



Christof Lenz, CEO

*“The clinical evidence is substantial: **m.pulse®** with Muscular CounterPulsation represents a whole new paradigm for successfully treating Chronic Heart Failure, non-surgically, in a patient’s home.”*

LEADERSHIP

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Chronic Heart Failure (CHF) is the most frequent cause of hospitalization in persons aged 65+. Current treatments, including drugs, implantable defibrillators/pumps and heart transplantation, have significant risks and side effects. Cardiola’s **m.pulse®** device, based on **Muscular CounterPulsation (MCP)** technology, is approved in Europe for treating CHF as a *nonsurgical, at-home* therapy. Battery-powered **m.pulse®**, the size of a cell phone that the patient attaches to his belt for about 45 minutes per treatment, is synchronized to his cardiac cycle to activate the muscles of the calves and thighs to make them contract *counter* to the heart’s beating. This well-established *counterpulsation* action results in increased blood flow to the heart muscle while decreasing the heart’s workload. CounterPulsation was previously only available in a clinical setting. **Now, m.pulse® is the world’s first and only device enabling CHF patients to receive MCP therapy at home.**

“Our clinical study demonstrated that use of a noninvasive MCP-based treatment for eight days *substantially* improved the cardiac function and *significantly* increased the physical performance of patients with CHF,” says heart surgeon Larry Lapanashvili, MD, the first to discover the beneficial effects of MCP. “Thus, MCP represents a new, promising, non-invasive technique which is associated with the unloading of the left ventricle.” His recent study’s results were published in 2008 in *The International Journal of Artificial Organs*.

“We have created a ‘win/win’ situation with **m.pulse** for both the physician and patient,” says Christof Lenz, CEO, former Global Innovation Manager at Siemens Medical. “CHF patients are very difficult to treat. They have co-morbidities and are challenging from a drug-dosage point of view—drugs have side effects that can act to deter patients’ compliance. And while highly invasive procedures may offer hope and relief as CHF progresses, these alternatives are also risky and costly. On the other hand, **m.pulse** offers patients a well-validated, affordable and non-surgical treatment alternative that they themselves can perform *in their own home*. In addition to helping patients, **m.pulse** with Muscular CounterPulsation offers cardiologists an additional source of revenue.”

Chronic Heart Failure is among the world’s most prevalent diseases and the cause of numerous other serious clinical disorders. Approximately 17 million people currently suffer from CHF in Europe, the U.S. and Japan. Some six million of these patients are classified as NYHA (New York Heart Assn.) classes II and III with systolic dysfunction, the primary patient population for **m.pulse®** with Muscular CounterPulsation from Cardiola. Due to rising life expectancies in the industrialized nations, the number of CHF cases is expected to swell. **Cardiola is targeting a market segment currently spending approximately \$7 billion each year to treat CHF with medical devices and growing at an annual rate of 18-20 percent.**