

Urgent Field Safety Notice

Afikim Electric Vehicles - Breeze C Scooter

FSCA identifier 24.10.2013
Type of action -
Recall/Correction Report

Date: 24.10.2013

Details on affected devices:
Electrical scooter for the use of elderly persons.

From # 10390024 to #12490193, Total 69 devices

10390024	11390060	11490426	12390107	12490181
10390025	11390061	11490433	12390117	12490182
10390029	11390069	11490435	12390120	12490183
10390030	11390074	11490445	12490169	12490184
10390034	11390095	12390096	12490170	12490185
10390037	11390101	12390097	12490172	12490186
10490100	11490111	12390098	12490173	12490187
10490108	11490147	12390099	12490174	12490188
10490111	11490176	12390101	12490175	12490189
10490113	11490189	12390102	12490176	12490190
10490119	11490277	12390103	12490177	12490191
10490121	11490304	12390104	12490178	12490192
10490124	11490305	12390105	12490179	12490193
11390058	11490425	12390106	12490180	

Description of the problem:

During intense product testing our company became aware of a potential scenario where an internal potentiometer wiper could become disconnected due to extensive wear on a certain number of assembled devices. If this were to occur the device could continue to drive forward at a slow speed of approximately 2-4 mph and the only way to stop the device would be by turning off the main ignition key. Although this is not expected to occur and was difficult to produce this scenario in a testing environment, there is a slight chance if the potentiometer wiper is extensively worn, it could occur. The root cause has been investigated and was identified as a mistake which occurred during assembly on these particular devices, this assembly mistake is not present on other devices which have been manufactured or distributed in the US. We have not been able to reproduce this malfunction and it has never been reported or experienced in the past. It was only during purposeful testing of the protection element of the potentiometer wiper of the device that the technician was able to identify the potential risk. The risk only affects the above mentioned 69 devices.
The movement of the scooter is controlled by a throttle which is based on an electrical potentiometer. The potentiometer is an electro-mechanical part which has mechanical movement internally, changing the electrical resistance between the output terminals of the potentiometer from 0 to 5 KΩ. The movement of the throttle (and corresponding potentiometer) is controlled by the user as they operate the throttle. Pushing the throttle lever one direction moves the device "forward" and other direction moves the device "backward". The risk with the devices which were incorrectly assembled is that after several million throttle operations (potentiometer actions) the potentiometer wiper may experience extensive wear which could affect the electrical resistance range (0-5 KΩ) so that the devices is unresponsive, and the device could be unresponsive during forward drive operation. According to the component manufacturer of the potentiometer (Curtis - PMC) and our design validations the number of actions with the potentiometer wiper can be exposed to without creating a fault condition is minimum 2 million. During normal use the device will be exposed to approximately 250-500 actions per day. If the device is in use 354 days per year the total number of actions per year is between 88,500-177,000 actions per year. This is how we determined the life of our device is 10 years.
If excessive wearing occurs on the potentiometer wiper contact during forward or revers operation, there could be partial loss of controlling the

movement of the device if the device is one of the 69 misassembled devices subject to this correction report. The correction includes an on-sight visit by a technical representative of the company who changes a parameter in the controller and replaces the front electronic board so that the required 18 KΩ resistor is in place between the wiper and the potentiometer low reference line to correct the problem. This keeps the controller input at a neutral state if the wiper line is disconnected. The devices should have had this resistor installed during assembly, and strict measures have been implemented through the companies CAPA system to ensure this resistor is not forgotten on future assembled devices.
The correction will prevent this potential fault conditioning from occurring so that if the wiper contact fails the scooter will come to a complete stop within 2-3 meters (7-10 feet). Technicians making the corrections will be properly trained and will perform the corrections at the home or another location convenient for the users. It will take 1 month to make all 69 corrections.
Injuries - There have been no injuries to patients and no MDR reports have been submitted at this time. The potential risk to the user would be that the device may drive forward at a slow speed and can only be stopped by turning off the ignition key; this could cause injury to the user if it occurs.

Serial Number	Manufacturing Date	Distribution Date	Serial Number	Manufacturing Date	Distribution Date
10390024	07.02.2010	09.15.2010	12390099	07.24.2012	04.14.2013
10390025	07.02.2010	09.15.2010	12390101	07.24.2012	03.19.2013
10390029	07.02.2010	09.15.2010	12390102	07.24.2012	04.30.2013
10390030	07.02.2010	09.15.2010	12390103	07.24.2012	05.27.2013
10390034	07.02.2010	09.15.2010	12390104	07.24.2012	03.20.2013
10390037	07.02.2010	09.15.2010	12390105	07.24.2012	11.27.2012
10490100	07.02.2010	09.15.2010	12390106	07.24.2012	07.25.2012
10490108	07.02.2010	09.15.2010	12390107	07.24.2012	03.21.2013

1049011	07.02.2010	09.15.2010	1239011	07.24.2012	09.10.2013
1049011	07.02.2010	09.15.2010	1239012	07.24.2012	12.16.2012
1049011	07.02.2010	09.15.2010	1249016	07.24.2012	04.14.2013
1049012	07.02.2010	09.15.2010	1249017	07.24.2012	09.27.2012
1049012	07.02.2010	09.15.2010	1249017	07.24.2012	03.13.2013
1139005	10.09.2011	03.30.2013	1249017	07.24.2012	04.04.2013
1139006	10.09.2011	04.02.2013	1249017	07.24.2012	07.25.2012
1139006	10.09.2011	11.18.2012	1249017	07.24.2012	03.16.2013
1139006	11.08.2011	02.07.2013	1249017	07.24.2012	01.21.2013
1139007	11.08.2011	04.08.2012	1249017	07.24.2012	03.21.2013
1139009	11.08.2011	08.05.2013	1249017	07.24.2012	07.25.2013
1139010	10.09.2011	04.11.2012	1249017	07.24.2012	04.23.2013
1149011	04.05.2012	07.31.2012	1249018	07.24.2012	03.24.2013
1149014	07.12.2011	04.03.2012	1249018	07.24.2012	07.15.2013
1149017	07.12.2011	02.03.2012	1249018	07.24.2012	04.17.2013
1149018	07.12.2011	03.29.2012	1249018	07.24.2012	07.02.2013
1149027	10.09.2011	04.18.2012	1249018	07.24.2012	04.04.2013
1149030	10.09.2011	06.24.2012	1249018	07.24.2012	07.25.2013

Expiration Date: 10 years from date of manufacture.

Advise on action to be taken by the user:

Please remove the ignition key and contact the manufacturer via telephone at 1-800-809-3010 between the hours of 9AM and 5PM (EST) or contact the company via e-mail at dov@afiscooters.com.
In order to prevent risk of injury the vehicles will be corrected by the manufacturer. The manufacturer has estimated it will take 1 month to correct all affected scooters.

Contact reference person:
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Signature