Timestrip® Temperature Indicator and Report (TIR) Operating Manual



Timestrip® TIR 0°C and 2-8°C (TIROC and TIR2-8C)

Timestrip TIR (temperature indicator & report) is a device for continuously monitoring temperature and calculating the remaining stability budget of pharmaceutical products or clinical studies along the entire supply chain.

Timestrip TIR is thin and small enough to go on clinical kits and sales units and durable enough to stay on the pharmaceuticals during the entire shelf life of up to 2 years.

The Timestrip TIR alarm status is always visible and can also be extracted by a compatible smartphone app.



Timestrip TIR shall only be applied on outer packaging – avoid usage on pharmaceutical primary packaging (such as blood bags or plastic vials).



INSTRUCTIONS

Storage

Store Timestrip TIR in a controlled environment and activate it prior to the "Start before" date.

Check mode before use:

Press button (▶) before usage for 1 second

- LED blinks orange (2x •): Indicator is ready for use
- LED blinks orange (1x): do not use indicator
- LED does not blink (O; expiration date or lifetime exceeded): do not use indicator

Indicator Usage:

- 1. Break tab to start the Timestrip TIR and enclose it with the product. Green LED indicates start (3x3 times blinking (•••O••O••) Alarm activation delay may be indicated by green LED (3x blinking every 30 seconds•••)
- 2. During temperature monitoring, alarm status will always be flashing

Green LED (1xo) indicates OK status

Red LED (1x ●) indicates ALARM status (irreversible)

Timestrip[™] TIR 0°C shows an ALARM ($1x \bullet$) when there is a single zero below occurrence lasting 10 minutes or more

Timestrip recommends checking the alarm status on a regular basis.

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ENVIRONMENTAL CONDITIONS		
Temperature	Do not expose to extreme hot temperatures outside specification (risk of gas explosion)	
Microwave	Do not expose to microwave radiation (risk of battery explosion)	
Shocks	Avoid violent knock and blows (risk of damage to the battery / short circuit)	
Water/Humidity	Ensure controlled non-condensing environment (risk of short circuit since Timestrip ITS has no protection against ingress of water)	
IR Radiation	Avoid exposure to IR radiation (heat and superheated steam can result in deformation of the case)	
X-ray	Avoid long-term exposure to X-ray (risk of harm to Timestrip ITS). Tests of short x-ray exposures as part of transportation processes (airports, customs) have been performed and documented.	



Safety Instructions

Button cell lithium battery:

- Lithium, manganese dioxide
- Non-rechargeable button cell battery contained in equipment UN3091 (IATA compliant)
- No shipping declaration required (exempt from DGR declaration)

Material Safety Data Sheets are available on request.

Disposal

Do not throw Timestrip TIR into fire, the battery could explode. This product has to be disposed of according to WEEE (Waste Electrical and Electronic Equipment, 2012/19/EU) or according to the local regulations.



Smartphone App

- Timestrip TIR is compatable with a smartphone via an app that is available for free in the App Store (iOS) and the Google Play Store (Android).
- The app calculates and records the stability budget left when you take a photo of the indicator with your smartphone. The app allows you to add relevant product information and create and send the PDF report.

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SPECIFICATIONS				
Operating range for TIR 2-8°C	-30°C to +70°C; TIR 472 range: 0°C to +25°C			
Operating range for TIR 0°C	-30°C to +70°C; TIR 471 range: -2°C to +30°C			
Measurement Accuracy	±0.4°C typ.			
Measurement Interval	1 minute			
Battery Life	Runs for up to 18 months, shelf life of 2 years			
Programmable Alarms	6 temperature alarm levels with alarm delay options			

LOGGING TIMESTRIP® TIR 0° C					
Start Delay (0 minutes-45 days)	30 Minutes				
		Temperature	Allowed Time		Event Mode
Alarm Conditions	Zone	°C	Time	Min/Hours/ Days	Single or Cumulative
Ultimate Upper Limit	H3		0	N/A	
High Zone 2	H2	30.0°C	730	Days	Cumulative
High Zone 1	H1	10.0°C	730	Days	Cumulative
Good Zone	G	0.0°C		No Alarm	1
Lower Zone	L1	-2.0°C	10	Minutes	Cumulative
Ultimate Lower Limit	L2	2.0 C	0	N/A	

LOGGING TIMESTRIP® TIR 2-8° C					
Start Delay (0 minutes-45 days)	30 Minutes				
		Temperature	Allowed Time		Event Mode
Alarm Conditions	Zone	°C	Time	Min/Hours/ Days	Single or Cumulative
Ultimate Upper Limit	H3	25.0°C	0	Minutes	Cumulative
High Zone 2	H2	15.0°C	60	Minutes	Cumulative
High Zone 1	H1	8.0°C	30	Minutes	Cumulative
Good Zone	G	2.0°C	No Alarm	N/A	N/A
Lower Zone	L1	0.0°C	30	Minutes	Cumulative
Ultimate Lower Limit	L2	0.0 C	0	Minutes	Cumulative

DEVICE OPTIONS		
LED-Blinking	Blink status always stays on	Note: Option "always blink alarm status" reduces battery life
Download Options	Read-out possible	
Stop Options	Never stop statistics	

NOTE: All information in this document is correct at the time of publication. Due to continuous product development, we reserve the right to change this information. Major changes in functionality & technical specifications are communicated and described in release notifications.

Contact us at **800.435.4242** or head to **pdchealthcare.com** to learn more today.