

Changes to the T.O.V.A. User's Manual

Purpose: This insert provides updates to the TOVA Company's T.O.V.A. User's Manual that have occurred post-printing. These changes will be incorporated into the next revision of the T.O.V.A. User's Manual.

1. The TOVA Company's current address (inside cover pages) is now:

The TOVA Company
222 Anthes Ave Ste 101
Langley, WA 98260

2. Section 4 (Regulatory Compliance) and added Section 5 (Quality Standards)

4 Compliance Information

4.1 Australia

The Test of Variables of Attention (T.O.V.A.) is a Class I medical device registered with the Australian Government's Therapeutic Goods Administration (TGA) under Australian Register of Therapeutic Goods (ARTG) Identifier 315322.

4.2 Australian Sponsor

Emergo Australia
Level 20, Tower II
Darling Park
201 Sussex Street
Sydney, NSW 2000
Australia

4.3 Canada

The Test of Variables of Attention (T.O.V.A.) is licensed by Health Canada as a Class I medical device manufactured under Medical Device Establishment License (MDEL) Number 9655.

4.4 European Union

The Test of Variables of Attention (T.O.V.A.) is a Class I medical device manufactured in accordance with the European Union's Medical Device Directive (MDD 93/42/EEC).



4.5 European Authorized Representative Information



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

For vigilance inquiries, use EmergoVigilance@ul.com

4.6 United States

The Test of Variables of Attention (T.O.V.A.) has been cleared for sale in the United States by the U.S. Food and Drug Administration (FDA).

5 Quality Standards

The TOVA Company is a medical device manufacturer that is certified under ISO 13485:2016 and the Medical Device Single Audit Program (MDSAP). Please see <http://www.tovatest.com/iso> for our certificate.



Intertek