



# **Get your peace of mind** with T-Edge, Class B Autoclave

### Sterilization at the Click of a Button

Just select the required program and press "start".

I'll take care of everything else. I like to call this "Click and Go".



The fully automatic sterilization autoclave from start to finish

# **So much more** than just an Autoclave

- Compliance with strict international standards
- Clinically proven sterilization capabilities
- → High-resolution tactile touchpad
- Innovative technology
- Simple-to-use interface
- Chic design
- Great user experience



Let me take care of the sterilization process while you take care of your patients!

# **Maximum Efficiency** Minimize Costs



## Reliability & Support

 Premium quality manufacturing for repeatable cycles



### **Safety & Traceability**

 Highest safety standards, including traceable technology that monitors all process parameters.



### **Advanced Technology**

 State of the art technology, wide range of applications, for ease-of-use.



### **Flexibility**

 Uses integrated water reservoir, allowing the autoclave to be completely independent of location and simple to install.



### **Performance**

Effective cycle times



# I'm so compact and stylish, you can display me anywhere



### **Optimal Chamber Capacity**

Designed to use more than 75% of the chamber capacity, with 5 extra-long trays

- ◆ T-Edge 10 3 full (1 DIN) + 3 half (1/2 DIN) dental cassettes
- ◆ T-Edge 11 4 full (1 DIN) + 4 half (1/2 DIN) dental cassettes



### **Compact & Elegant**

- Designed to fit on 60cm shelves or counters
- Comfortably fits in small spaces

### **Accessible & Ergonomic**

- Convenient and easy loading with door opening to 110°
- Assorted water filling and drainage: top, front or automatic

# Data and Connectivity



### **Data & Connectivity**

- ◆ Internal memory storing up to 1,000 cycles
- Transfer data to PC or Network via an Ethernet connection or USB port
- ◆ Built in Wi-Fi connection





# Enhanced Serviceability



- Sophisticated operating system that allows fast detection of faults
- Each part can be easily removed and repaired/replaced separately





### **Eco-friendly**

- → Reduced water consumption by about 40%
- Decreased energy consumption thanks to reduced cycle time
- Lower electricity costs with time-delay settings for machine to work off hours

# Documentation and Traceability



1. Place pouch in chamber.



2. Complete sterilization process.



**3.** Receive barcodes with sterilization data (including expiration date).



**4.** Apply barcode label to each pouch.



Scan barcode data for patient file during treatment, for safety and regulatory purposes.



Process completed

# T-Edge complies with the strictest international standards:

### **Quality Management System:**

- ◆ ISO 13485
- ◆ Confirms to Medical Device Directive 93/42/EEC

#### **Pressure Vessel Certification route:**

 ASME Code section I and section VIII. Div.I, PED 2014/68/EU

### **Electrical Safety:**

◆ EN/IEC 61010-2-40, IEC 61010-1

### **Electromagnetic Compatibility:**

◆ EN 61326-1

# Verification & Validation functional tests:

EN 13060, ANSI/AAMI ST55

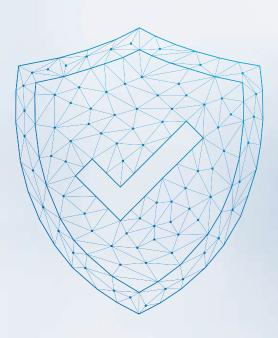
#### **Software Validation:**

EN 62304, FDA guidance

### **Usability tests:**

(User Experience, Human Factor Engineering)

◆ IEC 62366-1



## **Sterilization Programs**

lcon	Program name	Sterilization time	Load type	Type of use
*	Unwrapped 134°C	4 min	Solid / porous load	For immediate use
<b>×</b>	Wrapped 134°C	4 min		For storage
W	Unwrapped 121°C	20 min		For immediate use
¥	Wrapped 121°C	20 min		For storage
	Prion 134°C	18 min		For storage
Test cycles	Bowie and Dick/Helix/Vacuum test	Chemical indicator in a product challenge device Periodic testing as referred to in ISO 17665-1		

## **Technical Specifications**

	T-EDGE10	T-EDGE11	
Chamber Dim. Ø x L (mm)	250 x 460	280 x 460	
Chamber Volume	23 liters	27.2 liters	
External Dimention	480 (W) x 500 (H) x 580 (D) mm	500 (W) x 500 (H) x 580 (D) mm	
Tray Dimensions	189 (W) x 20.5 (H) x 421 (D) mm	207 (W) x 20.5 (H) x 421(D) mm	
Weight	53 kg	56 kg	
Power Supply	50/60Hz, 230V-1Ph+N+GND	50/60Hz, 230V-1Ph+N+GND	
Number of Trays	5	5	
Connections	1 Ethernet port, 2 USB ports, WIFI, integrated automatic water filling and drain connection		
Items Supplied	Drain tube, tray holder	Drain tube, tray holder	







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