

Agilent BIO-DIS Apparatus 3 / 7

Operator's Manual



Notices

Manual Part Number

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Safety Notices

CAUTION

A **CAUTION** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in damage to the product or loss of important data. Do not proceed beyond a **CAUTION** notice until the indicated conditions are fully understood and met.

WARNING

A WARNING notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in personal injury or death. Do not proceed beyond a WARNING notice until the indicated conditions are fully understood and met.

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1 Safety

Electrical Hazards 5

The Apparatus 3 / 7 has been designed and tested 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 an Apparatus 3 / 7 involves the use of solid dosage forms and aqueous liquids. Unskilled, improper, or careless use of this instrument can create shock hazards, fire hazards, or other hazards which can cause death, serious injury to personnel, or severe damage to equipment and property.

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

Observe all relevant safety practices at all times.

Safety

1

Electrical Hazards

The Apparatus 3 / 7 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 Agilent-trained, Agilent-qualified, or Agilent-authorized service engineers. Consult the manuals or product labels supplied with the 8020 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.

Warning

WARNING

A 'Warning' message appears in the manual when failure to observe instructions or precautions could result in death or injury.

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

Caution

CAUTION

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

Note

NOTE

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

6

Information Symbols

Switches main power on

Switches main power off



Indicates single-phase alternating current



The apparatus is marked with this symbol when the user shall refer to the instruction manual in order to protect risk of harm to the operator and to protect the apparatus against damage.



Confirms that a manufactured product complies with all applicable European Community directives. The European Declaration of Conformity is available at:



http://regulations.corporate.agilent.com/DoC/search.htm

Confirms that a manufactured product complies with all applicable UK Regulation.



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Indicates specific equipment meets standards of safety. These products are safe for use in the workplace for North America.



This product complies with the European WEEE Directive marking requirements. The affixed label indicates that you must not discard this electrical/electronic product in domestic household waste.

NOTE

Do not dispose of in domestic household waste!

To return unwanted products, contact your local Agilent office, or see http://www.agilent.com for more information.



Indicates the product complies with regulatory compliance requirements of New Zealand and Australia.

ISM1-A

ISM classification according to CISPR11/EN55011: ISM Group 1 Class A

CAN ICES-001(A) NMB-001(A)

This ISM device complies with Canadian ICES-001. Cet appareil ISM est conforme à la norme NMB-001 du Canada

2 Introduction

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Introduction

The patented Apparatus 3 / 7 is ideal for extended-release products or any dosage form requiring release profiling at multiple pH levels. Capable of running unattended for periods of up to six days, the unit can store up to 15 programs and allows almost any aspect of a test to be programmed including dip speed, time in each row, hold dip time, and drain time. The seven test samples traverse the six rows of corresponding outer media tubes filled with different media. The Apparatus 3 / 7 transports each sample from one medium to the next, automatically, without operator intervention. Virtually any solid dosage form can be accommodated including pellets, tablets, and capsules.

Custom Apparatus 3 / 7 are available. Depending on the Apparatus 3 configuration, media volume of the outer media tube can vary from 100 mL, 300 mL (USP), or 1000 mL. This manual covers the operation of the standard 7-tube, 6-row systems as well as the modified 12-tube, 12-row Apparatus 7 system (see Figure 1, "Standard 6-row Apparatus," and **Figure 2**, "Apparatus 7, Modified 12 x 12," on page 10).



Figure 1. Standard 6-row Apparatus



Figure 2. Apparatus 7, Modified 12 x 12

A built-in Report Center Printer provides hard-copy documentation of testing progress and conditions. A four-line digital display provides constantly updated operation information as a test proceeds.

The temperature is maintained by the heater / circulator. All parameters are controlled via the Apparatus 3 / 7 keypad. Automated sampling can be performed using the 8000. This unit can be pre-programmed to withdraw samples at designated time points. Samples can be collected into either test tubes or pre-capped HPLC vials for direct transfer to an HPLC system. Septa are pierced using the exclusive needle manifold, which lowers and raises at each sample time point. Sample trays are available in a variety of sizes to accommodate almost any size vial or test tube.

CAUTION

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

There are various types of Apparatus 7 sample holders. Reciprocating disks with O-rings (see **Figure 3**, "Reciprocating Disk," on page 11) hold the transdermal systems in place as they move through the medium. The 12-row system uses

custom sample holders. The inverted basket is a modified version of the Japanese sinker basket and can be used with many types of solid dosage forms.



Figure 3. Reciprocating Disk

NOTE

The sample holders used with the standard 6-row system cannot be used with the 12-row system.



The 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.

Conventions Used in this Manual

- Items you are asked to press are in bold. For example, "press **H** on the keypad".
- Key sequences you are asked to press appear like this: **MENU** > **0** > **8**.

Serial Number Format

The serial number contains 10 characters and follows this syntax:

CC1234xxxx

Syntax Code	Meaning	Description
CC	Country of origin	$2\mbox{alpha}$ characters matching the required trade designation for the country of origin
12	Year of manufacture	'09' for 2009, '10' for 2010, etc.
34	Week of manufacture	'01' for week 1 to '52' for week 52

USP Suitability Test

Before the first use of an Apparatus 3, run an apparatus suitability test with USP Chlorpheniramine Maleate extended-release calibrator tablets. Calibrator tablets are available from the USP at the following address:

USP 12601 Twinbrook Parkway Rockville, MD 20852 (301) 881-0666 or (800) 227-8772

Complete instructions come with the calibrators. Apparatus suitability tests can be very sensitive to factors such as shaft misalignment, vessel shape, vibration of the system, age of the calibrators, reference standards, and many other factors. Contact the Dissolution Systems Service Department if you have any questions regarding these procedures.

NOTE

There is no USP apparatus suitability test for the Apparatus 7.

USP Physical Parameters

In addition to the apparatus suitability test, you must monitor several physical parameters, such as stroke distance, dip speed, and temperature. A Certificate of Compliance is included with your Apparatus 3 / 7. Contact the Laboratory Services Department for more information on USP physical parameters.

3 Setting Up the Apparatus 3 / 7

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Unpacking Your Equipment

Complete the following steps to safely unpack your apparatus and accessories:

- 1 Open each carton carefully and check the contents for any damages which may have occurred during 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 are filed with the carrier, we can help you file a claim and get up and running as quickly as possible.
- **2** Carefully remove the Apparatus 3 / 7 from its shipping carton.

WARNING

The Apparatus 3 / 7 is heavy and the track on the left side is sharp. Do not lift it alone. Also, do not lift the instrument by the drive unit. Lift by holding the water bath frame.

- 3 Remove all cushioning material and tape.
- **4** Place the instrument on a clean, dry, level section of bench top with the drive unit front panel facing you.
- 5 Place the heater / circulator next to the unit.

WARNING

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

Environmental Requirements for Installation

- Humidity: max relative humidity 80% for temperatures up to 31 °C decreasing linearly to 50% relative humidity at 40°C
- Indoor use only
- Pollution Degree: 2
- Installation Category: II
- Altitude: 2000 m
- Temperature: 5 °C to 40°C
- Power: 115/230 V ac, 50/60 Hz, 2 A

Main supply voltage fluctuations are not to exceed \pm 10% of the nominal supply voltage

Setting up the Apparatus 3 / 7



Figure 4. Power inlet module without fuse drawer, at the rear of the device.

- 1 Level the Apparatus 3 / 7 by placing the circular level on the appropriate vessel carrier. Check for level in the front and rear center and the left and right sides. Turn the adjustable rubber feet on the bottom of the water bath frame until the bubble in the level is in the center circle at all four check points.
- 2 Ensure the power switch on the rear panel is in the OFF position.

3 Ensure the fuse drawer is oriented for the appropriate voltage. The fuse drawer shows two voltage ranges with a corresponding white arrow to the left. When the fuse drawer is inserted, one of these arrows will line up to the white rectangle on the machine indicating which voltage range the machine should be plugged into. If the voltage is incorrect, remove the fuse drawer, rotate it 180°, and reinsert.



Figure 5. Power inlet module with fuse drawer in 120 V position.



Figure 6. Power inlet module with fuse drawer in 230 V position..

- **4** Connect the power cord to the power receptacle on the Apparatus 3 / 7 rear panel.
- 5 Plug the power cord into an electrical outlet of the appropriate voltage. Ensure the Apparatus 3 / 7 is configured for the voltage available in your laboratory.

WARNING

Installation and Routing of Cannula Tubing

WARNING

Entrapment Risk

Do not attempt to perform maintenance activities or adjustments to the cannula tubing kit during machine operation.

 Disconnect instrument from power, before performing any tubing maintenance activities.

Installation of Cannula Tubing

1 Cannulas should be inserted into the evaporation cover, ensuring the sample and return lines are routed toward the rear of the instrument. Ensure that the air holes toward the center of the covers are left open.

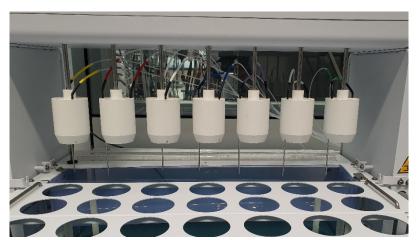


Figure 7. Front View of Bio-Dis - Showing Cannula routing toward the rear of the instruments

2 Once all cannulas have been routed into the evaporation covers, route the tubing toward the rear of the instrument, using the self-adhesive tie holders, cable tie the bundled tubing to the rear of the head unit on the arm nearest to the sampler.



Figure 8. Rear View of the Bio-Dis with Self Adhesive Pad and Cable-Tie Applied

NOTE

Overtightening the cable tie, may result in damage to the cannula tubing, during instrument operation.

• Allow sufficient maneuverability in the cannula tubing to account for movement of the head during instrument operation.

Installing the Heater / Circulator

The Apparatus 3 / 7 uses a single water bath connected directly to the inlet and outlet of the heater / circulator. Complete the following steps to install the heater / circulator:

1 Locate the heater / circulator tubing kit containing two lengths of 1/2-inch plastic tubing (one long, one short) and four tubing clamps.

NOTE

These instructions assume the heater / circulator is placed to the right of the Apparatus 3 / 7 when looking at the front of the equipment. If your heater / circulator is placed to the left of the Apparatus 3 / Apparatus 7, use the longer tubing when the instructions call for the shorter tubing and the shorter tubing when the instructions call for the longer tubing.

- 2 Locate the tubing clamps in the tubing kit. Place a clamp over one end of the shorter of the two lengths of tubing supplied. Carefully place this end of the tubing over the connector labeled IN on the heater / circulator. Slide the tubing on until it meets the panel.
- **3** Slide the tubing clamp over the connector and tighten securely.

CAUTION

Do not overtighten the clamp as damage may occur.

- **4** Place a tubing clamp over the opposite end of the same piece of tubing. Attach the tubing to the open end of the Y connector coming from the barbed-angle tubing adapter on the right side of the water bath (see Figure 9, "Tubing Connection," below).
- 5 Slide the tubing clamp over the connector and tighten securely.

CAUTION

Do not overtighten the clamp as damage may occur.

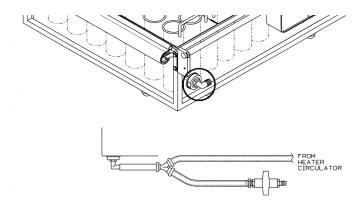


Figure 9. Tubing Connection

- 6 Connect the water bath inlet located on the rear of the water bath to the heater / circulator rear panel connector labeled OUT in the same fashion using the longer piece of tubing.
- **7** Plug the supplied temperature probe into the BATH TEMP jack on the Apparatus 3 / 7 right side panel.
- **8** Place the temperature probe through the small hole in the vessel table at the rear left side of the instrument so that approximately 3/4 of the probe is below the surface of the table.
- 9 Attach the four-pin DIN cable between the jack labeled CTRL IN on the heater / circulator rear panel and the jack labeled HEATER CIRCL. on the Apparatus 3 / 7 right side panel. The heater / circulator uses the temperature measured by the Apparatus 3 / 7 to control the water bath temperature.

NOTE

Do not fill the water bath at this time.

- **10** Ensure the heater / circulator is powered off.
- **11** Connect the power cord to the power receptacle on the rear panel of the heater / circulator.
- **12** Plug the power cord into an electrical outlet of the appropriate voltage.

Place the heater / circulator into its operating position.

CAUTION

Legs are not required when the heater / circulator is used with the Apparatus 3 / 7. If the heater / circulator is installed with legs, damage to the pump might occur if self-priming fails.

Filling the Water Bath

1 Pour ultrapure water through one of the outer media tube holes in the vessel carrier. Fill the water bath 3/4 full to allow for displacement by the tubes.

NOTE

If possible, preheat the water to the desired water bath temperature. Use ultrapure water when possible to minimize scale and mineral buildup. Use algaecide to inhibit mold and bacteria growth. Check the label to ensure the formulation is compatible with the plastic materials used in the water bath construction. The flow paths of the heater / circulator are primarily stainless steel and should tolerate most clear bath formulations.

- **2** Turn on the heater / circulator.
- **3** Check all connections for leaks. Occasionally, bubbles appear from the water bath inlet as the air in the system is purged. After a few minutes flow into the water bath is smooth and steady.

Installing Outer Media Tubes

The outer media tubes should be installed immediately prior to testing only. If the outer media tubes are placed in position without media, they float and can damage the agitator shafts and drive mechanism.

Installing the Sample Tubes (Apparatus 3)

- **1** At the first tube position, push up the evaporation cover to expose the stainless steel rod underneath.
- 2 Screw the inner sample tube into the stainless steel rod.
- 3 Release the evaporation cover.
- **4** Repeat steps 1 3 for each tube position.

Installing the Sample Holders (6-row Apparatus 7)

- 1 At the first tube position, push up the evaporation cover to expose the stainless steel rod underneath.
- **2** Loosen the set screw on the stainless steel rod.
- 3 Insert the sample holder into the bottom of the stainless steel rod.
- 4 Set the sample holder to the desired height.
- **5** Secure the sample holder by tightening the set screw.
- **6** Release the evaporation cover.
- **7** Repeat steps 1 6 for each tube position.

Installing the Sample Holders (12-row Apparatus 7)

- 1 At the first tube position, push up the evaporation cover to expose the stainless steel rod underneath.
- 2 Insert the sample holder into the white plastic retaining ring attached to the bottom of the stainless steel rod.
- **3** Release the evaporation cover.
- **4** Set the sample holder to the desired height.
- **5** Repeat steps 1 4 for each tube position.

Installing the Evaporation Curtains

There are two evaporation curtains located in the front and rear of the Apparatus 3 / 7 frame. Remove the tie wraps securing the curtains and carefully pull each curtain toward the drive unit. Place the left and right sides of the metal rods into the brackets located on the drive unit.

Tightening the Evaporation Curtains

- 1 Remove the front evaporation curtain rod ends from the brackets on the drive unit and allow it to carefully wind up.
- **2** Lift the flat end of the rod leaving the round end in its original position.
- **3** Using pliers, rotate the flat end approximately 20 25 times.

NOTE

To keep an accurate count, do not remove the pliers while turning.

4 Using the pliers, carefully slide the flat end of the rod back to its original position and replace it in the bracket on the drive unit.

NOTE

To prevent accumulation of media residue, wipe the evaporation curtains with a damp cloth. Then, wipe dry. Failure to do so may result in binding or "sticking" of the evaporation curtains.

5 Repeat steps 1 - 4 for the back evaporation curtain.

Powering Up the Apparatus 3 / 7

CAUTION

Ensure the retaining ties have been removed. Failure to do so could result in significant damage to the instrument.

Turn on the Apparatus 3 / 7. The drive unit moves slightly forward from its home position and returns.

WARNING

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

After the Apparatus 3 / 7 is powered up, the system monitor screen illuminates and displays the initial status screen briefly.

APP 3 / 7 TESTER

PROGRAM REVISION x.xx

INITIALIZING... PLEASE WAIT

TIME:10/16/18 10:08:00 ELAPSE:002:04:00

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

Firmware version

After three seconds, the Ready screen displays.

READY

PGM#1 Set DPM 15 BATH TEMP: 32.0 °C TIME:10/16/18 10:08:00 ELAPSE:002:04:00

Hidden Key Functions

Key Sequence	Function	
MENU > 0 > 8	Use this key sequence to select the plate style. Select option 1 , Module Plate. The Main Menu displays. Press ESC to return to the Ready screen. Note: Select option 1, Module Plate, or the instrument will not operate properly.	
MENU > 0 > 9	Use this key sequence to select the row style. See "Configuring the Apparatus 3 / 7" on page 29.	
MENU > 0 > A	Use this key sequence to configure the apparatus for a single universal DPM or a different DPM for each row. Select option 1, Single DPM, to run the same DPM throughout a program. Optionally, select option 2, DPM for Each Row, to run a different DPM for each row. The Main Menu displays. Press ESC to return to the Ready screen. See "SET SPEED" on page 31 and "1 Dip Per Minute" on page 38.	
MENU > 0 > B	Use this key sequence to enable or disable the peristaltic pump option. Select option 1 to enable or option 2 to disable the peristaltic pump. The Main Menu displays. Press ESC to return to the Ready screen.	
MENU > 0 > C	Use this key sequence to select the printer type. Select option 2 , Impact. The Main Menu displays. Press ESC to return to the Ready screen. Note: Select option 2, Impact, or the instrument will not operate properly.	
MENU > 0 > F	Use this key sequence to select the date display style. Select option 1, MM/DD/YY, or option 2, DD/MM/YY. The Main Menu displays. Press ESC to return to the Ready screen.	

Configuring the Apparatus 3 / 7

To configure the number of rows on your Apparatus 3/7, complete the following steps:

1 For firmware versions lower than 5.07, from the Ready screen press MENU > 0 > 9. The Select Row Style screen displays.

For firmware versions 5.07 or higher, from the Ready screen press **MENU** > **7**. The Select Row Style screen displays.

SELECT RO	OW STYLE		
1 ONE	2 TWO	3 THREE	4 SIX
5 EIGHT	6 TWELVE	7 TWELVE EXT	
TIME:10/16/18 10:08:49 ELAPSE:000:01:09			

2 Select one of the following options:

Option	Function	
1 One	Select option 1, One, for the 1L double row dip configuration. The Main Menu displays.	
2 Two	Select option 2 , Two, for the 2-row configuration. The Main Menu displays.	
3 Three	Select option 3 , Three, for the 1L configuration or the double row dip with the standard 6-row configuration. The Main Menu displays.	
4 Six	Select option 4 , Six, for the standard 6-row configuration. The Main Menu displays.	
5 Eight	Select option 5 , Eight, for the modified 8-row configuration. The Main Menu displays.	
6 Twelve	Select option 6 , Twelve, for the modified 12-row configuration. The Main Menu displays.	
7 Twelve Ext	Select option 7 , Twelve Ext, for the modified 12-row configuration. Selecting this option moves the drive unit an additional inch in order to bring the sample holders / tubes to rest over the drip tray rather than the last row.	

3 Press **ESC** to return to the Ready screen.

4 Operating the Apparatus 3 / 7

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Keypad Options

CAUTION

Verify the proper configuration of your Apparatus 3 / 7 before operating. Improper configuration may seriously damage your instrument. See "Configuring the Apparatus 3 / 7" on page 29..

The keypad on the Apparatus 3 / 7 is similar to a personal computer keyboard. For example, it has a SPACE key, an ENTER key, and a SHIFT key. These keys function exactly like their counterparts on a personal computer or typewriter keyboard. The keypad options are discussed on the following pages.

Option	Function	
MENU	See "Main Menu" on page 32.	
PRINT	Press PRINT to record the batch information, print the dip and drain times, enable or disable the Report Center Printer, select a local or remote printer, set the communications port identification number, and set the baud rate. See "Print" on page 35.	
SET SPEED	Press SET SPEED to manually enter the dips per minute. Enter the desired dips per minute and press ENTER . The Ready screen displays.	
PROG	Use this option to set the program parameters. See "Programing the Apparatus 3 / 7" on page 37.	
START PROG	Use this option to start a program. See "Starting a Program" on page 39.	
START DIP	Use this option to set the parameters for manual dipping. See "Start Dip / Stop Dip" on page 36.	
STOP DIP	Press STOP DIP to stop manual dipping. See "Start Dip / Stop Dip" on page 36.	
GOTO ROW	Press GOTO ROW to move the drive unit to the entered row. Enter a row number and press ENTER . The drive unit moves to the desired row and the Ready screen displays.	
CLEAR ROW	Press CLEAR ROW to move the drive unit to the next row providing clearance in the initial row. If the sample tubes / sample holders are at the rear-most row, press CLEAR ROW to move the drive unit to the home position. Press RESUME PROG to move the drive unit back to the initial row and continue the program. Note: it is necessary to pause the program before pressing CLEAR ROW . See " PAUSE PROG " below.	
PAUSE PROG	Press PAUSE PROG to pause a running program. The Apparatus 3 / 7 drive unit lifts the inner sample tubes / sample holders out of the media.	
RESUME PROG	Press RESUME PROG to resume a paused program.	
HOME	Press HOME to return the drive unit to the home position.	
LOCK KBRD	Press LOCK KBRD to lock the keypad. Press LOCK KBRD again to unlock the keypad.	

Main Menu

From the Ready screen, press MENU. The Main Menu displays.

MAIN MENU	
1 SET CLOCK	2 SET ALARMS
3 BATH TEMPERATURE	4 DELAY START TIME
5 MANUAL HOLD DIP	

Following is a description of the Main Menu screen options:4

Option	Function
1 Set Clock	Select option 1, Set Clock. Enter the current date in the appropriate format and press ENTER . Enter the current time in 24-hour format and press ENTER . The Main Menu displays.
2 Set Alarms	See "Setting Alarms" on page 33.
3 Bath Temperature	See "Heater / Circulator Control" on page 34.
4 Delay Start Time	Select option 4 , Delay Start Time. Enter the desired start time in 24-hour time format and press ENTER . Enter the start date in the appropriate format and press ENTER . The Main Menu displays. Note: this information is stored for use in all programs under Program Start. See " Starting a Program " on page 39.
5 Manual Hold Dip	Use this option to stop the inner sample tubes / sample holders at the bottom of the stroke for the length of time entered. For the Apparatus 3, this allows for adequate filling of the inner sample tube with dissolution medium before the dipping cycle begins. Select option 5 , Manual Hold Dip. Enter the desired duration and press ENTER . The Main Menu displays.

Setting Alarms

From the Main Menu, select option **2**, Set Alarms. The Activate/Deactivate Alarms screen displays.

ACTIVATE/DEACTIVATE ALARMS

1 ELAPSED TIMER 2 ROW DIP COMPLETION

3 PRG COMPLETION

TIME:10/16/18 10:08:49 ELAPSE:000:01:09

Following is a description of the Activate/Deactivate Alarms screen options:

Option	Function
1 Elapsed Timer	The elapsed time alarm sounds when the entered time span has passed. For example, use it as a reminder when the entire test has been completed or when a certain phase of the test is finished. Select option 1, Elapsed Timer. To activate the elapsed timer, enter the desired duration and press ENTER. To deactivate the elapsed timer, enter 00:00 and press ENTER. The Activate/Deactivate Alarms screen displays. Press ESC to return to the Main Menu. Press ESC again to return to the Ready screen. Note: press ENTER to silence the alarm.
2 Row Dip Completion	The row dip completion alarm sounds when a row dip is finished. Select option 2, Row Dip Completion. The Row Dipping Completion Alarm screen displays. Select option 1, Enable, to enable the alarm. Optionally, select option 2, Disable, to disable the alarm. The Activate/Deactivate Alarms screen displays. Press ESC to return to the Main Menu. Press ESC again to return to the Ready screen. Note: press ENTER to silence the alarm.
3 Prg Completion	The program completion alarm sounds when a program is finished. Select option 3, Prg Completion. The Program Completion Alarm screen displays. Select option 1, Enable, to enable the alarm. Optionally, select option 2, Disable, to disable the alarm. The Activate/Deactivate Alarms screen displays. Press ESC to return to the Main Menu. Press ESC again to return to the Ready screen. Note: press ENTER to silence the alarm.

Heater / Circulator Control

From the Main Menu, select option **3**, Bath Temperature, to control the heater / circulator. The Bath Temperature Control/Report screen displays.

BATH TEMPERATURE CONTROL/REPORT

1 SET BATH TEMP 2 DELAY HEATING

3 CALIBRATION 4 DISABLE (ENABLE) REPORT

TIME:10/16/18 10:08:49 ELAPSE:000:01:09

Following is a description of the Bath Temperature Control/Report screen options:

Option	Function
1 Set Bath Temp	Select option 1, Set Bath Temp. Enter the desired water bath temperature in xx.x format and press ENTER . The Main Menu displays. Press ESC to return to the Ready screen.
2 Delay Heating	Select option 2 , Delay Heating. Enter the desired start time in 24-hour format and press ENTER . Enter the start date in the appropriate format and press ENTER . The top line of the screen continues to flash until the function is canceled or until the set date and time are reached. To cancel the delayed heating function, press ESC . The Ready screen displays. Note: 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.
3 Calibration	Select option 3 , Calibration, to calibrate the temperature to 1/100 of a degree. Press ESC to return to the Ready screen.
4 Disable / Enable Report	Use this option to control whether or not the water bath temperature displays on the screen. Select option 4 to toggle between ENABLE REPORT and DISABLE REPORT. Press ESC twice to return to the Ready screen. Note: the Bath Temperature Control/Report screen displays the opposite of the current status. If the temperature control / report is enabled, DISABLE REPORT displays. If the temperature control / report is disabled, ENABLE REPORT displays. If the temperature control / report is disabled, the temperature does not display on the screen.

4 Operating the Apparatus 3 / 7

Print

From the Ready screen, press **PRINT**. Enter a program number and press **ENTER**. The Print Selections screen displays.

PRINT SELECTIONS	
1 BATCH INFORMATION	2 DIP/DRAIN TIMES
3 TURN OFF (ON) REP CENTER	4 CHANGE TO REMOTE (LOCAL)
5 SET COM PORT ID	6 SET BAUD RATE

Following is a description of the Print Selections screen options:

Option	Function
1 Batch Information	Select option 1 , Batch Information, to print the program number, operator, product and batch information.
2 Dip/Drain Times	Select option 2 , Dip/Drain Times, to print the dip and drain times.
3 Turn Off / On Rep Center	Select option 3 to toggle between TURN OFF REP CENTER and TURN ON REP CENTER. Note: this option displays the opposite of the current status. If the printer is enabled, TURN OFF REP CENTER displays. If the printer is disabled, TURN ON REP CENTER displays.
4 Change to Remote / Local	Select option 4 to toggle between CHANGE TO REMOTE and CHANGE TO LOCAL. Note: this option displays the opposite of the current status. If using the local printer on the Apparatus 3 / 7, CHANGE TO REMOTE displays. If using a remote or external printer, CHANGE TO LOCAL displays.
5 Set Com Port ID	Select option 5 , Set Com Port ID, to set the communications port identification number. Enter 01 and press ENTER . The Print Selections screen displays.
6 Set Baud Rate	Select option 6 , Set Baud Rate, to set the baud rate on the Apparatus 3 / 7. Select option 4 , 9600 Baud. The Print Selections screen displays.

Start Dip / Stop Dip

From the Ready screen, press **START DIP**. The Manual Dipping screen displays.

MANUAL DIPPING

1 START

2 SET SPEED (DPM)

3 GOTO ROW

4 SET HOLD DIP TIME

ROW # Set DPM xx Hold DIP TIME xxxxx

Following is a description of the Manual Dipping screen options:

Option	Function
1 Start	Select option 1 , Start, to begin manual dipping. To start dipping manually, the drive unit must be at a row position. If it is at home position, the start option is blocked. Note: select this option last.
2 Set Speed (DPM)	Select option 2 , Set Speed (DPM). Enter the desired DPM and press ENTER . The Manual Dipping screen displays. This option functions just like the SET SPEED function key. See "SET SPEED" on page 31.
3 Goto Row	Select option 3 , Goto Row. Enter the desired row number and press ENTER . The Apparatus 3 / 7 drive unit moves to the entered row. The Manual Dipping screen displays. This option functions just like the GOTO ROW function key. See "GOTO ROW" on page 31.
4 Set Hold Dip Time	Select option 4 , Set Hold Dip Time. Enter the desired interval and press ENTER . The Manual Dipping screen displays. This option functions just like Main Menu option 5, Manual Hold Dip. See "5 Manual Hold Dip" on page 32.

4 Operating the Apparatus 3 / 7

Press **STOP DIP** to manually stop dipping. The inner sample tubes / sample holders are lifted out of the outer media tubes and the instrument stops.

NOTE

Options 2 and 4 are also options on other screens. You can adjust these parameters from different points in the manual operation.

Programing the Apparatus 3 / 7

NOTE

Programs are not write-protected. Check with other users before proceeding.

From the Ready screen, press **PROG**. Enter a program number and press **ENTER**. The Program Variables screen displays.

NOTE

The Apparatus 3 / 7 can accept and store up to 15 different program sequences. All programming begins at the Ready screen.

PROGRAM VARIABLES

1 DIP PER MINUTE 2 DIP TIME INTERVAL 3 DRAIN TIME 4 HOLD DIP TIME 5 BATCH INFORMATION 6 PRINT FREQUENCY

4 Operating the Apparatus 3 / 7

Following is a description of the Program Variables screen options:

Option	Function
1 Dip Per Minute	Select option 1, Dip Per Minute. Enter the desired dips per minute and press ENTER . The Program Variables screen displays.
2 Dip Time Interval	Select option 2 , Dip Time Interval. Enter the duration of dipping time for each row and press ENTER to advance to each remaining row. To skip a row of outer media tubes, enter a dip time of 0 for that row and press ENTER . After the last row dip time interval has been entered, the Program Variables screen displays.
3 Drain Time	Select option 3 , Drain Time. Enter the duration the inner sample tubes / sample holders drain over the outer media tubes after being lifted from the media and press ENTER to advance to each remaining row. After the last drain time has been entered, the Program Variables screen displays.
4 Hold Dip Time	Select option 4 , Hold Dip Time. Enter the duration the inner sample tubes / sample holders are stopped at the bottom of the stroke before dipping begins and press ENTER to advance to each remaining row. After the last hold dip time interval has been entered, the Program Variables screen displays.
5 Batch Information	Select option 5, Batch Information. The Batch # Selections screen displays. For each option, enter the desired information and press ENTER . Press ESC to return to the Program Variables screen. Note: the Batch # Selections screen displays options for the report header information. The print field accepts ten characters. Characters can be letters, numbers, special characters or spaces. The information entered for each selection prints in the header of each printout. The entries made from this menu are attached to the active program. Since there are 15 programs, there can be a different set of entries for each. All are stored in the battery-protected memory and remain until changed via this menu.
6 Print Frequency	Select option 6 , Print Frequency, to enter how often the Apparatus 3 / 7 status prints during a dip time interval. Enter a time interval in minutes (for example, enter 005 for 5 minutes) and press ENTER . If no status printout is desired, enter 000 for the time interval. Note: do not use this option to disable the Report Center Printer. If no printout is desired, turn off the printer via the Print Selections screen option 3. See "3 Turn Off / On Rep Center" on page 35.

NOTE

After entering the desired parameters, press **ESC** to return to the Ready screen. Press **PRINT**, enter the program number and press **ENTER** to print and review the program before beginning the test.

Starting a Program

From the Ready screen, press **START PROG**. Enter a program number and press **ENTER**. The Select Start Mode screen displays.

SELECT START MODE

1 START NOW
2 DELAYED START
3 REMOTE START
4 MODIFY PROGRAM
PRG# 29 SetDPM 8

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

Option	Function
1 Start Now	Select option 1, Start Now, to begin the test according to the programmed variables.
2 Delayed Start	Select option 2 , Delayed Start, to begin the test at the delayed start time. The values entered under Main Menu option 4 display, if applicable. See "4 Delay Start Time " on page 32. To change the start time and date, enter the desired start time in 24-hour format and press ENTER . Enter the desired date in the appropriate format and press ENTER . Note: entering new values under Select Start Mode option 2 changes the values under Main Menu option 4 as well.
3 Remote Start	Select option 3 , Remote Start, to start the program from a remote unit. The Ready screen displays. Contact the Dissolution Systems Service Department to discuss the use of this option.
4 Modify Program	Select option 4 , Modify Program, to modify or review the program parameters. The Program Variables screen displays. See "Programing the Apparatus 3 / 7" on page 37 for information about the program variables and how to set them. Once all the variables have been changed or verified, press ESC . The Select Start Mode screen displays. Select a mode to start the program or press ESC to return to the Ready screen.

5 Conversion Procedures

Alignment Procedure 41
General Conversion Procedures 41

NOTE

Please contact Agilent for a Service Engineer to perform the procedure to convert the instrument Apparatus type or sampling Assembly.

CAUTION

Ensure proper row configuration is set on the Apparatus 3/7 program. Serious damage could occur if rows are not properly configured. See "Configuring the Apparatus 3/7" on page 29..

Alignment Procedure

Operating the instrument without proper alignment could cause damage. It may be necessary to perform both types of alignment. Please contact a service engineer to perform alignment.

General Conversion Procedures



Before performing any conversion procedure, turn off the instrument and remove the power cord.

Installing the Evaporation Cover

- 1 Slide the evaporation cover up and onto the agitator shaft.
- 2 Roll the black O-ring onto the agitator shaft until it sits in the groove.
- 3 Slide the evaporation cover down until it rests on the O-ring. Ensure the cap is secured on the agitator shaft.

Cannula Removal

- **1** Turn on the instrument.
- 2 Press GOTO ROW.
- **3** Enter **1** and press **ENTER**.
- 4 Press **START DIP** and select option **2**, Set Speed (DPM).
- **5** Enter **5** DPM and press **ENTER**.
- **6** Select option **1**, Start, to start dipping.
- 7 Allow the evaporation covers to move downward to the lowest position.
- 8 Turn off the instrument before dipping begins.
- **9** Grasp the sampling cannula at the top of the first evaporation cover and pull upward until the cannula is free. Repeat this action for the return cannula and all remaining sampling / return cannulas. Note the sampling cannula is the longer cannula in front. The return cannula is shorter and to the rear. Remove the evaporation cover if a conversion is being performed.
- **10** Turn on the instrument. The drive unit returns to the home position.

Cannula Installation

- **1** Turn on the instrument.
- 2 Press GOTO ROW.
- **3** Enter **1** and press **ENTER**.
- **4** Taking care not to bend the sampling cannula, guide it through the top of the position 1 evaporation cover.
- **5** Push the cannula through until stopped by the clear tubing that connects the cannula to the colored sample tubing.
- **6** Repeat the above procedure with the return cannula on position 1 as well as the remaining positions 2 7. Note the sampling cannula is the longer cannula in front. The return cannula is shorter and to the rear.
- 7 If a conversion is being performed, install the evaporation covers onto the agitator shafts in the appropriate order. See "Installing the Evaporation Cover" on page 41.
- 8 Press HOM

6 Maintenance and Troubleshooting

Preventive Maintenance 45 Report Center Impact Printer 50

Preventive Maintenance

WARNING

The 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.

Preventive maintenance intervals may vary depending on frequency of instrument usage.

Daily Maintenance

See "Holder Care" on page 46 and "Water Bath / Acrylic Care" on page 47 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 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 holders after each use.
- Carefully wash the media tubes after each use.

Weekly Maintenance

See "Water Bath / Acrylic Care" on page 47 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 "Water Bath / Acrylic Care" on page 47 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.
- It is recommended that the water bath temperature probe jack is checked for surface corrosion and wiped clean with a soft cloth or nonabrasive pad every one to three months.

NOTE

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

- Clean the agitator shafts. Inspect the agitator shaft evaporation cover O-rings for excessive wear. Replace the O-rings as necessary.
- Clean and lubricate the horizontal guide rods with a silicone-based lubricant.
- Clean the entire external surface of the instrument.

Holder Care

- 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.
- 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.
- We recommend that you *do not* use a laboratory dishwasher. Clean holders only by hand.
- Be sure to handle with care.
- Use care when removing outer media tubes from the apparatus while the holders are installed so that you do not bump them.
- Store holders properly between uses.

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 Apparatus 3 / 7 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.

- 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.
- 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.
- 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".
- Our recommendations include but are not limited to the following:
- Hot water:< 150 °F
- Vinegar (5% Glacial Acetic Acid)
- Ethyl alcohol: maximum 10%
- Isopropyl alcohol: maximum 25%

Repairing Leaking Fittings

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

- 1 Turn off the heater / circulator and drain the water bath completely.
- Remove the leaky bulkhead fitting.
- Remove the elbow fitting from the bulkhead fitting.
- Inspect the bulkhead fitting gaskets for damage and replace them as necessary.
- Remove the old PTFE tape from all male fittings. Inspect the threads for damage and replace the fitting as necessary.
- Apply new PTFE tape to the male fitting threads.
- 7 Reinstall and tighten the bulkhead fitting on the water bath.
- Reinstall and tighten the elbow fitting to the bulkhead fitting.
- Fill the water bath and turn on the heater / circulator.
- Inspect the fitting for leaks. If the fitting still leaks, contact the Dissolution Systems Service Department.

Visual Checks

CAUTION

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

- 1 Turn off power to the instrument and remove the power cord.
- 2 Remove the four screws from the top left panel and remove the panel.
- **3** Remove the four screws from the left side panel and remove the panel.
- 4 Inspect the drive belt for unusual wear, fraying, and tension.
- **5** Replace the left side cover and secure by reattaching the four Phillips screws.
- **6** Replace the top left cover and secure by reattaching the four Phillips screws.
- 7 Reconnect the power cord and turn on the instrument.

Report Center Impact Printer

The following is helpful information for using your impact printer.

Installing the Cartridge Ribbon

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

To install the cartridge, complete the following steps:

- 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.
- 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.
- **3** Push down on the right side of the ribbon cartridge (marked PUSH) and remove the old cartridge.
- 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.
- 5 Turn the cartridge knob (marked by an arrow) clockwise to stretch the ribbon taut
- **6** Replace the cover.
- 7 Toggle the printer online by pressing the printer toggle switch to the OnLine / Off Line position. The Ready LED illuminates.
- 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

- 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.
- **2** Grasp the paper roll cover firmly by the grooves on the side and the front edge. Pull outward to remove the cover.
- **3** Press the printer toggle switch to *Paper feed* to advance the paper approximately one inch beyond the paper cutter.
- **4** Using scissors, cut the paper feeding to the printer and remove the paper roll.
- **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.
- 6 Unroll several inches of paper on the new roll.
- 7 If it is jagged, cut a straight edge on the paper roll to facilitate the entry of the paper into the printer.
- 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.
- **9** While holding the paper in place, press the printer toggle switch to the *Paper feed* position and hold until approximately one inch of paper has emerged from the top of the printer.

CAUTION

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

- **10** Release the printer toggle switch.
- **11** Turn the paper roll to take up any slack in the paper feeding to the printer.
- **12** Place the paper roll into the paper compartment.
- 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.
- **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:

- 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.
- 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 "Obtaining Warranty and Other Services" on page 53 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:

- **1** Turn off the Apparatus 3 / 7.
- **2** Press and hold the printer toggle switch in the *Paper feed* position.
- 3 Turn on the Apparatus 3 / 7.
- **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.
- **5** Press the printer toggle switch to the *OnLine / Off Line* position to stop the printing operation.
- **6** The printer is ready to resume normal operation.

Obtaining Warranty and Other Services

To place a service order (warranty or other services), please contact your local Customer Care Center. Contact information can be found at www.agilent.com under your country using the Contact Us link. Place your service request using the displayed phone number or E-mail address.

In This Book

This manual contains technical reference information about the Agilent BIO-DIS Apparatus 3 / 7 (G7972A)

- Chapter 1 Safety
- Chapter 2 Introduction
- · Chapter 3 Setup
- · Chapter 4 Operation
- Chapter 5 Conversion Procedures
- Chapter 6 Maintenance and Troubleshooting

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