MEDICAL DEVICE FIELD CORRECTION

Dornier Holmium Lasers

Dear Valued Customer,

The purpose of this letter is to advise you that Dornier MedTech America, Inc. (DMTA), the manufacturer of the Dornier Holmium Lasers Models H20, Solvo, and Uropulse, is voluntarily issuing a field correction regarding the above mentioned lasers. Distribution and DMTA's service records indicate that you have received one or more of the devices that are the subject of this field action.

The Dornier Holmium Lasers are intended to be used for cutting, vaporization, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopes), or for open surgery for contact or non-contact surgery with or without a handpiece for use in incision/excision, vaporization, ablation and coagulation of soft tissue. They are indicated for use in medicine and surgery, in the following medical specialties:

- Arthroscopy
- Urology
- Lithotripsy
- Pulmonology
- Gastroenterology
- Gynecology
- ENT
- General Surgery

DMTA is initiating this voluntary field correction as a precautionary measure, to advise customers of the remote possibility of the malfunction described herein and how to prevent this issue from occurring.

Reason for the Voluntary Field Correction:

In rare occurrences and under specific multiple circumstances, it is possible for the product to inadvertently release laser energy without a laser fiber properly attached. Specifically, if the fiber interlock micro switch malfunctions (*i.e.*, remains closed when a fiber is removed), this could cause a fiber recognition error. If this specific micro switch event were to occur during use of the product, the laser could remain in the active mode even with no fiber attached. This fault mode could allow the laser to release energy without a laser fiber being attached. Though remote, there is

[redacted]

a potential for patient or user injury if all of the following multiple and consecutive events were to occur:

a) the laser's footswitch was inadvertently depressed;
b) both of the internal micro switch ball bearings failed simultaneously;
c) a person in the device's vicinity was not expecting the laser to fire and was not prepared for laser activation (in normal use, laser is designed to fire only with an attached laser fiber);
d) the person was within 0.7 M of the laser, as the beam diverges and becomes harmless (for ocular damage) beyond this distance (for naked skin damage, it is harmless beyond 0.21M);
e) the person was looking directly into or standing in front of the straight line of laser energy;
f) the user removed or took off their laser safety goggles;
g) the laser was not in standby mode (which occurs in 1 to 5 minutes of the last firing); and
h) on all Solvo models, the fiber connector cover door was open.

With respect to one of the foregoing steps above, it was determined that the micro switch ball bearing sticking condition could be caused by foreign matter accumulation or slight corrosion if the unit was exposed to high humidity in non-controlled operating environments. The reports on the original complaints that were being investigated were from high humidity regions.

Risk to Health:

If the malfunction described above occurs, it could result in inadvertent release of laser energy that could cause injury to the health care provider, patient, or other exposed individuals.

Potential hazards include:

- Harm to the retina could occur if someone's eyes are directly aligned with the beam propagation, they are within 0.7M of the laser and not wearing appropriate laser safety googles as required.
- A skin burn or irritation could occur if bare skin were placed directly in front of the beam at a distance of less than 0.21M.

How to recognize that the device may fail: Failure occurs when the fiber interlock micro switch erroneously remains closed upon removal of the laser fiber, which allows the system to emit laser energy without a laser fiber being attached. Device failure is easily recognizable by the user:

- For the Solvo models, if the fiber interlock micro switch fails and all the requisite causal conditions (as described above) are met, then if laser energy were released the user would hear both the audible alarm signifying energy emission and a crackling sound as the laser energy struck the closed laser fiber connector door.
- For the Uropulse and H20 models, if the fiber interlock micro switch fails and all the requisite causal conditions are met, then if laser energy were released the user would hear the audible alarm signifying energy emission and would notice the pilot beam's being on (which is abnormal when a fiber is not attached).

Given the number of simultaneous events that need to occur for the described malfunction and the limited distance of any potential dangerous effect, Dornier has determined that the risk of injury is negligible.

Actions to be Taken by the Customer/User:

Users of these lasers should take the following short-term preventive/corrective actions:

a) Assure the laser is always in standby mode or turned off prior to disconnecting and/or changing the laser fiber. (This prevents the potential for inadvertent laser energy release without a laser fiber being connected.)
b) Place the attached addendum, which re-emphasizes the above step, into the Operator's Manual that is provided with this letter.
c) Follow all warnings and cautions in the Operator's Manual.

As a long-term preventive action, all laser fiber interlock mechanisms will be checked at all future and service visits during Preventive Maintenance to confirm that they are in proper working order.

Risk Mitigation Factors: The Laser Fibers' Instructions for Use already indicate that to attach a fiber, the user should first attach the fiber to the laser and then turn the laser on in standby mode. If this is followed, inadvertent laser energy release cannot occur, even if the fiber interlock micro switch is not working properly. Furthermore, in normal clinical use, the laser will go into standby mode following completion of a treatment, prior to any fiber change. Energy release is then not possible unless the user manually switches out of standby mode (by pressing the standby switch) and then presses the laser fire switch.

The product subject to this field correction, if used according to the instructions can be utilized safely.

Product and Distribution Information:

Our records indicate you have been shipped the following Laser model/serial numbers:

<LIST SERIAL NUMBERS>

Removal of product pursuant to this field correction should not cause a market shortage.

Type of Action by the Company:

DMTA will work with you to inform you of the steps required to be taken. It will also instruct its service technicians to ensure that the addendum supplied with this letter is in the Operator's Manual during their next visits.

DMTA will track and tabulate responses to mailings, and will track and monitor all service calls to customers currently on service contracts or customers requesting service not under contract.
Field correction status reports will be updated at least bi-monthly until all identified customers with units are confirmed to have been notified.

Findings of failure investigation: This potential micro switch fault condition was not found during clinical use of the laser. DMTA is not aware of any product failures associated with this problem.

To date, there have been no reported clinical incidents of this malfunction and no reported customer complaints regarding the inadvertent or accidental release of laser energy when the laser fiber was not attached.

Other Information:

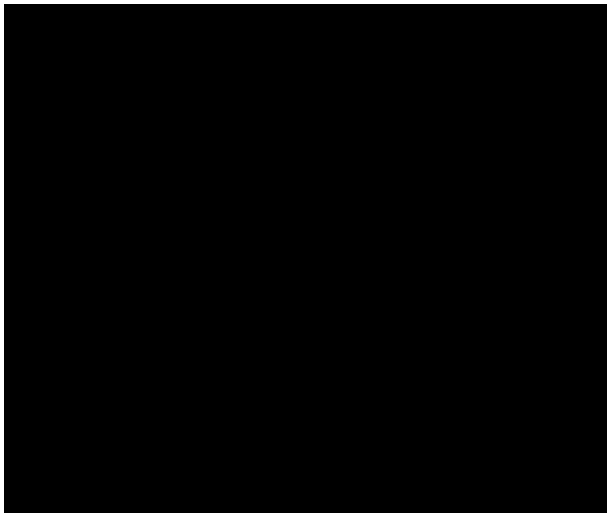
Please contact the DMTA Quality Department if you have any questions regarding this action or any of our products, or if you would like assistance with the action. We regret any inconvenience that this action may cause, but we appreciate your understanding as we take steps to ensure patient and customer satisfaction.

The following are included in this letter:

- Acknowledgement and Receipt Form
- Operators Manual Addendum

Dornier reminds you that Adverse reactions or quality problems experienced with the use of this product may be reported to the Food and Drug Administration (FDA)'s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Thank you for your support. Please contact the Dornier Quality Department if you have any questions regarding this field action, any of our products, or would like assistance with the action. We regret any inconvenience that this action may cause, but we appreciate your understanding as we take steps to ensure patient and customer satisfaction.



Enclosures

MEDICAL DEVICE CORRECTION RETURN RESPONSE
Acknowledgement and Receipt Form
Response is Required

Customer Information:
Customer Name _____
Street Address _____
Town, State, Zip Code _____

Dornier Holmium Lasers (H20, Solvo, and Uropulse Models)

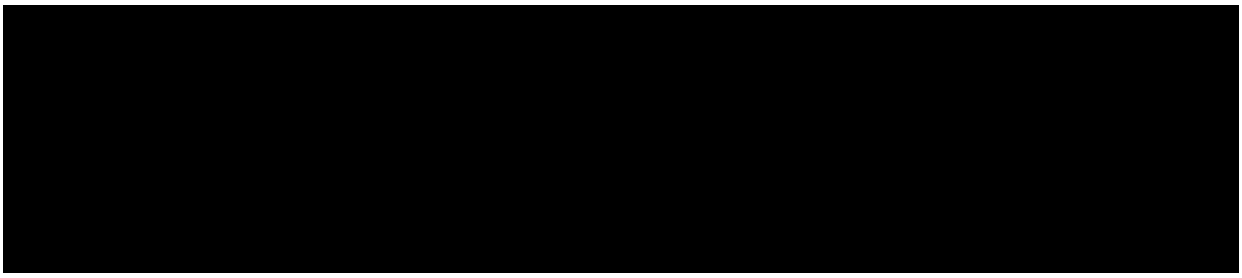
I have read and understand the field action instructions provided in the attached letter.
Yes _ No_

Any adverse events associated with subject product? Yes _ No _

If yes, please explain:
_____
_____

Affected Product Information:
Please indicate confirmation you have added the enclosed addendum to the originally supplied Operators Manual(s) with each laser you have received.

Operators Manual Addendum added to all units:
YES __
NO __ if no, list serial numbers of units not receiving addendums



OPERATORS MANUAL ADDENDUM

TO BE PLACED IN OPERATIONS SECTION OF THE OPERATORS MANUAL

REVIEW AND ASSURE ALL WARNINGS, CAUTIONS AND SAFETY INFORMATION CONTAINED IN THE OPERATORS MANUAL ARE FOLLOWED DURING THE USE OF THE LASER DEVICE

Each person within the laser area must wear protective goggles. Failure to comply with this requirement can result in irreversible eye damage!

For safety reasons, prior to attaching or disconnecting a laser fiber or during pauses in treatment the laser should ALWAYS be switched from READY mode to STANDBY mode or TURNED OFF to prevent unintended release of laser radiation.