

BLOODTEMP INDICATOR

Part of the WarmMark2 family, the Blood Temp indicator is an ascending temperature indicator, specifically designed to monitor the temperature of a blood bag during storage and transportation.

With the push of a button, the single use Blood Temp indicators track each blood bag to ensure that there has been no temperature abuse that would compromise the safety of the blood. The indicator alerts users when the temperature of the blood bag is exposed to temperatures over 10°C, the indicator window will turn from white to blue, informing users that the blood bag needs to be discarded. If the temperature hasn't been breached, the blood bag can return to storage for reissue at a later time.

The Blood Temp indicator provides a simple solution which improves blood safety practices, decreases blood waste and provides auditable proof that blood has been stored, transported and reissued in accordance with applicable regulatory standards.

The BloodTemp 10 includes optional FDA approval and validation documentation for this highly regulated industry.

SPECIFICATIONS

Instrument:

Dimensions:	19mm x 30mm x 0.5mm
Weight:	0.4 grams + 10%
Mounting Method:	Pressure sensitive adhesive
Product Life:	1 year from date of manufacture when stored as recommended
Storage Conditions:	Store in a cool, dark place. Recommended 22°C at 20-80% RH
Indication Type:	Visual, irreversible white to blue progressive colour change in activation window
Arming Method:	Manual – Blister squeeze
Moisture Resistance:	Not suitable for immersion in water

Indicator:

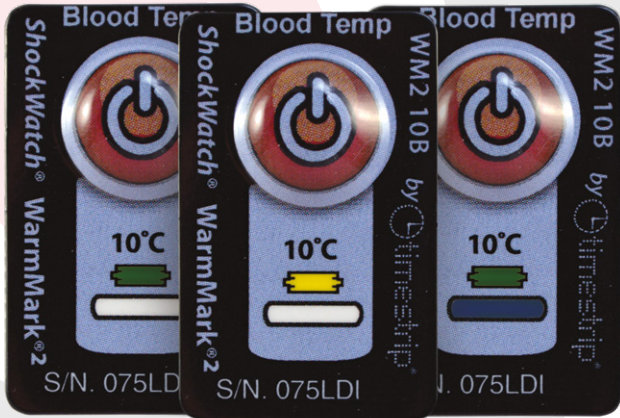
Activation Temperature – Blood Bag Temperature:	10°C / 50°C
Operating Temperature Range (Activated):	-30°C to 55°C
Temperature Accuracy:	+ 1°C

Product Features

- Field activated ascending temperature indicator
- Blood bag temperature monitoring
- Distinctive, irreversible colour change from white to blue when temperature breach occurs
- Unique identifier on every indicator for traceability
- FDA approval
- Validation documentation

Benefits

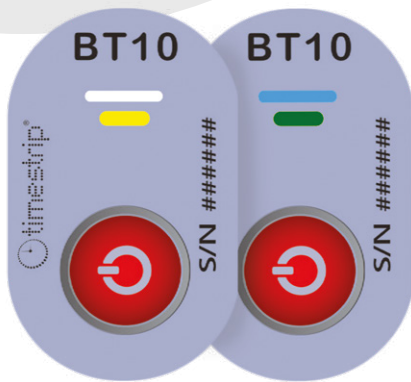
- Provides irreversible evidence of exposure to unacceptable temperature conditions
- Provides cost effective monitoring
- Easy to interpret
- Enables quick accept/reject decisions
- Aids in compliance with regulatory guidelines



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BLOODTEMP INDICATOR

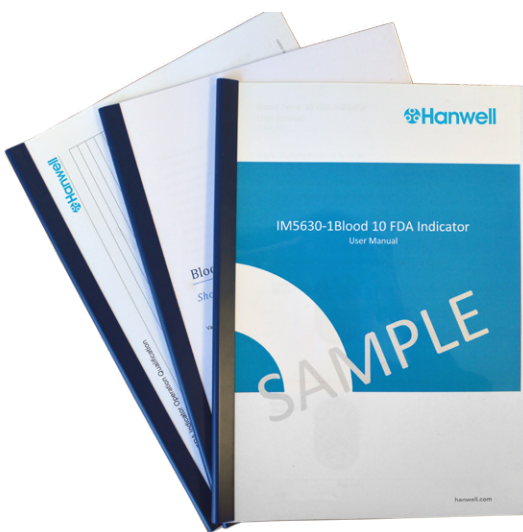
Specifications on page 1.



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BLOODTEMP 10 INDICATOR (FDA APPROVED)

Specifications on page 1.



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BLOODTEMP 10 VALIDATION DOCS

- User manual
- Operation Qualification workbook (OQ)
- BloodTemp validation testing by Spotsee Inc.

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