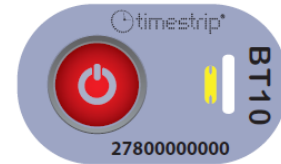


Product Specification

Item Code:
TP278

Product Name:
Timestrip® Blood Temp 10

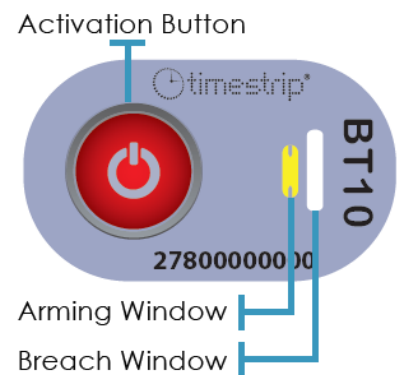


General:

The Blood Temp 10 blood bag indicator (BT10) 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, BT10 will begin to sense the blood temperature. Any breach of the blood temperature above 10°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.



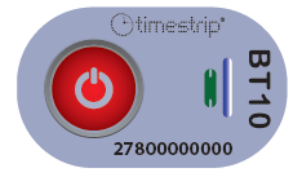
Instructions for Use:

1. Select a BT10 indicator and implement a QC visual test: make sure that the indicator is not activated - the arming window should be yellow and the breach window should be white.
BT10 does not require pre-conditioning.
2. Note: the activation button can only be squeezed when the BT10 is at or above 10°C.
3. Remove the pre-chilled blood bag from the controlled refrigerator (2°C/36°F – 6°C/43°F). Select a suitable location on the blood bag for the BT10 (for example, the lower 1/3rd of the blood bag, if stored upright). Ensure this area is oil & moisture free.
4. Firmly squeeze the button located on top of the indicator, between thumb and forefinger. Verify that the arming window changes colour immediately from yellow to dark green.
5. Immediately after activation, peel off the liner and firmly adhere the BT10 to the prepared location. Verify full adhesion to the blood bag.

Monitoring has begun!

BT10 does not need post- conditioning once on a pre-chilled blood bag, which can now either be transported right away or returned to the refrigerator for future use. BT10 may remain on a stored blood bag as long as no indication is observed.

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 10°C/50°F
- Temperature Accuracy: 9° - 10°C /48°F - 50°F
- Display: Irreversible

II) Product Specification:

- Blister Position: Button on Top (BOT)
- Colour of breach window during a breach event: Blue
- Adhesive: Option 1: DuploCOLL® 2353; Option 2: DuploCOLL® 3720 – 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 indoors, at room temperature up to 30°C.

VI) Shelf-life:

- 2.5 Years from date of manufacture.

Fig 1: Product Drawing

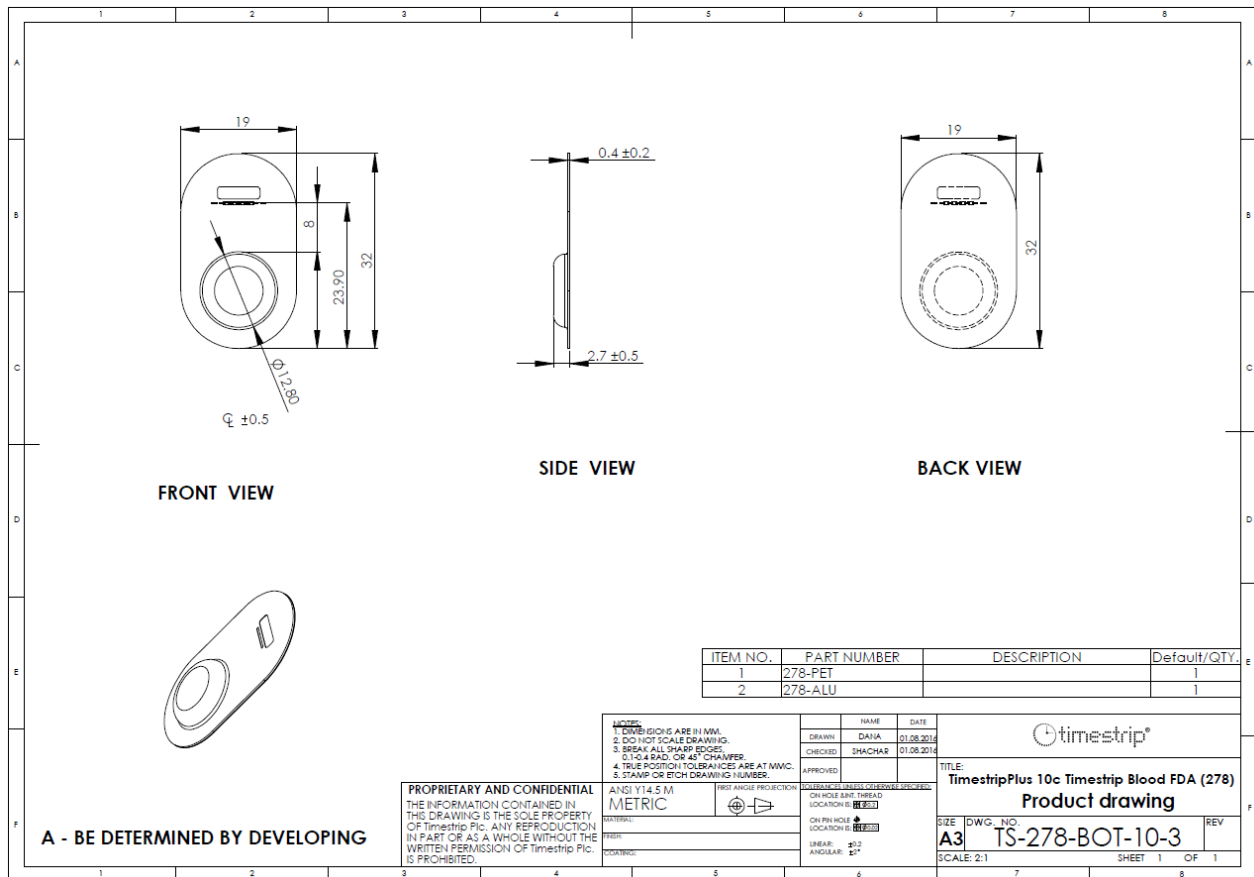


Fig 2: Graphics

Before
After activation
After

5-30 minutes

200%

Color printing

Pantone	for time-strip use only
 PANTONE Process black ec	0/0/6/0
 PANTONE 356c	
 PANTONE 1807 ec	
 PANTONE 536EC	
 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		Title: Timestrip BLOOD TEMP 10 BOT 5-30 minutes	
Sign.	Graphic Designer: DANA 18/07/2017	Graphic no.	Rev. 01
Date	Ln. Tolerance:±0.5mm. Drawing No.:	800-2781	SH. 1 OF. 1
		Printing DWG: TSP2-L-00000	

Appendix 1

Option 1:

DuploCOLL® 2353

Art. No. 11 02 20

Double-sided adhesive tape with special paper carrier

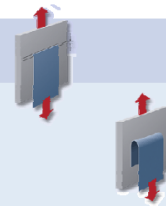
Specific technical data*

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

Initial adhesion	● ● ●
Final adhesion	● ● ○
Dimensional stability	● ○ ○
Adhesion on even surfaces	● ● ●
Adhesion on rough surfaces	● ● ○
Ageing resistance	● ● ●
Weathering resistance	● ● ●
Chemical resistance	● ● ●
Resistance to plasticizers	● ● ○

Applicability on

Foam	● ● ○
Rubber	● ● ○
Fabric	● ● ●
Glass/Ceramics	● ● ○
Wood	● ● ●
High energy plastics: PVC, PC, ABS,...	● ● ●
Low energy plastics: PE, PP,...	● ● ○
Metal	● ● ●
Paper/Cardboard	● ● ●

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

Option 2:**DuploCOLL® 3720**

Art. No. 11 01 15

Double-sided adhesive tape with special paper carrier for universal applications**Specific technical data***

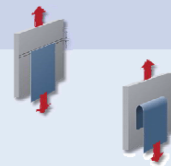
Temperature range	-40 °C to +150 °C**
Peel strength on polypropylene after 24 h at room temperature	21 N/25 mm
Peel strength on polyethylene after 24 h at room temperature	17 N/25 mm
Certified and recognized according to UL 969 	

* Specific test results, statistically not approved,

** Reached temperature in a rising heat test according to the internal test method PM-211 following DIN EN 1943 at 1 kg strength, beginning at 30 °C, increasing of temperature every 30 minutes by 10 °C

Technical Data

Shear strength	on steel according to DIN EN 1943, edition 1996, at +23 °C +/- 2°C	40 N/625 mm ²
Peel strength	on steel according to DIN EN 1939, edition 1996, at +23 °C +/- 2°C	30 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	800-278	01	18.07.17
Product Drawing	TS-278-BOT-10-3	04	01.08.16
Adhesive	DuploCOLL 2353	--	05.2011
	DuploCOLL 3720	--	04.2019
Product Specification Sheet	--	03	05.2019