

HemoTemp® II Indicator

Product Description:

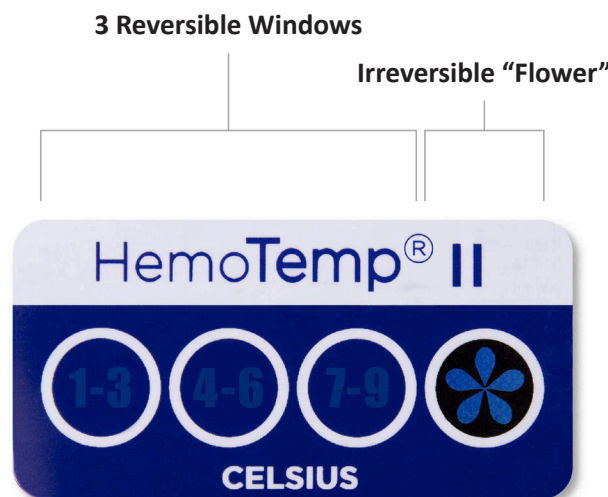
HEMOTEMP® II INDICATOR is a core correlated combination irreversible liquid crystal blood temperature indicator and a reversible liquid crystal thermometer for blood during transit and storage outside the blood bank.

The **REVERSIBLE** portion of the HemoTemp® II acts as a blood bag thermometer. It is calibrated to display the internal core temperature of the blood between 1-9°C under ambient conditions (18-26°C) and is accurate to $\pm 0.5^\circ\text{C}$. If the blood temperature falls below 1°C or rises above 9°C, no numbers will be visible.

The **IRREVERSIBLE** portion of the HemoTemp® II Indicator “flower” warns when the core temperature of the blood has exceeded approximately 6-10°C. After being activated, the irreversible window retains a blue color for at least **48 HOURS** if the blood is stored at 3°C and longer if the blood is stored at lower temperatures (see chart below). If stored at 6°C, the irreversible window will remain blue for 10-12 hours. As the blood is warmed, the irreversible indicator changes from BLUE to light blue, to gray and finally to a brownish color.

INTERPRETATION OF THE IRREVERSIBLE INDICATOR DEPENDS ON THE PRESENCE OR ABSENCE OF A BLUE COLOR.

When the internal core temperature of the blood is approximately $10^\circ\text{C} \pm 0.5^\circ\text{C}$, the indicator will lose its blue color. The length of time during which the irreversible indicator retains a blue color decreases as the temperature increases. After the irreversible indicator has lost its blue color, it will not return to blue even if the blood bag is subsequently cooled again.



New Improved Sensitivity
See Chart For Time/Temperature Duration

IMPORTANT!

READ BEFORE USING INDICATORS

Calibration Instructions:

EACH LOT SHOULD BE CALIBRATED BEFORE USE.

Follow the steps below to calibrate the indicator using a control bag:

1. To assemble a control bag, simply fill a blood bag of your choice with either distilled water or any other liquid of your choice which you consider to represent blood (i.e. tomato juice, glycerol/water mixture, sheep cell blood, etc.). Fill the control bag to the same weight that your blood units are filled (250-500 ml). Insert an ASTM thermometer into the center port and slide the thermometer into the bag so that the tip is in the center of the blood bag and at the other end you can read the temperature of 0°C and above. Make sure the thermometer is in the center of the bag measuring the liquid temperature and not touching either side of the bag. Avoid laying the control bag on a metallic surface during calibration.
2. Remove a HemoTemp® II indicator and activate it using the HemoTemp® II Activator as described in this Users Guide.
3. After heat activating the indicator, wait until the entire outline of the flower petals is a blue color.
4. Place the indicator on the center of the blood bag which has been maintained at 3°C or 4°C.
5. Now you can immediately calibrate the indicator or you may put the control bag in the refrigerator if needed until you are able to calibrate.

When comparing the temperature on the alcohol thermometer to the indicator, please remember that both the reversible and irreversible portions of the indicator are offset to read the core temperature of the blood.

DO NOT INVERT THE CONTROL BAG DURING THIS CALIBRATION PROCEDURE.

Indicator Activation, Application and Directions:

PLEASE NOTE: The indicator must be heated **(TO 38-42°C FOR 60 SECONDS)** and placed on a refrigerated blood bag for proper activation.

To heat the HemoTemp® II Indicators, place the indicators (irreversible “flower” portion down) into the HemoTemp® II Activator.

HemoTemp® II indicators can be used on blood bags stored at 1-6°C and during transportation on blood bags maintained at 1-10°C.

DO NOT USE A MICROWAVE OVEN.

DO NOT STORE INDICATORS DIRECTLY IN WATER.

1. Remove a HemoTemp II indicator from box and leave backing on. The irreversible “flower” portion will be a non-blue color under ambient conditions (18-26°C). **Place indicator in HemoTemp®II Activator for at least 60 seconds.**
2. Remove an indicator from the HemoTemp® II Activator. As soon as you start to see the irreversible blue “flower” portion, remove the backing on the indicator and press it onto the **center or near the bottom** of the refrigerated blood bag. **The indicator has now been activated.**

IMPORTANT: Before applying HemoTemp® II Indicator to a blood bag, make certain the blood bag (100ml to 500ml) is cool, dry, and free from excessive oil. If necessary, prep blood unit with alcohol wipe to insure good adhesion of indicator.

3. Place the blood bag with the face of the indicator down on a flat (not heated) surface and rotate the bag back and forth to insure proper adhesion.

(continued on the next page)

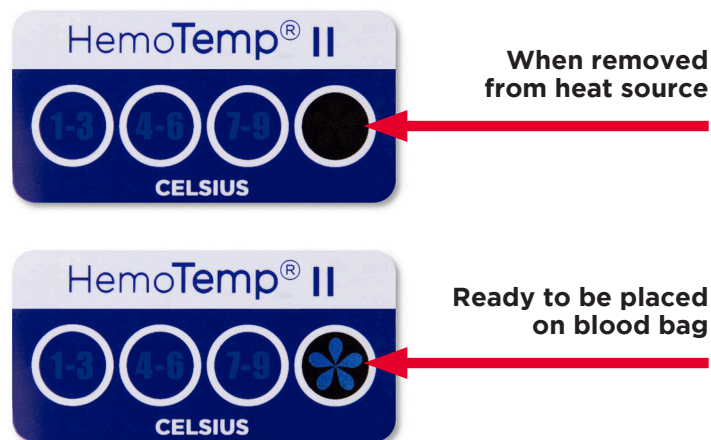


4. Check the color of the irreversible “flower” on the indicator.

IF IT APPEARS NON-BLUE, THE INDICATOR HAS NOT BEEN PROPERLY ACTIVATED.

5. Place the blood bag with the indicator back into a controlled environment. For calibration, leave in controlled environment to ensure the blood bag and indicator reach equilibrium.

The indicators may be stored in the HemoTemp® II Activator (#9000), set at 38-42°C for 3 to 4 weeks. Do not exceed this time period.

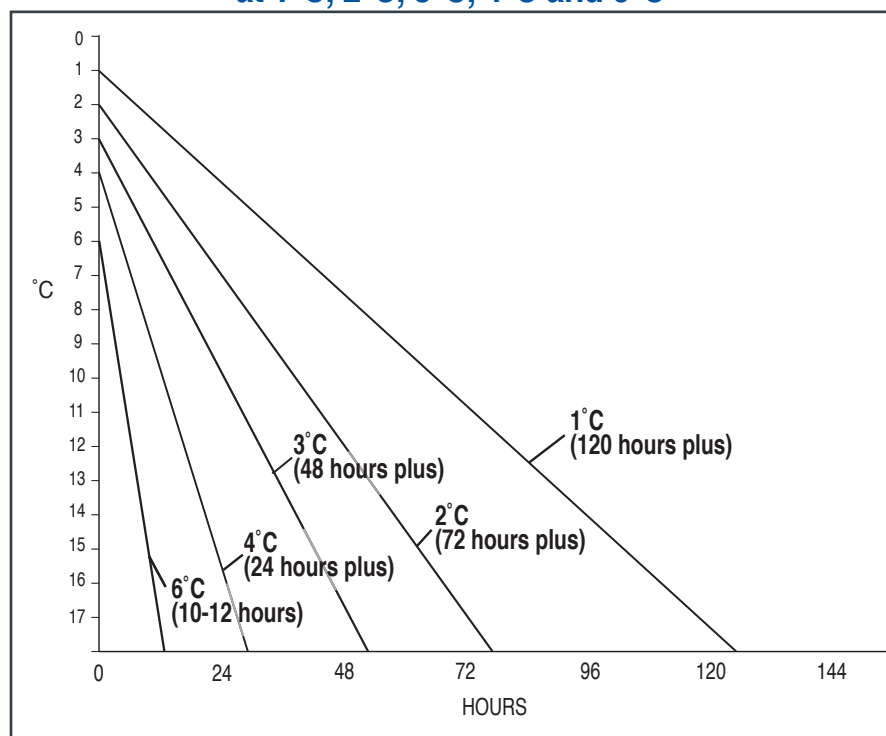


To insure the 48 hour plus time duration, the blood bag should be stored at 3°C for at least 10 hours prior to activation of the HemoTemp® II indicator. When blood is removed from the refrigerator and placed on a counter top, the blood needs to be protected from the ambient temperature of the room. IF NOT, the blood will warm to 6°C in minutes and will lead to a shorter time duration of the HemoTemp® II indicator.

HemoTemp® II Interpretation Chart:

Please note when using HemoTemp® II that the irreversible “flower” portion is dependent on both **TEMPERATURE** and **TIME** at that temperature (see chart below). For example, if you expose an ice cube to an environment of 40°F it will take a longer time to melt than if exposed to 70°F (time/ temperature).

HemoTemp® II time duration when the blood bag is stored at:
1°C, 2°C, 3°C, 4°C and 6°C
at 1°C, 2°C, 3°C, 4°C and 6°C



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