# VARIAN

# VK 7025 Dissolution Apparatus Operator's Manual

P/N 70-9033 January 2006 Revision G

#### Limitation of Liability

The information in this document is subject to change without notice. Varian, Inc. makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties or merchantability and fitness for a particular purpose. Varian, Inc. shall not be liable for errors contained herein or for incidental consequential damages in connection with the furnishing, performance, or use of this material.

All rights are reserved. Reproduction, adaptation, or translation without prior written permission is prohibited, except as allowed under copyright laws.

#### First Edition (January 2006) VK 7025 Dissolution Apparatus Operator's Manual Part Number 70-9033 Revision G Printed in the United States of America

The following terms are trademarks of Varian, Inc.:

- Benchsaver<sup>TM</sup>
- BIO-DIS III<sup>®</sup>
- Enhancer Cell<sup>®</sup>
- Full Flow Filters<sup>TM</sup>
- Peak Vessel<sup>TM</sup>

- Practical Solutions<sup>®</sup>
- QA and QAII<sup>TM</sup>
  TruCenter<sup>TM</sup>
- VanKel<sup>®</sup>
  - VK<sup>®</sup>

Varian. Inc. 13000 Weston Parkway Cary, North Carolina 27513-2250 800.229.1108 919.677.1108 Fax: 919.677.1138 www.varianinc.com



Copyright (c) 2002 - 2006 by Varian, Inc.

# **Table of Contents**

| Chapter 1 | Safetv Practices and Hazards 9  |
|-----------|---|
|           | Electrical Hazards <b>10</b><br>Other <b>10</b><br>General <b>13</b><br>WEEE Directive <b>13</b>                      |
| Chapter 2 | Introduction 15   |
|           | Conventions Used in this Manual <b>17</b><br>Quick Key Guide <b>18</b><br>Screen Saver <b>18</b>                      |
| Chapter 3 | Setup 19  |
|           | Unpacking Your VK 7025 <b>19</b><br>Setting Up the VK 7025 <b>22</b><br>Raising and Lowering the Drive Unit <b>23</b> |

Sliding Back the Drive Unit 24 Setting Up the Water Bath and Heater / Circulator 25 Filling the Water Bath **27** Installing and Centering the Vessels 28 Installing Paddle / Basket Shafts 28 Installing Paddles 29 Installing Basket Shafts 30 Installing Rotating Cylinders 31 Installing the Intrinsic Dissolution Apparatus 32 Removing the Dissolution Apparatus **33** Centering Verification 34 Installing Cannula Assemblies 35 Installing Standard Evaporation Covers 36 Installing Basket / Low-loss Evaporation Covers 37 Setting the Manual Sampling Cannula 38 Programming Administrative Control **40** Security Levels 40 Setting Up the User List **41** Deleting Preset User Definitions 42 Vessel Plate Layout **43** 

Chapter 4

#### Administrator Operation 45

User Settings 45 Administration 47 Calibration 48 Bath Vessel Difference 48 Setting an Alternate Drive Unit Position 49 Cannula Height Calibration 50 Alarms 52 Calibration Calendar 53 Diagnostics 54 Menu 2 55 Setting the Clock 56 Setting Communication Port Functions 56 Setting Serial Numbers 57

| Chapter 5 | Operation 59   |
|-----------|--|
|           | Main Menu 59<br>Manual Operation 60<br>Starting a Test 64<br>Paddles 65<br>Baskets 67<br>Paddle Over Disk 69<br>Rotating Cylinder 70<br>Setting Delayed Heating 72<br>Start Method 73<br>Method Editor 84  |
| Chapter 6 | Fiber Optics 93  |
|           | Installing Fiber Optics 93   |
| Chapter 7 | Maintenance and Troubleshooting 97   |
|           | Maintenance 97<br>Daily Maintenance 97<br>Paddle / Basket Shaft Care 99<br>Basket Care 100<br>Water Bath / Acrylic Care 101<br>Repairing Leaking Fittings 102<br>Removing the Top Cover 103<br>Replacing the Top Cover 103<br>Cleaning the Cannulas 103<br>Cleaning the Cannulas Using the VK 8000 Clean System<br>Function 104<br>Replacing the Flanges 106<br>Report Center Impact Printer 107<br>Installing the Cartridge Ribbon 107<br>Replacing the Paper Roll 108<br>Toggling Your Printer Online 110<br>Printer Self Test 110 |

Printer Configuration 111 Fuse Replacement 113 Troubleshooting 114

#### Chapter 8

#### Service and Warranty 117

Exclusions and Limitations118Obtaining Warranty Service118Warranty Limitations118Exclusive Remedies119

Index 121

#### Tell Us How We Are Doing 125

# List of Figures

- FIGURE 1. Lifting Straps 20
- FIGURE 2. VK 7025 Lifting Guide 21
- FIGURE 3. VK 7025 Foot 23
- FIGURE 4. Drive Unit Guide Rods 24
- FIGURE 5. Drive Unit Release Lever 24
- FIGURE 6. Centering Verification Gauge 34
- FIGURE 7. EaseAlign Centering Ring 34
- FIGURE 8. Standard Evaporation Cover 36
- FIGURE 9. Evaporation Cover for Low Loss or Baskets 37

- FIGURE 11. Vessel Plate Layout **43**
- FIGURE 12. Spindle Housing 50
- FIGURE 13. Standard Evaporation Cover, Dropping Dosage Unit and Sampling **65**
- FIGURE 14. Basket / Low-loss Evaporation Cover, Positioning and Sampling **68**
- FIGURE 15. Fiber Optic Assembly 93
- FIGURE 16. Fiber Optic Assembly Setting 94
- FIGURE 17. Fiber Optic Probe in Vessel 96
- FIGURE 18. Cannula Cleaning Tray **105**
- FIGURE 19. TruCenter Vessel—exploded view **106**

# Chapter 1

# Safety Practices and Hazards

The VK 7025 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 7025 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



Pinch point



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**

Switches main power on



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 that this product must not be disposed of as unsorted municipal waste (see "WEEE Directive" on page 13)

#### General

#### **CE Compliant Products**

The VK 7025 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.

# 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.

This page was intentionally left blank, except for this message.

# Chapter 2 Introduction

The VK 7025 is designed for dissolution testing of a variety of pharmaceutical products, including tablets, capsules, transdermal patches, and membranes. It can be configured as USP Apparatus 1, 2, 5, or 6.

The unique design of the VK 7025 has a lower profile than existing dissolution apparatus. The drive unit moves up and down with the touch of a key to move paddles or basket shafts into and out of the vessels. In order to allow clear access to the vessels, the drive unit slides back rather than continuing to move upwards. This compact design has the evaporation covers attached to the spindle housings on the drive unit and offers convenient access to the mechanics of the system through a hinged top cover.

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

The built-in Report Center Printer provides a complete report, either at pre-programmed time intervals or on demand, of several important test parameters. Printouts are on plain paper which will not fade or discolor over time or with exposure to chemical fumes.

The VK 7025 Dissolution Apparatus comes with all accessories needed for proper function:

- PETG water bath
- Heater / circulator
- USP dissolution paddles or rotating basket assemblies (14.5-inch shaft length)
- TruCenter Vessels, 1000 mL, with upper and lower magnetic ring flanges
- Standard evaporation covers
- Complete set of alignment tools to ensure full USP compliance
- Built-in Report Center Printer
- Sampling cannulas
- Dosage Delivery Module (DDM)
- AutoTemp Vessel Temperature Sensing System

These features are optional on the VK 7025:

- Individual clutches
- Fiber optic probes

#### 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.



The following illustration shows a VK 7025.



# **Conventions Used in this Manual**

- Quick keys you are asked to press are in bold. For example, "press MENU".
- To perform functions that require making selections from the display screen, for example, "select MANUAL OPERATION" means to press the key to the left or right of MANUAL OPERATION.
- Key sequences you are asked to press appear like this: **0** > **ENTER**.

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

# Quick Key Guide

| ESC          | Press ESC to return to the previous screen.   |
|--------------|---|
| MENU         | From any point after the Main Menu, press <b>MENU</b> to return to the Main Menu.   |
| ENTER        | After entering any input, press ENTER to complete the process.  |
| STOP / PAUSE | Press STOP / PAUSE to pause or abort the present program.   |
| RUN          | To manually begin operations that were not programmed to delay start, press <b>RUN</b> .  |
| CLEAR        | Press <b>CLEAR</b> to instantly clear an entry.   |
| DRIVE UP     | Press <b>DRIVE UP</b> to raise the drive unit. The drive unit<br>automatically rises to the home position unless another key is<br>pressed. Pressing <b>DRIVE UP</b> or <b>DRIVE DOWN</b> stops the upward<br>movement of the drive unit. |
| DRIVE DOWN   | Press and hold <b>DRIVE DOWN</b> to lower the drive unit. Release the key when the drive unit is in the appropriate position.   |

# Screen Saver

The VK 7020 / 7020 S / 7025 screen saver initiates after 30 minutes of inactivity and no program running. Press any key to reactivate the dissolution apparatus.

If security has been disabled, the last screen displays.

If security has been enabled, a screen requesting the current user's password displays. Enter the password and press **ENTER**. The last screen displays.

# Chapter 3 Setup

# **Unpacking Your VK 7025**

The VK 7025 is shipped in one carton containing the following:

- VK 7025 drive unit assembly, PETG water bath, power supply box, glassware, and accessories
- heater / circulator

Follow these steps to safely unpack your tester and accessories:

Step 1. Open the 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. Remove all packing from the dissolution apparatus.



- Step 3. There are four lifting straps included with the dissolution apparatus. One is positioned around each of the four legs.
- Step 4. Place the straps around your wrist as indicated in Figure 1, "Lifting Straps," below.

FIGURE 1. Lifting Straps





#### Warning

Because of its heavy weight, two people should lift the tester. *Do not* lift the tester by the drive unit. Lift by holding the base plate.

Step 5. Use the lifting straps to lift the dissolution apparatus off of the packing platform. Place the dissolution apparatus on the ground.

| Revision G, 01/06 |  |
|-------------------|--|
| P/N 70-9033       |  |

Page 21 Setup

Step 6. Once clear of the packaging materials, use the hand holds grooved into the base plate to lift the dissolution apparatus onto a sturdy benchtop (see Figure 2, "VK 7025 Lifting Guide," below).

#### Warning

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

#### FIGURE 2. VK 7025 Lifting Guide



# Setting Up the VK 7025

Complete the following steps to safely set up your VK 7025:

| Æ       | Warning<br>Ensure the tester is configured at the factory for the voltage<br>supplied.  |
|---------|---|
| Step 1. | Ensure the power switch on the power supply box is in the OFF position.   |
| Æ       | Warning<br>The electrical connection at the back of the tester is the primary<br>disconnect for the instrument.   |
| Step 2. | Connect the power cord between the receptacle on the side of the dissolution apparatus and an outlet of the appropriate voltage.  |
| Step 3. | Turn on the dissolution apparatus. PRESS DRIVE UP TO INITIALIZE INSTRUMENT displays.  |
| Step 4. | Press and release <b>DRIVE UP</b> to lift the drive unit to its home position.  |
| Step 5. | Turn off the dissolution apparatus.   |
| Step 6. | Remove the cushioning material between the drive unit and vessel plate.   |
| Step 7. | Level the instrument by placing the bubble 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 feet supporting the tester are adjustable. Turn them counterclockwise with a 3/4-inch open wrench until the bubble in the level is in the center at all four check points. |
| Step 8. | Lock the feet in place by tightening the nut snugly against the base plate (see Figure 3, "VK 7025 Foot," on page 23).  |

#### FIGURE 3. VK 7025 Foot



## Raising and Lowering the Drive Unit



#### Warning

Ensure your hands are not in the path of the drive unit as it rises and lowers.



To raise the drive unit, press **DRIVE UP**. The drive unit stops automatically when it reaches the home position. To stop the drive unit before it reaches the home position, press **DRIVE UP** again.

To lower the drive unit, ensure the drive unit is latched in the forward-most position and press and hold **DRIVE DOWN**. Release the key when the drive unit reaches the desired position. The drive unit stops automatically when at the lowest position. There is a safety mechanism located in the bottom of the left side guide rod which keeps the drive unit from lowering improperly. If the rods do not line up precisely with the holes in the vessel plate, the mechanism engages and the drive unit stops lowering and rises to the home position.

Page 24 Setup

The guide rods also serve to guarantee the drive unit is positioned with the apparatus in the correct centering location for operation. See Figure 4, "Drive Unit Guide Rods," below.





# Sliding Back the Drive Unit

There are two release levers for the drive unit which keep it from sliding back. One is located on either side of the drive unit.

#### FIGURE 5. Drive Unit Release Lever

latch  $\uparrow$ unlatch  $\downarrow$ 



To slide the drive unit back, complete the following steps:

- Step 1. Ensure the drive unit has been fully raised to the home position.
- Step 2. Place both hands on the two release levers and use your index fingers to depress the release levers.
- Step 3. Use your thumbs to slide the drive unit back far enough to disengage it from the latching mechanism.
- Step 4. Move your hand to the handle at the front of the drive unit and slide the drive unit back until it stops.

Step 5. When in the forward position, ensure the drive unit latches into place. This guarantees it is positioned in the correct centering location for operation.

# Setting Up the Water Bath and Heater / Circulator

The removable water bath connects directly to the inlet and outlet of the heater / circulator. Following are the connection procedures for the VK 7025 Dissolution Apparatus:

- Step 1. Ensure the water bath is positioned under the vessel plate and rests firmly on the base plate. Secure the vessel plate to the frame with three screws. Finger-tighten the screws. overtightening the screws could damage the vessel plate.
- Step 2. Locate the two tubing clamps.
- Step 3. The heater / circulator has two liquid ports, one on each end. The inlet is connected to the water bath outlet and the outlet (which is located next to the power switch) is connected to the water bath inlet.
- Step 4. Slip a tubing clamp over one end of the short length of tubing that is connected to the underside of the water bath. Carefully place this end of the tubing over the inlet port on the heater / circulator. Slide it on until it meets the heater / circulator.
- Step 5. Slide the clamp toward the end until it is over the inlet port and secure. This ensures a leak-free connection.



#### Caution

Do not overtighten the tubing clamps. Damage to the plastic tubing could result.

| Page 26 |  |
|---------|--|
| Setup   |  |

- Step 6. Slip a tubing clamp over one end of the longer length of tubing that is connected to the back of the water bath. Carefully place this end of the tubing over the outlet port on the heater / circulator. Slide it on until it meets the heater / circulator.
- Step 7. Slide the clamp toward the end until it is over the outlet port and tighten with a screwdriver. This ensures a leak-free connection.



#### Caution

Do not overtighten the tubing clamps. Damage to the plastic tubing could result.

- Step 8. Plug the supplied bath temperature probe into the jack on the rear panel of the tester labeled BATH TEMP. Place the end of the temperature probe through the small hole in the back of the vessel plate. Do not fill the water bath at this time.
- Step 9. Plug one end of the six-pin DIN cable into the rear of the heater / circulator and the other end of the cable into the jack on the rear panel of the tester labeled HEATER CIRC. The heater / circulator uses the temperature measured by the bath temperature probe to control the water bath temperature.
- Step 10. Ensure the power switch on the heater / circulator is in the OFF position.
- Step 11. Locate the accessory kit. Remove the power cord and plug the female end into the AC line / fuse connector on the rear panel of the heater / circulator.
- Step 12. Plug the heater / circulator into an AC outlet of the proper voltage.

# Filling the Water Bath

- Step 1. Raise the drive unit to its home position and slide it back to allow full access to the vessels.
- Step 2. If applicable, remove one of the vessels and set it aside. Fill the water bath with ultrapure water by pouring the water through the hole in the vessel plate. Fill to the level indicated by the operating water level tag located on the right side of the water bath.



- Step 3. Turn on the heater / circulator.
- Step 4. Check all connections for leaks. You may notice bubbles from the water bath inlet as the air in the system is purged. After a few minutes flow into the bath should be smooth and steady.



# Installing and Centering the Vessels

The tester is supplied with specially designed vessels and magnetic ring flanges. The magnetic ring flanges will keep the vessels centered at all times, without the use of tools, and prevent the vessels from "floating" even when they are empty.

- Step 1. Raise the drive unit to its home position and slide it back until it stops.
- Step 2. Place the vessel in the hole in the vessel plate. Press down so that the vessel and magnetic ring flanges fit securely in place and are flush with the vessel plate.
- Step 3. Twist the vessel slightly until the magnets in the ring flanges make contact with the magnets in the vessel plate.
- Step 4. Repeat steps 2 and 3 for each vessel.
- Step 5. The vessels are automatically centered and require no further adjustment.

# Installing Paddle / Basket Shafts

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  $25 \pm 2$  mm above the bottom of the vessel. See the current USP for a complete explanation.

### **Installing Paddles**



- Step 1. Raise the drive unit to its home position.
- Step 2. Carefully insert a paddle into each spindle until approximately half of the shaft is above the top of the spindle.
- Step 3. Place a 25 mm height sphere in each of the vessels.



Step 4. Press and hold **DRIVE DOWN** until the drive unit is at its lowest position.



- Step 5. Gently press down each paddle shaft until the bottom of the paddle blade rests against the height sphere.
- Step 6. Place a shaft locking ring on the top of each shaft and slide it down until it rests on the shaft collar.

| Step 7.  | 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 8.  | Tighten the set screws using the 7/64-inch T-handle Allen wrench provided.  |
| Step 9.  | Raise the drive unit to its home position. Remove the height spheres from the vessels.  |
| Step 10. | Lower the drive unit until it stops. The paddles are set at the   |

USP-specified height of  $25 \pm 2$  mm above the bottom of the vessel.

#### Installing Basket Shafts

- Step 1. Raise the drive unit to its home position.
- Step 2. Carefully insert a basket shaft into each spindle until approximately half of the shaft is above the top of the spindle.
- Step 3. Clip the basket height gauge onto a shaft.
- Step 4. Press and hold **DRIVE DOWN** until the drive unit is at its lowest position.



Step 5. Gently press down the basket shaft until the bottom of the gauge rests against the bottom of the vessel. Be careful not to use excessive pressure or the bottom of the vessel may crack.

| Step 6. | Place a shaft locking ring on the top of the shaft and slide it down until it |
|---------|---|
|         | rests on the shaft collar.  |

- Step 7. Rotate the 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 8. Tighten the set screw using the 7/64-inch T-handle Allen wrench provided.
- Step 9. Raise the drive unit to its home position. Remove the height gauge from the basket shaft.
- Step 10. Repeat steps 3 9 for each of the remaining positions.
- Step 11. The basket shafts are set at the appropriate height so when the baskets are installed and the drive unit lowered they are at the USP-specified height of  $25 \pm 2$  mm above the bottom of the vessel.

# Installing Rotating Cylinders



If using rotating cylinders, it is easier to install the evaporation covers prior to installing the rotating cylinders. See "Installing Standard Evaporation Covers" on page 36 or "Installing Basket / Low-loss Evaporation Covers" on page 37 as appropriate for the type of evaporation covers included with your system.

Note

- Step 1. Raise the drive unit to its home position.
- Step 2. Carefully insert a rotating cylinder shaft into the spindle until approximately half of the shaft is above the top of the spindle.

Step 3. Press and hold **DRIVE DOWN** until the drive unit is at its lowest position.



There is a safety mechanism in the bottom of the left side guide rod which keeps the drive unit from lowering improperly. If the rods do not line up precisely with the holes in the vessel plate, the mechanism engages and the drive unit stops lowering and rises to the home position. See Figure 4, "Drive Unit Guide Rods," on page 24.

Note

- Step 4. Using a height gauge tool (optional), gently press down the rotating cylinder shaft to set the height to the USP-specified height of  $25 \pm 2$  mm above the bottom of the vessel.
- Step 5. Place a shaft locking ring on the top of the shaft and slide it down until it rests on the shaft collar.
- Step 6. Rotate the 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 7. Tighten the set screw using the 7/64-inch T-handle Allen wrench provided.
- Step 8. Repeat steps 3 7 for each of the remaining positions.
- Step 9. Lower the drive unit until it stops. The rotating cylinders are set at the USP-specified height of  $25 \pm 2$  mm above the bottom of the vessel.

# Installing the Intrinsic Dissolution Apparatus

- Step 1. Raise the drive unit to its home position.
- Step 2. Carefully insert an intrinsic dissolution apparatus shaft into a spindle until approximately half of the shaft is above the top of the spindle.

Step 3. Press and hold **DRIVE DOWN** until the drive unit is at its lowest position.



- Step 4. Gently press down the shaft until the desired height is reached.
- Step 5. Place a shaft locking ring on the top of the shaft and slide it down until it rests on the shaft collar.
- Step 6. Rotate the shaft locking ring so the drive positioning teeth on both the shaft locking ring and the shaft collar rest against one another, locking Tighten the set screw using the 7/64-inch T-handle Allen wrench provided. The intrinsic dissolution apparatus is set at the desired height above the bottom of the vessel.
- Step 7. Repeat this procedure as applicable for additional positions.

# **Removing the Dissolution Apparatus**

To remove paddles, baskets, rotating cylinders or intrinsic dissolution apparatus, complete the following steps:

- Step 1. Loosen the set screw on the shaft locking ring using the 7/64-inch T-handle Allen wrench and remove the shaft locking ring. Repeat this step for all positions.
- Step 2. Raise the drive unit to its home position and gently remove the shafts taking care not to drop them into the vessels.

# **Centering Verification**

To verify the centering of the paddle / basket shafts, complete the following steps:

Step 1. Locate the centering verification gauge and the EaseAlign centering ring.

#### FIGURE 6. Centering Verification Gauge



#### FIGURE 7. EaseAlign Centering Ring



- Step 2. Place the EaseAlign centering ring on the first vessel (see Figure 7, "EaseAlign Centering Ring," above).
- Step 3. Place the centering verification gauge against the shaft with the shaft resting in the radial cutout (see Figure 6, "Centering Verification Gauge," above).

| Step 4. | Slide the centering verification gauge down the shaft until the tapered ends rest in two opposing slots of the EaseAlign centering ring.  |
|---------|---|
| Step 5. | Rotate the centering verification gauge 90 degrees and slide the gauge<br>down the shaft until the tapered ends rest in the other two opposing slots<br>of the EaseAlign centering ring. The shaft should remain within the<br>confines of the radial cutout of the gauge at both settings. |
| Step 6. | Repeat steps 2 - 5 for the remaining vessel positions.  |

# Installing Cannula Assemblies

- Step 1. Ensure the sampling and return lines are connected to the sampling and return cannulas of each cannula assembly according to the following order: red (1), white (2), blue (3), purple (4), yellow (5), clear (6), green (7), and brown (8).
- Step 2. Install the cannula assemblies in the appropriate opening in the top cover according to the order listed in step 1. Use the alignment pin and coordinating notch to guide each assembly through the opening in the top cover.
- Step 3. Complete "Cannula Height Calibration" on page 50 to perform the electronic adjustment.

## Installing Standard Evaporation Covers

To place the evaporation covers onto the spindles, complete the following steps:

Step 1. For vessel position 1, place the knobbed evaporation plug in the left manual sampling hole and the evaporation plug in the right manual sampling hole (see Figure 8, "Standard Evaporation Cover," below).

FIGURE 8. Standard Evaporation Cover



- Step 2. Align the appropriate openings in the evaporation cover with the plastic DDM tube extending from the bottom of the drive unit and the cannula assembly.
- Step 3. Apply gentle upward pressure until the top of the evaporation cover slides over the O-ring on the spindle housing. The evaporation cover floats in place.
- Step 4. Repeat steps 1 3 for vessel positions 2 and 3.
- Step 5. For vessel position 4, place the knobbed evaporation plug in the right manual sampling hole and the evaporation plug in the left manual sampling hole (see Figure 8, "Standard Evaporation Cover," above).
- Step 6. Repeat steps 2, 3, and 5 for the remaining vessel positions.
# Installing Basket / Low-loss Evaporation Covers

The evaporation cover for low loss or baskets comes with two DDM alignment attachments. Both attachments aid the alignment of the evaporation cover on the vessel. The open alignment attachment allows use of the DDM. The solid alignment attachment reduces evaporation and blocks use of the DDM.

If using the optional evaporation cover for use with baskets or for low loss, complete the following steps:

Step 1. Determine which DDM alignment attachment is appropriate for your system and screw the attachment into the opening in the evaporation cover (see Figure 9, "Evaporation Cover for Low Loss or Baskets," below).



#### FIGURE 9. Evaporation Cover for Low Loss or Baskets

Step 2. If using paddles or rotating cylinders, remove the apparatus from vessel position 1. Feed the shaft through the center hole of the evaporation cover and replace the apparatus following the instructions under "Installing Paddles" on page 29 or "Installing Rotating Cylinders" on page 31, as appropriate. Repeat for each vessel position.

If using baskets, place an evaporation cover on the vessel at each vessel position. Visually align the DDM tube with the DDM alignment attachment and the cannula assembly with the opening in the evaporation cover. Page 38 Setup

Step 3. When lowering the drive unit to run the method, stop the downward movement two inches above the vessel plate. Align the evaporation cover with the cannula assembly and the DDM tube at each vessel position. Lower the drive unit completely. The DDM tube should rest within the DDM alignment attachment.

## Setting the Manual Sampling Cannula

To sample manually from positions 7 and 8, it is necessary to set the manual sampling cannulas to the correct length.

For positions 7 and 8, complete the following steps:

| Step 1. | From the System Setup Menu 1 screen, select DIAGNOSTICS. The |
|---------|--|
|         | Diagnostic Menu screen displays.                             |

- Step 2. Select DDM TEST.
- Step 3. Position a DDM manual override adapter over the DDM at position 7. *Do not* press down on the adapter.
- Step 4. Select the corresponding location on the screen and the appropriate DDM opens. Gentle downward pressure slides the adapter into place. The adapter prevents the DDM from closing.
- Step 5. Press **ESC** twice to return to the System Setup Menu 1 screen.
- Step 6. Attach the cannula (part number 17-3315) to the syringe.
- Step 7. Place the manual sampling cannula through the DDM manual override adapter and into the vessel (see Figure 10, "Manual Sampling through the Top Cover," on page 39).



#### FIGURE 10. Manual Sampling through the Top Cover

- Step 8. Loosen the hex screw on the cannula bushing and slide the bushing up or down the cannula until it is positioned for the correct USP-specified sampling location.
- Step 9. If sampling from a 500 mL volume, remove the bushing.
- Step 10. When positioned correctly, tighten the hex screw.
- Step 11. Remove the manual sampling cannula and set aside for use during the test.
- Step 12. Gently remove the DDM manual override adapter.

# **Programming Administrative Control**



For initial setup, the preprogrammed user identification is 9 and the preprogrammed password is 9. It is recommended that you immediately change the user identification and password for Administrative control of the VK 7020 / 7020 S / 7025 Dissolution Apparatus once your unit is operational.

Note

## Security Levels

| ADMINISTRATOR | Allows access to all functions.   |
|---------------|---|
| SUPERVISOR    | Allows method editor privileges.<br>Does not allow access to the System Setup Menu 1 screen which<br>includes administration and calibration functions.   |
| OPERATE ONLY  | Allows access to user functions.<br>Does not allow access to the System Setup Menu 1 screen which<br>includes administration and calibration functions.<br>Does not allow method editor privileges. |

Up to 24 user identifications and passwords can be stored on the VK 7020 / 7020 S / 7025. User identifications are alphabetic and / or numeric combinations no longer than nine characters in length. Passwords are numeric and no longer than eight characters in length.



Note

If you erase or forget all system administrator passwords, contact the Dissolution Systems Service Department.

# Setting Up the User List

For initial set up of user identifications and passwords, the preprogrammed user identification is 9 and the preprogrammed password is 9. It is recommended that you immediately change the user identification and password for Administrative control of the VK 7025 Dissolution Apparatus once your unit is installed.

To set up the user list, complete the following steps:

| Step 1. | Ensure the dissolution apparatus is turned on.   |
|---------|--|
| Step 2. | If directed, press <b>DRIVE UP</b> to initialize the dissolution apparatus. The drive unit moves to the home position and the Login screen displays. |
| Step 3. | Enter the user identification (Login ID) and press ENTER.  |
| Step 4. | Enter the password and press <b>ENTER</b> . The System Setup Menu 1 screen displays.   |
| Step 5. | Select ADMINISTRATION. The Administration screen displays.   |
| Step 6. | Select ADD USER. The Enter User ID and Password screen displays.   |
| Step 7. | Enter the new user identification and press ENTER.   |



- Step 8. Enter the new user password and press **ENTER**.
- Step 9. Confirm the new password and press **ENTER**.

| Step 10. | Determine the security level for the new user by selecting |
|----------|--|
|          | ADMINISTRATOR, SUPERVISOR, or OPERATE ONLY. The            |
|          | Administration screen displays.                            |
|          |  |

- Step 11. Repeat steps 6 10 until all users' identifications, passwords, and security levels have been entered.
- Step 12. Delete the preprogrammed user identification and password that came with your dissolution apparatus (see "Deleting Preset User Definitions" below).

# **Deleting Preset User Definitions**

It is recommended that you immediately change the user identification and password for Administrative control of the VK 7025 Dissolution Apparatus once your unit is installed.

- Step 1. After entering the user identifications, passwords, and security levels, select LIST / DELETE USERS. The List and Delete Users screen displays.
- Step 2. Select the preset user identification and password by selecting NEXT until the cursor flashes over the number of the appropriate user identification.
- Step 3. Select DELETE.
- Step 4. Select YES to confirm deletion. The List and Delete Users screen displays.
- Step 5. Press **ESC** to return to the Administration screen.

Page 43 Setup

# Vessel Plate Layout

The vessels on the VK 7025 are numbered counterclockwise beginning with the back left corner.

#### FIGURE 11. Vessel Plate Layout



| Page  | 44 |
|-------|----|
| Setup | )  |

This page was intentionally left blank, except for this message.

# Chapter 4

# Administrator Operation

If your security level is "supervisor" or "operate only," continue to Chapter 5, "Operation," on page 59.

# **User Settings**

To add, list, or delete users, see "Programming Administrative Control" on page 40.

After adding the user identifications, passwords, and security, press **ESC** to return to the System Setup Menu 1 screen.

Following is a description of the System Setup Menu 1 screen options:

| Option         | Response  |
|----------------|---|
| Main Menu      | All operation functions begin at the Main Menu. See "Main Menu" on page 59.   |
| Administration | Select ADMINISTRATION to add, list or delete users, set edit method authority and set up security override. See "Administration" on page 47.  |
| Calibration    | Select CALIBRATION in order to set the calibration information, and if applicable, the cannula height, the bath vessel difference and the alternate start drive position. See "Calibration" on page 48.   |
| Alarms         | Select ALARMS to enter the preventative maintenance (PM) expiration date and the bath temperature limit and to view the calibration calendar menu. See "Alarms" on page 52.   |
| Diagnostics    | This option is for diagnostic purposes and if applicable, independent operation of the DDMs, cannulas and clutches. See "Diagnostics" on page 54.   |
| Temp Display   | Select TEMP DISPLAY to toggle between ENABLED and DISABLED. If temp display is enabled, the vessel temperatures / cannula positions display at the bottom of the system monitor screen. If temp display is disabled, the vessel temperatures / cannula positions do not display. This option is applicable only if AutoTemp is installed.                 |
| Paddle Spin    | Select PADDLE SPIN to toggle between ENABLED and DISABLED.  |
|                | If paddle spin is disabled, the paddles do not spin prior to the start of the test. <i>Note: if an initial temperature is taken in the method, the paddles spin regardless of whether paddle spin is enabled or disabled.</i>   |
|                | If paddle spin is enabled, the paddles spin prior to the start of the test<br>which allows the vessel temperature to equilibrate. This removes the<br>possibility of a temperature gradient—allowing for a more accurate<br>vessel temperature reading.   |
| Menu 2         | Select MENU 2 to access menus for the setting the clock and<br>communication port functions; entering serial numbers, the number of<br>vessels, and the tester identification number; enabling or disabling all<br>position spin; and to set a delay between the initial temperature<br>measurement and the opening of the DDMs. See "Menu 2" on page 55. |

# **Administration**

From the System Setup Menu 1 screen, select ADMINISTRATION. The Administration screen displays.

Following is a description of the Administration screen options:

| Option                | Response  |
|-----------------------|---|
| Add User              | Select ADD USER to enter user identifications and passwords.<br>See "Setting Up the User List" on page 41 for instructions on<br>adding a user.   |
| List / Delete Users   | Select LIST / DELETE USERS to list and delete user<br>identifications and passwords. See "Deleting Preset User<br>Definitions" on page 42 for instructions on deleting user<br>identifications and passwords.   |
| Edit Method Authority | Select EDIT METHOD AUTHORITY to toggle between ALL<br>USERS and ADMINISTRATOR. This function grants method editor<br>privileges to the administrator and supervisor or all users.<br>Select ALL USERS to override the limited access levels for<br><i>OPERATE ONLY</i> .  |
| Security Override     | <ul> <li>Select SECURITY OVERRIDE to toggle between ENABLED and DISABLED.</li> <li>If security override is enabled:</li> <li>when the machine is turned on, the System Setup Menu 1 screen displays without requiring you to log in.</li> <li>you cannot log out.</li> <li>If security override is disabled, when the machine is turned on, the Login screen displays and you must log in.</li> </ul> |
| Last User             | The user identification of the last user and the date and time of last login displays on the screen.  |

# Calibration

From the System Setup Menu 1 screen, select CALIBRATION. Spindle hours are displayed under the screen title. The Calibration Menu screen displays.

Following is a description of the Calibration Menu screen options:

| Option                                | Response   |
|---------------------------------------|--|
| Bath Vessel Diff.                     | Enter the difference between the water bath temperature and the vessel temperature. See "Bath Vessel Difference" below.  |
| Set Alternate Start<br>Drive Position | When performing a staggered start under manual operation<br>with Apparatus 1, you must set the drive unit to an alternate<br>start position. See "Setting an Alternate Drive Unit Position" on<br>page 49. |
| Cannula Height<br>Calibration         | This option displays only if AutoTemp and / or sampling cannulas are installed.  |
|                                       | To set the sampling position for the cannulas, see "Cannula Height Calibration" on page 50.  |

#### **Bath Vessel Difference**



Note For this option, if you enter a value outside of the acceptable range, an error message displays indicating appropriate values.

To set the bath vessel difference, complete the following steps:

- Step 1. From the System Setup Menu 1 screen, select CALIBRATION. The Calibration Menu screen displays.
- Step 2. From the Calibration Menu screen, select BATH VESSEL DIFF.

| Revision G, 01/06 | VK 7025 Dissolution Apparatus | Page 49                 |
|-------------------|-------------------------------|-------------------------|
| P/N 70-9033       | Operator's Manual             | Administrator Operation |

Step 3. Enter the observed difference in the temperature between the water bath temperature and the vessel temperature. The acceptable range is 0.0 to 10.0 °C. Press **CLEAR** to delete the entry or press **ENTER** to continue. The Calibration Menu screen displays with the new bath vessel difference value.



When all appropriate parameters on the Calibration Menu screen have been entered, press **ESC** to return to the System Setup Menu 1 screen.

## Setting an Alternate Drive Unit Position

When performing a staggered start and sampling manually with Apparatus 1, you must set an alternate drive unit start position.

| Note  |
|---|
| Ensure the basket assemblies are installed and the standard evaporation covers are removed prior to beginning this procedure. |

To set the height to an alternate position, complete the following steps:

- Step 1. From the System Setup Menu 1 screen, select CALIBRATION. The Calibration Menu screen displays.
- Step 2. Raise the drive unit to its home position.
- Step 3. If applicable, remove the cannula assembly.
- Step 4. Raise the basket shafts so the basket shaft heads rest against the spindle housings (see Figure 12, "Spindle Housing," on page 50).

#### FIGURE 12. Spindle Housing



- Step 5. Ensure the optional basket evaporation covers are in place.
- Step 6. Lower the drive unit to position the baskets just above the evaporation covers.
- Step 7. Select SET ALTERNATE START DRIVE POSITION to set the height. The drive unit automatically lowers to this position when a staggered start test is started with Apparatus 1 while under manual operation.
- Step 8. With the drive unit in this position, reset the basket height to the USP-specified  $25 \pm 2$  mm above the bottom of the vessel.

When all appropriate parameters on the Calibration Menu screen have been entered, press **ESC** to return to the System Setup Menu 1 screen.

#### Cannula Height Calibration



If it is necessary to adjust the factory-set sampling heights for the cannulas, complete the following steps:

Step 1. Ensure the drive unit is in its lowest position.

Step 2. From the Calibration Menu screen, select CANNULA HEIGHT CALIBRATION. The Set Sampling Depth screen displays with factory-set values for each apparatus.

| SET SAMPLING DEPTH     |              |
|------------------------|--------------|
| BASKET 900 mL<br>200   | MOVE<br>UP   |
| BASKET 500 mL<br>400   | MOVE<br>DOWN |
| PADDLE 900 mL<br>200   |              |
| PADDLE 500 mL<br>400   | MENU 2       |
| CANNULA POSITION = $0$ |              |

| Note  |
|---|
| The factory-set number displayed under each option is not a distance measurement. It refers to the number of steps the cannula motor moves. |

- Step 3. If you are using paddle over disk or rotating cylinder, select MENU 2 to view these apparatus.
- Step 4. To ensure the cannulas are in their home position, select MOVE DOWN to move the cannulas to their lowest position, then select MOVE UP to move the cannulas to their highest position.
- Step 5. Select MOVE UP or MOVE DOWN to position the cannulas at the appropriate height in the vessels.

| Page 52                 | VK 7025 Dissolution Apparatus | Revision G, 01/06 |
|-------------------------|-------------------------------|-------------------|
| Administrator Operation | Operator's Manual             | P/N 70-9033       |

Step 6. When the cannulas are in the correct position, select the appropriate apparatus and volume. The number of steps the cannula motor moved to reach that position displays under the selected apparatus and volume.

| Note   |
|--|
| For volumes between 500 mL and 900 mL, the appropriate cannula<br>height is interpolated from the 500 mL and 900 mL settings. For<br>volumes greater than 900 mL, the appropriate cannula height is<br>extrapolated from the 500 mL and 900 mL settings. |

Step 7. Press **ESC**. The cannulas return to the home position and the Calibration Menu screen displays.

When all appropriate parameters on the Calibration Menu screen have been entered, press **ESC** to return to the System Setup Menu 1 screen.

# Alarms

From the System Setup Menu 1 screen, select ALARMS. The Setup Alarms screen displays the basket and paddle expirations dates and the following options:

| Option             | Response   |
|--------------------|--|
| PM Expiration Date | Use this option to set the preventative maintenance alarm.<br>Select PM EXPIRATION DATE. The cursor flashes. Enter the<br>date in the appropriate format and press <b>ENTER</b> . The date<br>displays.  |
| USP Cal Menu       | Use this option to enter calibration and expiration dates. See "Calibration Calendar" on page 53.  |
| Bath Temp. Limit   | Use this option to set an alarm to sound if the water bath temperature exceeds the set limit. Select BATH TEMP. LIMIT. The cursor flashes. Enter the limit and press <b>ENTER</b> . The bath temperature limit displays on the screen. Entering a value of 0.0 disables the alarm. |

# **Calibration Calendar**

From the Setup Alarms screen, select USP CAL MENU. The Calibration Calendar screen displays.

Following is a description of the Calibration Calendar screen options:

| Option                  | Response  |
|-------------------------|---|
| Basket Calibration Date | Enter the date the calibration was performed in the appropriate format and press <b>ENTER</b> . |
| Paddle Calibration Date | Enter the date the calibration was performed in the appropriate format and press <b>ENTER</b> . |
| Basket Expiration Date  | Enter the calibration expiration date in the appropriate format and press <b>ENTER</b> .        |
| Paddle Expiration Date  | Enter the calibration expiration date in the appropriate format and press <b>ENTER</b> .        |

An alarm sounds when an entered date is reached. ALARM BASKET CAL DUE, ALARM PADDLE CAL DUE, or ALARM PM DUE displays. Press **CLEAR** to silence the alarm.

Press **ESC** to return to the Setup Alarms screen. When all appropriate parameters on the Setup Alarms screen have been entered, press **ESC** to return to the System Setup Menu 1 screen.

# Diagnostics

To check the operation of applicable options for your instrument, select DIAGNOSTICS from the System Setup Menu 1 screen. The Diagnostic Menu screen displays.

Following is a description of the Diagnostic Menu screen options:

| Option   | Response   |
|--|--|
| DDM Test<br>(if installed)                     | Select DDM TEST. Select each location and verify the corresponding DDM opens and closes. Press <b>ESC</b> to return to the Diagnostic Menu screen.   |
| Cannula Test<br>(if installed)                 | Select CANNULA TEST. Select a location and verify the corresponding cannula moves down. UP changes to DOWN. Select the location again and verify the corresponding cannula moves up. Repeat for all cannula positions. Press <b>ESC</b> to return to the Diagnostic Menu screen. |
| Shaft Brake &<br>Clutch Test (if<br>installed) | Select SHAFT BRAKE & CLUTCH TEST. Select a location<br>and verify the clutch activates. OFF changes to ON. Select the<br>location again and verify the brake activates. Repeat for all<br>shaft positions. Press <b>ESC</b> to return to the Diagnostic Menu<br>screen.          |
| Read Bath &<br>Heater Temp                     | Select READ BATH & HEATER TEMP. The Bath and Heater<br>Temp screen displays with the bath and heater temperatures.<br>This is the only screen where the heater temperature<br>displays.  |
|  | Press <b>ESC</b> to return to the Diagnostic Menu screen.  |

Communications Bus Diagnostic, Lift Board Input Test, and Input & Output Tests also display, but these options are for qualified service personnel only. If you have any questions about the operation of your VK 7025, see Chapter 8, "Service and Warranty," on page 117 or contact the Dissolution Systems Service Department.

# Menu 2

From the System Setup Menu 1 screen, select MENU 2. The System Setup Menu 2 screen displays.

Following is a description of the System Setup Menu 2 screen options:

| Option                  | Response   |
|-------------------------|--|
| Clock                   | Select CLOCK to set the date, time, and date format. See "Setting the Clock" on page 56.   |
| Comm. Port<br>Functions | Select COMM. PORT FUNCTIONS to set the baud rate,<br>communication port, and external control. The Comm. Functions<br>screen displays. See "Setting Communication Port Functions" on<br>page 56.   |
| Serial Numbers          | Select SERIAL NUMBERS to enter the serial numbers of equipment being used. See "Setting Serial Numbers" on page 57.  |
| Vessels                 | Select VESSELS to select the number of vessels being used.   |
|                         | Note: it is imperative to set the correct number of vessels being used or the instrument will not function properly.   |
| All Position Spin       | Select ALL POSITION SPIN to toggle between ENABLED and<br>DISABLED. When disabled, the paddles or baskets rotate only when<br>the drive unit is at the correct operating height.<br>When enabled, the paddles or baskets rotate when the drive unit is<br>at any height. |
| Tester ID               | Select TESTER ID to enter an identification number for the dissolution apparatus. This number appears with the dissolution apparatus serial number on the printout.  |
| Dly After Ini Tmp       | Select DLY AFTER INI TMP to enter a delay duration between the measuring of the initial temperature and the DDMs opening.  |

# Setting the Clock

From the System Setup Menu 2 screen, select CLOCK. The Clock Functions screen displays.

Following is a description of the Clock Functions screen options:

| Option      | Response  |
|-------------|---|
| Set Date    | Select SET DATE. The cursor flashes. Enter the correct date and press <b>ENTER</b> . The correct date displays.                   |
| Set Time    | Select SET TIME. The cursor flashes. Enter the correct time in 24-hour format and press <b>ENTER</b> . The correct time displays. |
| Date Format | Select DATE FORMAT to toggle between MM/DD/YYYY and DD/MM/YYYY.   |

Press **ESC** to return to the System Setup Menu 2 screen.

#### **Setting Communication Port Functions**

From the System Setup Menu 2 screen, select COMM. PORT FUNCTIONS. The Comm. Functions screen displays.

Following is a description of the Comm. Functions screen options:

| Option           | Response   |
|------------------|--|
| External Control | Select EXTERNAL CONTROL to toggle between DISABLED and ENABLED.  |
|                  | If external control is enabled, a VK 8000 or Total Solution software can control the VK 7025. To use external control, you must log off the dissolution apparatus. |

| Option    | Response   |
|-----------|--|
| Baud Rate | Select BAUD RATE to toggle between 2400, 4800, 9600, 19200, 28800, and 38400. The baud rate must be set to 9600 when connected to a VK 8000 or Total Solution system.  |
| Comm. ID  | Select COMM. ID. The cursor flashes. Enter the correct communications port identification number in xx format and press <b>ENTER</b> . The correct communications port identification number displays. The communications port identification number must be 01 when connected to a VK 8000 or single Total Solution system. |
|           | <i>Note: a leading zero is necessary when entering a communications port identification number between 01 and 09.</i>  |

Press **ESC** to return to the System Setup Menu 2 screen.

#### **Setting Serial Numbers**

To enter the serial numbers of your accessories, complete the following steps:

- Step 1. Select SERIAL NUMBERS from the System Setup Menu 2 screen. The Enter Serial Numbers screen displays.
- Step 2. Select VESSEL, PADDLE, BASKET / SHAFT, or ROTATING CYLINDER. The corresponding serial number screen displays with numbers 1 through 8 listed down the left side of the screen. If BASKET / SHAFT is selected, two columns display. The left column is for basket serial numbers and the right column is for shaft serial numbers.

| Page 58                 |  |
|-------------------------|--|
| Administrator Operation |  |

Step 3. Enter the serial numbers for the vessel, paddle, basket and shaft, or rotating cylinder for each of the corresponding spindle locations. See "Vessel Plate Layout" on page 43.



- Step 4. Press **ENTER** to accept an entry and move to the following line until all the serial numbers have been entered. When entering basket and shaft serial numbers, the cursor moves from basket location 1 to shaft location 1 and then to basket location 2 followed by shaft location 2 and so on.
- Step 5. Press **ESC** to return to the Enter Serial Numbers screen.
- Step 6. Repeat steps 2 5 to enter serial numbers for the remaining appropriate accessories. Press **ESC** to return to the System Setup Menu 2 screen.

When all appropriate parameters on the System Setup Menu 2 screen have been entered, press **ESC** to return to the System Setup Menu 1 screen.

# Chapter 5 **Operation**

# Main Menu

From the System Setup Menu 1 screen, select Main Menu. The Main Menu displays.

| MAIN MENU                           |      |                  |                  |
|-------------------------------------|------|------------------|------------------|
| MANUAL<br>OPERATION                 |      |                  | START<br>METHOD  |
| BATH TEMPERATURE<br>SET POINT: 37.5 |      | METHOD<br>EDITOR |                  |
| DELAYED<br>HEATING                  |      |                  | PRINT<br>REPORTS |
| RPM 000.0 BATH 37.2                 |      |                  |                  |
| 1:UP                                | 2:UP | 3:UP             | 4:UP             |
| 5:UP                                | 6:UP | 7:UP             | 8:UP             |
| WED DEC 3 08:32:42 2003             |      |                  |                  |

Following is a description of the Main Menu options:

| Option                        | Response  |
|-------------------------------|---|
| Manual Operation              | Select MANUAL OPERATION to set parameters for manual operation. See "Manual Operation" below.   |
| Bath Temperature<br>Set Point | Select BATH TEMPERATURE SET POINT. The cursor flashes.<br>Enter the desired bath temperature and press <b>ENTER</b> .   |
|                               | Note: use this option to heat the bath independent of running a program or performing manual operation.   |
| Delayed Heating               | Select DELAYED HEATING to enter date, time and temperature for heating to begin. See "Setting Delayed Heating" on page 72.  |
| Start Method                  | Select START METHOD to select the method to run, print the method parameters, enter information about the product being tested or start the test. See "Start Method" on page 73.                          |
| Method Editor                 | Select METHOD EDITOR to display options to create / modify, copy or store a method. See "Method Editor" on page 84.   |
| Print Reports                 | Select PRINT REPORTS to print the current method parameters, serial numbers or the results from the preceding method, set print frequency and turn on or off the printer. See "Print Reports" on page 90. |

## Manual Operation

From the Main Menu, select MANUAL OPERATION. The Manual Operation screen displays.

Following is a description of the Manual Operation screen options:

| Note   |  |  |
|--|--|--|
| For the following options, if you enter a value outside the acceptable range, an error message displays indicating appropriate values. |  |  |

| Option                        | Response  |  |  |  |
|-------------------------------|---|--|--|--|
| RPM Set                       | If a speed setting has previously been entered, the setting displays next to RPM SET.   |  |  |  |
|                               | To change the setting, select RPM SET. The cursor flashes. Enter<br>the desired speed in xx format. The acceptable range is 10 to<br>250 RPM. Press $\leftarrow$ or <b>CLEAR</b> to clear unwanted or incorrect<br>entries. Press <b>ENTER</b> to accept the speed setting.   |  |  |  |
| Bath Temperature<br>Set Point | If a temperature setting has previously been entered, the setting displays next to BATH TEMPERATURE SET POINT.  |  |  |  |
|                               | To change the setting, select BATH TEMPERATURE SET POINT.<br>The cursor flashes. Enter the desired temperature in xx.x format.<br>The acceptable range is 20.0 to 55.0 °C. Press $\leftarrow$ or <b>CLEAR</b> to<br>clear unwanted or incorrect entries. Press <b>ENTER</b> to accept the<br>temperature setting.               |  |  |  |
| Volume                        | If a volume setting has previously been entered, the setting displays below VOLUME.   |  |  |  |
|                               | To change the setting, select VOLUME. The cursor flashes. Enter<br>the media volume in xxxx format. The acceptable range is 500 to<br>1050. Press $\leftarrow$ or <b>CLEAR</b> to clear unwanted or incorrect entries.<br>Press <b>ENTER</b> to accept the volume setting.  |  |  |  |
| Apparatus                     | If an apparatus setting has previously been entered, the setting displays below APPARATUS.  |  |  |  |
|                               | To change the apparatus selection, select APPARATUS. The Select<br>Apparatus screen displays. The options listed include: Baskets,<br>Paddles, Paddle Over Disk, and Rotating Cylinder. Select the<br>apparatus being used. The Manual Operation screen displays and<br>the newly selected apparatus is listed below APPARATUS. |  |  |  |

| Option                                   | Response   |  |
|--|--|--|
| Sample Point Alarm                       | The sample point alarm allows the user to set an alarm to sound at<br>some time interval prior to the sample point. By default, the sample<br>point alarm is disabled.   |  |
|  | See "Setting Sample Points and Alarms" below.  |  |
| Use Alternate /<br>Standard Start Height | Select ALTERNATE / STANDARD START HEIGHT to toggle<br>between the two options. This selection is necessary only when<br>using Apparatus 1 (baskets). See "Setting an Alternate Drive Unit<br>Position" on page 49. |  |
| Manual Sample                            | See "Manual Sampling of Temperature" on page 63.   |  |

#### **Setting Sample Points and Alarms**

To enable the alarm, complete the following steps:

- Step 1. Select SAMPLE POINT ALARM. DISABLED changes to ENABLED and TIME MM:SS displays.
- Step 2. Enter the time and press **ENTER**. SAMPLE POINTS displays. Press  $\leftarrow$  to clear unwanted or incorrect entries.
- Step 3. Select SAMPLE POINTS. The Sample Points screen displays.
- Step 4. Enter up to 24 timepoints in hhh:mm:ss format and press **ENTER** to move to the next timepoint location. The maximum acceptable value is 999:59:59. Press ← to clear unwanted or incorrect entries.



Step 5. Select PREVIOUS and NEXT to scroll up and down the timepoints. Press **CLEAR** to delete unwanted timepoints.

Step 6. After all sample timepoints have been entered, press **ESC** to return to the Manual Operation screen.

| Note                              |  |
|-----------------------------------|--|
| Press CLEAR to silence the alarm. |  |

#### Manual Sampling of Temperature

From the Manual Operation screen, select MANUAL SAMPLE. The Manual Sampling screen displays.

| MANUAL SAMPLING     |               |      |      |  |  |
|---------------------|---------------|------|------|--|--|
| UP                  | JP SELECT ALL |      |      |  |  |
| UP                  | INDIVIDU      | DOWN |      |  |  |
| SELECT POSITION = 1 |               |      |      |  |  |
| VESSEL TEMPS        |               |      |      |  |  |
| 1:UP                | 2:UP          | 3:UP | 4:UP |  |  |
| 5:UP                | 8:UP          |      |      |  |  |

The vessel temperatures / cannula positions display only if temp display is enabled (see "Temp Display" on page 46).

To check the temperature in all vessels, select DOWN corresponding to SELECT ALL. The cannulas lower and the temperature readings display next to all vessel position numbers at the bottom of the screen. Wait one minute for the readings to stabilize. To raise all probes, select UP corresponding to SELECT ALL.

To check the temperature in a specific vessel location, enter the vessel position number and select DOWN corresponding to INDIVIDUAL PROBE. The temperature reading displays next to the appropriate vessel position number. Wait one minute for the reading to stabilize. To raise the individual probe, select UP corresponding to INDIVIDUAL PROBE.

Press **ESC** to return to the Manual Operation screen.

# Starting a Test

Before starting the test, complete the following steps to set the DDM manual override adapters in place at vessel positions 7 and 8:

- Step 1. From the System Setup Menu 1 screen, select DIAGNOSTICS. The Diagnostic Menu screen displays.
- Step 2. Select DDM TEST.
- Step 3. Position a DDM manual override adapter over the DDM at vessel position 7. *Do not* press down on the adapter.
- Step 4. Select the corresponding location and the appropriate DDM opens. Gentle downward pressure slides the adapter into place. The adapter prevents the DDM from closing.
- Step 5. Repeat steps 3 and 4 for vessel position 8.
- Step 6. Press **ESC** until the Main Menu displays.
- Step 7. Select MANUAL OPERATION. The Manual Operation screen displays.

When all parameters listed on the Manual Operation screen have been entered and the DDM manual override adapters are in place for vessel positions 7 and 8, complete the steps listed under the appropriate apparatus on the following pages to start the test immediately.

| Apparatus         | Procedures                          |
|-------------------|-------------------------------------|
| Paddles           | See "Paddles" on page 65.           |
| Baskets           | See "Baskets" on page 67.           |
| Paddle over disk  | See "Paddle Over Disk" on page 69.  |
| Rotating cylinder | See "Rotating Cylinder" on page 70. |

### **Paddles**



- Step 1. Press **RUN**. If paddle spin is disabled, METHOD STARTUP STATUS / MANUAL TABLET DROP / PRESS RUN TO CONTINUE displays. If paddle spin is enabled, METHOD STARTUP STATUS / MANUAL TABLET DROP / PRESS STOP TO STOP PADDLES / PRESS RUN TO CONTINUE displays.
- Step 2. If paddle spin is enabled, press **STOP**. If paddle spin is disabled, skip this step and continue to step 3.
- Step 3. Pull up the shaft locking ring to lift each paddle out of the medium.
- Step 4. Remove the knobbed evaporation plug on the outside of the evaporation cover at vessel position 1, drop the dosage unit and replace the knobbed evaporation plug. See Figure 13, "Standard Evaporation Cover, Dropping Dosage Unit and Sampling," below.

#### FIGURE 13. Standard Evaporation Cover, Dropping Dosage Unit and Sampling



- Step 5. Push down the paddle shaft at vessel position 1.
- Step 6. Press **RUN**. The Method Status screen displays and the paddles rotate.

| Note   |
|--|
| To quit the test from the Method Status screen, press ESC and select EXIT. The Manual Operation screen displays. |

Step 7. At the desired time intervals, manually drop a dosage unit into each additional vessel and push down the corresponding paddle shaft.

| Note   |
|--|
| For vessel positions 2 - 6, remove the knobbed evaporation plug<br>on the outside of each evaporation cover, drop the dosage unit,<br>and replace the knobbed evaporation plug (see Figure 13,<br>"Standard Evaporation Cover, Dropping Dosage Unit and<br>Sampling," on page 65). For vessel positions 7 and 8, drop a<br>dosage unit into each vessel through the corresponding DDM<br>tube. |

Step 8. Continue the dissolution test according to the prescribed method. At the desired time interval, pull samples from each vessel. Two minutes after the final keystroke, the Test in Progress screen displays.



## Baskets

#### Note On the Manual Operation screen, USE STANDARD START HEIGHT displays. To use this setting, continue with the directions indicated below. To switch to the alternate height setting, select USE STANDARD START HEIGHT. USE ALTERNATE START HEIGHT displays. Ensure the alternate drive position is set (see "Setting an Alternate Drive Unit Position" on page 49).

- Step 1. Press RUN. RAISE DRIVE TO INSTALL BASKETS / PRESS RUN TO MOVE / DRIVE TO STANDARD (ALTERNATE) / START POSITION displays.
- Step 2. Press **DRIVE UP** to raise the drive unit to the home position.
- Step 3. Install the baskets containing the dosage units.
- Step 4. Press **RUN**. If using the standard start height, LOWERING DRIVE displays and the drive unit lowers to the operating position. If using the alternate start height, MOVING DRIVE INTO POSITION displays. The drive unit lowers to the previously entered alternate start position.



Page 68 Operation

#### FIGURE 14. Basket / Low-loss Evaporation Cover, Positioning and Sampling



Step 5. The Method Status screen displays and the baskets rotate.



- Step 6. If using an alternate start height, manually press the basket shafts down so the baskets are lowered into the vessel at the desired time intervals.
- Step 7. Continue the dissolution test according to the prescribed method. At the desired time interval, pull samples from each vessel. Two minutes after the final keystroke, the Test in Progress screen displays.



## Paddle Over Disk



- Step 1. Press **RUN**. If paddle spin is disabled, METHOD STARTUP STATUS / MANUAL DISK DROP / PRESS RUN TO CONTINUE displays. If paddle spin is enabled, METHOD STARTUP STATUS / MANUAL DISK DROP / PRESS STOP TO STOP PADDLES / PRESS RUN TO CONTINUE displays.
- Step 2. If paddle spin is enabled, press **STOP**. If paddle spin is disabled, skip this step and continue to step 3.
- Step 3. Pull up the shaft locking ring to lift each paddle out of the medium.
- Step 4. Lift the evaporation cover at vessel position 1, manually drop the disk assembly into the vessel, and push down the paddle shaft.



Step 5. Press **RUN**. The Method Status screen displays and the paddles rotate.



To quit the test from the Method Status screen, press ESC and select EXIT. The Manual Operation screen displays.

Note

| Page 70   | VK 7025 Dissolution Apparatus | Revision G, 01/06 |
|-----------|-------------------------------|-------------------|
| Operation | Operator's Manual             | P/N 70-9033       |
|           |                               |                   |

- Step 6. At the desired time intervals, lift each evaporation cover, manually drop the disk assembly into each vessel and push down the corresponding paddle shaft.
- Step 7. Continue the dissolution test according to the prescribed method. At the desired time interval, pull samples from each vessel. Two minutes after the final keystroke, the Test in Progress screen displays.



## **Rotating Cylinder**

|         | Note   |  |  |
|---------|--|--|--|
|         | When using rotating cylinders, ensure USE STANDARD START<br>HEIGHT displays. If not, select USE ALTERNATE START HEIGHT.<br>USE STANDARD START HEIGHT displays. |  |  |
| Step 1. | Press RUN. RAISE DRIVE TO INSTALL PATCHES / PRESS RUN TO MOVE / DRIVE TO STANDARD / START POSITION displays.   |  |  |
| Step 2. | Press <b>DRIVE UP</b> to raise the drive unit to the home position.  |  |  |
| Step 3. | Install the patches on the rotating cylinders.   |  |  |

Step 4. Press **RUN**. LOWERING DRIVE displays and the drive unit lowers to the operating position. The Method Status screen displays and the cylinders rotate.



Step 5. Continue the dissolution test according to the prescribed method. At the desired time interval, pull samples from each vessel. Two minutes after the final keystroke, the Test in Progress screen displays.

| Note  |
|---|
| For vessel positions 1 - 6, remove the knobbed evaporation plug,<br>pull the sample, and replace the knobbed evaporation plug (see<br>Figure 14, "Basket / Low-loss Evaporation Cover, Positioning and<br>Sampling," on page 68). For vessel positions 7 and 8, place the<br>long cannula (part number 17-3315) into the vessel through the<br>opening in the DDM. See "Setting the Manual Sampling Cannula"<br>on page 38. |
| To quit the test from the Test in Progress screen, press ESC once to return to the Method Status screen and a second time to quit the test.   |

# Setting Delayed Heating

Note

For this option, if you enter a value outside of the acceptable range, an error message displays indicating appropriate values.

By default, the delayed heating option is disabled. To enable delayed heating, complete the following steps:

- Step 1. From the Main Menu, select DELAYED HEATING. The Delayed Heating screen displays.
- Step 2. Enter the desired start date in the appropriate format and press **ENTER**. ENTER TIME HH:MM:SS displays.



Any time and day of the week is acceptable. Pumping functions are not affected by the delay. This feature inhibits the growth of organisms and evaporation by allowing the water bath to be heated only when necessary rather than continuously.

Note

- Step 3. Enter the time in 24-hour format (for example, 3:00 pm is entered as 15:00:00).
- Step 4. Press ENTER. SET POINT 0.0 displays.
- Step 5. Enter the desired temperature in xx.x format. The acceptable range is 20.0 to 55.0 °C. Press ← or CLEAR to clear unwanted or incorrect entries. Press ENTER to accept the temperature setting. TIME TO HEATING START displays with a countdown in hh:mm:ss format.
- Step 6. To stop the delayed heating and reset it to the disabled mode, press **ESC**. The Main Menu displays.
## Start Method

| Note   |
|--|
| Methods are not write-protected. Check with other users before proceeding. |

From the Main Menu, select START METHOD. The Start Method screen displays.

Following is a description of the Start Method screen options:

| Option        | Response  |
|---------------|---|
| Select Method | Use this option to enter a number between 1 and 23 corresponding to the method desired. This is most easily achieved by using List Methods (see below).   |
|               | If a previous method has been selected, the method number displays<br>next to CURRENT and the method name displays next to METHOD. If a<br>different method is required, select SELECT METHOD. The cursor<br>flashes next to CURRENT. |
|               | Enter the method number and press <b>ENTER</b> . The method name displays next to METHOD.   |
|               | If no method exists, see "Creating / Modify Method" on page 84 to create a method.  |
| List Methods  | Use this option to display a list of the methods stored on the VK 7025 in order to select a specific method.  |
|               | To list the currently available methods by number and name, select LIST METHODS. The Select Method to Load screen displays.   |
|               | Scroll up or down the list by selecting NEXT or PREVIOUS.   |
|               | When the correct method is highlighted, select SELECT. The Start<br>Method screen displays with the new method number and name in place.  |
|               | If no method exists, see "Creating / Modify Method" on page 84 to create a method.  |

| Option                 | Response   |  |  |
|------------------------|--|--|--|
| Print Method           | Use this option to print the method parameters.  |  |  |
|                        | To print the information stored under the method number displayed on<br>the Start Method screen, select PRINT METHOD. The printer must be<br>turned on and enabled.  |  |  |
|                        | To enable the Report Center Printer, see "Print Reports" on page 90.   |  |  |
| Lot / Batch Data       | To enter information about the product being tested, select LOT / BATCH DATA. The Lot / Batch Data Menu 1 screen displays. The following options are listed: Product Name, Lot Number, Batch Number, Note, and Menu 2 (which displays Ref. Number and Strength).   |  |  |
|                        | Select the parameter and the cursor flashes on the corresponding line.   |  |  |
|                        | Enter the appropriate information for each item up to 25 characters.<br>Additional notes and comments up to 30 characters can be entered by<br>selecting NOTE. Complete each field using any combination of letters or<br>numbers. To display a letter, hold down the number key until the<br>appropriate letter displays, then release the key. Press <b>ESC</b> to return to<br>the Start Method screen. |  |  |
|                        | When running a method, the text displays on the printout along with the method parameters. In manual operation, the lot / batch data note does not display on the printout.  |  |  |
| Instant Start          | Use this option to begin the test according to the currently selected method. See "Instant Start" on page 75.  |  |  |
| Delay Start            | This option displays only when using paddles with a VK 7025.   |  |  |
| (VK 7025 with Paddles) | Use this option to program the test to begin automatically on a specific date and time. See "Delay Start" on page 82.  |  |  |

| Option   | Response   |
|--|--|
| Vessel Temp<br>Start (VK 7025<br>with Paddles) | This option displays only when using paddles with a VK 7025.   |
|  | You can program the test to begin automatically when the dissolution medium reaches a programmed temperature. See "Vessel Temp Start" on page 83.  |
| Wait External<br>Start                         | The VK 7025 can be used with an external device (for example, the Waters Alliance System). The external start command is supplied as a simple TTL closure through a four-pin DIN cable (supplied separately) connected to the START INPUT port located on the rear panel of the VK 7025. |
|  | Select WAIT EXTERNAL START. WAITING EXTERNAL START displays. The test runs according to the program entered on the VK 7025 once the external start command is received.  |

## **Instant Start**

Depending upon the apparatus listed in the method and the options installed on your tester, complete the steps listed under the appropriate apparatus on the following pages to start the test immediately.

| Apparatus         | Procedures                          |
|-------------------|-------------------------------------|
| Paddles           | See "Paddles" on page 76.           |
| Baskets           | See "Baskets" on page 78.           |
| Paddle over disk  | See "Paddle Over Disk" on page 79.  |
| Rotating cylinder | See "Rotating Cylinder" on page 80. |

### Paddles

### Note



Before starting the test, ensure DDM is enabled or disabled (see "Controlling Dosage Delivery Module (VK 7025 with Paddles only)" on page 87), paddle spin is enabled or disabled (see "Paddle Spin" on page 46) and initial and final temp are enabled or disabled (see "Sample Vessel Temp" on page 88) depending on your configuration.

Step 1. From the Start Method screen, select INSTANT START.

| DDM                                       | Paddle<br>Spin         | Initial<br>Temp | Final<br>Temp          | After selecting INSTANT START, the following information displays:  |
|---|------------------------|-----------------|------------------------|---|
| disabled                                  | enabled or<br>disabled | enabled         | enabled or<br>disabled | METHOD STARTUP STATUS / SAMPLING<br>INITIAL TEMPERATURE / MANUAL TABLET<br>DROP / PRESS STOP TO STOP PADDLES /<br>PRESS RUN TO CONTINUE |
| disabled                                  | enabled                | disabled        | enabled or<br>disabled | METHOD STARTUP STATUS / MANUAL<br>TABLET DROP / PRESS STOP TO STOP<br>PADDLES / PRESS RUN TO CONTINUE                                   |
| disabled                                  | disabled               | disabled        | enabled or<br>disabled | METHOD STARTUP STATUS / MANUAL<br>TABLET DROP / PRESS RUN TO CONTINUE   |
| enabled—<br>simultaneous or<br>sequential | enabled or<br>disabled | enabled         | enabled or<br>disabled | METHOD STARTUP STATUS / SAMPLING<br>INITIAL TEMPERATURE / SIMULTANEOUS<br>(SEQUENTIAL) DELIVERY STARTED                                 |
| enabled—<br>simultaneous or<br>sequential | enabled or<br>disabled | disabled        | enabled or<br>disabled | METHOD STARTUP STATUS /<br>SIMULTANEOUS (SEQUENTIAL) DELIVERY<br>STARTED  |

| Revision G, 01/06 | VK 7025 Dissolution Apparatus | Page 77   |
|-------------------|-------------------------------|-----------|
| P/N 70-9033       | Operator's Manual             | Operation |

Step 2. If DDM is disabled and paddle spin or initial temp is enabled, press **STOP** to drop the dosage unit into non-rotating media. Manually drop a dosage unit into each vessel.



Otherwise, skip this step and continue to step 3.

Step 3. Press **RUN**. The Method Status screen displays and the paddles rotate.



Step 4. Continue the dissolution test according to the prescribed method. Two minutes after either the cannulas return to the home position or the final keystroke, the Test in Progress screen displays.



### Baskets

TE

#### Note

If using baskets, ensure final temp is enabled or disabled. See "Sample Vessel Temp" on page 88.

- Step 1. From the Start Method screen, select INSTANT START. RAISE DRIVE TO INSTALL BASKETS / PRESS RUN TO MOVE / DRIVE TO STANDARD / START POSITION displays.
- Step 2. Press **DRIVE UP** to raise the drive unit to the home position.
- Step 3. Install the baskets containing the dosage units.
- Step 4. If using the low-loss evaporation covers, replace the covers on the vessels. Visually align the DDM tube with the DDM alignment attachment and the cannula assembly with the opening in the evaporation cover.
- Step 5. Press **RUN**. LOWERING DRIVE displays and the drive unit lowers. If using the standard evaporation covers, the drive unit lowers to the operating position. The Method Status screen displays and the baskets rotate.



Step 6. Continue the dissolution test according to the prescribed method. Two minutes after either the cannulas return to the home position or the final keystroke, the Test in Progress screen displays.



### Paddle Over Disk



Step 1. From the Start Method screen, select INSTANT START.

| Paddle Spin | Final Temp          | After selecting INSTANT START, the following information displays:                               |
|-------------|---------------------|--|
| enabled     | disabled or enabled | METHOD STARTUP STATUS / MANUAL DISK DROP / PRESS<br>STOP TO STOP PADDLES / PRESS RUN TO CONTINUE |
| disabled    | disabled or enabled | METHOD STARTUP STATUS / MANUAL DISK DROP / PRESS<br>RUN TO CONTINUE                              |

Step 2. If paddle spin is enabled, press **STOP**. If paddle spin is disabled, skip this step and continue to step 3.

Step 3. Lift each vessel evaporation cover and manually drop the disk assembly into each vessel.



Step 4. Press **RUN**. The Method Status screen displays and the paddles rotate.



Step 5. Continue the dissolution test according to the prescribed method. Two minutes after either the cannulas return to the home position or the final keystroke, the Test in Progress screen displays.

| Note  |
|---|
| To quit the test from the Test in Progress screen, press ESC once to return to the Method Status screen and a second time to quit the test. |

### **Rotating Cylinder**

- Step 1. From the Start Method screen, select INSTANT START. RAISE DRIVE TO INSTALL PATCHES / PRESS RUN TO MOVE / DRIVE TO STANDARD / START POSITION displays.
- Step 2. Press **DRIVE UP** to raise the drive unit to the home position.
- Step 3. Install the patches on the rotating cylinders.

Step 4. Press **RUN**. LOWERING DRIVE displays and the drive unit lowers to the operating position. The Method Status screen displays and the cylinders rotate.



Step 5. Continue the dissolution test according to the prescribed method. Two minutes after either the cannulas return to the home position or the final keystroke, the Test in Progress screen displays.



For the first two minutes of a test, the Method Status screen displays the following information:

- method name
- selected apparatus
- set speed
- set bath temperature
- next timepoint
- elapsed time
- last vessel temperatures

- current time
- current date
- current speed
- current bath temperature
- manual sample (if autosampler is installed)
- (if AutoTemp is installed and enabled in your method)
- user id

After the first two minutes of a test, the Test in Progress screen displays. The Test in Progress screen details the current speed and bath temperature, the time to the next sample point (if applicable), the elapsed time, and the Manual Sample option (if autosampler is installed). Press **ESC** to return to the Method Status screen.

If you press **STOP / PAUSE**, the Method Paused screen displays. The time paused and the current elapsed time display. Select EXIT to stop the current method. ABORTING METHOD STAND BY displays and the screen returns to the Start Method screen. To continue the test, select CONTINUE. The Method Status screen displays.

## **Delay Start**



If you are using paddles, DDMs, and an autosampler, you can program a delayed start based on a specific date and time. If you do not select paddles and DDM in your method, this option is not available. To set the delayed start, complete the following steps:

- Step 1. From the Start Method screen, select DELAY START. The Time Delay Start Setup screen displays the current date and time below the RPM and water bath temperature. If temp display is enabled (see "Temp Display" on page 46), the vessel temperatures / cannula positions display as well.
- Step 2. The cursor flashes under ENTER DATE. Enter the date in the appropriate format and press **ENTER**. ENTER TIME displays.
- Step 3. Enter the time in 24-hour format (for example, 3:00 pm is entered as 15:00:00) and press **ENTER**. The Time Delay Start Status screen displays the time until the test starts. Once the test begins, the Method Status screen displays (see page 81).



### **Vessel Temp Start**

| Note  |
|---|
| For this option, if you enter a value outside of the acceptable range, an error message displays indicating appropriate values. |

If you are using paddles, DDMs, and an autosampler, you can program the instrument to start based on the dissolution medium reaching a specific temperature. To set the temperature start, complete the following steps:

- Step 1. From the Start Method screen, select VESSEL TEMP START. VESSEL TEMPERATURE START / BATH TEMP WILL BE ADJUSTED TO CONTROL VESSEL TEMP / INPUT VESSEL START TEMP displays on the screen and the cursor flashes.
- Step 2. Enter a temperature and press **ENTER**. The acceptable range is 20.0 to 55.0 °C.
- Step 3. The shafts rotate at 15 RPM and the cannulas lower. The following screen displays:

|        | VESSEL TEMP                 | START STATUS                 |        |
|--------|-----------------------------|------------------------------|--------|
| E      | BATH TEMP WIL<br>TO CONTROL | L BE ADJUSTED<br>VESSEL TEMP | )      |
|        | WAITING FOR<br>STABILIZ     | VESSELS TO<br>E AT 37.0      |        |
|        | TIME SINCE HE<br>00H:01     | EATING START<br>M:00S        |        |
| RPM    | 015.0                       | BATH                         | 037.2  |
| 1:37.1 | 2:36.9                      | 3:37.1                       | 4:37.0 |
| 5:37.0 | 6:36.9                      | 7:36.9                       | 8:37.1 |
|        | FRI MAY 23 1                | 15:23:04 2003                |        |

Step 4. To stop the heating process, press and hold **ESC** until the screen goes blank. The cannulas return to the home position and the Start Method screen displays.

# **Method Editor**

From the Main Menu, select METHOD EDITOR. The Method Menu screen displays. You can view the method, but only those with appropriate security levels can change information in this section. The Method Menu screen displays the following options: Modify Method (see "Creating / Modify Method" below), Copy Method (see "Copying Methods" on page 89) and Store Method (see "Storing Methods" on page 90).

## **Creating / Modify Method**

To create a new method or modify an existing method, complete the following steps:

- Step 1. From the Method Menu screen, select MODIFY METHOD to display the Select Method Location to Modify screen.
- Step 2. Scroll up or down the list by selecting NEXT or PREVIOUS until the correct method number is highlighted.
- Step 3. Select SELECT. If no method exists, scroll through the list until the desired method location is highlighted and select SELECT. The Method Menu 1 screen displays.

Following is a description of the Method Menu 1 screen options:

| Option                        | Response   |
|-------------------------------|--|
| Method                        | Select METHOD to name the method. The cursor flashes. Enter the desired name and press <b>ENTER</b> . The method name displays.      |
| Apparatus                     | Select APPARATUS to change the apparatus being used for the test.<br>See "Apparatus" on page 61.                                     |
| RPM Set                       | Select RPM SET to set the speed in rotations per minute. See "RPM Set" on page 61.   |
| Bath Temperature<br>Set Point | Select BATH TEMPERATURE SET POINT to set the water bath temperature in degrees Celsius. See "Bath Temperature Set Point" on page 61. |

| Option                      | Response  |
|-----------------------------|---|
| Sampling Setup              | Use this option to enable or disable autosampling and set cannula down time, AutoTemp, volume, sample points, and sample point alarms. See "Sampling Setup" below.  |
| DDM Disabled (if installed) | This option indicates the status of the dosage delivery module. DDM is disabled by default. See "Controlling Dosage Delivery Module (VK 7025 with Paddles only)" on page 87 to enable the DDM.  |
| Test Length                 | Select TEST LENGTH to set the desired test length. The cursor flashes. Enter the desired test length in hhh:mm:ss format and press <b>ENTER</b> . The maximum acceptable input is 999:59:59. Press $\leftarrow$ to clear incorrect or unwanted entries. |
| Menu 2                      | After the appropriate parameters have been entered on Method Menu<br>1, select MENU 2. The Method Menu 2 displays. See page 88 for<br>information on Method Menu 2.   |

### Sampling Setup

To set the sample timepoints, select SAMPLING SETUP from the Method Menu 1 screen. The Sampling Setup screen displays.

Following is a description of the Sampling Setup screen options:

| Option                     | Response   |
|----------------------------|--|
| Auto Sampling              | Select AUTO SAMPLING to toggle between ENABLED and DISABLED.   |
|                            | If an autosampler is installed, ensure ENABLED displays next to the option. If DISABLED displays on the screen, select DISABLED to enable this option.   |
|                            | Once autosampling is enabled, you are prompted to enter the cannula downtime. See Set Cannula Down Time and AutoTemp below.  |
| Set Cannula<br>Down Time   | Select SET CANNULA DOWN TIME to enter the amount of time the cannula remains in the vessel. The cursor flashes. Enter a time in mm:ss format and press <b>ENTER</b> . The minimum acceptable time is one minute. |
| AutoTemp<br>(if installed) | Select AUTOTEMP to toggle between ENABLED and DISABLED.<br>AutoTemp must be enabled to measure vessel temperatures.  |

| Option            | Response   |
|-------------------|--|
| Volume            | Select VOLUME to enter the media volume. The cursor flashes. Enter a volume and press <b>ENTER</b> . The acceptable range is 500 to 1050 mL.   |
| Sample Points     | Select SAMPLE POINTS to toggle between ENABLED and DISABLED. If enabled, SET SAMPLE POINTS and SAMPLE POINT ALARM ENABLED / DISABLED display. See below.   |
| Set Sample Points | To set the sample timepoints, see "Setting Sample Points" below.   |
| Sample Point      | The sample point alarm is disabled by default.   |
| Alarm             | To enable the sample point alarm, select SAMPLE POINT ALARM<br>DISABLED from the Sampling Setup screen. SAMPLE POINT ALARM<br>ENABLED and TIME MM:SS display. Enter the time interval prior to the<br>sample point for the alarm to sound and press <b>ENTER</b> . Press <b>CLEAR</b><br>to silence the alarm. |

### Setting Sample Points

- Step 1. Select SET SAMPLE POINTS. The Sample Points screen displays a list of timepoints 01 through 24. The cursor flashes next to timepoint 01.
- Step 2. Enter the timepoint in hhh:mm:ss format and press ENTER to move to the next timepoint location. Press ← to clear unwanted or incorrect entries one character at a time. Press CLEAR or 0 > ENTER to delete the current timepoint or any unwanted timepoints.



Step 3. Select PREVIOUS or NEXT to scroll up or down the timepoints.

Step 4. Enter the desired timepoints and press **ESC** to return to the Sampling Setup screen.

When all appropriate parameters have been entered on the Sampling Setup screen, press **ESC** to return to the Method Menu 1 screen.

### Controlling Dosage Delivery Module (VK 7025 with Paddles only)



DDM can only be enabled if this option is installed on your tester and paddles are selected as the apparatus. Sequential DDM is an option only if clutches are installed.

To enable the dosage delivery module, complete the following steps:

- Step 1. Select DDM DISABLED from the Method Menu 1 screen. The DDM Setup Menu screen displays.
- Step 2. Select DOSAGE DELIVERY DISABLED. DOSAGE DELIVERY ENABLED and DOSAGE DELIVERY METHOD SIMULTANEOUS display.
- Step 3. To change to sequential, select DOSAGE DELIVERY METHOD SIMULTANEOUS. DOSAGE DELIVERY METHOD SEQUENTIAL and DELIVERY INCREMENT display. If clutches are not installed, the paddles rotate during a sequential dosage delivery. If clutches are installed, the paddle stops for approximately three seconds as the corresponding DDM opens.
- Step 4. Select DELIVERY INCREMENT. The cursor flashes.

- Step 5. Enter a delivery increment time in mm:ss format and press **ENTER**. The maximum acceptable value is 59:59.
- Step 6. Press **ESC** to return to the Method Menu 1 screen.

When all the appropriate parameters have been entered on the Method Menu 1 screen, select MENU 2. The Method Menu 2 screen displays.

Following is a description of the Method Menu 2 screen options:

| Option             | Response  |
|--------------------|---|
| Final Spin RPM     | To program a final spin, select FINAL SPIN RPM. The cursor flashes. Enter the desired speed in xxx format. The acceptable range is 10 to 250 RPM. Press <b>ENTER</b> . Press $\leftarrow$ to clear unwanted or incorrect entries. |
| Final Spin Time    | Select FINAL SPIN TIME to set the final spin time. The cursor flashes. Enter the desired spin time in hhh:mm:ss format and press <b>ENTER</b> . The maximum allowable time is 999:59:59.  |
| Sample Vessel Temp | This option is only available if AutoTemp is enabled.   |
|                    | To read the initial vessel temperature, select INITIAL to toggle between ENABLED or DISABLED.   |
|                    | Note: initial vessel temperature is only available if the apparatus selected is paddles.  |
|                    | To read the final vessel temperature, select FINAL to toggle between ENABLED or DISABLED.   |
| Alarm Point        | Select ALARM POINT to set an alarm to sound during the test.<br>Enter the desired alarm time in hhh:mm:ss format and press<br>ENTER.  |

When all appropriate parameters have been entered on the Method Menu 2 screen, press **ESC** twice to return to the Method Menu screen. Select STORE METHOD to save the previously entered information (see "Storing Methods" on page 90). If you do not

select STORE METHOD and press **ESC** to go back further in the system, the following screen displays:

|          | USER: xxxxx                                  |        |
|----------|--|--------|
| С        | HANGES HAVE NOT BEEN STORED                  |        |
|          | PRESS CONTINUE TO CONTINUE<br>WITHOUT SAVING |        |
|          | OR RETURN TO RETURN<br>TO EDITOR             |        |
| CONTINUE |  | RETURN |

Select CONTINUE to disregard the changes and return to the Main Menu.

Select RETURN to display the Method Menu 1 screen and the current changes. The changes have not been saved. To save the changes, see "Storing Methods" on page 90.

## **Copying Methods**

To copy an existing method, complete the following steps:

| Step 1. | From the Method Menu screen, select COPY METHOD. The Select Method Location to Copy From screen displays.              |
|---------|--|
| Step 2. | Select the method location to copy from by selecting PREVIOUS and NEXT until the desired method number is highlighted. |
| Step 3. | Select SELECT. The Select Method Location to Copy To screen displays.  |
| Step 4. | Select the location to copy to by selecting PREVIOUS and NEXT until the desired method location is highlighted.        |
| Step 5. | Select SELECT. The Method List screen displays with the copied method listed.  |
| Step 6. | Press ESC to return to the Method Menu screen.   |

Step 7. Press **ESC** again to return to the Main Menu.

## Storing Methods

To save a new or modified method, complete the following steps:

- Step 1. From the Method Menu screen, select STORE METHOD to save the information. The Select Method Location to Store At screen displays.
- Step 2. Scroll up or down the list by selecting NEXT or PREVIOUS until the desired method location is highlighted.
- Step 3. Select SELECT. The Method List screen displays with the stored method listed.
- Step 4. Press **ESC** to return to the Method Menu screen or press **MENU** to return to the Main Menu.

### **Print Reports**

To print information to the Report Center Printer, select PRINT REPORTS from the Main Menu. The Print Reports screen displays.

| PRINT REPORTS     |              |
|-------------------|--------------|
| PRINT             | PRINT SERIAL |
| METHOD:           | NUMBERS      |
| PRINT             |              |
| PREVIOUS RESULTS: |              |
| REPORT PRINTER    |              |
| OFF               |              |
| PRINT FREQUENCY   |              |
| 00:00:00          |              |

Following is a description of the Print Reports screen options:



**Note** In order to operate any of the printer functions listed, the printer must be enabled. See "Report Printer On / Off" below.

| Option                     | Response   |
|----------------------------|--|
| Print Method               | Select PRINT METHOD to print method parameters.  |
|                            | Enter a method number and press ENTER.   |
| Print Previous<br>Results  | Select PRINT PREVIOUS RESULTS to print the results from the last test run.   |
|                            | The printer buffer is 8K. If you exceed the storage capacity, a complete copy of the previous results will not print. The printer buffer resets to 0 whenever a new test is started.   |
| Report Printer<br>On / Off | Select REPORT PRINTER to toggle between ON and OFF. Once this option is set, the selection becomes the default.  |
|                            | In order to use the Report Center Printer, this option must be set to ON.  |
| Print Frequency            | Select PRINT FREQUENCY to enter the time interval the current program information should be sent to the Report Center Printer in hh:mm:ss format. Do not enter 00:00:00 to turn off the printer function. See "Report Printer On / Off" above. |
| Print Serial<br>Numbers    | Select PRINT SERIAL NUMBERS to print the serial numbers of the vessels, paddles, baskets and shafts, and rotating cylinders entered under the System Setup Menu 2 screen (see "Setting Serial Numbers" on page 57).                            |

| Page 92   |
|-----------|
| Operation |

This page was intentionally left blank, except for this message.

# Chapter 6 Fiber Optics

# Installing Fiber Optics

To install and set the height for the fiber optic assemblies, complete the following steps:

- Step 1. Log into the VK 7025 as an administrator.
- Step 2. Clip the ferrule onto the fiber optic probe (see Figure 15, "Fiber Optic Assembly," below).

FIGURE 15. Fiber Optic Assembly



- Step 3. Insert the fiber optic probe into the PEEK assembly housing.
- Step 4. Ensure the ferrule is positioned so once inside the assembly housing, the window is oriented away from the set screws.
- Step 5. Ensure the upper locking clip is in place near the top of the thermistor and insert the thermistor into the PEEK assembly housing (see Figure 16, "Fiber Optic Assembly Setting," below).
- Step 6. Slide both the fiber optic probe and thermistor through the assembly housing so the top of the thermistor is 1.5 inches from the assembly housing and the top of the fiber optic probe is 4.4 inches from the top of the assembly housing (see Figure 16, "Fiber Optic Assembly Setting," below).

### FIGURE 16. Fiber Optic Assembly Setting



| Step 7. | Tighten the two set screws to lock the fiber optic probe in place (see |
|---------|--|
|         | Figure 16, "Fiber Optic Assembly Setting," on page 94).                |

- Step 8. Ensure the locking clip is in place against the assembly housing.
- Step 9. Ensure the drive unit is in the lowest position.
- Step 10. Place the fiber optic assembly into the opening in the top of the drive unit corresponding to vessel position 1.
- Step 11. Use the alignment pin and coordinating notch to guide the assembly through the opening in the top cover leaving approximately 1/4 inch of the PEEK assembly housing exposed.
- Step 12. Repeat steps 2 11 for all remaining vessel positions.
- Step 13. From the System Setup Menu 1 screen, select CALIBRATION > CANNULA HEIGHT CALIBRATION. The Set Sampling Depth screen displays with factory-set values for each apparatus. If you are using paddle over disk or rotating cylinder, select MENU 2 to view these apparatus.

| SET SAMPLING DEPTH     |              |
|------------------------|--------------|
| BASKET 900 mL<br>200   | MOVE<br>UP   |
| BASKET 500 mL<br>400   | MOVE<br>DOWN |
| PADDLE 900 mL<br>200   |              |
| PADDLE 500 mL<br>400   | MENU 2       |
| CANNULA POSITION = $0$ |              |



The factory-set number displayed under each option is not a distance measurement. It refers to the number of steps the cannula motor moves.

Note

Page 96 Fiber Optics

- Step 14. To ensure the fiber optic probes are in their home position, select MOVE DOWN to move the fiber optic probes to their lowest position, then select MOVE UP to move the fiber optic probes to their highest position.
- Step 15. Select MOVE UP or MOVE DOWN to position the fiber optic windows at the appropriate height in the vessels. See Figure 17, "Fiber Optic Probe in Vessel," on page 96.

### FIGURE 17. Fiber Optic Probe in Vessel



- Step 16. When the fiber optic windows are in the correct position, select the appropriate apparatus and volume. The number of steps the cannula motor moved to reach that position displays under the selected apparatus and volume.
- Step 17. Press **ESC**. The fiber optic probes return to the home position and the Calibration Menu screen displays.
- Step 18. Press **ESC** again to return to the System Setup Menu 1 screen.

# Chapter 7

# Maintenance and Troubleshooting

# 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 99, "Basket Care" on page 100, and "Water Bath / Acrylic Care" on page 101 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 99, "Basket Care" on page 100, and "Water Bath / Acrylic Care" on page 101 as applicable for additional information on proper maintenance of your equipment.

 Inspect the water bath and 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 99, "Basket Care" on page 100, and "Water Bath / Acrylic Care" on page 101 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.



# 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





### Caution

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

The water bath supplied with the VK 7025 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 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
  - Household ammonia
  - 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.

# Removing the Top Cover

| STO     | Caution<br>Panels or covers that are retained by fasteners which require<br>the use of a tool for removal may be opened only by<br>Varian-trained, Varian-qualified, or Varian-authorized service<br>engineers. |
|---------|---|
| Step 1. | Turn on the dissolution apparatus.  |
| Step 2. | Lower the drive unit to the lowest position.  |
| Step 3. | Turn off the dissolution apparatus and remove the power cord.   |
| Step 4. | Remove the two screws in the top cover located just behind the display screen.  |
| Step 5. | Lift the top cover from the front of the machine. It hinges back to allow access to the machinery.  |

## Replacing the Top Cover

- Step 1. Pull down the front end of the top cover and rest it in place.
- Step 2. Replace the two screws in the cover behind the display screen.
- Step 3. Reconnect the power cord and turn on the instrument.

# **Cleaning the Cannulas**

Step 1. Turn off the dissolution apparatus.

| Step 2. | Remove the cannulas from the dissolution apparatus by pulling up the |
|---------|--|
|         | entire cannula assembly housing which contains the cannulas and, if  |
|         | applicable, the thermistor.  |

- Step 3. Disconnect the cannulas from the sample tubing.
- Step 4. Remove the sample cannulas from the cannula assembly and clean using an appropriate cleaning solution.
- Step 5. Wipe any surface discoloration from the cannula assembly housings with a clean, damp cloth.
- Step 6. Carefully place the sample cannulas back into the cannula assemblies.
- Step 7. Reconnect the sample tubing.
- Step 8. Use the guide pin and coordinating notch to position the cannula assembly housing and reinsert it into the top cover of the dissolution apparatus. Push the cannula down until it engages with the gears in the motor housing.
- Step 9. Turn on the dissolution apparatus. The cannulas return to the home position.

# Cleaning the Cannulas Using the VK 8000 Clean System Function

- Step 1. Ensure the VK 7020 S / 7025 is connected correctly to the VK 8000 and that external control is enabled. See "External Control" on page 56.
- Step 2. Ensure the drive unit is raised to the home position.
- Step 3. Ensure the baskets or paddles are out of the way of the cleaning solution containers by pushing them up against the spindle housings.

Step 4. Position the cannula cleaning tray on the vessel plate so the cannulas are centered above the containers.

#### FIGURE 18. Cannula Cleaning Tray



- Step 5. From the Manual Operation screen, set the volume to 500 mL.
- Step 6. Select MANUAL SAMPLE. The Manual Sampling screen displays.
- Step 7. From the Manual Sampling screen, select DOWN corresponding to SELECT ALL.
- Step 8. Lower the drive unit by pressing **DRIVE DOWN** until the tips of the sample cannulas are below the surface of the cleaning solution.
- Step 9. Log off the dissolution apparatus.
- Step 10. Press **CLEAN SYSTEM** on the VK 8000. The cleaning process begins immediately.
- Step 11. When the cleaning process is complete, press **DRIVE UP** to raise the drive unit to the home position.
- Step 12. Remove the cannula cleaning tray from the vessel plate. Use a clean, soft cloth to dry the exterior surfaces of the cannulas.

# **Replacing the Flanges**

The tester is supplied with specially designed vessels and magnetic ring flanges. The magnetic ring flanges will keep the vessels centered at all times, without the use of tools, and prevent the vessels from "floating" even when they are empty.



| Note   |
|--|
| There are two flanges—an upper ring flange and a lower ring flange. The lower ring flange is thicker and contains the magnets which secure the vessel to the vessel plate. |

#### FIGURE 19. TruCenter Vessel—exploded view



|         | Note Do not overtighten the tangential screw or damage to the vessel  |
|---------|---|
| Step 5. | Tighten the tangential screw on the ring flange.  |
| Step 4. | Slide the ring flanges onto the new vessel so they rest in the groove in the vessel.  |
| Step 3. | Align the upper and lower ring flanges so they nestle together and do not slide.  |
| Step 2. | To slide the upper and lower ring flanges off the old vessel, gently pull out and up until they clear the groove in the vessel. |

```
Report Center Impact Printer
```

The following is helpful information for using your impact printer.

could occur.

## 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 111 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<br>should be performed only if the printer displays erroneous<br>characters. Contact the Dissolution Systems Service<br>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.

### 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 Variantrained, Varian-qualified, or Varian-authorized service engineers.

The fuse is located in the power entry module on the rear of the heater / circulator.

- Step 1. Before checking or attempting to replace a fuse, remove the power cord from the heater / circulator.
- Step 2. There is a release slot on the bottom of the fuse compartment. The fuse compartment holder is released by inserting a small screw driver beneath the slot.
- Step 3. A slight application of pressure upward releases the compartment.
- Step 4. Pull the fuse compartment holder out of the power entry module. The fuse and a spare are located inside. The fuse is a 10 amp metric (5 x 20 mm) fuse for 115 V and 5 amp metric (5 x 20 mm) fuse for 230 V.
- Step 5. Replace the fuse in the compartment.



Step 6. Push the fuse compartment 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:

| Problem  | Suggested Solution   |
|--|--|
| The display screen freezes.                            | Press <b>STOP / PAUSE</b> and <b>ENTER</b> at the same time to restart the system. |
| All administrative passwords are forgotten or deleted. | Contact the Dissolution Systems Service Department.                                |

Following is a list of error messages that may display on your screen and the suggested solution:

| Error Message   | Suggested Solution   |  |
|---|--|--|
| Spindle board error:<br>RPM NOT AT SETPOINT                                   | Ensure nothing is blocking the paddle or basket preventing it from rotating.               |  |
| Temperature board error:<br>HEATER SENSOR EXCEEDS BATH<br>SENSOR BY 5 DEGREES | Check bath water level. Ensure the heater / circulator is primed and water is flowing.     |  |
| Temperature board error:<br>HEATER TEMP RISE EXCEEDS<br>0.284 DEGREES PER SEC | Check bath water level. Ensure the heater / circulator is primed and water is flowing.     |  |
| Temperature board error:<br>HEATER SENSOR OPEN                                | Ensure the cable from the heater / circulator to the back of the VK 7025 is connected.     |  |
| Temperature board error:<br>BATH SENSOR OPEN                                  | Ensure the bath temperature probe is plugged into the back of the VK 7025.                 |  |
| Temperature board error:<br>HEATER SENSOR OVER 70                             | Check the bath water level. Ensure the heater / circulator is primed and water is flowing. |  |

Revision G, 01/06 P/N 70-9033

If any of the listed problems persist, contact the Dissolution Systems Service Department. 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. This page was intentionally left blank, except for this message.

### Chapter 8

# 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.

This page was intentionally left blank, except for this message.

# Index

#### а

acrylic care 101 administration screen 47 administrative control 40 administrator operation 45 apparatus, selecting 61

#### b

basket care 100 basket height, setting 30 basket shaft care 99 basket shaft installation 30 bath vessel difference 48

#### С

calibration calendar 53 calibration menu screen 48 cannula height calibration 50 cartridge ribbon 107 centering vessels 28 cleaning the cannulas 103 clear key 18 clock functions screen 56 comm. port functions 56 conventions 17 copying methods 89

#### d

delay start 74, 82 delayed heating, setting 72 deleting user ids 42 diagnostic menu 54 drive down key 18 drive up key 18

#### е

enter key 18 esc key 18 exclusions 118 exclusive remedies 119

#### f

fiber optic assembly 94 fiber optics, installation 93 filling the water bath 27 final sample vessel temp 88 final spin rpm 88 fuse replacement 113

#### h

hazards 9

#### i

initial sample vessel temp 88 installing fiber optics 93 installing paddle / basket shafts 28 installing the printer cartridge ribbon 107 installing vessels 28 instant start 75 introduction 15

#### k

key guide 18

#### 

leaking fittings, repairing 102 limitations 118 list methods 73 lot / batch data 74

#### m

main menu 59 maintenance 97 manual operation 60 manual operation screen 60 manual sampling screen 63 menu key 18 method editor 84 method menu 1 screen 84 method menu 2 screen 88 method status screen 81 modify method 84 monthly maintenance 98

#### 0

obtaining warranty service 118 operation 59

#### р

paddle care 99 paddle height, setting 29 paddle installation 29 print method 74 print reports 90 printer configuration 111 self test 110 toggling online 110

#### r

reader comment form 125 repairing leaking fittings 102 rpm set 61 run key 18

#### S

safety practices 9 sample point alarm, setting 62 sampling setup 85 sampling temperatures 63 screen saver 18 security levels 40 select method 73 selecting apparatus 61 self test, printer 110 service 117 setting alarms 52 setting alternate drive unit position 49 setting basket height 30 setting comm. port functions 56 setting delayed heating 72 setting paddle height 29 setting sample points 62, 86 setting serial numbers 57 setting speed 61 setting up the heater / circulator 25 setting up the vk 7025 22 setting up the water bath 25 setting volume 61,86 setup 19 start method screen 73 starting a test 64 stop / pause key 18 store methods 90 system setup menu 1 screen 46 system setup menu 2 screen 55

#### t

temp set 61 temperature start 75, 83 top cover 103

#### u

unpacking your vk 7025 19 user list 41 user settings 45 using the vk 8000 clean system function 104

#### V

vessel installation 28, 106 vessel plate layout 43 vessel temperature start 83 volume, setting 61, 86

#### W

warranty 117 warranty limitations 118 water bath care 101 weekly maintenance 98 This page was intentionally left blank, except for this message.



# 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 1.919.677.1550. Always, feel free to telephone us to discuss your comments at 1.800.229.1108.