99 Seaview Blvd
Port Washington, NY 11050
800.338.1988
www.drivemedical.com

EC-REP:
DRIVE MEDICAL GMBH & CO. KG
Leutkircher Straße 44
DE-88316 Isny/Allgäu

URGENT NOTICE
MEDICAL DEVICE RECALL

Drive DeVilbiss Healthcare Car Charger Power Cord Accessory (provided with the iGo®2 Portable Oxygen Concentrator)

Isny, May 30th, 2025

[Customer Name
Street Address
City, State or Province, Postal Code
Email Address]
Verification Code: ___XXXXX____

Dear Portable Oxygen Concentrator Customer/Distributor,

Purpose
The purpose of this Notice is to inform you that Drive DeVilbiss Healthcare is voluntarily initiating a recall for the car charger cord provided as an accessory with the 125A, 125K series iGo®2 Portable Oxygen Concentrator (POC) system or as a standalone replacement part.

The voluntary recall will apply to product sold from January 1, 2023, through February 21, 2025. See **Table 1** on page 5 for the range of impacted lots and serial numbers.

Reason for Voluntary Recall
The iGo®2 POC car charger cord is a non-critical accessory to the iGo®2 POC. It allows the user to operate their iGo®2 POC from a DC power supply, such as the charging port in a vehicle. Under normal operating conditions, the car charger cord will power the unit, while concurrently charging the device's internal battery.

After receiving complaints related to overheating of the plug portion of the car charger cord, an investigation determined the root cause was an assembly error; specifically, the fuse and the retention spring were installed in the reverse positions. It was confirmed that during use, the adapter connection may become hot to the touch, and in some cases, cause deformation of the plastic housing. The manufacturing assembly error has now been corrected.

Drive Devilbiss Healthcare is voluntarily implementing this recall of affected car charger cords. Please note that the car charger cord defect has no impact on the functioning of the iGo®2 Portable Oxygen Concentrator device or any other accessories.

Risk to Health

To date, there are no complaints of serious injury associated with this issue. During use, the adapter connection may become hot to the touch, and in a low number of cases, cause a minor burn to the fingers or hand. To date we have received a total of 58 (0.044% of devices in distribution) thermal-related complaints associated with the adapter connection. There have been two complaints of minor injury (0.002% of the affected population), which were transient and did not require medical intervention.

We have conducted simulated use testing. We have determined for the car charger adapter connection to get hot, the iGo2 oxygen setting needs to be >3 lpm, and/or the battery capacity very low or fully depleted, and actively undergoing charging, as these conditions together may increase the device energy demand.

Actions To Be Taken By Our Customers

Please take the following actions:

1. Identify any inventory in your possession using the following identifiers:
    a. model DV6X-619 Rev E car charger cords of lot numbers 2023-01-01 through 2024-12-31 (see **Figure 1** below). Not all Rev E cords are recalled. Refer to step 1c below to confirm if the Rev E unit is recalled.

Figure 1: "Rev E" label and lot number placement

b. If the cord that was originally included with the iGo®2 POC unit is still with the POC, the affected cords can also be identified by the serial number on the iGo®2 POC unit (see **Figure 2** below). The range of applicable serial numbers is provided in **Table 1** on page 5.

Figure 2: Serial number placement on iGo®2 POC Device

c. If there is any doubt, or if you do not maintain the car charger cord with the original POC unit as part of your rental distribution process (i.e., used cords are stored and comingled in a box), inspection and confirmation of the condition of the car charger cord adapter can be easily performed by unscrewing the metal cap. (See **Figure 3** for spring and fuse position.)

   i. ***If it reveals the internal spring next to the cap***, this configuration ***is being recalled.***

   ii. ***If it reveals the fuse next to the cap***, this configuration ***is not recalled.*** *Note: For every product confirmed to be unaffected by this recall, we recommend that you mark the label as acceptable in some permanent manner to ensure future inspections are unnecessary after rental redistribution and return.*

Figure 3: Inspecting the car charger cord adapter for spring or fuse position.

2. Destroy all affected car charger cords by cutting the cord with wire-cutters or unscrewing the cap and then discarding the car charger parts.

3. To obtain replacement car charger cords, click on the Verification Code hyperlink, located on the first page of this notice directly below the address block, or go to www.recallrtr.com/iGo2DME and input the Verification Code. Using that code on the website, you will be able to:
    a. Please confirm receipt of this recall and confirm the quantity of affected car charger cords in your possession (see **Table 1** on page 5 for the full range of affected lots and serial numbers)
    b. Order replacement products; and
    c. Fill out a web form to acknowledge receipt of and compliance with this recall.

    If you experience any issues with the website you can contact us via email regarding this recall at iGo2DME@realtimeresults.net or you can also contact your Sales Manager.

4. Please contact all customer/end users who purchased or rented an affected unit and provide them these instructions for compliance with this recall. A draft notification to end-users can be provided from Drive Medical GmbH & Co. KG for your convenience. Please contact your Sales Manager.

5. As these items are typically rented to end users, we recommend that you continue to check units as they return from rental use.

6. Until such time as you obtain replacement car charger cords, we recommend you consider the following:
    a. If you do not have inventory with unaffected car chargers, distribute the iGo®2 POC system without the car charger as this is a non-critical accessory.
    b. Advise end users that if they must use the car charger before it has been inspected and/or replaced, they should ensure the battery is fully charged and/or flow setting is at or below 3 lpm.

Table 1: Product identifiers subject to this recall

Product Name	Catalog Number	UDI	Recalled Product Identifiers
Autoladekabel-Adapter	DV6X-619	00885304020585	Chargen mit den Nummern 01.01.2023 bis 31.12.2024; und/oder Autoladekabel mit der Bezeichnung „Rev E“
Tragbares Sauerstoff-konzentrator iGo®2	125A	00885304022251	D23116001AS to D23A25055AS
	*125K	00885304022244	D23109001KS to D23A24200KS
			F23B30003KS to F24926050KS
	*125K-XB	00885304032502	D23109001KS to D23A24200KS
			F23B30003KS to F24A28055KS
	*125K-BT	00885304033233	F23912001KH to F24C11099KH
	*125K-BT-XB	00885304033240	F23912001KH to F24821095KH

***Note: <u>The iGo®2 POC is not recalled</u>** as it is not impacted by the car charger cord adapter defect. The iGo®2 identifiers are provided to assist in identifying defective car charger cords packaged with portable oxygen concentrators.

Contact Information

Once again, to acknowledge this notice and arrange for replacement of affected car charger cords, please follow one of the options listed here:

- click on the Verification Code hyperlink, located on the first page of this notice directly below the address block, or
- access our dedicated website, www.recallrtr.com/iGo2DME and input the verification code located on the first page of this notice, directly below the address block, or
- access the website manually, or
- contact Drive Medical GmbH & Co. KG customer service at info@drivedevilbiss.com with reference BfArM 16266/25, Phone: +49 (0)7562 97240
- or you can also contact your Drive Medical GmbH & Co. KG Sales Manager.

Sincerely,

Drive Medical GmbH & Co. KG