

MAG & More GmbH, Machtlfinger Str. 13, 81379 Munich, Germany

To all PMD70-pCool customers

Your contact person:

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Munich, October 18th 2019

PMD70-pCool Safety Update - Precaution "Impact of defective components"

Dear customer,

The purpose of this statement is to inform you about the following, additional precaution note for chapter 3.1. "Warnings - Basics" of the PowerMAG Manual (510601).



High voltage on the damaged coil

 Danger to life! The stimulation coil must be carefully inspected for cracks or other damage before each use. The device may only be operated safely if the coil is in perfect condition! A defective coil can make life-threatening high voltages accessible during operation.

In general, every TMS system consists of a high voltage generator (the energy source – the so called magnetic stimulator) emitting a high voltage (2,300 V) and high current (6,000 A) TMS pulse into the stimulation coil. Your TMS system is designed and manufactured compliant to several international electrical and medical safety standards. However, use of defective components / coils may lead to severe damage to the system and, as a consequence of continued operation, to a dangerous, life-threatening situation to patient and operator.

Defective coils can be identified by:

- Mechanical irregularities in the coil's head or coil's cable (e.g. dents, cuts)
- Visual signs of damaged contact pins within the stimulator socket or the coil plug (e.g. bent or burned golden pins)
- Leakage of the cooling medium (e.g. white wax-like residue)
- Increased (louder than usual) noise level of TMS pulses

If any of these signs can be observed

- 1. do not use the affected components anymore and
- 2. contact our support team at support@magandmore.com or +49 89 2018 5248.



My name is Kerstin Häringer, I am the managing director and quality manager at MAG & More GmbH, the German manufacturer of your PowerMAG / Apollo TMS Therapy system. Safety is my highest priority – therefore we are emphasizing this aspect with this information, and we will update the Apollo manual accordingly.

Should you have any questions, remarks or concerns please do not hesitate to reach out to me by cell phone +49 179 6354 301 or email: khaeringer@magandmore.com.

Thank you.

Sincerely yours,

Dr. Kerstin Häringer MAG & More GmbH

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Please confirm that you have received and fully understand this information by signing below. Please return the signed page via Email (khaeringer@magandmore.com) or Fax (+49 89 2018 5328).

Place, Date Full name of primarily Signature responsible operator