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iLogger Case 4A User's Guide

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www.maksense.com

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Introduction

The iLogger Case 4A system allows for transports to be monitored with iRACK, without the need for any additional procedures by the user, and in accordance with sample transport standard UN3373 – Cat. B.

Manual

This manual explains how to use the iLogger Case 4A system. It also provides some information regarding the iLogger Case 4A's main functions, as well as instructions on the system's maintenance and sanitization.

Patent Info

iSens Electrónica Lda. owns all the intellectual property rights over the iLogger Case 4A technology, as described in this document.

Warranty

All products supplied by **iSens Electrónica Lda.** are covered by our 2-year-warranty.

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FCC Regulatory info:

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

No changes shall be made to the device without the manufacturer's permission as this may void the user's authority to operate the device.

This device complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. The iLogger Case 4A complies with the safety requirements for RF exposure in accordance with FCC Part 2.1093 for portable use conditions.

ISED Canada Regulatory info:

This device complies with ISED's licence-exempt RSS standard(s). Operation is subject to the following two conditions:

- (1) this device may not cause interference, and
- (2) this device must accept any interference, including interference that may cause undesired operation of the device.

This device complies with ISED Canada RF radiation exposure limits set forth for an uncontrolled environment. The iLogger Case 4A complies with the safety requirements for RF exposure in accordance with RSS-102 for portable use conditions.

Informations réglementaires d'ISDE Canada:

Ce dispositif est conforme à la norme RSS exemptée de licence de l'ISED. L'opération est soumise aux deux conditions suivantes :

- (1) ce dispositif peut ne pas causer d'interférence, et
- (2) ce dispositif doit accepter toute interférence, y compris les interférences qui peuvent causer le fonctionnement indésirable de l'appareil.

Cet appareil est conforme aux limites d'exposition aux rayonnements RF d'ISED Canada établies pour un environnement non contrôlé. L'iLogger Case 4A est conforme aux exigences de sécurité pour l'exposition aux RF conformément à la norme RSS-102 pour les conditions d'utilisation portables.

General Notice

The internal case must not be removed from inside the external bag. To do so, please first remove the batteries following the instructions set below for batteries replacement.

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1. General Description

1.1 iLogger Case 4A

iLogger Case 4A provides for sample transport monitoring with iRACK, without the need for any additional procedures by the user, and in accordance with sample transport standard UN3373 – Cat. B.

The iLogger automatically records data on the iRACK's RFID, such as temperature conditions, time in the iLogger and possible impacts; this data is then accessible in Indexor Systems.

1.2 General characteristics

iLogger Case 4A	
Dimensions	420 [L] x 420 [W] x 370 [H] mm
Max. number of Samples carried	240
Ice pack slots	5
Mechanical resistance	1100 kPa
Thermal conductivity	0.023 W/mK
Weight	3.4 Kg
Temperature Sensor (TSYS01)	-40 °C to 125 °C (+/-0.1 °C)
Time interval for temperature recording*	1, 5 or 10 min
G-force impact sensor (SQ-ASE-060)	>60 G
Power Source	3 x Type C alkaline batteries
outdoor use	the equipment is not intended to be constantly subjected to an outdoor environment
Operating Temperature Range	-5 to 45C°
Operating humidity	maximum relative humidity 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C Suitable for use in wet locations
Operating pollution degree	PD2
IP Rating	Not rated
Maximum Altitude	3 000 Meters

***time interval is factory defined**

System components

The iLogger Case 4A system includes:

1.2.1 Isothermic bag



- Bag with nylon exterior cover with Velcro opening/closing system;
- Inner isothermic cover in polyamide and polyethylene;
- Upper double pocket with Velcro fastener;

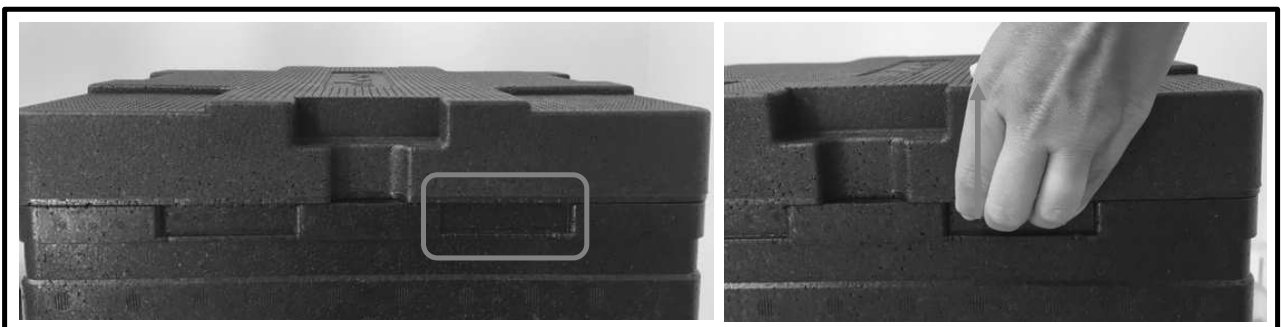
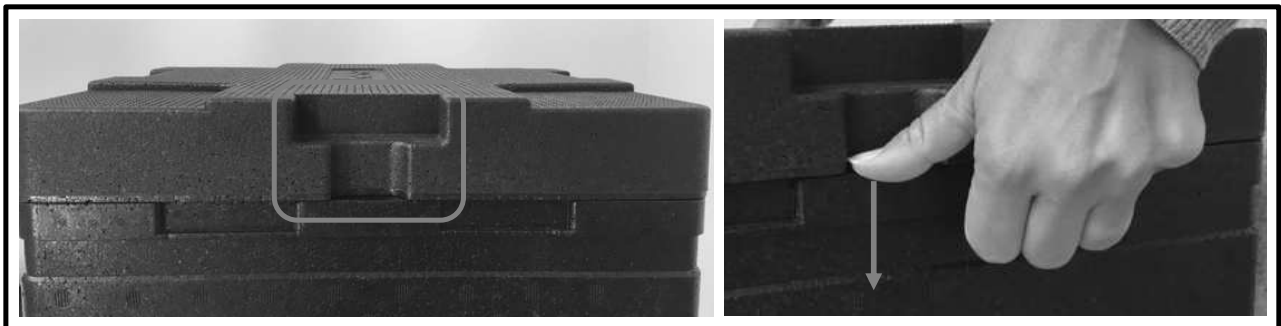
1.2.2 Isothermic EPP Box



- Lightweight EPP (expanded polypropylene) box with high mechanical and thermal resistance;
- Can accommodate up to 240 samples in four iRACKs and 5 Ice packs;
- Hermetically sealed when properly closed;
- 100% recyclable and chemically inert;

To open the box:

Place your hands as depicted. Press down with your thumb in the middle section [1] and at the same time push up with your fingers on the bottom part of the lid [2].



1.2.3 Temperature and impact controller



-The iLogger Case 4A creates an electronic registry of the data in the iRACK, such as transport conditions:

- Temperature
- Time in bag
- Impacts above 60G;

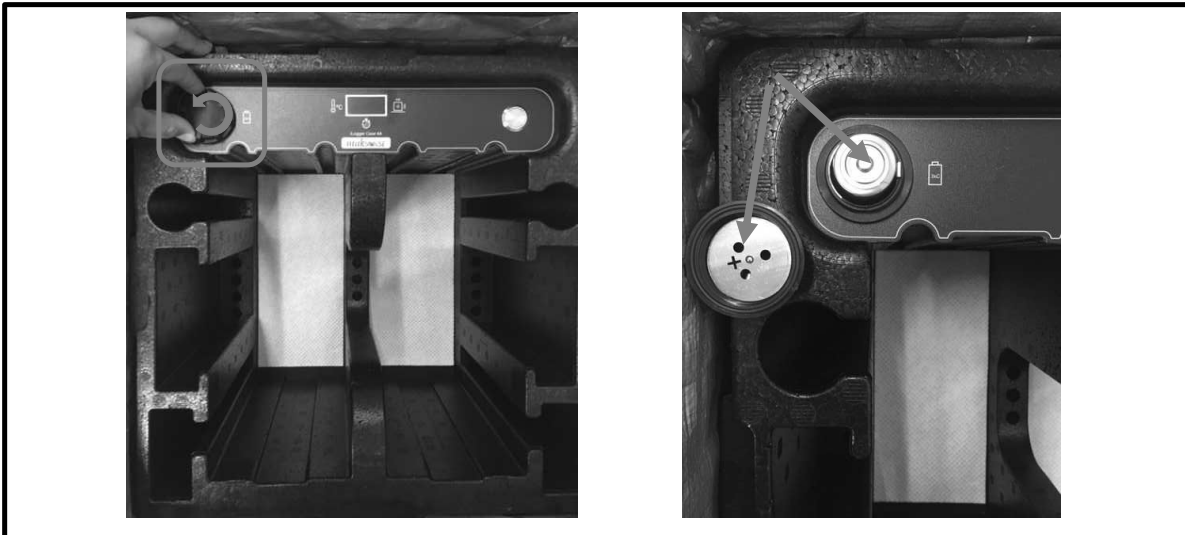
-Power is supplied by 3 type C alkaline batteries (see image below), expected to last for over a year (batteries not included);



To change the batteries, turn the compartment lid anti-clockwise (see below). Once open, tilt the case so you can remove the 3 batteries. Insert new batteries with the + pole always up as indicated on the compartment lid (bottom right image) and turn the lid clockwise to properly secure the batteries in place.

Replacement batteries must be a non-rechargeable alkaline type. Replacing with the incorrect type of battery may result in hazard to the equipment.

Do not dispose in fire. Please follow local environmental applicable regulations.



- The iLogger Case 4A also has a status button, which activates the display for 5 seconds, displaying the following information:

- Slots occupied with iRACKs;
- iLogger serial number;
- Battery level;
- Temperature;

- The TSYS01 temperature sensor model is highly accurate (+/- 0.1 °C) and capable of measuring temperatures from -40 °C to 125 °C. The recommended calibration frequency is every 2 years;

- Recommended validation time interval for the SQ-ASE-060-ICT impact sensor is of 5 years. Validation should be done according to expected conditions of use.

For internal validation of both the temperature and impact sensors please follow this procedure: [An empty sample tube without a label is required to proceed.]

- place an empty iRack into an indexor standard module;
- at the indexor standard, type "12345678" on the keyboard and immediately insert a tube without a label in the iRack; if the tube is inserted after the acceptable time, indexor will blink red and one should repeat the instruction;

- press the iRack name in the touchscreen display of the indexor and select Check-out; please wait, while indexor records information in the iRack; put the iRack cover;
 - open the iLogger case, press the button and check the screen display to confirm it has batteries;
 - take the iRack from indexor and place it into the iLogger, closing the iLogger lid and the bag; please
- wait for six minutes;
- pick up and then vertically drop the bag from an height of over 1,2 meter; wait for 10 seconds; repeat the drop test;
 - take the iRack from inside the iLogger and place it back into the indexor standard;
 - press again the iRack name and select Check-in;
 - a new window will be presented where the impact alert is shown; exit this alert window;
 - to check for the temperature, go to "Database"/"Transport" and the new window will show the test values for the iRack in the "Temp Min-Max" column.

As long as impact alerts are shown the iLogger impact sensor is functional.

- Please contact iSens Electrónica Lda after a validation fail in order to assess if it is to be returned, retired or calibrated.

1.2.4 Absorbent "Pads"

- The super absorbent pad is a single use item made of a unique super absorbent polymer
- They transform liquid into compact gel quickly and efficiently. They can jellify between 65 to 450 times their weight;
- Anti-odor;
- Each slot contains one absorbent "pad" with an absorption capacity of 450 ml;

The Absorbent Pads are of single use until damaged by spillage. In such case, simply remove the pads and dispose to waste following applicable guidance at site for potentially bio-hazardous substances waste disposal.

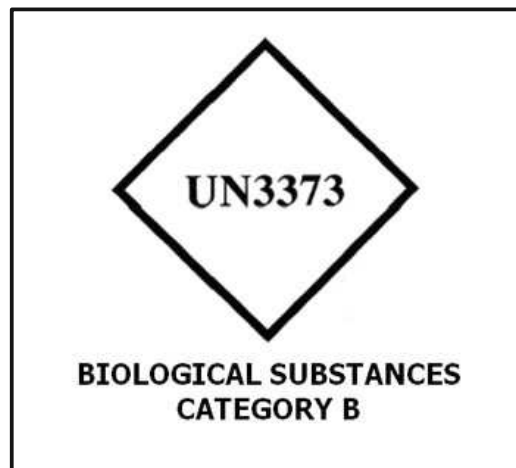
Absorbent Pads replacements can be found in any major laboratory safety material provider. Gelmax Superabsorbent Pad is recommended.

2. Working principles

2.1 Compliance with transport standard UN3373

The presented procedures for transporting biological samples are in accordance with transport standard UN3373 – Cat. B – Packing instructions P650.

The external packaging indicates, in dimensions greater than 10 x 10 [cm], the content being carried (see image below).



The packaging system includes three components:

1 – Primary: sample tube - should be able to hold its content in normal transportation conditions.

2 – Secondary: iRACK with cover + EPP Box - are rigid components with high mechanical resistance (tensile strength >1100 kPa) with Absorbent "Pads", which prevent contamination of the external case if leakage occurs. It also includes sufficient absorbent material to absorb the products in the primary package.

3 – External: Isothermic bag - includes straps to facilitate transportation and a highly resistant coating (nylon). The isothermal internal layer (polyamide and polyethylene) optimizes the thermal stability of the package

2.2 Handling procedures

The iLogger Case 4A has a total capacity of 4 iRACK (240 tubes) with cover. The dents in the iLogger indicate the correct position to place the iRACK (see image below).



1. Place the four iRACKs correctly oriented, in order to keep the samples from moving as much as possible.

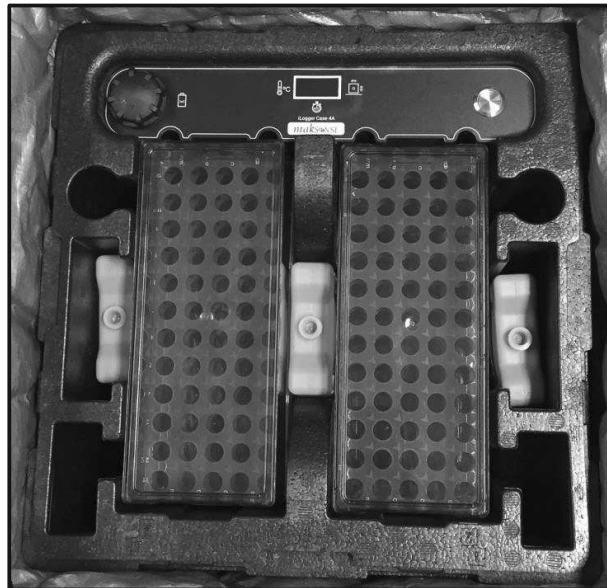
No additional steps are required to record temperature and impacts. This is automatically recorded in the iRACK.

After placing the iRACK, you can push the *status* button to activate the display to check if the iRACK has been correctly detected (see image below) or to check the current temperature inside the case.



Depending on the required temperature for transportation, and on the external temperature, it is possible to accommodate up to 5 Ice packs (see image below):

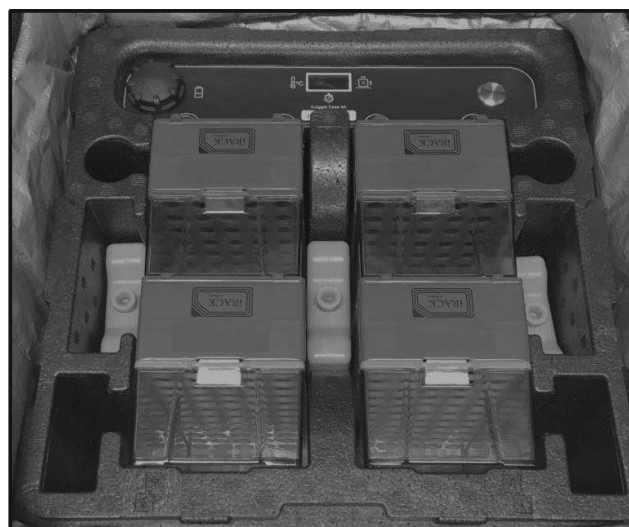
- 3 Ice packs on the sides;
- 2 Ice packs on top of the iRACKs (the cover is designed with enough space to accommodate them);



2. Close the EPP Box correctly. The box has 8 protrusions. Ensure they have been correctly sealed.

3. Seal the external bag with the Velcro fastener.

4. To transport an iRACK without any samples, for instance: after transportation, upon returning the iRACKs along with the iLogger Case 4A, you can place them vertically on the box, in order to maximize battery life (see image below).



3. Safety Instructions

The iLogger Case 4A system was designed to be safe. However, for safe operation and to avoid damage, the following instructions should be respected:

- Avoid shaking the iLogger Case 4A system and always place it on **stable surfaces**.
- Keep it away from **high temperatures (such as heaters)**.
- Do not place the iLogger Case 4A system under **direct light** or under **high-power lamps**.

Maintenance

- The iLogger Case 4A system **does not require any special maintenance**.



Warning

- The safety of users may be impaired if the equipment is used in a manner not specified by the manufacturer in this manual

- Please do not perform any kind of maintenance on the iLogger Case 4A system yourself. Do not try to disassemble, modify, change, alter or repair the iLogger Case 4A system.

Environmental Information



This symbol means that this product is in accordance with EU Directive 2012/19/EU (WEEE Directive), regarding waste electrical and electronic equipment. Disposal must be carried out in accordance with applicable national legislation.

For more information on how to treat, recover or recycle this product, please contact the supplier.



Important: Proper disposal of the equipment will help to avoid potentially harmful consequences to the environment and human health.

4. Cleaning and disinfection

Cleaning the iLogger Case 4A system

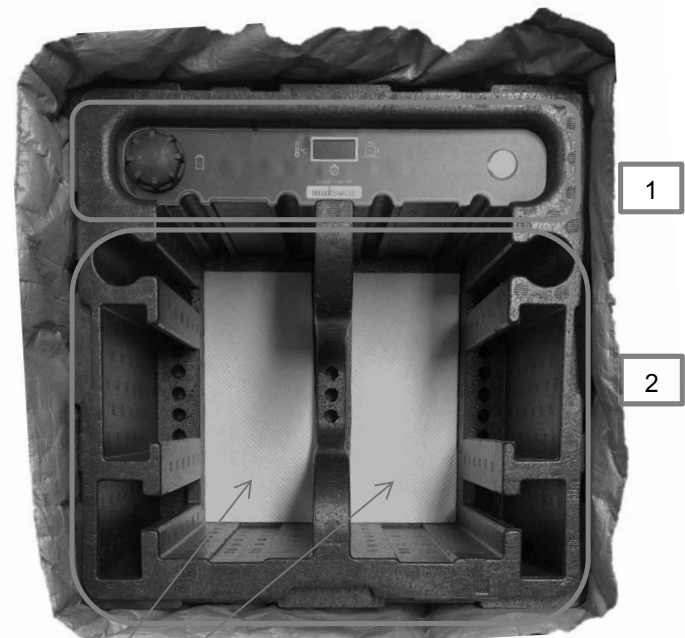
Exterior:

It can be cleaned with a **soft cloth slightly moistened with ethyl alcohol (70%)**.



Interior:

Be careful not to spill any liquids on or near the display of the iLogger Case 4A system [1]. For this area, we advise using a **soft cloth slightly moistened with ethyl alcohol (70%)**.



Following on from case [2], using liquids is allowed, as long as they are not acid or caustic chemicals.

Before starting the cleaning process, please remove the "absorbent pads". If any spilling occurs, they will be destroyed and need to be replaced.

5. Manufacturer's Declaration

iSens - Electronica Lda. declares that this device is in compliance with the essential and other relevant requirements of the RED and EMC Directive.

The full text of the EU Declaration of Conformity is available at:
<https://support.maksense.com>.