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QAII Station Operator's Manual

P/N 70-9018
November 2010
Revision K

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QAII Station Operator's Manual
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List of Figures

Chapter 1 Safety Practices and Hazards

The QAII Station has been carefully designed so that when used properly you have an accurate, fast, flexible, and safe instrument.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

The QAII Station is operated in conjunction with equipment that uses aqueous liquids. Unskilled, improper, or careless use of this instrument can create shock hazards, fire hazards, or other hazards which can cause death, serious injury to personnel, or severe damage to equipment and property.

Information on safety practices is provided with your instrument and operation manuals. Before using your instrument or accessories, you must thoroughly read these safety practices.

Observe all relevant safety practices at all times.

Electrical Hazards

The QAII Station contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.

Panels or covers that are retained by fasteners which require the use of a tool for removal may be opened only by Varian-trained, Varian-qualified, or Varian-authorized service engineers. Consult the manuals or product labels supplied with the QAII Station to determine which parts are operator-accessible.

Application of the wrong supply voltage, connection of the instrument to an incorrectly wired supply outlet, or lack of proper electrical grounding can create a fire hazard or a potentially serious shock hazard and could seriously damage the instrument and any attached ancillary equipment.

Always use a three-wire outlet with ground connection which is adequately rated for the load. The installation must comply with local, state, and federal safety regulations.

Do not connect the instrument to the main power supply until you have made sure that the operating voltage is correctly set for the main power supply in the specific outlet in your laboratory to which the equipment will be connected.

Other

Other specific warnings and cautions appear in the manuals where appropriate and detail the specific hazard, describe how to avoid it, and specify the possible consequences of not heading the warning or caution.

Warning

A 'Warning' message appears in the manual when failure to observe instructions or precautions could result in death or injury. Symbols depicting the nature of the specific hazard are also placed alongside warnings.

These symbols are also used on warning labels attached to the instrument. When you see one of these symbols, you must refer to the relevant operation or service manual for the correct procedure referred to by that warning label.

The meaning of the symbols that appear alongside warnings in this manual are as follows:

Electrical shock

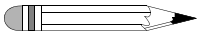
Caution
Refer to accompanying documents

Read all warnings and cautions carefully and observe them at all times.

Caution

A 'Caution' message appears in the manual when failure to observe instructions could result in damage to equipment (Varian supplied and / or other associated equipment).

A 'Note' appears in the manual to give advice or information.



Information Symbols

I	Switches main power on
0	Switches main power off
	Indicates single-phase alternating current
	Indicates the product complies with the requirements of one or more European Union (EU) directives
	Indicates specific equipment meets consensus-based standards of safety to provide assurance, required by OSHA, that these products are safe for use in the workplace for North America
	Indicates that this product must not be disposed of as unsorted municipal waste (see "WEEE Directive" on page 13)

General

CE Compliant Products

The QAII Station has been designed to comply with the requirements of the Electro-magnetic Compatibility (EMC) Directive and the Low Voltage Directive (LVD) of the EU.

Varian, Inc. has confirmed that each product complies with the relevant directives by testing a prototype against the prescribed European Norm (EN) standards.

Proof that a product complies with the directives is indicated by:

- the CE marking appearing on the rear of the product.
- the documentation package that accompanies the product containing a copy of the declaration of conformity. This declaration is the legal declaration by Varian, Inc. that the product complies with the directives and also shows the EN standards to which the product was tested to demonstrate compliance. The declaration of conformity is signed by the representative of the manufacturing plant.

cTUVus - U.S. and Canadian Product Approvals

The QAII Station has been designed to comply with North American safety requirements.

This product has been tested and certified for the North American market by TUV Rheinland of North America, Inc. The TUVus mark signifies that this product has been tested to U.S. standards and certified for the U.S. market. The cTUV mark signifies that this product has been tested to Canadian standards and certified for the Canadian market. When the two marks are coupled, the cTUVus mark signifies that this product has been tested to standards and certified for both markets.

WEEE Directive

All Varian products that are subject to the WEEE directive shipped after August 13, 2005 are compliant with the WEEE marking requirements. Such products are marked with the "crossed out wheelie bin" WEEE symbol shown on page 12 in accordance with European Standard EN 50419.

This symbol on the product or on its packaging indicates that this product must not be disposed of as unsorted municipal waste. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.

For more information on collection, reuse, and recycling systems, please contact your local/regional waste administration, your local distributor, or Varian, Inc.

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Chapter 2 Introduction

The QAII Station is designed to help you easily check the critical physical parameters specified in the USP General Chapters <711> Dissolution and <724> Drug Release.

The QAII Station tests and documents the parameters of the following variables:

- shaft wobble (also known as runout)
- instrument level
- vessel temperature
- spindle speed
- vibration

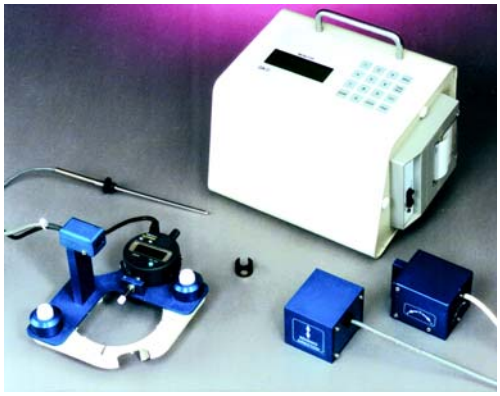
Regulatory authorities emphasize these factors since they can lead to major variances in your dissolution results. Test data from up to 30 dissolution apparatus can be stored in the QAII Station's non-volatile memory. The data can be printed via the Report Center Printer. The QAII Station records the serial numbers of the apparatus in addition to test values.

The built-in printer provides a detailed hard-copy calibration report listing all parameter values for each vessel position. If you use Varian serialized paddles or basket shafts, you can enter the shaft serial numbers for each dissolution apparatus in your lab and have these numbers print on the report as well.

Base Unit

The base unit contains the keypad, display screen and Report Center Printer. This unit stores information for up to 30 apparatus. The five remote sensors plug into the keyed jacks on the rear panel. The base unit has a rechargeable battery for portable use and its own AC power supply for printing or charging the battery. There is a power switch on the left side panel that controls the battery power to the unit and there is a power switch on the rear panel that controls AC power to the unit. You must operate under AC power in order to print via the Report Center Printer. A certified calibration shaft is included and guaranteed to be within USP specifications.

FIGURE 1. QAII Station



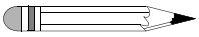
Caution

Panels or covers that are retained by fasteners which require the use of a tool for removal may be opened only by Varian-trained, Varian-qualified, or Varian-authorized service engineers.

Conventions Used in this Manual

- Items you are asked to press are in bold. For example, "press **TEST** on the keypad" or "Press **ENTER**".
- Key sequences you are asked to press appear like this: **MENU** > **2**.

Note



Remember to return the warranty card supplied with this manual. Completing and returning the card ensures your right to protection under the terms and conditions of your warranty. It also enables us to better assist you in the event of any problems. Additionally, it guarantees you will be informed of any issues that arise concerning your equipment, such as upgrades, retrofits, or regulatory changes.

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Chapter 3 Installation and Setup

Unpacking Your QAII Station

Follow these steps to safely unpack your QAII Station:

Step 1. Open each carton and check the contents for damage which may have occurred during shipping. Shipping damage rarely occurs, but if it does contact both the carrier who delivered the instruments and the Dissolution Systems Service Department. Though claims for damage should be filed with the carrier, we can help you file a claim.

Step 2. Carefully remove the QAII Station base unit, digital wobble gauge and magnetic tachometer sensor (attached to an EaseAlign mounting bracket and universal adapter), magnetic clip, electronic level sensor, precision temperature probe, electronic vibration sensor, calibration shaft, and all the cables from the shipping carton.

Step 3. Remove as much cushioning material and tape as possible.

Step 4. Place the base unit and accessories on a clear, dry, level section of the bench top close to the dissolution apparatus. The preferred placement of the QAII Station is on the right side of the dissolution apparatus.

Warning

The electrical connection at the back of the QAII is the primary disconnect for the instrument. The QAII should be positioned to allow accessibility to the power cord for easy disconnection.

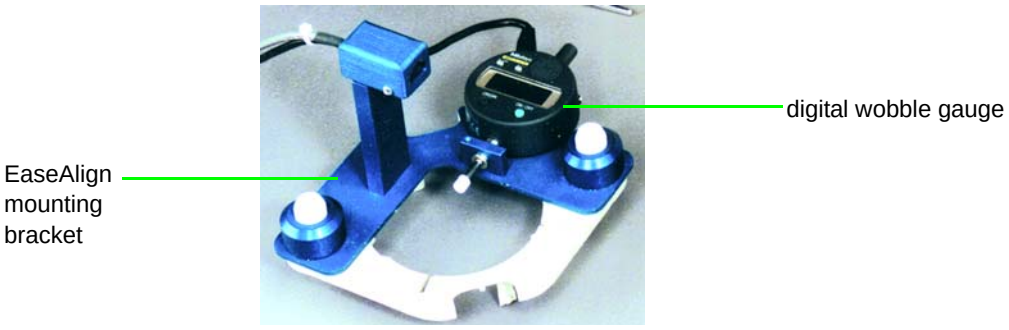
QAII Attachments

The QAII comes with attachments necessary to measure and document individual spindle speeds, shaft wobble, shaft perpendicularity, temperature, instrument level, and vibration.

Digital Wobble Gauge

Mounted on a self-aligning bracket (the EaseAlign mounting bracket), the wobble gauge has a built-in display screen and indicates wobble in terms of inches or millimeters. A power switch preserves the life of the lithium battery. The ORIGIN button makes it easy to zero the gauge prior to starting the spindles. A cable transmits the gauge reading to the QAII Station base unit.

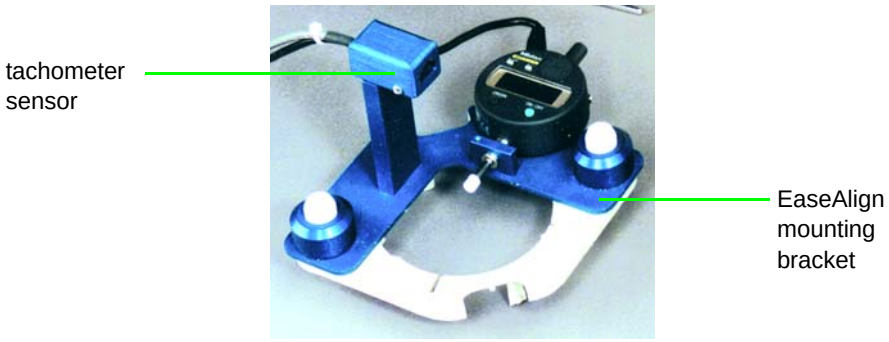
FIGURE 2. Digital Wobble Gauge



Magnetic Tachometer Sensor

The magnetic tachometer sensor is also mounted on the EaseAlign mounting bracket. The sensor detects the rotations per minute of the paddle or basket shaft with the use of a magnetic clip.

FIGURE 3. Magnetic Tachometer Sensor



Magnetic Clip

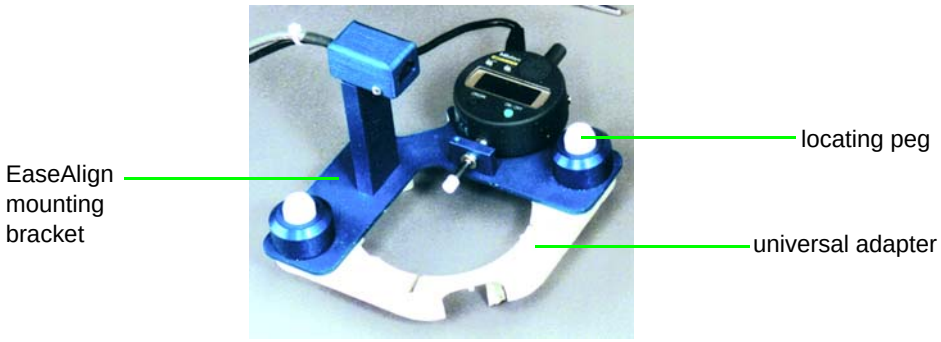
The magnetic clip is used in conjunction with the magnetic tachometer sensor. Each time the magnet passes the sensor, one rotation is counted.

FIGURE 4. Magnetic Clip

Universal Adapter

The supplied universal adapter allows the QAII Station to be used in conjunction with any Varian dissolution apparatus, including older models, or with any non-Varian dissolution apparatus. The adapter provides locating pegs to secure the EaseAlign mounting bracket with wobble gauge and tachometer sensor to the dissolution apparatus vessel.

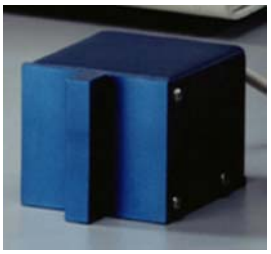
FIGURE 5. Universal Adapter



Electronic Level Sensor

The electronic level sensor allows you to check the level of the vessel plate and drive unit as well as the perpendicularity of each shaft from side-to-side and front-to-back, simultaneously. The sensor has a range of -9.9 to 9.9 degrees.

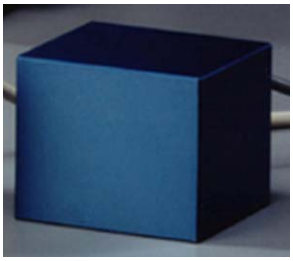
FIGURE 6. Electronic Level Sensor



Electronic Vibration Sensor

The electronic vibration sensor can be placed either on the vessel plate or on the drive unit in the upright position to obtain readings. The sensor can be used to measure vibration on the X, Y, and Z axes individually.

FIGURE 7. Electronic Vibration Sensor



Temperature Probe

The temperature probe allows you to measure the temperature of the medium in the vessel. The temperature probe can also be used to measure the temperature of the water in the water bath or any other aqueous-based solutions.

FIGURE 8. Temperature Probe

Warning

The QAII Station contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.

Power Switch Functions

Warning

Ensure the AC power setting is at the correct voltage for your power supply. The power setting is indicated on the line fuse holder located next to the on/off switch on the instrument back panel. To change the voltage, see "Fuse Replacement" on page 51.

The electrical connection at the back of the QAII is the primary disconnect for the instrument.

The QAII Station has a main power switch and a battery power / charge switch.

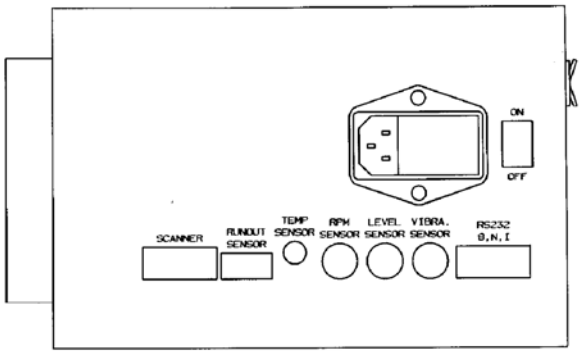
The main power switch is located on the rear panel. See Figure 9, "QAII Station Rear Panel," on page 25. With the switch in the ON position, the QAII Station is on and you can charge the battery and print.

The battery power / charge switch is on the left side panel. When AC power is not present, such as when the power cord is not attached or when the main switch is off, the battery power /charge switch allows battery power for data collection and monitoring. If the AC power is on, the battery power / charge switch is used to charge the battery only.

It is recommended that you fully discharge the battery before the next charge to extend the battery life. When the power is weak, leave the battery switch on overnight without AC power. This drains the remaining power so that it can be recharged. Each charge period takes five to six hours. Note that the internal printer can be operated only with AC power.

Setting up the QAII Station

FIGURE 9. QAII Station Rear Panel



Warning

Ensure the AC power setting is at the correct voltage for your power supply. The power setting is indicated on the line fuse holder located next to the on/off switch on the instrument back panel. To change the voltage, see "Fuse Replacement" on page 51.

The electrical connection at the back of the QAII is the primary disconnect for the instrument.

Step 1. Ensure the power switches on the rear panel and left side panel are in the off position.

Step 2. Connect the cables between the remote sensors and their corresponding jacks on the QAII Station rear panel. Each cable has a different kind of connector making it impossible to plug it into the wrong jack.

Step 3. Connect the AC power cord between the receptacle on the rear panel and an appropriate AC power receptacle.

Note

AC power is necessary for battery charging or printing.

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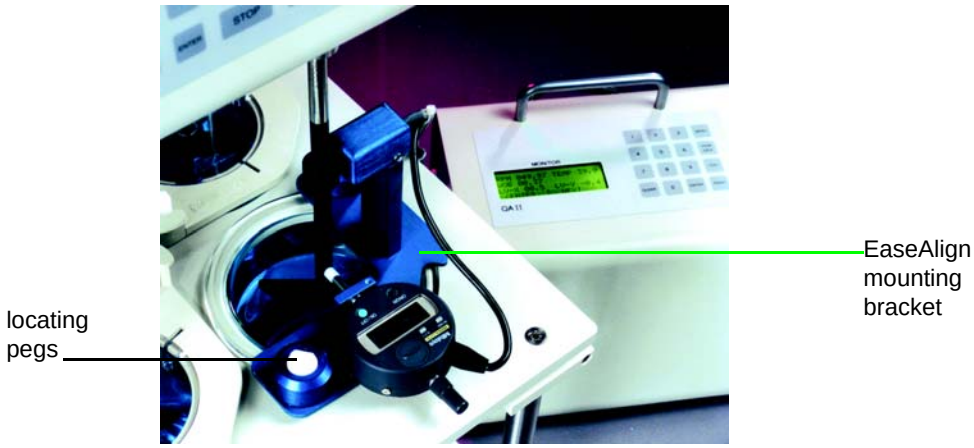
Chapter 4 Operation

The QAII Station can be used in conjunction with any Varian dissolution apparatus, including older models, or with any non-Varian dissolution apparatus.

For dissolution apparatus that do not have EaseAlign centering rings, the QAII Station comes with a universal adapter. This adapter mounts to the dissolution apparatus vessel in the same manner as the EaseAlign centering rings. Once this adapter is in place, the procedures for using the QAII Station are the same for all dissolution apparatus. The purpose of the adapter is to provide the locating pegs to secure the EaseAlign mounting bracket to the dissolution apparatus (see “locating pegs” in Figure 10 on page 28).

FIGURE 10. EaseAlign Mounting Bracket Secured to Dissolution Apparatus



Placing the Universal Adapter on Apparatus without EaseAlign Centering Rings

Note

Before beginning operation, the paddles or basket shafts must be set to their proper operating heights.

Step 1. Raise the dissolution apparatus drive unit.

Step 2. Position the universal adapter over the vessel and push down gently so the adapter is held in place by the short legs that rest against the inside of the vessel. The bracket should fit without having to be forced and it should sit flat on the dissolution apparatus vessel plate.

Operating the QAII Station

Step 1. Ensure the power switch is in the OFF position.

Step 2. Ensure all accessories are connected to the QAII Station rear panel. See "Setting up the QAII Station" on page 25.

Step 3. Turn on the QAII Station. The monitor screen displays.

RPM 000.00_	TEMP -1.5
WOB .0000	VIB 0.000
LV-X -6.8	LV-Y -6.8
09/30/04	15:35:30

Step 4. Press **MENU** to display the QA Main Menu screen.

QA MAIN MENU	
1 SET CLOCK	2 SETUP
3 VIBRATION	4 TEMP
09/30/04	15:37:37

Following is a description of the QA Main Menu screen options:

Option	Response
1 Set Clock	The QA Main Menu screen displays the date and time of day (in 24-hour format). For example: 14:55 indicates 2:55 pm; 09:05 indicates 9:05 am. To change or correct the date or time of day, select option **1**, Set Clock. The date displays. Press **ENTER** to accept the current date or enter the new date and press **ENTER**. The time displays. Press **ENTER** to accept the current time of day or enter the correct time in 24-hour format and press **ENTER**. The QA Main Menu screen displays.
2 Setup	See "Main Menu Option 2, Setup" on page 30.
3 Vibration	See "Main Menu Option 3, Vibration" on page 30.
4 Temp	No action required.

Main Menu Option 2, Setup

Select option **2**, Setup, from the QA Main Menu screen. The System Set Up screen displays.

```
***SYSTEM SET UP***
1 POSITION          2 METRIC
3 SCREEN SAVER TIME
4 EUROPE DATE STYLE
```

Following is a description of the System Set Up screen options:

Option	Response
1 Position	Select option **1**, Position, to select the number of positions being tested on the dissolution apparatus. Select option **1** for six or option **2** for eight. The System Set Up screen displays.
2 Metric	Select option **2**, Metric, to select the vibration unit of measure. Select option **1** for inch or option **2** for metric. The System Set Up screen displays.
3 Screen Saver Time	Select option **3**, Screen Saver Time, to enter the number of minutes (0 - 9) the back lighting for the display screen remains on. Enter the desired duration and press **ENTER**. The System Set Up screen displays.
4 Europe Date Style	Select option **4**, Europe Date Style, to select the date format as American or European. Select option **1**, America (mm/dd/yy), or option **2**, Europe (dd/mm/yy). The System Set Up screen displays.

Press **MENU** to return to the QA Main Menu screen.

Main Menu Option 3, Vibration

The monitor screen displays the g value only. To display all other values associated with the vibration reading, select option 3, Vibration, from the QA Main Menu screen. Ensure

the vibration sensor is in place prior to selecting this option. See "Measuring and Recording Vibration" on page 40.

Select option **3**, Vibration, from the QA Main Menu screen. The Vibration Analysis screen displays:

```
***VIBR ANALYSIS***
g 0.000              FRQ 000.00Hz
VELOCITY  .0000 IN/S
DISPLACEMENT 0.000MIL
```

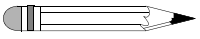
- "g" represents acceleration expressed in mm/sec² or in/sec².
- "FRQ" represents frequency expressed in Hz.
- "Velocity" is expressed in mm/sec or in/sec.
- "Displacement" is expressed in mm or mils.

Press **MENU** to return to the QA Main Menu screen.

Running a Test

The QAII Station is programmed to portably test up to 30 different dissolution apparatus.

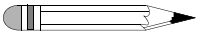
To run a test, complete the procedures through "Measuring and Recording Shaft Verticality" on page 38 for each position, then complete "Measuring and Recording Vessel Plate (Table) Level" on page 39 and "Measuring and Recording Vibration" on page 40.



Note

For each of the following procedures, the previously stored value prints for any skipped parameters.

Entering Storage and Serial Numbers



Note

Press MENU from the QA Main Menu screen to view the RPM, temperature, wobble, vibration, and level data.

Step 1. From the monitor screen, press **TEST**. The most recently stored storage number displays.

Step 2. Press **ENTER** to accept the storage number or key in a new storage number (1 to 30) and press **ENTER**. A serial number displays if one was previously entered.

Step 3. Press **ENTER** to accept the serial number or key in a new number, up to nine digits, and press **ENTER**. The following screen displays:

TEST ON POSITION 1	
1 TEST	2 SKIP NEXT
3 EXIT	
09/30/04	16:11:14

Step 4. Select from the following options on the Test on Position 1 screen:

Option	Response
1 Test	Use this option to run a test on the selected position. See "Entering Shaft Identification Numbers" on page 33.
2 Skip Next	Select option **2** to skip the position number listed and move to the next position number. The previously stored values for all of the parameters print for any skipped position number.
3 Exit	Select option **3** to return to the monitor screen.

Entering Shaft Identification Numbers

Step 1. Select option **1**, Test. A shaft identification number displays if one was previously entered.

Step 2. Press **ENTER** to accept the current identification number or enter a new number, up to six digits, and press **ENTER**.

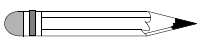
Step 3. Continue to "Measuring and Recording RPM" below.

Measuring and Recording RPM

Caution

To avoid damage to the EaseAlign mounting bracket, check the clearance between the paddle blade and the bottom of the mounting bracket before running the test.

Immediately after entering the shaft identification number, the parameters being measured display on the screen.



Note

Before beginning operation, the dissolution apparatus must be set up with the paddles or basket shafts at their proper operating heights.

Step 1. Raise the drive unit to remove the EaseAlign centering rings, if applicable, from the vessels to be tested.

Step 2. Lower the drive unit until there is a distance of approximately one centimeter from the top of the paddle blade or the bottom rim of the basket to the top of the vessel or adapter.

Step 3. Place the EaseAlign mounting bracket with the magnetic tachometer sensor and digital wobble gauge on the first vessel position to be tested. The locating holes in the self-aligning mounting bracket slip over the locating pegs (see "locating pegs" in Figure 10 on page 28).

Step 4. Press down until the mounting bracket is level and firmly seated.

Step 5. The tip of the wobble gauge pointer should be positioned against the paddle shaft or the bottom rim of the basket.

Step 6. Place the magnetic clip on the paddle or basket shaft being checked (see Figure 11, "Placement for RPM Reading," below). To avoid damage to the paddle or basket shaft, place the clip at or near the top of the shaft, just below the spindle chuck, then slide it down into its operating position in front of the tachometer sensor.

FIGURE 11. Placement for RPM Reading

Step 7. Set the desired RPM on the dissolution apparatus.

Step 8. Turn on the spindles.

Step 9. On the QAII, press **ENTER** to store the RPM or press **CLEAR** to skip the RPM.

Note

If you press CLEAR, the previously stored value prints for the RPM.

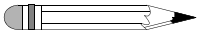
Step 10. Continue to "Measuring and Recording Temperature" on page 35.

Measuring and Recording Temperature

Complete the following steps to record the temperature:

Step 1. Ensure the temperature probe is in the vessel being measured. Be careful not to entangle the temperature probe with the rotating spindles.

Step 2. Press **ENTER** to store the temperature or press **CLEAR** to skip the temperature.

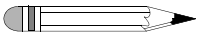


Note

If you press CLEAR, the previously stored value prints for the temperature.

Step 3. Continue to "Measuring and Recording Wobble" below.

Measuring and Recording Wobble



Note

For highest accuracy, runout readings should be recorded with shafts turning at 50 RPM or less.

The shaft or basket wobble value, as measured by the wobble gauge in either millimeters or inches, is the absolute difference between high and low values. After zeroing the gauge, the reading on the display screen may be negative or positive since there is no way for the unit to determine whether you placed the gauge pointer on the shaft high point, low point or somewhere in between. For example, if the reading ranges between - 0.05 mm and + 0.1 mm, the QAII Station displays the runout value as 0.15 mm.

Complete the following steps to record the shaft or basket wobble:

Step 1. Turn off the spindles.

Step 2. Press **ON/OFF** on the wobble gauge. The display screen activates.

Step 3. Press **in/mm** on the gauge key to select inches or millimeters as the measurement unit.

Step 4. Press and hold briefly **ORIGIN** to auto zero the gauge. The screen displays 0.0000 in or 0.00 mm.

Note

It is not necessary to zero the wobble gauge before measuring and recording runout, since the value recorded is the absolute difference between the high and low values.

Step 5. Ensure the wobble gauge is properly positioned with the tip of the wobble gauge pointer positioned against the paddle shaft or the bottom rim of the basket. See Figure 12, "Wobble Gauge with Paddle," below and Figure 13, "Wobble Gauge with Basket," on page 37.

Note

To avoid damage to the EaseAlign mounting bracket when using Apparatus 2 (paddles), check the clearance between the paddle blade and the bottom of the mounting bracket before rotating the shafts.

FIGURE 12. Wobble Gauge with Paddle

Note

When using Apparatus 1 (baskets), it is necessary to reposition the runout gauge pointer to the bottom rim of the basket before obtaining a reading. Take extra care to avoid damage to the runout gauge pointer. When repositioning the drive unit for proper alignment with the lower rim of the basket, use a thin ruler to hold the pointer safely away from your fingers.

FIGURE 13. Wobble Gauge with Basket

Step 6. Turn on the spindles.

Step 7. On the QAII, press **ENTER** to store the wobble value or press **CLEAR** to skip the wobble.

Note

If you press CLEAR, the previously stored value prints for the wobble.

Step 8. Continue to "Measuring and Recording Shaft Verticality" on page 38.

Measuring and Recording Shaft Verticality

This apparatus is used in conjunction with a centering tool to verify proper shaft alignment. Complete the following steps to record the shaft verticality:

Step 1. Turn off the spindles.

Step 2. Hold the level sensor flush against the shaft. The perpendicular groove of the sensor should be placed high up on the shaft, approximately 1 inch or 25.4 mm below the bottom of the dissolution apparatus drive unit. This sensor measures in degrees the verticality or perpendicularity of the shaft from side-to-side and front-to-back simultaneously.

FIGURE 14. Electronic Level Sensor Placement

Step 3. On the QAII, press **ENTER** to store the shaft verticality or press **CLEAR** to skip the shaft verticality. Immediately after storing or skipping the shaft verticality, the Test on Position 2 screen displays prompting you to test position 2.

Note

If you press CLEAR, the previously stored value prints for the shaft verticality.

Step 4. Select option **1**, Test, to repeat the above procedures beginning with step 2 under "Entering Shaft Identification Numbers" on page 33 for each remaining position.

Select option **2**, Skip Next, to skip the position number listed and move to the next position number.

Select option **3**, Exit, to return to the monitor screen.

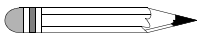
Step 5. After testing the last position, continue to "Measuring and Recording Vessel Plate (Table) Level" below.

Measuring and Recording Vessel Plate (Table) Level

Complete the following steps to record the vessel table level:

Step 1. Place the level sensor in the upright position on the vessel plate. The sensor measure in degrees the level from side-to-side and front-to-back simultaneously.

Step 2. Press **ENTER** to store the vessel table level or press **CLEAR** to skip the level.



Note

If you press CLEAR, the previously stored value prints for the level of the vessel table (Table-X, Table-Y).

Step 3. Continue to "Measuring and Recording Vibration" on page 40.

Measuring and Recording Vibration

Complete the following steps to record the vibration:

Step 1. Place the vibration sensor on the vessel plate. The vibration sensor can be placed either on the vessel plate as shown below or on the drive unit to obtain readings.

FIGURE 15. Vibration Sensor

Step 2. On the dissolution apparatus, set the shafts to rotate at the desired speed and activate the spindles.

Note

For highest accuracy, vessel table vibration should be read with the drive unit in the operating position and the shafts rotating at 100 RPM. If possible, the vessels should be filled with 900 mL of dissolution medium.

Step 3. Position the sensing arrow in the direction of the axis to be measured.

Note

For each axis vibration below, if you press CLEAR, the previously stored value prints for the vibration.

Step 4. Press **ENTER** to store vibration on the X axis or press **CLEAR** to skip the X-axis vibration.

Step 5. Press **ENTER** to store vibration on the Y axis or press **CLEAR** to skip the Y-axis vibration.

Step 6. Press **ENTER** to store vibration on the Z axis or press **CLEAR** to skip the Z-axis vibration. The monitor screen displays.

Printing Results

To print results, the QAII Station must be plugged into AC power with the main (rear panel) power switch in the ON position.

Step 1. From the monitor screen, press **PRINT** on the keypad.

Step 2. Enter the storage number (1 - 30) of the desired stored data and press **ENTER**. The following screen displays:

TEST REPORT	
1 PRINT	2 SEND DATA
3 COM ID	4 BAUD RATE
09/30/04	08:40:09

Step 3. Select option **1** to print a full report.

The report prints out the following data:

- storage number
- apparatus serial number
- date and time of test
- position (vessel/shaft position)
- shaft ID (serial number)
- actual RPM
- wobble (in or mm)
- temp (vessel temp in °C)
- shaft level (X and Y measured in degrees)

Table level and vibration data display at the end of the report:

- table level (X and Y measured in degrees)
- vibration (g)
- frequency (Hz)
- velocity (mm/sec or in/sec)
- displacement (mm or mil)

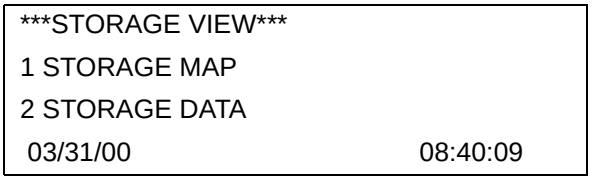
Note: Vibration, frequency, velocity, and displacement are expressed for the three dimensions of X, Y, and Z.

Storage Table and Viewing Data

Complete the following steps to manually review the collected data:

Step 1. From the Test Report screen, press **MENU**. The monitor screen displays.

Step 2. Press **VIEW DATA**. The Storage View screen displays.



Step 3. Select option **1**, Storage Map, to view dissolution apparatus serial numbers stored in the QAII Station memory. To scroll through the list, press **ENTER** to go to the next entry or **CLEAR** to return to the previous entry.

Step 4. Press **MENU** to return to the Storage View screen.

Step 5. Select option **2**, Storage Data, to review the previous results of an individual apparatus.

Step 6. Enter the storage number of the apparatus that you would like to review and press **ENTER**. The dissolution apparatus data displays. To scroll through the data, press **ENTER** to go to the next entry or **CLEAR** to return to the previous entry.

Step 7. Press **MENU** to return to the Storage View screen.

Step 8. Press **MENU** twice to return to the QA Main Menu screen.

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Chapter 5 Maintenance and Troubleshooting

Periodic Maintenance

Warning

The QAII contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.

Periodic maintenance needs may vary depending on frequency of instrument usage.

Calibration

We recommend the QAII Station be calibrated at six-month intervals. However, based on your own SOPs, this can be extended for up to a year. Call the Dissolution Systems Service Department for a quote, packing instructions and a Return Authorization Number before sending your unit for re-calibration.

Report Center Impact Printer

The following is helpful information for using your impact printer.

Installing the Cartridge Ribbon

If the printer is used infrequently, the print impression sometimes becomes weak because the ribbon dries out. If the printed material is difficult to read and you suspect this is the cause of the problem, advance to a new section of the ribbon by pressing the printer toggle switch to the *Paper feed* position. If the printing is still faint, replace the cartridge.

To install the cartridge, complete the following steps:

Step 1. Toggle the printer off line by pressing the printer toggle switch to the *OnLine / Off Line* position. When the printer is off line, the Ready LED does not illuminate.

Step 2. Four small grooves are embossed on the printer cover. Gently push on these grooves to tilt the cover. When the printer cover is tilted up, you can lift it off completely.

Step 3. Push down on the right side of the ribbon cartridge (marked PUSH) and remove the old cartridge.

Step 4. Install the new cartridge. If there is already paper in the printer, hold the cartridge between your thumb and index finger, slide it over the paper and into the printer compartment. Ensure the paper is between the ribbon cartridge and the ink ribbon. Ensure the ink cartridge is inserted firmly to prevent weak or irregular printing. The cartridge must be properly seated and aligned for the best printing.

Step 5. Turn the cartridge knob (marked by an arrow) clockwise to stretch the ribbon taut.

Step 6. Replace the cover.

Step 7. Toggle the printer online by pressing the printer toggle switch to the *OnLine / Off Line* position. The Ready LED illuminates.

Step 8. Replace the paper if necessary.

If you get ribbon ink on the printer's plastic cover, remove it immediately. Once dried, it is difficult to remove.

Replacing the Paper Roll

Step 1. Toggle the printer off line by pressing the printer toggle switch to the *OnLine / Off Line* position. When the printer is off line, the Ready LED does not illuminate.

Step 2. Grasp the paper roll cover firmly by the grooves on the side and the front edge. Pull outward to remove the cover.

Step 3. Press the printer toggle switch to *Paper feed* to advance the paper approximately one inch beyond the paper cutter.

Step 4. Using scissors, cut the paper feeding to the printer and remove the paper roll.

Step 5. Pull the remaining paper through the printer mechanism. *Pull the paper from the front (paper cutter side)*. Pulling the paper out of the back of the printer will damage the print mechanism.

Step 6. Unroll several inches of paper on the new roll.

Step 7. If it is jagged, cut a straight edge on the paper roll to facilitate the entry of the paper into the printer.

Step 8. Slide the paper through the slot connecting the paper compartment and the printer compartment. You can slide it in approximately 1/4 inch before it stops.

Step 9. While holding the paper in place, press the printer toggle switch to the *Paper feed* position and hold until approximately one inch of paper has emerged from the top of the printer.

Caution

Ensure the roll of paper feeds squarely. If it does not, the paper can jam and possibly damage the printer mechanism.

Step 10. Release the printer toggle switch.

Step 11. Turn the paper roll to take up any slack in the paper feeding to the printer.

Step 12. Place the paper roll into the paper compartment.

Step 13. Replace the paper roll cover. If the cover is difficult to remove or replace, the left and right edges can be trimmed or shaved with a utility knife allowing the cover to slide easier.

Step 14. Toggle the printer online by pressing the printer toggle switch to the *OnLine / Off Line* position. The Ready LED illuminates.

Toggling Your Printer Online

Complete these steps to toggle your printer online:

Step 1. Toggle the printer online by pressing the printer toggle switch to the *OnLine / Off Line* position. When the printer is off line, the Ready LED does not illuminate.

Step 2. Release the switch and it returns to the center position. The Ready LED illuminates and a READY message prints if the PRINT READY command has not been turned off. See "Printer Configuration" on page 49 for

instructions on turning on and off the PRINT READY command. When you first turn on the instrument, it prints a READY message to assure you that the built-in microprocessor is operating properly.

When you turn off the printer, wait at least three seconds before turning it on again.

Printer Self Test

You can test the print head and ribbon only *after* inserting paper. Do not attempt to print without paper. Follow these steps to perform a printer self test:

Step 1. Turn off the QAII Station.

Step 2. Press and hold the printer toggle switch in the *Paper feed* position.

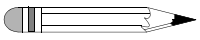
Step 3. Turn on the QAII Station.

Step 4. Hold the printer toggle switch until printing begins. The printer prints a list of the current configuration settings and performs a continuous print test.

Step 5. Press the printer toggle switch to the *OnLine / Off Line* position to stop the printing operation.

Step 6. The printer is ready to resume normal operation.

Printer Configuration



Note

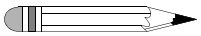
The printer configuration is set by the factory. This procedure should be performed only if the printer displays erroneous characters. Contact the Dissolution Systems Service Department for assistance, if necessary.

Step 1. Turn off the QAII Station.

Step 2. Press and hold the printer toggle switch in the *OnLine / Off Line* position while turning on the instrument. Hold the printer toggle switch in the *OnLine / Off Line* position for six seconds after the instrument is turned on, then release the switch.

Step 3. The printer should print: *** SETUP MENU *** and CONFIGURE... [NEXT/OK]. If this message does not print, repeat steps 1 through 3.

Step 4. The printer toggle switch is used to complete the configuration. Pressing the left side of the printer toggle switch selects NEXT to advance to the next menu item. Pressing the right side of the printer toggle switch selects OK to accept what is stated on this line of the menu item. Each time the switch is pressed, another part of the menu prints. Allow the printer to finish printing before pressing the switch again. See the table of commands below.



Note

The printout is easier to read if the printer cover is removed.

*** SETUP MENU***		
CONFIGURE	[NEXT/OK]	Press NEXT to avoid configuration
CUSTOM	[NEXT/OK]	Press OK to enter custom mode
CUSTOM MENU		
PRINT CUSTOM SETUP	[NEXT/OK]	Press NEXT
AUTO SEQ = NO	[NEXT/OK]	Press OK
ZERO = Ø	[NEXT/OK]	Press OK
POUND SIGN = #	[NEXT/OK]	Press OK
_(UNDERSCORE)	[NEXT/OK]	Press OK
ONLINE/OFFLINE = YES	[NEXT/OK]	Press OK
EXT CH SET = NO	[NEXT/OK]	Press OK
PRINT READY = YES	[NEXT/OK]	Press NEXT
PRINT READY = NO	[NEXT/OK]	Press OK
READY...		

Your printer is now configured correctly.

Fuse Replacement

Warning

The QAII Station contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.

Panels or covers that are retained by fasteners which require the use of a tool for removal may be opened only by Varian-trained, Varian-qualified, or Varian-authorized service engineers.

The fuse compartment is located beside the power cord receptacle on the QAII rear panel. See Figure 9, "QAII Station Rear Panel," on page 25.

Step 1. To check or replace the fuse, remove the power cord from the QAII.

Step 2. A release tab is located on the right side of the fuse compartment. Insert a slotted screwdriver under the tab. A slight application of pressure forward releases the compartment door.

Step 3. The fuses are located in the removable holders marked with an arrow on the top of each. The QAII uses one 500 mAmp, metric (5 x 20 mm) standard fuse for each holder.

Step 4. Replace the fuse in the holder and insert the fuse holder into the fuse compartment with the arrows pointing toward the bottom of the compartment.

Step 5. The holder is designed for multiple voltages. The voltage displays through a window in the fuse compartment door. To change the voltage, gently pull the wheel to remove it from the holder. Rotate the wheel and snap it back in place displaying the correct voltage.

Step 6. Push the fuse compartment door closed. It snaps into place.

Step 7. Replace the power cord.

Troubleshooting

The Dissolution Systems Service Department can assist you if you experience problems or have questions concerning your QAII. Many problems can be traced to simple sources and are easily solved.

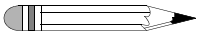
Following is a troubleshooting guide which may help you. The Dissolution Systems Service Department can be reached at 800.229.1108 (inside the US) or 919.677.1108 (outside the US). Optionally, you can send a fax to 919.677.1138. You can also e-mail the Dissolution Systems Service Department at dissolution.service@varianinc.com.

Symptom	Probable Cause	Suggested Solution
The unit does not respond when the main power switch is turned on.	There is a blown fuse.	Replace the fuse. See "Fuse Replacement" on page 51.
	The unit is not plugged in.	Check the rear panel AC power cord receptacle. Plug in the power cord.
The unit does not respond when the battery switch is turned on.	The battery is dead.	Recharge the battery. See "Power Switch Functions" on page 24.
The Report Center Printer does not function.	The printer is disabled.	Ensure the Report Center Printer is online and the Ready LED is illuminated. See "Toggling Your Printer Online" on page 48.
	THE QAII is not plugged in or the main power switch is not turned on.	Plug the instrument into a wall outlet and ensure the main (rear panel) power switch is in the ON position.
The Report Center Printer is active but nothing prints.	The ribbon needs to be replaced.	Install a replacement ribbon cartridge. See "Installing the Cartridge Ribbon" on page 46.
The RPM readings are erratic.	The reflective clip is not registering.	Align the clip with the sensor.
The RPM sensor is not reading.	The sensor has come loose or is not plugged into the QAII rear panel.	Restore connections.

Symptom	Probable Cause	Suggested Solution
The wobble gauge is not reading.	The sensor has come loose or is not plugged into the QAII rear panel.	Restore connections.
	The pointer is not touching the shaft or rim of the basket.	Realign the mounting bracket.
	The wobble gauge is not turned on.	Turn on the wobble gauge.
The level sensor is not reading.	The sensor has come loose or is not plugged into the QAII rear panel.	Restore connections.
The level sensor displays erratic readings.	The sensor is not in the upright position.	Correct positioning.
The vibration sensor is not reading.	The sensor has come loose or is not plugged into the QAII rear panel.	Restore connections.
There is excessive wobble.	The paddle or basket shaft is damaged.	Verify spindle wobble is within specifications using the certified calibration shaft.
The shaft verticality or perpendicularity is excessive.	The paddle or basket shaft is damaged.	Verify the spindle perpendicularity is within specifications using the certified calibration shaft.
	The drive unit is not level.	Contact the Dissolution Systems Service Department.
	The spindle is not centered.	Contact the Dissolution Systems Service Department.

QAII Default Values

The default value prints for any sensor which is not plugged into the unit during testing. The values listed below apply for both standard and metric units (see "Measuring and Recording Wobble" on page 35 and "Main Menu Option 2, Setup" on page 30 for instructions on selecting inches or millimeters for wobble and vibration respectively).



Note

If any of the following default values display, ensure all connections are tight.

Variable	Default Values
RPM	000.00
Wobble	00.00
Temp	-1.5
Shaft-X	-6.8
Shaft-Y	-6.8
Table-X	-6.8
Table-Y	-6.8
Vibration-X Vibration-Y Vibration-Z	0.000 0.000 0.000
Frequency	000.00
Velocity	00.00
Displacement	.0000

Chapter 6 Service and Warranty

The warranty is provided by Varian, Inc. or one of its authorized representatives.

Service and Warranty Information

Varian Dissolution products carry a one-year warranty on parts and labor. The Dissolution Systems Service Department (or one of its representatives) will, at its option, either repair or replace any mechanical and electrical components in your instrument which prove to be defective. During the first year of warranty coverage, there is no charge for the labor to repair your unit. The Dissolution Systems Service Department (or one of its representatives) will determine the best site to repair the unit, either onsite or returned to Varian, Inc. Any onsite warranty services are provided only at the initial installation point. Installation and onsite warranty services are available only in Dissolution Systems service travel areas.

Exclusions and Limitations

Excluded from this warranty are expendable or consumable items such as, but not limited to, paddles, baskets, vessels, and acrylic water baths. Also excluded are defects from improper or inadequate maintenance by the customer, user-induced chemical action or contamination, unauthorized modification or misuse, and improper site preparation and maintenance.

Operation of software is not warranted to be uninterrupted or error-free.

Obtaining Warranty Service

To obtain warranty service in the United States, contact the Dissolution Systems Service Department at 800.229.1108 to obtain authorization to return units for repair. At the option of the customer, onsite warranty service is available, but travel charges may be incurred. The customer should prepay all shipping charges for products returned to the Dissolution Systems Service Department (unless otherwise authorized), and Varian, Inc. will pay all charges for return to the customer.

Warranty Limitations

Varian, Inc. makes no other warranty, either express or implied, with respect to this product. Specifically disclaimed are any implied warranties of merchantability and fitness for a particular use. In no event will Varian, Inc. be liable for any indirect, incidental, or consequential damages arising from the use of this product. This warranty gives you specific legal rights which may vary from state to state or province to province, so you may have other rights and some of these exclusions may not apply to you.

Exclusive Remedies

The remedies provided herein are the customer's sole and exclusive remedies. In no event shall Varian, Inc. or its representatives be liable for any direct, indirect, special, incidental, or consequential damages, whether based on contract, tort, or any other legal theory. Some states or provinces do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

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We listen to our customers. We work hard to make our technical documentation user friendly, and to make the information in our manuals easy to retrieve and use. We'd like you to tell us the kinds of additional information you'd find helpful in our documentation. Your feedback will be carefully considered when we prepare future editions of this manual.

This manual should contain the following additional information:

The most useful thing about this book is:

This manual would be more helpful if:

My general impressions of this book are:

May we contact you regarding your comments? ____ YES ____ NO (If yes, please write your name, address, and telephone number here.)

Please return this form via mail to: Technical Writing / Dissolution Systems, Varian, Inc., 13000 Weston Parkway, Cary, North Carolina 27513-2250 USA. Optionally, you can return this form via fax at 1.919.677.1550. Always, feel free to telephone us to discuss your comments at 1.800.229.1108.