

# ANS Controlled Closed-Loop Cardiac Pacing- A Multicenter Study

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## Summary

*Single- and dual-chamber pacemaker systems (BIOTRONIK Neos-PEP, BIOTRONIK Diplos-PEP) providing ANS-controlled rate-adaptation were implanted in 240 patients in 16 clinical centers worldwide. Clinical exercise protocols, Holter monitoring, and psychological stress tests were performed over a mean total follow-up time of  $2.6 \pm 1.3$  years. In a subset of patients additional investigations aimed at provoking variations of the sympathetic tone were performed to confirm physiological rate-adaptation for various types of hemodynamic challenges. The results confirm that physiological rate-adaptation can be achieved using the ANS closed-loop concept.*

## Introduction

For patients with chronotropic incompetence, the most attractive concept providing rate-adaptive cardiac pacing is the physiological restoration of a closed-loop chronotropic control.<sup>[1]</sup> In the healthy patient, the autonomic nervous system (ANS) adjusts the cardiac output (CO) to meet hemodynamic and metabolic requirements.

Even in the presence of chronotropic insufficiency the ANS controls the performance of the heart through myocardial contractility. The ANS pacemaker system evaluates this effector-level ANS-signal to establish a physiological closed-loop system which supplies the body with the demand for CO requested by the ANS to maintain an adequate mean arterial blood pressure (MABP).

The local motion of the ventricular walls near the stimulating electrode was used as a sensor for changes in myocardial contractility. The mechanical contraction is mapped to the time course of the unipolar intracardiac impedance measured between the stimulating electrode and the pacemaker housing. Since sympathetic influence changes this contraction pattern (increase in peak tension, steeper rise in tension of contractile elements of the myocardium),

the impedance signal inherently contains ANS-information.<sup>[4]</sup>

Thus, in the ANS-controlled pacemaker, the electrode serves three functions:

- a) as an actuator for stimulation,
- b) as a sensor to detect the intracardiac evoked potentials for control of the pacemaker, and
- c) to detect the sympathetic tone by intracardiac impedance measurements.<sup>[3]</sup>

This method has the clinical advantage that the pacing electrode itself serves as a sensor. Therefore, no additional device is required for that purpose.

## Methods

ANS-controlled pacemakers have been implanted in 240 patients in 16 clinical centers worldwide. The average age of these patients was  $62 \pm 7$  years (64% male). 178 were single-chamber pacemakers (BIOTRONIK Neos-PEP) and 62 were dual-chamber versions (BIOTRONIK Diplos-PEP).