8 Technical specifications for the medical device

8.1 Identification

Manufacturer	SATELEC®
Name of the medical device	NEWTRON® BOOSTER

8.2 Mains Adapter

Manufacturer	CINCON ELECTRONICS CO.LTD
Model	TR60M36
Supply voltage	100 VAC - 240VAC
Power supply frequency	47Hz - 63Hz
Power consumption	60 W
Output voltage	36 VDC
Output current	1.66A
Width (in mm)	58
Height (in mm)	30.5
Depth (in mm)	132
Weight (in g)	1620 with mains cord

8.3 Control unit

Width (in mm)	130
Height (in mm)	88
Depth (in mm)	161
Weight (in g)	1 110 with
Ingress protection rating	IPX0

8.4 Ultrasonic generator

Supply voltage	36 VDC
Power consumption	25 W
Voltage supplied to handpiece	150 VAC
Output frequency	Minimum 28 kHz
Power setting range	1 to 20
Operating mode	Intermittent: 10 minutes ON / 5 minutes OFF
Type of leakage currents	BF
Electrical rating	2
Internal fuse not accessible to the user	Ref: F1 / 750 mAT - 125 V – SMD - Breaking capacity: 50 A

8.5 Length of cords

Scaler handpiece cord (in mm)	2 040
Control pedal cord (in mm)	2 000

8.6 Irrigation

Water pressure at inlet	1 to 5 bars
Maximum water output flow at the end of the handpiece	80 ml/min to 100 ml/min at 5 input bars

8.7 Control pedal

Width (in mm)	70
Height (in mm)	30
Depth (in mm)	95
Weight (in g)	150

Ingress protection rating: IPX1

8.8 Environmental characteristics

Operating temperature	+10°C to +30°C
Storage temperature	-0°C to +60°C
Operating humidity	30 % to 75 %
Storage humidity	10 % to 70 %, including condensation
Atmospheric pressure	Between 800 hPa and 1060 hPa
Altitude	Less than or equal to 2000 metres

8.9 Environmental restrictions

Usage premises	Can be used at all medical premises. The medical device must not be used in an operating theatre, or outside.
Use in gas-filled atmosphere	The medical device is not designed for use in a type AP or APG gas-filled atmosphere or in the presence of anaesthetic gases.
Immersion	The must not be immersed.

8.10 Main performance characteristics

Ultrasonic vibrations of the tip or file fitted to the end of the conventional dental ultrasonic handpiece.

- Vibration frequency ≥ 28 kHz.
- Tip amplitude ≤ 200 µm.

9 Regulations and standards

9.1 Official Texts

This medical device complies with the essential requirements of European Directive 93/42/EEC. This equipment is designed and developed in compliance with Electrical Safety standard IEC60601-1 in force. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.

9.2 Medical class of the device

This medical device is a class IIa device according to European Directive 93/42/EEC.