



MILO OWNER'S MANUAL

Milo Vagus Nerve Stimulation System

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Introduction to the system

Brief description

The Milo Vagus Nerve Stimulation (VNS) System is a therapeutic system intended to reduce the frequency and severity of epileptic seizures and improve the quality of life for dogs. The system is comprised of implantable, external wearable, and software components.

Implantable Pulse Generator (IPG) or “Implant”

An active implantable device that delivers pulses of electrical current to stimulate the vagus nerve. The IPG is an electronics assembly encapsulated in glass, with integrated platinum electrodes.

Smart Collar

An externally worn, battery powered device that wirelessly powers and communicates with the implanted IPG through the skin.

MiloApp

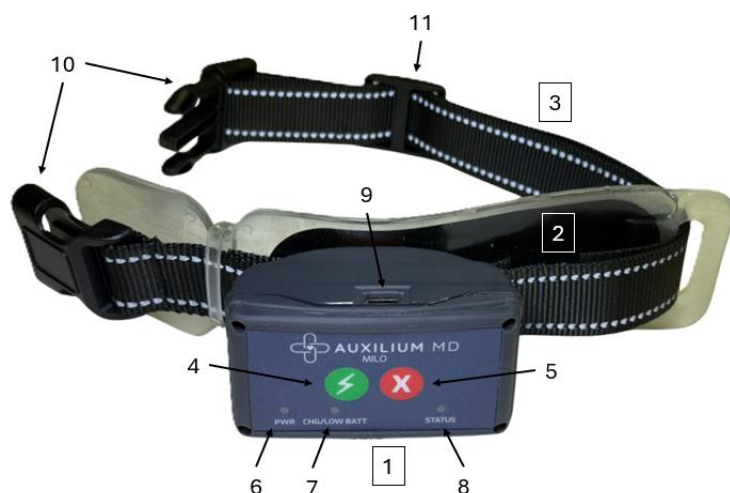
An application that runs on a mobile phone or tablet and allows the dog owner additional means of interacting with the therapeutic system. MiloApp can be used to set up the system, monitor therapy, receive messages, create reports, and notify Auxilium support staff of any issues.

Technical Information

Smart Collar

Description

The Milo Smart Collar consists of three major components: 1) the electronics module housed in a rigid plastic enclosure, 2) the flexible collar coil, and 3) the nylon neck band. The electronics module contains a battery and a circuit board with wireless antennas. The external interfaces include a green push button with a lightning symbol, a red push button with an “X” symbol, a green power LED, a red/blue low battery and charging LED, a multi-use multi-color status LED, and a USB charging port. The electronics module energizes the collar coil in order to provide power to the IPG. The nylon neck band has a neck size adjustment feature in the form of a buckle slide, as well as a side release buckle for quickly taking the collar on and off.



No.	Description
1	Electronics Module
2	Collar Coil
3	Neck Band
4	Green Lightning Button
5	Red X Button
6	Power LED
7	Charge & Low Battery LED
8	Status LED
9	USB Charging Port
10	Side Release Buckle
11	Buckle Slide

Figure 1 – Smart Collar

Specifications

Electronics module dimensions	78 mm x 44 mm x 33 mm
Collar coil dimensions	126 mm x 54 mm x 7 mm
Neck band width	1 inch (2.5 mm)
Neck band circumference	Adjustable 8 – 28 inches (20 – 71 cm)
Weight	174 g
IP rating	Not rated
Electronics module material	Resin
Collar coil material	Resin
Neck band material	Nylon
Battery life	24 hours

System Directions for use

Collar fitting

Fit the collar to patient and adjust the tightness appropriately. When first applying the collar to the patient, snap the side release buckle together, and then tighten the buckle slide so the PCM coil is snug against the neck without being uncomfortable for the patient. Typically, two fingers should be able to fit under the collar. If the collar is too loose it may not be able to provide sufficient power to the IPG. Rotate the collar so the electronics module is centered on the ventral midline.



Figure 2 – Proper collar fit on dog

System communication

IPG-collar communication

Alignment of collar over IPG

The collar coil emits an electromagnetic field in a local area around the coil. This electromagnetic field powers the IPG and allows bidirectional communication. Therefore, the coil must be located directly over and ideally centered on the location of the implanted IPG. Figure 3 shows how to position the collar coil over the IPG for best communication. The less distance between the collar coil and IPG, the more robust the communication.

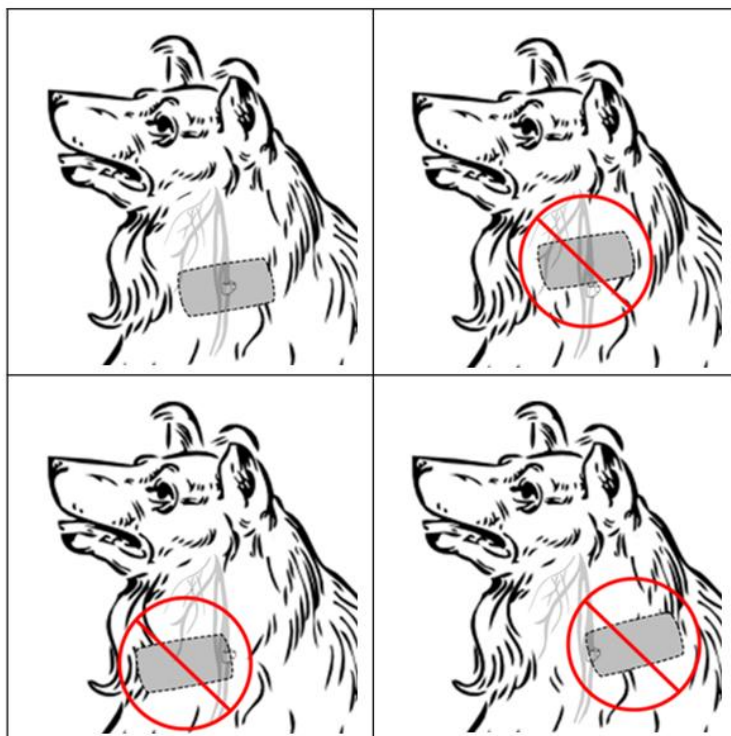


Figure 3 – Alignment of collar coil over IPG. IPG should be centered on collar coil as shown in top left panel.

Collar wireless communication

Wi-Fi communication

The Smart Collar uses Wi-Fi to send and receive data from Auxilium MD's servers when connected to a Wi-Fi network with internet access. Data sent over Wi-Fi can include stimulation parameter updates from the veterinarian to the Milo system, monitoring data from the Milo system to the veterinarian, and software updates from Auxilium MD to the Milo system.

Entering Wi-Fi network information via Wi-Fi

The Smart Collar will come pre-loaded with the veterinary clinic's Wi-Fi credentials that were entered during clinic registration. Additional Wi-Fi network credentials can be entered during new patient registration. The Smart Collars can download new Wi-Fi network credentials any time they are already connected to a Wi-Fi network by using the Milo App. To add new Wi-Fi network credentials when the Smart Collars are not connected to a Wi-Fi network, a special Bluetooth mode can be used (see Bluetooth Communication below).

Bluetooth communication

The Smart Collar uses Bluetooth to communicate with a nearby mobile device running the Milo App. However, this communication modality is used only for adding Wi-Fi network credentials when the Smart Collars are not connected to a Wi-Fi network. See the Setup section under MiloApp for instructions on how to enter Wi-Fi information via Bluetooth.

System modes

There are two main system modes for normal control of therapy: Standby and Active. These will be used by the pet owner on a daily basis. There is also a special mode for troubleshooting: IPG Finder Mode. System modes can be changed using the green and red buttons on the electronics module of the collar. For an up-to-date list of button press sequences for changing modes, please visit:

<https://milo.auxiliummd.com/info/buttons?app=AuxDoc>

Standby Mode

In Standby Mode the collar will not deliver therapy or attempt to communicate with the IPG. Wi-Fi communication will remain available so the collar can still receive updates from the server and send status reports. When communicating with the server over Wi-Fi a blue, blue blink pattern will be indicated by the status LED. In Standby Mode the power LED will be off. The power LED will also be off in IPG Finder Mode, but this mode will be differentiated by the status LED. To enter Standby Mode, press and hold the red X button until a 3-tone chime is played, or at least 5 seconds.

Active Mode

In Active Mode the collar will deliver therapy by commanding the IPG to stimulate on a schedule according to the programmed stimulation parameters. Successful stimulation will be indicated by a white, white blink pattern from the status LED. Wi-Fi communication is available during active mode. In Active Mode the power LED will be green. To enter Active Mode, press the green lightning button.

IPG finder mode

IPG Finder Mode is a special mode that allows the veterinarian to easily map the positions of the collar coil which allows communication with the IPG. It does this by rapidly and repeatedly attempting to communicate with the IPG while continuously indicating whether communication is successful or not. In IPG Finder Mode the power LED will be off and the status LED will either be white (communication successful) or red (communication unsuccessful). To enter IPG Finder Mode, first ensure the collar is in Standby Mode. Next, perform the following button press sequence:

1. Press and hold the green button.
2. While holding the green button, press and release the red button.
3. While still holding the green button, press and hold the red button.
4. While holding the red button, release the green button.
5. While still holding the red button, press and release the green button.
6. Release the red button.

Maneuver the collar coil around the implant area to determine the zone of IPG communication. There is a small delay before the indicator changes so move slowly for accurate results. To exit IPG Finder Mode, press the red X button or the collar will automatically exit IPG Finder Mode after 5 minutes.

System status indicators

The most common LED indicators are discussed throughout this manual. While the power LED and the charge & low battery LED have just a few dedicated uses, the status LED is used to indicate a variety of statuses and errors. These are updated semi-regularly, so for the most up-to-date list of blink codes, please visit:

<https://milo.auxiliummd.com/info/blinkcodes?app=AuxDoc>

Manual stimulation

Stimulation can be initiated manually by the user prior to the next scheduled stimulation. This is typically used by pet owners to attempt to prevent a seizure or reduce the duration and severity of a seizure in cases where a seizure is imminent or is ongoing. To initiate stimulation manually, the collar must be in Active Mode, then press and release the green lightning button. Successful stimulation will be indicated by a white, white blink pattern from the status LED. There is a 30-second refractory period beginning at the end of each stimulation period that prevents overstimulation. If manual stimulation is attempted during this refractory period, stimulation will not occur, and the status LED will issue a white, red, red blink pattern.

Charging the battery

When the collar battery is low, the charge & low battery LED will turn red. To charge the battery connect one end of the cable to the USB port on the electronic module and the other end to a USB charger capable of supplying at least 5W of power. During charging, the charge & low battery LED will blink blue. When charging is complete the charge & low battery LED will be solid blue. Charging the battery from empty to full should take approximately 2 hours.

MiloApp

The Milo Application (MiloApp) is the program that the pet owner runs on their smartphone to interact with the Milo services monitoring their pet and the status of the collar, and file feedback reports to send back to the server.

Getting Started

The pet owner can download MiloApp from Apple's App Store or Google's Play Store. The owner can sign up for an account directly from the app and start to record their dog's seizures (see Reports) to provide baseline information before therapy begins, even without having any Milo equipment. This pre-therapy baseline is important to assess how well the therapy works once it begins.

Home Page

The home page shows the status of the collars as well as their communication status with the implant. This information is updated periodically, typically every 5 to 15 minutes. Each collar shows a wireless signal indicator and a battery level indicator. These icons change to reflect the strength of the Wi-Fi connection and the battery charge respectively. Each collar icon also has a colored dot near it, which helps differentiate one collar from another. When first unplugged from a USB connection, the status LED will briefly show that collar's uniquely assigned color, which is the same as the colored dot in the app. The lines between each collar and the implant reflect the communication status with the implant. A gray line indicates that the collar is in standby mode and is not attempting communication with the implant. A green line indicates the collar is successfully communicating with the implant. A yellow line indicates the collar has lost communication with the implant for a short time, and a red line indicates the collar has lost communication with the implant for a long time. Since only one collar can communicate with the IPG at a time, one of the lines should be gray at any given time, signifying that collar is in standby mode.

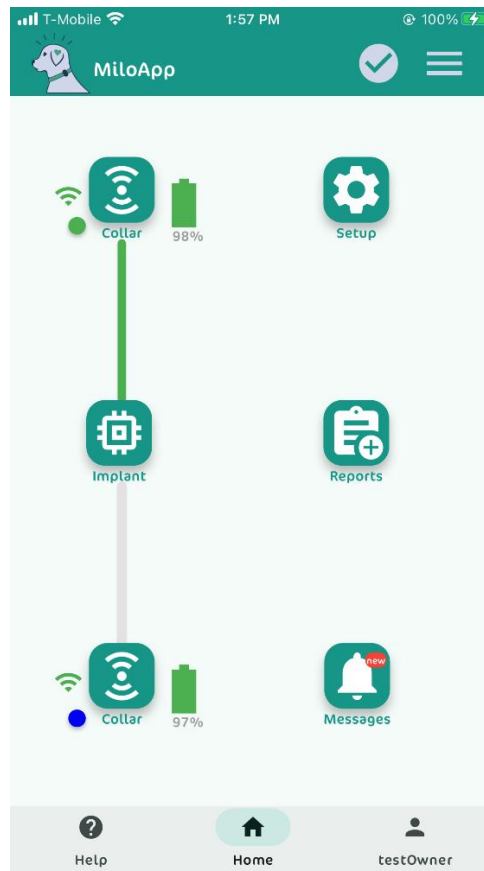


Figure 4 – MiloApp home page

Setup

The setup page is accessible from the home page and allows the user to configure the Wi-Fi network information for the collars. The collars support credentials for up to seven Wi-Fi networks: one for Auxilium, one for the veterinary clinic, and five that are configurable for the pet owner. These can be used for any location with Wi-Fi the dog may be for an extended period of time such as a vacation home, boarding location, or even roaming using a mobile hotspot. There are two ways of editing Wi-Fi information, depending on whether the collars are already connected to a Wi-Fi network or not.

If the collars are currently connected to Wi-Fi with an internet connection, Wi-Fi information can be changed by pressing the WiFi Setup button. This will display a list of the five owner-configurable Wi-Fi networks. After entering in network SSID and password, press the Update button to upload the information to the secure Auxilium server and then download the information to the collars the next time they communicate over Wi-Fi.

If the collars are not connected to Wi-Fi with an internet connection, Wi-Fi information can be transferred directly to each collar via Bluetooth. To enter Wi-Fi credentials via Bluetooth,

the mobile device running MiloApp must have Bluetooth turned on and be within range of the Smart Collars. First, enter the Wi-Fi information you wish to store on the Smart Collars as described above and press the Update button. Then press the Bluetooth button at the top of the page. For each Smart Collar in turn, follow the button press sequence shown on the screen to enable Bluetooth on the Smart Collar. Once enabled, the Milo App should display the Smart Collar device. If no connections are made within 5 minutes, the Smart Collar Bluetooth mode will time out and go back to Standby mode. Press the Connect button and on the next page, press the Send Wi-Fi information to PCM button. A dialog box will appear indicating the result of the data transfer. Repeat this process for each Smart Collar to be given the Wi-Fi information.

Reports

The Reports page is accessible from the home page and allows the user to send event reports to their veterinarian and Auxilium staff. Reports are primarily used to log seizure events, but can also be used log any other events the user feels are significant. Reports are presented to the veterinarian and Auxilium staff, and stored in the Auxilium database for analysis. When entering the Reports page, the current date and time are chosen by default, but these can be changed if entering a report that occurred at a previous time. If reporting a seizure, choose Focal or Generalized, and optionally enter any other desired information. If reporting any other event, choose None and enter the event-related information. Press Send when finished to upload the report.

The Reports page also manages surveys. Survey requests appear periodically to help track therapy progress and gather efficacy data. When a new survey is available, text will indicate this at the bottom of the page near the survey buttons. Press the Take Survey button to take the survey.

Messages

The messages page is accessible from the home page, and allow the user to view a list of past events related to the Milo therapy. The types of events listed can include plugging the collar into the charger, implant connection events, Wi-Fi signal strength updates, and support tickets.

Help

The help page is accessible at the bottom panel from any page in the app. This page has several buttons which help you with using the Milo system.

The Support button opens a page that allows you to create and submit a ticket. This is a way to communicate with Auxilium staff to get help with an issue or to notify them of some information.

The LED code button shows a table listing the various information communicated by the status LED on the collar in the form of blink codes.

The Training button will display some training videos on various aspects of using the Milo system.

The Touchpad button shows a table listing the different button press sequences for the collar, and the resulting action of these sequences.

Profile

The profile page is accessible at the bottom panel from any page in the app. This page provides buttons at the top which allow you to edit your profile information, reset your password, or deactivate your account. It is strongly recommended that you do not deactivate your account without first discussing with Auxilium staff.

Regulatory Information

FCC Compliance Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION: The grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment has been tested and meets applicable limits for radio frequency (RF) exposure. This device was tested simulation typical 0mm to body.

Supplier's Declaration of Conformity

47 CFR § 2.1077 Compliance Information

Product Name: Milo Smart Collar

Product Model: 113305

Manufacturer:

Auxilium MD, Inc.

1301 N Plano Rd

Richardson, Texas 75081

info@auxiliummd.com

www.auxiliummd.com

Modular Components Used:

NAME: 2.4GHz Wi-Fi & BT IoT Module

MODEL: ESP32-S3-MINI-1

FCC ID: 2AC7Z-ESPS3MINI1

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.