

SAFETY ADVISORY: Safety information (FSCA)

Billy-lès-Chanceaux, 27th June 2022

Trademark name: Light Drive 2 - Benoit Systemes

Benoit Systemes' reference: FSCA-2022-01

Measure: Batteries replacement requirement

Concerned batch number: HJ51

Battery serial numbers	18RN0200 to 18RN0700
------------------------	----------------------

Dear Sirs,

Benoit Systemes informs you of an important communication pertaining to the safety of the above-mentioned products.

Our records show that you received one or several of the above-mentioned products.

Identified incident

We have been made aware of a preoccupying malfunction, potentially dangerous without harm to individuals, of a 12 Ah battery put into service in June 2018.

At the end of the charging process, a thermal runaway has occurred, increasing both temperature and pressure within the battery pack, and leading to a carbon gas venting during the battery wreckage.

This is generally caused by an overheating of one or several cells inside the pack, hence the self-combustion followed by a venting of carbon dust, sometimes along with a whistling sound.

In use for 4 years, this battery was reaching its end-of-life when the malfunction occurred.

We compared this incident to a similar one, thus allowing us to identify the battery batch that may be concerned by this malfunction.

You delivered to one or several customers, during this period in 2018, a power add-on fitted with a battery of this same batch.

Measures to be taken by the distributor

Please take the following measures immediately:

- **Forthwith** warn your customer(s) that could still be in possession of this battery to have it replaced.
- Fill out and sign the reply slip and send it back to the person in charge of Regulatory Affairs: Mrs Marie PLARD by e-mail to marie.plard@benoitsystemes.com or by post to 7 rue du Pont 21450 Billy-lès-Chanceaux.
- Retrieve and dispose of the battery according to waste management requirements.
- Provide proof of battery disposal
- Keep a copy of the receipt confirmation in your materiovigilance records: it can be asked in case of documentation audit.

For your information, batteries delivered in 2018 and still in use are not covered by the warranty.

Please reply within 7 days following the receipt of the present notice.

Safety notice distribution

This notice has been sent to you because your establishment received the device mentioned in reference. This notice must be distributed to everyone that must be made aware within your establishment and every user that received it.

In accordance with the European directive and the recommendations on market vigilance, we state that the French competent authority (ANSM - French Agency for the Safety of Health Products) has been alerted of this safety corrective action.

Thanks for your help and involvement in implementing this action, we sincerely apologize for any inconvenience caused. We would like to assure you that Benoit Systemes is fully committed to paying attention to its customers safety.

We remain at your disposal for any possible question.

Yours sincerely,

Marie PLARD
Quality Manager



Acknowledgement of receipt

FSCA-2022-01 safety notice issued by Benoit Systemes

As distributor:

- I state that I have received, read and understood the present safety notice.
- I hereby state that every concerned users listed in the appendix supplied by Benoit Systemes have been made aware of the requirement to change the affected batteries.
- For each battery in use: I commit to replace the battery and enclose a purchase order for a battery.
- For each battery that is no longer in use, I commit to enclose a written proof stating the device serial number, in order to ensure our traceability follow-up.
- In the event that the user refuses to replace the battery from affected batch, I commit to give a waiver signed by the device owner.
- I commit to retrieve the spoken battery, take care of its disposal and give a proof of it.

Name and Title:

Establishment:

Phone number:

E-mail address:

Date and signature:

Company stamp:

Please fill out this document and send it back to:

E-mail: marie.plard@benoitsystemes.com

Post: Benoit Systèmes

Marie PLARD

7 rue du Pont

21450 BILLY LES CHANCEAUX

SAS BENOIT SYSTEMES • 7, rue du Pont • 21450 Billy-lès-Chanceaux FRANCE

Tél. +33 (3).80.96.51.25 • www.benoitsystemes.com

Siret : 80306648900011 • Code APE : 3092Z



Appendix 1: List of power add-ons serial numbers concerned by batteries replacement for batch HJ51.

Distributor: MMS Medical - Ireland

Power add-on serial number	Battery serial number
0218MIH016 - 019	18RN0192 - 195
Spare parts order POR072599	18RN0330
0418MIH008 - 011	18RN0434 - 0435 - 0436 - 0447
0418MIH071	18RN0448
0418MIH072	18RN0437
0618MIH016	18RN0614
0618MIH017	18RN0616
0618MIH018	18RN0615
0618MIH019	18RN0613