

ConFirm™ Rapid Read 20-Minute Biological Monitor

Step-by-Step Guide



Applicable Products:

ConFirm™ Rapid Read 20-Minute Biological Indicator (**RR20BI**)

ConFirm™ Rapid Read 20-Minute Reader (**RR20READER**)

Note: Ensure the incubator has gone through setup and is sufficiently heated.

Step 1

Inspect lot label and **confirm process indicator is pink**. Confirm **no media is present** in vial.



Step 2

Place the Biological Indicator (BI) in an appropriate representative instrument pack/challenge test pack in a manner consistent with items being sterilized.

Step 3

Place pack in a loaded sterilizer in the most challenging location for steam to penetrate, typically on the bottom shelf near the door and over the drain.

Step 4

Run appropriate sterilization cycle.

Dynamic Air Removal Cycles		Gravity Cycles	
Prevacuum			
Steam Flush Pressure Pulse (SFPP)			
Temperature	Time	Temperature	Time
270°F (132°C)	4 min	250° (121°C)	30 min
275°F (135°C)	3 min	270° (132°C)	15 min

Step 5

Upon cycle completion, **review cycle parameters or printout**. Allow the test pack to cool.

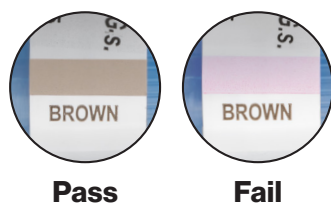
Step 6

Open the test pack and **interpret any chemical indicators** (such as indicators on sterilization pouch; Type 5 integrating indicator) per manufacturer's instructions.

Step 7

Remove the BI from the test pack and **interpret the process indicator on the label**.

NOTE: If the BI will not be incubated immediately, do not activate. Store the BI at room temperature for up to 72 hours following completion of the sterilization cycle.



Step 8

Scan BI: Hold the BI in the scanner with the barcode facing up. If necessary, slowly rotate the BI left and right until a beep is heard.



Step 9

Activate the BI

Twist cap clockwise.

After twisting, grab cap between your thumb and fingers, raise your hand and flick vial downward.

Once downward flicking motion is complete, media will appear at bottom of vial.



Step 10

Place BI into an incubator well.

Final results available within 20 minutes.



Step 11

Interpret Results

Via well light:

- GREEN:** negative and does not show signs of spore activity (pass)
- RED:** positive and shows signs of bacterial spore activity (fail)



Pass



Fail

Via LCD screen:

- "-" next to the well number for a negative result (pass)
- "+" for a positive result (fail)



Pass



Fail

If the BI is negative for the detection of remaining organisms, the conditions for sterilization were achieved. Record the results per facility process.

If the BI is positive for the detection of remaining organisms, the conditions for sterilization were not achieved. Follow departmental procedures for reporting sterilization failures.

Use of Controls

- An unprocessed Control BI from the same lot as the test BI should also be activated and incubated.
- The Control BI will ensure both the validity of the current BI lot and the proper functioning of the Incubator.
- Repeat steps 8-10 above to activate and incubate unprocessed Control BI from the same lot as the test BI.

Storage

- Prior to use, the ConFirm™ Rapid 20-Minute STEAM BI should be stored at 60-75°F (16-24°C), 30-60% relative humidity (RH).
- Avoid contact with sterilants or chemicals.

Disposal

- BIs should be treated as standard microbiological waste, non-pathogenic species. Use a steam sterilization cycle at 250°F (121°C) for no less than 30 minutes, incineration, or other suitable means to safely dispose.