



## Frequently asked questions

**Q: What types of pacemakers can you test with the SigmaPace™ 1000?**

**A:** The SigmaPace™ 1000 is designed to test external cardiac pacemakers only. The two compatible types of external cardiac pacemakers are these:

**Transcutaneous:** This type of pacemaker (typically built into a cardiac resuscitation unit with a defibrillator) has output currents ranging from 30 to approximately 200 mA. External adhesive electrode pads are attached across the patient's intact chest to deliver the energy.

**Transvenous:** This typically small handheld unit, powered by a single 9-volt dc battery, generates pacing pulses at levels from 1 to approximately 25 mA. This type of pacemaker is available in many different configurations from simple single chamber models to more sophisticated AV sequential dual chamber models. The pacing electrodes are introduced via the patient's venous circulatory system via a temporary indwelling cardiac catheter connected directly to the heart.

**Q: Can I test implantable pacemakers with the SigmaPace™ 1000?**

**A:** No! The SigmaPace™ 1000 is designed to test a wide range of external pacemaker parameters, it is not intended for use with implantable pacemakers. Manufacturers of implantable cardiac pacemakers offer sophisticated test systems that are designed for their specific brand and range of available implantable pacemaker models. These test systems typically perform specialized functions such as tissue impedance measurement, and also program operational parameters of these implantable cardiac pacemakers. These diagnostic test systems are utilized during surgical implantation procedures and have direct contact to the patient's heart. Fluke Biomedical's FDA 510(k) submission reflects this "external only" intended use.

**Q: Can I test two single chamber external pacemakers at the same time with the SigmaPace™ 1000?**

**A:** No! The SigmaPace™ 1000 is designed to test only one ventricular transcutaneous pacemaker or one transvenous pacemaker at a time. The transvenous pacemaker can be one of these types:

- Single chamber-atrial type
- Single chamber-ventricular type
- Dual chamber atrial + ventricular type

The only restriction for dual-chamber transvenous-pacemaker testing is to separate the atrial and ventricular output pulses by at least 10 ms. This restriction does not limit the testing capabilities of the SigmaPace™ 1000 because the minimum pacemaker-selectable AV interval (delay time) is >20 ms.

**Q: How do I test Medtronic External Pacemakers with the SigmaPace™ 1000?**

**A:** We have check out procedures for the 5388, 5391 and 5392 Medtronic models. You can access each procedure by clicking the links below or manually typing in the URL in your browser.

Medtronic 5388—[www.flukebiomedical/medtronic5388](http://www.flukebiomedical/medtronic5388)

Medtronic 5391—[www.flukebiomedical/medtronic5391](http://www.flukebiomedical/medtronic5391)

Medtronic 5392—[www.flukebiomedical/medtronic5392](http://www.flukebiomedical/medtronic5392)

**Q: Will I damage the SigmaPace™ 1000 if I inadvertently discharge a defibrillator across the front panel dual-channel input jacks?**

**A:** No! The SigmaPace™ 1000 dual-channel input jacks on the SigmaPace™ 1000 are protected against an application of a high-voltage defibrillator output. The analyzer's protection circuitry is designed to withstand accidental discharges at 360 J.