

DIGITAL DECLOAKING CHAMBER | OPERATION HANDBOOK



U.S. patent number 6,580,056

PRESSURE SYSTEM FOR HEAT-INDUCED EPIOTOPE-RETRIEVAL

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Not For Use With Flammable Solvents or Gases

WARRANTY

The Decloaking Chamber warranty is for one year from receipt of purchase and covers all parts and labor when performed solely by Biocare Medical.

Warranty is invalidated if equipment is abused, damaged, or improperly maintained by customer.

Warranty is not transferable to any other party should the equipment be resold or transferred by the customer to another party.

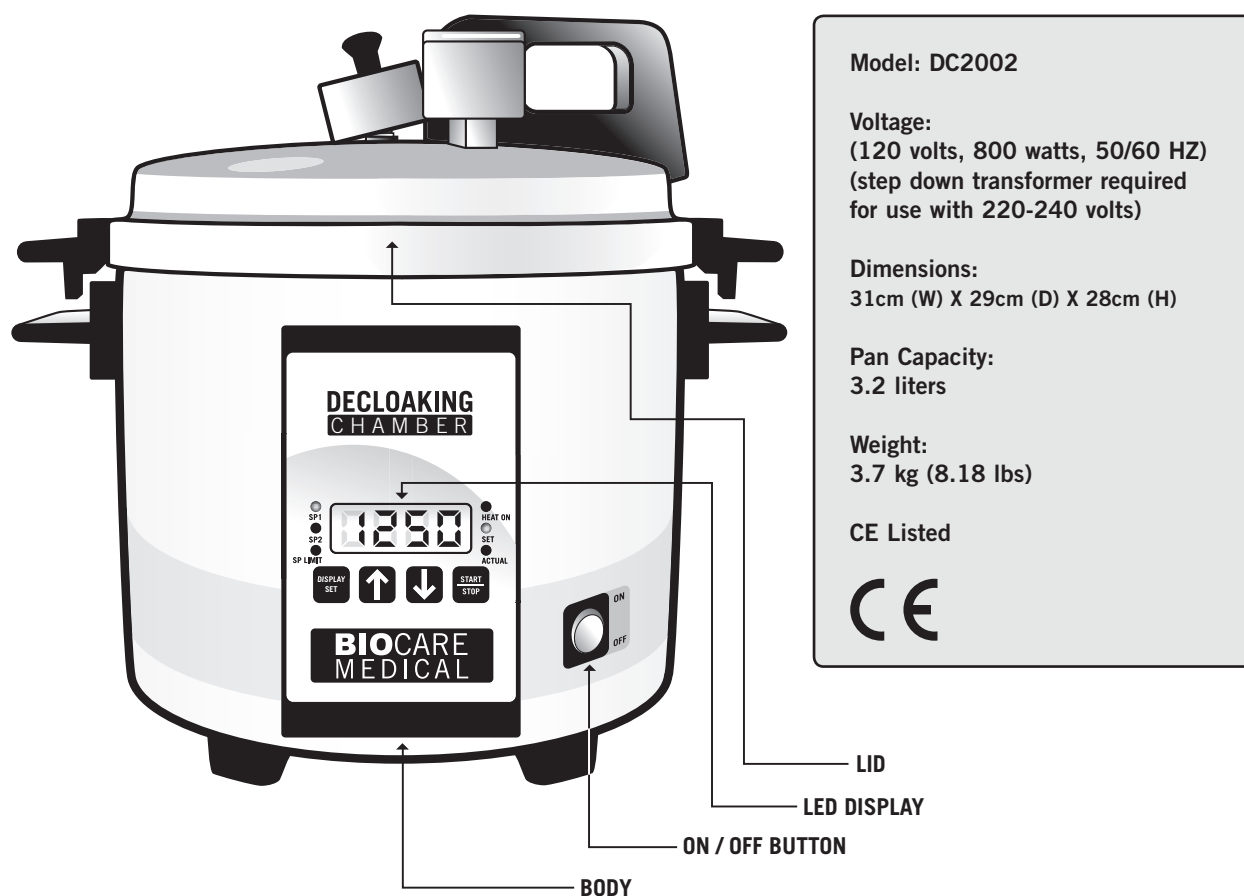
To the extent permitted by law, Biocare Medical disclaims any liability for any incidental or consequential damages related to this equipment or for any warranty related services it performs.

SPECIFICATIONS

Decloaking Chamber

The Decloaking Chamber is a programmable bench top pressure cooker intended for laboratory use. It is programmed to allow the precise pressurized heating necessary for antigen retrieval and also has the capability to perform at a variety of temperatures ranging from 37° C to 125° C.

The Decloaking Chamber is an excellent tool for heat-induced epitope-retrieval (HIER) methods. The proper use of heat and pressure in conjunction with the appropriate buffer solutions is of the utmost importance for consistent immunohistochemistry (IHC) staining. The Decloaking Chamber is designed to optimize and standardize antibody staining procedures and has been engineered to pass strict laboratory safety requirements. Temperature, pressure and pH can be monitored and recorded with the Decloaking Chamber to produce consistent staining, which will reduce repeat testing and false negatives.



ASSEMBLY

Review the Contents of Your Package

Upon receipt of the Decloaking Chamber, inspect the packaging and become familiar with the parts. Save the packaging in case returning the instrument becomes necessary.

You should have:

- Lid with pressure gauge and hot sticker
- Gasket (removable)
- Weight (petcock)
- Pan (removable)
- Body with three-prong electric cord, programmable digital timer
- Heat shield

The Decloaking Chamber is compatible with 110V-120V. A step-down transformer is required for laboratories using a 220V-240V electrical source. When necessary, the step-down transformer will be shipped with the unit.

TOP LID



WEIGHT (PETCOCK)

PRESSURE GAUGE

HOT STICKER

INSIDE LID



VENT NOZZLE

DESCRIPTION OF PARTS

Gasket:

The rubber seal between the pan and the lid that ensures an airtight chamber.

Cat. No. DC-GKT

Pan:

The main removable metal chamber that is placed within the outer shell. The pan comes in contact with the heat sensor and heat plate.

Vent Nozzle:

The top center of the chamber lid that where the weight (petcock) is placed.

Heat Shield:

A circular, concave metal disc with perforations on it that is placed in the center of the pan.

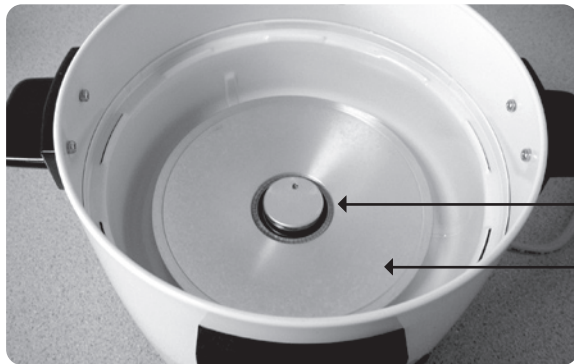
Heat Sensor:

A circular spring-loaded device within the main body that records the Actual Temperature during operation.

Heat Plate:

A large metal disc area within the main body of the chamber that surrounds the Heat Sensor.

INSIDE BODY



HEAT SENSOR

HEAT PLATE

HEAT SHIELD





GASKET

REMOVABLE PAN

HOT STICKER

HOT STICKER

Hot sticker will show this warning when instrument is hot.



***NOTE** Be sure to remove any packing material from inside of the Decloaking Chamber before operating!
Failure to do so will result in FIRE.

RELATED PARTS / PRODUCTS

Retrieval Solutions

Biocare Medical retrieval solutions are specially formulated for pH stability at high temperature. Our retrieval solutions incorporate ASSURE™ technology that contains a color-coded pH indicator for quality control and visual inspection.

Steam Monitor Strips

The heat and pressure sensitive steam strip allows the end-user to monitor both pressure and heat inside the Decloaking Chamber. The best temperature for a Steam Monitor Strip to show quality control is +/- 125° C. It is at this temperature and relative pressure that a dark brown to black color is achieved. Lower temperature and pressure will produce a lighter strip. The steam strip can be dated and recorded for laboratory and CAP inspections. **Cat. No. 613 (C,D,H)**

QC Heat-Tested pH Strips

The pH of retrieval solutions at high temperatures can be critical for proper IHC staining. However, the pH of retrieval solutions can change at high temperatures. To assure quality control and consistent staining, Biocare Medical has developed heat-tested strips that give accurate and true pH at high temperatures. The pH of a solution at a certain temperature can be recorded on a daily basis to comply with JCOHA and CAP recommendations. **Cat. No. PH615**

OPERATING INSTRUCTIONS

Setting Up

The Decloaking Chamber must be on a level surface, away from direct sunlight and any source of heat or cold, near an electrical outlet. It is recommended that a surge protector be used, and if possible a dedicated outlet. Make sure that other types of high voltage equipment such as incubators, microwave ovens or refrigerators are not plugged into the same circuit, as this may affect the performance of the instrument.

- Place the body of the Decloaking Chamber on a flat surface.
- Fit the rubber gasket into the top of the pan (Figure 1).
- Place the heat shield in the center of the pan (Figure 2).
- Add 500ml of deionized water (Figure 3).
- Place the pan into the body. Make sure the outside of the pan is completely dry and clean (Figure 4).
- Place the weight (petcock) onto the vent nozzle, making sure it is snug (Figure 7).
- Rest the lid on the pan until ready to use.
- Plug the instrument into a grounded electrical outlet.

If you are facing the Decloaking Chamber, the on/off switch is located to the right of the display panel on the front. It will illuminate red if the instrument is turned on.

Beginning Operation

Adjust the pan by matching the pan handles with the body handles. Be certain that the outside of the pan is dry, as any wetness will cause the Decloaking Chamber to make a crackling noise and may cause a malfunction.

- Make sure the heat shield is in the center of the pan (Figure 2) and the pan is filled with 500ml DI water (Figure 3).
- Turn the red main power switch to the ON position (the red light will go on).
- Place one to four Tissue Tek™ containers filled with 250 ml of heat-induced epitope-retrieval (HIER) solution in the pan. Alternatively, Coplin jars can be used with 50 ml HIER solution in each one (Figure 5).
- Place a dry Steam Monitor Strip on top of the staining dish or Coplin jar (Figure 6).
- Place the lid on the pan and secure in place by aligning the OPEN arrow on the surface of the lid with the white dot on the handle (Figure 8).
- Grip the handle and rotate clockwise to the CLOSE position. Make sure the weight (petcock) is on the vent nozzle located on the lid. It will drop to a flat horizontal seating when the lid is closed (Figure 9).
- Always cycle through the SP settings to check your time and temperature settings (See Programming Display, p. 11). Turn the main power switch to the ON position.

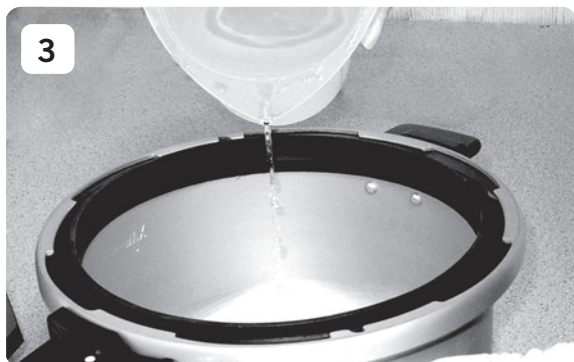
OPERATING INSTRUCTIONS



Place the gasket into the groove on the top of the pan.



Place the heat shield in the center of the pan at the bottom.



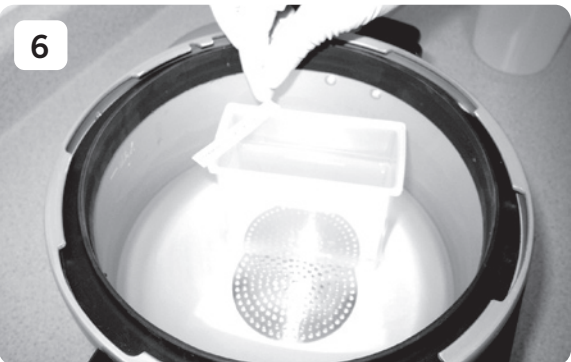
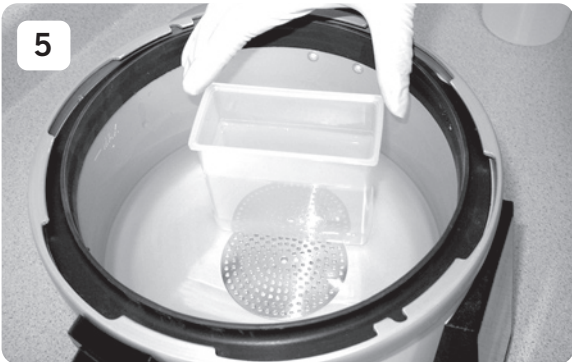
Add 500ml of DI water.

OPERATING INSTRUCTIONS



Place pan into the body of the instrument.

Place the container with the retrieval solution on top of the heat shield. Do not place the container on the center of the heat shield where the heat is concentrated, but towards the edge of the heat shield. Do not use glass containers.



Place steam monitor strip across the retrieval solution container.

6a Unused Steam Monitor Strip.

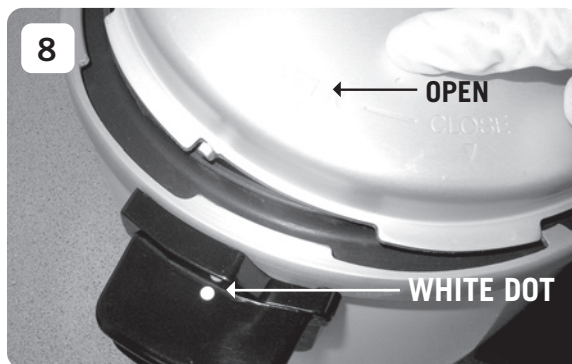


6b Steam Monitor Strip at 125° C for 30 seconds.



OPERATING INSTRUCTIONS

Place the weight (petcock) onto the vent nozzle.
Make sure there is a snug, flat connection.



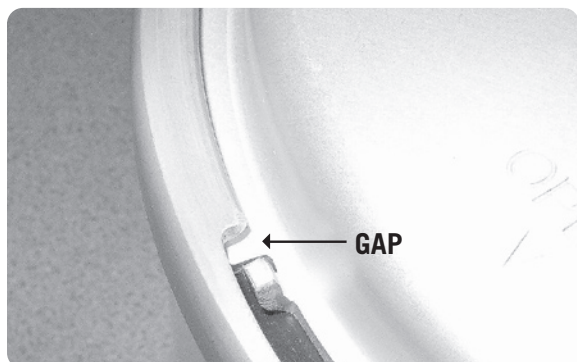
Match the word "OPEN" on the lid to the white dot
on the handle.

Secure lid by turning clockwise until the word "CLOSED"
is matched with the white dot on the handle.



OPERATING INSTRUCTIONS

Correctly secured lid.



Gap indicates that the lid is not correctly secured.

PROGRAMMING DISPLAY

Control Panel

(See the inside back cover for a recommended factory settings guide.)

Heat On light:

Indicates that the heating element is heating up.

Set light:

Indicates that the current area can be programmed.

Actual light:

Shows the actual immediate internal temperature.

LED Screen:

Displays the current setting or error message.

Display Set button: Cycles the user through the two programs SP1 and SP2 (SP = Set Point). Pressing "Display Set" multiple times will navigate the user from SP1 temperature and time, to SP2 temperature and time, then to SP Limit, Actual Temperature and back to SP1.

Up and Down arrows: Adjusts the settings for temperature and time higher and lower.

Start/Stop button: Starts and stops the instrument depending upon the temperature and time settings.

SP1 LED readout: Set Point 1 has two LED readouts on the digital display. The first readout is the temperature at which the user wants to set the Decloaking Chamber, the second is the time interval the user wants to maintain the SP1 temperature.

SP2 LED readout: Set Point 2 has two LED readouts on the digital display. The first readout is the temperature to which the chamber has to be cooled in order to be able to remove the slides. The second readout is the amount of time the SP2 temperature is to be maintained before an alarm goes off. The purpose of the second alarm is a quality control that allows for standardization between runs. It also ensures that the slides remain inside the chamber for a standardized amount of time.

SP Limit readout: The Set Point Limit is an internal circuit breaker that is set by temperature. It is an absolute limit on temperature that cannot be exceeded or the heating element will turn itself off. For example: if SP1 is set to 125° C and the SP Limit is set to 10° C, the element will automatically turn off if a temperature of 135° C is reached. This is a safety feature that avoids overheating if there is not enough water added to the system.

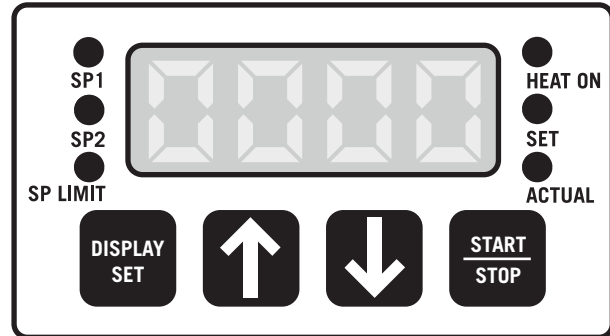
Error Messages

The LED panel will display the letters "ERR" if the following technical problems occur:

- The pan is not filled with enough water, causing the heat and pressure to rise beyond normal limits
- The SP Limit is set so low that the normal temperature tolerance heats beyond the SP1 + SP Limit
- Failure of the Heat Sensor

Audible Alerts

Single beep: When the chamber reaches the SP1 time and the SP2 temperature, a single alarm will beep. The temperature and pressure should be recorded at these set points for quality control.



Factory Default Settings

When the main power switch is turned on, the temperature for SP (Set Point) 1 is displayed. If you hit the "Display Set" button once, the time for SP1 is displayed. Hit the "Display Set" button again and the temperature setting for SP2 displays. Hitting the "Display Set" button at this point will cycle the indicator to show the SP2 time. The next time you hit the "Display Set" button, it will cycle to the SP Limit temperature (there is no SP Limit time setting). Hit it again, and the actual temperature will display. This is the last display in the cycle, if you hit the "Display Set" button again, it will return to the SP1 temperature display.

As you cycle through the SP displays, notice that the "Set" light on the right hand side will light up, indicating that the SP mode you are in can be reset by the user. (See the inside back cover for illustrations).

Above are the factory default settings, which can be changed by the user. For optimal immunostaining, we recommend that you set the SP1 at four to five minutes; however, always refer to the assay or analyte specification sheet for the specific antigen retrieval protocol as the times may vary.

The best temperature for Steam Monitor Strips to show quality control is $\pm 125^{\circ}\text{C}$. It is at this temperature and relative pressure that a dark brown to black color is achieved (Figure 6b). Lower temperature and pressure will produce a lighter strip, which will remain consistent for runs of the same temperature and pressure, but it is easier to use the darker color that is achieved at higher temperature and pressure as a quality control.

Start Program

- With the main power switch on, press the "Display Set" button until the SP1 LED light comes on.
- Press the Start/Stop button to start the program.
- Push the down arrow to display the actual temperature. Both the Heat On and the Actual Temperature lights will be on.
- When the programmed temperature is attained, the Heat On light will turn off and the timer will start counting down. The instrument will typically overshoot the programmed temperature by about 2°C to 4°C , then settle down to the programmed temperature. When the timer counts down to zero, an alarm will sound.
- At this point, record the temperature and pressure for quality control. The temperature may vary by $\pm 3^{\circ}\text{C}$.
- After the alarm sounds, press the Start/Stop button and the SP2 LED light will come on.
*Note: the alarm will stop automatically after SP1 has been achieved. The instrument will cool down to SP2).

The amount of time required to reach the programmed temperature and pressure are variable, depending upon the voltage source and frequency, the number of slides in the chamber and the altitude at which the instrument is operated.

End Program

- When the programmed SP2 time and temperature is reached, another alarm will sound and all the indicator lights will flash. Press the Start/Stop button to end the program. Before unlocking the lid, confirm that the pressure reads 0 (zero) on the LED. Toggle the weight (petcock) to release pressure.
- Push down on the lid and rotate it counter clockwise to the OPEN position, making sure the steam is directed away from yourself. Turn the main power switch off and lift off the hot lid. Let the slides cool about 10 minutes on the counter top.
- Check the Steam Monitor Strip for the proper dark brown to black color (Figure 6b).
- Rinse the slide container with reagent-grade water. The slides should remain in the container while rinsing.
- In order to maintain consistency between runs, the unit must be started at the same temperature for each run. The user can cool the unit by adding cool water to the pan to bring the temperature down to 37°C .

CHANGING THE FACTORY SETTINGS

- Set the SP1 temperature and time by pressing the "Display Set" button until the SP1 LED light comes on. Use the up and down arrows to adjust the temperature to the desired retrieval temperature. Press the "Display Set" button once and the SP1 time will display. Use the up and down arrows to adjust to the proper time. The SP1 settings can be used exclusively if necessary if the SP2 time is set to 0 (zero).
- Cycle to the SP2 settings by pressing the "Display Set" button again. Set the SP2 temperature to the desired cool down temperature. Press the "Display Set" button again to set the SP2 time.
- To now set the SP Limit, press the "Display Set" button again and use the up and down arrows to set the SP Limit.
- **Do not exceed the 135° C maximum temperature SP1 and SP limit.**
*Note: To speed up the process of setting the temperature and time, push the second arrow while holding the original direction arrow down.
- Time Bypass Feature: If the SP1 time is set to 99:00 minutes, the Decloaking Chamber will maintain a continuous temperature without a time countdown. The Time Bypass Feature cannot be set higher than 100° C as a safety precaution. When SP1 is set to 99:00 minutes, the SP2 feature is disabled.
- When the programmed SP1 temperature and time has been reached, the heating element will turn off automatically and cannot be turned on again until it reaches 37° C.
- The SP2 will not be maintained when it is reached; the alarm is only an indicator that the SP2 temperature has been reached.

FACTORY SETTINGS

Factory Settings	Temperature	Time
SP1	125° C	30 seconds
SP2	90° C	10 seconds
SP Limit	10° C	n/a

SETTING LIMITS

	Minimum	Maximum
SP Temperature	37° C	125° C
SP Time	:01 second	99:00 minutes

MAINTENANCE

Daily

Pour the water out of the pan, rinse it with deionized water and dry.
Inspect the gasket for wear. The lid may be left atop the chamber, but should be slightly ajar.

Monthly

Preventative maintenance should be done once a month. Unplug the instrument before cleaning. Use only a mild dish detergent, as abrasive powders or metal scrubbers will damage the surface and may cause contamination. Do not attempt to wash the instrument in a dishwasher.

DO NOT IMMERSE THE BODY OR ELECTRICAL CORD IN WATER!

Pan, Gasket, Lid, Vent and Nozzle

Remove the pan, lid and weight and soak them in warm water. Wash thoroughly with a sponge and dry well. Inspect the gasket for tears or wear. If the vent nozzle becomes blocked with debris, clear the path with a toothpick or similar device then wash clean.

Heat Plate and Heat Sensor

Wipe off anything stuck to the heat plate or heat sensor and dry with a soft cloth.

Body

Wipe the surface with a soft cloth soaked in warm water, making sure that no water gets into the body.

Electrical Precautions

Basic safety precautions should always be followed when using electrical equipment.

Do not immerse cord or plug or the body of the Decloaking Chamber in water or attempt to clean in a dishwasher.

- Unplug the instrument when not in use and before cleaning.
- Do not operate the instrument with a damaged cord or plug.
- Do not let the cord hang over the edge of a table or counter or touch hot surfaces.
- Do not place near a heat source, an open flame or gas outlet.

SHORT INSTRUCTIONS

- Plug the Decloaking Chamber into a 110-120 volt power source with surge protection.
- Place the gasket in the lip of the Decloaking Chamber lid.
- Place Decloaking Chamber pan into the Decloaking Chamber shell (body).
- Place the heat shield in the center of the pan.
- Pour 500 ml of deionized (DI) water into the pan.
- Ensure that the heat shield is in the center of the pan after the addition of DI water.
- Place slides into Tissue Tek™ racks.
- Place Tissue Tek™ racks into Tissue Tek™ containers containing 200 ml of desired retrieval buffer (Example: Diva) on top of the heat shield off center to avoid heat concentration. Containers must not be covered.
- Do not use glass containers.
- Place a Steam Monitor Strip across the edge of the Tissue Tek™ containers.
- Align the shell and pan handles.
- Match the lid etching “OPEN” with the white dot on the pan handle.
- Hold both the shell and pan handle with your left hand while turning the lid clockwise with the right hand until the lid etching that reads “CLOSED” is aligned with the white dot of the pan handle on the left side.
- The metal tabs on the lid should be tightly seated against the pan’s lip.
- Turn the instrument on by flipping the red toggle to the right of the control panel to the “ON” position.
- Press “DISPLAY SET” once, until the SP1 LED illuminates.
- The user can scroll through the instrument settings by pushing the “DISPLAY SET” button multiple times.
- Recommended factory settings for IHC are SP1 of 125° C for 30 seconds, SP2 of 90° C for 10 seconds, SP Safety Limit of 10° C, unless otherwise specified by the data sheet.
- Push “Start/Stop” button to initiate programmed run.
- When the alarm sounds (approximately 10-15 minutes) push “Start/Stop” button. The SP2 will illuminate. Record the time, temperature and pressure.
- When the alarm sounds a second time (approximately 20 minutes) the temperature has cooled to your programmed SP2 temperature.
- Visually confirm that the pressure has dropped to 0 (zero) psi.
- Toggle the weight (petcock) to release any residual pressure. Turn the unit off.
- Open the lid with the steam directed away from yourself.
- Confirm that the Steam Monitor Strip has changed to a dark brown to black color (Figure 6b).
- Carefully remove the Tissue Tek™ containers from the instrument.
- Place the containers on the counter top to cool down for a at least 10 minutes.
- Decant half of hot retrieval solution and add DI water.
- Do five changes of DI water.
- Proceed with immunohistochemistry (IHC) staining.

QUICK OPERATING NOTES / IMPORTANT SAFETY GUIDELINES

The Decloaking Chamber has been designed with many unique safety features. However, when using heating and electrical equipment, basic precautions should be used. This is a heating device under pressure. Please read these operating notes before operating the instrument.

- 1. Lift the lid gently**
When operating, make sure the lid is in the *closed position*. When there is resistance, don't open the lid by force. Tip the weight (petcock) carefully to release any residual pressure and make sure that the pressure in the pan is at zero on the pressure gauge. Gently push down on the brown handle, turn the lid counter clockwise and slowly lift off the lid.
- 2. Always be sure there is water in the chamber before use**
VERY IMPORTANT! Make sure there is deionized or distilled water in the pan. Do not turn on the heat when the pan is empty as it may cause a malfunction.
- 3. Check the weight each time of use**
Make sure the weight (petcock) is secure.
- 4. Handle with care**
Dropping or roughly jolting the instrument will cause damage and deformation leading to malfunctions.
- 5. Avoid touching the pan or lid when in use—HOT!**
When in use, the pan, lid and weight get very hot—avoid touching them. There is a hot sticker to warn that the lid is hot. The circular sticker reads "HOT" at elevated temperatures.
- 6. Do not operate the Decloaking Chamber near a heat, flame or gas source**
Never place the instrument directly on a stove or other heat source.
- 7. Keep the exterior dry**
Remove foreign matter and water drops. The heating plate, sensor and the area outside of the pan must be dry and clean to work properly.
- 8. Cool down after each use**
Make sure the Decloaking Chamber is cooled down after each use. Replace hot water with cool water and make sure the temperature is 37° C or less before starting again. If starting temperature is above 37° C, an error signal might be activated or optimum temperature and pressure may not be obtained.
- 9. Check the gasket periodically**
The gasket must be consistently checked for tears or damage. A replacement gasket can be ordered (Cat. No. DC-GKT). A weak Steam Monitor Strip color may indicate that the gasket needs replacement.
- 10. Fill the pan with only 500 ml deionized water**
500 ml is all that is needed for heat-induced epitope-retrieval methods. Special stains and other histology procedures may require 1,000-2,500ml.
- 11. Do not use glass containers**

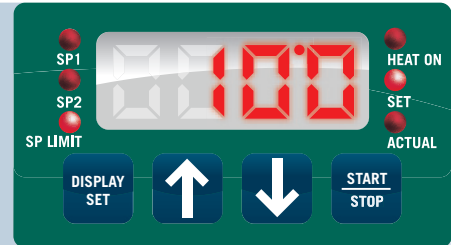
CYCLING THROUGH THE PROGRAMMABLE DISPLAY

STEP
1



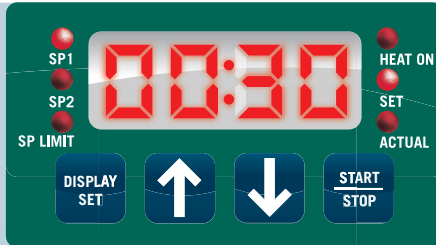
Turn on the Decloaking Chamber. The current setting for the SP1 temperature will be shown on the LED display. You can adjust this setting to be higher or lower by pressing the up or down arrow button.

STEP
5



Pressing the "Display Set" button once more will cause the SP Limit temperature to display. You can adjust this setting higher or lower by pressing the up or down arrow button.

STEP
2



Pressing the "Display Set" button once will cause the SP1 time to display. You can adjust this setting higher or lower by pressing the up or down arrow button.

STEP
6



Pressing the "Display Set" button once more will cause the actual ambient temperature to display.

STEP
3



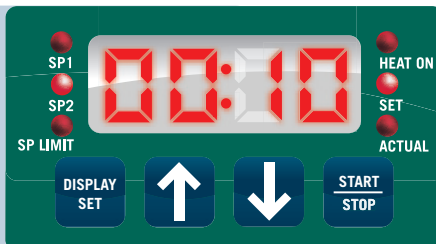
Pressing the "Display Set" button once more will cause the SP2 temperature to display. You can adjust this setting higher or lower by pressing the up or down arrow button.

STEP
7



Pressing the "Display Set" button once more will bring you back to the SP1 time setting.

STEP
4



Pressing the "Display Set" button once more will cause the SP2 time to display. You can adjust this setting higher or lower by pressing the up or down arrow button.

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