

De: "Lena Ratianidze" <medinserv@gol.ge>  
 À: "isos.laprie" <isos.laprie@wanadoo.fr>  
 Objet: questions  
 Date : jeudi 11 septembre 2003 14:18

Dear Alain Laprie,

I'd like to thank you for prompt reply. We have studied carefully the information you provided; for us this is the first time of dealing with ISOS and ALCAL, and we need more explanations to realize what we can offer for the tender. Therefore, your help will be appreciated much.



**Questions**

1. Carrier case (56 cm x 30 cm x 33 cm) with the lid and protection corners:



- is this a one- standard case, or variations of sizes are available?  
 What is the inner space, actually used for storage?

**There is one size for ISOS04.**

**Two products are available :**

	
<p><b>ISOS04</b>  <b>Ext : 560*300*330mm</b>  <b>Int : design to use carrier pouches (6)</b>  <b>480*220*330mm</b></p>	<p><b>ISOS02</b>  <b>Ext : 440*350*100</b>  <b>Int : 320*260*70</b></p>

- "suitable in extreme temperature conditions - 30C/ + 40C":  
 does the case have its own thermo-isolation (also, what does the "complementary isolation" mean)? If yes, shall we understand +4C to be the preservation temperature and what are the limits of preservation time, provided that tempature outside comes to about +40C/+43C?

	
<p><b>ISOS04</b></p>	<p><b>ISOS04 with complementary isolation</b></p>

**The first preservation device is ALCAL.**  
**The complementary isolation allows longer preservation.**

- Is that possible to use Carrier Case + ALCAL in tight pouches (without carrier pouches) for preservation temperature +4C? What would be the preservation time in such case?

**That is possible. The preservation time will depend of configuration (quantity of ALCAL and Blood for example).**

- What is the serviceable life of a Carrier Case (or how many times a carrier case can be used)?

**Serviceable life of carrier cases ISOS : many years.**

**Serviceable life of ALCAL : one year.**

## 2. ISOS carrier pouch with handle

- Can it be used separately, without other components?

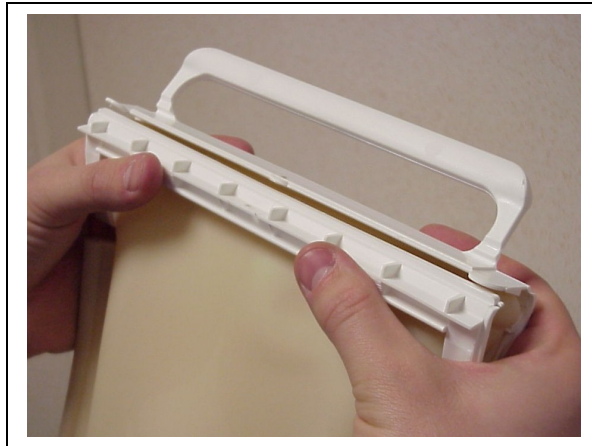
Sizes inner/outer, weight, preservation temperature and regimes, preservation time, serviceable life, etc. - ?

The same features for ISOS carrier pouch + tight pouches with ALCAL -?

**The carrier pouch can be used separately.**

**Size : 160\*270\*60, weight : 330g, serviceable life : many years**

# PICTURES :





### 3. ALCAL products

- Are there the three separate types of ALCAL (+22C, +4C and - 30C), or other types can be offered precisely to required preservation temperature? Please, provide the detailed features in the light of difference between the types. We have asked for data/quotation regarding ALCAL +4C and ALCAL -20C;-25C, whereas the price list only contains AL04 - +4C (330g) and AL22, which is ALCAL +22C. Please, clarify.

- Sizes of tight pouches, volume of filling of ALCAL, serviceable life, etc. - ?

**There is 2 types of ALCAL :**

- one for +4°C preservation,
- one for +22°C preservation.

**The -30°C one is in progress of testing.**

**The ALCAL pouches contain ±400mL.**

- What maximum time does it take to get the ALCAL pack hardened enough for safe preservation of +4C; -20C? Could you also specify the amounts of energy/ refrigerating negative kilocalories/ with respect to the above-mentioned preservation temperatures?

	ISOS® and ALCAL® “+22°C”(72°F)	ISOS® and ALCAL® “+4°C”(39°F)	ISOS® and ALCAL® “-30°C”(-22°F)
Minimum preservation within the limits of tolerance of a defined temperature level.	at least six hours	at least six hours	in progress of examination.

In a 40°C environment, you can hope a 4 hours preservation.

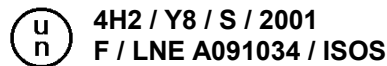
#### 4.General

- Certification - does your certificate meet the requirements of ISO certificate? - possibility of training for personnel that would use ISOS and ALCAL? - guarantee for each component? - to offer your products to the tender we would need the appropriate letters of authorization from the manufacturers. Please, let us know, if you can provide such letters.

#### CERTIFICATIONS

- ISOS® has been approved by the Ministry for transports, infrastructure and housing as fulfilling the requirements for the transportation of dangerous material according to the tests carried out by the National French testing laboratory.

Markings :



- ISOS knows that it is dangerous to transport organic material that may be infectious, and has therefore subjected ISOS® to extensive and severe testing. ISOS® has proven that it fulfils all the requirements for safety and that it is conform to the highest quality and security standards :
  - the security standards for road transport (ADR, January 1999)
  - the recommendations of the French blood bank and blood transfusion agency ( July, 17<sup>th</sup> 1996 signed by Laurent Vachey).
  - the recommendations and regulations of the French ministry of health
- ISOS® also meets the requirements of industrial safety regulations and environmental protection, since the choice of select processing material makes it entirely recyclable.

#### GUARANTEE

- ISOS® and every ALCAL® pack has a guarantee of one year starting with the date of delivery.

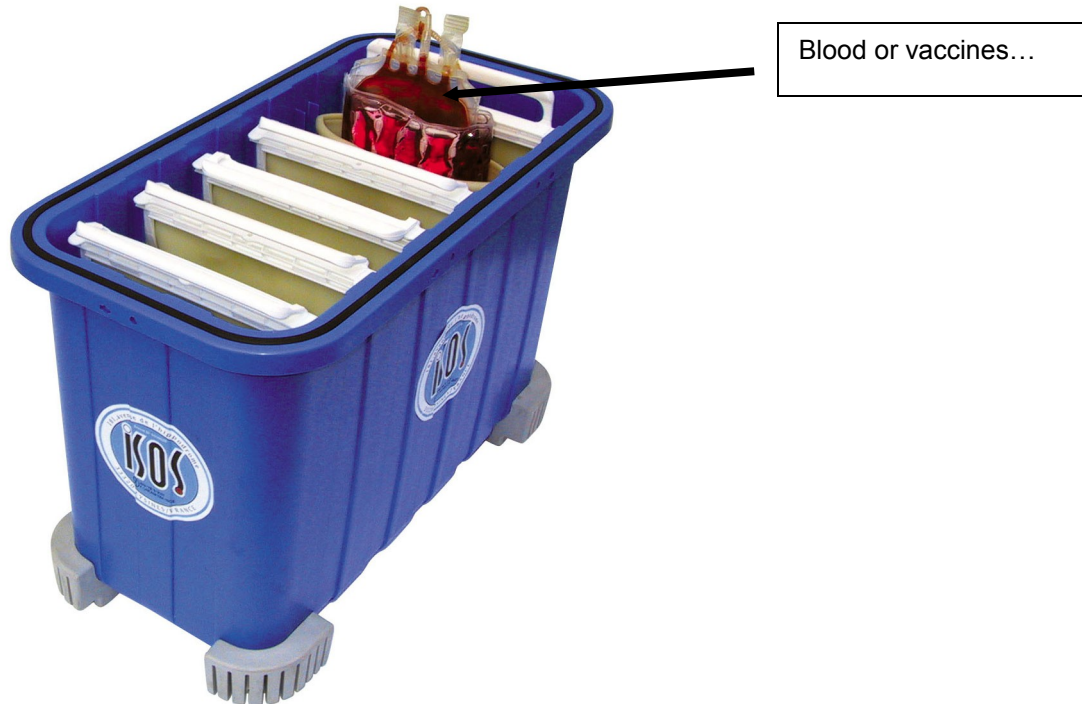
Information about the expected requirements of the tender

1. "Cold chain" transportation device(for vaccines, etc.)

- Inner/storage/ space:  $8 \pm 1$  liters;
- Required preservation temperature:  $+4^{\circ}\text{C}$ ;  $-20^{\circ}\text{C}$  for outside temperature:  $+43^{\circ}\text{C}$  (in "closed" mode);
- Quantity: 53

**ISOS04 is design for it use.**

**The carrier pouches can receive tubes of examination or vaccines, etc...**



**The need is :**

**53x2=106 ISOS04**

**We must not forget ALCALs for the cycle (stocked during others ALCAL are used).**

2. "Cold chain" transportation device (for vaccines, etc.)

- Inner/storage/ space:  $2 \pm 0,5$  liters;
- Required preservation temperature:  $+4^{\circ}\text{C}$ ;  $-20^{\circ}\text{C}$  for outside temperature:  $+43^{\circ}\text{C}$  (in "closed" mode);
- Quantity: 130

**130 ISOS04**

3. Cold Elements

- for temperature, as specified above;
- Quantity: 1960

We would be very thankful, if you could help us to prepare a complete list of your products, which can be offered in consideration of tender requirements or, in case of any difference in features, - as an alternative offer of ISOS and ALCAL components to meet general requirements. In any case, all your suggestions will be of great support to us.



**For more precision, please give us more information : nb of cycles/day...**

In addition, please, let us know if you can recommend a supplier of temperature monitoring indicators:

- temperatures: -20C, 0C, +10 C, +34C
- single or multiple use
- Quantity: 10000 units

We thank you in advance and look forward to future co-operation.

Awaiting for your reply,

Sincerely Yours,

Lena Ratianidze

Friday, September 05, 2003, 7:07:35 PM, you wrote:

il> Dear Lena Ratianidze,

il> With reference to your e-mail, you could find in joined files, prices and  
il> conditions for distributing ISOS. You could find to more information about  
il> ISOS products.

il> Best regards,

il> Alain LAPRIE  
il> ISOS

## INSTRUCTIONS FOR USE ISOS® SAFETY PACKING

### ISOS®

ISOS® can be used with or without a carrier bag, with or without ALCAL® packs.

- **Preparation of an ISOS® container with hanging pouches :**

- For thermo-regulated transportation put the suitable ALCAL® packs into the carrier pouches.
- Put the transport material into the carrier pouches.
- To close the pouch, squeeze its edges tightly together and fix them with the fastening handles. If you here a “click” this shows that the pouch is correctly closed and ready to be sealed.
- Proceed this way for each pouch needed for transport purposes.
- Put the pouches into a hanging position inside the carrier case by gliding them right down into the guide-slots on the sides of the ISOS® carrier case as far as they will go.
- Push down the holders of the pouches.

For maximum efficiency, ISOS® should be used with its **six ALCAL®-filled hanging pouches**, even if they do not contain any transport material.

- Put on the lid and close it by firmly pushing down the four corners one after the other. You need to hear a distinct “click” to assure you that the lid is correctly fitted.
- Shut down the six clasps before sealing if this is required.

- **Unpacking the ISOS® container :**

- Break the seals.
- Open the six clasps.
- Take off the lid by **lifting up one corner after the other**.
- Take each pouch one after the other by its holder and pull it out of its division.
- Break the seals on each carrier pouch.
- Take the holders of each pouch on their extreme ends and push up the fastening clip.
- Take out the transport material.
- Put the ALCAL® packs back into storage conditions as soon as possible.

### L'ALCAL®

- **Preparation of the ALCAL® elements for transportation purposes :**

- Put the suitable ALCAL® packs and the carrier pouches into the storage area several hours before the intended transportation.

Alcal®	Alcal® « +22°C »	Alcal® « +4°C »	Alcal® « -30°C »
Storage temperature	20°C < T < 21°C	3°C < T < 4°C	in progress of testing

- ALCAL® packs can be used as soon as they have become completely solid. The time required for solidification depends on the storage conditions.



- **For best results, ALCAL® elements should be used as follows :**
  - For transportation temperatures of +4°C(39°F), +22°C(72°F) or –30°C(-22°F):
 

**The ALCAL® packs need to be in a SOLID state before any use.**

The solidity of the ALCAL® packs should be manually tested before use so as to make sure that at a temperature of +4°C(39°F) the pack is hardened enough not to allow for any squeezing, whereas at +22°C(72°F) or –30°C (-22°F) a certain malleability can be tolerated.

**Warning :** The use of ALCAL® packs that are only partially solid, reduces the period for safe preservation of the transport material.
  - Each ALCAL® pack is specifically made for use at a certain temperature that needs to be observed.
  - In order to avoid damage to your ALCAL® product do not try to change the form of a solid ALCAL® pack by force.
  - After use, the ALCAL® packs should be put back into storage conditions as soon as possible in order to reduce the time necessary for the material to become solid again.
  - Every ALCAL® pouch carries a mark to indicate the date limit by which it should be used. Do not use the ALCAL® pouch once this date has expired.

## **EMERGENCY INSTRUCTIONS**

- Any problem occurring during or in relationship with the transportation of an unstable blood product, is compulsorily notifiable.
- ALCAL® is a greasy substance. If any **leaking of an ALCAL® pack in a pouch with stored blood** should occur, then this blood product should not be used but should be destroyed for security reasons.  
Immediately remove the carrier pouch from the transportation device and carry out the following operations :
  - Take down the reference of the damaged biological product.
  - Destroy the damaged product.
  - Even if it is empty, the ALCAL® pouch should be returned to your Baxter's representative within 48 hours together with his references and exact information about the conditions in which it has been used and about the transport material.
- In case that a certain quantity of an **unstable blood product should leak inside an ISOS carrier pouch**, all the measures should be taken that are generally necessary for the handling of material that may be infectious.  
Immediately remove the carrier pouch from the transportation device and carry out the following operations :
  - Take down the reference of the damaged biological product.
  - Destroy the damaged product.
  - Clean the ALCAL® pack and the carrier pouch thoroughly with water and with an antiseptic and bleaching agent (a solution of chlorinated potash or of sodium hypochlorate).

After thorough cleaning and disinfection, the ALCAL® pack and the carrier pouch can be used again normally.

## **INSTRUCTIONS FOR CLEANING**

All the parts of the ISOS® transportation device as well as the ALCAL® packs can be easily cleaned and disinfected with chlorinated potash or of sodium hypochlorate.

## **TECHNICAL DATA**

# **ISOS<sup>®</sup> SAFETY PACKING<sup>®</sup>**

### **ISOS<sup>®</sup> SAFETY PACKING – PRODUCT FEATURES**

The ISOS<sup>®</sup> container (industrial patent no. 9809526) is a special device for the transportation of delicate material requiring cautious handling, like stored blood, tubes with pathological test material or human tissue.

ISOS<sup>®</sup> containers include the following characteristic elements :

- an injection-moulded polypropylene carrier case body with elastomeric protections on its four corners and a gasket.
- an injection-moulded polypropylene lid for the carrier case with elastomeric protections on its four corners and a handle.
- six elastomere carrier pouches with injection-moulded polypropylene holders.

The advanced design of the ISOS<sup>®</sup> Safety Packing device has been specially conceived to ensure a maximum of security for the transport material as well as for the persons handling it and for the environment :

- Each of the interior carrier pouches is equipped with a tight fastening system that can be sealed and allows for perfect isolation of the pouch's content.
- The use of separate carrier pouches avoids any direct contact with the transport material.
- The container itself is perfectly tight due to the gasket serving as sealant between the carrier case body and the lid.
- The sealable fastenings of the lid are such that the container cannot open by accident.
- The elastomere protections of the corners function as shock-absorbers.
- The manner in which the pouches are stored inside the carrier case keeps them isolated and provides an excellent protection against any shocks and vibrations.

The qualities of ISOS<sup>®</sup> have been tested and approved by the National French testing laboratory.

An ISOS<sup>®</sup> carrier case is about 56 cm long (22 inches), 30 cm wide (12 inches) and 33 cm high (13 inches). The total empty weight of an ISOS<sup>®</sup> carrier device is about 5,9 kg (13 pounds). Suitable in extreme temperature conditions : -30°C (-22°F)/+40°C

### **ALCAL<sup>®</sup> PRODUCT FEATURES**

ALCAL<sup>®</sup> is an advanced material that has been developed and registered by the French institute for scientific research C.N.R.S. in cooperation with the University of Bordeaux I and the company ISOS (invented by Mrs Haget, Mr Cuevas and Mrs Mondieig, registered patent no 9108695).

ALCAL<sup>®</sup> is a molecular alloy that can change from the solid into the fluid state at a constant temperature producing in this process an important amount of energy : refrigerating negative kilocalories. The temperature obtained in the process of changing states is determined by the compound's molecular composition.

**⇒ In combination with the ISOS<sup>®</sup> carrier system, ALCAL<sup>®</sup> provides thermo-regulation for safe transport conditions.**

Different types of ALCAL<sup>®</sup> products have been developed for temperatures of +4°C(39°F), +22°C(72°F) and -30°C(-22°F), in order to make a safe and thermo-regulated transport possible even for unstable derivatives.

ALCAL<sup>®</sup> is provided in a ready-to-use pouch of 330 gr. The ALCAL<sup>®</sup>-pouches are specially designed to fit into the ISOS<sup>®</sup> carrier pouches and it is usable for one year.

The total empty weight of an ISOS® carrier case with its six ALCAL®-filled carrier pouches is about 7,5 kg (about 16,5 pounds).

Please contact us for further information if you need ALCAL® packs of a different weight and for different temperatures

## **ISOS® AND ALCAL® : A PERFORMING COMBINATION**

If employed correctly according to the enclosed instructions for use, at a temperature that corresponds to normal, average outdoor conditions in France, ISOS® and ALCAL® will ensure the preservation of delicate material for a minimum period as specified below.

The degree of efficiency of the ISOS®-ALCAL® transportation device may vary along with variations of the outdoor weather conditions.

If necessary, the product can be adapted to users' requirements of longer preservation periods for their transportation needs.

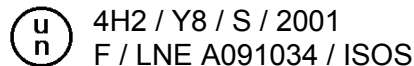
	ISOS® and ALCAL® “+22°C”(72°F)	ISOS® and ALCAL® “+4°C”(39°F)	ISOS® and ALCAL® “- 30°C”(-22°F)
Minimum preservation within the limits of tolerance of a defined temperature level.	at least six hours	at least six hours	in progress of examination.

These results have been obtained by testing the ISOS® carrier device with six ALCAL® pouches of 330g (about 0,72 pounds) under normal conditions. Please contact us if you require further information.

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