Closed Loop Stimulation
Practical Guide

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Contents

The Perfect Sensor

What Are the Main Features a Perfect Sensor Must Have?

Proportional to methabolic demand

Adequate rate response especially during the start and the end of the physical exercise

Sensitive to detect the increase of metabolic demand due to physical and mental stress

Integrated in the pacemaker, without the need for a dedicated lead

Specific in detecting true changes in metabolic demand

Proper optimization of hemodynamics is not just a matter of adaptation to physical activity but also needs to respond to changes in mental activity of each patient, such as anxiety or stress. Taking the information for heart rate adaptation from where it originates is the key for...

- Reacting to changes in cardiac contractility
- Emulating the healthy sinus node
- Delivering proven physiologic therapy
- Restoring quality of life

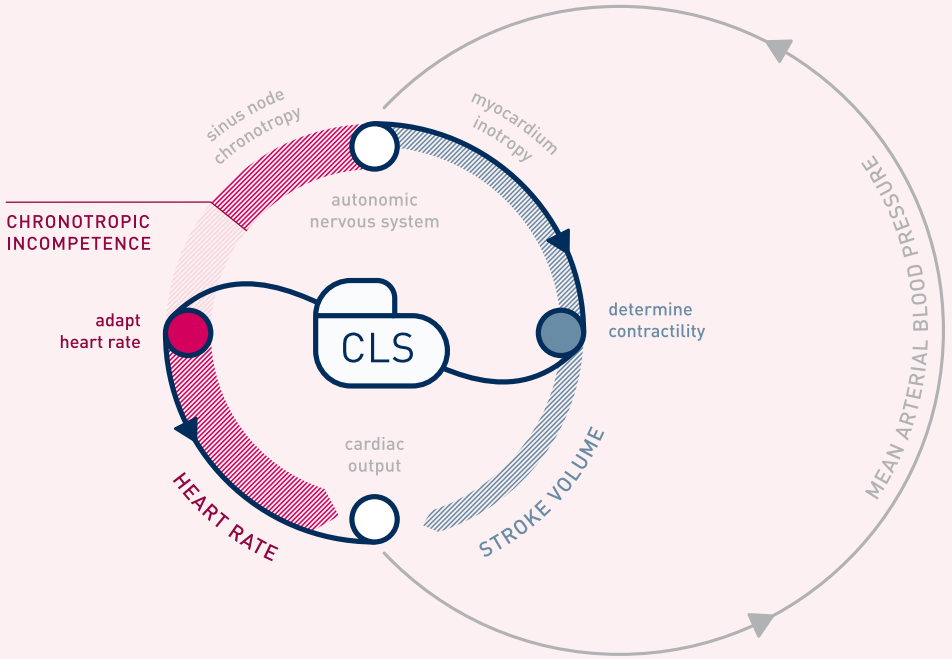
Why Do We Need Closed Loop Stimulation?

- CLS has been designed to mimic the physiologic rate modulation of the healthy sinus node.
- It is based on the most physiologic sensor for rate adaptation currently available and offers a hemodynamic response with optimal blood pressure profiles.
- The unique CLS is not limited to respond to physical activity, it also offers adequate rate response during mental stress.
- In this way, CLS offers optimal physiologic rate response also in those circumstances where conventional rate adaptive algorithms remain virtually ineffective.

CLS is the only algorithm able to modulate physiologic rate response during every type of physical and mental stress, in total synchrony with the autonomic balance.

What Is Closed Loop Stimulation?

- Integrated into the cardiovascular loop, CLS is an algorithm able to measure the contraction dynamics of the myocardium. Myocardial contractility is controlled by the same neural and humoral mechanisms as the sinus rate.
- Changes in the intracardiac impedance are a direct result of increased or decreased contractility and therefore provide the basis for true physiological rate modulation with Closed Loop Stimulation.
- CLS is the only sensor capable of offering physiological rate response during physical and/or mental activity.
- CLS measures unipolar impedances.
- CLS functions with all standard pacing leads.

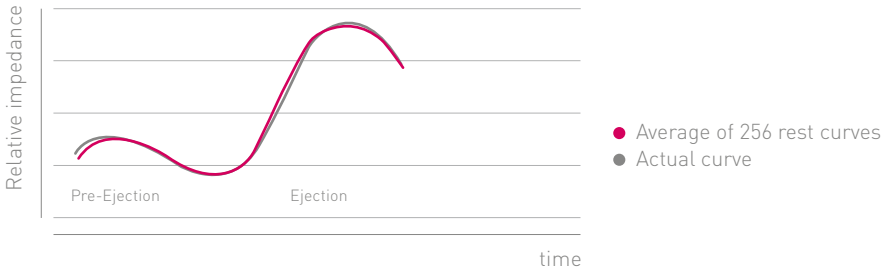


How Does Closed Loop Stimulation Work?

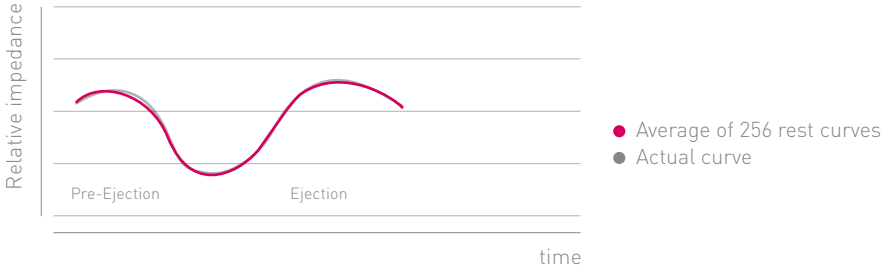
Step 1 – Creation of the Rest Curve

- CLS measures the intracardiac impedance throughout EACH ventricular contraction.
- The device carries a low intensity current between the lead tip and can. The algorithm delivers a train of impulses in order to obtain more specific data on the tissue impedances avoiding the influence of breathing.
- During the "resting state" (monitored by accelerometer) the impedance values will establish continuously updated reference curves, which reflect the contraction dynamics at rest. These reference curves are composed out of the latest 256 resting curves of the paced and sensed events.

Rest curve for sensed event



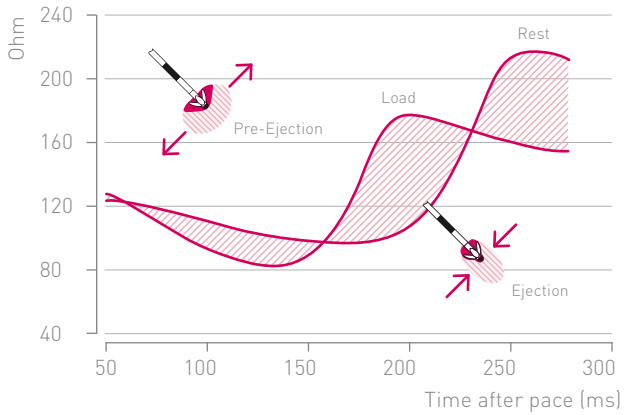
Rest curve for paced event



How to Program Closed Loop Stimulation

Step 2 – Comparing the Rest Curve with the Load Curve

With each heartbeat, CLS determines the impedance curve during the ventricular contraction and compares it to its reference curve at rest.



- Slight changes between the reference curve and the next load curve will result in a minimum change in rate adaptation.
- Moderate changes between the reference curve and the next load curve will result in a moderate increase in heart rate.
- Large changes between the reference curve and the next load curve will result in heart rate adaptation up to the maximum CLS rate.
- CLS does not require any special leads or fixation positions for measuring contraction dynamics. CLS responds adequately even when the lead is positioned in high septum or outflow tract.

Step 3 – Automatic Adjustments of CLS

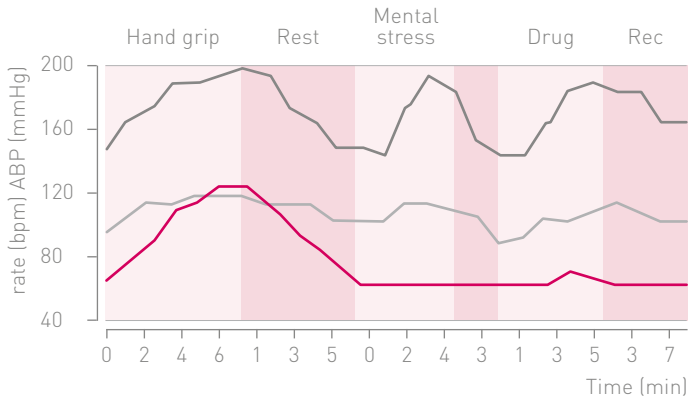
- CLS is initialized during the auto-initialization phase of the implant. The CLS rate is calculated even when the algorithm is not activated.
- Closed loop stimulation is self-calibrating and automatically adjusts to the patient's situation within just a few minutes. Typically, there is no need to manually fine-tune the system. Automatic fine-tuning is active during the entire operating time of the pacemaker.
- Changes in patient's drug therapy or cardiac remodelling does not affect the system as it automatically updates the curves with the new data.

Proper Heart Rate Adaptation

Examples – Zecchi P., A New Philosophy of Pacing, Progress in Biomedical research 2000

- Clinical tests have demonstrated that "CLS reacts proportionally to exercise and to metabolic needs in every patient, taking into account individual hemodynamic conditions and the state of the disease"
- CLS "doesn't induce excessively high heart rates, which may be harmful to patients with coronary artery disease, and improves their quality of life through proper physiological rate regulation"
- The test was based on a single, consecutive sequence of an exercise test (treadmill, 6 min. walking), a mental stress test (colour words – one step), and provocative drug test (infusion of isoproterenol at standard dosage).
- The HR, the systolic (SABP), and diastolic (DABP) arterial blood pressure were monitored every minute during the test sequence.

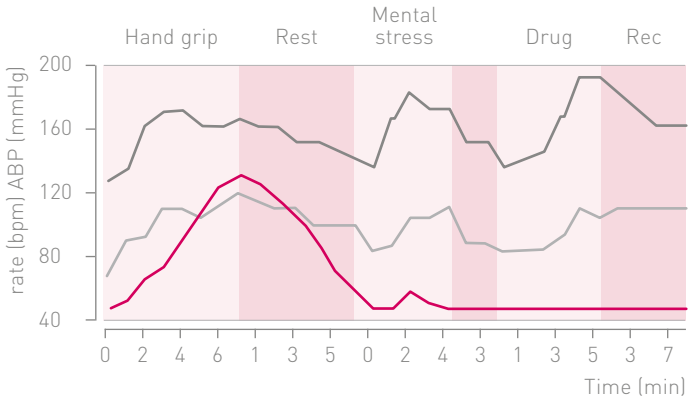
Example: Patient with conventional DDDR pacing



DABP
SABP
HR

Heart rate (HR), Systolic arterial blood pressure (SABP) and Diastolic arterial blood pressure (DABP) trends in a patient with a DDDR pacemaker with an activity sensor.

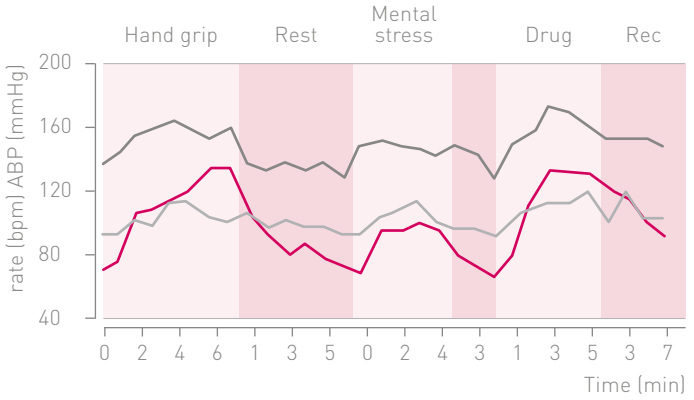
Example: Patient with dual sensor: accelerometer and minute ventilation



DABP
SABP
HR

HR, SABP and DABP trends in a patient with a DDDR pacemaker with a dual sensor: minute ventilation and activity.

Example: Patient with CLS

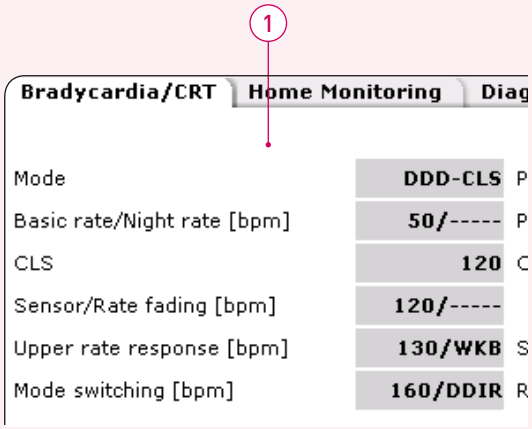


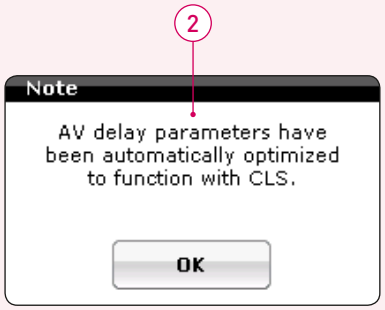
DABP
SABP
HR

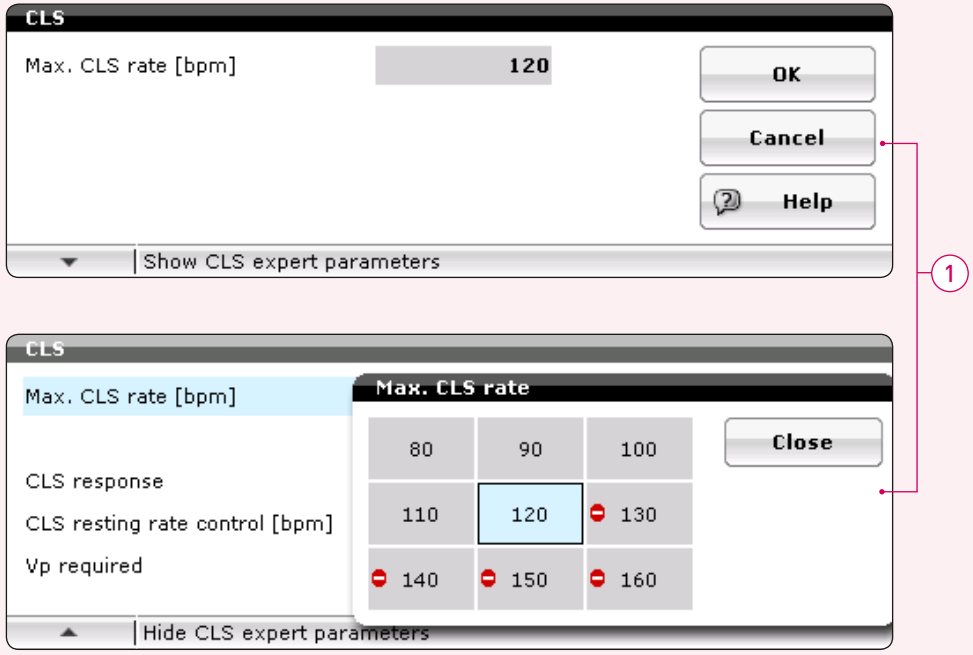
HR, SABP and DABP trends in a patient with a CLS pacemaker.

- All three pacemaker modes show a similar response to exercise. The pacemaker operating in closed loop control (INOS2CLS) reacts in a more physiologic manner, during both stress increase and recovery, than the other two devices.
- Only CLS responds to mental stress and drug infusion by properly modulating the HR. The small reactions of the conventional DDDR pacemaker that were shown at the end of drug infusion should be attributed to the patient's body movements. During mental stress, the dual-sensor device shows some modulation of HR, which is not sufficient to prevent the excessive increase of SABP.

How to Program Closed Loop Stimulation







Step 1

Choose CLS Mode

1 Once CLS mode is selected, it will be activated with standard settings.

2 In dual chambers devices, standard AVD settings will automatically optimize the reduction of Vp and fusion beats.

Step 2

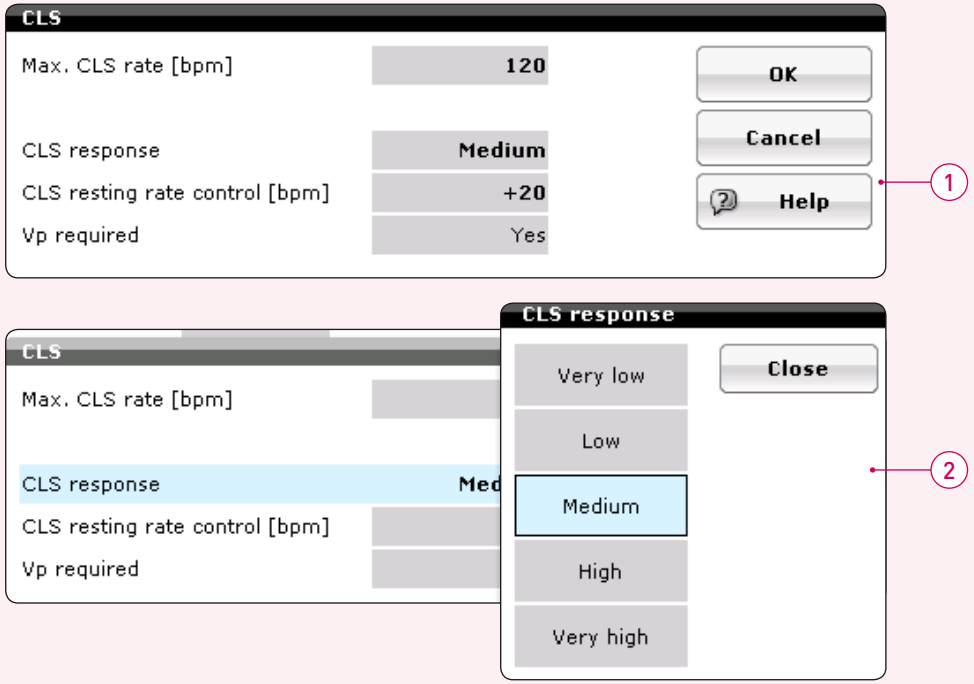
Program max CLS rate

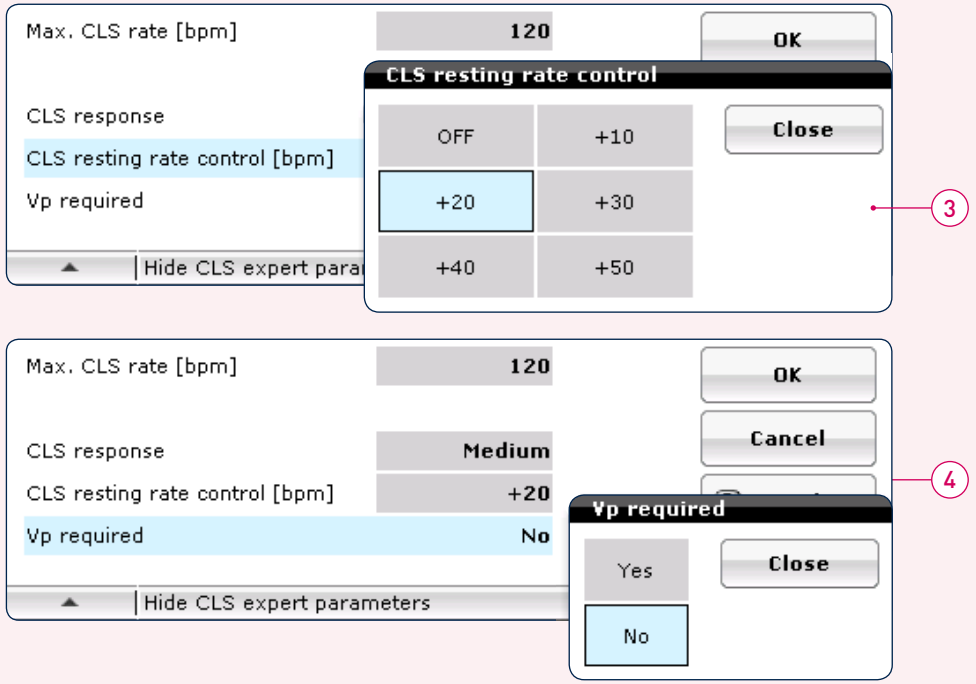
1 The maximum CLS rate can be programmed. The conflicts, shown here, depend on the maximum heart rate programmed.

Note
Expert options should only be adapted in special cases such as...

Please see appendix

Appendix – Expert Options





How to Program

Choose CLS Mode

1 Adapting the expert options has direct influence on the response of CLS with respect to...

2 ...the pacing rate profile for very active or inactive patients. Very Low (mean rate distribution) for inactive patients, Very High (mean rate distribution) for very active patients

3 ...the maximum allowed heart rate during mental activity. > 20 in case of vasovagal syncope. OFF: no limitation in heart rate increase during resting

4 ...patients with high degree AV block where continuous ventricular pacing is required.

In HF devices, "Vp required" cannot be programmed. It is always set to "Yes".

Frequently Asked Questions

Are there special leads required for CLS to work?
No, the proper function of CLS does not depend on the type or fixation position of the lead. Every unipolar or bipolar lead with passive or active fixation is compatible, as long as the lead is positioned in the right ventricle.

When should “Vp required” be programmed to "Yes"?
Only when the patient has developed a high degree AV block, because then there is no need to search for intrinsic rhythms.

When should “Resting rate control” be adapted?
In case of vasovagal syndrome, the heart needs to be paced well above the heart rate at rest. In this case the Resting Rate Control should be adapted to +50 bpm or OFF. If the patient is symptomatic and/or is experiencing heart rate increases at rest during postural changes, the Resting Rate Control can be limited +20 bpm.

When should CLS be disabled?
In principle, CLS adapts to all situations. When there are special situations in which CLS cannot function, it will be automatically disabled and automatically resume its functionality after the situation normalizes again.

What about CLS in combination with Beta Blockers?
CLS uses a rolling average of the previous 256 resting curves and therefore can quickly and effectively react to changes in the contraction dynamics. Beta-blockers exert an influence on basic contractility and consequently update the reference curve, delivering optimal rate modulation.

What about CLS in combination with vasovagal syncope?
CLS has been proven to be very effective for patients with vasovagal syncope. Due to the early increase in contractility just before the syncopic event, CLS is able to immediately increase the heart rate, preventing the rate drop, which is usually the cause of the vasovagal syncope.

What about changes in basic contractility (e.g. DCM, infections, AMI)?
The reference curve adapts to the changed state in basic contractility and calibrates CLS automatically to suit these circumstances.

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