Operations Manual

LIBERO ITS

Profile A008

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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. All changes are subject to change management according to ISO 9001:2015. Major changes in functionality and the technical specifications are communicated and described in release notifications.

Safety Instructions

Battery

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 Sheet is available at ELPRO on request.

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 LIBERO 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 LIBERO ITS). Tests of short x-ray exposures as part of transportation processes (airports, customs) have been performed and documented (available at ELPRO).

Intended Use

All electrical devices produced by ELPRO-BUCHS AG are for commercial use LIBERO ITS are for commercial use ("business to business") exclusively.

Disposal

Do not throw LIBERO ITS 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. The device may be returned at own cost to any ELPRO subsidiary for proper recycling.

Applicable Documents

The actual Technical Specifications for LIBERO ITS can be retrieved from www.elpro.com

Description

LIBERO ITS is a device for continuously monitoring temperature and calculating remaining stability budget of pharmaceutical products or clinical studies along the entire supply chain. LIBERO ITS 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 5 years. LIBERO ITS manages deviations up to 6 alarm zones. The alarm status is always visible and can be extracted by a smartphone app. LIBERO ITS is compatible with ELPRO's cold chain database liberoMANAGER.

IMPORTANT: LIBERO ITS monitors temperature exposure and not the product quality. Its purpose is to indicate if product quality evaluation/testing is required. LIBERO ITS shall only be applied on outer packaging – avoid usage on pharmaceutical primary packaging (such as blood bags or plastic vials).

Instructions

Storage

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

Check Configuration Profile and press button before usage for 1 second

=> LED blinks orange (2x ●●): Indicator is **ready for use**

ⓘ If LED blinks orange (1x ●; idle) **or** LED does not blink (○; expiry date or lifetime exceeded): **do not use indicator**

Indicator usage

1) Break tab to start the LIBERO ITS and enclose it with the product

=> Green LED indicates start (3x3 times blinking ●●●○●●●○●●●)

ⓘ Alarm activation delay may be indicated by green LED (●●● 3 times blinking every 30 seconds)

2) During temperature monitoring, alarm status can be detected by pressing button for 1 second

=> Green LED (1x ●) indicates OK status

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

ⓘ ELPRO recommends to the customer to check the alarm status on a regular basis

ⓘ A stopped indicator shows additionally an orange LED (1x ●● - OK status / 1x ●● - ALARM status)

3) If configured, stop indicator by pressing button for 3 seconds

=> Green & Orange LED (3 times blinking ●●○●●○●●) indicates stop - OK status

=> Red & Orange LED (3 times blinking ●●○●●○●●) indicates stop - ALARM status

Smartphone app for read-out

1) Download and install smartphone app "LIBERO ITS"

=> Available for iOS (App Store) or Android (Google Play Store) operating systems

2) Start smartphone app and follow instructions

=> Press button on LIBERO ITS for 3 seconds to transfer alarm statistics (LED flickering ●●●)

ⓘ Use indoor (<800 lux) and avoid backlighting or direct sunlight on the LIBERO ITS

ⓘ Keep the smartphone stable and avoid trembling

ⓘ If web communication is filtered by a firewall, ensure that ports 50002 / 4003 are open and the domain "elpro.com" can be reached

3) Add relevant product information and proceed

=> Upload and archive record in liberoMANAGER database

=> Create and send PDF report

ⓘ ELPRO recommends to upload and archive every report in liberoMANAGER database

Specification

Technical Specification (in detail can be retrieved from http://www.elpro.com/liberoits)

Operating range	-30 °C..+70 °C
Measurement accuracy	±0.4 °C typ.
Measurement interval	1 minute
Battery life	runs for up to 4 years
Programmable alarms	6 temperature alarm levels with alarm delay options (single or cumulative)
Expiry date (start before)	36 months from production

Configuration Profile ID A008 – WHO Type 2

The Configuration Profile can be identified via the first four characters of the Device ID

=> In this example **A001**0000001 => Profile A001)

5	Profile Text					
6	Line 1	WHO	(shown on device label and Validation certificate)			
7	Line 2	Type 2	(shown on device label and Validation certificate)			
8	Line 3		(shown on device label and Validation certificate)			
9	Line 4		(shown on device label and Validation certificate)			
10	Button instruction line 1	Press for status	(shown on device label; depending on LED-option)			
11	Button instruction line 2	Hold 3 seconds	(shown on device label; depending on Stop-option)			
12	Button instruction line 3	to stop / read	(shown on device label; depending on Stop-option)			
13	**Logging**					
14	Start Delay (0 minutes to 45 days)	60	minutes			
15	**Alarm Conditions**	**Zone**	**Temperature** in °C	**Allowed Time** time	minutes hours days	**Event Mode** single or cumulative
16	active Ultimate upper limit	H3		1	hours	single
			44.9			
17	active High-Zone 2	H2		10	hours	cumulative
			29.9			
18	active High-Zone 1	H1		20	hours	cumulative
			9.9			
19	Good-Zone	G		No Alarm		
20	disabled Lower Zone	L1				
21	Ultimate lower limit	L2				
22	**Device Options**					
23	LED-Blinking	blink status on request	Note: Option "always blink alarm status" reduces battery life			
24	Download options	read-out possible				
25	Stop-options	stop statistics allowed	Note: Option "stop statistics allowed" does not allow download during tr			
26	**Logistics**					
27	Box label Line 1		WHO	(included in data matrix on box, and visible on box)		
28	Box label Line 2		Type 2	(included in data matrix on box, and visible on box)		
29	Box label Line 3			(included in data matrix on box, and visible on box)		