

Product Specification

Item Code:
TP302

Product Name:
Timestrip[®] Blood Temp 6

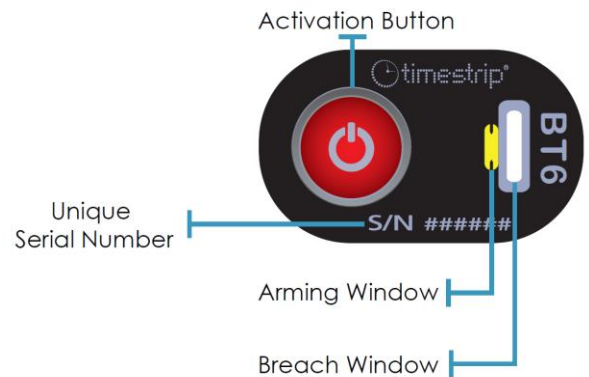


General:

The Blood Temp 6 blood bag indicator (BT6) is a temperature-sensitive indicator that can be used by blood banks and transfusion services to maintain quality control in blood storage and transportation.

When applied to a blood bag, BT6 will begin to sense the blood temperature. Any breach of the blood temperature above 6°C will be indicated on the breach window by the appearance of blue colour in the window.

Any blue colouration in the “breach-window” (from partial to full colour change) is defined as a breach event.



Instructions for Use:

1. Select a BT6 indicator and ensure it is not activated: the arming window should be yellow and the breach window should be white.

BT6 does not require pre-conditioning.

2. Note; BT6 can be activated at normal room temperature - any temp above 6°C/43°F will do.
3. Firmly squeeze the button located on top of the indicator, between thumb and forefinger.
4. Verify that the arming window changes colour immediately from yellow to dark green.
5. Immediately after activation, refrigerate BT6 to temperatures of +3°C/38°F or below for a minimum of 15 minutes.
6. Remove the pre-chilled blood bag from its controlled refrigerator (2°C/36°F – 6°C/43°F).
7. Select a suitable location on the lower third of blood bag where there is always a large volume of blood product. Ensure this area is oil & moisture free.
8. Remove BT6 from refrigeration, peel its liner and firmly adhere the BT6 to the prepared location. Verify full adhesion to the blood bag.

Monitoring has begun!

Note: any blue colouration in the “breach-window” (from partial to full colour) is defined as a breach.



Inactive product



Active product



Triggered product

I) Performance Specifications:

- Threshold temperature 6°C/43°F
- Temperature Accuracy: 5° - 6°C /41°F - 43°F
- Display: Irreversible

II) Product Specification:

- Blister Position: Button on Top (BOT)
- Colour of breach window during a breach event: Blue
- Adhesive: DuploCOLL[®] 2353 – for reverse coating of labels employed for labelling blood bags – see Appendix 1
- Product drawing: See Fig. 1
- Graphics: See Fig. 2
- Other: Not suitable for immersion in water

III) Product Construction:

The indicator is constructed of polymeric assembly multilayer and aluminium-plastic laminate. It encapsulates coloured liquid chemicals*.

* Maximum weight of colorant is <0.5 mg.

** Liquid chemicals are 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).

*** All materials are non-toxic, latex and PVC free.

IV) Packaging & Presentation:

Singles in a box of 100 products.

V) Storage Conditions (un-activated):

- Store in a cool dark environment away from heat sources.
- Recommended: 22°C/72°F at 20-80% RH.
- Please note that before activation, the product can tolerate short term exposure during transit (hours or a few days) to temperatures in the range -30°C to +55°C. However, long term storage should be under recommended conditions.

VI) Shelf-life:

- 2 Years from date of manufacture.

Fig 1: Product Drawing

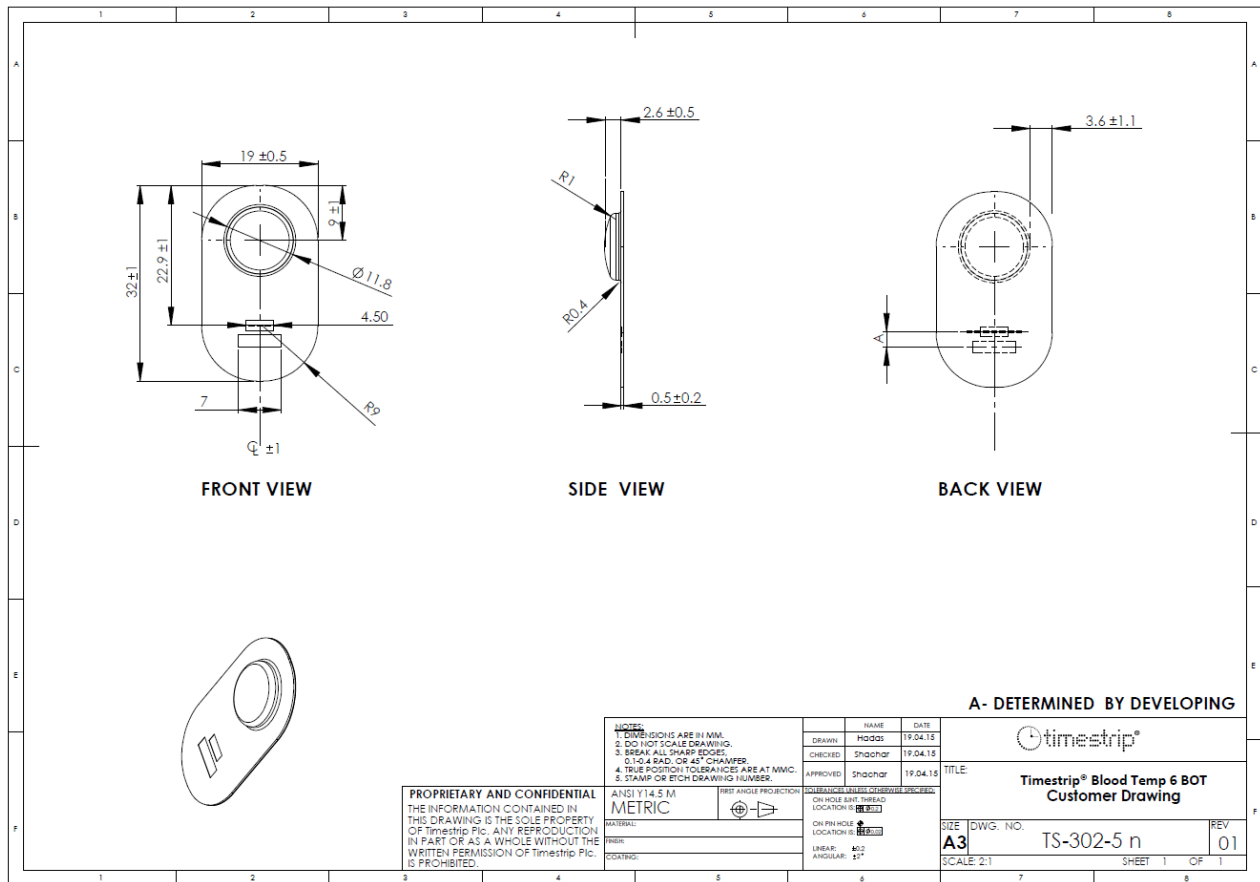


Fig 2: Graphics

100%

200%

CMYK 8/5/1/75

CMYK 15/9/3/50

CMYK 23/14/4/25

Pantone 536 EC

Pantone Process Blac EC

Pantone 1807 EC

Pantone 356 EC

Pantone Process Yellow EC

***For Approval:**

1. Print out, sign and Fax to +972-9-8991347 or
2. Send a Mail with the approved graphics attached to mail.

Customer approval *			
Name		Graphic Designer: Hadas30.04.15	
Sign.		Lin. Tolerance: ±0.5mm.	
Date		Drawing No.:	
		Printing DWG:	

Title: Timestrip® Blood Temp 6 BOT	
Graphic no.	Rev. 1
800-302B	SH. 1 OF. 1

Appendix 1

DuploCOLL® 2353

Art. No. 11 02 20

Double-sided adhesive tape with special paper carrier

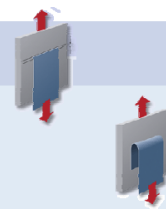
Specific technical data*

Temperature range	-40 °C to +100 °C
Rising heat test in a steel-PET-bond, beginning at 20 °C, increasing temperature every 30 minutes by 10 °C; no loss of adhesion up to	106 °C

* Specific test results, statistically not approved.

Technical Data

Shear strength	on steel according to DIN EN 1943, edition 1996, at +23 °C +/- 2°C	25 N/625 mm ²
Peel strength	on steel according to DIN EN 1939, edition 1996, at +23 °C +/- 2°C	17 N/25 mm



Product features

Applicability on

Initial adhesion	● ● ●	Foam	● ● ○
Final adhesion	● ● ○	Rubber	● ● ○
Dimensional stability	● ○ ○	Fabric	● ● ●
Adhesion on even surfaces	● ● ●	Glass/Ceramics	● ● ○
Adhesion on rough surfaces	● ● ○	Wood	● ● ●
Ageing resistance	● ● ●	High energy plastics: PVC, PC, ABS,...	● ● ●
Weathering resistance	● ● ●	Low energy plastics: PE, PP,...	● ● ○
Chemical resistance	● ● ●	Metal	● ● ●
Resistance to plasticizers	● ● ○	Paper/Cardboard	● ● ●

● ● ● very suitable ● ● ○ suitable ● ○ ○ suitable with reductions ○ ○ ○ not suitable

Document information

Document Type	Identifying No.	Rev./Issue	Date
Graphics	800-302B	01	30.04.15
Product Drawing	TS-302-5 n	01	19.04.15
Adhesive	DuploCOLL 2353	--	05/2011
Product Specification Sheet	--	00	22.06.15