

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2015-RN-01065-1
Product Name/Description ⁱⁱⁱ	IOLMaster 500, software version 7.5.2, 7.7.2 and 7.7.3 (used for the treatment of axial length, corneal curvature, anterior chamber depth and for the determination of the white-to-white distance (WTW) of the human eye, as well as for the calculation of the required intraocular lens) ARTG Number: 128166
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	3/11/2015
Responsible Entity ^{vii}	Carl Zeiss Pty Ltd
Reason / Issue ^{viii}	These versions of software have a software defect which can result in incorrect IOL calculations being presented on screen and in a printout/export in rare cases when a specific non-standard workflow is used. This could lead to order and implantation of IOLs with wrong lens power and to (correctable) impairment of patient's visual acuity.
Recall Action ^{ix}	Recall for Product Correction
Recall Action Instructions ^x	To correct the software anomaly users are advised to perform the software update to version 7.5.3 or 7.7.4 using the USB stick by following the instructions provided in customer letter.
Contact Information ^{xi}	1300 365 470 - Carl Zeiss

Footnotes

ⁱ Type of Product: Medicine, Medical Device, or Biological

ⁱⁱ TGA Recall Reference: Unique number given by the TGA

ⁱⁱⁱ Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

^{iv} Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale