ConFirm™ 20 Minute Incubator
Operator Manual
REF RR20READER

KEY

❶	Well Blocks
❷	Well LED
❸	LCD Screen
❹	Temperature Display (Use Up/Down arrows to view)
❺	HOME Button
❻	NAVIGATION Up Button
❼	NAVIGATION Down Button
❽	ENTER Button
❾	Barcode Scanner
❿	Name Plate
⓫	Power Cord Inlet
⓬	USB Port (For HuFriedyGroup Use Only)
⓭	RS-232 Communication Port (Printer Connectivity)
⓮	RJ-45 Communication Port (Network Connectivity)

RECOMMENDED PRINTER SPECIFICATIONS:

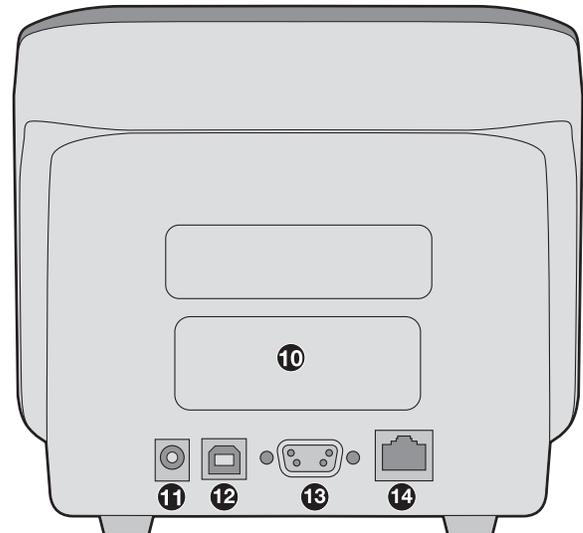| |
|---|
| Thermal Line Printer |
| Minimum Dot Density 200 DPI x 200 DPI |
| 32-42 Columns |
| 1/6 inch line spacing |
| 14K Byte Minimum Data Buffer |
| Interface: RS-232 |

INCUBATOR - TOP VIEW

INCUBATOR - BACK VIEW

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⚠ WARNING:

- For indoor use only.
- Do not immerse.
- Clean only with recommended products.
- Unit does not contain any user serviceable parts. Return to HuFriedyGroup for authorized repairs (Call authorized sales representative or HuFriedyGroup Customer service).
- To avoid personal injury or damage to device use the properly rated power cord supplied.
- The Incubator is intended to be used solely with ConFirm™ Rapid 20 Minute BIs. Do not substitute any other products for the ConFirm™ Rapid 20 Minute BIs.
- Do not remove BI from well during incubation for more than 10 seconds until result is shown. Removal of BI may invalidate test.

⚠ Caution:

- To avoid possible environmental contamination, dispose of the Incubator per applicable government regulations.
- To avoid incorrect readings, place the ConFirm™ Rapid 20 Minute BI vial so that it does not come into direct contact with chemical indicators or tape.
- Do not touch the hot surface of the metal incubator block.
- Do not use abrasive materials to clean or disinfect the Incubator.
- To avoid incorrect readings, do not place the Incubator in an environment exposed to direct sunlight or strong incandescent light.
- To avoid incorrect readings, do not move the Incubator while incubation is in-progress.
- Do not spray water, cleanser, or disinfectant on or into the Incubator.

⚠ **Well blocks may be HOT. Use caution when inserting BI.**

A. Product Description:

The ConFirm™ 20 Minute Incubator is designed exclusively to incubate and read activated ConFirm™ Rapid 20 Minute Biological Indicators (BIs). The device serves as both an Incubator and a fluorescence detector. The Incubator heats the activated BIs to temperatures which promote the metabolism and subsequent detection of viable test organisms under evaluation. While the activated BI is incubating, viability is determined by an increase in a fluorescent signal from the enzymatic breakdown of a fluorogenic substrate present in the media.

B. Intended Use:

Use the ConFirm™ 20 Minute Incubator to incubate and automatically read ConFirm™ Rapid 20 Minute Biological Indicators for Steam and Vaporized Hydrogen Peroxide sterilization at 55°C-60°C for a fluorescent result.

Refer to the Instructions for Use for the ConFirm™ Rapid 20 Minute BIs to confirm the validated readout times.

C. Specifications:

AC Input Voltage:	100-240 VAC +/-10%	Audible Alarm:	Low: 50-60 dB Medium: 70-80 dB High: 80-100 dB
AC Input Frequency:	50-60 Hz		
Input Current:	1.0A (rms) max		
Overvoltage:	Category II	Weight:	3 lbs 10 oz (1.64 kg)
Operating voltage:	12 VDC	Dimensions:	6.5 (W) x 6.0 (H) x 11 (D) inches 165 (W) x 153 (H) x 280 (D) mm
Operating current:	3.0 A max		
Well Temperature Specifications:	55-60°C	Incubator Environmental Conditions	
Detection Modes:	Fluorescence	Temperature:	15°C-40°C/59°F-104°F
Emissions Wavelength:	410-450 nm	Relative Humidity:	20-80%
		Altitude:	Up to 2000 m
User Interface:	LCD and Navigation Buttons	Pollution degree:	2
Interface with Optional Printer:	RS-232 port	Degree of ingress protection per IEC 60529:	IPX0

⚠ **Caution:**

To avoid incorrect readings, do not place the Incuabator in an environment exposed to direct sunlight or strong incandescent light.

Device Safety Information

The Incubator meets the applicable requirements for the following standards:

- Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements [UL 61010-1:2012 Ed.3+R:19 Jul 2019]
- Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements [CSA C22.2#61010-1-12: 2012 Ed.3+U1; U2; A1
- Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 2-010: Particular Requirements for Laboratory Equipment for The Heating of Materials [UL 61010-2-010:2019 Ed.4; CSA C22.2#61010-2-010:2019 Ed.4]
- EMC Directive 2014/30/EU
- EN 61326-1; EN 55011
- FCC CFR 47, Part 15, subpart B:2007
- ICES-003, Issue 7: 2020
- AS/NZS CISPR 11:2011
- IEC 61326-1
- EMC Testing CISPR 11
- KS C 9811

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at the user's own expense.

Product & Packaging Label Symbols

Symbol	Definition	Symbol	Definition
	Manufacturer		Tested to comply with FCC standards
	Mark of Conformity to European Directives		Compliant to all applicable ACMA regulatory arrangements (RCM)
	ETL Listed to US and Canadian Safety Standards	REF	Catalog number

D. Getting Started

Description

The ConFirm™ 20 Minute Incubator is intended to incubate and read the ConFirm™ Rapid 20 Minute Biological Indicators (BI). The ConFirm™ Rapid 20 Minute BIs are intended for use in monitoring and qualification of steam and vaporized hydrogen peroxide sterilization processes and to be used exclusively with the ConFirm™ 20 Minute Incubator. The Incubator is designed to detect the presence or absence of a fluorescent signal upon incubation of the ConFirm™ Rapid 20 Minute BIs. Each of the eight wells has dedicated optics for excitation and detection. Once initiated, each well will independently monitor and determine the result for an individual BI within the validated readout time. The Incubator also features a Barcode Scanner that is located on the front end of the Incubator. The barcode scanner is used to the scan the barcode on the BI label to ensure proper reading and allows for quick and easy BI documentation.

⚠️ **WARNING: The Incubator is intended to be used solely with ConFirm™ Rapid 20 Minute BIs. Do not substitute any other products for the ConFirm™ Rapid 20 Minute BIs.**

Unpacking and Inspection

Upon receiving and unpacking the Incubator, carefully inspect it for any damage. Check to be certain that all items listed below are included:

- ConFirm™ 20 Minute Incubator
- Power Supply with multiple AC input clips (packaged in a separate box within the Incubator packaging)
- Operator Manual

Instrument Set-up

1. Place the Incubator on a flat, level surface. Position the Incubator so that the LCD screen faces forward and the navigation buttons are easily accessible.

2. Attach the appropriate AC Input Clip to the power supply.

3. Plug the power supply into the power connector on the back panel of the ConFirm™ 20 Minute Incubator. Plug the power supply into a power outlet.

4. If using a printer (optional), plug the larger (25 pin) end of the RS-232 cable into the back of the optional printer and the smaller (9 pin) end of the RS-232 cable into the back panel of the Incubator. Secure both ends of the RS-232 cable using the finger screws on each end of the cable. Follow the printer manual's instructions to plug in the power supply and turn on the printer.

5. To connect to the facility network (optional), plug an RJ-45 LAN cable into the back of the Incubator and a facility LAN port.

6. Set the Language, Date, Time and Network connection (optional) after start-up sequence. Reference section F for more information.

NOTE: USB port is not used for daily operation.

Typical Start-Up Sequence

Hu-Friedy Mfg. Co., LLC. Rev XX.XX.XX Model: RR20READER	Warming To 59.0C <xx:xx> 1 <r>C 5 <r>C 2 <r>C 6 <r>C 3 <r>C 7 <r>C 4 <r>C 8 <r>C	1 5 2 6 3 7 4 8	1 <r>C 5 <r>C 2 <r>C 6 <r>C 3 <r>C 7 <r>C 4 <r>C 8 <r>C
1	**2**	**3**	**4**

1. Once plugged in, Screen 1, shown above, will appear on the Incubator display.

2. The Incubator will automatically begin heating the wells for up to 30 minutes to the previously set temperatures and a diagnostic test will run concurrently. Screen 2 will appear on the Incubator display. NOTE: Ensure no BIs are in the wells during the Warm Up & Diagnostic Testing.

3. When the target temperature has been reached and the diagnostic test has concluded successfully, Screen 3 will display on the LCD. If the diagnostic test fails, cycle power to the Incubator by unplugging for 2 minutes or longer. See Troubleshooting section for guidance.

4. The well temperatures can be checked at any time by pressing the Up and Down Navigation buttons.

E. Routine Operations

Precautions:

Do not use the ConFirm™ 20 Minute Incubator to incubate and read any biological indicator other than the ConFirm™ Rapid 20 Minute BIs. Examples of BIs that should not be used in the ConFirm™ 20 Minute Incubator include, but are not limited to:

- ConFirm™ 24 Steam Biological Indicators
- ConFirm™ 10 Steam Biological Indicators
- SporeCheck™ Steam Biological Indicators
- VERIFY® Assert™ Self Contained Biological Indicator (Clear cap)
- 3M® Attest® Rapid Readout Biological Indicators for steam sterilization
- 3M® Attest® Super Rapid Readout Biological Indicator for steam sterilization

NOTE: BIs processed through steam sterilization may still be hot.

NOTE: BIs processed through vaporized hydtrogen peroxide sterilization may contain residual hydrogen peroxide. Always wear gloves when handling the BI.

BI Activation and Incubation

```
            Insert BI

1              5
2              6
3              7
4              8

```

1. When on the Home Screen, scan the BI by holding the BI in the scanner with the barcode facing up. If necessary, slowly rotate the BI left and right until a beep is heard. The screen as shown on the left will then display "Insert BI". Activate the BI following the BI's Instructions for Use. Confirm media is present in the bottom of the BI vial.

2. Place the activated BI into an empty well of the Incubator. The Incubator will automatically detect and begin reading the BI.

3. A slow flashing green light will indicate that the well is actively in use. At any point in the process, the user may scan and insert additional BIs into any remaining unoccupied wells. Remaining incubation time is displayed on the LCD screen next to the corresponding well number for each incubating BI.

4. Scan, activate and read at least one unprocessed ConFirm™ Rapid 20 Minute BI (positive control) from each lot currently in use, each day that a newly processed BI is incubated. A separate control BI must be run for each type of test BI that is incubated. This will ensure both the validity of the current BI lot and the proper functioning of the Incubator.

   a. Label the sample as the positive control.

   b. Once placed in the well, the Incubator will automatically detect and begin reading the BI.

⚠ **WARNING:** Do not remove BI from well during incubation for more than 10 seconds until result is shown. Removal of BI may invalidate test.

⚠ **Caution:** To avoid incorrect readings, do not move the Incubator while incubation is in progress.

Interpretation of Results

```
1              5
2              6 —
3              7
4              8

```

5. For a Negative result, the Incubator will sound an alarm (a single beep every five minutes) and the LED adjacent to the well will turn from slow flashing green to a rapid flashing green light. The LCD screen will display a "-" next to the well number. The operator must press the ENTER button to acknowledge the result and silence the alarm. Once the result is acknowledged, the LED will turn solid green.

NOTE: The alarm for a negative result is optional and may be turned off. See Changing the Buzzer Mode section for more information.

6. The final negative fluorescence response for a processed BI indicates an acceptable sterilization process. The BI can be removed from the well.

```
1          5
2          6
3 +        7
4          8
```

7. For a positive result, the Incubator will sound an alarm (three beeps every five minutes) and the LED adjacent to the well will turn from slow flashing green to a rapid flashing red light. The LCD screen will display a "+" next to the well number. The operator must press the ENTER button to acknowledge the result and silence the alarm. Once the result is acknowledged, the LED will turn solid red.

    a. The final unprocessed or control BI must show a positive result.

    b. If the processed (test) BI shows a positive result, this indicates a sterilization process failure. Follow facility guidelines for reporting sterilization failures.

F. Options

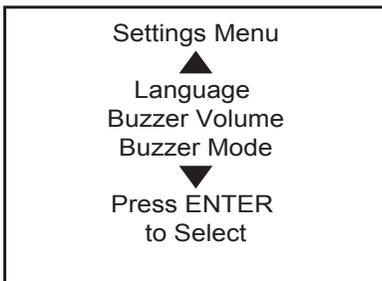To access options, use the following buttons to navigate the Incubator's on screen interface.

(🏠) **HOME Button**   (▼)(▲) **Up and Down NAVIGATION Buttons**   (✓) **ENTER Button**

```
    Settings Menu
         ▲
      Language
    Buzzer Volume
    Buzzer Mode
         ▼
    Press ENTER
     to Select
```

Settings Menu:

Press the **HOME** button on the Incubator. This will bring up the Settings Menu. The Settings Menu screen is displayed on the left. Use the **NAVIGATION** buttons to toggle through the available options and highlight the following options:

Language · Buzzer Volume · Buzzer Mode
**Date · Time · Network · Set Broker IP · Set Broker Port**

Press the **ENTER** button to select the desired option.

```
      Language
         ▲
      English
     Portuguese
      French
         ▼
    Press ENTER
     to Select
```
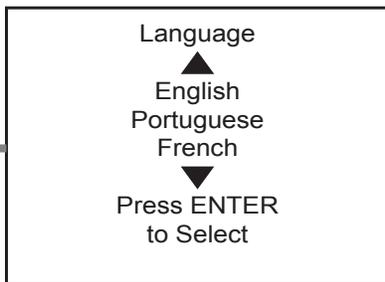
Changing the Language Setting:

The default language in which the incubator will communicate can be set at any time. The Language Selection display screen will appear.
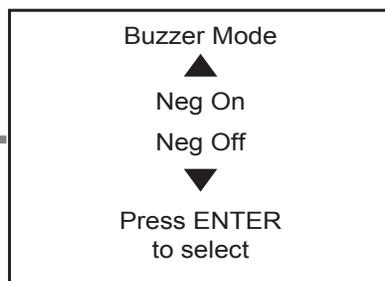
Use the **NAVIGATION** buttons to highlight the desired language and select by pressing the **ENTER** button.

```
    Buzzer Volume
         ▲
        Low
      Medium
       High
         ▼
    Press ENTER
     to Select
```
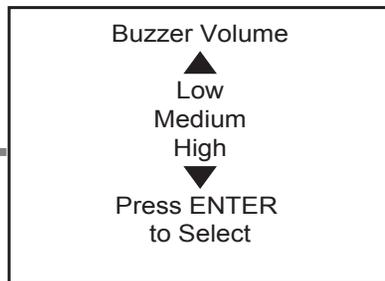
Changing the Buzzer Volume:

The Buzzer Volume has been factory set to "Medium". The setting can be changed at any time.
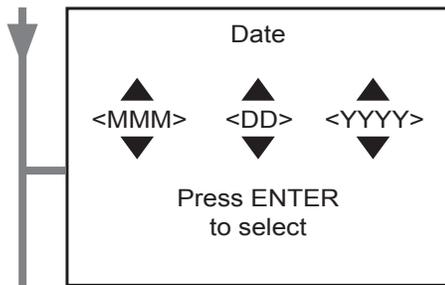
Use the **NAVIGATION** buttons to highlight the desired volume option and select by pressing the **ENTER** button.

```
     Buzzer Mode
         ▲
      Neg On
      Neg Off
         ▼
    Press ENTER
     to select
```

Changing the Buzzer Mode:

The Buzzer Mode has been factory set to "Neg Off". This means that the Incubator will not sound an audible alarm once a negative result is available. This setting can be changed at any time. If "Neg On" is selected, an audible alarm will be sounded once a negative result is available.
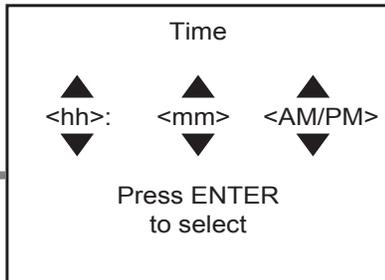
Use the **NAVIGATION** buttons to highlight the desired buzzer mode option and select by pressing the **ENTER** button.

```
          Date

    ▲      ▲      ▲
<MMM>   <DD>   <YYYY>
    ▼      ▼      ▼

     Press ENTER
       to select
```

Changing the Date:

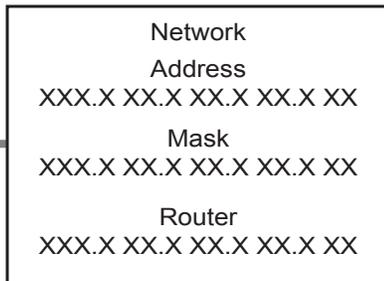The Date can be set during initial Incubator set up and at any time after that.

Use the **NAVIGATION** buttons to highlight the correct month, day and year. Select by pressing the **ENTER** button.

```
          Time

    ▲      ▲      ▲
<hh>:   <mm>  <AM/PM>
    ▼      ▼      ▼

     Press ENTER
       to select
```
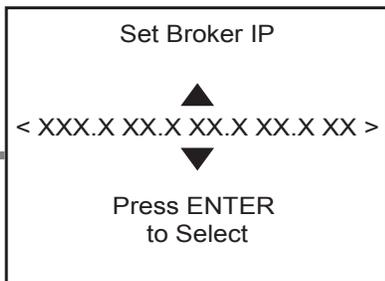
Changing the Time:

The Time can be set during initial Incubator set up and at any time after that.

Use the **NAVIGATION** buttons to highlight the correct hour, minute and am/pm. Select by pressing the **ENTER** button.

```
        Network
        Address
XXX.X XX.X XX.X XX.X XX
          Mask
XXX.X XX.X XX.X XX.X XX
         Router
XXX.X XX.X XX.X XX.X XX
```

View the Network Info:

The device's network address, mask, and router can be viewed at any tme. Dismiss by pressing the **ENTER** button.

```
      Set Broker IP

            ▲
< XXX.X XX.X XX.X XX.X XX >
            ▼

      Press ENTER
       to Select
```

Setting the Process Tracking System IP Address:

The Broker IP adderss can be set when the Incubator is connected to the facility network.

Use the **NAVIGATION** buttons to highlight the correct numeric value. Select by pressing the **ENTER** button. Press the **HOME** button to go back to a previously entered value and follow the steps above to select the correct numeric value.

```
     Set Broker Port

            ▲
     < X  X  X  X  X >
            ▼

      Press ENTER
       to Select
```
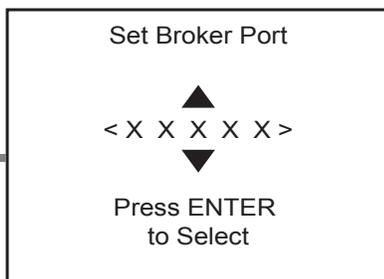
Setting the Process Tracking System Port:

The Broker Port can be set when the Incubator is connected to the facility network.

Use the **NAVIGATION** buttons to highlight the correct numeric value. Select by pressing the **ENTER** button. Press the **HOME** button to go back to a previously entered value and follow the steps above to select the correct numeric value.

G. Cleaning and Care of the Incubator:

⚠️ **Caution: Do not spray water, cleanser, or disinfectant on or into the Incubator.**

⚠️ **Caution: Do not use abrasive materials to clean or disinfect the Incubator.**

To avoid spills within the individual wells:

- Always keep BIs in the upright position when handling to keep recovery media from spilling out of the BI.

If foreign materials get into the wells of the Incubator, please follow the procedure outlined below:

Step 1.   Shut off the Incubator by unplugging it from its power supply.

Step 2.   If the foreign material is dry in nature, e.g. dust, paper or plastic, carefully remove the object(s) using a swab or forceps.

Step 3.   If the foreign material is liquid in nature, e.g. culture medium, carefully blot up the excess moisture using dry swabs.

3a.   Once all the standing liquid is removed, clean the affected area using another swab dampened with deionized water. Then dry completely with a fresh swab.

Step 4.   Test the affected well(s) by first running a diagnostic cycle. If the diagnostic test fails, contact HuFriedyGroup.

Step 5.   If the diagnostic cycle is successful, then scan, activate and insert an unprocessed BI.

Step 6.   If a positive result is indicated, proceed with use of the Incubator. If a positive result is not indicated, the Incubator may have been damaged. Contact HuFriedyGroup or an authorized sales representative.

To clean and disinfect the outside of the Incubator:

Step 1.   Wipe down the Incubator with a paper towel dampened with water. Do not submerge the Incubator in water.

Step 2.   Disinfect the Incubator using germicidal surface wipes. Follow the instructions of the germicidal surface wipes to properly disinfect.

H. Calibration and Diagnostics:

Calibration of the Incubator is not required at the user site. The Incubator has been factory calibrated and will maintain that calibration throughout the life of the product.

The Incubator performs diagnostic testing upon power up. To perform diagnostic testing anytime BIs are not under evaluation, simply unplug the Incubator, wait two minutes and plug back in.

Verifying the Temperature of the Incubator

Unlike traditional incubators that require the user to verify the actual temperature of the incubator, the ConFirm™ 20 Minute Incubator has built in temperature sensors for each heating block. The actual temperature of each well is displayed by pressing the UP/DOWN arrows when on the Home Screen.

If you still desire to verify the temperature of the Incubator, use the following procedure.

1.   Plug in the Incubator.

2.   Autoclave a BI to kill the viable spores.

3.   Activate the BI to release the media from the cap to the vial.

4.   Remove the BI cap and drill a 1/8" hole in the top of the cap.

5.   Thread the thermocouple wire through the hole in the cap.

6.   Insert the thermocouple wire into the vial so that it is covered by the liquid.

7.   Replace the cap on the BI, leaving the thermocouple wire submerged in the media and tighten.

8.   Scan a BI cap and then place the BI with the thermocouple wire in it into the Incubator. Ensure media is still present in the vial prior to placing in a well.

9.   The Incubator will automatically detect and begin reading the BI.

10.   Allow the BI to equilibrate for a minimum of 10 minutes.

11. Verify the temperature reading on the thermocouple thermometer. If the temperature falls out of range for incubation, contact HuFriedyGroup or any authorized dealer. Do not use failing wells. The other panel of wells may still be operational.

12. If the recorded temperature is within the range for incubation, abort the reading by removing the BI. Dispose of the BI as per BI instructions.

I. Troubleshooting Guide

```
   BI Prematurely Removed


1                  5
2                  6
3 ERR 13           7
4                  8
```

In the case of a temporary user error, the Incubator will sound an alarm (one beep every five minutes) and the LED adjacent to the well will flash a yellow/amber light. The LCD screen will display an error message at the top the screen and an "ERR" next to the well number. The operator must take corrective action based on error presented, then press the ENTER button to acknowledge the alert and silence the alarm.

See Troubleshooting Guide below for sample error messages.

```
1                  5
2                  6
3                  7
4                  8 ERR 01
```

In the case of a permanent error, the LED adjacent to the well will turn to a solid yellow/amber light. The LCD screen will display an "ERR" next to the well number but no error message at the top since no user action can correct the issue. These are permanent errors that may require the user to contact HuFriedyGroup or an authorized dealer. Do not use the affected wells. The operator must press the ENTER button to acknowledge the alert.

ERROR MESSAGE AND DESCRIPTION	RECOMMENDED ACTION
Remove BI from Well <#>. Scan BI First. The BI was not scanned before inserting into well.	Scan BI first and then place into any empty well. If the fault returns, contact HuFriedyGroup.
Invalid Barcode, Scan Again. The barcode scanned was not recognized as a valid barcode.	Check BI type and scan BI again. If the fault continues, contact HuFriedyGroup.
Expired BI, Please Discard. The BI is expired or the Date setting is not correct.	Check expiration date of BI, check date setting, and scan BI again. If the fault continues, contact HuFriedyGroup.
BI Not Activated, Well <#>. The corresponding well has started a reading but either there was no BI placed into the well or the BI was not activated.	Verify that a BI is in the well and that it is activated. Press ENTER to acknowledge the message. If this error continues to occur following verification that a BI is present and activated, contact HuFriedyGroup or an authorized dealer.
Instrument Failure. <error code>. Irrecoverable diagnostic fault.	Contact HuFriedyGroup or an authorized dealer. The Incubator is unusable. Discard affected sample(s).
Return BI To Well <#>. The BI was removed from the well before the incubation period was over.	Return BI to well <#> before timer reaches zero
BI Prematurely Removed. The BI was removed from the well for longer than 10s.	Discard sample as per BI instructions. Press ENTER to acknowledge the message.
Remove All BIs. The BI is in the well during warm-up and diagnostics test	Discard sample as per BI instructions. Press ENTER to acknowledge the message.
Power Lost, Shutting Down . . . Device is uplugged or lost power	Return power to the device before timer reaches zero. Check power is plugged into the wall and power cord inlet.
Discard BIs. Power was interupted for longer than 60 seconds	Discard sample as per BI instructions. Press ENTER to acknowledge the message.
No message, but error code next to well status.	Step 1: Error message may have been previously acknowledged. Remove BI(s) from well(s) with error code and discard BI. If error continues, go to step 2. Step 2: Clean wells per the Operators Manual. Cycle power to the device by unplugging for > 2 minutes. If fault returns, contact HuFriedyGroup or an authorized dealer. **Note:** Do not attempt while actively incubating BIs in another well.

J. Disposal

Dispose of device in accordance with federal, state and local requirements.

K. *Hu-Friedy*

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.∴∷**HuFriedyGroup**
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