

## Changes to the Clinical Manual

**Purpose:** This insert provides updates to the TOVA Company's T.O.V.A. Clinical Manual that have occurred post-printing. These changes will be incorporated into the next revision of the T.O.V.A. Clinical 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 6 (Terms and Concepts)

Removed the word, "*disorder*" from full definition and replaced it with: "**Attention deficits**" is a general term for symptoms of impaired attention and inhibitory control that are the result of many causes (e.g. ADHD, head injuries, toxic exposure, sleep apnea, and other conditions.).

### 3. Section 8.1.2 (Secondary variables)

Clarified, Secondary Variables. These variables provide additional information that can be helpful in understanding a person's performance of the TOVA.

### 4. Section 9.3.1 (Pre-test Preparation)

Added "Consider giving both practice tests if the subject is between the ages of 6 to 29".

### 5. 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](mailto: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**