lined up over the membrane. The laser pointer is meant for long distance measurements.*

5. Using a mirror, check for any bubbles under the membrane and remove them by lifting and tipping the cell.
6. Remove the dosage lid cover.
7. Dispense the donor material into the donor chamber of the dosage lid. If necessary, use a spatula to remove any bubbles and/or excess material from the dosage.
8. Place the dosage lid cover on top of the dosage lid.
9. Touch the START button to begin the protocol.
10. After waiting an appropriate time for an offset, repeat steps 6 - 8 for the next cell to be tested. There will be a message which cell should receive the dosage in the lower left corner of the screen.

An offset of 30 seconds is recommended for micro-pipette sampling. An offset of 1 minute is recommended when sampling with a syringe.

## F. Diffusion Testing

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11. When the sample point appears, the screen will change to the figure below.
  - a. A blue cell indicates the cell should have already been sampled.
  - b. The countdown at the top of the screen indicates the time until the next sample. The green flashing cells indicate the cell that should currently be sampled.
  - c. Yellow cells have yet to be sampled.
  - d. To close the screen before all the cells are complete, touch the OK button.
12. At the sample point use a micro-pipette or syringe to collect a sample. Then replace the volume that was removed with clean receptor media.

### **Post-Test Disassembly and Cleaning**

When a test is completed, disassemble and clean up as follows:

1. Finish recording any observations and results before disassembling the test setup.
2. Remove the cells from the heater block.
3. Disassemble the cells and wash the components.

Warm water is recommended. If the API and/or excipients will not dissolve in water an appropriate solvent should be used. Refer to the wetted materials list in this user guide as needed.

4. Allow the cell components to dry.

## G. Maintenance

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### Scheduled Maintenance

The DB-6 diffusion system does not have any parts which are serviced on a regular interval. Verification of speed and cell temperature is recommended every 6 months.

Any spills on the DB-6 should be cleaned up immediately.

Cells and cell components should be cleaned after every test.

Warm water is recommended for cleaning in most situations. If a more aggressive solvent is required in order to remove the API and/or excipients from cell components the following wetted materials list should be consulted.

Parts/Location	Material
Diffusion cell	Borosilicate glass
Mixer Cell cap Dosage lid	PEEK
Dosage lid cover	Borosilicate glass
Arm cover, slotted	Low density polyethylene
Arm cover, solid	EPDM

### Viewing the Firmware Version

The firmware versions can be viewed on the ABOUT screen under INFO from the Main menu.

### Firmware Upgrades

To upgrade firmware please contact technical support.



### Determination of Cell Volume

Knowing the actual volume of the receptor media is critical for ensuring accuracy and reducing variability in results. There are two approaches to use for this.

The first is the user could dispense a known volume into each of the diffusion cells.

The second is that the user can fill to the mark located on the cell arm when using the cells. The volume mark would represent a known value derived from the following calibration procedure.

1. Ensure the diffusion cell, and cell components are completely dry.
2. Place the desired stirrer into the diffusion cell.
3. Cut a disk of parafilm into a diameter of 25 mm.
4. Place the parafilm disk into the desired cell cap.
5. Snap the desired dosage lid into the cell cap.
6. Weigh the dry assembled cell and record the tare weight.
7. Fill the cell with DI water until the meniscus is in line with the mark on the cell arm.
8. Reweigh the cell.
9. Subtract the weight of the filled cell from the tare weight. Divide by the density of water corrected for temperature to determine the volume of that cell configuration.
10. Empty the cell and repeat steps 7 through 10 until 3 measurements are obtained.
11. It is recommended that the average of the 3 measurements be used as the true cell volume. The measurements should agree within a relative standard deviation (RSD) of not more than 2%.

## H. Troubleshooting

### Troubleshooting

If the DB-6 diffusion system shows signs of improper operation, refer to the troubleshooting chart below to assess and resolve the problem.

Problem	Possible Causes	Recommended Action
Display will not turn on.	Display is not plugged in or DB-6 is not plugged in.	Connect display to DB-6; ensure display cable is in good condition; check and connect power cable; check wall outlet
Temperature is not stable.	Instrument affected by draft or direct sunlight.	Move instrument to location free of drafts and direct sunlight.
	No sleeves with diffusion cells	Ensure small and medium cells have sleeves properly installed.
	DB-6 is not covered	Run DB-6 with a cover over the cells.
Temperature stays at 0.0.	Temperature probe has failed.	Contact tech support.
Temperature setpoint stays at 0.0.	Over-temperature sensor triggered.	Wait for block to cool and retry. If problem persists, contact tech support.
Temperature is not correct.	Probe offset must be adjusted.	Use TOOLS screen to adjust temperature probe offset.
	Measurement point not in the center of the block.	Use one of the measurement holes near the center of the heater block.
Stirring speed is not correct.	Stirrers are out of sync with stirring device.	Set speed to 0, then set the speed to desired set point and allow stirrers to accelerate to the proper speed.
	One or more motors failing.	Cycle power to unit and if problem continues contact technical support.
	Stirrer is damaged.	Replace stirrer.
Brushing or grinding noise when motors running.	Not serviceable by end user.	Contact technical support.
System will not print.	Printer is out of paper or printer is turned off.	Replace paper; turn on printer.
	Printer not configured.	Set printer options in system configuration.

# I. Specifications

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## Phoenix DB-6 Diffusion System Specifications

Part numbers:

- Phoenix DB-6 Manual Diffusion System: 59-201-101

Weight:

- 4.22 kg (9.3 lbs.) dry

Dimensions

- Heater/Stirrer: 36.8 cm L x 7.6 cm W x 14.0 cm H (14.5 in L x 3.0 in W x 5.5 in H)
- Display: 12.7 cm L x 7.62 cm W x 2.22 cm H (5.0 in L x 3.0 in W x 0.875 in H)

USP <1724> conformance:

- Stirring speed:  $\pm 10\%$  of set point
- Temperature:  $\pm 1\text{ }^{\circ}\text{C}$

## DB-6 Wetted Materials

Parts/Location	Material
Diffusion cell	Borosilicate glass
Mixer Cell cap Dosage lid	PEEK
O-rings for call cap and dosage lid	Viton
Dosage lid cover	Borosilicate glass
Arm cover, slotted	Low density polyethylene
Arm cover, solid	EPDM

# I. Specifications

## Cell Volumes and Dosage Volumes

The nominal cell volumes and dosage volumes for various combinations of cells, mixers, and caps can be identified in the tables below.

Cell Size	Cell P/N (Clear)	Cell P/N (Amber)
Small	59-207-051	59-207-061
Medium	59-207-052	59-207-062
Large	59-207-053	59-207-063

Part Numbers for Mixers, PEEK			
Mixer Height	For Small Cells	For Medium Cells	For Large Cells
13 mm	59-207-122	59-207-126	59-207-130
30 mm	59-207-123	59-207-127	59-207-131

Nominal Cell Volume with Mixer Installed			
Mixer Height	Small Cell	Medium Cell	Large Cell
13 mm	14 mL	21 mL	30 mL
30 mm	10 mL	15 mL	21 mL

Part Numbers for Cell Cap Kits, 4 mm Deep, PEEK			
Orifice Diameter	For Small Cells	For Medium Cells	For Large Cells
9.0 mm	59-207-201	N/A	N/A
11.3 mm	59-207-203	59-207-215	N/A
15.0 mm	N/A	59-207-217	59-207-231
20.0 mm	N/A	N/A	59-207-233

Part Numbers for Cell Cap Kits, 20 mm Deep, PEEK			
Orifice Diameter	For Small Cells	For Medium Cells	For Large Cells
9.0 mm	59-207-202	N/A	N/A
11.3 mm	59-207-204	59-207-216	N/A
15.0 mm	N/A	59-207-218	59-207-232
20.0 mm	N/A	N/A	59-207-234

Nominal Dosage Volume Based on Cell Cap Orifice and Depth		
Orifice Diameter	With Cell Cap 4 mm Deep	With Cell Cap 20 mm Deep
9.0 mm	0.254 mL	1.272 mL
11.3 mm	0.400 mL	2.000 mL
15.0 mm	0.707 mL	3.534 mL
20.0 mm	1.257 mL	6.283 mL

## J. General Warranty

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### **General Warranty**

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