Vagus Device

Instruction For Use

CE 0483

TD 01-03-01 IFU VagusDevice EN v4.3

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Introduction

The Vagus Device enables early detection of autonomic neuropathy (AN) using **4 individual tests** which altogether takes less than 10 minutes. If one of the four test produces an abnormal result, this indicates autonomic dysfunction (early stage) – if two or more test produce abnormal results, the diagnosis AN can be made. While the full testing protocol is recommended for optimal diagnostic accuracy, completion of all tests is not mandatory. A clinical diagnosis of AN may be supported if two (2) or more tests yield abnormal results, in alignment with internationally accepted criteria [1-2]. As such, the device may be used in settings where only a partial test battery is feasible, provided a minimum of two valid and interpretable test results are available. This flexibility enables the Vagus Device to be effectively applied in outpatient screening workflows while maintaining diagnostic validity.

The symptoms of neuropathy may be weak and uncharacteristic for years and are therefore easily overlooked. Thus, the disease may be diagnosed very late and unfortunately often not until permanent nervous damage is recognized. Internationally, autonomic neuropathy screening/monitoring is recommended [3-5].

The device uses a single-lead ECG to record heart rate during cardiovascular reflex tests and features a display that guides both patient and examiner.

[1] BMJ. 1982;285(6346):916-918; [2] Diabetes Metab Res Rev. 2011;27(7):639-653; [3]Diabetes Care 2024;47(Suppl. 1):S231-S243; [4]Eur Heart J 28(1):88-136, 2007; [5]Diabetes Care 28(4):956-962, 2005

Inspection of Received Items

Check the contents:
- Compare the received items with the list below. Ensure the items are without visual damage.

In case of defects or damage:
- Take photos of any damage or missing items immediately and contact support@medicuseng.com
- Do not use the device/part

Keep the storage case
- To ensure save storage, it is important to keep the original Storage case. Storage the device in the case when not in use.

Vagus™ kit

Tabel 1: Content for the Vagus™ kit V100.1

Part Name	Number	Qnty	Lifespan / Capacity	Replaceability / Ordering	Disposal
Vagus™ Device	V01.1	1	5 years	Can be reordered	Recycling centre
Electrodes	V02.1	2	50 measurements	Replaceable/Can be reordered	Ordinary waste disposal
Valsalva mouthpiece	V03.1	2	Single-use only	Replaceable/Can be reordered	Ordinary waste disposal
Instruction for use	V04.2	1	-	Can be reordered	Ordinary waste disposal
Vagus™ Examen pad	V05.1	1	-	Can be reordered	Ordinary waste disposal
SD memory card	V06.1	1	480 measurements	Replaceable/Can be reordered	Recycling centre
AA (LR6) batteries	V07.1	2	500 meas. per year	Replaceable/Can be reordered	Recycling centre
Storage case	V08.1	1	-	-	Ordinary waste disposal

Instructions

Customer instructions

Thank you for purchasing Vagus™ for identification of auto- nomic neuropathy. Please read this manual carefully before using Vagus™ for the first time. Failure to comply with these instructions may lead to incorrect measurements and may cause damage to Vagus™. We take no responsibility for any personal injury in connection with the use of Vagus™.

Definitions

HR – Heart rate (Unit – beat pr minut - BPM)
RS – Response from laying to Standing (No unit - ratio)
EI – Deep breathing (No unit - ratio)
VM – Valsalva manoeuvre (No unit – ratio)
CAN - Cardiac Autonomic Neuropathy (Score = 0-3)

Intended purpose

Heart rate measurements in response to paced breathing and controlled exercises to support the diagnosis of autonomic nervous system dysfunction (autonomic neuropathy).

Indication for use

Persons with diabetes.

Patient target group

Vagus™ is a medical device for screening of autonomic neuropathy in adults (>18 years).

Intended users

Vagus™ must be used by a physician or instructed staff. Vagus™ must not be used by patients for self-diagnosis.

Clinical benefits to be expected

The presence of autonomic neuropathy, irrespective of other complications, is a negative prognostic factor. Its detection should prompt a reassessment of the patient's risk stratification and inform decisions regarding diagnosis, treatment, and follow-up care.

Identification for diagnosis

If one of the four steps produces an abnormal result, this indicates autonomic dysfunction (early stage) – if two or more steps produce abnormal results, the diagnosis autonomic neuropathy can be made.

⚠

Contra indications

- Do not use Vagus™ if the patient has a pacemaker.
- Using the device will not harm the patient or damage the pacemaker, but the pacemakers cardiac pacing will interfere with the value of the Vagus™ algorithm.
- If the patient is undergoing laser treatments for proliferative retinopathy Valsalva manoeuvre, should be avoided due to a hypothetical risk of bleeding in retina.

Recommendations

- It is recommended that patients refrain from smoking or consuming caffeinated beverages before the measurements, and that they fast for at least two hours beforehand.
- The patient should wash his/her hands with water and soap before the examination. Do not use alcohol-based hand rub since this will dry out the patient's hands. You may moisturize the patient's hands with water.
- To protect the Vagus™ electrodes, patients should not wear rings, as these may scratch the electrodes.
- The patient should remain silent and avoid any sudden or unprompted movements during the measurements.

Warnings/Safety instructions

- Use only authorised components for this device.
- The mouthpiece must be used only for one patient examination.
- Do not use this device on pacemaker patients.
- Do not use this device near flammable anaesthetics, drugs or pressurised oxygen (e.g. a pressure chamber or ultraviolet steriliser).
- Do not use this device on patients with wounds on his/her hands due to risk of irritation or rash.
- Keep out of the reach of children and persons who cannot express their intentions.
- Do not use this device for any other purpose than screening of autonomic dysfunction.
- Do not expose this device to severe shock or vibration.
- Do not use this device near strong electromagnetic fields.
- Do not use other types of batteries than stated in this manual.

Recommended Pre-Use Inspection

- Inspect the device for any visible damage.
- Inspect the electrodes for visible damage.
- Ensure the SD card has sufficient free space.
- Check the battery status in the top right corner of the display.
- Ensure that the battery cover is mounted correctly.

Periodic maintenance

- Replace electrodes after 50 patient examinations or early if data error occurs often.
- Replace batteries as needed (Battery indicator is shown in the display).

Recommendation: Perform a visual inspection and functional test at least once a year.

Tabel 2 Service lifetime

	Vagus	Mouthpiece	Electrode
Shelf life		5 years	5 years
Service life	5 years*	1 patient examination single use	~50 patient examinations

*Minimum 5 years with proper storage, use and maintenance

Post-5-year use

The Vagus Device may continue to be used after passing visual inspection and functional test.

The functional test shall include:

- Verification of display functionality.
- Verification of buttons functionality.
- Performance of a VM examination to confirm proper operation of the pressure sensor.

The test must be performed by physician or instructed staff. Instruction for use must be read and understood.

Manufacturer service policy

No service is provided for the product – repair or replacement of components is not offered by the manufacturer. There is a two (2) year warranty on production failure.

Caution

- Be aware that some medication may affect the autonomic nerve system.
- Avoid transmission of static electricity before use.
- Always install the batteries according to the instruction on the battery cover.
- The battery cover and the electrodes MUST be placed correctly before use.
- Use only ALKALINE batteries (LR6).
- Make sure that at least 1/3 of the battery life is shown on the battery indicator.
- Check on the display screen that there is sufficient storage on the SD memory card, like 480/122, (122 measurements storage).
- Usage of this device is recommended at a temperature between 18°C and 25°C and with a relative humidity below 80%.
- Do not use a mobile phone near this device.
- Do not sterilize this device.
- Do not disassemble, attempt to repair or modify this device.
- This device must not be exposed to or washed in water, acetone, ether, freon or petroleum derivatives.
- Always store Vagus™ in the accompanying storage case.
- Do not expose Vagus™ to direct sunlight, high air humidity or temperatures or to dusty, wet or moisturized surroundings. Do not store the device close to open fire, strong vibrations or electromagnetic fields.
- Dispose Vagus™ and its components according to applicable local regulations.
- Keep Vagus™ in the storage case when not in use.
- Remove batteries if Vagus™ will not be used for one month or longer.
- Keep device and accessories away from direct sunlight.
- For more information, please see table: Specifications

Electromagnetic Compatibility (EMC)

The application environment for the Vagus Device is: Professional environment, hospital and medical practice.

The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

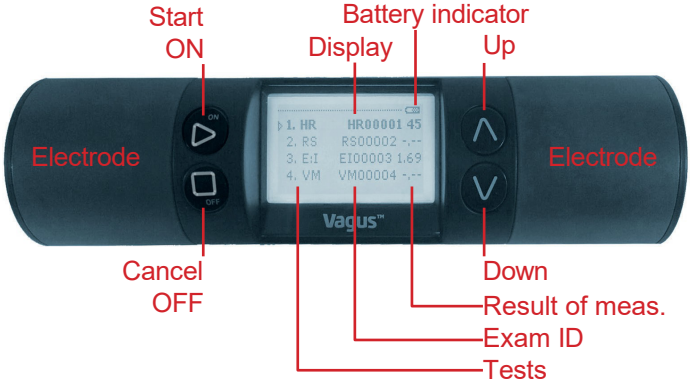
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device. Otherwise, degradation of the performance of the equipment could result.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

Vagus™ Examination

Usage and navigation

Vagus™ applies the hands as ”electrode positioning” instead of ordinary disposable ECG electrodes.
Vagus™ is turned on by pressing ▷ for two seconds.
Start the test by pressing ▷ and follow the instructions on the display. Choose test by pressing ⋁ or ⋀. Disconnect or return to previous test by pressing □. Vagus™ is turned off by pressing □ for two seconds.
Vagus™ will automatically turn off after two minutes of inactivity.



Using Vagus™ for the first time

Install the batteries and Turn on Vagus™ by pressing ▷ make sure that the Vagus™ logo appears on the display.
Select language (Danish or English,) under 'Settings' on the display. Vagus™ is now ready for use.

To obtain the best measurement results, it is recommended that:

The patient should wash his/her hands with water and soap before the test begins.
To protect the Vagus™ electrodes, patients should not wear rings, as these may scratch the electrodes.
The patient should remain silent and avoid any sudden or unprompted movements during the measurements.
It is recommended that patients refrain from smoking or consuming caffeinated beverages before the measurements, and that they fast for at least two hours beforehand.
Check the display to ensure that at least 1/3 of the battery life is shown on the battery indicator.

How to handle Vagus™

Do not “squeeze” Vagus™ during the test. Either hand position A or B may be used during the test.

A

B

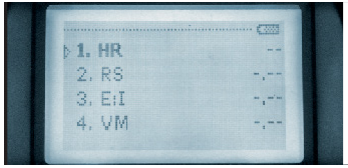
Vagus™ Examination

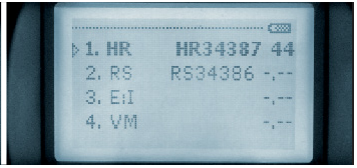
1. Heart rate (HR) 5 min.

Measuring heart rate while resting in a supine position

- Choose 1. HR on Vagus™.
- Place Vagus™ in the palms of the patient.
- Press ▷ and Vagus™ counts down and then starts the measurement.
- The measurement lasts for five minutes, short beep = approved. Take the device - The patient must lie still after the HR measurement.
- The display shows an Exam ID, a consecutive number starting with HR (e.g. HR34387), and the result of the measurement (e.g. 44).
- Note down the Exam ID and the result of the measurement on the Vagus™ Examen pad.

⚠
A long beep (two seconds) = Error measurement.
See sources of errors on page 9.
This generally applies for all four steps. In case of error measurement, no result is obtained.
Repeat the step, no more than three times though, and then continue to the next step.





2. Response from lying to standing (RS) 1 min.

Measuring the heart rate response from supine to upright position

- The patient must lie still after the HR measurement.
- Choose 2. RS on Vagus™.
- Place Vagus™ in the palms of the patient.
- Press ▷ and Vagus™ counts down (5 seconds)
- When the device ”beeps” the patient must stand up holding Vagus™ in his/her hands.*
- Press ▷ again as soon as the patient is standing upright with his/her arms hanging relaxed.
- The measurement lasts for one minute, short beep = approved.
- The display shows an Exam ID, a consecutive number starting with RS (e.g. RS34388), and the result of the measurement.
- Note down the Exam ID and the result of the measurement on the Vagus™ Examen pad.

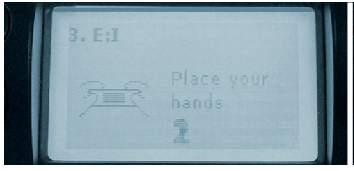
*In the event, If the patient cannot stand up with the Device in his/her hands. The device must be handed over when the patient is in an upright position.

Vagus™ Examination

3 . Deep breathing (E:I) 1 min.

Measuring the heart rate response during deep breathing

- The patient must be sitting in a relaxed manner.
- The patient must follow the instructions on the display while slowly breathing in and out.
- Choose 3. E:I on Vagus™. Place the device in the hands of the patient.
- Press ▷ and device counts down (5 seconds) and starts the measurement.
- The examination starts with the patient inhaling through his/her nose until inhaling is no longer possible. When the text changes and the bar moves downwards, the patient must passively exhale through his/her mouth following the pace of the bar.
- The measurement lasts for one minute, short beep = approved. The display shows an Exam ID, a consecutive number starting with EI (e.g. EI34389), and the result of the measurement. Note down the Exam ID and the result of the meas- urement on the Vagus™ Examen pad.

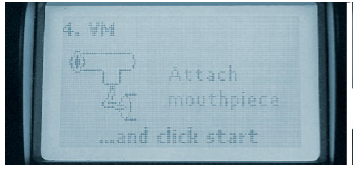


4 . Valsalva manoeuvre (VM) 1 min.

Measuring the heart rate response during expiration with a regular pressure of 40 mmHg and during rest

- The patient must be sitting in a relaxed manner.
- Insert the tube from the Valsalva mouthpiece to the connection of the Vagus™ manometer.
- Choose 4. VM on Vagus™.
- Place the Valsalva mouthpiece in the patient's mouth and Vagus™ in his/her hands.
- Press ▷ and Vagus™ counts down (5 seconds) and starts the measurement.
- Follow the instructions on the display: the patient should take a deep breath, then exhale forcefully through the mouthpiece for 15 seconds. Afterwards, remove the mouthpiece while the patients continues to hold the device in thir hands. The measurement continues for an additional 45 seconds. Short beep = approved. Note down the Exam ID (e.g. VM34390) and the resultof the measurement on the Vagus™ Examen pad.

If the patient is undergoing laser treatments for proliferative retinopathy, step 4 should be avoided due to a hypothetical risk of bleeding in retina.



Vagus™ Examination

Shutdown, cleaning and storage

Turn off Vagus™ by pressing ☐.

After each examination, carefully clean Vagus™ once with a disposable wet alcohol or disinfection wipe, such as ”Wet Wipe PHMB Disinfection”. Then use a dry, soft cloth and make sure that the electrodes are completely dry before the device is placed in the storage case.

Always keep Vagus™ in the storage case when not in use. Always remove all batteries if Vagus™ will not be used for one month or longer. Only remove the electrodes when it is time to replace them. Do not clean the connector of the Valsalva tube.

Warning

Do not clean Vagus™ using acetone, ether, freon or petroleum derivatives. Do not submerge Vagus™ in any fluids. Do not subject Vagus™ to extreme temperatures, humidity, dust, strong shocks or vibrations.

The batteries must not be in direct contact with soap or water.

Symbols

CE 0483	Vagus device - CE marking, with Notified Body (NB) Reference no. 0438	GTIN(01) Production date (11) Serial number(21)	Vagus device - Data Matrix : Unique Device Identifier (UDI)
	Important safety instructions		Manufacture
SN	Serial number	DK	Country of manufacture
MD	Medical Device	mm-yyyy	Date of manufacture
(LR6)	Alkaline AA battery		This product is a Class BF electrical device
⎓	Direct current		Recycle: Electronic Equipment
CE	Electrode and mouthpiece - CE marked Class I medical device	GTIN(01) Batch/Lot(10) Production date (11)	Electrode and mouthpiece - Data Matrix: Unique Device Identifier (UDI)
	Read the manual before operating this device		Keep dry
REF	Indicates the manufacturer's catalogue number – stock keeping unit.	mm-yyyy	Used by date
	Do not re-use/ **Single use only**	MD	Medical Device
	Atmospheric pressure limit		Humidity limitations
	Fragile, handle with care		Keep away from sunlight
	This side up		Temperature limitations
	Warning		Caution

Troubleshooting - information and sources of error

Tabel 3: Troubleshooting Vagus device and accessories

Display / Sound	Cause	Solutions / Recommendations
Vagus™ cannot be turned on	Worn-out batteries.	1. Replace with new AA (LR6) batteries. 2. Check that the batteries are installed properly. Refer to 'Replacement of batteries'. 3. Check that the SD memory card is installed properly.
The SD memory card is full (no sound)	Unable to start examination Full memory card.	1. Clear the SD memory card. Refer to 'Clearing the SD memory card'.
Warning. Unstable beats (Short beep)	Possible cause: Abnormal heart rate.	1. Repeat the measurement. However, no more than three times. 2. Conduct a standard ECG examination.
Error. Data error (Long beep)	Possible cause: Signal interference. The data quality is insufficient.	1. Hold your arms and hands still. You may moisten your hands. 2. Repeat the measurement. However, no more than three times. 3. Replace the electrodes. Refer to “Replacement of Electrodes”
Error. Low pressure (Long beep)	Possible cause: The patient exhales below the predetermined value of the VM test.	1. Repeat the measurement. However, no more than three times.
Error. Result error (Long beep)	Possible cause: The result is outside the measurable area.	1. Repeat the measurement. However, no more than three times. 2. Conduct a standard ECG examination.

Vagus™ Service/Replacement

Replacement of electrodes (V02.1)

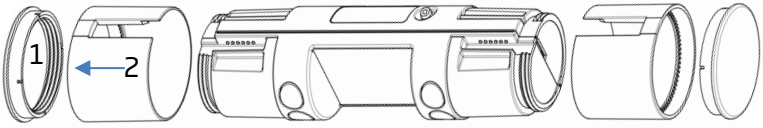
Electrodes will gradually become lighter and lose the conductivity ability, and it is recommended that the electrodes are replaced after approximately 50 patient examinations or when they become light or heterogeneous on the surface.

Electrode Replacement

Place the Vagus device so that the power-off button (square icon) is positioned by the left hand.Turn off Vagus™ by pressing ☐ for two seconds.

Proceed with the following steps to replace the electrodes.:

1. Unscrew the left end cover.
2. Carefully remove the worn-out left electrode.
3. Carefully place the new electrode labelled with “left”.
4. Screw the end cover back on.
5. Repeat the procedure on the right side.
6. Dispose of worn-out electrodes using ordinary waste disposal.



Disposal: Electrodes consist of ABS plastic and silver ion coating. It can be disposed off like plastic. No electrical parts are in the electrodes.

Replacement of batteries (V07.1)

The lifespan of the batteries should be enough for app. 500 measurements. Replace the batteries if the battery symbol indicates low battery or if a prompt is displayed. Turn off Vagus™ and turn the device until the battery cover is in front of you. Follow these instructions:

1. Open the battery cover by pulling the latch in the middle.
2. Note the battery type and +/- positions. Remove the worn-out batteries.
3. Install the new AA (LR6) batteries so the + (positive) and - (negative) polarities match the polarities of the battery compartment as indicated.
4. Close the battery cover.
5. Disposal: Worn out battery must be disposed in accordance with national regulation. Do not through battery in the waste bin or nature, must be disposed of as battery waste.

Vagus™ Service/Replacement

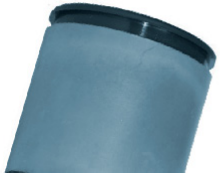
Clearing the SD memory card (V06.1)

Vagus™ memory card is sufficient for 480 measurements and must then be cleared. Turn off Vagus™ by pressing ☐ for two seconds. Follow these instructions:

1. Place the Vagus device so that the power-off button (square icon) is positioned by the left hand. Remove the batteries and unscrew the right end cover.
2. Push in the SD memory card to release it and then pull it out.
3. Insert the SD memory card into a Mac or PC. The card will be cleared while data are being transferred or delet- ed. Do not remove the file: _SETUP_.text from the SD memory card. Insert the memory card back into the slot on Vagus™. There is only one way to insert the card.
4. Screw the end cover back on.
5. Install the batteries and replace the battery cover.
6. Turn on Vagus™.

⚠

You need an SD card reader and a Mac or PC for clearing the SD memory card.



⚠

Note

Replacement of batteries, SD memory card and electrodes may be carried out by a physician or instructed staff. Then, make sure that Vagus™ is working properly by turning on the device. Press ▷ so that the Vagus™ logo appears on the display.

Vagus™ does not work without the SD memory card.
If the device is turned on without the SD memory card inserted, the display will light up, but the Vagus™ logo will not appear. Follow these instructions:

1. Remove the batteries and unscrew the right end cover.
2. Reinsert the SD memory card. There is only one way to insert the card.
3. Screw the end cover back on.
4. Install the batteries and replace the battery cover.
5. Turn on Vagus™.

If, by mistake, the file:_SETUP_.text has been deleted from the SD memory card, ”Exam ID” and all settings will be reset. Repeat the procedure "Using Vagus™ for the first time", refer to page 6.
Contact support@medicuseng.com for help.

Do not disassemble or attempt to repair Vagus™.

Vagus™ Contact

Order placements

Find the local distributors add: vagusdevice.com
or send an e-mail to: order@medicuseng.com

Part Name*	Number
Vagus™ kit	V100.1
Electrodes 1 set of Vagus Electrode (right and left electrode)	V02.1
Valsalva mouthpiece	V03.1
Vagus Exam kit V02.1 - 1 set of Electrodes V03.1 - 50x Valsalva Mouthpieces	V300.1

*See page 2, Table 1 for information about the content

Support

If you need guidance or external service please contact Medicus Engineering ApS for technical support:
mail@medicuseng.com

Manufacturers address

Medicus Engineering ApS
Palle Juul-Jensens Blvd 82 .
DK-8200 Aarhus N, Denmark . medicuseng.com

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Vagus™ Device Specifications

Product name	Vagus Device
Medical equipment:	Risk class IIa
Electrical safety:	Risk class A
Product dimensions:	L: 169 mm / Ø: 45 mm
Product weight:	120 g not including batteries
Display:	LCD display with backlight
Batteries:	2 AA batteries, (LR6) 1.5V
Electrodes:	Silver/silver chloride
Measurement method:	1-lead ECG measurements
Measurement range, pressure:	0 to 66 mmHg
Measurement range, pulse:	28 to 200/min.
Memory card capacity:	480 measurements
Pressure accuracy:	±3 mmHg
Pulse accuracy:	±1% of reading
RR sampling:	1000 Hz
Operating humidity:	<80% RH
Operating temperature:	+5°C to +40°C
Atmospheric pressure:	80 to 106 kPa
Storage humidity:	<80% RH
Storage temperature:	-20°C to +50°C
Transportation humidity:	<80% RH
Transportation temperature:	-20°C to +50°C

Normative threshold (pathological tests equal or below)

Age:	15-19	20-29	30-39	40-49	50-59	60-69	70-79
RS	>1,23	>1,18	>1,13	>1,10	>1,07	>1,05	>1,04
E:I	>1,36	>1,27	>1,19	>1,14	>1,10	>1,07	>1,05
VM	>1,42	>1,38	>1,33	>1,30	>1,26	>1,21	>1,19

Age-specific normative thresholds for the cardiovascular autonomic reflex tests specific for the Vagus Device: DOI: 10.1007/s10286-024-01069-6

Vagus™ Examen pad – (V05.1)

Date: / /
Conducted by:

TD 01-03-02

Patient:

Name / Name label

Measurement values

CAN test	Exam ID	Results	CAN
HR*		BPM	
RS		Ratio	0 / 1
E:I		Ratio	0 / 1
VM		Ratio	0 / 1
		CAN Score:	0-3

No CAN ☐ Borderline CAN ☐ Definitive CAN ☐

**HR is recommended, advanced disease is associated with HR (>100 bpm)*

- Do not use Vagus™ if the patient has a pacemaker. Using the device will not harm the patient or damage the pacemaker, but the pacemakers cardiac pacing will interfere with the value of the Vagus™ algorithm.
- If the patient is undergoing laser treatments for proliferative retinopathy the (VM) Valsalva manoeuvre, should be avoided due to a hypothetical risk of bleeding in retina.

Normative threshold (pathological tests equal or below)

Age:	15-19	20-29	30-39	40-49	50-59	60-69	70-79
RS	>1,23	>1,18	>1,13	>1,10	>1,07	>1,05	>1,04
E:I	>1,36	>1,27	>1,19	>1,14	>1,10	>1,07	>1,05
VM	>1,42	>1,38	>1,33	>1,30	>1,26	>1,21	>1,19

Age-specific normative thresholds for the cardiovascular autonomic reflex tests with the Vagus Device: DOI: 10.1007/s10286-024-01069-6

CAN score:

Diagnosing Cardiac Autonomic Neuropathy (CAN)
Diagnose by adding numbers of deviating pathological tests from RS, E:I and VM as follows:

No CAN:	0 pathological tests
Borderline CAN:	1 pathological test
Definitive CAN:	2 or 3 pathological tests