



ILR ECG Analyzer

Instructions for use

Document Reference	Date
IFU2-IM007-INSTRUCTIONS FOR USE	2021-12-02

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1 Introduction

This document describes the intended use and operation of the device ILR ECG Analyzer when it is used with a compatible Remote Monitoring Platform.

Device name	ILR ECG ANALYZER version 1.1.2
Manufacturer	IMPLICITY USA 185 Alewife Brook Parkway Suite 210, Cambridge, MA 02138 (USA) Europe 29 RUE DU LOUVRE 75002 Paris (FRANCE)
Contact information and technical support	support@implicity.com phone USA: (+1) 929 350 7056 (9a.m to 6p.m EST) Europe: +33 (0) 9 61 67 41 14 (9a.m to 6p.m CET)
First CE mark	July 2020 

***Carefully read all instructions prior to use.
Observe all warnings and precautions noted throughout these instructions.
Failure to do so may result in complications in use of this product.***

2 ILR ECG ANALYZER device information

2.1 Device description

ILR ECG ANALYZER is a software medical device for the analysis of ECG signals from Insertable Cardiac Monitor (ICM) devices and confirms the presence or absence of arrhythmias.

When it is interfaced with the compatible Remote Monitoring Platform, ILR ECG ANALYZER provides additional data to healthcare professionals to support the analysis of abnormal episodes detected by ICM devices.

As with ICM data, information about the cardiac rhythm may help to identify if patient symptoms are related to arrhythmias, or to detect asymptomatic arrhythmias. Continuous and long-term cardiac monitoring may help to make informed decisions about the patient's need for medication, cardioversion, or other rate or rhythm control therapy.

ILR ECG ANALYZER receives as input an ECG data signal via the remote monitoring platform, then processes the signal with a proprietary algorithm designed to detect arrhythmias and generates as output the result of the analysis to the remote monitoring platform. The output label from ILR ECG ANALYZER is combined with the original ICM data including the ECG, and the ICM interpretation of the signal. ILR ECG ANALYZER is designed to improve both sensitivity and specificity in the interpretation of device-detected ECG abnormalities. In particular, it is designed to reduce the rate of false positive (FP) events from ICM devices.

ILR ECG ANALYZER comprises:

- An algorithm (the Algorithm) that analyzes ECG files in order to detect cardiac rhythm abnormalities.
- A communication interface to external applications (compatible platforms) with the Algorithm and processing of ECG files. The Application Programming Interface (API) consists of 2 messaging queues (an input and an output).

ILR ECG ANALYZER works as follows:

- ILR ECG ANALYZER receives input data (an ECG file and device parameters) from the Remote Monitoring Platform using the input queue.
- The file is processed by the Algorithm which delineates zones with abnormal waveforms (ECG signals not defined as normal sinus rhythm). The output format is a descriptive label of the ECG episode analyzed (see Table 1 below). The output also includes start time and end time.
- ILR ECG ANALYZER sends a response to the Remote Monitoring Platform using the output queue.

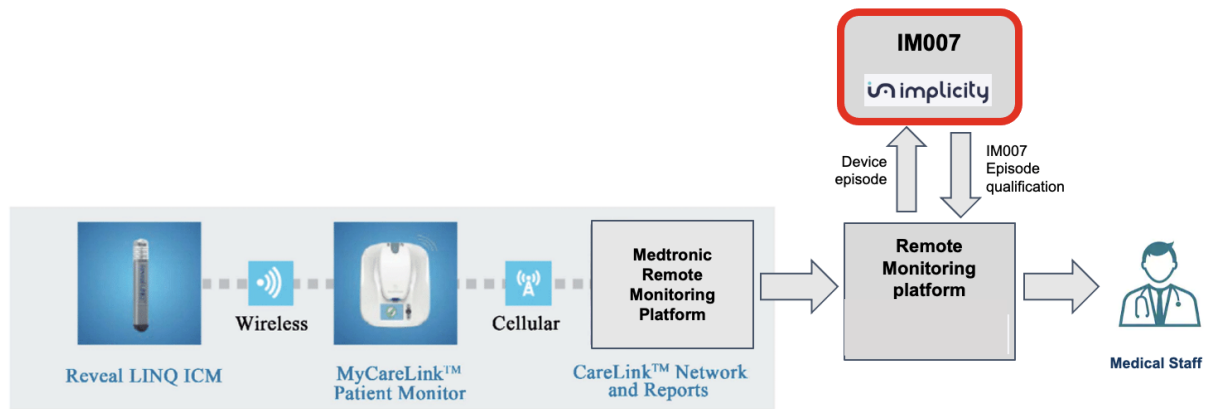


Figure 1: Diagram flow of ICM data with ILR ECG ANALYZER interface. ECG data from a Reveal LINQ ICM is processed by ILR ECG ANALYZER via the Implicit remote monitoring platform.

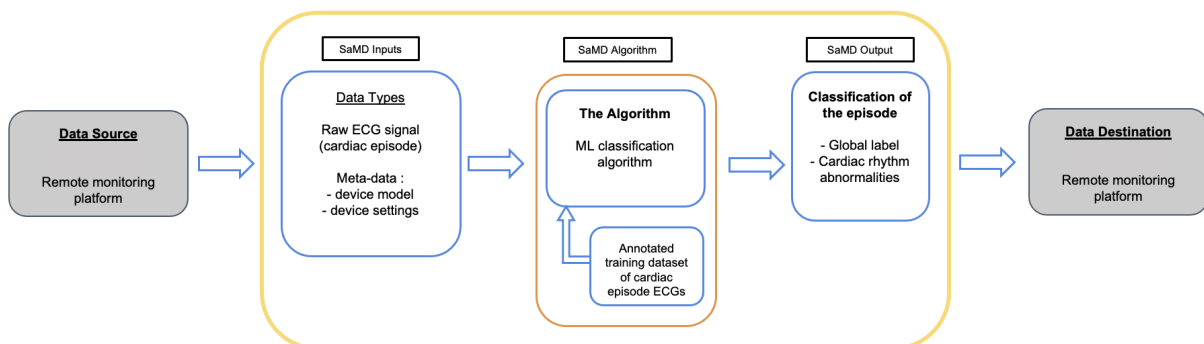


Figure 2: Schematic diagram of the ILR ECG ANALYZER device, showing the inputs and outputs.

ILR ECG ANALYZER is interfaced with the compatible remote monitoring platform from which it receives ICM data file input and to which it transmits the output.

ILR ECG ANALYZER is designed to be interfaced with a remote monitoring platform, to enable algorithmic analysis of ECGs to identify abnormalities and provide categorization of arrhythmias.

ILR ECG ANALYZER operates as an adjunct to the ICM and its own user interface. As ICM data is stored on the Medtronic Carelink platform, the ICM output data is always directly available from the Medtronic Carelink platform.

2.2 Indication for use

ILR ECG ANALYZER is intended for use by qualified healthcare professionals for the assessment of arrhythmias in Insertable Cardiac Monitor (ICM) ECG data.

ILR ECG ANALYZER supports downloading and analyzing data recorded in compatible formats from ICMs. This version of the ILR ECG ANALYZER only supports ECG data from Medtronic ICMs.

ILR ECG ANALYZER is intended to be electronically interfaced with other computer systems (remote monitoring platforms) that supply the ECG data to ILR ECG ANALYZER and receive the output of ILR ECG ANALYZER (analysis) for viewing by healthcare professionals.

ILR ECG ANALYZER provides ECG signal processing and analysis, to detect asystole, bradycardia, atrial tachycardia or atrial fibrillation, ventricular tachycardia, normal rhythm and artifacts.

ILR ECG ANALYZER is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.

IMPLICITY

ILR ECG ANALYZER interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

2.3 List of compatible ICM devices for use with ILR ECG ANALYZER

This version of ILR ECG ANALYZER is compatible with the following devices:

- Medtronic LNQT1
- Medtronic REVEAL XT 9529
- Medtronic REVEAL DX 9528

2.4 Device output labels

The output of ILR ECG ANALYZER is an electronic report containing the classification labels detected by the Algorithm in the ICM ECG episode (the input data). This report is made up of a list of defined labels, as described in the table below.

Name	Description
Normal Rhythm	The ECG does not present any significant abnormality.
Asystole	Ventricular pause. Absence of ventricular contraction for a duration equal to or greater than the asystole programmable duration.
Bradycardia	Slow ventricular rate. Lower than the programmable brady rate.
AT/AF	Atrial Tachycardia / Atrial Fibrillation At least one of the following: - Atrial tachycardia (ectopic) - Atrial flutter - Atrial fibrillation
VT	Ventricular Tachycardia (VT) At least one of the following: - Tachycardia that originates in a ventricle. Sometimes life-threatening. - Non-sustained ventricular tachycardia (NSVT)
Artifact	Uninterpretable signal. Presence of a non-cardiac noise, which distorts the signal and prevents proper medical interpretation of the specified portion.

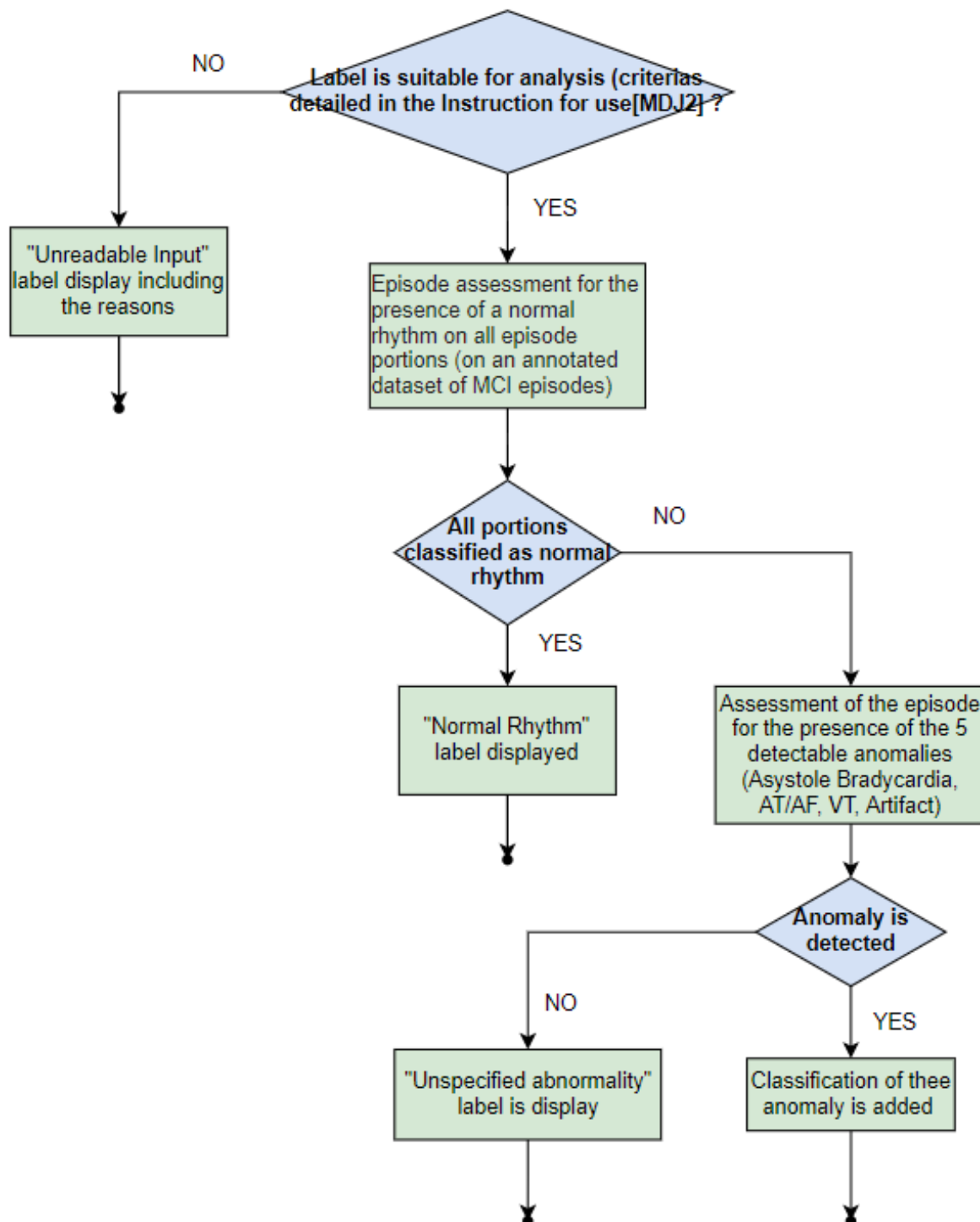
IMPLICITY

Unspecified abnormality	An abnormality is detected in the signal, but the abnormality is not classified as one of the other abnormality labels by the algorithm. This output prompts the healthcare professional to review the ECG
Unreadable input: [...]	The input has a format which is unrecognized or unanalyzable by ILR ECG ANALYZER. The reason is included in the name of the label.

Table 1: ILR ECG ANALYZER output classification labels

The arrhythmia categories output from ILR ECG ANALYZER and shown in table 1 are standard terms that are also utilized by the ICM device.

ILR ECG ANALYZER receives data for episodes identified as arrhythmias by the ICM. First, the episode data is filtered as readable or unreadable, and readable data proceeds to assessment. Next the episode is classified as normal or abnormal. Abnormal episodes are classified and labeled according to the detection criteria described in Table 2. Refer to Figure below for an overview of the process to determine the episode labels.



Detection thresholds for the identification of Asystole, Bradycardia, AT/AF, and VT have been referenced from the Medtronic LINQ Reveal Instructions for Use. See Table 2.

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ILR ECG ANALYZER output classification label	Output Label Detection Criteria	Use of Output Label in Clinical Practice
Asystole	One beat with interval between R waves greater than the programmable asystole rate*	Standard definition of asystole for ICMs. Prompts clinician to scrutinize the ECG strip, further investigate the asystole diagnosis and initiate proper therapeutic measures.
Bradycardia	4 consecutive beats with interval between R waves greater than the programmable brady rate*	Standard definition of bradycardia for ICMs. Prompts clinician to scrutinize the ECG strip, further investigate the bradycardia diagnosis and initiate proper therapeutic measures.
AT/AF	Signal classified by the algorithm as at least one of the following: - Atrial tachycardia (ectopic) - Atrial flutter - Atrial fibrillation	Standard definition of AT/AF. Prompts clinician to scrutinize the ECG strip, further investigate the AT/AF diagnosis and initiate proper therapeutic measures.
VT	16 consecutive premature ventricular contractions with interval between R waves lesser than the programmable tachy rate*	Standard definition of VT. Prompts clinician to scrutinize the ECG strip, further investigate the ventricular tachycardia diagnosis and initiate proper therapeutic measures.
Unspecified abnormality	An abnormality is detected in the signal, but the abnormality is not classified as one of the other abnormality labels by the algorithm.	Prompts clinician to scrutinize the ECG strip, further investigate the episode in search for a diagnosis, considering the worst-case scenario, and initiate proper therapeutic measures.
Artifact	Presence of a non-cardiac noise, which distorts the signal and prevents proper algorithmic interpretation.	Prompts clinician to scrutinize the ECG strip and determine whether an underlying rhythm can be determined. Intervention to reduce the source of noise may be possible.
Normal Rhythm	Signal classified by the algorithm as not presenting any significant abnormality.	Prompts clinician to confirm if this event is a false positive from the ICM, or to reannotate patient records accordingly. Note: all ECGs reviewed by ILR ECG ANALYZER are abnormalities detected by ICMs.

Table 2: ILR ECG ANALYZER output detection and clinical use

*Each programmable rate refers to a programmable ICM setting. The rate used by ILR ECG ANALYZER for a given episode is the rate used by the ICM device and transmitted to the remote monitoring platform on which ILR ECG ANALYZER is installed. The modification of

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these programmable rates by the user requires the modification of these programmable rates on the ICM device itself.

ILR ECG ANALYZER does not provide data on heart rate intervals or amplitudes. Internal measurements are used by the algorithm to accurately determine the signal classification, but these measures are not provided as an output to the user.

Note: The original ECG, and measurement data from the ICM device should be available to the user. This information is not modified by ILR ECG ANALYZER and is not considered as an output to ILR ECG ANALYZER. The ILR ECG ANALYZER algorithm is used as adjunct information to improve the sensitivity and specificity of the output for the benefit of the user.

2.5 PHI storage

ILR ECG ANALYZER does not store any patient health information (PHI) data permanently. ILR ECG ANALYZER is intended to be interfaced with a Remote Monitoring Platform which manages user authentication and PHI permanent data storage.

3 Directions for use

3.1 Warnings and precautions

 WARNING	In rare event that a VT episode is detected by ILR ECG ANALYZER OR by the ICM, ECG signal <u>must</u> be reviewed and scrutinized by a qualified healthcare professional for the presence of an abnormality. More generally, all episodes analyzed by ILR ECG ANALYZER should be reviewed and scrutinized by a qualified healthcare professional to confirm the diagnosis.
 WARNING	ILR ECG ANALYZER is not intended to be the sole means of diagnosis. It is offered to physicians and clinicians in an advisory capacity only in conjunction with the physician's knowledge of ECG patterns, patient history, clinical history, symptoms and other diagnostic information. Physicians should review the ECG to confirm the diagnosis before any treatment to the patient (even for normal rhythm). in case of doubt, we recommend you to seek the advice of another professional.

- ILR ECG ANALYZER is intended to be used:
 - to analyze **subcutaneous** ECG signals from ICMs
 - for patients with clinical symptoms or with high risk of cardiac arrhythmia.
 - for patients who have transitory symptom like dizziness, palpitations, syncope and chest pain
 - for patients aged eighteen and over
- ILR ECG ANALYZER is intended to be used on episodes:
 - With segments of duration between 9.5 seconds and 5 minutes
 - Which were detected as abnormality by the device, excluding patient activated episodes

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- ILR ECG ANALYZER should be used in accordance with the conditions of these instructions for use and the instructions for use of the remote monitoring platform.
- **Cybersecurity:** ILR ECG ANALYZER must be hosted in secure environment isolated from direct access from the Internet. Requirements are defined in the installation instruction “IFU1-installation instruction”.
- This manual contains screenshot examples. These screenshots are provided for reference only and are not intended to convey actual operating techniques.

Any serious incident related to the device should be reported to Implicity and to the competent authority of the Member State in which the user and/or patient is located, and/or other regulatory authorities as appropriate

3.2 Device installation

Prior to use, ILR ECG ANALYZER must be installed on a remote monitoring platform according to the *ILR ECG ANALYZER Installation Instructions*. Please refer to this document for information on requirements for Platform compatibility.

3.3 Activation / deactivation of ILR ECG ANALYZER

Once authenticated to the Platform, the user (the clinician) has to enable a setting page for its Medical Center.

The user can find information regarding ILR ECG ANALYZER (version, description), and can download the instructions for use.

The user can also decide at any time to activate or deactivate ILR ECG ANALYZER for all the compatible ICM devices associated to his or her medical center in the Platform (by selecting the check box “use the algorithm”):

- Once **“use” is checked**, ILR ECG ANALYZER is **activated** and every new episode file received from a compatible ICM associated with the medical center will **be processed by ILR ECG ANALYZER** upon receipt in the Platform.
- When **“use” is not checked**, ILR ECG ANALYZER is **deactivated** and new episode files received from ICMs associated with the medical center will **not be processed by ILR ECG ANALYZER**.

Figure 3 shows the setting page of IMPLICIT Remote Monitoring Platform used to activate/deactivate ILR ECG ANALYZER.

Dashboard
All Patients
To Do
Billing
Documents

J Cartier Clinic

Julien DURAND

Medical Center Settings

Alerts
Professionals
Reports
Default settings
Medical Devices

Medical Devices

IM007 Implantable Cardiac Monitor Analysis Solution

This algorithm is intended for use by qualified healthcare professionals for the assessment of arrhythmias in Insertable Cardiac Monitor recorder ECG data from subjects over 18 years of age.

It supports downloading and analyzing data from ICM Medtronic Reveal LINQ recorded in compatible formats.

It is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.

Its interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

For more information, refer to the [Instructions for Use](#)

☒ Use the algorithm last changed 14 Jan 2021 by Dr John Smith

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Figure 3. Setting page of IMPLICIT Remote Monitoring Platform

3.4 ILR ECG ANALYZER output displayed for each episode received

ILR ECG ANALYZER output results are displayed in the section “Arrhythmias” of the Platform.

The following screenshot is an example of how ILR ECG ANALYZER results can be displayed in the IMPLICIT Remote Monitoring Platform, next to the classification label provided by the ICM device itself.

In Figure 4, five episodes are listed from an ICM device stored in the platform. For each episode, the physician can see, side-by-side:

- the classification by the ICM device (displayed as “Device classification”)
- the classification by ILR ECG ANALYZER (displayed as “Implicit suggestion” in column “Classification”)

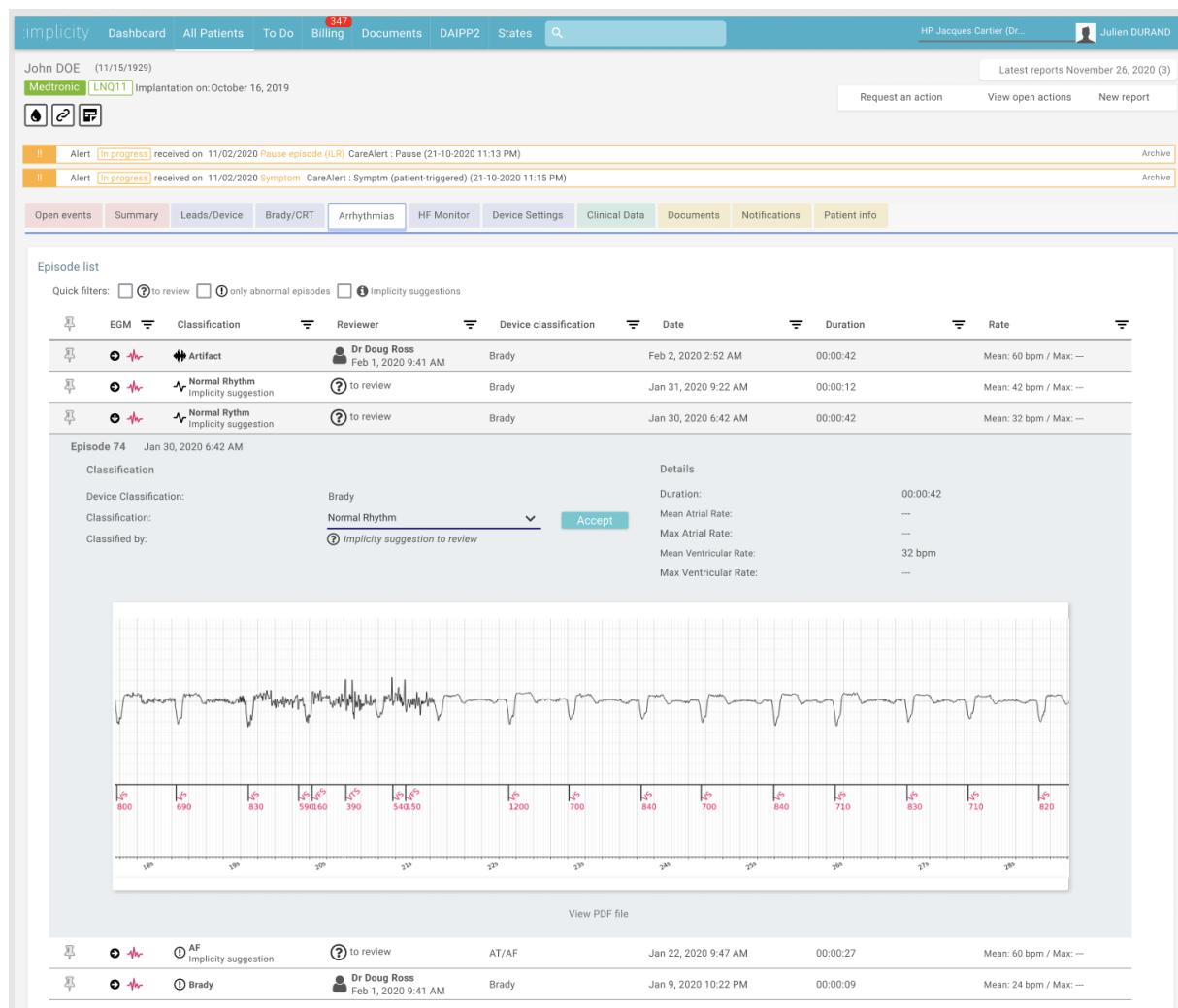


Figure 4: Screenshot example of ICM episodes displayed in the IMPLICIT Remote Monitoring Platform with additional information from ILR ECG ANALYZER (“Implicit suggestion”)

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In the example in Figure 5, we can see 2 false positive “Brady” outputs from the ICM are corrected to “Normal Rhythm” by ILR ECG ANALYZER, demonstrating how false positive arrhythmias can be reduced using ILR ECG ANALYZER.

The physician can always check the ECG strip to perform his or her own signal analysis and has the ability to register a review of the classification by selecting a new label from the list. His or her name and date is then added as “Reviewer” of the episode, next to the labels from the device (ex: “classified by Dr Doug Ross”).

Episode list

Quick filters: ☐ (?) to review ☐ only abnormal episodes ☐ Implicity suggestions

EGM	Classification	Reviewer	Device classification	Date	Duration
	Artifact	Dr Doug Ross Feb 1, 2020 9:41 AM	Brady	Feb 2, 2020 2:52 AM	00:00:42
	Normal Rhythm Implicity suggestion	(?) to review	Brady	Jan 31, 2020 9:22 AM	00:00:12
	Normal Rhythm Implicity suggestion	(?) to review	Brady	Jan 30, 2020 6:42 AM	00:00:42

Episode 74 Jan 30, 2020 6:42 AM

Classification

Device Classification: Brady

Classification: Normal Rhythm

Classified by: (?) Implicity suggestion to review

Details

Duration: 00:00:42

Mean Atrial Rate: 75 bpm

Max Atrial Rate: 100 bpm

Mean Ventricular Rate: 75 bpm

Max Ventricular Rate: 100 bpm

Accept

Figure 5: Screenshot example of ICM episodes displayed in the IMPLICIT Remote Monitoring Platform with additional information from ILR ECG ANALYZER (“Implicity suggestion”)

If the episode has not been analyzed by ILR ECG ANALYZER for some reason (ILR ECG ANALYZER not activated or error in process), the Classification row is filled with the message “(?) to review” as shown:

EGM	Classification	Reviewer	Device classification
	(?) to review	(?) to review	Asystole

4 Examples of output results from ILR ECG ANALYZER

The following examples show output results from ILR ECG ANALYZER compared to original labels from the ICM.

Example #1

EGM	Classification	Reviewer	Device classification	Date	Duration	Rate
	Asystole Implicit suggestion	to review	Asystole	Jan 30, 2020 6:42 AM	00:00:42	Mean: 61 bpm / Max: --

Episode 74 Jan 30, 2020 6:42 AM

Classification

Device Classification: Asystole

Classification: Asystole Accept

Classified by: Implicit suggestion to review

Details

Duration: 00:00:42

Mean Atrial Rate: --

Max Atrial Rate: --

Mean Ventricular Rate: 61 bpm

Max Ventricular Rate: --

View PDF file

Label by the internal algorithm of the ICM:	Asystole
Label suggested by ILR ECG ANALYZER:	Asystole

Example #2

EGM	Classification	Reviewer	Device classification	Date	Duration	Rate
	VT Implicit suggestion	to review	VT	Jan 30, 2020 6:42 AM	00:00:42	Mean: 140 bpm / Max: --

Episode 74 Jan 30, 2020 6:42 AM

Classification

Device Classification: VT

Classification: VT/AF Accept

Classified by: Implicit suggestion to review

Details

Duration: 00:00:42

Mean Atrial Rate: --

Max Atrial Rate: --

Mean Ventricular Rate: 140 bpm

Max Ventricular Rate: --

View PDF file

Label by the internal algorithm of the ICM:	VT
Label suggested by ILR ECG ANALYZER:	VT/AF

Example #3

EGM	Classification	Reviewer	Device classification	Date	Duration	Rate
	Normal Rhythm Implicitly suggestion	 to review	Asystole	Jan 30, 2020 6:42 AM	00:00:42	Mean: 57 bpm / Max: ---

Episode 74 Jan 30, 2020 6:42 AM

Classification

Device Classification: Asystole

Classification: Normal Rhythm

Classified by:  Implicitly suggestion to review

Details

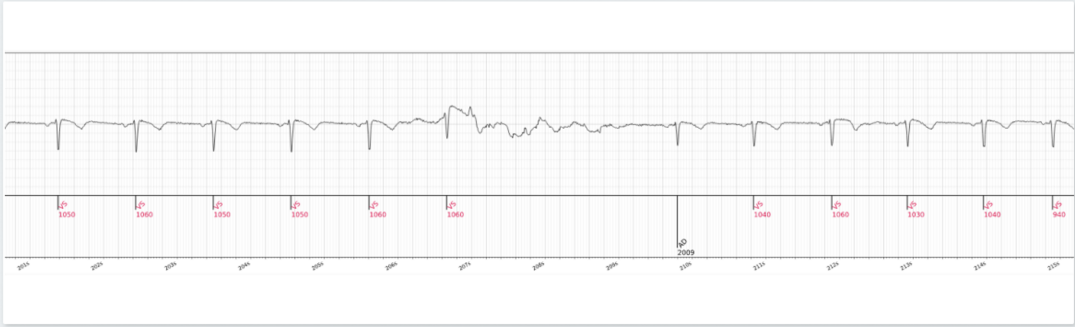
Duration: 00:00:42

Mean Atrial Rate: ---

Max Atrial Rate: ---

Mean Ventricular Rate: 57 bpm

Max Ventricular Rate: ---



View PDF file

Label by the internal algorithm of the ICM:

Asystole

Label suggested by ILR ECG ANALYZER:

Normal Rhythm

Remark: in this case, the Asystole detected by the ICM device is due to undersensing. The Normal Rhythm is still visible, and it is classified as Normal Rhythm by ILR ECG ANALYZER.

Example #4

EGM	Classification	Reviewer	Device classification	Date	Duration	Rate
 [Sans titre]	Normal Rhythm Implicitly suggestion	 to review	AT/AF	Jan 30, 2020 6:42 AM	00:00:42	Mean: 76 bpm / Max: ---

Episode 74 Jan 30, 2020 6:42 AM

Classification

Device Classification: AT/AF

Classification: Normal Rhythm

Classified by:  Implicitly suggestion to review

Details

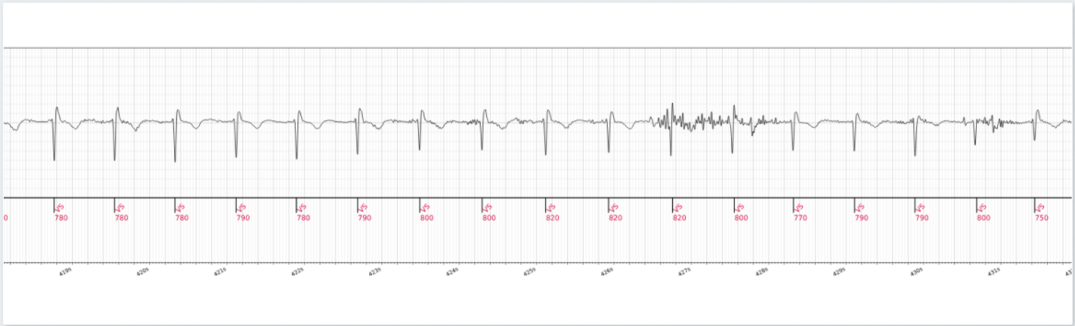
Duration: 00:00:42

Mean Atrial Rate: ---

Max Atrial Rate: ---

Mean Ventricular Rate: 76 bpm

Max Ventricular Rate: ---



View PDF file

Label by the internal algorithm of the ICM:

AT/AF

Label suggested by ILR ECG ANALYZER:

Normal Rhythm

Remark: In this case the signal is noisy but the normal rhythm is still visible, leading ILR ECG ANALYZER to classify it as "Normal Rhythm".

Example #5

EGM	Classification	Reviewer	Device classification	Date	Duration	Rate
	 Unspecified Anomaly Implicitly suggestion	 to review	Asystole	Jan 30, 2020 6:42 AM	00:00:42	Mean: 32 bpm / Max: ---

Episode 74 Jan 30, 2020 6:42 AM

Classification

Device Classification: Asystole

Classification: Other ▼

Classified by:  Implicitly suggestion to review

Details

Duration: 00:00:42

Mean Atrial Rate: ---

Max Atrial Rate: ---

Mean Ventricular Rate: 32 bpm

Max Ventricular Rate: ---



View PDF file

Label by the internal algorithm of the ICM:	Asystole
Label suggested by ILR ECG ANALYZER:	Unspecified Anomaly

Remark: In this case, a loss of signal is classified as Asystole by the ICM device, and classified as “Unspecified Anomaly” by ILR ECG ANALYZER, as it failed to identify another abnormality in the signal.

Example #6

EGM	Classification	Reviewer	Device classification	Date	Duration	Rate
	 VT Implicitly suggestion	 to review	VT	Jan 30, 2020 6:42 AM	00:00:42	Mean: 187 bpm / Max: ---

Episode 74 Jan 30, 2020 6:42 AM

Classification

Device Classification: VT

Classification: VT ▼

Classified by:  Implicitly suggestion to review

Details

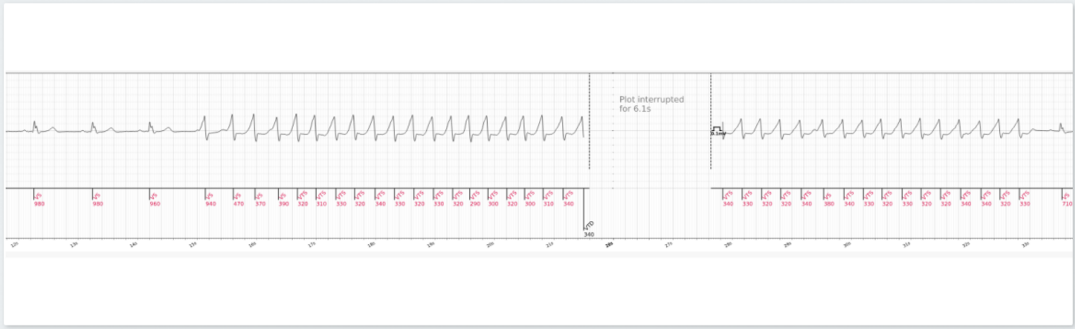
Duration: 00:00:42

Mean Atrial Rate: ---

Max Atrial Rate: ---

Mean Ventricular Rate: 187 bpm

Max Ventricular Rate: ---



View PDF file

Label by the internal algorithm of the ICM:	VT
Label suggested by ILR ECG ANALYZER:	VT

Example #7

Remark: In this case, a noisy signal is detected as VT by the ICM device. However, the artifact prevents proper medical interpretation of the ECG, leading ILCR ECG ANALYZER to classify it as "Artifact".

Example #8

The screenshot displays the ECG analysis software interface. At the top, there is a navigation bar with icons for EGM, Classification, Reviewer, Device classification, Date, Duration, and Rate. Below this, the main area shows the ECG rhythm strip with a grid. The strip is labeled 'Episode 74' and 'Jan 30, 2020 6:42 AM'. The classification is 'AT/AF'. The device classification is 'VT' with a dropdown menu showing 'VT' and 'Implicity suggestion to review'. The duration is '00:00:42'. The mean atrial rate is '107 bpm / Max: --'. The rhythm strip shows a regular rhythm with a rate of 107 bpm. The x-axis is labeled with time in seconds (3400, 3475, 3550, 3625, 3700, 3775, 3850, 3925, 4000, 4075, 4150, 4225, 4300, 4375, 4450, 4525, 4600, 4675, 4750, 4825, 4900, 4975, 5050, 5125, 5200, 5275, 5350, 5425, 5500, 5575, 5650, 5725, 5800, 5875, 5950, 6025, 6100, 6175, 6250, 6325, 6400, 6475, 6550, 6625, 6700, 6775, 6850, 6925, 7000, 7075, 7150, 7225, 7300, 7375, 7450, 7525, 7600, 7675, 7750, 7825, 7900, 7975, 8050, 8125, 8200, 8275, 8350, 8425, 8500, 8575, 8650, 8725, 8800, 8875, 8950, 9025, 9100, 9175, 9250, 9325, 9400, 9475, 9550, 9625, 9700, 9775, 9850, 9925, 10000). The y-axis is labeled with voltage in millivolts (740, 750, 760, 770, 780, 790, 800, 810, 820, 830, 840, 850, 860, 870, 880, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 990, 1000). The rhythm strip shows a regular rhythm with a rate of 107 bpm. The x-axis is labeled with time in seconds (3400, 3475, 3550, 3625, 3700, 3775, 3850, 3925, 4000, 4075, 4150, 4225, 4300, 4375, 4450, 4525, 4600, 4675, 4750, 4825, 4900, 4975, 5050, 5125, 5200, 5275, 5350, 5425, 5500, 5575, 5650, 5725, 5800, 5875, 5950, 6025, 6100, 6175, 6250, 6325, 6400, 6475, 6550, 6625, 6700, 6775, 6850, 6925, 7000, 7075, 7150, 7225, 7300, 7375, 7450, 7525, 7600, 7675, 7750, 7825, 7900, 7975, 8050, 8125, 8200, 8275, 8350, 8425, 8500, 8575, 8650, 8725, 8800, 8875, 8950, 9025, 9100, 9175, 9250, 9325, 9400, 9475, 9550, 9625, 9700, 9775, 9850, 9925, 10000). The y-axis is labeled with voltage in millivolts (740, 750, 760, 770, 780, 790, 800, 810, 820, 830, 840, 850, 860, 870, 880, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 990, 1000). The rhythm strip shows a regular rhythm with a rate of 107 bpm. The x-axis is labeled with time in seconds (3400, 3475, 3550, 3625, 3700, 3775, 3850, 3925, 4000, 4075, 4150, 4225, 4300, 4375, 4450, 4525, 4600, 4675, 4750, 4825, 4900, 4975, 5050, 5125, 5200, 5275, 5350, 5425, 5500, 5575, 5650, 5725, 5800, 5875, 5950, 6025, 6100, 6175, 6250, 6325, 6400, 6475, 6550, 6625, 6700, 6775, 6850, 6925, 7000, 7075, 7150, 7225, 7300, 7375, 7450, 7525, 7600, 7675, 7750, 7825, 7900, 7975, 8050, 8125, 8200, 8275, 8350, 8425, 8500, 8575, 8650, 8725, 8800, 8875, 8950, 9025, 9100, 9175, 9250, 9325, 9400, 9475, 9550, 9625, 9700, 9775, 9850, 9925, 10000). The y-axis is labeled with voltage in millivolts (740, 750, 760, 770, 780, 790, 800, 810, 820, 830, 840, 850, 860, 870, 880, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 990, 1000). The rhythm strip shows a regular rhythm with a rate of 107 bpm. The x-axis is labeled with time in seconds (3400, 3475, 3550, 3625, 3700, 3775, 3850, 3925, 4000, 4075, 4150, 4225, 4300, 4375, 4450, 4525, 4600, 4675, 4750, 4825, 4900, 4975, 5050, 5125, 5200, 5275, 5350, 5425, 5500, 5575, 5650, 5725, 5800, 5875, 5950, 6025, 6100, 6175, 6250, 6325, 6400, 6475, 6550, 6625, 6700, 6775, 6850, 6925, 7000, 7075, 7150, 7225, 7300, 7375, 7450, 7525, 7600, 7675, 7750, 7825, 7900, 7975, 8050, 8125, 8200, 8275, 8350, 8425, 8500, 8575, 8650, 8725, 8800, 8875, 8950, 9025, 9100, 9175, 9250, 9325, 9400, 9475, 9550, 9625, 9700, 9775, 9850, 9925, 10000). The y-axis is labeled with voltage in millivolts (740, 750, 760, 770, 780, 790, 800, 810, 820, 830, 840, 850, 860, 870, 880, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 990, 1000). The rhythm strip shows a regular rhythm with a rate of 107 bpm. The x-axis is labeled with time in seconds (3400, 3475, 3550, 3625, 3700, 3775, 3850, 3925, 4000, 4075, 4150, 4225, 4300, 4375, 4450, 4525, 4600, 4675, 4750, 4825, 4900, 4975, 5050, 5125, 5200, 5275, 5350, 5425, 5500, 5575, 5650, 5725, 5800, 5875, 5950, 6025, 6100, 6175, 6250, 6325, 6400, 6475, 6550, 6625, 6700, 6775, 6850, 6925, 7000, 7075, 7150, 7225, 7300, 7375, 7450, 7525, 7600, 7675, 7750, 7825, 7900, 7975, 8050, 8125, 8200, 8275, 8350, 8425, 8500, 8575, 8650, 8725, 8800, 8875, 8950, 9025, 9100, 9175, 9250, 9325, 9400, 9475, 9550, 9625, 9700, 9775, 9850, 9925, 10000). The y-axis is labeled with voltage in millivolts (740, 750, 760, 770, 780, 790, 800, 810, 820, 830, 840, 850, 860, 870, 880, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 990, 1000). The rhythm strip shows a regular rhythm with a rate of 107 bpm. The x-axis is labeled with time in seconds (3400, 3475, 3550, 3625, 3700, 3775, 3850, 3925, 4000, 4075, 4150, 4225, 4300, 4375, 4450, 4525, 4600, 4675, 4750, 4825, 4900, 4975, 5050, 5125, 5200, 5275, 5350, 5425, 5500, 5575, 5650, 5725, 5800, 5875, 5950, 6025, 6100, 6175, 6250, 6325, 6400, 6475, 6550, 6625, 6700, 6775, 6850, 6925, 7000, 7075, 7150, 7225, 7300, 7375, 7450, 7525,

5 Performance of ILR ECG ANALYZER

Performance of ILR ECG ANALYZER has been evaluated to establish the sensitivity of the algorithm and to determine the clinical benefit. Evaluation has been done on a dataset of 879 episodes from Medtronic ICM devices, including 635 Reveal LINQ (LNQ11) episodes, extracted from the Implicit remote monitoring platform, including about half US patients and half European patients.

A statistically significant clinical evaluation was performed to validate the ILR ECG ANALYZER algorithm, and the summary results are as follows.

These performance results (Table 3 and 4) demonstrate that ILR ECG ANALYZER meets the unmet clinical need described above, with a low false positive rate while having a very high sensitivity.

The misclassification proportion (proportion of misclassified, False Positive or False Negatives episode over the 635 LNQ11 episodes included in the study) of LNQ11 alone versus LNQ11 used with ILR ECG ANALYZER demonstrates a 26.84% absolute reduction (79.45% relative reduction) in the misclassification proportion, in favor of LNQ11 + ILR ECG ANALYZER.

- ILR ECG ANALYZER sensitivity was evaluated on the 516/879 episodes adjudicated as “Abnormality” (AT/AF, Asystole, Bradycardia, VT, Other) by the adjudication committee
- ILR ECG ANALYZER False Positive rate was evaluated on the 283/879 episodes adjudicated as “Normal Rhythm” by the adjudication committee
- The misclassification proportion was evaluated over the 635/879 LNQ11 episodes included in the primary study.

	Results	95% CI
ILR ECG ANALYZER Sensitivity	98.64 % (509/516)	[97.22%; 99.45%]
ILR ECG ANALYZER False Positive rate	24.03 % (68/283)	[19.17%; 29.44%]

Table 3: Performance summary on ICM dataset

Misclassification Proportion (n/N) LNQ11	Misclassification Proportion (n/N) LNQ11 + ILR ECG ANALYZER	Difference 95% CI	P-value
34.49% (219/635)	7.56% (48/635)	-26.84% [-30.58%; -23.52%]	P < 0.0001

Table 4: Misclassification summary on Reveal LNQ11 dataset, comparing LNQ11 alone to LNQ11 used with ILR ECG ANALYZER

6 Material Requirements

No material required.

7 Explanation of Symbols used

Symbol	Name	Description
	Manufacturer	This symbol displayed on the label is accompanied by the name, address of the manufacturer (Implicitly) and product version release date (date of manufacture).
	Catalogue Number	This symbol displayed on the label is accompanied by the manufacturer's catalogue number.
	Caution	This symbol displayed on the label is a safety symbol, indicating that there are specific warnings or precautions associated with the device which are not found on the label. These precautions/warnings are described in the Instructions for Use.
	Consult Instruction for Use	This symbol displayed on the label indicates that the Instruction for Use for the device should be consulted.
	CE mark	This symbol displayed on the label indicates that medical device has been awarded the CE mark.
RxOnly	Rx Only	This symbol displayed on the label is applicable in the United States and means: "CAUTION: Federal law restricts this device to sale by or on the order of a physician."