IM007 (v1.1.2) interfaced with the IMPLICITY Remote Monitoring Platform

Instructions for use

Document Reference	Date
IFU2-IM007-INSTRUCTIONS FOR USE	2021-08-16

Table of contents

1 Objective of this document

This document provides the instructions for use of the medical device IM007 when it is used with a compatible Remote Monitoring Platform (as “the Platform” in this document).

Prior to use, IM007 must be installed on a remote monitoring platform according to the *IM007 Installation Instructions*. Please refer to this document for information on requirements for Platform compatibility.

Device name	**IM007** version 1.1.2
Manufacturer	**IMPLICITY** **USA** 185 Alewife Brook Parkway Suite 210, Cambridge, MA 02138 (USA) **Europe** 5 rue Saint-Fiacre 75002 Paris (FRANCE)
Contact information and technical support	contact@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.

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2 IM007 device information

2.1 Device description

IM007 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 Platforms, IM007 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.

IM007 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 IM007 is combined with the original ICM data including the ECG, and the ICM interpretation of the signal. IM007 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.
IM007 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).

IM007 works as follows:

- IM007 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.
- IM007 sends a response to the Remote Monitoring Platform using the output queue.

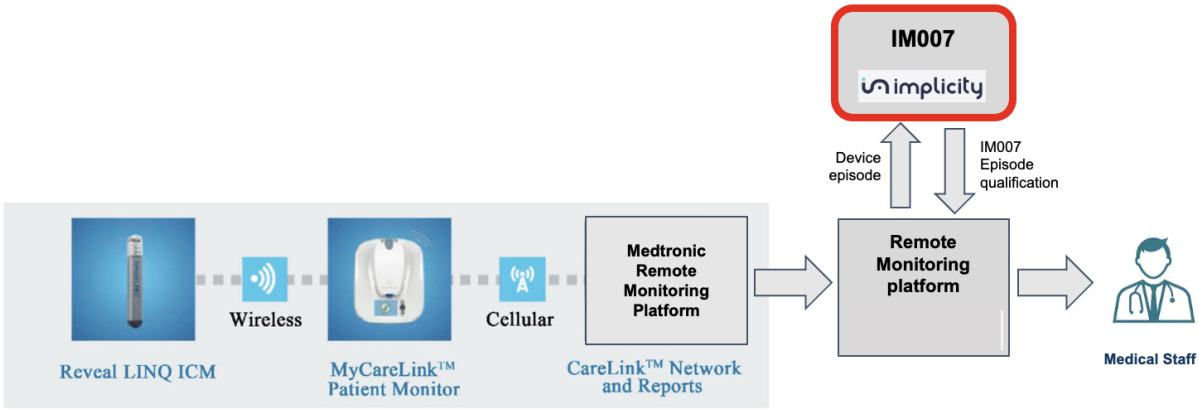


Figure 1: Diagram flow of ICM data with IM007 interface. ECG data from a Reveal LINQ ICM is processed by IM007 via the Implicity remote monitoring platform.

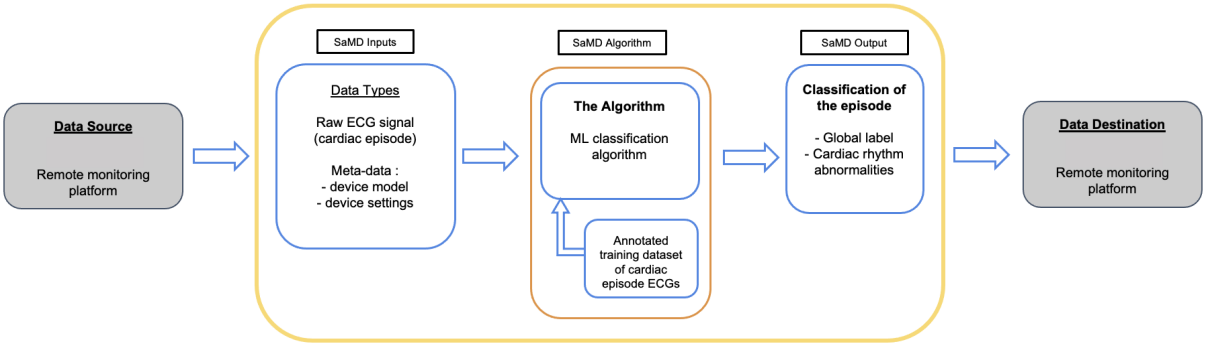


Figure 2: Schematic diagram of the IM007 device, showing the inputs and outputs.

IM007 is interfaced with the Implicity or other compatible remote monitoring platform from which it receives ICM data file input and to which it transmits the output.
IM007 is designed to be interfaced with a remote monitoring platform, to enable algorithmic analysis of ECGs to identify abnormalities and provide categorization of arrhythmias.
IM007 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 viewable from the Medtronic Carelink platform.

2.2 Indication for use

IM007 is intended for use by qualified healthcare professionals for the assessment of arrhythmias in Insertable Cardiac Monitor (ICM) ECG data.
IM007 supports downloading and analyzing data recorded in compatible formats from ICMs. This version of the IM007 only supports ECG data from Medtronic ICMs.
IM007 is intended to be electronically interfaced with other computer systems (remote monitoring platforms) that supply the ECG data to IM007 and receive the output of IM007 (analysis) for viewing by healthcare professionals.
IM007 provides ECG signal processing and analysis, to detect asystole, bradycardia, atrial tachycardia or atrial fibrillation, ventricular tachycardia, normal rhythm and artifacts.
IM007 is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.
IM007 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 IM007

This version of IM007 is compatible with the following devices:

- Medtronic LNQ11
- Medtronic REVEAL XT 9529
- Medtronic REVEAL DX 9528

2.4 Device output labels

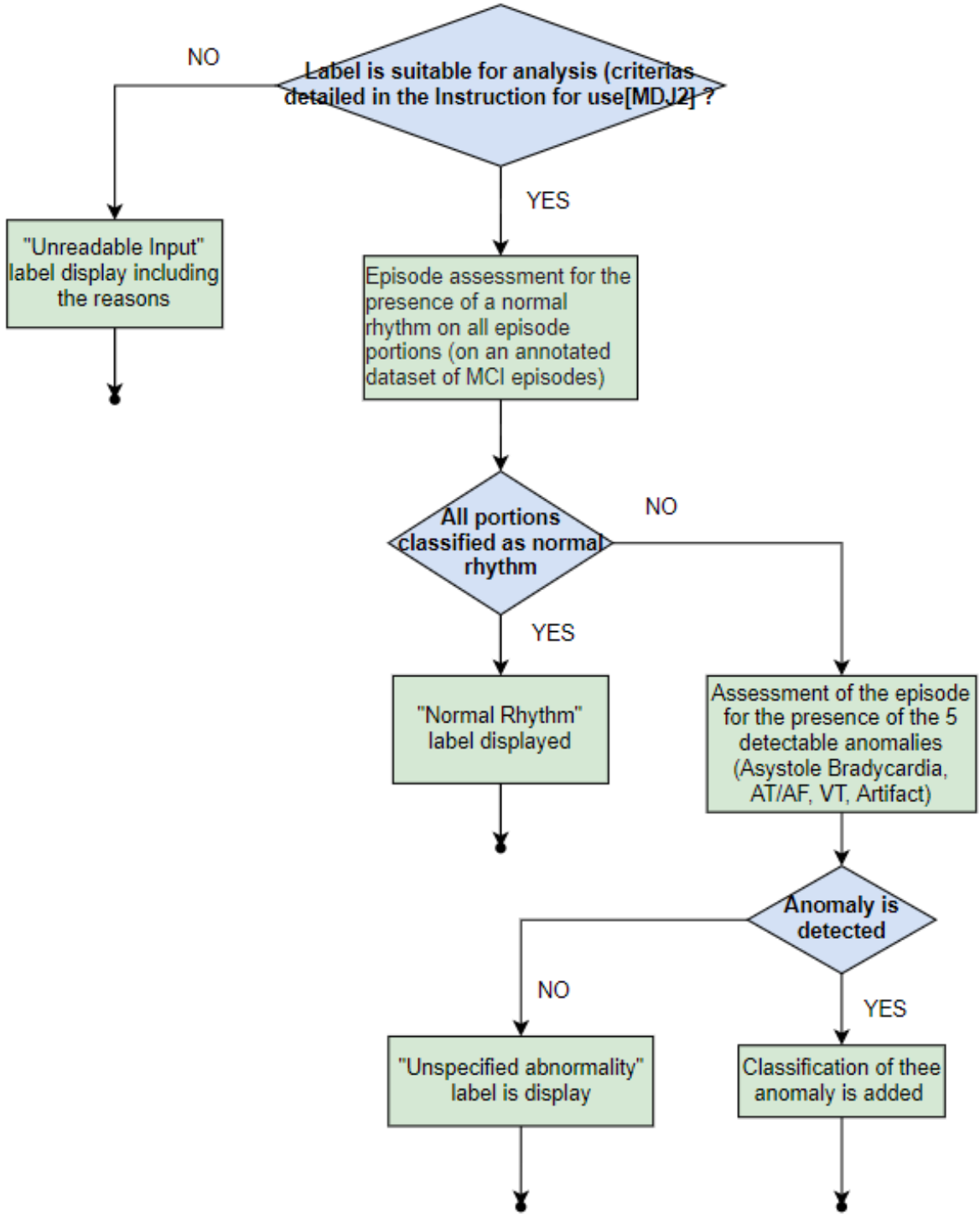
The output of IM007 is an electronic report containing the classification labels detected by the Algorithm in the ICM ECG episode (the input data). This report is made up of a list of defined labels, as described in the table below.

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.
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 IM007. The reason is included in the name of the label.

Table 1: IM007 output classification labels

The arrhythmia categories output from IM007 and shown in table 1 are standard terms that are also utilized by the ICM device.

IM007 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 X. Refer to Figure X 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 XXXXXXXXXXXX. See Table 2.

IM007	Output Label Detection Criteria	Use of Output Label

output classification label		in Clinical Practice
Asystole	One beat with interval between R waves greater than the programmable asystole rate*	Prompts clinician to further investigate asystole diagnosis and initiate proper therapeutic measures. Standard definition of asystole.
Bradycardia	4 consecutive beats with interval between R waves greater than the programmable brady rate*	Prompts clinician to further investigate bradycardia diagnosis and initiate proper therapeutic measures. Standard definition of bradycardia.
AT/AF	Signal classified by the algorithm as at least one of the following: - Atrial tachycardia (ectopic) - Atrial flutter - Atrial fibrillation	Prompts clinician to further investigate AT/AF diagnosis and initiate proper therapeutic measures. Standard definition of AT/AF.
VT	16 consecutive premature ventricular contractions with interval between R waves lesser than the programmable tachy rate*	Prompts clinician to further investigate ventricular tachycardia diagnosis and initiate proper therapeutic measures. Standard definition of VT.
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 further investigate the episode in search for a diagnosis and initiate proper therapeutic measures.
Artifact	Presence of a non-cardiac noise, which distorts the signal and prevents proper algorithmic interpretation.	Prompts clinician to review 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, and to reannotate patient records accordingly. Identify possibility of false positive arrhythmia detection from ICM devices. **Note:** all ECGs reviewed by IM007 are abnormalities detected by ICMs.

Table 2: IM007 output detection and clinical use

*Each programmable rate refers to a programmable ICM setting. The rate used by IM007 for a given episode is the rate used by the ICM device and transmitted to the remote monitoring platform on which IM007 is installed. The modification of these programmable rates by the user requires the modification of these programmable rates on the ICM device itself.

IM007 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 IM007 and is not considered as an output to IM007. The IM007 algorithm is used as adjunct information to improve the sensitivity and specificity of the output for the benefit of the user.

3 Directions for use of IM007

3.1 Warnings and precautions

- /!\ Warning : **All episodes** with an output label from IM007 **other than** **"Normal Rhythm"** should be **reviewed and scrutinized by a qualified healthcare professional** for the presence of an abnormality.

- IM007 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

  IM007 is intended to be used on signals from patients aged **eighteen and over.**

- **IM007 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).**
  We recommend you to seek the advice of another professional in case of doubt.

- This manual contains screenshot examples. These screenshots are provided for reference only and are not intended to convey actual operating techniques.

- IM007 should be used in accordance with the conditions of these instructions for use and the instructions for use of the remote monitoring platform.

- IM007 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

- Cybersecurity:
  As IM007 is a software device hosted by a Remote Monitoring Platform, cybersecurity is managed by the Remote Monitoring Platform. Users must follow the instructions for use of the Platform.

If you have any questions, please contact Implicity Customer Service :
support@implicity.fr

Any serious incident related to the device should be reported to Implicity at support@implicity.fr 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 Activation / deactivation of IM007

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 IM007 (version, description), and can download the instructions for use.

The user can also decide at any time to activate or deactivate IM007 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**, IM007 is **activated** and every new episode file received from a compatible ICM associated with the medical center will **be processed by IM007** upon receipt in the Platform.
- When **“use” is not checked**, IM007 is **deactivated** and new episode files received from ICMs associated with the medical center will **not be processed by IM007**.

Figure 3 shows the setting page of IMPLICITY Remote Monitoring Platform used to activate/deactivate IM007.

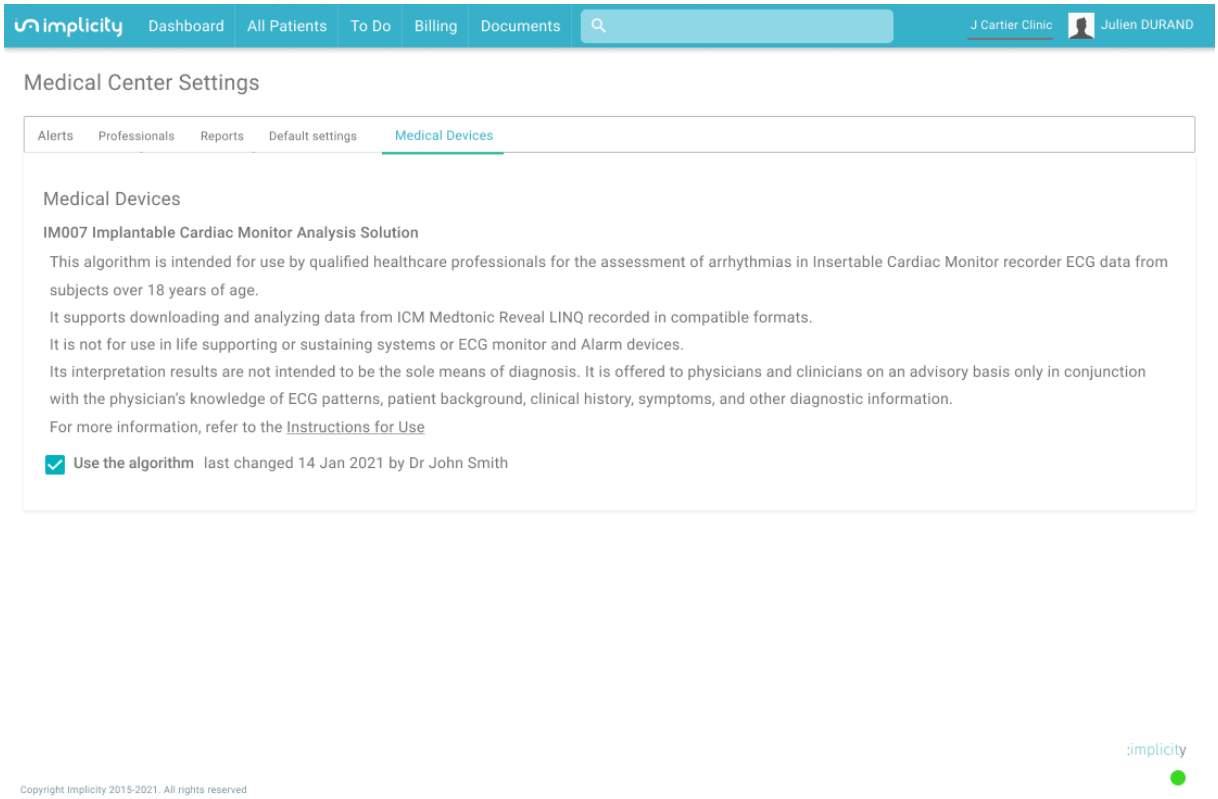


Figure 3. Setting page of IMPLICITY Remote Monitoring Platform

3.3 IM007 output displayed for each episode received

IM007 output results are displayed in the section “Arrhythmias” of the Platform.
The following screenshot is an example of how IM007 results can be displayed in the IMPLICITY 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 IM007 (displayed as “Implicity suggestion” in column “Classification”)

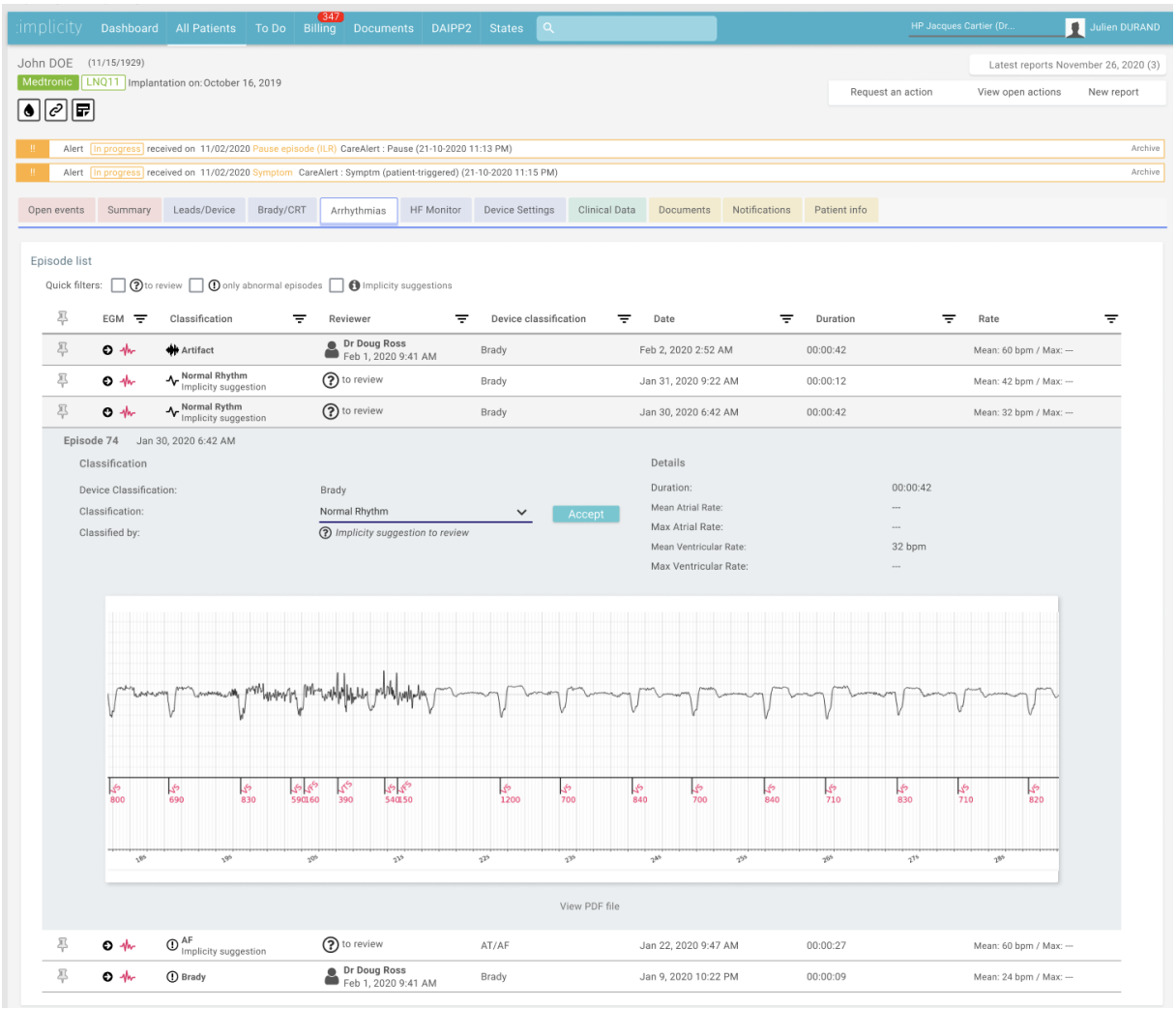


Figure 4: Screenshot example of ICM episodes displayed in the IMPLICITY Remote Monitoring Platform with additional information from IM007 (“Implicity suggestion”)

In the example in Figure 5, we can see 2 false positive “Brady” outputs from the ICM are corrected to “Normal Rhythm” by IM007, demonstrating how false positive arrhythmias can be reduced using IM007.
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 and IM007 (ex: “classified by Dr Doug Ross”).

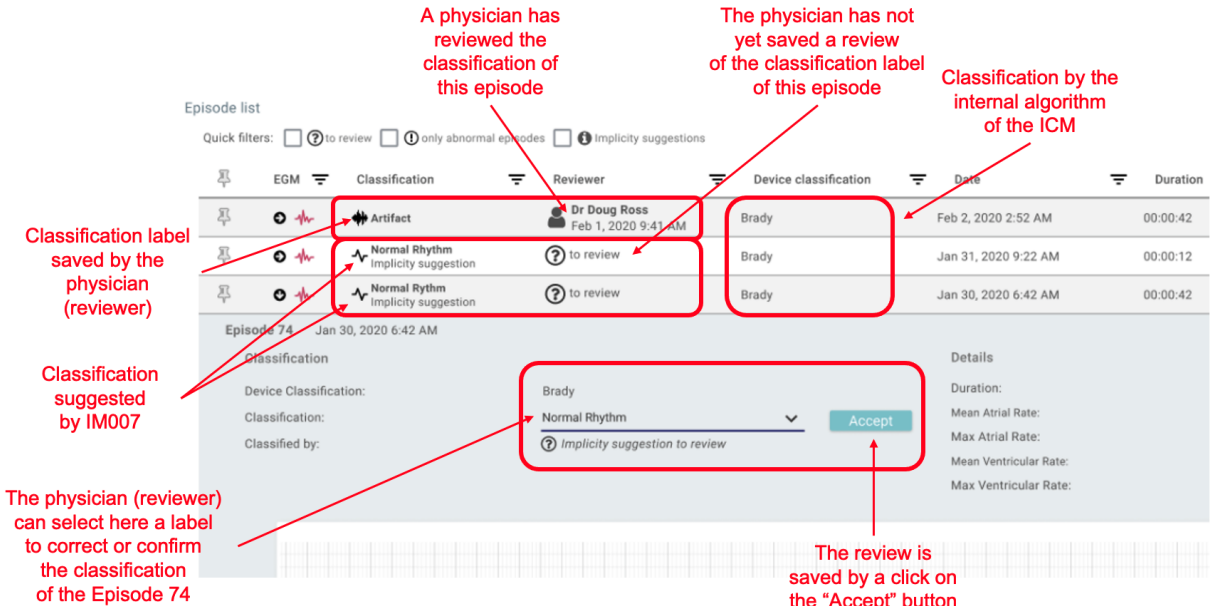
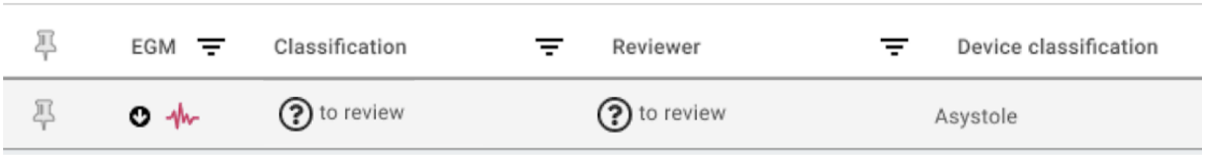


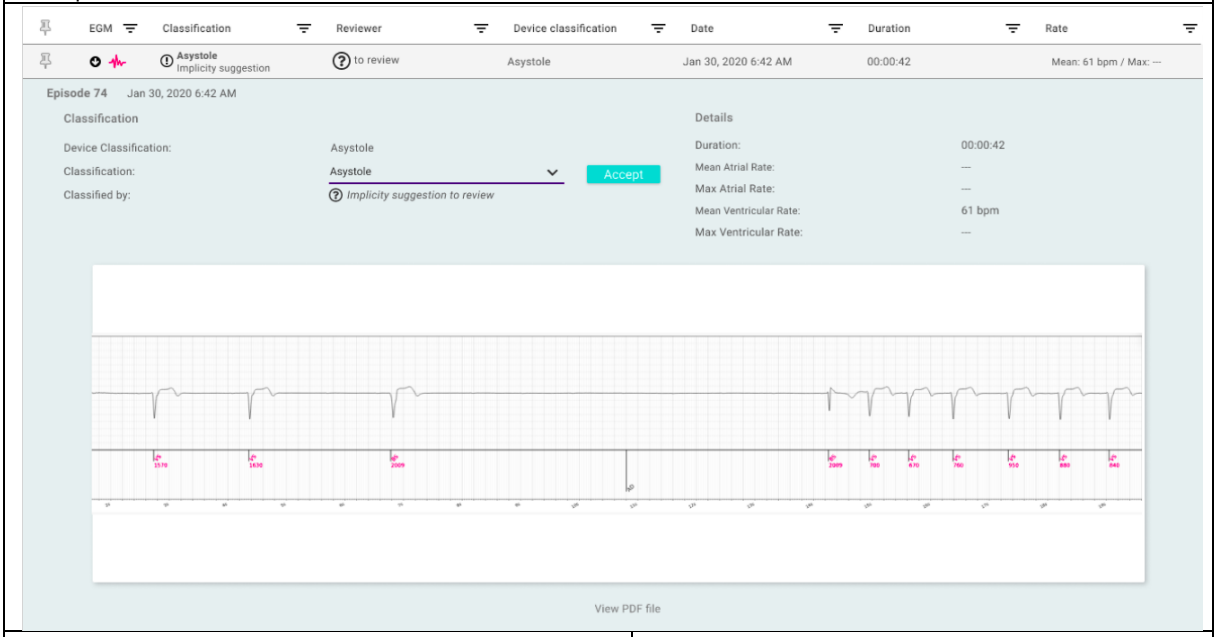
Figure 5: Screenshot example of ICM episodes displayed in the IMPLICITY Remote Monitoring Platform with additional information from IM007 (“Implicity suggestion”)

If the episode has not been analyzed by IM007 for some reason (IM007 not activated or error in process), the Classification row is filled with the message “(?) to review” as shown:



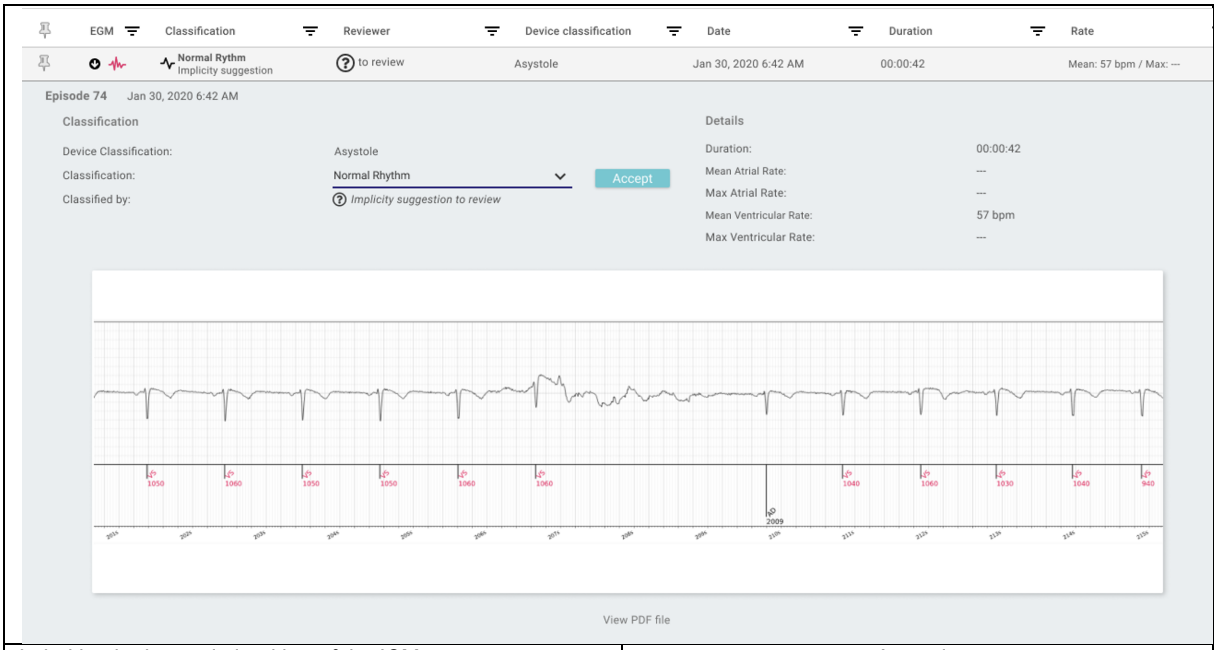
4 Examples of output results from IM007

The following examples show output results from IM007 compared to original labels from the ICM.

Example #1	
	
Label by the internal algorithm of the ICM:	Asystole
Label suggested by IM007:	Asystole

Example #2	
	
Label by the internal algorithm of the ICM:	VT
Label suggested by IM007:	AT/AF

Example #3



Label by the internal algorithm of the ICM:	Asystole
Label suggested by IM007:	Normal Rhythm

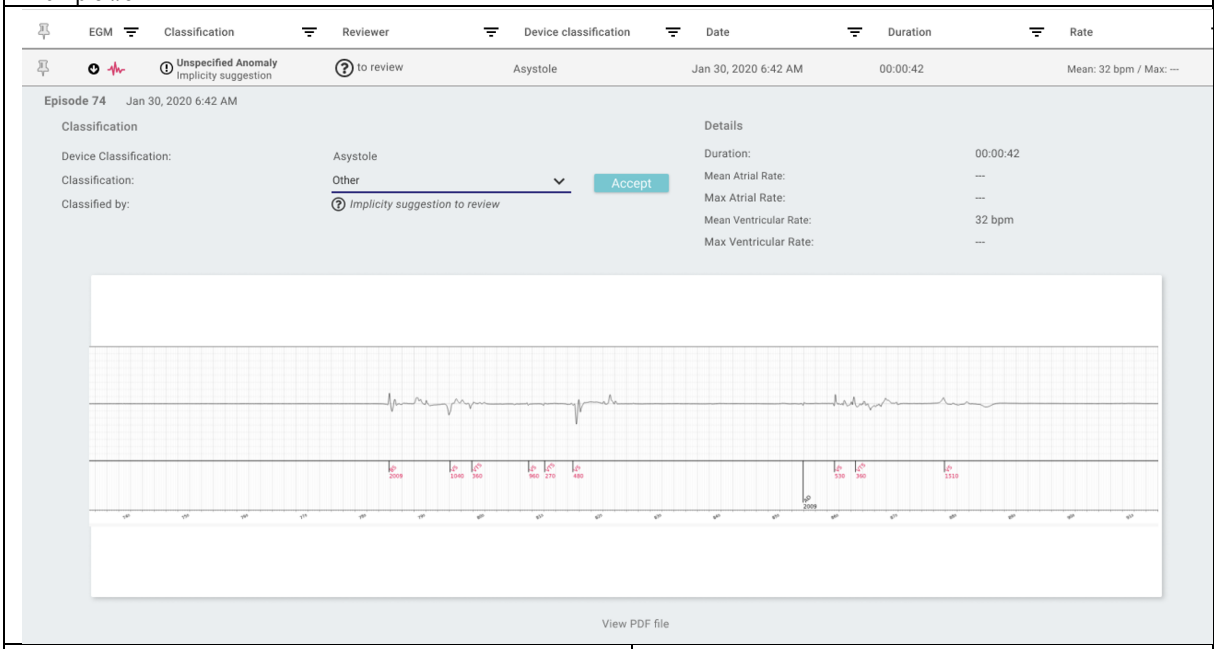
Remark: in this case, the Asystole detected by the ICM device is due to undersensing. The Normal Rhythm is still visible, and it is classified as Normal Rhythm by IM007.

Example #4

Label by the internal algorithm of the ICM:	AT/AF
Label suggested by IM007:	Normal Rhythm

Remark: In this case the signal is noisy but the normal rhythm is still visible, leading IM007 to classify it as “Normal Rhythm”.

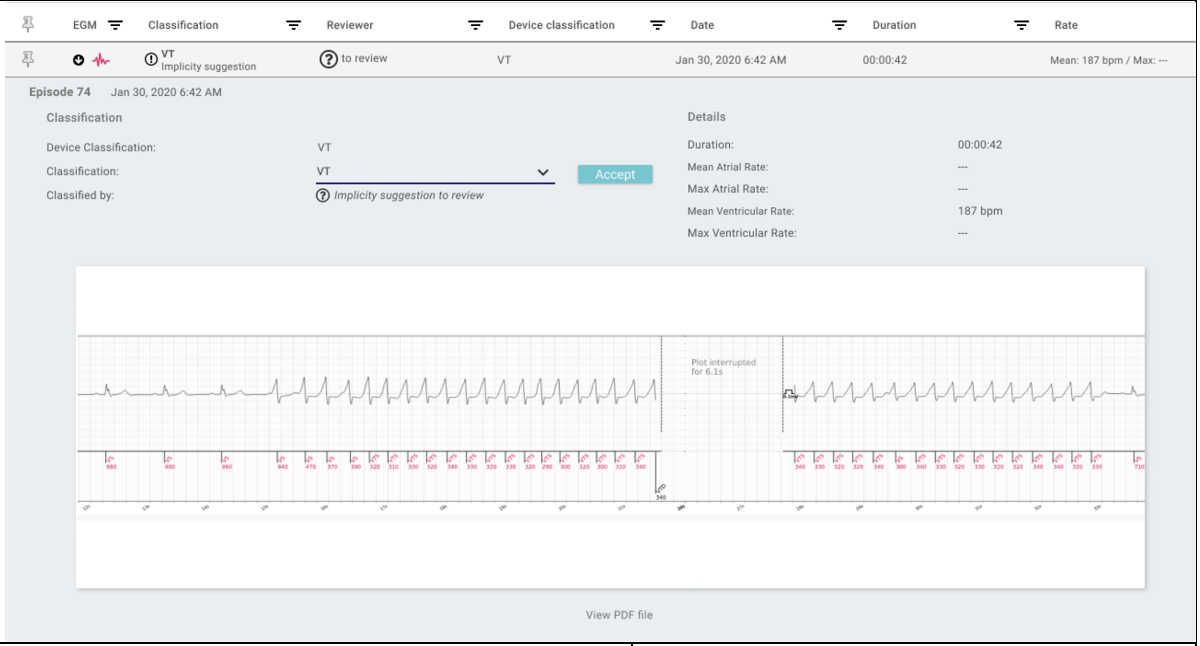
Example #5



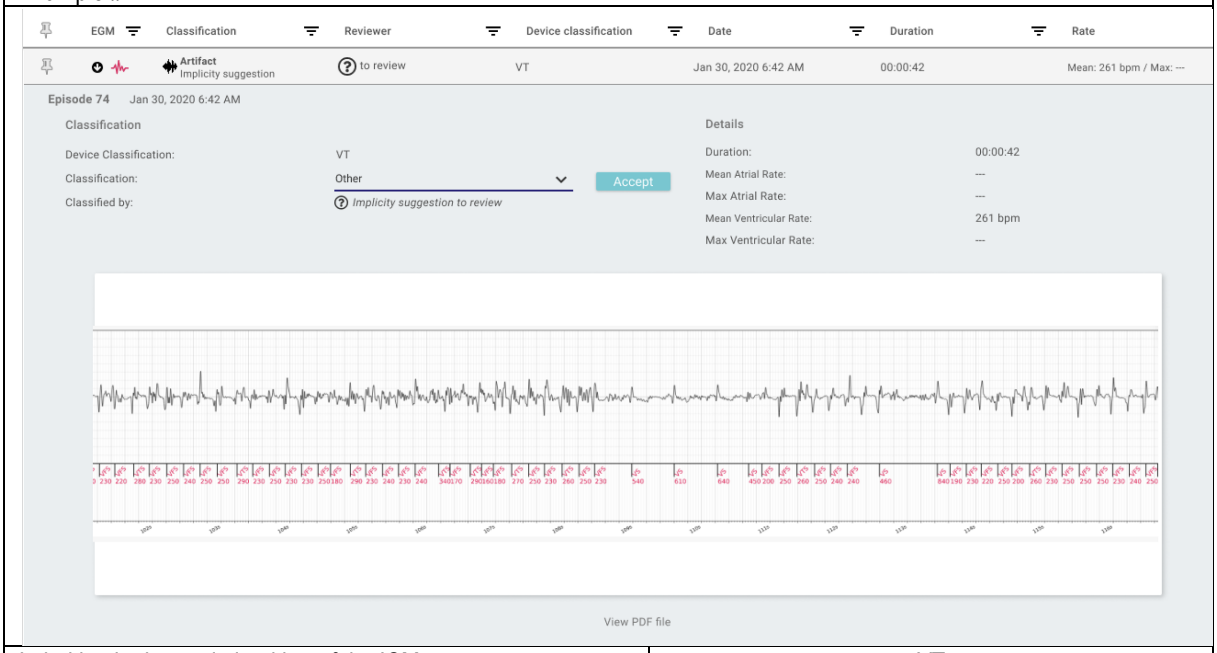
Label by the internal algorithm of the ICM:	Asystole
Label suggested by IM007:	Unspecified Anomaly

Remark: In this case, a loss of signal is classified as Asystole by the ICM device, and classified as “Unspecified Anomaly” by IM007, as it failed to identify another abnormality in the signal.

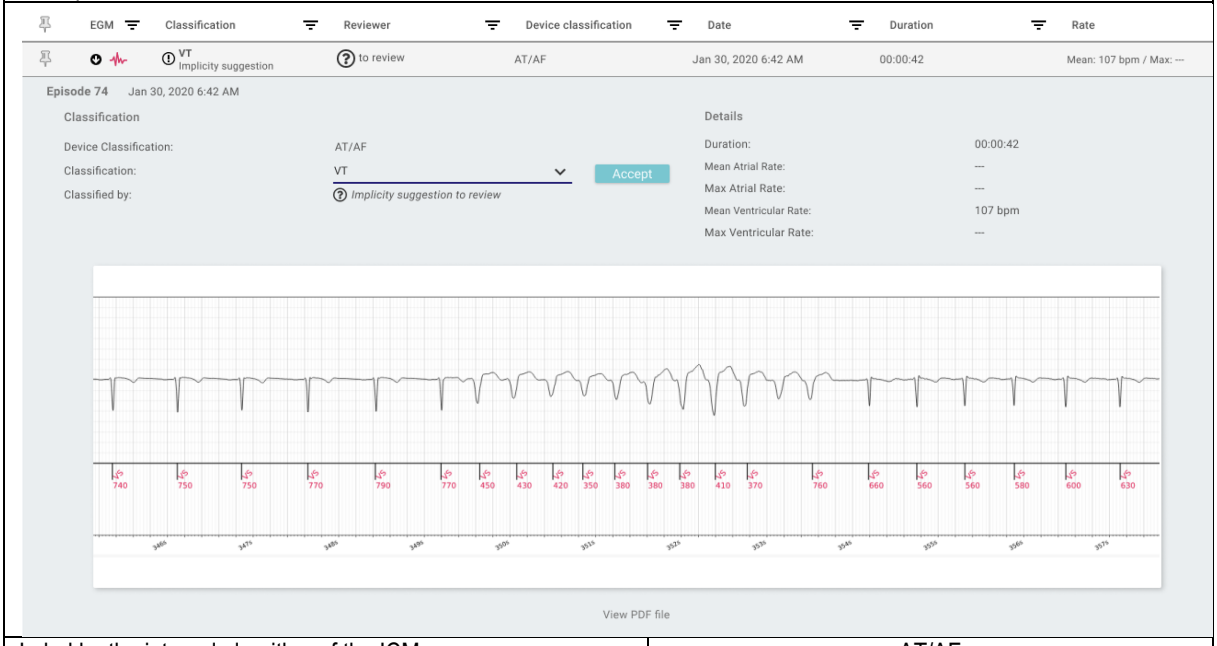
Example #6



Label by the internal algorithm of the ICM:	VT
Label suggested by IM007:	VT

Example #7	
	
Label by the internal algorithm of the ICM:	VT
Label suggested by IM007:	Artifact

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 IM007 to classify it as “Artifact”.

Example #8	
	
Label by the internal algorithm of the ICM:	AT/AF
Label suggested by IM007:	VT

5 Performance of IM007

Performance of IM007 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 Implicity remote monitoring platform, including about half US patients and half European patients.
A statistically significant clinical evaluation was performed to validate the IM007 algorithm, and the summary results are as follows.
These performance results (Table 3 and 4) demonstrate that IM007 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 IM007 demonstrates a 26.84% absolute reduction (79.45% relative reduction) in the misclassification proportion, in favor of LNQ11 + IM007.

- IM007 sensitivity was evaluated on the 516/879 episodes adjudicated as “Abnormality” (AT/AF, Asystole, Bradycardia, VT, Other) by the adjudication committee
- IM007 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**
IM007 Sensitivity	98.64 % (509/516)	[97.22%; 99.45%]
IM007 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 + IM007**	**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 IM007

6 Security

IMPLICITY maintains an ISO 27001:2013 Information Security Management System (ISMS) to ensure security is managed, monitored and continuously improved in all activities of the company. IMPLICITY ISMS has been certified by independent notified body and is evaluated regularly.

IM007 is not directly accessible from the internet. It is secured by a host infrastructure and is interfaced to a Remote Monitoring Platform which manages user authentication and PHI permanent data storage. IM007 does not store any data permanently. All data is cleared in IM007 after the output is sent.
If you suspect a cybersecurity incident or experience unexpected behavior of the system, please contact Implicity Customer Service at support@implicity.fr.

7 Material Requirements

No material required.

8 Explanation of Symbols used

Symbol	Name	Description
	Manufacturer	This symbol displayed on the label is accompanied by the name, address of the manufacturer (Implicity) 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 Stated and means: "CAUTION: Federal law restricts this device to sale by or on the order of a physician."