

Timestrip® Blood Temp 10 (BT10)

Frequently Asked Questions

What are Blood Temp 10 indicators?

Blood Temp 10 (BT10) are single-use temperature breach indicators in a self-adhesive label format. They have been engineered specifically for use on blood bags. Blood Temp 10 indicates if the core temperature of blood in a blood bag has reached or exceeded 10°C/50°F. They require no power and can be quickly and easily be read. Indication is irreversible and each indicator has a unique serial number to ensure traceability.

Why do I need to use Blood Temp 10 if all of our blood bags are kept in temperature-controlled refrigerators?

Blood Temp 10 indicator allows you to monitor the core temperature of blood in a blood bag when it is removed from the controlled blood bank refrigerator in order to be transported to another location; or if it is temporarily returned to the refrigerator for storage.

How does Blood Temp 10 work?

A blue liquid housed in a blister is held next to a porous membrane. Upon squeezing the activation button the liquid comes into contact with the membrane. If the temperature of the product is below the stated 'STOP' temperature of 8°C/46°F, the liquid turns solid and in this state is unable to move through the membrane. If the temperature rises to the threshold temperature of 10°C/50°F, it melts back its liquid state allowing it to move through the membrane causing the breach window to change from white to blue.

How does the blue liquid sense the blood temperature?

BT10 has been engineered for optimum heat conduction of the blood bag. It uses a unique, ultra-thin (20 micron) foil on the side adhered to the blood bag, facilitating heat transfer properties between the blood bag skin and the liquid. This allows the liquid to quickly turn solid once the Blood Temp 10 is activated and adhered firmly to a blood bag.

Where should I apply the activated Blood Temp 10 on the blood bag?

The BT10 indicator should be adhered to the lower third of the blood bag, where the bulk of the blood is held.

Does Blood Temp 10 have any special storage requirements before activation?

No. Unlike some other indicators, prior to being activated, BT10 can be stored at normal room temperature conditions (22°C/72°F at 20-80% relative humidity), and can also be stored in a freezer or refrigerator, wherever it is most convenient. A cool dark environment is recommended.

Is Blood Temp 10's shelf life affected by temperature?

No! Regardless of the *storage-temperature* (e.g. freezer, refrigerator, room temp...), the *storage-period* goes only according to the expiry date which is printed on each box of indicators. *Unlike some other indicators which if stored in a refrigerator require cycling from refrigerator to room temperature every few months*, BT10's pre-activation **shelf life** is always according to the expiry date printed on the pack. The post-activation shelf life for the BT10 indicator is one year or until breached (breach window turns blue).

Does Blood Temp 10 require conditioning before activating and applying to a blood bag?

No! BT10 doesn't require any conditioning prior to application. The moment you decide to monitor the blood bag temperature is the time which you can apply BT10 to the blood bag. Simply activate it and adhere it to the blood bag. Please note that BT10 can be activated at normal room temperature or any temperature above 10°C.

Does Blood Temp 10 require conditioning after applying to a blood bag?

No! BT10 does not require any conditioning after applying to a blood bag.

Immediately after BT10 is activated and firmly adhered to the blood bag, it starts to monitor the blood bag temperature. BT10 is engineered to obtain high thermal diffusivity, so it senses and reacts to the blood bag temperature right away *so there is no need to return the BT10 monitored blood bag back to refrigeration*. However, if after applying the activated BT10 you don't need to issue or transport the blood, the blood-bag can be placed temporarily back in the fridge for future use with the BT10.

Is there a stage during Blood Temp 10 storage, application or use which requires refrigeration to cool it down to blood-bag temperature?

No! Unlike some other indicators, refrigeration of the BT10 (prior, during or after its application to the cold blood-bag) is not required.

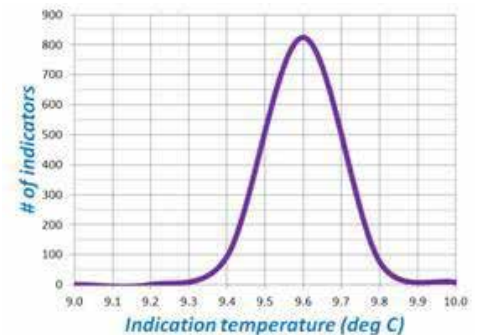
When is it best to apply Blood Temp 10 to the blood-bag?

It is advised to activate and apply BT10 as soon as the blood bag is taken out of the fridge to be transported. This will help reduce condensation on the blood-bag and can dramatically enhance the adhesion of the BT10 to the blood-bag.

How accurate is the Blood Temp 10 indicator?

On the BT10 indicators, the breach window is set to be triggered at 9.5 °C +/- 0.5 °C.

Statistical analysis of over one thousand indicators taken from different production batches have shown that all of the indicators triggered at a tighter spec of between 9.2 and 10.0. **90.7%** of the indicators triggered between 9.5 °C – 10.0 °C.



Is there any unique identification of Blood Temp 10 indicators?

Yes! Each BT10 indicator has a unique serial number printed on its viewing side. This unique alphanumeric code can be used to ensure traceability and can be traced back to the level of raw materials and production processes of a specific indicator. It can obviously also be used for your own transport documents and paperwork.

Does Blood Temp 10 require any calibration prior to use?

No! It is ready to use.

Does Blood Temp 10 have a shelf-life?

Blood Temp 10 has a pre-activated shelf life of 2 years from the time it leaves Timestrip's manufacturing facility. An expiry date is provided for each batch of products supplied. Post activation, the shelf life for the BT10 indicator is one year or until breached (breach window turns blue).

What is your Acceptable Quality Limits (AQL)?

The Acceptable Quality Limits (AQL) is based on ANSI/ASQC Z1.4 (formally MIL-STD-105E) Level II Normal Inspection. For Blood Temp 10 the AQL is 0.65%. We supply a few extra indicators free of charge in each pack of 100 to cover this AQL.

Blood Temp 10 indicators go through extensive quality checks before they are shipped. Central to this process are tests against defined specifications for; environment sensitivity (high heat and vacuum tests to check resilience to harsh conditions during shipping) and also accuracy of the threshold melting point. A full pack of release reports is provided with each shipment. Further details are available on request.

What if one of the indicators in my pack has got a green arming window or the breach window is already blue, before I've pressed the activation button?

In the unlikely event in which BT10 has auto-activated before use (i.e. the yellow arming window is already showing green and/or the breach window is showing blue), discard the indicator and select another.

There is no need to contact us, as we ship a few extra indicators per pack of 100 anyway.

Is the Blood Temp 10 adhesive certified to be used on blood bags?

Yes! BT10 adhesive is certified to be used safely for the reverse coating of labels, suitable for labeling of blood bags.

Does the Blood Temp 10 have an MSDS?

Yes! MSDS for all Timestrip products are available on request.

Is the indication chemical (i.e. melt/freeze dye) used in Blood Temp 10 safe?

Yes! The chemical in BT10 is completely safe and is listed in the Food Chemicals Codex and/or approved by the Food and Drug Administration (FDA) under Title 21, and/or considered Generally Recognized as Safe (GRAS).

Why does Blood Temp 10 have an arming window and a breach window?

The arming window gives an immediate confirmation that the indicator is armed as it turns from yellow to green. If this doesn't happen immediately, fully re-squeeze the button between thumb and finger. The breach/arming window is separate so that you can clearly see if there has been a breach of the 10°C/50°F temperature threshold. If no breach has occurred the breach window will remain white; it will turn blue if there is a breach.

What does a partial coloration of Blood Temp 10's breach window mean?

Any blue coloration of the indication window (partial or full) denotes a temperature breach of 10°C.

How can I find the batch / lot codes on Timestrip products?

Our batch / lot codes are in the format of AB XYZ-CDE where:

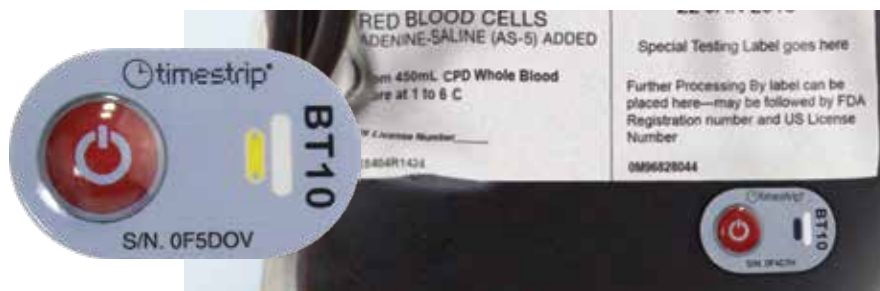
AB – is the type of roll material.

XYZ – Batch / Lot number

CDE – Number only for Timestrip internal use.

For the purpose of identifying QC batches or lots, you would only use the first 2 letters plus the next 3 numbers. The final 3 numbers are for Timestrip's internal use and are to be disregarded.

Therefore, it is sufficient to identify the batch according to its mothers' roll type and number (i.e. ABXYZ for example EM119).



This product is not a replacement for the professional judgement of laboratory/blood bank professionals and/or policies and procedures that are applicable to your institution.

Contact Us Today for More Information & Free Samples!
Call **800.435.4242** or visit **pdhealthcare.com/bloodtemp10**