

SENSUS Technical Specifications

Output

| | |
|--|---|
| Waveform | Biphasic with alternating leading phase, symmetrical, rectangular |
| Regulated Current or Voltage | Current |
| Net Charge per Pulse | 0±1 µC into 500Ω load |
| Maximum Output Voltage (± 10%) | 100 V |
| Maximum Output Current (<1KΩ load) (± 10%) | 100 mA |
| Pulse Duration (± 4%) | 200-400 µsec |
| Pulse Frequency (± 4%) | 60-100 Hz, randomly varying |
| Pulse Pattern | Continuous |
| Maximum Phase Charge | 20 µC |
| Maximum Current Density | 0.71 mA/cm ² into 500Ω load |
| Maximum Average Current | 4 mA into 500Ω load |
| Maximum Average Power Density | 7 mW/cm ² into 500Ω load |

Output Trips

| | |
|---------------------|---------------------------------|
| No Load | Device not connected to patient |
| Insufficient Charge | Delivered charge below target |
| Over Load | Delivered charge above target |
| Short Circuit | Low impedance |
| Electrode Peeling | Electrode dislodging from skin |

Therapy Session

| | |
|------------------------------------|--|
| Timer | 60 minutes |
| Start Therapy | Briefly press button |
| Halt Therapy | Press button 4 times within 10 seconds |
| Manual Intensity Increase/Decrease | Increase +1.25% per second, decrease -5% |
| Habituation Compensation | Adaptive stepwise increase in intensity during session |

Electrode

| | |
|----------------------|--|
| Type | Self-adhering, single-patient use, multiple applications |
| Materials | Mylar substrate, silver electrode pads |
| Number of Electrodes | 2, outer electrode area 28 cm ² , inner electrode area 33 cm ² |
| Connector | Medical snap (male) |
| Dimensions | 0.2 cm x 5.3 cm x 28.3 cm (exterior) |

Power

| | |
|------------------------------------|---------------------------------------|
| Source | Permanent rechargeable battery |
| Battery Type | Rechargeable 3.7V Lithium-Ion battery |
| Charging Source | AC line adapter |
| Line Current Isolation | Patient disconnected when charging |
| Patient Leakage Current, DC | < 10 μ A |
| Patient Leakage Current, Enclosure | < 100 μ A |

Physical

| | |
|------------|------------------------|
| Dimensions | 176 mm x 63 mm x 15 mm |
| Weight | 82 g |

Environmental

| | |
|----------------------------|-------------------|
| Operating | |
| Temperature Range | 10° C to 40° C |
| Atmospheric Pressure Range | 50 kPa to 106 kPa |
| Relative Humidity Range | 30% to 75% |
| Transport and Storage | |
| Temperature Range | -40° C to 50° C |
| Atmospheric Pressure Range | 50 kPa to 106 kPa |
| Relative Humidity Range | 10% to 90% |

Guidance Documents & Standards

| | |
|-----|---|
| FDA | Draft Guidance for Industry and Staff: Class II Special Control Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief (April 5, 2010) |
| IEC | IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62304 |