



IM009

Alert Management

Solution

Instruction for use

Document Reference	Date
IFU-IM009-EN-MDD	20260527

Table of content

1 Purpose of the document	5
2 Device information	5
2.1 Device description	5
2.2 Intended use	8
2.3 Indication for use	8
2.4 Intended user	9
2.5 Intended clinical benefit	9
2.6 Residual risks	9
2.7 Performance	9
2.8 Warning and precautions	10
2.8.1 Clinical warnings	10
2.8.2 Cybersecurity warnings	10
3 Device installation	10
4 Functioning	10
4.1 General description	10
4.2 Observation categorization	10
4.3 HF Observations triggering	11
4.3.1 General description	11
4.3.2 Output	11
4.3.3 Interpolation	11
4.3.4 Rule-of-Thumb (RoT) algorithm	11
4.3.5 Rolling Average Algorithm	11
4.3.6 Rolling Average Algorithm for weight loss	11
4.3.7 Preset weight thresholds	12
4.4 AF observations analysis	12
4.5 AF observations triggering	12
4.5.1 General Principles	12
4.5.2 Types of AF observations	12
4.5.3 Interpretation and use	13
4.5.4 Data availability and limitations	13
4.5.5 Comments	13
4.5.6 A delay in the smart observation trigger can occur due to the transmission frequency of the patient's CIED. This delay is capped by the CIED transmission frequency under normal conditions but can be higher if the patient is temporarily away from his transmitter.	13
5 Interpretation of the observations	14
5.1 Observation categorization	14
5.2 HF Observations triggering	14
5.3 AF observation triggering	14
6 Starting procedure	15

7 Shutdown procedure	16
8 Software deactivation	16
9 Material Requirements	16
10 Explanation of Symbols used	16

Document revisions

Version	Modifications
20210424	Document creation for the version 1.0.0 of the device
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20260527	Review for simplification

1 Purpose of the document

This document is the user manual of the following medical device:

Name of the device	Alert Management Solution
Reference	IM009
Manufacturer	IMPLICITY
Address	29 rue du Louvre 75002 Paris, France
Web site	www.implicity.com
Contact information and technical support	support@implicity.com phone Europe: +33 (0) 9 61 67 41 14 (9a.m to 6p.m CET)
First CE mark	25/05/2021
Software version	1.1.1
Basic UDI DI	3770025266IM009RP
UKRP name	Obelis UK LTD
UKRP address	Sandford Gate, East Point Business Park OX4 6LB, Oxford, UK



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 Device information

2.1 Device description

As an end objective, IM009 is designed to:

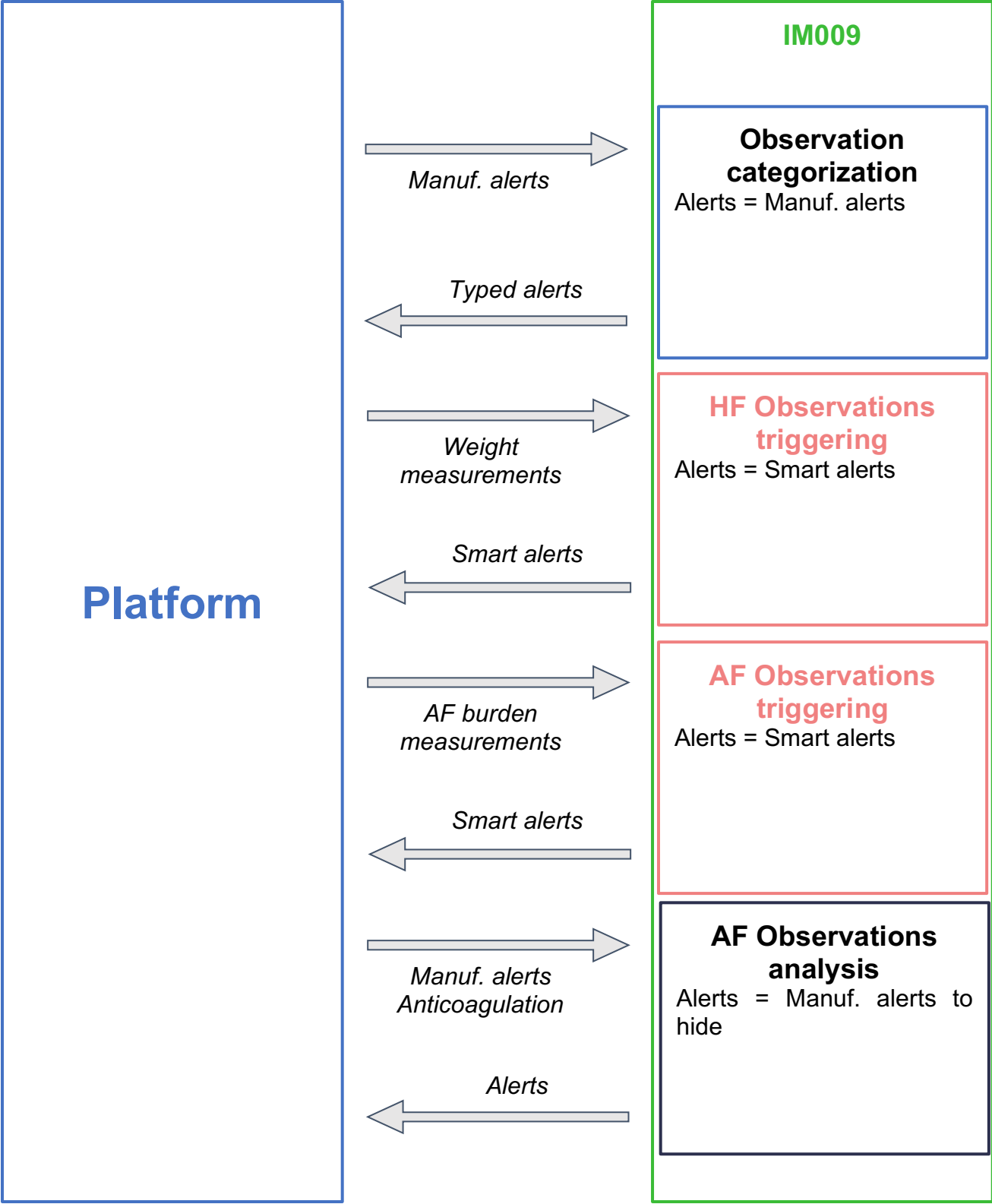
1. Categorize observations generated by devices
2. Create relevant (“smart”) observations, based on signals recorded by the devices
3. Suggest hiding observations that are not clinically relevant, based on clinical data (e.g. anticoagulants)

This would allow medical teams to be more efficient dealing with devices remote monitoring. This solution would save medical staff time and above all increase the adoption of telemonitoring by physicians. In addition, by generating more relevant observations, it may further reduce the number of visits or hospitalizations.

IM009 is designed to be integrated in a remote monitoring data platform environment such as the IMPLICIT platform.

Modules	Input	Output
Observation categorization	<ul style="list-style-type: none"> • observations text 	<ul style="list-style-type: none"> • observations type
AF Observations analysis	<ul style="list-style-type: none"> • manufacturer atrial fibrillation observations • anticoagulation periods 	<ul style="list-style-type: none"> • manufacturer observations that can be hidden
HF Observations triggering	<ul style="list-style-type: none"> • body weight measurements 	<ul style="list-style-type: none"> • heart failure-related observations, triggered by the algorithm
AF Observations triggering	<ul style="list-style-type: none"> • atrial burden daily measurements • anticoagulation periods 	<ul style="list-style-type: none"> • atrial fibrillation observations, triggered by the algorithm

Simplified architecture of IM009 modules



2.2 Intended use

IM009 is a software as a medical device (SaMD) intended to be used as an adjunct of a remote monitoring platform to follow-up target population patients.

IM009 is compatible with devices with remote monitoring feature such as:

- cardiac implantable electronic devices
- connected weight scales

The three main intents of IM009 are to:

- Label observations generated by medical devices according to predefined categories.
- Create clinically relevant observations for worsening atrial fibrillation and/or rapid weight gain in the context of heart failure, based on data recorded by the device.
- Label Atrial Fibrillation burden observations generated by cardiac implantable electronic devices (CIED) as to be hidden or relevant for health care providers based on the patient's anticoagulation status.

Hence, IM009 is designed to reduce the workload burden of healthcare providers/professionals in charge of reviewing the observations received from the patients' devices.

IM009 is not intended for use:

- in life supporting or sustaining systems or Alarm devices.
- as a solely means of diagnosis. It is offered to healthcare providers/professionals 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 Indication for use

The population of patients concerned is patients with cardiac implantable electronic devices or with risk of heart failure.

For AF Observations analysis algorithm:

IM009 has been designed to be compatible with all models of devices if they can trigger "Atrial burden above threshold" observations (which is the typical Atrial Burden observation) and potentially send daily atrial burden measurements.

IM009 is intended to be used on data from patients aged eighteen and over.

The software integrating IM009 may enable users to decide to use all or only some of the algorithms for all or part of their patients. In that case, the software must clearly indicate which algorithm will be activated and what are its expected outputs.

The user may activate or deactivate the algorithms via the integrator interface, on the Implicity platform it can be done via the page "Alert settings".

2.4 Intended user

IM009 is intended to be used by qualified healthcare professionals (HCPs) such as heart failure physicians and nurse practitioners, in charge of the remote monitoring program of patients at risk of heart failure decompensation.

2.5 Intended clinical benefit

The IM009 is used in the field of cardiac diseases such as atrial fibrillation (AF) and heart failure (HF). Both medical conditions represent a huge medico-economic burden, as these patients have associated comorbidities and general worsening of their medical status. Some of these patients are implanted with a CIED connected via a remote monitoring system to the healthcare professionals (ECP), which are able to follow the alerts generated by the CIED. This follow-up of the alerts is time consuming for the ECP, especially in the context of limited specificity of the CIED manufacturers alerts, due to the number of false positive alerts.

The intended clinical benefit is to demonstrate that the IM009 device offers a solution to improve remote monitoring alerts in patients with AF and/or HF.

2.6 Residual risks

Following the risk analysis of Alert Management Solution, there are five (5) residual risks which are acceptable under condition after mitigation.

Those risks are:

- Algorithm development error (development error/specification error)
- DDOS Cyber Attacks from external threats, or overload of RabbitMQ queues leading to false output
- Man in the middle attack leading to false output
- Defective or compromised output leading to false output
- Malware infection leading to false output

2.7 Performance

Technical performance:

- response time: less than 2 minutes
- maximum amount of Atrial Burden input values: at most 50,000 measurements
- output a text message in case of alert or error
- trigger an error if the input is incorrect

2.8 Warning and precautions

2.8.1 Clinical warnings

- Alert Management Solution should be used within the scope of its intended use described in section 2.2 of these instruction for use
- Alert Management Solution should be used in accordance with the conditions of these instructions for use and the instructions for use of the remote monitoring platform.

2.8.2 Cybersecurity warnings

- Cybersecurity: IM009 must be hosted in a secure environment isolated from direct access from the Internet. Requirements are defined in the installation instruction **IFU-IM009-Installation Instructions**.
- Risks associated with the use of IM009 include missing observation due to cyberattack issues.
- 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 is established.

3 Device installation

Prior to use, IM009 must be installed on a remote monitoring platform according to the **IFU-IM009-Installation Instructions**. Please refer to this document for information on requirements for Platform compatibility.

4 Functioning

4.1 General description

IM009 is a software device that:

- Categorizes observations generated by CIED devices
- Creates relevant (“smart”) observations, based on signals recorded by the devices
- Suggests to hide observations that are not clinically relevant, based on clinical data (anticoagulants)

4.2 Observation categorization

The algorithm processes the CIED observation text, in order to classify it. For each manufacturer, the algorithm uses a list of regular expressions-based rules to map observation text to their corresponding classification.

4.3 HF Observations triggering

4.3.1 General description

This component is made of 2 complementary and independent algorithms. The observations returned by the component are concatenation of the output of each algorithm.

Each algorithm has its own settings, which can be adapted to different medical needs and practices. The combined result of the algorithms enables to maximize the sensitivity of the component in order to avoid the medical team missing a significant weight increase.

4.3.2 Output

The component generates three types of observations:

- there has been a significant weight increase
- there has been an anomaly in the data (may be related to a device fault or to an improper use of a weightscale)
- there is not enough measurements to enable the proper functioning of the algorithm

The text of these observations is self explanatory.

4.3.3 Rule-of-Thumb (RoT) algorithm

This algorithm generates observations when the weight difference over a defined period of time crosses a defined threshold.

Two thresholds can be defined:

- An absolute threshold defined as a constant weight value (e.g. 2kg)
- A relative threshold defined as a percentage (e.g. 3%) and applied on the patient weight

4.3.4 Rolling Average Algorithm for weight gain

This algorithm generates observations about weight gain.

- It first computes the short term and long-term patient weight. Period lengths used for both calculations can be defined.
- Then generates an observation if the difference between short term and long-term patient weight crosses a defined threshold.

Like for the RoT algorithm absolute and relative thresholds can be defined.

4.3.5 Rolling Average Algorithm for weight loss

This algorithm generates observations about weight loss in the same way as the rolling average algorithm for weight gain:

- It first computes the short term and long-term patient weight. Period lengths used for both calculations can be defined.
- Then generates an observation if the difference between short term and long-term patient weight crosses a defined threshold.

4.3.6 Preset weight thresholds

This algorithm generates observations when the weight crosses a minimum or maximum threshold that was manually defined by the user.

4.4 AF observations analysis

The algorithm analyzes atrial burden information together with relevant clinical context available on the remote monitoring platform, in order to classify AF-related manufacturer observations.

Based on this analysis, the algorithm may suggest whether certain AF-related manufacturer observations should be considered relevant for review or deprioritized for notification, according to predefined and validated criteria.

All manufacturer observations remain available in the patient record regardless of their notification or prioritization status.

The algorithm does not provide a diagnosis and does not replace clinical judgment. The final interpretation of observations remains the responsibility of the qualified healthcare professional.

Warnings about anticoagulation completeness on the platform by the user:

- The anticoagulation periods taken as input by the IM009 are computed using the anticoagulant field of the remote monitoring platform. On one hand, if the field is not completed by the user, the device won't be able to classify the atrial burden observations as diagnostics to hide. On the other hand, if the user doesn't keep the field up-to-date, the device might suggest observations that shouldn't be hidden. So the user must ensure that the field is up to date.
- If IM009 is activated on the monitoring platform, as soon as the anticoagulant field is completed for a patient, every new manufacturer observation about "atrial burden above threshold" will have the priority "OFF" so they won't lead to any notification (sms, email, platform notification). But these observations will still be available in the patient's observation history.

4.5 AF observations triggering

4.5.1 General Principles

The triggering of AF-related observations is based on the longitudinal evaluation of atrial burden data transmitted by compatible devices. IM009 identifies significant changes or patterns in atrial fibrillation activity that may require the attention of healthcare professionals.

These observations are intended to:

- support the follow-up of patients with atrial fibrillation,
- reduce the cognitive load associated with the review of large volumes of device-generated data,

- improve prioritization of clinically meaningful events.

4.5.2 Types of AF observations

Depending on the observed evolution of atrial fibrillation activity, IM009 may generate different types of AF-related observations, such as:

- detection of atrial fibrillation activity in patients previously considered in sinus rhythm,
- identification of paroxysmal atrial fibrillation patterns,
- identification of persistent or evolving atrial fibrillation patterns,
- identification of a reduction or cessation of previously observed atrial fibrillation activity.

The exact conditions used to generate these observations are defined and validated within the technical documentation of the device.

4.5.3 Interpretation and use

AF-related observations generated by IM009 are intended to be used as advisory information only. They do not constitute a diagnosis and must always be interpreted in conjunction with:

- the patient's clinical history,
- other available diagnostic information,
- the healthcare professional's clinical expertise.

IM009 does not trigger therapeutic actions and does not modify device programming or patient management autonomously.

4.5.4 Data availability and limitations

The ability of IM009 to generate AF-related observations depends on the availability and regular transmission of atrial burden data from the patient's device. Temporary delays or absence of data transmission may affect the timing or generation of observations.

All manufacturer-generated observations and IM009-generated observations remain accessible within the remote monitoring platform, regardless of their notification or prioritization status.

4.5.5 Comments

About the atrial burden daily measurements:

- A minimum data quantity criterion is required for the sample duration. The algorithm will notify with a warning on output if not enough data is received. Therefore, if a patient's CIED doesn't transmit atrial burden daily measurements the algorithm won't be able to trigger the smart observations.
- A delay in the smart observation trigger can occur due to the transmission frequency of the patient's CIED. This delay is capped by the CIED transmission frequency under normal conditions but can be higher if the patient is temporarily away from his transmitter.

5 Interpretation of the observations

5.1 Observation categorization

IM009 categorizes observations received from compatible medical devices into predefined clinical and technical categories.

The text of these observations is self-explanatory.

This categorization is intended to improve readability and facilitate the review of observations by healthcare professionals.

The categorization does not alter the content of the original manufacturer observations and does not modify the medical meaning of the information provided by the device.

All categorized observations remain accessible within the patient record.

5.2 HF Observations triggering

IM009 may generate HF-related observations based on the analysis of body weight measurements provided by compatible connected weight scales. The text of these observations is self-explanatory.

HF-related observations are intended to highlight significant changes or patterns in body weight that may be relevant for the follow-up of patients at risk of heart failure decompensation.

HF-related observations may include, but are not limited to:

- detection of significant weight variations,
- identification of inconsistent or insufficient weight measurements,
- identification of data anomalies that may affect interpretation.

HF-related observations are advisory only and must be interpreted by qualified healthcare professionals within the context of the patient's overall clinical situation.

5.3 AF observation triggering

M009 may generate AF-related observations based on the analysis of atrial burden data transmitted by compatible cardiac implantable electronic devices.

AF-related observations are intended to highlight relevant changes or patterns in atrial fibrillation activity over time, in order to support the prioritization of remote monitoring data.

AF-related observations may include, but are not limited to:

- identification of atrial fibrillation activity,
- identification of sustained or evolving atrial fibrillation patterns,

- identification of a reduction or resolution of previously observed atrial fibrillation activity.

AF-related observations are provided as advisory information only. They do not constitute a diagnosis and do not trigger therapeutic actions.

All manufacturer-generated observations and IM009-generated observations remain available within the remote monitoring platform regardless of their notification or prioritization status.

Name	Description	Interpretation
First recorded AT/AF episode	Atrial burden greater than 0% for the 1st time [with or without] anticoagulant (date)	After initialization, this is the first time that an atrial burden measurement is above 0%.
Persistent AF	Atrial burden trending above [90]% during [7] days (date)	Atrial Fibrillation can be considered as persistent
Paroxysmal AF	Atrial burden trending between [5]% and [90]% for [7] days (date)	Atrial Fibrillation can be considered as paroxysmal
Increasing paroxysmal AF	Atrial burden [7] days trend increasing by [30]% (date)	Atrial Fibrillation can be considered as paroxysmal and has been increasing significantly recently
End of persistent AF: back to sinus rhythm	Atrial burden trending down below [5]% during [7] days (date)	Atrial Fibrillation is no longer observed (from Persistent)
End of persistent AF: back to paroxysmal AF	Atrial burden trending down below [90]% during [7] days (date)	Atrial Fibrillation is back to Paroxysmal (from Persistent)

6 Starting procedure

In order to start IM009, the integrator must follow the instructions of **IFU-IM009-Installation Instructions**, then connect the platform integrating IM009 making sure it sends the compatible input data to IM009 and displays the results of IM009.

7 Shutdown procedure

In order to shut down IM009, the integrator must disconnect the platform integrating IM009, making sure that it no longer filters observations or displays observations produced by IM009, and does not send it any more input data. He can then stop the IM009 service. The instructions are detailed in **IFU-IM009-Installation Instructions**

8 Software deactivation

IM009 is a software device and does not store internal medical data.

Deactivation consists of simply removing (deleting) the software from the environment of use. It can be done anytime by the administrator of the software environment using IM009, or by the Implicity customer support: support@implicity.fr.






The default lifetime of IM009 is 5 years after first deployment by Implicity and depends on medical guidelines which evolve every 5 to 10 years.




IMPLICITY will monitor new medical guidelines and if necessary, may update IM009 according to new medical guidelines, or future needs for interoperability (input/output data formats).

9 Material Requirements

The material requirements is available in the installation instruction: IFU-IM009-Installation Instruction

10 Explanation of Symbols used

Symbol	Name	Description
	Date of manufacture	Symbol indicating the "date of manufacture." The symbol shall be adjacent to the date that the product was manufactured, expressed as four digits for the year and two digits for the month and where appropriate, two digits for the day
	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).
	Medical Device	This symbol is displayed on the label to indicate that the product is a medical device.
	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.

	<p>Consult Instruction for Use</p>	<p>This symbol displayed on the label indicates that the Instruction for Use for the device should be consulted. The Instruction for use is Available online.</p>
	<p>CE mark</p>	<p>This symbol displayed on the label indicates that this medical device has been awarded the CE mark.</p>
	<p>UDI</p>	<p>This symbol displayed before the unique device identifier</p>