



The Commonwealth of Massachusetts
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URGENT NOTICE UPDATED

TO: All MA Ambulance Services
All MA EMTs
FROM: Abdullah Rehayem, Director
RE: Ferno PROFlexx **Model 35-X** Stretcher Failures and Cot Handling Safety
DATE: August 11, 2008

This is to let you know that Ferno-Washington, Inc. has contacted the Department to clarify that it is the Ferno PROFlexx **Model 35-X stretcher**, not the Ferno PROFlexx Model 35-P stretcher, which is experiencing instances of metal fatigue and breakage of the telescoping legs. The area of highest concern is the X frame axle (where both telescoping legs connect).

Ferno reported to the Department that it is working diligently to analyze data related to the issues involving the Ferno PROFlexx **Model 35-X stretcher**, and will be contacting customers which may be affected and require further attention. It is important to note that the entire Ferno PROFlexx series of ambulance stretchers is not affected, and the documented reports the Department received with regard to the Model 35-P had meant to refer to the Model 35-X. With this clarification, the Department is not aware of any significant failures involving the Model 35-P, as reported in the August 7, 2008 Urgent Notice.

Ferno officials said the company “applauds the Department’s proactive notice to all ambulance services and EMTs within the Commonwealth of Massachusetts and affirms the proper operational comments offered by the Department reiterating the importance of proper patient handling and patient restraint.”

To reiterate, all ambulance services using the **Ferno PROFlexx model 35-X stretcher** should immediately inspect all of these cots for signs of metal fatigue (shavings, bent support arms, cracks, etc.). If such signs are discovered, remove the cot from service immediately and arrange for inspection and maintenance by a factory authorized representative as soon as possible. Even if you do not discover any signs of metal fatigue, you should contact Ferno-Washington, or the dealer who provided your stretcher, for immediate inspection and/or maintenance.

Furthermore, EMTs should be reminded to keep both hands firmly on the cot **AT ALL TIMES**, since at least one cot leg break occurred as the EMTs wheeled a patient toward the ambulance. In addition, wheeling the patient at the lowest cot height is the safest method to minimize any potential harm to the

patient, since catastrophic failure can occur without warning. Finally, all patients must be firmly secured to the cot using the over the shoulder harness, hip and leg straps.

If your service has experienced failure of a **Ferno PROFlexx 35-X cot**, or any other medical device, please complete a Serious Incident Report Form and submit it to this office. (For the form, go to www.mass.gov/dph/oems, scroll down to “Forms,” then click on the “Ambulance Services” section).

In addition, ambulance services should also file a “Medical Devices Report” report with the FDA at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>.