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VK 7000 / 7010 Dissolution Apparatus Operator's Manual

P/N 70-9003
January 2006
Revision J

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Chapter 1 Safety Practices and Hazards

The VK 7000 / 7010 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.

Operation of a VK 7000 / 7010 involves the use of aqueous liquids and various pharmaceutical dosage forms. 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 dissolution apparatus 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 dissolution apparatus 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 heeding 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

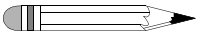
Caution
Refer to accompanying documents

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
CE	Indicates the product complies with the requirements of one or more European Union (EU) directives
TÜV Rheinland of North America, Inc. C US	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 VK 7000 / 7010 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 VK 7000 / 7010 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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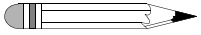
Chapter 2 Introduction



Note

This manual applies to the VK 7000 and the VK 7010. The VK 7010 comes complete with all the features of a VK 7000 as well as the DDM and AutoTemp features.

The VK 7000 / 7010 is designed for dissolution testing of a variety of pharmaceutical compounds, including tablets, capsules, transdermal patches, and membranes. It can be configured as USP Apparatus 1, 2, 5, or 6.

The front panel displays the status screen during a run, providing full information on spindle speed, elapsed time, water bath temperature, and more. Most operating parameters are programmable including spindle speed, test length, vessel temperature, and test start times.

The Dosage Delivery Module (DDM) can be easily programmed to operate in either simultaneous or sequential mode with up to 99 minutes between drops. When using rotating baskets (Apparatus 1), you can program a run and preload your sample dosages before starting the test. At the specified start time, the drive unit automatically lowers the baskets into the vessels to the proper depth.

AutoTemp measures and records the temperature of the medium inside each vessel. Temperature readings can be taken before, after, and periodically during a run, if desired. Readings display on the status screen and can be printed on the built-in Report Center Impact Printer. You can monitor the vessel temperatures and signal the internal DDM to begin the test run once all vessel temperatures are within USP guidelines.

The built-in Report Center Printer provides a complete report—either at the end of a test or on demand—which includes instrument identification number, date, time, set temperature, print time, elapsed time, spindle speed, and water bath temperature. Units equipped with AutoTemp also print vessel temperatures. Printouts obtained at preprogrammed time intervals include print time, elapsed time, spindle speed, water bath temperature, and optionally vessel temperatures. Printouts are on plain paper which will not fade or discolor over time or with exposure to chemical fumes.

The VK 7000 and the VK 7010 are supplied with the standard VK 750D Heater / Circulator. The heater / circulator is controlled by the dissolution apparatus. The VK 750D runs quietly and efficiently without vibration which could affect dissolution results.

The dissolution apparatus comes with all accessories needed for proper function:

- Molded PETG water bath
- VK 750D Heater / Circulator
- USP paddles or rotating basket assemblies
- USP glass or plastic 1000 mL vessels
- Complete set of alignment tools to ensure full USP compliance

Warning

The dissolution apparatus 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.

These features are standard on the VK 7010 and optional on the VK 7000:

- Dosage Delivery Module
- AutoTemp Vessel Temperature Sensing System
- Automated Sampling Manifold

FIGURE 1. VK 7000 Dissolution Apparatus

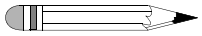
Caution

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 **1** on the keypad".
- Key sequences you are asked to press appear like this: **MENU** > **4**.

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.

USP Suitability Test

Before initial use of any dissolution instrument, and periodically thereafter, the USP requires that you run an Apparatus Suitability Test with both disintegrating and non-disintegrating USP Dissolution Calibrators. These calibrator tablets are available from the USP at the following address:

USP-NF Reference Standards
12601 Twinbrook Parkway
Rockville, MD 20852
301.881.0666

Complete instructions come with the calibrator tablets. Calibration tests can be very sensitive to factors such as paddle or vessel misalignment, vessel shape, vibration of the system, age of the calibrator tablets and reference standards, and many other factors.

USP Physical Parameters

In addition to the Apparatus Suitability Test, several physical parameters must be monitored, such as shaft wobble, centering, speed, and shaft verticality. A Certificate of Compliance is included with all dissolution apparatus. Contact the Dissolution Systems Service Department for more information on USP Physical Parameters.

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Chapter 3 Setting Up

Unpacking the Dissolution Apparatus

Follow these steps to safely unpack your apparatus and accessories:

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 apparatus, accessory kit, and heater / circulator from their shipping cartons.

Warning

Because of its heavy weight, two people should lift the apparatus. Do not lift the apparatus by the drive unit. Lift by holding the legs or vessel plate. Use care; the tracks on the inside of the front legs can cut hands.

Step 3. Remove cushioning material and tape (you will not be able to remove the cushion between the drive unit and vessel plate until the power is turned on). If any item is missing, contact the Dissolution Systems Service Department or your local representative for replacements.

Step 4. Place the apparatus and heater / circulator on a clean, dry, and level section of the bench.

Warning

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

Drive Unit Setup

Step 1. Ensure the power switch on the left side panel is in the OFF position.

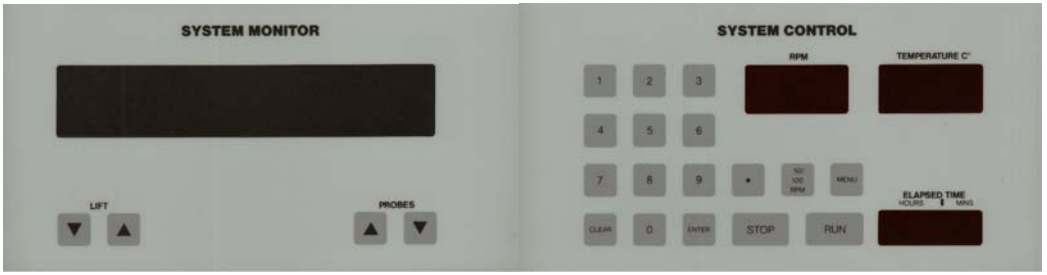
Step 2. Connect the power cord between the receptacle on the drive unit rear panel and an outlet of the appropriate voltage.

Warning

Ensure the apparatus is configured for the voltage available in your laboratory.

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

FIGURE 2. System Monitor and System Control Panel



Step 3. Turn on the dissolution apparatus. The red LEDs on the system control panel illuminate. The initial status screen displays for three seconds.

VANKEL TECHNOLOGY GROUP
VK 7010 PROGRAM VER. x.xx
S/N 1-4000-1000
TIME: 09/01/05 15:58:33 ELAPSE: 000:00:00

The firmware version (program ver.) displays. This is the only time the firmware version level displays. Record the number below and refer to it if you need to call the Dissolution Systems Service Department.

Firmware version	

After three seconds, the system status screen displays:

RPM SET: 100.0 MANUAL ACTUAL: 000.0
BATH TEMP SET: 37.0°C ACTUAL: 37.1°C
START TIME: 12:15:34 PRINTER: ON 000m
TIME: 09/01/05 12:15:47 ELAPSE:000:00:00

Step 4. Press and hold **LIFT ▲**. The drive unit moves up until you release the button or the drive unit reaches the highest position. Press **LIFT ▲** twice in rapid succession to automatically lift the drive unit to its highest position. Press **LIFT ▲** or **▼** to cancel the automatic lift. For safety reasons, the drive unit does not lower automatically. You must keep your finger on the button to lower the unit.

Caution

If you are using the 2L VK 7010, ensure the 4-inch spacer is in place on the middle left leg of the apparatus (see "Left Leg of VK 7000 / 7010" on page 36). If the appropriate spacer for this configuration is not in place, the drive unit can lower too far, hitting the vessel plate and damaging the unit.

FIGURE 3. Lift Down and Lift Up Buttons

Note

Safety microswitches, located above and below the drive unit, turn off the lift motor automatically when it reaches its maximum travel. An adjustable lower stop actuates the lower switch.

Step 5. Remove the cushioning material between the drive unit and vessel plate.

Step 6. Check the level of the instrument by placing the circular level provided in the accessory kit on the vessel plate. Check for level in the center of the front and rear of the instrument and on the left and right sides of the instrument. The rubber foot on the bottom of each leg is adjustable. Adjust the feet until the bubble in the level is in the center circle at all four check points.

Caution

Do not place items on top of the drive unit. Damage to the items or drive unit could result.

Quick Key Guide

See Figure 2, "System Monitor and System Control Panel" on page 23. The following is a description of the front panel options:

Panel Keys	Function
LIFT	Press and hold **LIFT ▲** to raise the drive unit. Press and hold **LIFT ▼** to lower the drive unit. Release the button when the drive unit is in the appropriate position. The drive unit stops automatically when it reaches the highest position or the lowest position (based on the stop ring on the left leg of the dissolution apparatus).
PROBES	If your dissolution apparatus is equipped with the automated sampling manifold, press **PROBES ▲** or **PROBES ▼** to raise or lower the manifold respectively.
50 / 100 / RPM	Since paddles are usually run at 50 RPM and baskets at 100 RPM, a hotkey on the keypad lets you toggle between the two preset choices. The unit must be stopped and the status screen displaying to change the setting. Press the hotkey until the speed you need is indicated on both the graphics display and the LED speed display. Press **RUN** to start the spindles.
MENU	Press **MENU** to display to the Main Menu.
CLEAR	Press **CLEAR** to instantly clear an entry.
ENTER	After entering any input, press **ENTER** to complete the process.
STOP	Press **STOP** to pause or abort the present program.
RUN	To manually begin operations that were not programmed to delay start, press **RUN**.

Hidden Key Functions

Key Sequence	Function
CLEAR > **5**	Use this key sequence to select the date display style. Select option **1**, American Style (for mm/dd/yy) or option **2**, European Style, (for dd/mm/yy). The system status screen displays.
CLEAR > **6**	Use this key sequence to select the printer type. Select option **2**, Impact Printer. The system status screen displays. ***Note: do not select option 1, Thermal Printer. The printer will not operate correctly.***
CLEAR > **8**	Use this key sequence to select DDM and vessel temperature options. To enable DDM, select option **1**, Enable Dosage Delivery. To enable AutoTemp for reading individual vessel temperatures, select option **2**, Enable Vessel Temp Probe. To enable both options, select option **3**, Both 1 & 2. To disable both options, select option **4**, None. The system status screen displays.
CLEAR > **9**	Use this key sequence to select the number of spindles used in your system configuration. Select option **1**, Six, or option **2**, Eight. The system status screen displays.
MENU > **7** > **6**	Use this key sequence to select the model of your instrument. Select option **1**, VK 7000, or option **2**, VK 7010. The system status screen displays.

Water Bath and Heater / Circulator Setup

A single water bath, which is connected directly to the inlet and outlet of the VK 750D Heater / Circulator, is used with 6- or 8-vessel systems (see "6- or 8-vessel System Setup" on page 27). Two dissolution apparatus can be used in conjunction with a single VK 750D Heater / Circulator to obtain 12- or 16-vessel versions (see "12- or 16-vessel System Setup" on page 29). In 12- or 16-vessel setups, the output from the heater / circulator is split using a Y connector and sent to each water bath simultaneously. The outputs from the water baths are recombined using a second Y connector. To ensure identical fill levels in both water baths, the bottom drains are also connected.

6- or 8-vessel System Setup

Step 1. The PETG water bath is mounted under the vessel plate at the factory. Ensure it is tightly mounted directly underneath it. If necessary, tighten the corner clamps.

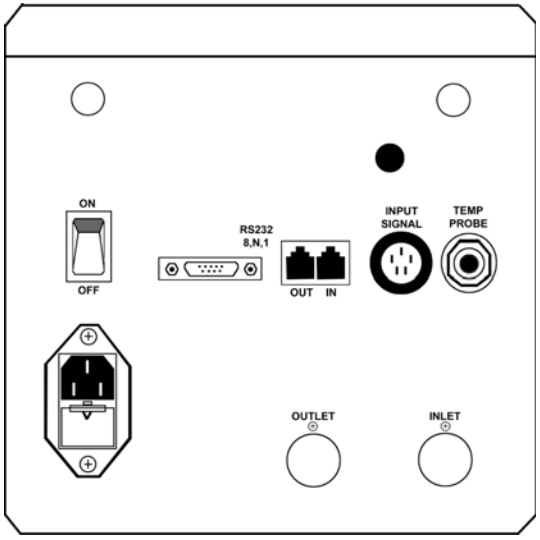
Step 2. Locate the VK 750D tubing kit. The kit contains two lengths of 1/2-inch plastic tubing (one long, one short) and four tubing clamps.

Caution

Hand-tighten the barbed connectors onto the bulkhead fittings. Over-tightening could damage the water bath and fitting and cause leakage.

Step 3. The VK 750D Heater / Circulator has two liquid ports on its rear panel (see Figure 4, "VK 750D Heater / Circulator Rear Panel Connections" below). The inlet is connected to the water bath outlet and the outlet is connected to the water bath inlet.

FIGURE 4. VK 750D Heater / Circulator Rear Panel Connections



Step 4. Slip a tubing clamp over one end of the short length of tubing. Carefully place this end of the tubing over the connector labeled OUTLET on the VK 750D rear panel. Slide it on until it meets the rear panel.

Step 5. Slide the clamp toward the end until it is over the outlet connector, then tighten. This ensures a leak-free connection.

Caution

Do not over-tighten the tubing clamps. Damage to the plastic tubing could result.

Step 6. Slide another tubing clamp over the other end of the same piece of tubing and place it on the barbed-angle adapter installed in the inlet water bath connector. The inlet connector is on the left side of the water bath, when viewed from the front, and has a deflector screen attached on the inside (see Figure 5, "Barbed-angle Tubing Adapter with Flow Deflector" below). Slide the clamp until it is over the adapter, then tighten.

FIGURE 5. Barbed-angle Tubing Adapter with Flow Deflector

Step 7. Repeat steps 4 thru 6 with the longer piece of 1/2-inch plastic tubing to connect the VK 750D inlet port to the water bath outlet.

Step 8. Plug the supplied water bath temperature probe into the jack on the dissolution apparatus rear panel labeled BATH TEMP. Place the end of the temperature probe through the small hole in the vessel plate behind the vessel hole in the rear right side. Do not fill the water bath at this time.

Step 9. Plug one end of the five-pin DIN cable into the jack on the VK 750D rear panel labeled INPUT SIGNAL and the other end of the cable into the jack on the rear of the dissolution apparatus labeled HEATER CIRC. The VK 750D uses the temperature measured by the apparatus to control the water bath temperature.

12- or 16-vessel System Setup

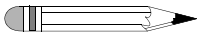
Step 1. The PETG water bath is mounted under the vessel plate at the factory. Ensure it is tightly mounted directly underneath it.

Step 2. Locate one of the precut two-foot lengths (approximate) of tubing from the tubing kit. Slip a tubing clamp over one end of the tubing and attach it to the connector labeled OUTLET on the VK 750D rear panel. Slide the tube on until it meets the rear panel and secure the tubing clamp.

Step 3. Slip another tubing clamp over the other end of the same piece of tubing and attach it to the straight branch of one of the supplied Y connectors. Secure the tubing clamp.

Step 4. Locate two of the precut seven-foot lengths (approximate) of tubing. Slip a tubing clamp over each tube and attach one end of each tube to the two remaining branches of the Y connector. Secure the tubing clamps.

Step 5. Slip a tubing clamp over the free end of each of the seven-foot lengths of tubing and attach a tube to the barbed-angle tubing adapters on each of the water bath inlets (water bath inlets have deflector screens). Secure the tubing clamps.



Note

You can cut the tubing to any length required if the precut pieces are too long.

Step 6. Repeat steps 2 - 5 for the inlet return tubing.

Step 7. Locate the two remaining two-foot lengths of precut tubing. Slip a tubing clamp over one end of each tube and attach one end of each tube to the barbed-angle adapters in the bottom drains. Secure the tubing clamps. Slip a tubing clamp over the other end of each tube and attach the free end of each tube to the straight arms of the plastic T connector supplied and secure the tubing clamps.

Step 8. Slip a tubing clamp over the end of the final piece of tubing, which has the drain valve connected and attach the free end to the 90-degree branch of the T connector. Secure the tubing clamp. Do not fill the water bath at this time.

Installing and Centering the Vessels

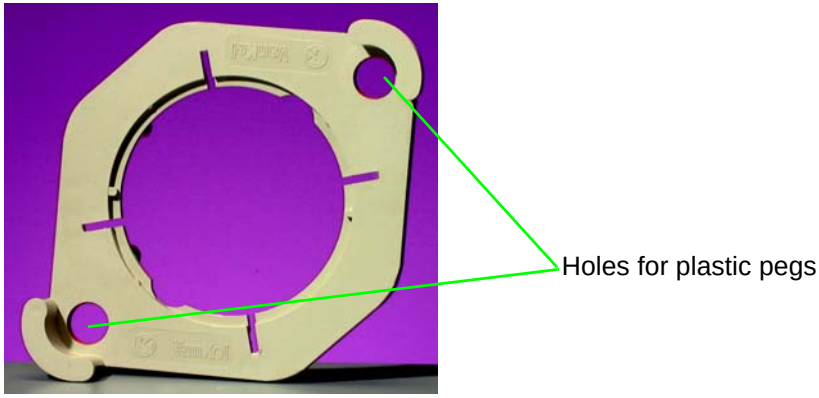
The apparatus is supplied with self-centering EaseAlign centering rings. EaseAlign centering rings keep the vessel centered at all times, without the use of tools, and prevent vessels from "floating" even when they are empty.

Step 1. The EaseAlign centering rings are normally shipped in place on the vessel plate. Remove the rings from the vessel plate.

Step 2. Place each of the vessels on the vessel plate. The EaseAlign centering rings have two large holes to accommodate the plastic pegs adjacent to each vessel location on the vessel plate. Press one EaseAlign centering ring firmly into each vessel with the alignment fingers inside the vessel. See Figure 6, "EaseAlign Centering Ring" below.

Step 3. When pushed down securely, the vessels are automatically aligned and require no further adjustment.

FIGURE 6. EaseAlign Centering Ring



Installing and Centering TruCenter Vessels

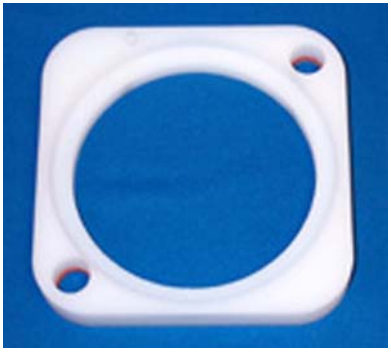
Specially designed TruCenter vessels with magnetic ring flanges can also be used with the VK 7000 / 7010. The magnetic ring flanges keep the vessel centered at all times, without the use of tools, and prevent vessels from "floating" even when they are empty.

Complete the following steps to install the TruCenter vessels:

Step 1. Raise the drive unit to its highest position.

Step 2. Situate the adapters on the vessel plate. The adapters have two large holes to accommodate the plastic pegs adjacent to each vessel location on the vessel plate.

FIGURE 7. TruCenter Vessel Adapter



Step 3. Press the adapters securely into place.

Step 4. Place the vessels on the adapters. Press down so the vessels and magnetic ring flanges fit securely in place and are flush with the adapters.

Step 5. Twist the vessels slightly until the magnets in the ring flanges make contact with the magnets in the adapters.

Step 6. The vessels are automatically centered and require no further adjustment.

Caution

Heat over 65 °C can damage the plastic of the magnetic ring flange of the TruCenter vessels.

Installing Paddles / Basket Assemblies for VK 7000 / 7010

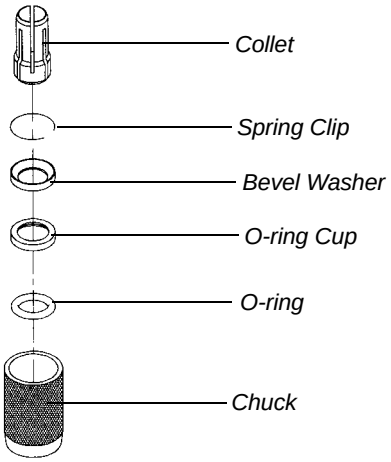
USP guidelines require that the paddle or basket shaft be aligned with the center vertical axis of the vessel and that the bottom of each paddle or basket be 25 ± 2 mm above the bottom of the vessel. See the current USP for a complete explanation.

Follow these steps to install the paddles or rotating basket assemblies:

Step 1. Raise the drive unit to its highest position.

Step 2. Loosen the chuck on one of the spindle assemblies (see Figure 8, "Spindle Assembly" below) by turning it counterclockwise. Carefully insert the end of the paddle or basket shaft (with basket attached) into the spindle assembly. Because the shaft is held very firmly, it could be necessary to use moderate force.

FIGURE 8. Spindle Assembly



Step 3. Slide the paddle or basket shaft approximately six inches into the spindle assembly. Tighten the chuck to hold it in place.

Step 4. Repeat the procedure for the remaining paddles or baskets. Leave the drive unit in the UP position.

Installing Paddle / Basket Assemblies for VK 7000 / 7010 E

USP guidelines require that the paddle or basket shaft be aligned with the center vertical axis of the vessel and that the bottom of each paddle or basket be 25 ± 2 mm above the bottom of the vessel. See the current USP for a complete explanation.

Step 1. Raise the drive unit to its highest position.

Step 2. Carefully insert a paddle or basket assembly into each spindle until approximately half of the shaft is above the top of the spindle.

Step 3. Place a shaft locking ring on the top of each shaft and slide it down until it rests on the shaft collar.

Step 4. Rotate each shaft locking ring so the drive positioning teeth on both the shaft locking ring and the shaft collar rest against one another, locking the shaft in place.

Step 5. Tighten the set screws using the 7/64-inch T-handle Allen wrench provided. Leave the drive unit in the fully raised position.

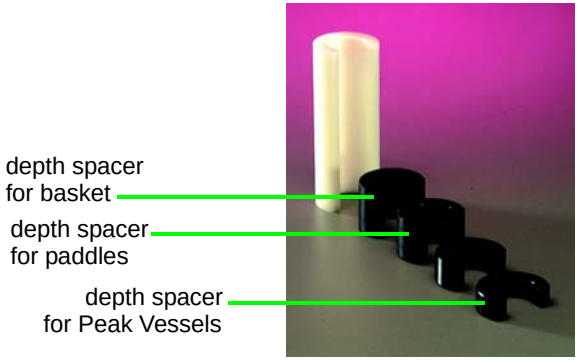
Setting Paddle or Basket Heights with Standard Accessories

Use the height spacers to quickly set paddles and rotating basket assemblies to their USP-required height of 25 ± 2 mm from the bottom of the vessel. When using the spacers, there is no need to insert tools or gauges into the vessels. The spacers snap onto the middle left leg under the stop ring of the dissolution apparatus, signaling the drive unit to stop and automatically setting paddles or rotating baskets at the proper depth.

Caution

If you are using the 2L VK 7010, in addition to the basket, paddle, or Peak Vessel spacer, ensure the 4-inch spacer is in place on the middle left leg of the apparatus (see "Left Leg of VK 7000 / 7010" on page 36). If this spacer is not in place, the drive unit can lower too far, hitting the vessel plate and damaging the unit.

FIGURE 9. Depth Spacers



Complete the following steps to set paddle or basket heights:

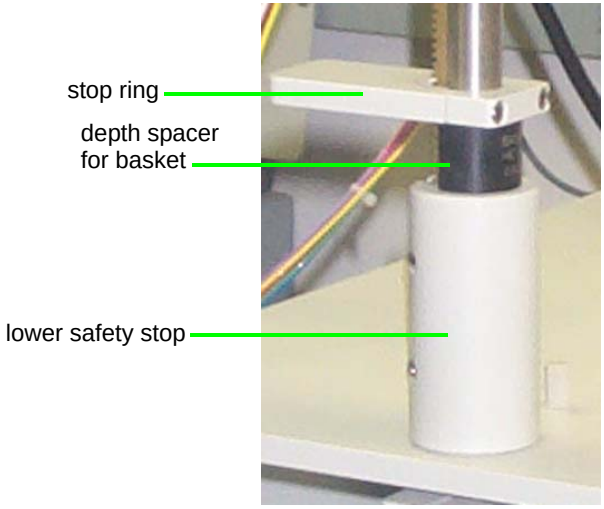
Step 1. Ensure the drive unit is raised to the highest position and each paddle or rotating baskets assembly is secured in the spindles with approximately half of the shaft above the top of the spindle.

Step 2. Ensure the stop ring on the left middle leg of the apparatus is resting on top of the lower safety stop (see Figure 10, "Left Leg of VK 7000 / 7010" below). Lower the apparatus drive unit until it stops automatically.

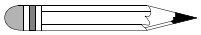
Caution

Do not allow the paddles or basket assemblies to hit the bottoms of the vessels as the drive unit lowers. Damage to the vessels could result.

FIGURE 10. Left Leg of VK 7000 / 7010



Step 3. Loosen the chuck on each spindle and carefully lower each paddle or basket assembly until the paddle blade or basket is resting on the bottom of the vessel. Tighten each chuck securely.



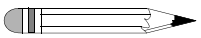
Note

When using paddle over disk, insert the disk in the vessel and set the paddle height to 25 ± 2 mm over the disk.

Step 4. Select either the paddle or basket spacer, depending on the apparatus being used. Spacers are clearly stenciled. Note they are not the same. The basket spacer is slightly taller than the paddle spacer (see Figure 9, "Depth Spacers" on page 35).

Step 5. Raise the drive unit two or three inches. Slide the stop ring up the left leg of the apparatus and clip the spacer onto the leg between the stop ring and the safety stop (see Figure 10, "Left Leg of VK 7000 / 7010" on page 36). Slide the spacer down so it rests on top of the safety stop and slide the stop ring down until it rests on top of the spacer. Tighten the stop ring thumbscrew to secure it in place.

Step 6. Lower the drive unit until it stops automatically. The paddles or baskets are set to their USP-specified height of 25 ± 2 mm above the bottom of the vessel.



Note

To set the paddle height when using Peak Vessels, complete the steps above except ensure you are using peak vessel spacers. Spacers are clearly stenciled. Note they are not the same. The paddle spacer is higher than the peak vessel spacer. See Figure 9, "Depth Spacers" on page 35.

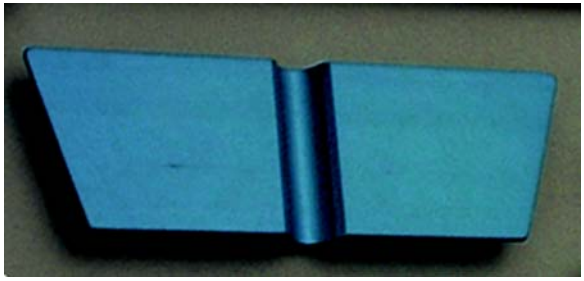
Once complete, the paddles are set to their USP-specified height of 25 ± 2 mm from the bottom of the vessel (10 mm from the top of the peak).

Centering Verification

To verify the centering of the EaseAlign vessels, complete the following steps:

Step 1. Locate the blue EaseAlign Centering Verification Gauge (see Figure 11, "EaseAlign Centering Verification Gauge" on page 38).

FIGURE 11. EaseAlign Centering Verification Gauge



Step 2. Lower the drive unit until the top of the paddle blade or basket is approximately 2 inches (5 cm) below the rim of the vessel.

Step 3. Place the gauge against the shaft with the shaft resting in the radial cutout.

Step 4. Slide the gauge down the shaft until the tapered ends pass through the slots in the EaseAlign centering ring. See Figure 6, "EaseAlign Centering Ring" on page 31. The tapered sides of the gauge rest against the inside rim of the vessel. The gauge is level in this position indicating the vessel is centered.

Step 5. Lift the gauge and rotate it 90 degrees.

Step 6. Repeat steps 3 - 5 fitting the gauge in the remaining two slots on the EaseAlign centering ring.

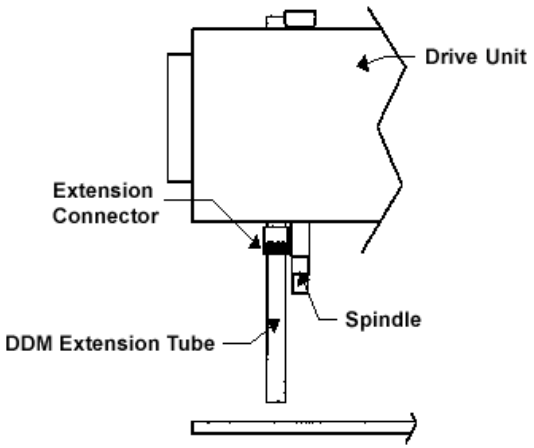
Installing Dosage Delivery Module Tubes (Optional on the VK 7000)

Note

The VK 7010 is equipped with a factory-installed DDM, which automates the process of tablet dropping. This feature is an optional upgrade for the VK 7000.

The solenoids which drop the dosage units are mounted on the underside of the top cover. When dropped, each dosage unit travels through an acrylic tube which exits the underside of the drive unit and guides the dosage unit into the vessel (see Figure 12, "DDM Tube Extensions" below).

FIGURE 12. DDM Tube Extensions



Refer to "Dosage Delivery Mode" on page 50 for information on using the DDM. Since the module in the VK 7010 is factory-installed, you only need to install the lower halves of the DDM tubes.

Complete the following steps to install the DDM tube extensions:

Step 1. Insert the threaded end of a DDM tube extensions into the fitting adjacent to the spindle on the underside of the drive unit at vessel position 1.

Step 2. While holding the extension connector under the drive unit, carefully turn the tube extension clockwise until secure but do not over tighten.

Step 3. Place a DDM-compatible evaporation cover over the vessel. Ensure the semicircular cutout for the DDM tube extension is positioned under the end of the extension tube.

Step 4. Repeat steps 1 - 3 for each vessel position.

Installing the Sampling Manifold (Optional on the VK 7000)

Step 1. Locate the two metal guide shafts that hold the ends of the manifold in place.

Step 2. Insert the guide shafts in the holes on the bottom cover of the dissolution apparatus drive unit located between the left set of spindles and right set of spindles. Screw them securely in place.

Step 3. Locate the internal drive shaft that protrudes through the middle of the bottom cover of the dissolution apparatus drive unit. Attach the extension bar.

Step 4. Slide the manifold onto the drive shaft extension and guides until the bottom of the drive shaft extension is relatively flush with the underside of the manifold assembly. Tighten the screw on the manifold block with an Allen wrench to secure the manifold to the drive shaft.

Step 5. Prior to analysis, verify that the positions of the sampling cannula tips conform to the proper sampling position per USP.

Installing AutoTemp (Optional on the VK 7000)

Note

The VK 7010 is equipped with AutoTemp to measure and record the temperature of the medium inside each vessel. This feature is an optional upgrade for the VK 7000.

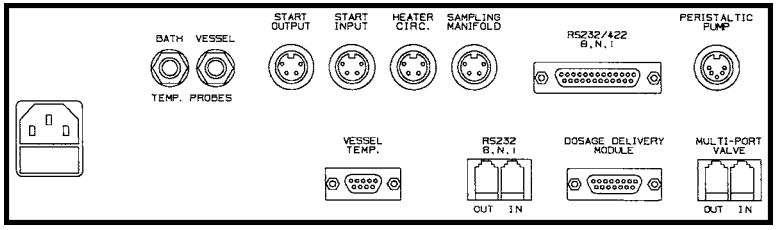
Temperature readings can be taken before, after, and periodically during a run. Readings are displayed on the status screen and printed on the built-in Report Center Printer. Refer to "Main Menu Option 3 Set Temperature" on page 47 for information on using AutoTemp.

Complete the following steps to install AutoTemp:

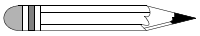
Step 1. Attach one end of the nine-pin coiled cable to the AutoTemp box at the rear of the sampling manifold.

Step 2. Attach the other end of the nine-pin coiled cable into the corresponding communication port labeled VESSEL TEMP. located on the dissolution apparatus rear panel. Refer to the diagram of the dissolution apparatus rear panel below.

FIGURE 13. Rear Panel



Setting the Baud Rate



Note

The baud rate must be set to 9600 to ensure proper functioning of the AutoTemp Vessel Temperature Sensing System.

Complete the following steps to change the baud rate:

Step 1. Press **MENU**. The Main Menu displays.

Step 2. Select option **4**, Documentation. The Documentation screen displays.

Step 3. Select option **6**, Set Com Port ID.

Step 4. Enter the communication port identification number and press **ENTER**. The Select Com Port Baud Rate screen displays.

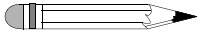
Step 5. Select option **4**, 9600 Baud.

Step 6. Press **MENU** to return to the Main Menu.

Filling the Water Bath

Step 1. Remove one vessel and set it aside. Pour ultrapure water through the hole in the vessel plate. Fill the water bath 3/4 full to allow for displacement by the vessels (refer to the sticker on the water bath for the appropriate fill level). You can also fill through the bottom drain valve if you have a pressurized ultrapure water hose.

Note

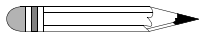


If possible, preheat the water to speed achievement of the desired water bath temperature. Use ultrapure water whenever possible to minimize scale and mineral buildup. Algaecides may be used to inhibit algae and bacteria growth. Check the label to ensure the formulation is compatible with the plastic materials used to construct the water bath.

Step 2. Turn on the VK 750D Heater / Circulator.

Step 3. Check all connections for leaks. Bubbles may appear at the water bath inlet as the air in the system is purged. After a few minutes flow into the water bath should be smooth and steady.

Note



Though the VK 750D is designed to be self-priming, it might be necessary to help the priming process in a dry unit. To help clear the air, hold the unit below the level of the water bath for a minute or two with the rear end up.

Setting the Initial Bath Temperature

The water bath temperature can be set via the dissolution apparatus or the VK 750D. Once connected via a five-pin DIN cable, the dissolution apparatus controls the VK 750D and makes programming the heater / circulator from its keypad unnecessary. See "Main Menu Option 3 Set Temperature" on page 47 for more information. The VK 750D displays a series of dashes (-----) instead of the temperature. Read the temperature from the dissolution apparatus display screen. Refer to the *VK 750D Heater / Circulator Operator's Manual* for further details on how to set the water bath temperature from the VK 750D keypad.

Although the water bath temperature probe supplied with the system is a high-accuracy unit, there is a slight differential between the water bath temperature and the temperature inside the vessels. This is due to the heat transfer characteristics of glass and plastic vessels. The Dissolution Systems Service Department suggests using a NIST-traceable calibrated thermometer to determine the water bath temperature setting which generates the desired in-vessel temperature. For example, set the water bath temperature to 37.4 °C to achieve an in-vessel temperature of 37.0 °C. This 0.4 degree differential is typical, but you should calibrate the temperature at setup and periodically thereafter to ensure accuracy of the in-vessel temperature.

Chapter 4 Operating and Programming

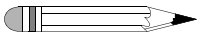
Warning

This is a rotating apparatus. Keep hair and loose clothing away from the spindles.

Main Menu

From the system status screen, press **MENU**. The Main Menu displays.

MAIN MENU	4 DOCUMENTATION
1 SET RPM	5 WRITE PROGRAM
2 SET CLOCK	6 START PROGRAM
3 SET TEMPERATURE	7 ALARMS/COUNTER



Note

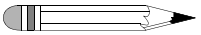
Toggle between the Main Menu and the status screen by pressing MENU. After 45 seconds of inactivity, the status screen displays. The Main Menu can be accessed even if a program is running. Several of the selections can be changed while the unit is functioning. Most selections can be queried and changed via a computer connected to the RS232 port on the apparatus.

Option	Function
1 Set RPM	Select option **1,** Set RPM, to set the RPM. Enter the desired speed between 10.0 and 255.0 and press **ENTER**. The Main Menu displays. For speeds of 50 and 100 RPM, see 50 / 100 / RPM under "Quick Key Guide" on page 25. ***Note: to change the speed while the unit is running, press MENU > 1. Enter the new RPM and press ENTER. The RPM changes to the new value.***
2 Set Clock	Select option **2,** Set Clock, to set the clock. Enter the date in the appropriate format and press **ENTER**. Enter the time in 24-hour format and press **ENTER**. The Main Menu displays.
3 Set Temperature	The dissolution apparatus can control the VK 750D Heater / Circulator. See "Main Menu Option 3 Set Temperature" on page 47. ***Note: if your unit is equipped with AutoTemp, you can specify the required vessel temperature instead of the water bath temperature. When you specify a vessel temperature, the water bath is heated until the AutoTemp sensors indicate the temperature in all vessels has reached the specified temperature.***
4 Documentation	Use this options to control the Report Center Printer. See "Main Menu Option 4 Documentation" on page 48.
5 Write Program	Use this option to program the test parameters. See "Main Menu Option 5 Write Program" on page 49.
6 Start Program	Use this option to start the test. See "Main Menu Option 6 Start Program" on page 55.
7 Alarms/Counter	Use this option to set alarms and timers. See "Main Menu Option 7 Alarms / Counter" on page 57.

Main Menu Option 3 Set Temperature

From the Main Menu, select option **3**, Set Temperature. The Select Temperature Set Mode screen displays.

```
***SELECT TEMPERATURE SET MODE***
1 SET BATH TEMP        2 SET VESSEL TEMP
3 DELAYED BATH HEATING
4 DELAYED VESSEL HEATING
```



Note

Options 2 and 4 are available only if AutoTemp is installed on your dissolution apparatus. All four options display even if AutoTemp is not installed.

Following are the Select Temperature Set Mode screen options:

Option	Function
1 Set Bath Temp	Select option **1**, Set Bath Temp. Enter the temperature required for the water bath and press **ENTER**. The status screen displays. Press **MENU** > **3** to return to the Select Temperature Set Mode screen. ***Note: to correct an error, press CLEAR and re-enter the temperature.***
2 Set Vessel Temp	Select option **2**, Set Vessel Temp. Enter the desired vessel temperature and press **ENTER**. The Change Temp Diff. Of Bath / Vessel screen displays.Press **MENU** > **3** to return to the Select Temperature Set Mode screen. ***Note: the temperature differential is the offset between the water bath temperature and the vessel media temperature needed to overcome the thermal loss due to the vessel walls.*** To accept the current temperature differential, selection option **2**, No. To change the differential, select option **1**, Yes. Enter the temperature differential to the nearest 0.01 °C and press **ENTER**. The normal setting is 0.20. Press **MENU** to stop the spindles. The status screen displays. ***Note: to correct an error, press CLEAR and re-enter the temperature.***

Option	Function
3 Delayed Bath Heating	Select option **3**, Delayed Bath Heating. Enter the desired water bath temperature and press **ENTER**. Enter the desired start time in 24-hour format and press **ENTER**. Enter the desired start date in the appropriate format and press **ENTER**. The status screen displays. Press **MENU** > **3** to return to the Select Temperature Set Mode screen.
4 Delayed Vessel Heating	Select option **4**, Delayed Vessel Heating. Enter the desired vessel temperature and press **ENTER**. The Change Temp Diff. Of Bath / Vessel screen displays. ***Note: the temperature differential is the offset between the water bath temperature and the vessel media temperature needed to overcome the thermal loss due to the vessel walls.*** To accept the current temperature differential, selection option **2**, No. To change the differential, select option **1**, Yes. Enter the temperature differential to the nearest 0.01 °C and press **ENTER**. The normal setting is 0.20. Enter the desired start time in 24-hour format and press **ENTER**. Enter the desired start date in the appropriate format and press **ENTER**. The status screen displays. Press **MENU** > **3** to return to the Select Temperature Set Mode screen.

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

Main Menu Option 4 Documentation

From the Main Menu, select option **4**, Documentation, to control the Report Center Printer. The Report Center Control screen displays.

REPORT CENTER CONTROL	
1 ON	2 OFF
3 INSTANT PRINT	4 PRINTOUT FREQUENCY
5 SET PRINTOUT ID	6 SET COM PORT ID

Following are the Report Center Control screen options:

Option	Function
1 On	Select option **1**, On, to enable the Report Center Printer. The Main Menu displays.
2 Off	Select option **2**, Off, to disable the Report Center Printer. The Main Menu displays.
3 Instant Print	Select option **3**, Instant Print, to print all programmed documentation. Selecting this option does not affect regular periodic printouts during a test. ***Note: ensure the Report Center Printer is turned on and enabled.***
4 Printout Frequency	Select option **4**, Printout Frequency, to set the time between printing documentation. Enter the number of minutes from 1 to 999 in mmm format (for example, 005 indicates 5 minutes) and press **ENTER**. The Report Center Control screen displays. ***Note: the printout frequency displays next to PRINTER: ON on the system status screen.***
5 Set Printout ID	Select option **5**, Set Printout ID. Enter the unit identification number (up to five digits) and press **ENTER**. The Report Center Control screen displays. ***Note: the default printout identification number is 12345***
6 Set Com Port ID	Select option **6**, Set Com Port ID. Enter a communication port identification number and press **ENTER**. The Select Com Port Baud Rate screen displays. Select option **4**, 9600 Baud. The Report Center Control screen displays. ***Note: this option is useful when more than one unit is on the same serial communication loop.***

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

Main Menu Option 5 Write Program

From the Main Menu, select option **5**, Write Program. Each of the following sections are individual screens that display in sequence.

Select Paddle / Basket Mode

The Select Basket or Paddle screen displays. The currently selected option is marked with an asterisk (*).

```
***SELECT BASKET OR PADDLE***
     1 BASKET                2 PADDLE *
* = SELECTED
TIME: 09/01/05    16:40:22    ELAPSE:000:00:00
```

Following is a description of the Select Basket or Paddle screen options:

Option	Function
1 Basket	Select option **1**, Basket, to enable basket mode. Set the baskets to the proper height in the vessels as discussed in "Setting Paddle or Basket Heights with Standard Accessories" on page 35. Position the stop ring and raise the drive unit so that the baskets are completely out of the vessels. Load the dosage units into the baskets and clip a basket to each shaft. Skip to "Spindle Speed" on page 51.
2 Paddle	Select option **2**, Paddle, to enable paddle mode. Continue to "Dosage Delivery Mode" below.

Dosage Delivery Mode

The Select Dosage Delivery Mode screen displays only if your system configuration includes DDM and you select option 2, Paddle, on the previous screen. The currently selected option is marked with an asterisk (*).

```
***SELECT DOSAGE DELIVERY MODE***
 1 SEQUENTIAL              2 SIMULTANEOUS *
* = SELECTED
TIME: 09/01/05    16:40:22    ELAPSE:000:00:00
```

Following is a description of the Select Dosage Delivery Mode screen options:

Option	Function
1 Sequential	Select option **1**, Sequential, to drop the dosage units sequentially with a user-defined delay between each drop. The Enter Increment Time screen displays. Enter the delay value from 1 to 999 seconds and press **ENTER**.
2 Simultaneous	Select option **2**, Simultaneous, to drop all dosage units simultaneously.

Spindle Speed

The following screen displays:

ENTER RPM: 100.0

TIME: 09/01/05 16:40:22 ELAPSE:000:00:00

Enter an RPM value between 10.0 and 250.0 and press **ENTER**. RPM values less than 10 RPM are possible but not recommended.

Water Bath Temperature

The following screen displays:

ENTER SET BATH TEMP: 37.4°C

TIME: 09/01/05 16:40:22 ELAPSE:000:00:00

Enter the desired water bath temperature to the nearest 0.1 °C and press **ENTER**. The maximum achievable temperature is 55 °C.

Test Length

The following screen displays:

ENTER TEST LENGTH:
ENTER hh:mm UP TO 99:59 HOURS
TIME: 09/01/05 16:40:22 ELAPSE:000:00:00

Enter the desired length of the test in hh:mm format and press **ENTER**.

Final Spin at 250 RPM

The following screen displays:

FINAL SPIN AT 250RPM: 00:00
ENTER mm:ss UP TO 99:59 MINUTES
TIME: 09/01/05 16:40:22 ELAPSE:000:00:00

Enter the length of time in mm:ss format for the spindles to run at 250 RPM at the end of the test and press **ENTER**. For example, to add a 2 minute spin time to the end of a 30 minute test, enter 02:00. At minute 30, the spindles speed up to 250 RPM and stop after 2 minutes. To end the test without a final spin, enter 00:00.

Sample Initial Vessel Temperature

Note

You cannot measure the initial vessel temperature when using baskets. The Sample Initial Vessel Temperature screen does not display.

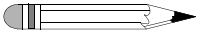
If your system configuration includes AutoTemp and you have enabled paddle mode, the Sample Initial Vessel Temperature screen displays. Select whether or not to sample and

record the vessel temperatures at the beginning of the run. The in-vessel readings are captured on the Report Center printout. The currently selected option is marked with an asterisk (*).

```
***SAMPLE INITIAL VESSEL TEMPERATURE***
              1 YES          2 NO *
* = SELECTED
TIME: 09/01/05   16:40:22   ELAPSE:000:00:00
```

Following is a description of the Sample Initial Vessel Temperature screen options:

Option	Function
1 Yes	Select option **1**, Yes, to program the temperature probes to lower into the vessels at the beginning of the run and read the initial vessel temperatures. The Report Center Printer prints the initial in-vessel readings.
2 No	Select option **2**, No, to program the temperature probes not to lower into the vessels at the beginning of the run and read the initial vessel temperatures.



Note

The vessel temperatures display on the system status screen only when the media temperature is 30 °C or higher in at least one vessel.

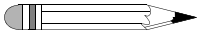
Sample Final Vessel Temperature

The Sample Final Vessel Temperature screen displays. Select whether or not to sample and record the vessel temperatures at the end of the test. The in-vessel readings are captured on the Report Center printout. The currently selected option is marked with an asterisk (*).

```
***SAMPLE FINAL VESSEL TEMPERATURE***
              1 YES          2 NO *
* = SELECTED
TIME: 09/01/05   16:40:22   ELAPSE:000:00:00
```

Following is a description of the Sample Final Vessel Temperature screen options:

Option	Function
1 Yes	Select option **1**, Yes, to program the temperature probes to lower into the vessels at the end of the programmed test length (or after the final spin) and read the final vessel temperatures. The Report Center Printer prints the final in-vessel readings.
2 No	Select option **2**, No, to program the temperature probes not to lower into the vessels at the end of the programmed test length (or after the final spin) and read the final vessel temperatures.



Note

The vessel temperatures display on the system status screen only when the media temperature is 30 °C or higher in at least one vessel.

Sampling Manifold Control

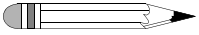
The Sample Manifold Auto-Control screen displays.

```
***SAMPLE MANIFOLD AUTO-CONTROL***
      1 ENABLE          2 DISABLE *
* = SELECTED
TIME: 09/01/05   16:40:22   ELAPSE:000:00:00
```

If your apparatus is equipped with the optional automated sampling manifold, either interfaced to an automated system, such as an online spectrophotometer, or as part of a VK 8000 sampling system, you can program it to lower and raise the sampling cannulas during the test. This feature is especially useful if your system configuration includes instrumentation which does not actually control the dissolution apparatus. The currently selected option is marked with an asterisk (*).

Following is a description of the Sample Manifold Auto-Control screen options:

Option	Function
1 Enable	Select option **1**, Enable, to display the Manifold Time Pt screen. Enter a time in 24-hour format for the sampling manifold to lower the cannulas into the vessels for sampling and press **ENTER**. You can enter up to 30 timepoints. The Main Menu displays.
2 Disable	Select option **2**, Disable, to stop the manifold from lowering at specific timepoints. The Main Menu displays.



Note

You must enter a down time length after programming manifold timepoints. Down time length is the duration the manifold remains lowered during the manifold timepoint. Enter a value in mm:ss format up to 99:59. Ensure the down time is long enough to allow for any removal of samples.

After all parameters have been entered, the Main Menu displays. Press **MENU** to return to the system status screen.

Main Menu Option 6 Start Program

From the Main Menu, select option **6**, Start Program. The Select Start Mode screen displays.

```
***SELECT START MODE***
1 INSTANT START    2 TIME DELAY START
3 SET TEMP START 4 REMOTE START OUTPUT
TIME: 09/01/05     16:40:22      ELAPSE:000:00:00
```

Following is a description of the Select Start Mode screen options:

Option	Function
1 Instant Start	Select option **1**, Instant Start, to begin an instant start. Press **RUN** to start the program immediately.
2 Time Delay Start	Select option **2**, Time Delay Start, to specify when a delayed start will begin. Enter the time you want the program to begin in 24-hour format and press **ENTER**. Enter the start date in the appropriate format and press **ENTER**. The system status screen displays. The entered start time flashes alternately with the printer on / off status and print frequency. At any time prior to the scheduled start of the program, press **CLEAR** to cancel the delayed start.
3 Set Temp Start	Select option **3**, Set Temp Start, to start the program when AutoTemp determines that all vessels are at the desired temperature. Enter the vessel temperature to the nearest 0.1 °C and press **ENTER**. The Change Temp Diff. Of Bath / Vessel screen displays. ***Note: the temperature differential is the offset between the water bath temperature and the vessel media temperature needed to overcome the thermal loss due to the vessel walls.*** To accept the current temperature differential, selection option **2**, No. To change the differential, select option **1**, Yes. Enter the temperature differential to the nearest 0.01 °C and press **ENTER**. The normal setting is 0.20. The temperature probes lower into the vessels and continuously monitor the temperature until the selected temperature is reached and the test starts. Press **MENU** to stop the spindles. The system status screen displays. ***Note: this option is only applicable if your system configuration includes DDM and you have enabled paddle mode.***
4 Remote Start Output	Select option **4**, Remote Start Output, to send a TTL signal to start another device. Enter a delay length of up to 99 hours and 59 minutes. Enter **0** if you want to send the signal as soon as the spindles begin turning. The Select Start Mode screen displays. Press **MENU** to return to the system status screen.

Main Menu Option 7 Alarms / Counter

From the Main Menu, select option **7**, Alarms/Counter. The Alarms or Hour Counter screen displays.

```
***ALARMS OR HOUR COUNTER***
1 TIMER                      2 BATH TEMP ERROR
3 USP CALIBRATION            4 READ SPINDLE HOURS
TIME: 09/01/05   16:40:22    ELAPSE:000:00:00
```

Following is a description of the Alarms or Hour Counter screen options:

Option	Function
1 Timer	Select option **1**, Timer, to set the timer. Enter a duration in hh:mm format and press **ENTER**. The Alarms or Hour Counter screen displays. Press **CLEAR** to silence the alarm after it sounds. ***Note: the timer is a simple timer you can use to time any interval from 1 minute to 99:59 hours.***
2 Bath Temp Error	Select option **2**, Bath Temp Error, to set the water bath temperature error alarm. Enter the desired acceptable water bath temperature range and press **ENTER**. The Alarms or Hours Counter screen displays. If the water bath temperature strays above or below this range, the bath temperature alarm sounds. Press **CLEAR** to silence the alarm after it sounds.
3 USP Calibration	The USP calibration alarm sounds prior to the next scheduled suitability test. Select option **3**, USP Calibration, to set the alarm. Enter the date for the next calibration in the appropriate format and press **ENTER**. The Alarms or Hours Counter screen displays. Press **CLEAR** to silence the alarm after it sounds.
4 Read Spindle Hours	Select option **4**, Read Spindle Hours, to display the number of hours your spindles have spun. Press **MENU** to exit this screen. The Alarms or Hours Counter screen displays.

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

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Chapter 5 Maintenance and Troubleshooting

Periodic Maintenance

Warning

The dissolution apparatus 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.

Daily Maintenance

See “Paddle / Basket Shaft Care” on page 61, “Basket Care” on page 62, and “Water Bath / Acrylic Care” on page 63 as applicable for additional information on proper maintenance of your equipment.

- All parts exposed to the dissolution media should be cleaned after each use. Parts made from stainless steel, such as paddle and basket shafts, cannulas, and temperature probes, are particularly susceptible to surface corrosion if not cleaned

thoroughly after use. If any stainless steel parts show signs of surface discoloration, lightly wipe the surface with a soft cloth or nonabrasive pad to remove it.

- Carefully wipe the paddles or basket shafts after each use.
- Carefully wash the dissolution baskets after each use.
- Carefully wash the dissolution vessels after each use.

Caution

Use care when washing the TruCenter vessels as heat over 65 °C can damage the plastic of the magnetic ring flanges.

Weekly Maintenance

See "Paddle / Basket Shaft Care" on page 61, "Basket Care" on page 62, and "Water Bath / Acrylic Care" on page 63 as applicable for additional information on proper maintenance of your equipment.

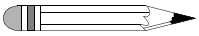
- Inspect the water bath and VK 750D Heater / Circulator tubing for algae or other materials. If algae is present, change the bath water and add an algaecide. If you use a water bath algaecide or clear bath product, ensure it is compatible with PETG and acrylic.

Monthly Maintenance

See "Paddle / Basket Shaft Care" on page 61, "Basket Care" on page 62, and "Water Bath / Acrylic Care" on page 63 as applicable for additional information on proper maintenance of your equipment.

- Drain the water from the water bath and clean the bath thoroughly. Refill the water bath and add an algaecide.
- Clean and lubricate the upper and lower portion of the support legs with the recommended synthetic lubricant.

- It is recommended that the water bath temperature probe jack is checked for surface corrosion and wiped clean with a soft cloth or nonabrasive pad every one to three months.



Note

Depending on the frequency of use, it may be necessary to complete this maintenance procedure more often.

Paddle / Basket Shaft Care

1. When using with corrosive materials such as hydrochloric acid or media containing salts, be sure to rinse them thoroughly with deionized water immediately after each use, and dry thoroughly with a soft towel or cloth.

2. Do not clean with abrasive cleansers or cloths. Use deionized water whenever possible. If you must use a cleanser or solvent, be sure that it is as mild as possible, non-abrasive, and fully compatible with fluorocarbons and stainless steel before use. If in doubt, call the service department for advice before proceeding.

3. We recommend that you do not use a laboratory dishwasher. Clean paddles and basket shafts only by hand. The high temperatures to which your items would be subject in a dishwasher may damage the fluorocarbon coating.

4. Be sure to handle with care. Our QC laboratory has checked the shafts for straightness, to ensure that they will operate without significant wobble. If you must clean or handle them while they are still mounted on the instrument, use minimal pressure on the shaft to prevent them from bending. While in the chucks, just a little bit of pressure exerted on the shaft—especially near the blade or basket—can easily bend the shaft and cause significant wobble.

5. Use care when removing vessels from the apparatus while the paddles or basket shafts are installed so that you do not bump them.

6. When attaching or removing baskets, do not bend the clips excessively.

7. Please store paddles and basket shafts properly between uses. Do not simply place these items in a drawer. They will be subject to nicks, chips, and scratches as they

bump against each other. Place them back into the original styrofoam shipping container or other appropriate container between uses. This will prevent them from coming into contact with each other or anything else in the storage area.

Basket Care

1. When using with corrosive materials such as hydrochloric acid or media containing salts, be sure to rinse them thoroughly with deionized water immediately after each use, and dry thoroughly with a soft towel or cloth.

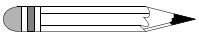
2. Please do not clean baskets or shafts with abrasive cleansers or cloths, especially if they're gold or Teflon coated. Mesh openings on baskets could enlarge, which could have an effect on results. Use deionized water whenever possible. If you must use a cleanser or solvent, be sure that it is as mild as possible, non-abrasive, and fully compatible with fluorocarbons and stainless steel before use. If in doubt, contact the service department for advice before proceeding.

3. We recommend that you do not use a laboratory dishwasher. Clean baskets only by hand. The high temperatures to which your baskets would be subject in a dishwasher may damage the fluorocarbon coating.

4. Use caution when handling baskets. It is important that they retain their cylindrical shape, so take care not to kink or bend the mesh. Check frequently to ensure that the mesh is completely open and that there are no rips or tears.

5. Please store baskets properly between uses. Do not simply place these baskets in a drawer. They will be subject to nicks, chips, and scratches as they bump against each other and they may get bent out of shape. Place them back into the original shipping container or other appropriate container between uses. This will prevent them from coming into contact with each other or anything else in the storage area.

Water Bath / Acrylic Care



Note

The following information pertains to any items, in addition to the water bath, made of acrylic.

Caution

Do not use cleaning compounds containing ammonia or abrasive cleaners on your water bath.

The water bath supplied with the VK 7000 / 7010 Dissolution Apparatus should be maintenance free except for an occasional cleaning. If you use a water bath algaecide or clear bath product, ensure it is compatible with PETG and acrylic. The flow paths in the VK 750D Heater / Circulator are primarily stainless steel and should tolerate most clear bath formulations. Check with the product manufacturer to be sure the product is safe for your water bath.

1. All of our water baths are fabricated entirely of commercial grade acrylic. When using them with corrosive materials such as hydrochloric acid or media containing salts, be sure to rinse them thoroughly with deionized water immediately after each use, and dry thoroughly with a soft towel or cloth.

2. Do not clean with abrasive cleansers or cloths. Use deionized water whenever possible. If you must use a cleanser or solvent, be sure that it is as mild as possible, non-abrasive, and fully compatible with PETG and acrylic before use. If in doubt, call the service department for advice before proceeding.

3. Do not use ammonia, window-cleaning sprays, kitchen scouring compounds, or solvents such as acetone, gasoline, benzene, alcohol, carbon tetrachloride, or lacquer thinner. These can scratch the material's surface and / or weaken it causing small surface cracks called "crazing".

4. Our recommendations include but are not limited to the following:

- Hot water:< 150 °F
- Vinegar (5% Glacial Acetic Acid)
- Ethyl alcohol: maximum 10%

- Isopropyl alcohol: maximum 25%

Repairing Leaking Fittings

Complete these steps if any of your water bath fittings are leaking:

Step 1. Turn off the heater / circulator and drain the water bath completely.

Step 2. Remove the leaky bulkhead fitting.

Step 3. Remove the elbow fitting from the bulkhead fitting.

Step 4. Inspect the bulkhead fitting gaskets for damage and replace them as necessary.

Step 5. Remove the old Teflon tape from all male fittings. Inspect the threads for damage and replace the fitting as necessary.

Step 6. Apply new Teflon tape to the male fitting threads.

Step 7. Reinstall and tighten the bulkhead fitting on the water bath.

Step 8. Reinstall and tighten the elbow fitting to the bulkhead fitting.

Step 9. Fill the water bath and turn on the heater / circulator.

Step 10. Inspect the fitting for leaks. If the fitting still leaks, contact the Dissolution Systems Service Department.

Visual Checks

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.

Step 1. Turn on power to the instrument.

Step 2. Lower the drive unit to the full down position.

Step 3. Turn off power to the instrument and remove the power cord.

Step 4. The top cover is attached with six screws. The top center screw on each side panel must be removed, as well. These eight screws are located under the white plastic caps. The white plastic caps must be removed carefully by inserting a thin blade under the edge of the cap. Do not force the blade any deeper than 1/16 of an inch under the cap. A very slight lift removes the cap and exposes the screw.

Step 5. Remove the Phillips-head screws that are exposed when you remove the snap caps.

Step 6. Disconnect the limit switch on the left back corner. Be sure to replace these connectors when you reassemble the apparatus. For the VK 7010, also disconnect the DDM cable on the main PCB as well as the power cables from the DDM power supply. Be sure to replace these connectors when you reassemble the apparatus.

Step 7. Lift the top cover and secure it to the underside of the top plate with clamps.

Step 8. Inspect the drive belt for unusual wear, fraying, and tension. A small amount of belt material may be observed in the form of black dust or powder on the bottom plate. This is normal and no cause for alarm.

Step 9. Check the spindle motor brushes for wear every three months.

Step 10. Remove the clamps securing the top cover to the underside of the top plate.

Step 11. Replace the top cover.

Step 12. Reconnect the limit switch on the left back corner. For the VK 7010, also reconnect the DDM cable on the main PCB as well as the power cables from the DDM power supply.

Step 13. Replace the Phillips-head screws and the white snap caps.

Step 14. Reconnect the power cord and turn on the instrument.

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:

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. Make sure the roll of paper feeds squarely. If it does not, the paper will 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 70 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 dissolution apparatus.

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

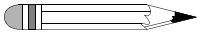
Step 3. Turn on the dissolution apparatus.

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

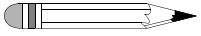
The printer configuration is set by the factory. This procedure should be performed only if the printer displays erroneous characters. Contact the Dissolution Systems Service Department for assistance, if necessary.

Step 1. Turn off the dissolution apparatus.

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 on the following page.



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.

Water Bath Temperature Probe Accuracy Test

The temperature probe can be tested using a high quality voltmeter capable of at least four digit resolution and a water bath of known temperature. Both the multi-meter and the bath temperature probe or calibrated thermometer must be traceable to a known reference standard such as NIST.

Step 1. Place the probe into a known temperature water bath and allow several minutes for the probe to equilibrate.

Step 2. The resistance is measured by attaching the leads of the multi-meter to the top and shank of the 1/4-inch phone plug.

Step 3. Refer to the following table to find the resistance value of the probe at the known bath temperature. Temperatures between the values listed may be interpolated.

Step 4. Probes are interchangeable and manufactured with a tolerance of ± 0.2 °C. Probes found to be outside the tolerance of ± 0.2 °C should be replaced.

Temp. °C	Resistance Ohms	Temp. °C	Resistance Ohms	Temp. °C	Resistance Ohms
-5.0	9530	24.0	2354	53.0	724.50
-4.0	9046	25.0	2252	54.0	697.90
-3.0	8586	26.0	2156	55.0	672.50
-2.0	8151	27.0	2064	56.0	648.10
-1.0	7741	28.0	1977	57.0	624.80
0.0	7355	29.0	1894	58.0	602.40
1.0	6989	30.0	1815	59.0	580.90
2.0	6644	31.0	1739	60.0	560.30
3.0	6319	32.0	1667	61.0	540.50
4.0	6011	33.0	1599	62.0	521.50
5.0	5719	34.0	1533	63.0	503.30
6.0	5444	35.0	1471	64.0	485.80
7.0	5183	36.0	1412	65.0	469.00
8.0	4937	37.0	1355	66.0	452.90
9.0	4703	38.0	1301	67.0	437.40
10.0	4482	39.0	1249	68.0	422.50
11.0	4273	40.0	1200	69.0	408.20
12.0	4074	41.0	1152	70.0	394.50
13.0	3886	42.0	1107	71.0	381.20
14.0	3708	43.0	1064	72.0	368.50
15.0	3539	44.0	1023	73.0	356.20
16.0	3378	45.0	983.80	74.0	344.50
17.0	3226	46.0	946.20	75.0	333.10
18.0	3081	47.0	910.20	76.0	322.30
19.0	2944	48.0	875.80	77.0	311.80
20.0	2814	49.0	842.80	78.0	301.70
21.0	2690	50.0	811.30	79.0	292.00
22.0	2572	51.0	781.10	80.0	282.70
23.0	2460	52.0	752.20		

Fuse Replacement

Warning

The dissolution apparatus 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 holder is located in the lower section of the power entry module on the rear of the dissolution apparatus.

Step 1. Before checking or attempting to replace a fuse, remove the power cord from the dissolution apparatus.

Step 2. There are two release slots; one on the left and one on the right. The fuse holder is released by inserting a small screwdriver into one of the slots. However, two screwdrivers, one in each slot, may work best.

Step 3. A slight application of pressure toward the center of the compartment releases the fuse holder.

Step 4. Pull the fuse holder out of the power entry module. The fuse is located in the removable holder. The fuse for the 230 V apparatus is a 2 amp metric (5 mm x 20 mm) fuse and for the 115 V apparatus is a 3 amp metric (5 mm x 20 mm) fuse.

Step 5. Place the new fuse into the holder and insert the fuse holder into the power entry module. The holder is keyed and can be inserted only one way.

Step 6. Push the fuse holder into the power entry module until both sides snap. Replace the power cord.

Troubleshooting

The Dissolution Systems Service Department can assist you if you experience problems or have questions concerning your dissolution apparatus. 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.

Problem	Possible Cause	Suggested Solution
The unit does not respond when main power is ON.	There is a blown fuse in the rear panel AC line cord receptacle.	Replace if necessary. See "Fuse Replacement" on page 74.
	The unit is not plugged into a power outlet.	Plug the unit into an appropriate power outlet.
	The electrical outlet does not have power.	Check the outlet for electrical current.
The spindles are not synchronized.	The drive belt is loose.	Tighten the drive belt.
The printer does not print.	The printer is offline.	Ensure the printer is online and enabled. See "Main Menu Option 4 Documentation" on page 48.
	The printer frequency is set to 0.	Set the correct printer frequency. See "Main Menu Option 4 Documentation" on page 48.
	The printer is out of paper.	Ensure paper is installed in the printer.

Problem	Possible Cause	Suggested Solution
The water bath will not heat.	The heater / circulator is not powered on.	Ensure the heater / circulator is powered on.
	The temperature probe is not in the water bath.	Place the temperature probe in the water bath.
	The water bath temperature is set incorrectly.	Set the correct water bath temperature. See "Main Menu Option 3 Set Temperature" on page 47.
The keypad does not respond to user input.	The keypad is locked.	Press **CLEAR** > **2** to unlock the keypad.
The vessel temperatures do not display.	The sample manifold is not lowered.	Lower the sample manifold.
	The media temperature is not 30 °C or higher in at least one vessel.	Heat the water bath to a temperature greater than 30 °C.

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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Index

VARIAN

Tell Us How We Are Doing

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 1.919.677.1138. Always, feel free to telephone us to discuss your comments at 1.800.229.1108.