

# Product Specification

Item Code:  
**TP278**

Product Name:  
**Timestrip® Blood Temp 10**

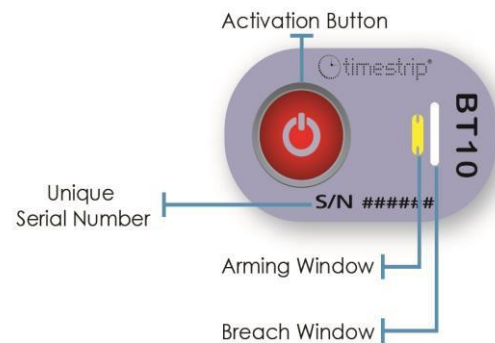


## General:

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: DuploCOLL<sup>®</sup> 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.

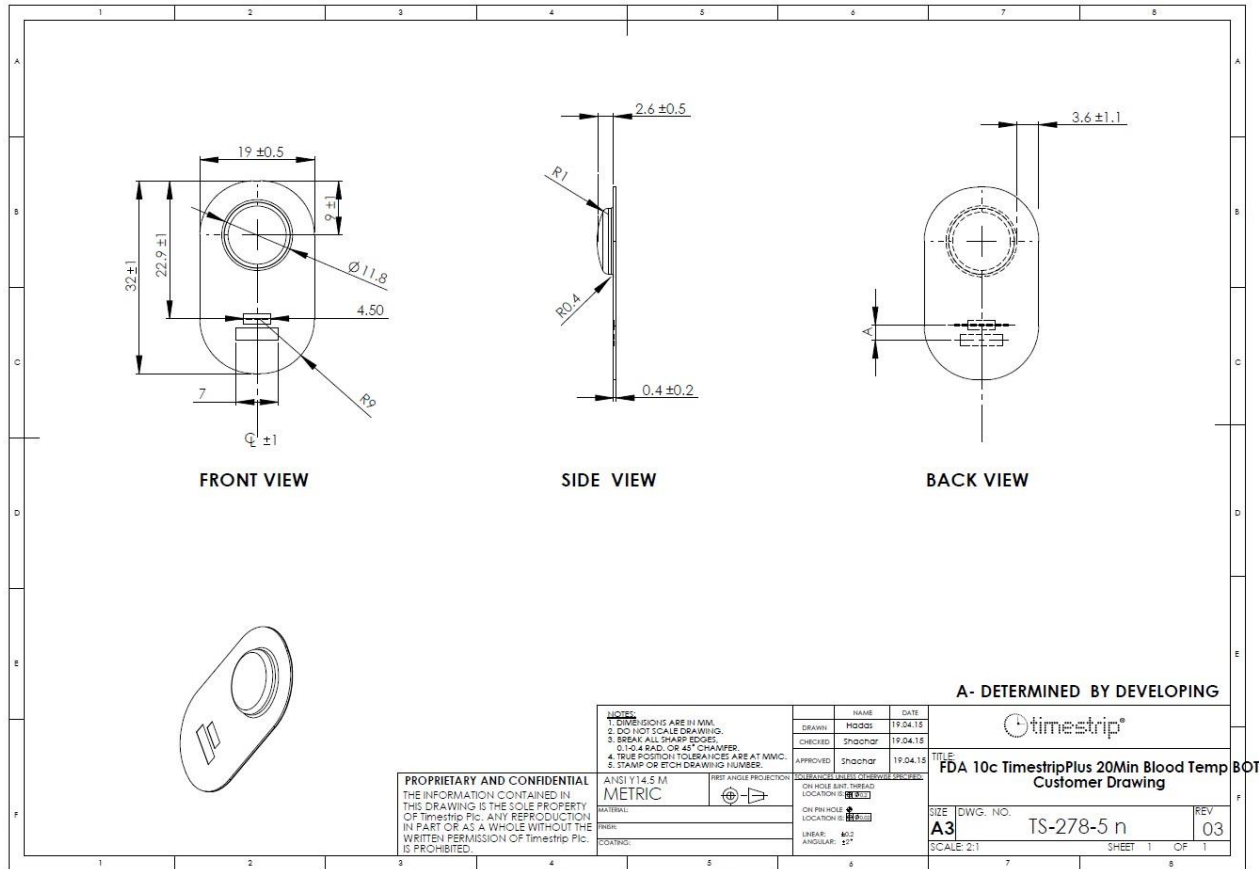
**V) Storage Conditions (un-activated):**

- 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.

<b>Customer approval *</b>			
<b>Name</b>		Title: 10C BLOOD MONITOR FDA BOT	
<b>Sign.</b>		Graphic no. 800-278F	
<b>Date</b>		Rev. 1 SH. 1 OF. 1	

## Appendix 1

# DuploCOLL® 2353

Art. No. 11 02 20

### Double-sided adhesive tape with special paper carrier

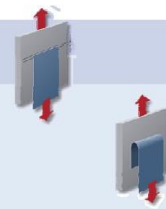
#### Specific technical data\*

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

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

#### Document information

Document Type	Identifying No.	Rev./Issue	Date
Graphics	800-278F	01	30.04.15
Product Drawing	TS-278-5 n	03	19.04.15
Adhesive	DuploCOLL 2353	--	05/2011
Product Specification Sheet	--	02	25.09.16

