FSN Ref: FSN_Mediprema_NITE_20230804 FSCA Ref: FSCA_Mediprema_NIHM_20230804

Reminder of instructions for use of the internal heating battery and NIMH external battery, NITE transport incubator (Ref. 5020)

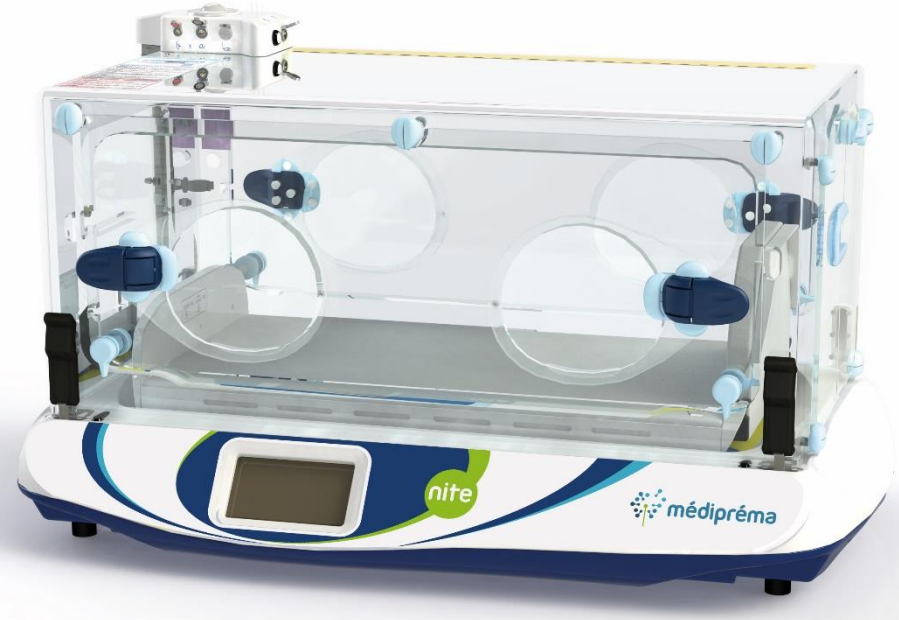
Date: 08/04/2023 (Translated on 2023-08-08)

Urgent Safety Notice

Reminder of instructions for use

internal heating battery and external NiMH battery,

NITE transport incubator (Ref. 5020)



To the attention of :

Local materialovigilance correspondent
And/or maternity and neonatal departments
And/or biomedical services
And/or Site Director of the establishment

Contact information for local representative
If you have any questions about this recall, please contact Médipréma: Mail : qualite@mediprema.com Phone : +33 02.47.25.56.51 Fax : +33 02.47.27.35.85

FSN Ref: FSN_Mediprema_NITE_20230804 FSCA Ref: FSCA_Mediprema_NIHM_20230804

Reminder of instructions for use of the internal heating battery and NIMH external battery, NITE transport incubator (Ref. 5020)

Urgent Safety Notice

Reminder of instructions for use internal heating battery and external NiMH battery, NITE transport incubator (Ref. 5020)

1. Information on the products concerned	
1.	**1. Type(s) of product**
	This safety notice concerns the following references: - NITE transport incubator (Ref. 5020), - The internal heating battery (Ref. 44410103728) for the NITE incubator, - The NIMH external battery (Ref. 5139 / 4595033260) accessory to the NITE incubator.
1.	**2. Primary clinical purpose of the device(s)**
	The internal heating battery maintains heating capacity when the NITE is disconnected from the power supply. This battery is fitted in the incubator by default. The external NIMH battery is designed to provide back-up power to the NITE when no other power source is available. This battery is used in conjunction with the internal heating battery to extend the NITE's autonomy.
1.	**3. Serial numbers or batches concerned**
	All customers with : - NITE transport incubator (Ref. 5020), - NIMH external battery (Ref. 5139).

2. Reason for the Corrective Action (FSCA)	
2.	**1. Description of the problem**
	We would like to inform you that our customers have noted a low level of autonomy in the batteries used to operate the NITE transport incubator when no power source is available. So, to ensure that you can use your NITE properly in emergency transport situations, we are issuing a reminder of the best practice for charging : - The internal heating battery (Ref. 44410103728) for the NITE incubator, - The NIMH external battery (Ref. 5139 / 4595033260) accessory to the NITE incubator.
2.	**2. Risk that caused this Safety Corrective Measure (FSCA)**
	We have concluded that the lack of autonomy is due to : - Failure to follow the battery charging procedure, and in particular the recharging times indicated in the user manual, which explains the short battery life and may lead to premature degradation.
2.	**3. Probability of occurrence of the problem**
	Since 2020, there have been : - 4 incidents involving battery autonomy problems.
2.	**4. Foreseeable risk to the patient/users**
	Poor battery charging make it impossible to use the NITE transport incubator, and therefore impossible to take on a patient for emergency transport. For this reason, we are issuing a reminder of the instructions for use to ensure that your NITE is operational in an emergency situation.

2.	**5. Background of the problem**
	No clinical consequences have been reported by the establishment concerned by the NITE transport incubator battery autonomy difficulties. The reported incident occurred on 05/21/2023.

	3. Action to be taken to mitigate the risk
3.	**1. Measures to be taken by the user**

☒ Identifying devices ☐ Quarantining devices
☐ Return devices ☐ Destroy device
☐ Device modification / inspection
☒ Follow patient management recommendations
☐ Take into account modification of instructions for use
☐ Other ☐ None

We would like to remind you of the following **operating instructions**, which can be found in your owner's manual.

NITE transport incubator user manual :
- Operation Part - § 1.6 Use of internal batteries,
- Operation Part - §12 Battery condition

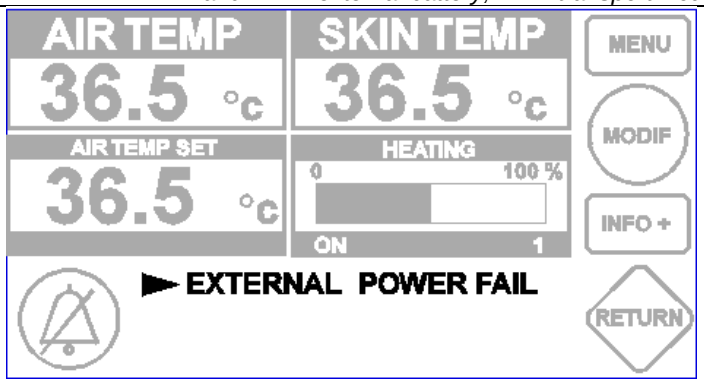
NIMH battery user manual :
- Operation Part – § 2 Use of the NIMH battery to power the NITE

OPERATION Part – 1.6 Use of internal batteries

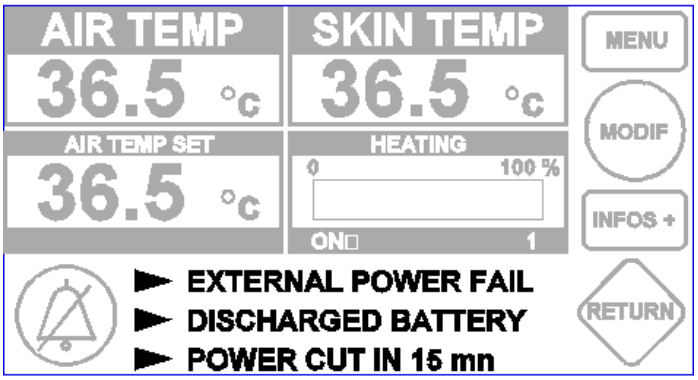
NITE transport incubator user manual

NITE is equipped with two internal batteries: an electronic battery and a heating battery.
The electronic battery manages operation of the device in the event of power failures or electric power supply fluctuations.
The heating battery is used to maintain heating capacity when ***NITE*** is disconnected from any power supply.

It is important to load the batteries before each use. If the NITE is used without connection to a power supply while the internal battery is flat, the message "POWER CUT IN 30 SECONDS" is displayed immediately. After 30 seconds, the screen switches off and NITE shuts down.



This screen is displayed when the 2 incubator plugs are disconnected from the power supply or in the event of an electric power failure. In this event, the incubator continues to warm the infant using its internal battery.



When the heating battery has no more charge, ***NITE*** displays “DISCHARGED BATTERY” and stops heating but continues to display the settings for 15 minutes.
As time goes on, the message “POWER CUT IN 15 MN” changes to “POWER CUT IN 10 MN”, then “POWER CUT IN 5 MN”, then “POWER CUT IN 30 SECONDS”.

The audible alarm sounds.

After 15 minutes, the screen switches off and ***NITE*** shuts down completely.

As an option, ***NITE*** may be connected to an external battery pack (1-hour or 2-hour battery pack, reference 5064 and 5024 respectively) to significantly increase its autonomy. Refer to the corresponding manual or contact the ***MÉDIPRÉMA*** Customer Service Department for more information.

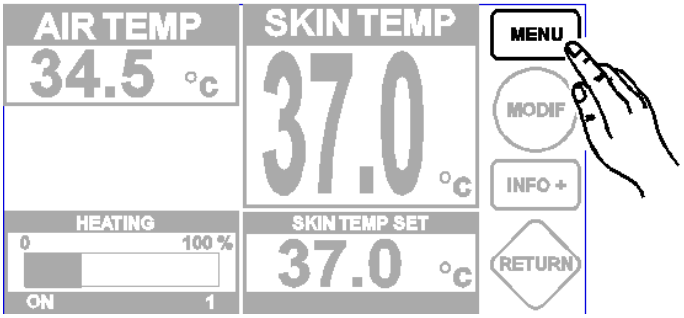
OPERATION Part – 12 Battery condition

NITE transport incubator user manual

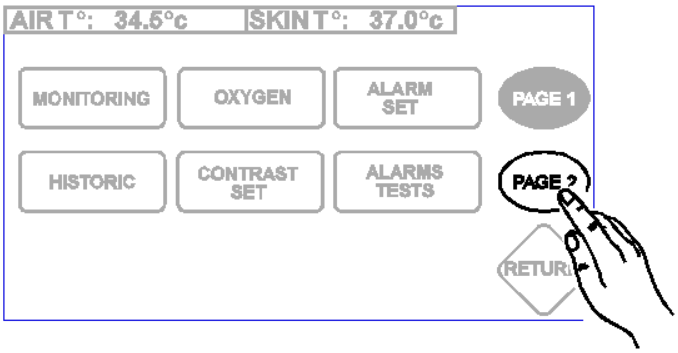
Reminder: NITE is equipped with 2 batteries: an electronic battery (management of power failures or electric power supply fluctuations) and a heating battery (maintenance of heating capacity in the event of electric power failures).

The electronic battery life is expressed in total number of hours of incubator operation. The heating battery life is expressed in number of charge and discharge cycles.

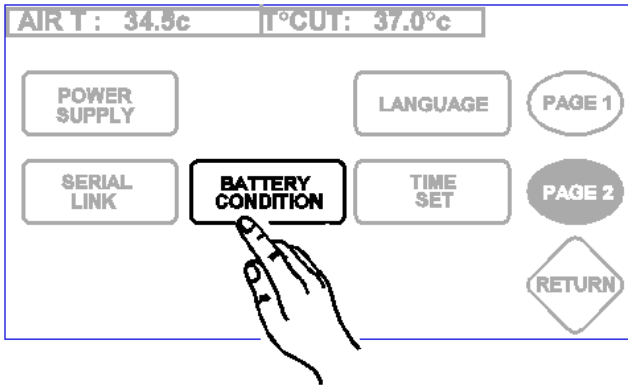
To access the **"BATTERY CONDITION"** menu perform the following operations:



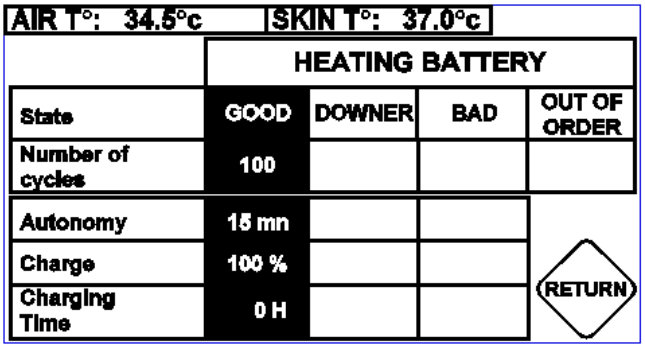
Press the **"MENU"** key.



Press the **"PAGE 2"** key.



Press the **"BATTERY CONDITION"** key.



The heating battery condition depends on its number of charge and discharge cycles. The condition is considered to be:
- good if the number of cycles is less than 250.
- average if the number of cycles is between 250 and 400.
- bad if the number of cycles is between 400 and 450.
- out of order if the number of cycles is more than 450.

Any battery indicated as being our of order must be replaced

In some cases, (low temperatures, low external 12V supply) the heating battery life may be lower than its theoretical life.

The autonomy corresponds to the remaining time for which the heating battery can be used.

The autonomy value varies depending on:
- The battery condition:
- 15 minutes maximum when fully charged if the condition is good.
- 10 minutes when fully charged if the condition is average.
- 5 minutes when fully charged if the condition is bad.
- The battery charge status.

10 hours of recharging is necessary to fully charge to 100% and to obtain maximum autonomy.

NOTE : The autonomy values correspond to the following use conditions :
- Control temperature 39°C.
- Ambient temperature 15°C.

NOTE : The total duration of electronic battery use can be seen by a trained and approved technician only. The scheduled battery life is 15,000 hours of use.

OPERATION Part – 2. Use of the NIMH battery to power the NITE

NIMH Battery user manuel

2.1 Connection

Warning : Check the charger is not connected to the battery.

Step 1: Connect the DC cable adapter (if needed) to the NiMH battery.

Figure 7 : Battery NIMH with DC adapter

Step 2: Connect the DC cable adapter to the DC connector of the NITE.

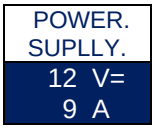
Figure 8 : Battery NIMH connected to NITE

2.2 Automatic switch between power supplies

If the ***NITE*** is not connected to an AC power input with voltage superior to 110VAC, the ***NITE*** will switch automatically its power input to the NiMH 12V battery.

As soon as the ***NITE*** is connected to an AC power input with voltage superior to 110VAC, the ***NITE*** will switch automatically its power input to this AC power input and charge its internal batteries (but not the NiMH 12V battery!).

The ***NITE*** can be connected simultaneously to the NiMH battery and AC power input, it will not take power from the NiMH battery.
The ***NITE*** indicates the power source details on its screen as follow (press the “Info+” button on the screen to see this information):

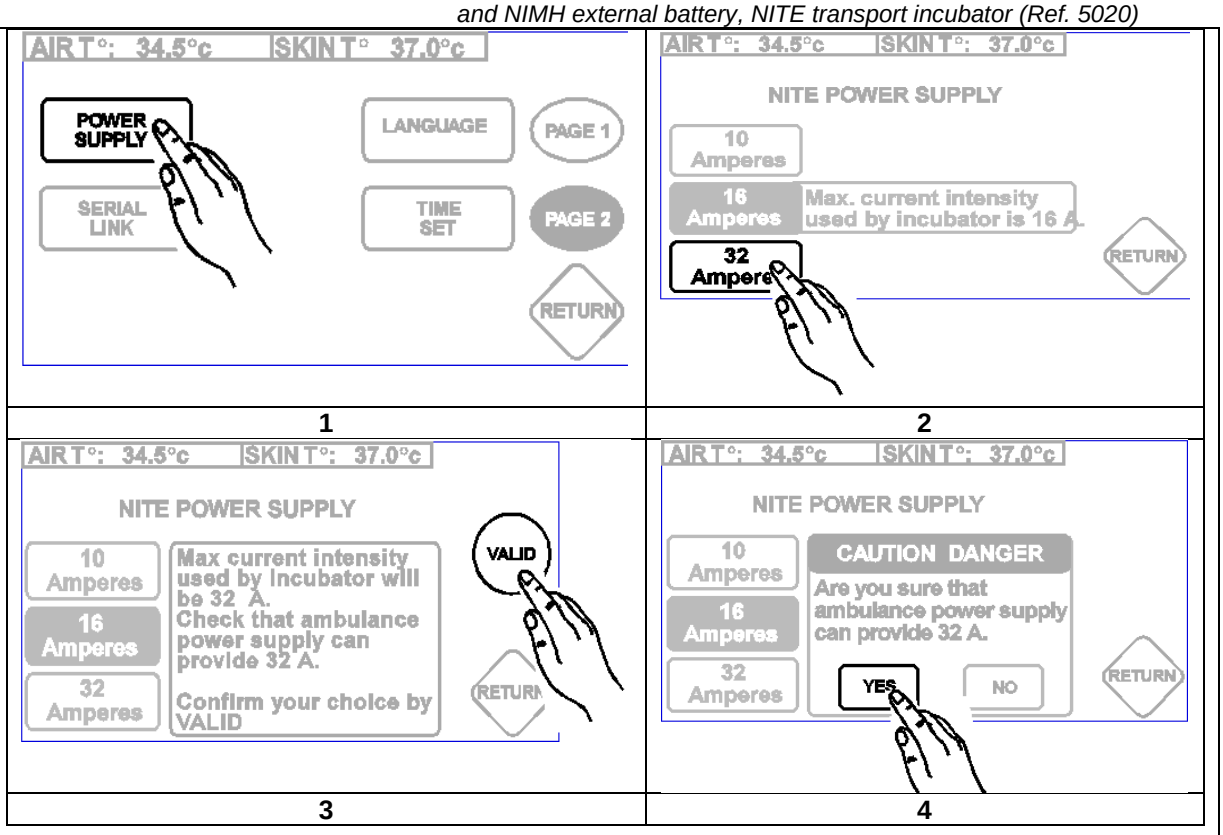


2.3 Discharge of the battery to power the NITE

The ***NITE*** is powered by the NiMH battery until the state of charge of this external battery reaches 0%. When the external battery is fully discharged, the ***NITE*** will automatically switch to its internal batteries (the autonomy on internal batteries is between 15 to 30 minutes depending on the setting, environment and state of health of its batteries).
A press on the key « Info+ » enables to check the state of capacity of the internal batteries of the ***NITE:***

To ensure optimal warming performances of the NITE, the current intensity limitation on 12V DC power supply shall be set to 32A.

To access the setting, press « POWER SUPPLY» in the « PAGE 2» of the « MENU ». Then select the setting « 32 Amperes » and validate with « VALID » then « YES ».



Make sure to adjust the current limitation of the *NITE* if the DC cable of the incubator needs to be connected on another DC power source than the battery. The *NITE* can require up to 30A when supplied with 12 DC voltage.

After a full discharge, it is recommended to fully charge the battery as soon as possible. Otherwise, after a prolonged time fully discharged, the duration of the charge will increase.

Unlike lead batteries, the NiMH battery technology is not affected by full discharges. The battery can be repeatedly fully discharged without damaging it.

2.4 Discharge range

The NiMH 12V battery is fitted with a NiMH 12V 30Ah battery pack.

When used with the NITE incubator with new, fully-charged batteries, this corresponds to total autonomy in Air mode with set point at 36°C (including the autonomy provided by the internal heating battery):

Ambient temperature	Autonomy (hours)
10°C	2h
15°C	2,5h
20°C	3,75h
24°C	5h

We therefore remind you that all users of the device must have received prior training in its use. Use of the device is reserved for suitably trained personnel, under the supervision of qualified medical staff who have been informed of the risks and benefits associated with the use of the NITE transport incubator.

	We also remind you that all maintenance work must be carried out by médipréma or by approved technicians trained by médipréma. Training sessions are available on request. If you have any questions about training, please contact the manufacturer, médipréma. If you have any questions about the device, please contact the manufacturer médipréma: Sales department: service.commercial.france@mediprema.com / +33 (0)2 47 28 23 86 After-sales service: sav@mediprema.com / +33 (0)2 47 28 36 86 Quality department: qualite@mediprema.com / +33 (0)2 47 29 49 34	
3.	**2. Deadline** for implementation of these measures	09/19/2023
3.	**3. Is a response from the client necessary ?** (see acknowledgement of receipt form in attachment)	No
3.	**4. Measures taken by the manufacturer** ☒ Reminding users of operating instructions	
3.	5. Should the FSN be **communicated** to the patient/end user ?	Yes, communication to the end user
3	6. If yes, has the manufacturer provided **addtitional information** tailored to the patient/user in an information letter ?	
	No, reminder of the safety instructions already given in the respective user manuals for the NITE transport incubator (Ref. 5020) and the NIMH battery (Ref. 5139).	

	4. General information	
4.	**1. Type of notification FSN**	New
4.	**2. Other advice or information expected in the follow-up to this notification**	None
4.	**3. Manufacturer's information** (For the contact information of the local representative see the first page of this security notice)	
	a. Name	**Médipréma**
	b. Address	**ZA Node Park Touraine** **470 rue Gilles de Gennes** **37310 Tauxigny** **France**
4.	**4. The competent (regulatory) authority in your country has been informed of this communication to customers :**	Yes

4.	**5. Name / Signature**	**Didier Delavault** **CEO**

	Transmission of this security notice
	This notice should be forwarded to all affected individuals within your facility or to any facility to which you have transferred affected products (if applicable). Please forward this notice to any other organization that may be impacted by these measures (if applicable). It is important that this information and the resulting actions are regularly reiterated for as long as necessary to ensure the effectiveness of the corrective actions taken. Please report any product-related incidents to the manufacturer, distributor or its local representative, and to the competent authority if applicable, as this provides important feedback.