National Cancer Institute-Frederick, Frederick, MD BDP Biopharmaceutical Development Program	STANDARD OPERATING PROCEDURE	Effective Date JAN 5 2005	Procedure Number 11116
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Title: **Operating the VHP® 1000ED-AB Generator**

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SOP References: 11115, 11117	Supersedes: NA

Purpose: The objective of this procedure is to describe the step-by-step operations to program change values and setpoints for the operation of VHP® 1000ED-AB Generator.

Scope: This procedure covers the VHP® 1000ED-AB Generator (BDP MEF 76720, Model number EDA-120, serial number 0126203-05) installed for the Biodecontamination of cGMP Virus Production in the BDP.

Contents:

1.0 Authority and Responsibility

1.1 The Director, Business Operations, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

1.2 The Development Engineer, BDP is responsible for training personnel in this procedure and for documenting this training to Biopharmaceutical Quality Assurance (BQA).

1.3 BDP personnel are responsible for implementation and performing this procedure.

1.4 BQA is responsible for quality oversight of this operation.

2.0 Definitions

2.1 Setpoints: The setpoints are used to control the general way the VHP® 1000ED-AB Generator operates. Unit Setpoints include time/date, out-of-cycle values, and setup values.

2.2 Cycle Parameters: The cycle parameters are used to control the decontamination cycle performing by a VHP® 1000ED-AB Generator.

2.3 VHP: Vapor Hydrogen Peroxide.

3.0 Equipment

3.1 Steris VHP® 1000ED-AB Generator.

4.0 Description of the Generator Controls

The VHP® 1000ED-AB Generator (henceforth will be referred to as VHP Generator) has two power switches, a main power disconnect switch, and a power ON/OFF switch. The control panel is operated as follows:

4.1 The main power disconnect switch is located on the back of the unit. This switch controls power supply to the generator and its control system.

4.2 The power ON/OFF switch is located on the back of the unit. This switch supplies power to the generator and its controls.

4.3 The operator can control cycle operation, program cycle, and unit operating parameters, as well as monitor cycle performance through the control panel.

4.4 Use of the PV300 display is normally self-explanatory. Many screens include the text “F4-Next/F8-Previous” to indicate that additional screens are available.

4.5 The following table identifies the special functions given to particular touch pads located on the PV300 display.

Touch Pad Special Functions	
Touchpad	Special Function
F1	Start the selected cycle (from Standby Mode)
F2	Reset from Cycle Complete phase back to Main Menu
F4	Displays the previous screen
F5	Abort cycle if a cycle is active
F6	Force a status print (demand print) from the Run Screen
F8	Displays the next screen when available
◄►	Move the cursor to the left/right or navigate through text selection screens
▲▼	Select from a screen list or navigate through text selection screens
↵	Enter typed value at the cursor
←	Clears the last character entered

4.6 The printer records the status of VHP 1000ED-AB Generator – Power up, cycle parameters, and actual cycle data.

NOTE: Refer Operator Manual (129383-120) page numbers 5-2 to 5-8 for sample printouts.

5.0 Controls Overview

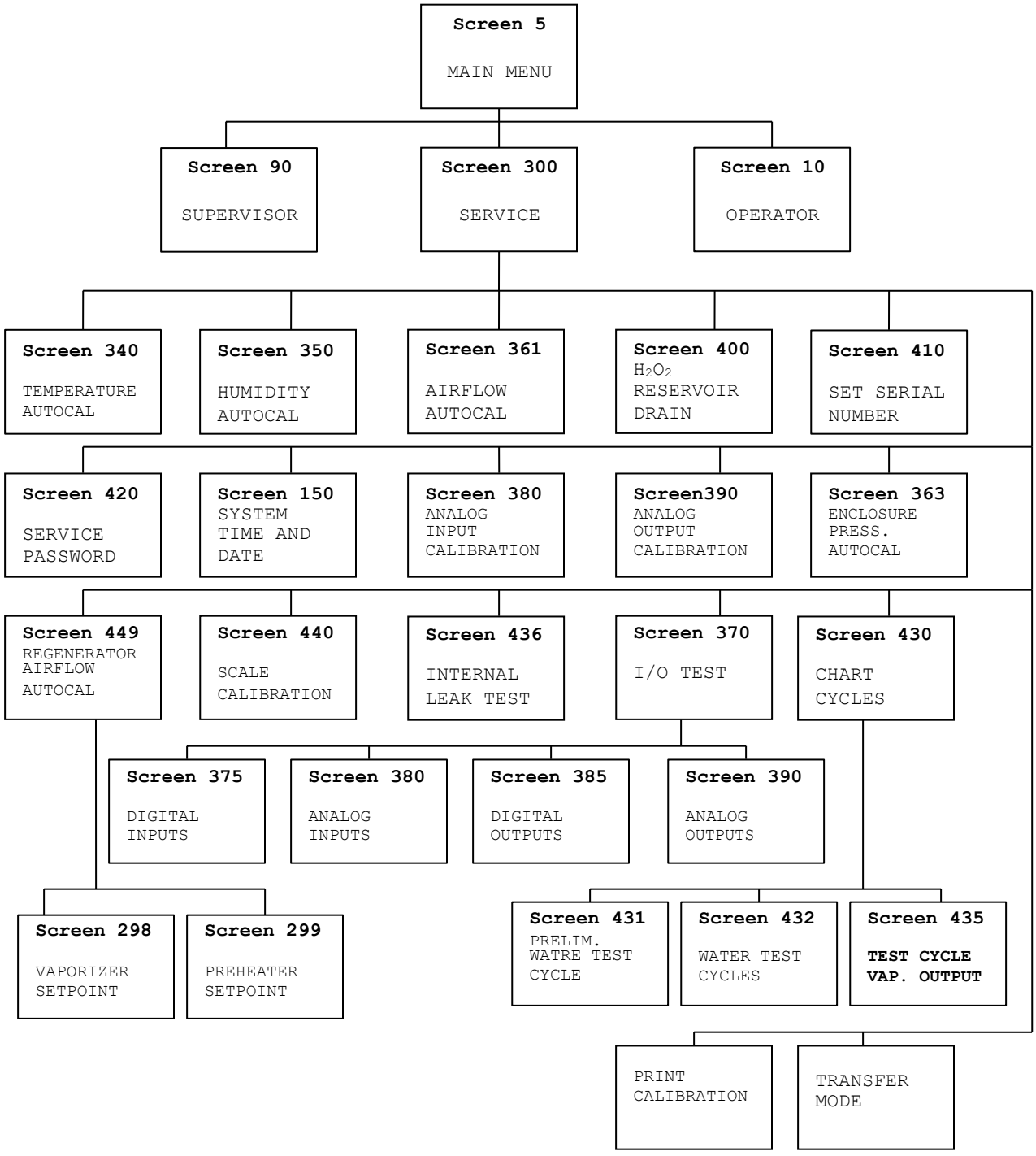
The VHP Generator is provided with user-programmable cycles and sepoints, a complete operator interface, and a printout of generator cycles and critical data. Security for operation, system, and cycle setpoints access and service mode functions is provided with password requirements. The VHP Generator is operated by using one of the following modes:

5.1 Operator Mode – enables selection of cycle and starting and aborting of cycles.

5.2 Supervisor Mode – enables setting of cycle setpoints and system setpoints and options.

5.3 Service Mode – enables I/O testing, device calibration functions, and other service-related functions.

5.4 Refer to the following flow charts for the basic structure of the VHP Generator screen sequence.


Screen 5
MAIN MENU
Screen 90
SUPERVISOR
Screen 300
SERVICE
Screen 10
OPERATOR
Screen 340
TEMPERATURE AUTOCAL
Screen 350
HUMIDITY AUTOCAL
Screen 361
AIRFLOW AUTOCAL
Screen 400
H_2O_2 RESERVOIR DRAIN
Screen 410
SET SERIAL NUMBER
Screen 420
SERVICE PASSWORD
Screen 150
SYSTEM TIME AND DATE
Screen 380
ANALOG INPUT CALIBRATION
Screen390
ANALOG OUTPUT CALIBRATION
Screen 363
ENCLOSURE PRESS. AUTOCAL
Screen 449
REGENERATOR AIRFLOW AUTOCAL
Screen 440
SCALE CALIBRATION
Screen 436
INTERNAL LEAK TEST
Screen 370
I/O TEST
Screen 430
CHART CYCLES
Screen 375
DIGITAL INPUTS
Screen 380
ANALOG INPUTS
Screen 385
DIGITAL OUTPUTS
Screen 390
ANALOG OUTPUTS
Screen 298
VAPORIZER SETPOINT
Screen 299
PREHEATER SETPOINT
Screen 431
PRELIM. WATRE TEST CYCLE
Screen 432
WATER TEST CYCLES
Screen 435
TEST CYCLE VAP. OUTPUT
PRINT CALIBRATION
TRANSFER MODE

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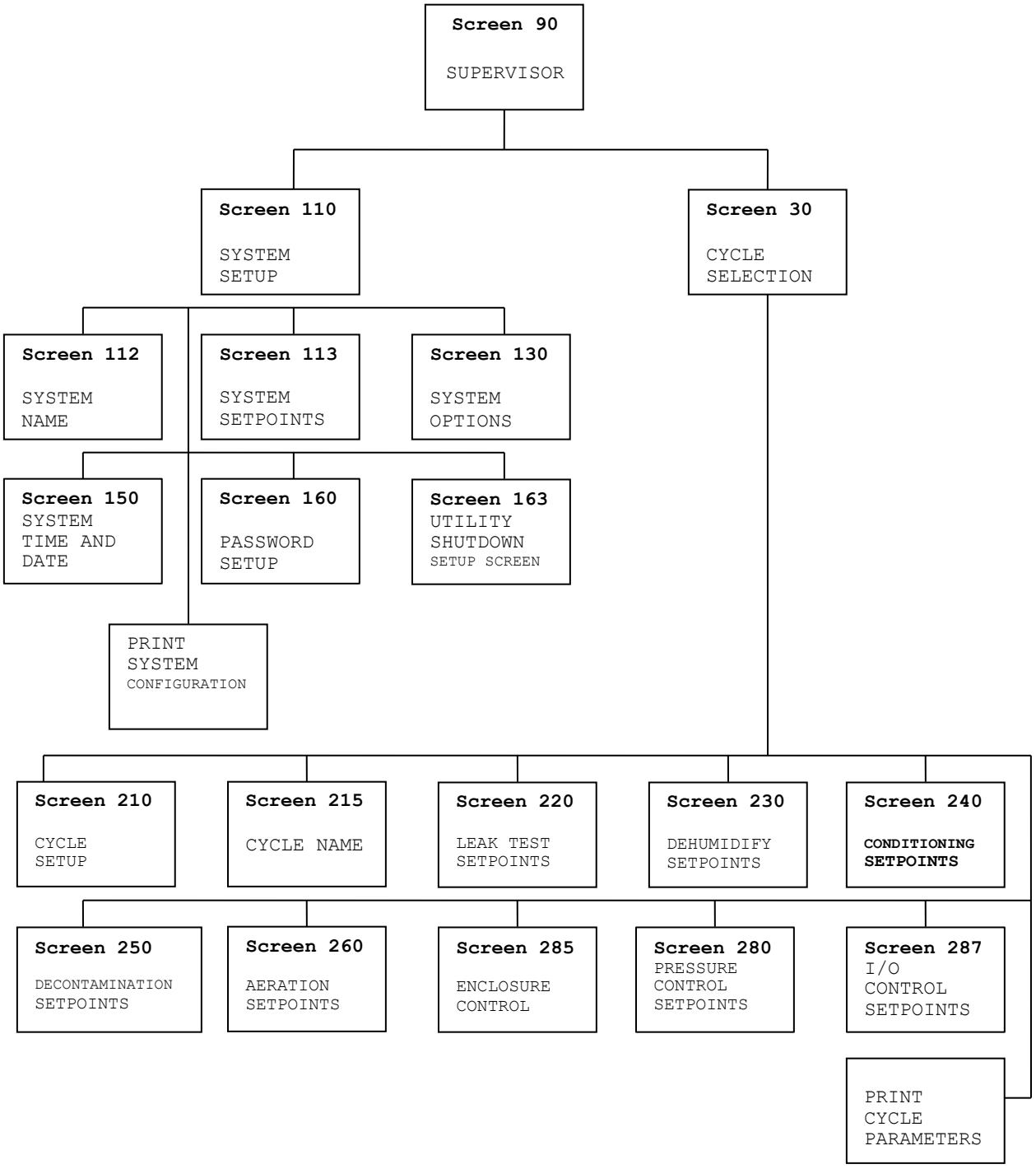

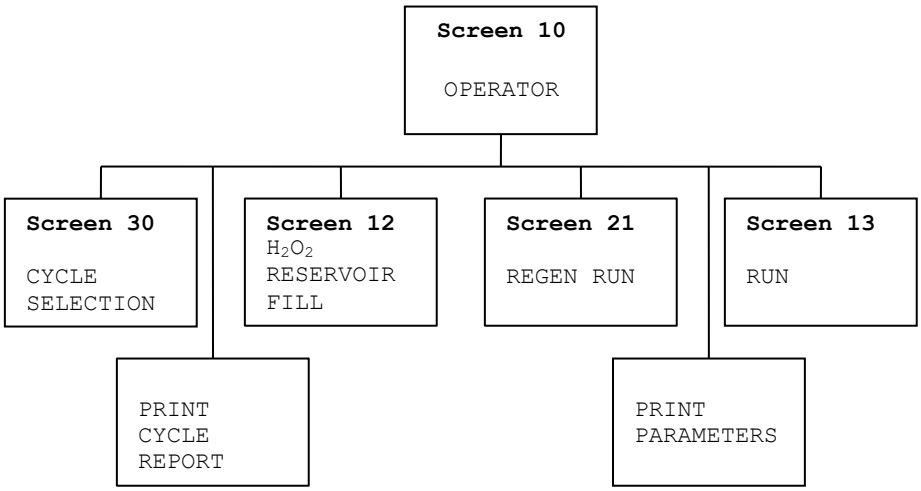

6.0 Controls Procedure

6.1 Position the Power switch to ON. The display will advance to the Main Menu screen and the following printout will occur.

```
**************************************
* STERIS VHP 1000ED-AB *
*   BIO-DECON SYSTEM    *
*      MADE IN THE USA  *
*      GEN.TITLE LINE 1 *
*      GEN.TITLE LINE 2 *
*   SERIAL #XXXXXXXXX   *
* CPU P/NXXXXX-XXX RXX *
*   PV   P/NXXXXX-XXX   *
(DATE)                (TIME)
**************************************
```

6.2 At the Main Menu Screen (shown below), the display prompts for selection of modes (Operator, Supervisor, or Service). Note that cycles may be initiated from the External Interface from this screen.

```
(date)                          (time)

MAIN MENU          PV01
F1-Operator        F2-Sprvsr
F5-Service
```

F1 = Enter Operator Mode
F2 = Enter Supervisor Mode.
F5 = Enter Service Mode.

6.3 Password Screen: Password screen appears when F1, F2, or F5 is pressed at the Main Menu.

```
Type in the Password
and press <ENTER>
xx
```

The Operator Mode requires entry of any of the programmable operator passwords, the supervisor password, or service password. The Supervisor Mode requires entry of the supervisor or service password. The Service Mode requires entry of the service password.

All Passwords are defaulted to the respective user number. Refer to the following table.

Password Defaults			
User Number	User Type	**Accessible Modes**	Default Password
1	Operator	Operator	1
2	Operator	Operator	2
3	Operator	Operator	3
4	Operator	Operator	4
5	Operator	Operator	5
6	Operator	Operator	6
7	Operator	Operator	7
8	Operator	Operator	8
9	Operator	Operator	9
10	Operator	Operator	10

6.4 The Operator Control Sequence

6.4.1 The Operator Mode is accessed from any valid password entry made at the Main Menu. The first screen, Operator Screen, displayed on the OP7 Display enables selection of the cycle to be started (by the operator), operation of the Reservoir Fill Cycle, the Run Screen, or initiation of a Regeneration Cycle.

```
        Operator Screen
F1-Cycle Selection
F2-H2O2 Res. Fill
F3-Run Screen
F5-Regeneration Cycle

F4-Previous              F8-Next
```

Press F8 and this screen is displayed:

```
        Operator Screen
F1-Print Report
F2-Print Parameter

F4-Previous
```

NOTE: The alphanumeric label (i.e. F1) corresponds to the controller keypad for selecting the task as displayed on the screen. The printouts listed above may be generated even if the system printer option is disabled. The regeneration Cycle will be initiated immediately when F5 is pressed.

6.4.2 Press F1 to select a cycle. The Cycle Selection Screen will appear. Choose a cycle.

```
          CYCLE SELECTION nn
   F1- #1-XXXXXX
   F2-#2-XXXXXX
   F3-#3-XXXXXX
F4- Previous          F8-Next
```

Where: nn = current selected cycle
XXXXXX = cycle name for the respective cycle
Press F8 will display all the available cycle screens.

6.4.3 Once a cycle has been selected, the PV300 Display will advance to the Run Screen

```
Cycle- #nn
Time Rem.: 00:00:00
Phase: Standby
F1-START
F4- Previous              F8-Next
```

Where: nn = selected cycle, set per the Cycle Selection Screen

6.4.4 At any time while the Run Screen is active, the scrolled-down screens indicate VHP Generator actual readings (A) and their corresponding setpoints (S), if applicable

Typical setpoint readings are shown in the displays below.

```
Scale
S: aaaa          A: bbbb      g
Injection Rate
S: cccc          A: dddd      g/m
F4-Previous           F8-Next
```

Where: aaaa = Reservior required weight setpoint for the selected cycle, in grams.
bbbb = Actual Scale reading, in grams.
cccc = Setpoint Injection Rate, in gram/minute.
dddd = Actual Injection Rate (output rate from the Reservoir), in grams/minute (updated every 15 seconds)

Press F8 and this screen is displayed:

```
Encl. Pressure (yyy)
S: aaaa          A: bbbb
Cycle Airflow (xxx)
S: cccc          A: dddd
F4-Previous           F8-Next
```

Where: aaaa = Setpoint Enclosure pressure.
bbbb = Actual Enclosure pressure.
cccc = Setpoint Cycle airflow.
dddd = Actual Cycle airflow.
Xxx = cfm or cmh, depending upon airflow unit set
yyy = "WC or Pa depending upon pressure unit set.

Press F8 and this screen is displayed:

```
Vapor. Temp.
S: aaaa          A: bbbb     xx
Pre-Heater Temp.
S: cccc          A: dddd     xx
F4-Previous            F8-Next
```

Where: aaaa = Setpoint Vaporizer temperature.
bbbb = Actual Vaporizer temperature.
cccc = Setpoint Preheater temperature
dddd = Actual Preheater temperature
xx = C or F depending upon temperature unit set.

Press F8 and this screen is displayed:

```
Humidity (%RH)
S: aaa           A: bbb
Enclosure Humidity
A: ccc      %RH
F4-Previous            F8-Next
```

Where: aaa = Setpoint Air Inlet Relative Humidity.
bbb = Actual Air Inlet Relative Humidity.
ccc = Actual Enclosure Relative Humidity.

Press F8 and this last screen is displayed:

Dryer Temp. S: aaaa A: bbbb xx H_2O_2 Return Temp. S: cccc A: dddd xx F4-Previous

bbbb = Actual Dryer temperature.
cccc = Setpoint H_2O_2 Return temperature.
dddd = Actual H_2O_2 Return temperature.
xx = C or F depending upon temperature unit set.

Press F4 to return to previous screen.

6.4.5 When back to the Operator Screen, select “F2-H22 Reservoir Fill” and the following screen(s) is displayed:

H_2O_2 Reservoir Fill F1-Start S: aaaa F5-Stop A: bbbb F4-Previous

Where: aaaa = Setpoint in gram.
bbbb = Actual in gram.

6.4.6 On the Operator Screen, select “F3-Run Screen” and the following screen occur.

Cycle-#nn Time Rem.: hh:mm:ss Phase: PHASE NAME F-Start F4-Previous F8-Next

Press F8 and all the series of screens seen in section 6.4.4 are displayed.

6.4.7 On Operator Screen, select “F5-Regeneration Cycle” and the regeneration cycle will be started immediately with this screen displayed.

```
Cycle-RGN
Time Rem.: hh:mm:ss
Phase: PHASE NAME
F-Start                F5-Abort
F8-Next
```

6.5 Supervisor Operating Sequence

6.5.1 Supervisor Mode: supervisor mode is accessed from supervisor or service password entry made at the Main Menu. Supervisor Mode enables setting of the system setpoints and options and the cycle setpoints. The display shows as follows.

```
F1-System Setup
F2-Cycle Setup
F3-Phase Advance
F4-Previous
```

F1 = Set system setpoints, options, time and date, and passwords.
F2 = Set Cycle setpoints.
F3 = If a cycle is active, advance to the next phase.

6.5.2 System Setup (F1): For System Setup, the display shows as follows

```
          SYSTEM SETUP
F1-Name                F6-Print
F2-Setpoints
F3-Options

F4-Previous                F8-Next
```

F1 = Set Generator system name (printed at power-up).
F2 = Set system setpoints.
F3 = Set system configuration options.
F6 = Print system setpoints and options.
F8 = Scroll down screen.

Press F8 and the this screen is displayed:

SYSTEM SETUP
F1-Time/Date
F2-Passwords
F3-Utility Shutdown
F4-Previous F8-Next

F1 = Set time and date.
F2 = Set operator and supervisor passwords.
F3 = Set times and days for utility shutdown and restart.

4.1.1 The following points describe each selection.

4.1.1.1 Set System Name (F1)

The system name is printed at the power-up print of the VHP Generator.

SYSTEM NAME
(Sys Name 1)_____
(Sys Name 2)_____

The user may set two lines of 20 characters. Characters entered must be limited to those of the ASCII set from 20 hex to 7F hex (generally upper and lower case letters, numbers, and basic typographic symbols).

4.1.1.2 Set System Setpoints (F2)

The system setpoints apply to the VHP Generator, not to specific cycles. Pressing F8 scrolls the screen (down) to additional setpoints. Pressing F4 scrolls the screen back (up) to previous screens.

Values shown on the following screens are the typical default values.

SYSTEM SETPOINTS
Reservoir Fill
600 grams
F4-Previous F8-Next

This setpoint (above) is the weight to which the reservoir is filled during the H_2O_2 Reservoir Fill Cycle and may be set from 0 to 999.9 grams.

NOTE: That this applies only to the stand-alone fill cycle. During a Decontamination Cycle, the reservoir is filled to the necessary amount and not to this setpoint.

SYSTEM SETPOINTS
Dryer Capacity
900 grams
F4-Previous F8-Next

This setpoint (above) is the amount of hydrogen peroxide that can be injected before the dryer must be regenerated and may be set from 0.0 to 999.9 grams.

SYSTEM SETPOINTS
Vap. Temp. (Out Cycle)
25.0°C
F4-Previous F8-Next

This setpoint (above) is the temperature at which the vaporizer heater is maintained when the VHP Generator is out-of-cycle, and may be set from 0-200.0°C/°F. This value is normally set to approximately room temperature to conserve energy and to reduce heat buildup within the VHP Generator. This heater is necessary for proper vaporization of H_2O_2 during injection phases.

SYSTEM SETPOINTS
Host PLC Node Address
15
F4-Previous F8-Next

This setpoint (above) is the designated address of the Host PLC in the Siemens MPI system, used for the External Interface, and may be set from 1-31. Refer to the External Interface procedure (STERIS Part Number P129383-161) for more information.

SYSTEM SETPOINTS
Host PLC Int. File
130
F4-Previous F8-Next

This setpoint (above) is the starting Host PLC data block number at which the Generator monitors for Host PLC commands and status to the VHP Generator, and may be set from 0-255. Refer to the External Interface procedure (STERIS Part Number P129383-161) for more information

SYSTEM SETPOINTS
Host PLC FP File
131
F4-Previous F8-Next

This setpoint (above) is the starting Host PLC data block number at which the VHP Generator monitors for remote cycle download data to the VHP Generator, and may be set from 0-255. Refer to the External Interface procedure (STERIS Part Number P129383-161) for more information.

SYSTEM SETPOINTS	
Cycle Count	
0	
F4-Previous	F8-Next

This setpoint (above) is the VHP Generator running cycle count, or the number of cycles run, and may be set from 0-999999. This is automatically tracked by the VHP Generator and has a maximum value of 1,000,000 before being reset to “0”.

NOTE: That all started cycles are considered in this count, including aborted cycles.

SYSTEM SETPOINTS	
Flexible PID Params	
Prp. Gain:	0.0110
Int. Time:	800 FLEX
Der. Time:	70
F4-Previous	F8-Next

These setpoints (above) are the Proportional, Integral, and Derivative setpoints for the enclosure pressure PID loop of the Flexible Enclosure Type.

SYSTEM SETPOINTS	
Semi Rigid PID Params	
Prp. Gain:	0.0075
Int. Time:	800 SEMI
Der. Time:	70
F4-Previous	F8-Next

These setpoints (above) are the Proportional, Integral, and Derivative setpoints for the enclosure pressure PID loop of the Semi-Rigid Enclosure Type.

SYSTEM SETPOINTS	
Rigid PID Params	
Prp. Gain:	0.0035
Int. Time:	800 RIGD
Der. Time:	20
F4-Previous	F8-Next

These setpoints (above) are the Proportional, Integral, and Derivative setpoints for the enclosure pressure PID loop of the Rigid Enclosure Type.

6.5.3.3 Set System Options (F3)

The System options are configuration options of the VHP Generator. Pressing F8 scrolls the screen (down) to additional setpoints. Pressing F4 scrolls the screen back (up) to previous screens. Settings shown on the screens below are the typical default values. Pressing F1 enables the option shown, while pressing F5 disables the option. The current setting is shown on the right side of the screen (i.e., “ENABLED” or “DISABLED”).

SYSTEM OPTIONS	
System Printer	
F1-Enable	ENABLED
K1-Disable	
F4-Previous	F8-Next

The System Printer option enables or disables the printer at the Operator Interface Module. Disabling this option disables only cycle and power-up prints, or any other printouts generated automatically by the VHP Generator. Any forced prints are always enabled. Cycle report data of the last-run cycle is always retained within the memory of VHP Generator controller and may be printed from the Operator Mode after the cycle is completed.

SYSTEM OPTIONS	
Host PLC Interface	
F1-Enable	DISABLED
K1-Disable	
F4-Previous	F8-Next

This option (above) enables or disables the cycle start External Interface to the Host PLC. If this option is enabled, the Host PLC will start the VHP Generator cycles. If this option is disabled, the Host PLC is not able to start a cycle. Refer to the External Interface procedure (STERIS Part Number P129383-161) for more information.

SYSTEM OPTIONS	
Engineering Mode	
F1-Enable	DISABLE
F5-Disable	
F4-Previous	F8-Next

This option (above) enables or disables use of additional features or options intended for validation or verification use of the VHP Generator. If this option is enabled, all the parameters and cycle setpoints may be changed during a cycle run (permitted by pressing ESC from the Run Screen). This option should not be enabled during normal cycle operation.

SYSTEM OPTIONS	
Airflow Units	
F1-cmh	cmh
F5-cfm	
F4-Previous	F8-Next

This option (above) determines the displayed/printed units of airflow readings/calculations. Unit “cmh” is cubic meters per hour, and unit “cfm” is cubic feet per minute. This option may be changed after airflow calibration is done.

SYSTEM OPTIONS	
Pressure Units	
F1-Pa	Pa
F5-”wc	
F4-Previous	F8-Next

This option (above) determines the displayed/printed units of pressure readings. Unit “”wc” is inches of water column, and unit “Pa” is Pascals. This option may be changed after pressure (optional enclosure pressure) calibration is done

SYSTEM OPTIONS	
Temperature Units	
F1-°C	°C
F5-°F	
F4-Previous	F8-Next

This option (above) determines the displayed/printed units of temperature readings. Unit “°C” is degrees Celsius, and unit “°F” is degrees Fahrenheit. This option may be changed after temperature calibration is done.

SYSTEM OPTIONS	
Volume Units	
F1-cf	cf
F5-cm	
F4-Previous	F8-Next

This option (above) determines the displayed/printed units of Enclosure Volume readings. Unit “cf” is Cubic Feet, and unit “cm” is Cubic Meters.

6.5.3.4 Print System Configuration (F6)

This printout documents system setpoints and options to the printer at the Operator Interface. This print is also provided in each cycle printout.

6.5.3.5 Set Time/Date (F1)

The time of day is set and operated in military units (hours:minutes:seconds) and the date is set and operated in format month/day/year (m-d-y). After entering in the desired time and/or date, press F3 to set the values.

Time hh:mm:ss	
(MIL) xx:xx:xx	
Date mm-dd-yyyy	F3
M-D-Y xx-xx-xxxx	SET

6.5.3.6 Set Passwords (F2)

Passwords may be set for multiple operators and the supervisor, set as 4-digit numbers from 0-9999. The operator passwords correspond to users 1-10 and allow entry to the Operating Mode only. The supervisor password allows entry to Operator Mode and Supervisor Mode. Press F4 / F8 to scroll up/down for entry of additional passwords.

OPERATOR PASSWORDS	
1-xxxx	4-xxxx
2-xxxx	5-xxxx
3-xxxx	6-xxxx
F4-Previous	F8-Next

OPERATOR PASSWORDS	
7-xxxx	9-xxxx
8-xxxx	10-xxxx
F4-Previous	F8-Next

OPERATOR PASSWORDS	
11-xxxx	
F4-Previous	F8-Next

6.5.3.7 Set Utility Shutdown (F3)

Utility Shutdown and Restart times may be set for each day of the week. If the Utility Shutdown option is Enabled, the vaporizer will turn off from the shutdown time to the restart time and regeneration will start. Press F4/F8 to scroll up/down for entry of additional setpoints.

UTILITY SHUTDOWN	
Utility Shutdown	
F1-Enable	DISABLED
F5-Disable	
F4-Previous	F8-Next

Scroll Down. Use the numeric keypad to enter the Utility Shutdown and Restart time. Time appears on the PV300 Display as it is being entered.

UTILITY SHUTDOWN	
Monday	
Shutdown hh:mm	
Restart hh:mm	
F4-Previous	F8-Next

Scroll down to enter the Utility Shutdown and Restart times for each day of the week.

During Utility Shutdown, the PV300 Display will show the following screens.

Cycle-UTL
Time Rem.: hh:mm:ss
Phase: Regen HeatUP
F5-ABORT

While in Regeneration Heat Up.

Cycle-UTL
Time Rem.: hh:mm:ss
Phase: Regen CoolDown
F5-ABORT

While in Regeneration Cool Down.

Utility Shutdown
Restart Time
Monday: hh:mm
F5-ABORT

When Regeneration is complete.

6.5.3.8 Cycle Setup Selection (F2)

The Cycle Setup Selection (F2) screen enables selection of the cycle to be set up or edited. Thirteen selectable cycles are available.

CYCLE SELECTION	
F1-#1-xxxxxx	
F2-#2-xxxxxx	
F3-#3-xxxxxx	
F4-Previous	F8-Next

Where: nn=the number of the last cycle selected/run.
xxxxxx=set name of the particular cycle.
F1 = Edit Cycle #1 setpoints.
F2 = Edit Cycle #2 setpoints.
F3 = Edit Cycle #3 setpoints.
F8 = Scrool down screen.

Scroll-down screens allow for selection of additional cycles, using buttons F1-F3:

CYCLE SELECTION nn	
F1-#4-xxxxxx	
F2-#5-xxxxxx	
F3-#6-xxxxxx	
F4-Previous	F8-Next

CYCLE SELECTION nn	
F1-#13-xxxxxx	
F2-#14-xxxxxx	
F3-#15-xxxxxx	
F4-Previous	F8-Next

CYCLE SELECTION nn	
F1-#7-xxxxxx	
F2-#8-xxxxxx	
F3-#9-xxxxxx	
F4-Previous	F8-Next

CYCLE SELECTION nn	
F1-#16-xxxxxx	
F2-#17-xxxxxx	
F3-#18-xxxxxx	
F4-Previous	F8-Next

```
   CYCLE SELECTION  nn
F1-#10-xxxxxx
F2-#11-xxxxxx
F3-#12-xxxxxx

F4-Previous          F8-Next
```

Where: xxxxxx=cycle name for the respective cycle.

Once a cycle selection is made, the control advances to the Cycle Setup screen.

6.5.3.9 Cycle Setup

Cycle setpoints are set from this screen. Each of the available cycles is set up in the same way.

```
        CYCLE SETUP   ##
     F1-Cycle Name
     F2-Print Cycle
     F3-Leak Test
     F5-Dehumidify

F4-Previous                F8-Next
```

F1 = Set cycle name (printed at the cycle printout header).
F2 = Print cycle setpoints.
F3 = Set cycle Leak Test setpoints.
F5 = Set cycle Dehumidify phase setpoints.
F8 = Scroll down screen.
F4 = Scroll up screen
= Cycle Number Selected.

The Scroll down screen shows the following.

```
        CYCLE SETUP   ##
    F1-Conditioning
    F2-Decontaminate
    F3-Aeration
    F5-Pressure Control

F4-Previous          F8-Next
```

F1 = Set cycle Condition phase setpoints.
F2 = Set cycle Decontaminate phase setpoints.
F3 = Set cycle Aeration phase setpoints.
F5 = Set cycle Pressure Control phase setpoints.
F8 = Scroll down screen.
F4 = Scroll up screen
= Cycle Number Selected.

The Scroll down screen shows the following.

```
        CYCLE SETUP   ##
    F1-Enclosure Control
    F2-I/O Control
    F3-Vaporizer Setup
    F5-Preheater Setup

F4-Previous          F8-Next
```

F1 = Set cycle Enclosure Control phase setpoints.
F2 = Enable/disable phase inputs/outputs.
F3 = Set cycle Vaporizer temperature.
F5 = Set cycle Preheater temperature.
F4 = Scroll up screen
= Cycle Number Selected.

- Set Cycle Name (F1)
  The cycle name is printed at the header of the cycle printout.

```
        CYCLE NAME   ##
_____
_____I
```

The user may set two lines of characters.

- Print cycle (F2)
  This printout documents cycle setpoints and is also provided in each cycle printout (refer to Cycle Report Printout paragraph in Operator Mode Section).

- Set Leak Test Setpoints (F3)
  The cycle name is printed at the header of the cycle printout.

LEAK TEST SETPOINTS	
Leak Test Enable	
F1-Enable	DISABLED
F5-Disable	
F4-Previous	F8-Next

This setpoint (above) enables or disables the Leak Test portion of the cycle. The Leak Test is a pressure leak test of the enclosure.

LEAK TEST SETPOINTS	
Enclosure Pressure	
75.0 Pa	
F4-Previous	F8-Next

This setpoint (above) is the enclosure pressure value at which the enclosure is pressurized, and may be set from 0.00-622.00 Pa or “WC.

LEAK TEST SETPOINTS	
Cycle Airflow	
14 cmh	
F4-Previous	F8-Next

This setpoint (above) is the cycle airflow maintained during the pressurization portion of the Leak Test, and may be set from 0-999 cfm. The normal range is 8-20 scfm (14-34 cmh).

LEAK TEST SETPOINTS
Max. Pressure Time
5 Minutes
F4-Previous F8-Next

This setpoint (above) is the maximum allowed time for pressurization of the enclosure, and may be set from 0-999 minutes. If the measured time period exceeds this value, a Leak Test Failure alarm occurs and the cycle is aborted.

LEAK TEST SETPOINTS
Maximum Leak Rate
15.0 Pa/min
F4-Previous F8-Next

This setpoint (above) is the maximum allowed pressure leak rate of the enclosure during the Leak Test, and may be set from 0.00-622.00 Pa/minute or “WC/minute. A measured leak rate higher than this value forces a Leak Test Failure alarm and aborts the cycle.

LEAK TEST SETPOINTS
Pressure Stable Time
2 Minutes
F4-Previous F8-Next

This setpoint (above) is hold period after pressurization is stopped before the timed Leak Test phase is started, and may be set from 0-999 minutes.

LEAK TEST SETPOINTS
Print Interval
1.0 Minutes
F4-Previous F8-Next

This setpoint (above) is the enclosure pressure status print interval during the Leak Test Cycle, and may be set from 0.0-999.9 minutes.

- Set Dehumidify Phase Setpoints (F5)
  The cycle name is printed at the header of the cycle printout.

DEHUMIDIFY SETPOINTS
TIME
00:00
HH:MM
F4-Previous F8-Next

This setpoint (above) is the Dehumidify phase time, in hours and minutes, and may be set from 00:00-99:59 minutes:seconds.

DEHUMIDIFY SETPOINTS
Cycle Airflow Rate
30 cmh
F4-Previous F8-Next

This setpoint (above) is the controlled cycle airflow rate during the Dehumidify phase, and may be set from 0-999 cfm or cmh. The normal operable range of cycle airflow is 8.0 to 20 cfm (14 to 34 cmh).

DEHUMIDIFY SETPOINTS
Absolute Humidity
x.x (mg/l)
F1 – 2.3 F2 – 4.6 F3 – 6.9
F4-Previous F8-Next

This setpoint (above) is the required Enclosure Absolute Humidity level, and may be set to 2.3, 4.6, 6.9 mg/L. This setpoint measures the amount of water in the enclosure's air at a specific temperature. Refer to the Appendix located at the end of this manual for the Relative Humidity equivalents.

DEHUMIDIFY SETPOINTS
Print Interval
10.0 minutes
F4-Previous F8-Next

This setpoint (above) is the status print interval during the Dehumidify phase, and may be set from 0.0-999.9 minutes. Pertinent data is printed at each printout.

- Set Conditioning Phase Setpoints (F1)
  The cycle name is printed at the header of the cycle printout.

CONDITION SETPOINTS	
H_2O_2 Injection Print	
F1-Enable	ENABLED
F5-Disable	
F4-Previous	F8-Next

This setpoint (above) determines whether a printout is made every minute of the measured injection rate.

CONDITION SETPOINTS
TIME
00:00
HH:MM
F4-Previous F8-Next

This setpoint (above) is the Condition phase time, in hours and minutes, and may be set from 00:00-99:59 minutes:seconds.

CONDITION SETPOINTS
Cycle Airflow Rate
30 cmh
F4-Previous F8-Next

This setpoint (above) is the controlled cycle airflow rate during the Condition phase, and may be set from 0-999 cfm or cmh. The normal operable range of cycle airflow is 8 to 20 cfm (14 to 34 cmh).

CONDITION SETPOINTS
H_2O_2 Injection Rate
5.0 g/min
F4-Previous F8-Next

This setpoint (above) is the controlled H_2O_2 injection rate, and may be set from 0.0-99.9 grams/minute. The normal operable range of injection rate is 1.0 to 12.0 grams/minute.

CONDITION SETPOINTS	
Print Interval	
10.0 minutes	
F4-Previous	F8-Next

This setpoint (above) is the status print interval during the Condition phase, and may be set from 0.0-999.9 minutes. Pertinent data is printed at each printout.

- Set Decontamination Phase Setpoints (F2) The cycle name is printed at the header of the cycle printout.

DECONTAMINATION SETPOINTS	
H_2O_2 Injection Print	
F1-Enable	ENABLED
F5-Disable	
F4-Previous	F8-Next

This setpoint (above) determines whether a printout is made every minute of the measured injection rate.

DECONTAMINATION SETPOINTS	
TIME	
xx:xx	
HH:MM	
F4-Previous	F8-Next

This setpoint (above) is the decontamination phase time, in hours and minutes, and may be set from 00:00-99:59 minutes:seconds.

DECONTAMINATION SETPOINTS	
Cycle Airflow Rate	
30 cmh	
F4-Previous	F8-Next

This setpoint (above) is the controlled cycle airflow rate during the decontamination phase, and may be set from 0-999 cfm or cmh. The normal operable range of cycle airflow is 8 to 20 cfm (14 to 34 cmh).

DECONTAMINATION SETPOINTS
H_2O_2 Injection Rate
12.0 g/min
F4-Previous F8-Next

This setpoint (above) is the controlled H_2O_2 injection rate, and may be set from 0.0-99.9 grams/minute. The normal operable range of injection rate is 1.0 to 12.0 grams/minute.

DECONTAMINATION SETPOINTS
Print Interval
10.0 minutes
F4-Previous F8-Next

This setpoint (above) is the status print interval during the decontamination phase, and may be set from 0.0-999.9 minutes. Pertinent data is printed at each printout.

- Set Aeration Phase Setpoints (F3)
  The cycle name is printed at the header of the cycle printout.

AERATION SETPOINTS
TIME
00:15
HH:MM
F4-Previous F8-Next

This setpoint (above) is the Aeration phase time, in hours and minutes, and may be set from 00:00-99:59 minutes:seconds. It is recommended that this time period be set to no less than 15 minutes, to allow for cooling of the VHP Generator heaters.

AERATION SETPOINTS	
Cycle Airflow Rate	
30 cmh	
F4-Previous	F8-Next

This setpoint (above) is the controlled cycle airflow rate during the Aeration phase, and may be set from 0-999 cfm or cmh. The normal operable range of cycle airflow is 8 to 20 cfm (14 to 34 cmh).

AERATION SETPOINTS	
Print Interval	
30.0 minutes	
F4-Previous	F8-Next

This setpoint (above) is the status print interval during the Aeration phase, and may be set from 0.0-999.9 minutes. Pertinent data is printed at each printout.

AERATION SETPOINTS	
Aux. Aeration TIME	
00:15	
HH:MM	
F4-Previous	F8-Next

This setpoint (above) is the Auxiliary Aeration phase time, in hours and minutes, and may be set from 00:00-99:59 minutes:seconds.

AERATION SETPOINTS	
Blower On After	
Aeration: YES	
F1-Yes	F5-No
F4-Previous	F8-Next

Press F1 to select the chamber blower ON after the Aerate phase (Auxiliary Aerate), or press F5 to have the chamber blower OFF after the Aerate phase (Auxiliary Aerate).

- Set Pressure Control Setpoints (F5)
  The cycle name is printed at the header of the cycle printout.

ENCL. PRESS. SETPOINTS		
CYCLE PRESS. CONTROL		
PRESSURE		
F1-PRES	F2-VAC	F3-NO
F4-Previous		F8-Next

Press F1 (to control at positive pressure) or F2 (to control at negative pressure) to select the cycle pressure control or press F3 for NO cycle pressure control.

ENCL. PRESS. SETPOINTS	
Nominal Press. Diff:	
200.00 Pa	
F4-Previous	F8-Next

This setpoint (above) is the controlled cycle Nominal Pressure Differential, and may be set from 00.00-999.99 Pa or “wc. Use the touch pad to enter a value for the Nominal Pressure Differential. The normal range is 0.00 to 622.00 Pa (0.00 to 2.50 “wc).

NOTE: It is the Operator’s responsibility to ensure the selected Operating Pressure (or Vacuum) does not exceed the enclosure manufacturer’s recommendations.

ENCL. PRESS. SETPOINTS	
Low Pressure Alarm	
Setpoint: 370.00 Pa	
Abort Tm: 35 sec.	
F4-Previous	F8-Next

This setpoint (above) is for the Low Pressure Alarm, the low limit that the enclosure will maintain a pressure or vacuum before an alarm occurs. The low alarm setpoint is closer to atmosphere than the high alarm setpoint (see above). Once the proper enclosure pressure has been reached, if the enclosure pressure

exceeds the low alarm setpoint, the cycle will be aborted AFTER the LOW Pressure Alarm Abort timeout has expired.

ENCL. PRESS. SETPOINTS
High Pressure Alarm
Setpoint: 0.00 Pa
Abort Tm: 35 sec.
F4-Previous F8-Next

This setpoint (above) is for the High Pressure Alarm, the high limit that the enclosure will maintain a pressure or vacuum before an alarm occurs. The high alarm setpoint is further away from atmosphere than the low alarm setpoint (see below). Once the proper enclosure pressure has been reached, if the enclosure pressure exceeds the high alarm setpoint, the cycle will be aborted AFTER the HIGH Pressure Alarm Abort timeout has expired.

ENCL. PRESS. SETPOINTS
Pressurize Timeout
xx:xx
MM:SS
F4-Previous F8-Next

Use the touch pad to enter a value for the Pressurize Timeout. This timeout (maximum time to reach pressure) is the maximum time for the VHP Generator to reach the enclosure pressure or vacuum. If this time is exceeded, the cycle ABORTS.

- Set Enclosure Control (F1)
  The cycle name is printed at the header of the cycle printout.

```
ENCL. SETPOINTS
Enc. Type: FLEXIBLE
F1-Rigid                F2-Flexible
F3-Semi Rigid
F4-Previous             F8-Next
```

F1 = If the enclosure is made of a rigid material (for example, glass).
F2 = If the enclosure is made of a flexible material (for example, plastic).
F3 = If the enclosure is made of a combination of flexible and rigid materials.
F4 = Scroll down screen.

```
ENCL. SETPOINTS
Enc. Volume: xxx cm

F4-Previous             F8-Next
```

This setpoint (above) is the enclosure volume to be used for the selected cycle. Enclosure volume range is 0.0-9999 cm (0.0-9999 cf).

- I/O Control Setpoints (F2)
  The cycle name is printed at the header of the cycle printout.

```
I/O CONTROL
Utilize I/O Control?
YES
F1-YES          F2-NO
F4-Previous     F8-Next
```

F1 = To enable the use of Phase Inputs and Outputs for this cycle.
F2 = To disable the use of Phase Inputs and Outputs for this cycle.
F3 = If the enclosure is made of a combination of flexible and rigid materials.
F4 = Scroll up screen.
F8 = Scroll down screen

I/O CONTROL	
Dehumidify	
Phase Output = NO	
F1-YES	F5-NO
F4-Previous	F8-Next

F1 = To enable the use of Phase Output for the Dehumidify Phase.
F5 = To disable the use of Phase Output for the Dehumidify Phase.
F4 = Scroll up screen.
F8 = Scroll down screen

NOTE: If Phase Output is selected for a phase (YES), the output will only be ON if I/O Control is enabled (YES).

Use F4/F8 Keys to scroll between screens and enable or disable Phase Outputs for the following phases.

- Dehumidify
- Condition
- Decontaminate
- Aeration
- Auxiliary Aeration
- Out of Cycle

NOTE: The external output may be 24 VAC or 24 VDC, maximum 1.0 Amp.

Continue to scroll down to find settings for Phase Inputs.

I/O CONTROL	
Dehumidify	
Phase Input = NO	
F1-YES	F5-NO
F4-Previous	F8-Next

F1 = To have the external input detected for the Dehumidify Phase.
F5 = To ignore the external input for the Dehumidify Phase.
F4 = Scroll up screen.
F8 = Scroll down screen.

NOTE: If Phase Input is selected for a phase (YES), the input will only be detected if I/O Control is enabled (YES) for the cycle. Also, if the Phase Input is enabled for a phase, and the external input is open during the selected phase, the cycle automatically ABORTS.

Use F4/F8 Keys to scroll between screens and enable or disable Phase Inputs for the following phases.

- Dehumidify
- Condition
- Decontaminate
- Aeration

- Vaporizer Setpoints (F3)
  The cycle name is printed at the header of the cycle printout.

VAPORIZER SETPOINTS	
Vap. Temp. (In Cycle)	
100.0 C	
F4-Previous	F8-Next

This setpoint (above) is the temperature at which the vaporizer heater is maintained when the VHP Generator is in-cycle, and may be set from 0.0-300.0°C/°F. This value is normally set to 100.0°C to ensure proper vaporization of the H_2O_2 during injection phases.

- Preheater Setpoints (F5)
  The cycle name is printed at the header of the cycle printout.

PREHEATER SETPOINTS	
Pre. Temp. (In Cycle)	
90.0 C	
F4-Previous	F8-Next

This setpoint (above) is the temperature at which the preheater is maintained when the VHP Generator is in-cycle, and may be set slightly below the "Vap. Temp. (In Cycle)" value to aid the vaporizer in maintaining its setpoint temperature during injection phases.

6.5.3.10 Save Cycle Setup Changes

Press F4 at one of the Cycle Setup screens and after made changes the following screen appears.

Save the Changes to Cycle nn?	
	F2-Edit
F1-Save	F5-Exit

Where: nn=the selected cycle number (1-13)
F2 = Return to Cycle Setup for the selected cycle.
F1 = Save changes made to selected cycle and exit Cycle Setup.
F5 = Ignore changes made to selected cycle and exit Cycle Setup.

7.0 Sequence of Operation for the VHP Generator

7.1 Installing Sterilant Cartridge
The control displays a message when the sterilant cartridge needs replacement. Also, the windowed door on the sterilant cartridge compartment allows to easily check the cartridge to see when it is empty.

7.1.1 Put on chemical splash goggles, vinyl or neoprene gloves and protective clothing.

7.1.2 Turn the cartridge control knob clockwise 180° to the REPLACE position and open the cartridge compartment door.

7.1.3 Gently grasp the spent cartridge with both hands. Carefully lift the cartridge about 1/16” and then remove the cartridge from the holder.

7.1.4 With water running in a sink, empty all remaining cartridge contents into the sink. When the cartridge is empty, carefully and thoroughly rinse the cartridge with tap water before disposal.

7.1.5 Remove a new cartridge from the carton. Check the expiration date on the new cartridge. Do not use the cartridge if beyond its expiration date listed on the label. Additionally, only use QC released VHP cartridge.

7.1.6 Remove the vented shipping cap from the new cartridge.

7.1.7 Gently grasp the new cartridge with both hands, align it with the groove in the cartridge holder, and carefully slide it all the way into the holder. Lower the cartridge into the 1/16” recess in the holder.

7.1.8 Turn the cartridge control knob clockwise 180° to the ENGAGE position. Do not turn the knob past this position.

7.1.9 The cartridge is now locked in place and cannot be removed until the cartridge control knob is turned to the REPLACE position. Once the cartridge control knob is turned to the replace position, the previously used cartridge is rendered unusable regardless of the amount of liquid remaining.

7.1.10 Close the cartridge compartment door. Select “Reservoir Fill” command from the PLC and the VHP Generator unit will now automatically fill to the programmed level.

NOTE: Always turn the cartridge control knob clockwise. The cartridge is not properly installed if it does not rest in the recess. Do not use the cartridge beyond its expiration date or 45 days after installation.

Running a Decontamination Cycle

7.2 Running a Decontamination Cycle

7.2.1 The cycle proceeds as shown in the following table. Operator action may be required during the Reservoir Fill phase and at Cycle Complete. A cycle printout is generated if the system printer in enabled.

Decontamination Cycle Sequence		
Phase Name	Process Description	Phase Advance Requirement
Standby or Main Menu	Idle state, ready to run cycle	Start Cycle command
Reservoir Fill	If the Reservoir does not contain enough H_2O_2 to complete the selected cycle, the reservoir is filled from the H_2O_2 Cartridge.	Required reservoir weight (per the selected cycle) is met
Inject. Prime	The injection line is primed with H_2O_2 liquid. This phase removes air from the injection line in preparation for injection and also purges the fill line.	Setpoint time expired
Dehumidity	Airflow through VHP Generator is maintained at Dehumidify phase cycle airflow setpoint. Phase operates by time and by relative humidity setpoint.	Humidity level meets setpoint and setpoint time expired
PreHTR Warm-up	The preheater is heated to setpoint temperature.	Temperature meets setpoint
Vapor Warm-up	The vaporizer is heated to setpoint.	Temperature meets setpoint temperature.
Condition	Airflow control is maintained per Condition phase setpoint. Injection of vapor hydrogen peroxide begins and is controlled according to set rate for the Condition phase.	Setpoint time expired
Decontaminate	Airflow control is maintained per Decontamination phase setpoint. Injection of vapor hydrogen peroxide begins and is controlled according to set rate for the Decontamination phase.	Setpoint time expired
Aeration	Airflow control is maintained per Aerate phase setpoint and injection is stopped.	Setpoint time expired
Auxiliary Aeration	Airflow control is maintained per Aerate phase setpoint if the blower is enabled during this phase.	Setpoint time expired or manual phase advance.
Cycle Complete	Airflow is stopped. Cycle is completed.	Operator acknowledgment

7.2.2 During the cycle Reservoir Fill phase of the cycle, the VHP Generator determines the VHP Generator determines the amount of H_2O_2 required for the cycle and, if the Reservoir contains less than the required amount, the reservoir filled with H_2O_2.

7.2.3 The required amount is 20 grams more than the necessary amount per the Condition and Sterilize phase setpoint times and injection rates.

7.2.4 Filling occurs by means of the following procedure.

7.2.4.1 Before filling begins, the VHP Generator performs a brief check of the filling system.

7.2.4.2 If the filling system check is successful, filling begins. If not successful, the cycle is aborted and an alarm message is shown.

7.2.4.3 If the VHP Generator detects the H_2O_2 cartridge is empty and the cycle is not yet complete, an alarm is indicated with the message: "H_2O_2 SUPPLY EMPTY" and filling is stopped. Proceed as follows.

- Set the Cartridge Control Knob to REPLACE and remove the cartridge.
- If the cartridge is not empty, there is a problem in the filling system or with the cartridge itself; otherwise, install a new cartridge.
- Set the knob to ENGAGE, the alarm screen will clear and filling will resume.

7.2.4.4 Filling is completed once the Reservoir weight has met the required amount.

7.2.5 Depending upon the External Interface options used, the VHP Generator will pause at certain cycle phases until a handshake signal is received from the interface.

7.2.6 If a cycle is started from the Host PLC, the VHP Generator will pause at the Vaporizer Warm-up phase after its normal phase requirement is met, until a signal received from the interface.

7.2.7 This is done to allow external equipment to prepare the VHP Generator for the cycle at the same time that the external equipment prepares the enclosure for decontamination. During this time, the display will show the following:

```
Cycle-#nn          RD
Time Rem.: 00:00:00
Phase: Vapor. Warm-up
-ACTIVE-           F5-ABORT
F4-Previous        F8-Next
```

Where: nn = selected cycle, set per the Cycle Selection screen. "RD" indicates that the cycle is paused until a signal is received from the External Interface.

7.2.8 At completion of the Decontamination cycle, the Unit holds until acknowledgement is received from the operator or from the Host PLC. The display shows the following:

```
Cycle-#nn
Time Rem.: 00:00:00
Phase: Cycle Complete
F2-RESET
F4-Previous                F8-Next
```

Where: nn = selected cycle, set per the Cycle Selection screen.

7.2.9 Operator acknowledgement occurs by pressing the F2 touchpad. Once acknowledgement is received (from the operator or Host PLC), the VHP Generator returns to the Main Menu.

NOTE: If the cycle is an aborted cycle, the display indicates "ABORT" to the right of the cycle number indication.

7.3 Running a Regeneration Cycle After Decontamination Cycle.

7.3.1 The Run Screen will appear on PV300 Display. Phase should read: "Reagent HEAT UP". Press F1 to START cycle.

```
Cycle-#nn
Time Rem.: 00:00:00
Phase: Regen HEAT UP
F1-START              F5-ABORT
F4-Previous             F8-Next
```

7.3.2 Once the cycle has started, use F8 to get to "Dryer Temp." Screen.

Dryer Temp.
S:aaaa. A: bbbb xx
H_2O_2 Return Temp.
S: cccc. A: dddd xx

Where: aaaa=Setpoint Dryer temperature.
bbbb=Actual Dryer temperature.
cccc=Setpoint H_2O_2 Retyrn temperature.
dddd=Actual H_2O_2 Return temperature.
Xx=C or F, depending upon temperature unit set.

7.3.3 The HEAT UP phase of cycle begins. The Dryer temperature will heat up to at least 400°F (204°C). The phase will end when 212°F (100°C) is achieved by H_2O_2 return RTD (Resistive Temperature Detector).

7.3.4 The COOL DOWN phase will follow. The dryer temperature will cool down. The phase will end when 130°F (54.4°C) or less is achieved by H_2O_2 return RTD, or after two hours has elapsed, whichever occurs first.

7.3.5 When the cycle is complete, press F1 (PRINT REPORT) from the Operator Screen for a complete duplicate print of the cycle. Press F2 (RESET) to advance to the Main Operator Screen.

7.4 Manually Drain Reservoir

7.4.1 The manually Drain Reservoir Cycle is available in Service Mode only. Only qualified Service Technician should perform this cycle.

8.0 Reference

8.1 Operator Manual VHP® 1000ED-AB Biodecontamination System P129383-120 (09/11/03).