
	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20

Investigational Medical Device Dossier


AUTHORS

Name	Position and organisation	Responsible for the following part(s) of IMDD
Willem Baelde	Chief of Quality & Regulatory Affairs, Corsano Health	Writing of the document
Peter Stas	Chief Executive Officer, Corsano Health	Reviewing of the document

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20


Inhoudsopgave

Abbreviations	3
1. Device description and specification, including variants and accessories	4
1.1 Device description and specification	4
1.2 Reference to previous and similar generations of the device	6
2. Information to be supplied by the manufacturer	6
3. Design and manufacturing information	7
4. General safety and performance requirements	13
5. Benefit-risk analysis and risk management	16
6. Product verification and validation	16
6.1 Pre-clinical and clinical data	16
6.1.1. Physical, chemical and microbiological characterisation	16
6.1.2. Electrical safety and electromagnetic compatibility	16
Test reports of performed tests	17
6.1.3. Stability, including shelf life	19
Planning and overview of performed tests	19
Storage stability	19
Transport stability	19
In-use stability	19
Evaluation of data and test results	19
Other pre-clinical tests	19
Clinical evaluation	19
References	23
Appendix: Corsano Privacy & Security	24

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20

Abbreviations

CE	Conformité Européenne
EN	European standard
ECG	ElectroCardioGraphy
EDA	ElectroDermal Activity
GSPR	General Safety and Performance Requirement
GTIN	Global Trade Item Number
IMDD	Investigational Medical Device Dossier
ISO	International standard
MDR	Medical Devices Regulation 2017/745
MREC	Medical Research Ethics Committee
QMS	Quality Management System
SpO2	Saturation of peripheral Oxygen
SSCP	Summary of Safety and Clinical Performance
STED	Summary TEchnical Documentation
AF	Atrial Fibrillation
PPG	Photoplethysmography
GLN	Global Local Number
GTIN	Global Trade Item Number
UDI	Unique Device Identifier
UDI-DI	Unique Device Identifier – Device Identifier
UDI-PI	Unique Device Identifier – Production identifier
AI	Application Identifier

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20

1. Device description and specification, including variants and accessories

1.1 Device description and specification

A. The CORSANO CardioWatch 287-2 is a rechargeable wearable which can monitor continuous heart rhythm, activity, sleep cycles, SpO₂, ECG, EDA and temperature. The main purpose of the CardioWatch is to monitor body metrics, in patients either symptomatic or asymptomatic and aid current standard cardiology care with novel, easy accessible ways to detect arrhythmias and thereby improving healthcare by early detection. The heart rhythm is monitored through continuous signal measurement on the wrist using photoplethysmography (PPG). The device also provides an ambulatory continuous measurement of vital signs.

The device is distributed by:
CORSANO HEALTH B.V.
Isaac da Costalaan 20
1401BH Bussum
The Netherlands

CORSANO HEALTH Global Local Number (GLN) is issued by GS1. This number uniquely defines the company. It is issued by:
GS1 Nederland
Amsterdamseweg 206
1182 HL Amstelveen
The Netherlands

B. From the GLN number, GS1 provides Global Trade Item Number (GTIN), numbers to uniquely define worldwide commercial products. GS1 standard can be used to comply with the UDI system.

GTIN numbers of the CORSANO CardioWatch 287 are:

CardioWatch 287 – 2	8720256776529
---------------------	---------------


GS1 provides GTIN and AI numbers correspondence:

UDI	GS1
UDI-DI	GTIN

Each CORSANO device has a label indicating the UDI-DI (GTIN).



C. The intended patient population in the study where the CardioWatch will be used are patients >50 year. The patients have no known prior cardiac disease.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20

There are no known contra indications for patients to wear the CardioWatch. It is water resistant and still has accurate PPG signals through darker skin colours, fat tissue and tattoos.

D. The principle of operation is the following. The band includes sensors and an accelerometer. By combining these signals, vital signs are calculated and sent to the smartphone or gateway.

E. The product is intended for use to monitor vital signs and in the early diagnosis of cardiac arrhythmias in patients who could be asymptomatic and thereby preventing the consequences of undetected arrhythmias such as stroke and heart failure. Therefore, the Corsano CardioWatch is considered a medical device.

F. The device is intended for diagnosis and monitoring. According to MDR rule 10 & 11, the device is in risk class IIa.

G. Wrist wearables with PPG sensor exist on the market. The novel feature is to use the PPG signal to monitor vital signs and clinically validate it in patients

H. The device is a wearable that communicates with an application running on a smartphone or a gateway. The application will anonymously send the data to the cloud, where it will be analysed. It is not possible for the patient to see any data on the application. More information on our application and the data management is given in the appendix: Corsano Privacy & Security.

I. This is described in the document Corsano CardioWatch 287-2 BoM, see attachment.


J. The device is a wearable composed of a strap and a case. In the case is embedded the electronics part and the rechargeable battery. The inside electronics is responsible for acquiring the PPG signals and transfer them to the smartphone. The data is then analysed by the algorithms detecting the AF episodes.

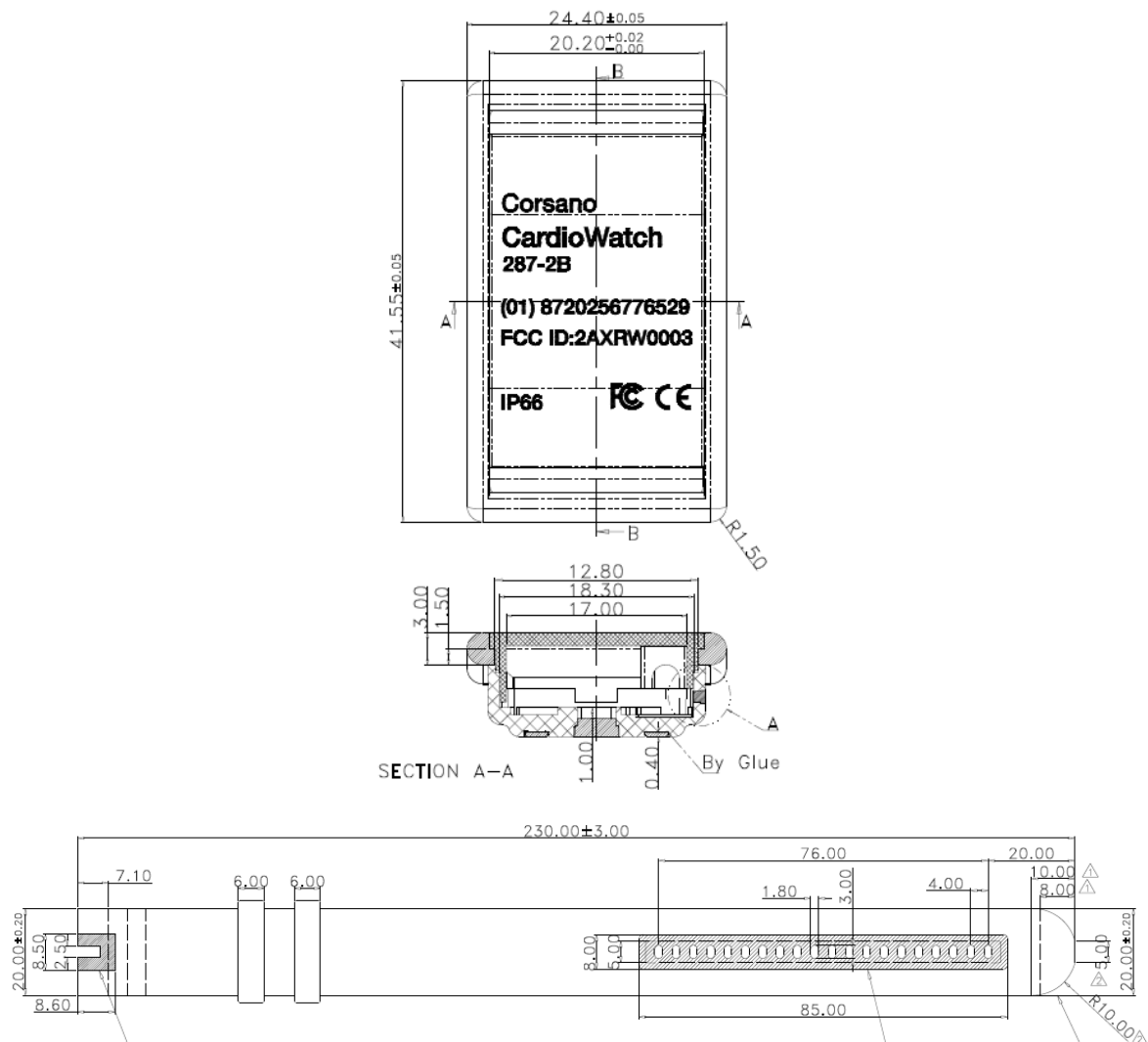


K. Description of raw materials in contact with the skin:

Part	Material	Comment
Strap	PET Polyester	RoHS/REACH declaration provided by the supplier
Case	<ul style="list-style-type: none"> - Glass Fiber - Stainless steel (contact inserts) 	RoHS/REACH declaration provided by the supplier
PPG lens	PMMA Plexiglas 8N	RoHS/REACH declaration provided by the supplier

I. External dimension of the case.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20




1.2 Reference to previous and similar generations of the device

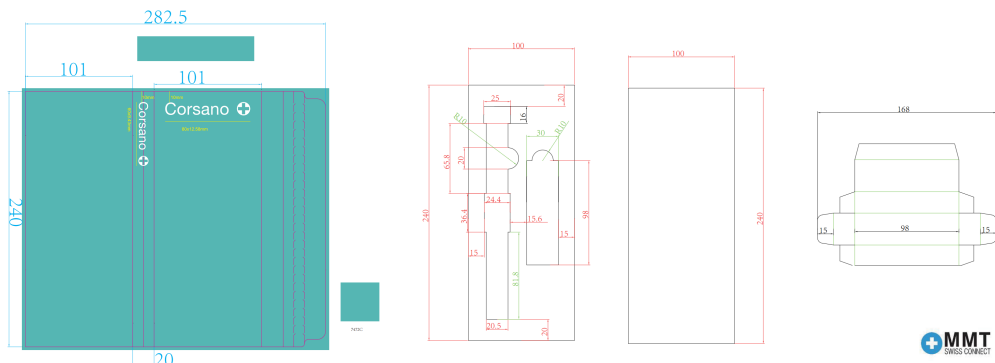
A. The CardioWatch 287-2 is a similar device as the previous generation CardioWatch 287-1, with more sesnosrs (EDD, ECG, SpO2). It uses the same software platform. The CW287-1 is CE marked, clinically validated and is under MDR certification. Numerous previous studies demonstrate that cardiac arrhythmias can be detected with wrist-based wearable using PPG signals [13].

B. Bonomi, Alberto G., et al. "Atrial Fibrillation Detection Using a Novel Cardiac Ambulatory Monitor Based on Photo-Plethysmography at the Wrist." Journal of the American Heart Association 7.15 (2018): e009351.

2. Information to be supplied by the manufacturer

A. The CORSANO CardioWatch 287 is packaged in a printed paperboard.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20



The product label indicates the manufacturer name and address, the GTIN number and date.

For the clinical investigation, a label indicating “exclusively for clinical investigations” will be stuck on the packaging.

B. The Instructions For Users (IFU) is provided to the user as a documents or online, in different languages. It is provided as a separate document in the English version for this clinical investigation. Please see the attachment for the IFU.

3. Design and manufacturing information

CORSANO HEALTH has received ISO 13485 certification. From the start of the design and development, processes have been put in place in compliance with the ISO 13485 norm. Its main supplier for hardware and software (Manufacture Modules Technologies, Switzerland) is also ISO 9001 and ISO 13485 certified and CORSANO HEALTH has put in place Quality Agreements to ensure the end product will comply with the MDR regulation.

Development Process


We describe here the development process which follows the ISO 13485 requirements. The software development complies with the medical software development requirements since it was developed in compliance with the IEC 62304 norm (Medical device software – Software life cycle processes).

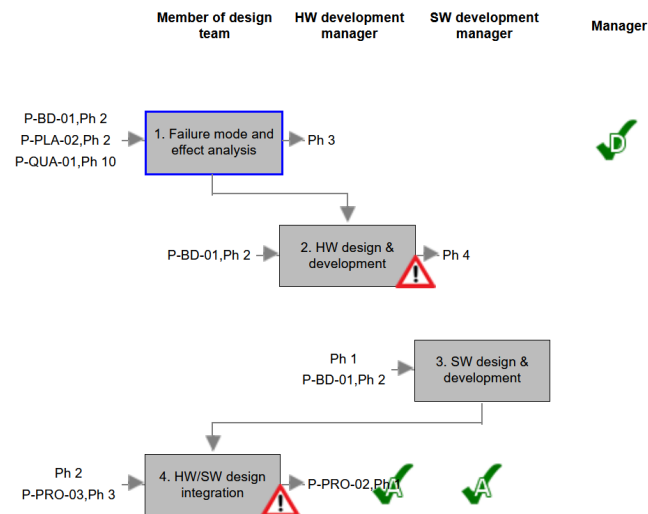
The design:

▼ P-RD-02 - Design & Development (Version 0.2 - Published 2019-12-10)

To ensure that :

- 1) failure modes in line with the expected functions or uses of the device are identified, their effects evaluated and the likely causes listed and put under control
- 2) prototypes (incl. UI/UX) are available for technical and functional testing, as well as integration in the final device
- 3) the results of the design validation are recorded for further use.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20



The design of the medical device is done under an ISO 13485 certified process, composed of different procedures. The main procedure is called “Design & Development”. An input of this procedure is the “Technical specification”, that was translated from the “Functional description”, which is written based on the requirements of the stakeholders.

The first phase consists in a failure mode and effect analysis (FMEA), then happens the hardware (HW) design and the software (SW) design. Finally, the HW/SW integration.


HW Development

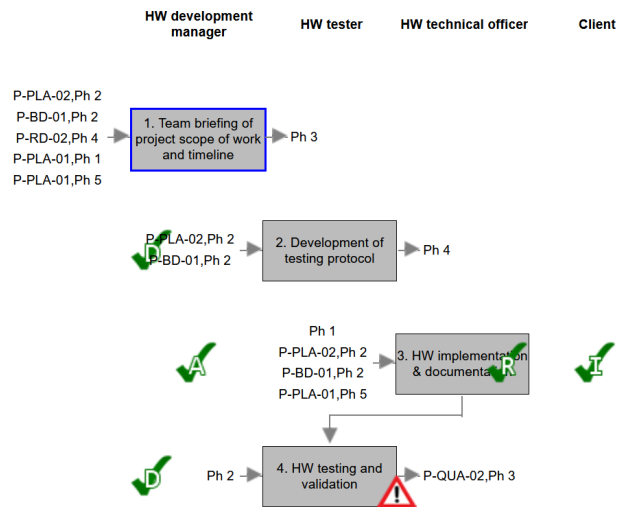
The HW development is also detailed in the “HW development” procedure. It has the “Technical specification” as an input and includes the development of the testing protocol in accordance with the objectives of the specification, the HW implementation itself and the testing/validation. The HW development also follows the Technical Compliance procedure, which ensures the developed HW complies with the regulations (EMC, RF for instance).

▼ P-PRO-02 - HW development (Version 0.2 - Published 2019-11-30)

To ensure that :

- 1) functional and technical requirements are fulfilled
- 2) the supply chain costs always fit within the project budget
- 3) outsourced components and assembled modules are conform
- 4) mass production is industrialized in conformance with the project budget and timeline as well as with the validated prototype

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20

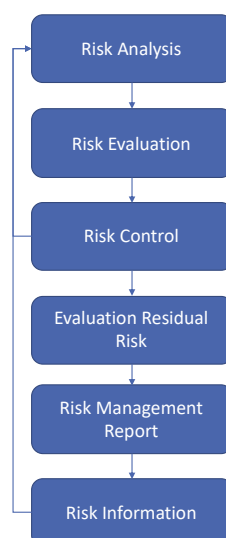


SW Development


The SW development process fully complies with the IEC 62304 standard “Medical device software – Software life cycle processes”. It is composed of 5 procedures. They are briefly described below.

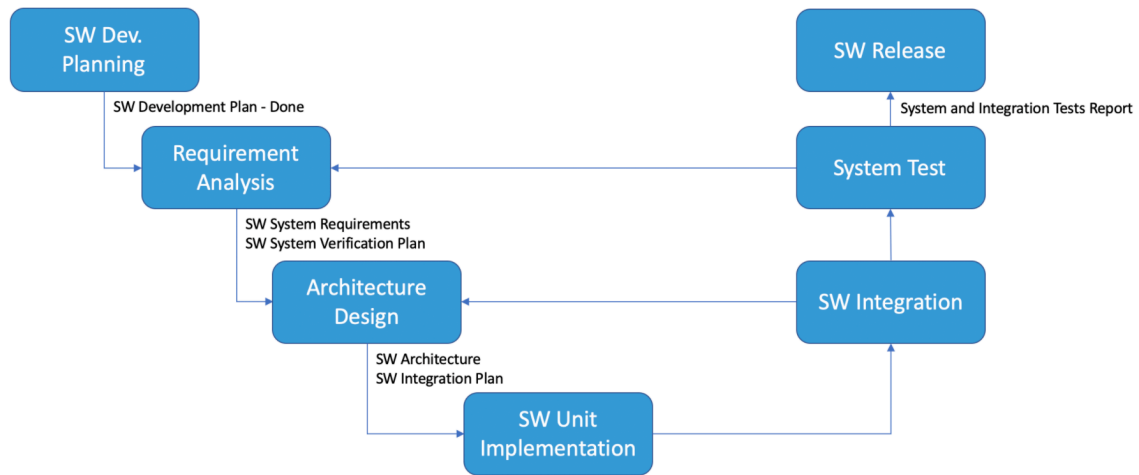


The **SW Risk Management** procedure follows the ISO 14971 standard recommendations, risks are expressed as a combination of the probability of a harm and the severity of that harm.



The **SW development** is the central procedure. It is performed in a classical V-structure as described below.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20

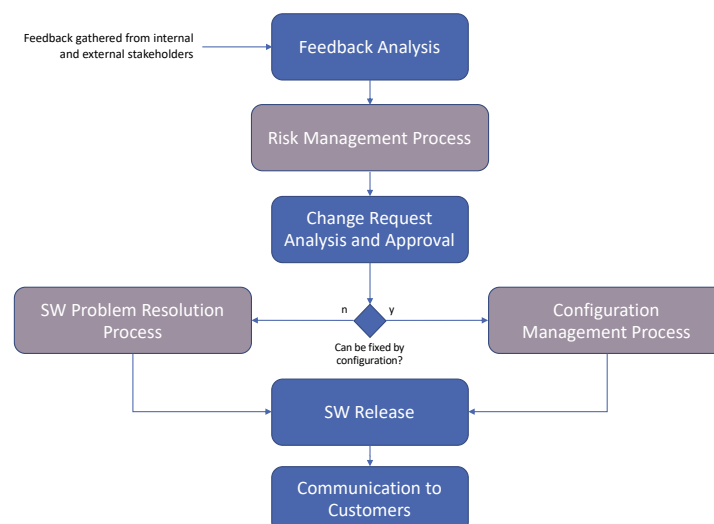



A Software Development Plan is defined in order to prepare and conduct the software development activities. The software development plan contains the following sections:

- Processes to be used
- Timelines for each deliverables and tasks to be done during the development
- Software configuration and change management, including SOUP (Software of Unknown Provenance) configuration items.
- Software problem resolution for handling problems detected in the Software Product, deliverables and activities at each stage of the life cycle.

The Corsano bracelet utilizes an accelerometer to measure acceleration, the change in velocity of the patient wearing the device. The accelerometer measures acceleration in three directions to capture the complete physical movement of the wrist of the patient. Using the accelerometer data, an AI model is build that detects if and when a fall does or does not occur. Every time a fall is detected a warning is given by the software.

Once the software is released and delivered, any change either in the release or in the configuration has to be managed according to the **SW Maintenance procedure**.

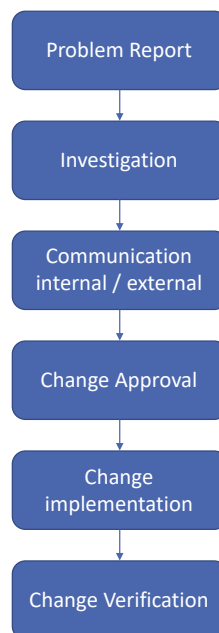


	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20

The **SW Configuration Management** procedure defines the following points:

- Configuration Identification: The items to be configured and managed have to be identified
- Change Control: Configurations have to be changed only in response to an approved change request upon feedback analysis of the SW Maintenance plan
- Configuration Status Accounting: very released build has to be stored in the versioning system

The **SW Problem Resolution** procedure is described in the following diagram.



Manufacturing Process

The Manufacturing Process is part of a certified ISO 13485 procedure "Planning & Procurement".


▼ P-PLA-01 - Planning & Procurement (Version 0.4 - Draft)

Ensure that :

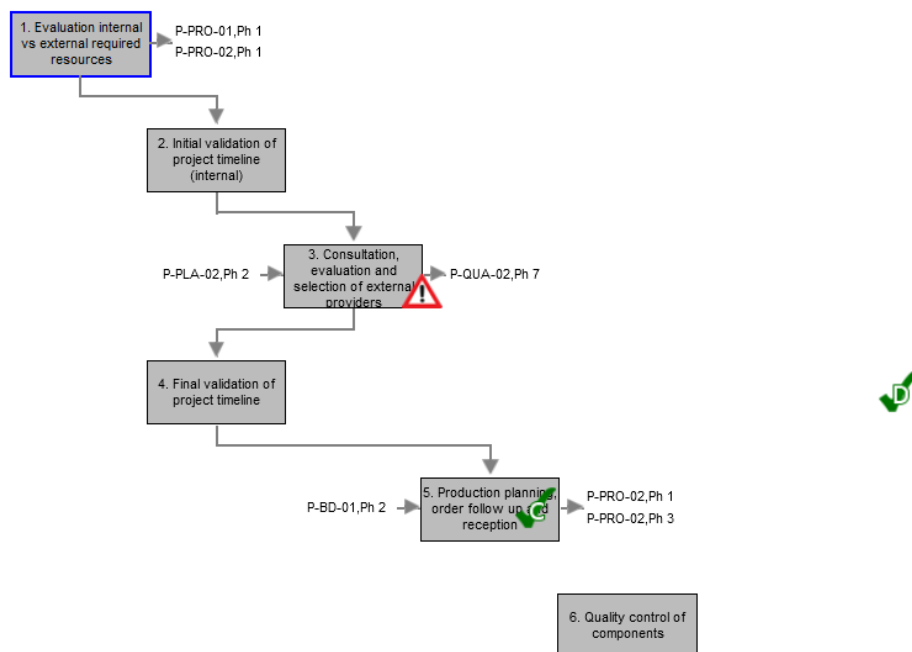
- 1) Quantities and lead times are computed
- 2) Suppliers are solicited wrt the technical specifications and are selected according to their ability to comply with them
- 3) Components are ordered and the supply process is followed up
- 4) The received components/services are controlled

First, the external providers are regularly evaluated. A production plan is set up to align the orders of the necessary parts and the deliveries.

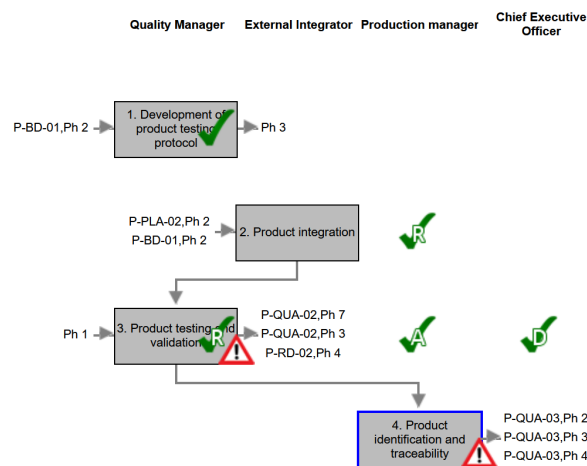
An input quality check is performed on the incoming parts, before they can be used in the manufacturing operation itself. Then, the output quality control is performed on assembled products.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287-2 20230303.docx	
	Reference: IMDD CardioWatch 287-2	Author W. Baelde Approval P. Stas Date 31-Okt-20

Member of design team Business Development Manager Procurement manager Production manager Technical Officer SW development manager Client



Traceability is applied to track the critical components and identify different production batches. It is also made sure all parts comply with the regulations in particular about RoHS and REACH directives. Certificates are requested and archived, together with the technical documentation.




The main supplier is Manufacture Modules Technologies SA
Chemin du Pre-Fleuri 5
1228 Plan-les-Ouates
Switzerland

Certified ISO 9001 :2015 and ISO 13485 :2016 by Polycert. (certificate is provided as a part of the IMDD documentation)

[illegible]

Devices incorporating materials of biological origin	Not applicable	Does not contain such substances			
Construction of devices and interaction with their environment	Applicable	EN 60601-1-2	See info for GSPR Chapter 1		
Devices with a diagnostic or measuring function	Applicable	Clinical evaluation			
Protection against radiation	Not applicable	Does not emit ionizing radiations. Non ionizing radiations are covered by ETSI EN 301 489-1			
Electronic programmable systems-devices that incorporate electronic programmable systems and software that are devices themselves	Applicable	IEC 62304 - Software Lifecycle process	MMT ISO 13485 QMS documentation		Corsano File System
Active devices and devices connected to them	Applicable	ETSI EN 301 489-1 IEC 60601-1-2	See info for GSPR Chapter 1		
Particular requirements for active implantable devices	Not applicable	Not implantable device			
Protection against mechanical and thermal risks	Applicable	IEC 60601-1	See info for GSPR Chapter 1		
Protection against the risks posed to the patient or user by devices supplying energy or substances	Not applicable	Does not supply energy or substances			
Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons	Not applicable	Not in intended use			
Chapter 3: Requirements regarding the information supplied with the device					
Label and instruction for use	Applicable	UDI identification	Corsano CardioWatch 287 IFU V2	30/07/2020	Corsano File System

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

5. Benefit-risk analysis and risk management

The CORSANO CardioWatch was developed under ISO 13485 compliant procedures and the main supplier, MMT as well. A Risk Analysis has therefore been used, using ISO14971 standard.

The risk analysis is described in the document: REC-73-2 Risk Management File CardioWatch 287.

The CORSANO CardioWatch is a wearable and has no particular medical risks. The main risk is the are a risk on the privacy and security of the data and a risk of mis-diagnostics.

The risk on the data is covered and reduced to minimum by the use of data management best practices and cyber-security process. This is covered by the ISO62304 standard that was applied for the SW development of the device.

The risk of mis-diagnostics is reduced to minimum by implementing a signal quality measurement and rejecting the low-quality samples for analysis.

Finally, the benefit-risk ratio is obviously very high. Indeed, the CORSANO CardioWatch does not represent any particular known risk. At the same time, the benefit is very high on multiple cardio vascular deceases, incl. arrhythmias. Since studies estimate that 7.6 million people over 65 in the EU had atrial fibrillation in 2016, which leads to a high risk of stroke. [14] Thus, wearing the CORSANO CardioWatch with continuous monitoring of cardiac disorder can potentially reduce the risk of stroke for users.

6. Product verification and validation

6.1 Pre-clinical and clinical data

6.1.1. Physical, chemical and microbiological characterisation

The materials in contact with the skin are non-allergic:

Part	Material	Comment
Strap	PET Polyester	RoHS/REACH declaration provided by the supplier
Case	- Glass Fiber - Stainless steel (contact inserts)	RoHS/REACH declaration provided by the supplier
PPG lens	PMMA Plexiglas 8N	RoHS/REACH declaration provided by the supplier

6.1.2. Electrical safety and electromagnetic compatibility

The product Test Plan was elaborated with the test laboratory DARE!! Measurements in Woerden.


For the test program a split has been made between Bluetooth connection functionality and the EMC immunity testing.

Bluetooth connection functionality

Bluetooth connection functionality has been verified with the Frédérique Constant Smartwatch Vitality FC-287™ and CardioWatch 287-1, which are based on the same hardware as the Corsano CardioWatch 287-1. Testing has been executed by TÜV SÜD certification and Testing (China) Co. and DARE!! Services according to the following standards:

ETSI EN 300 328 V2.2.2	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum
EN 50663:2017	Generic standard for assessment of low power electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (10 MHz - 300 GHz)

Medical Directive safety testing

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

The test program will be executed by DARE!! Measurements, Test & measurement services in Woerden, The Netherlands.
Summary of the test program:

EN 60601-1:2006 + A1:2013 + AC:2016 + A12:2014	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8:2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 60601-1-11:2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 62366-1:2008	Medical devices - Application of usability engineering to medical devices

ElectroMagnetic Compatibility (EMC) testing

The test program will be executed by DARE!! Measurements, Test & measurement services in Woerden, The Netherlands.
Summary of the test program:

EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 61000-3-2:2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
EN 61000-3-3:2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection

Test reports of performed tests

Bluetooth connection functionality

Bluetooth connection functionality has been verified by TÜV SÜD certification and Testing (China) Co. (Report Number 4842020214500B) based on the Frédérique Constant Smartwatch Vitality FC-287™.

Based on the test results Bluetooth Launch Studio has issued Declaration ID D050535 stating the compliance of the Frédérique Constant FC287, FC286, AL286 & AL284. The actual certificate can be found on:

<https://launchstudio.bluetooth.com/ListingDetails/107323>

Medical Directive safety testing


Testing has not yet been completed.

ElectroMagnetic Compatibility (EMC) testing

Testing has not yet been completed.

However, these tests have been performed for the Frédérique Constant FC-287™, as the use the same Bluetooth chipset, PCB hardware, antenna and RF layout. For this reason, it is believed that all tests performed on Frédérique Constant FC-287™ are fully valid for Corsano 287 CardioWatch. The Frédérique Constant FC-287™ is CE certified. Underneath are the Attestation of Conformity and the OEM Declaration. In the attachements the EMC test report and the RF test report of the Frédérique Constant FC-287™ are added.



	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20


FREDERIQUE CONSTANT
GENEVE

FREDERIQUE CONSTANT SA
Chemin du champ-des-Filets, 32
1228 Plan-les-Ouates
Switzerland

By this letter, FREDERIQUE CONSTANT SA gives the authorization to Manufacture Modules Technologies SA (MMT), to use all test results, performed on the product FC287 (including, but not limiting to, tests performed for EMC testing, safety testing, RF testing, Bluetooth compatibility and Bluetooth conformance) to prove the conformity of the products brought to market by other brands and using the same technology, provided by MMT as an OEM.

FREDERIQUE CONSTANT SA
Chemin du Champ-des-Filets 32
1228 Plan-les-Ouates
Switzerland

Name: Niels EGGERING
Title: Managing Director
Date: 03/07/2020
Place: Geneva, Switzerland
Signature: 


SWISS CONNECT

Manufacture Modules Technologies SA
Chemin du Pré-Fleuri, 5
1228 Plan-les-Ouates
Switzerland


OEM DECLARATION

By this letter, Manufacture Modules Technologies SA (MMT), declares that the products provided by MMT to Corsano Health BV (reference 287 CardioWatch) and to Frederique Constant (FC287) are exactly the same. In particular they use exactly the same Bluetooth chipset, PCB hardware, antenna and RF layout.

For this reason, we believe that all tests performed on Frederique Constant FC287 (EMC, electrical safety, Bluetooth conformance, etc.) are fully valid for Corsano 287 CardioWatch.

MMT
Manufacture Modules Technologies SA
Chemin du Pré-Fleuri 5
1228 Plan-les-Ouates
Switzerland

Name: Philippe Fraboulet
Title: CEO
Date: 02/07/2020
Place: Geneva, Switzerland

Signature: 

CE

Attestation of Conformity
No. T8A 107911 0003 Rev. 00

Holder of Certificate: FREDERIQUE CONSTANT SA
32 Chemin Du Champ Des Filets
1228 Plan-les-Ouates
SWITZERLAND

Product: Short range device / SRD
Smartwatch with BT module

This Attestation of Conformity is issued on a voluntary basis in support of the Conformity Assessment Module A of Radio Equipment Directive 2014/53/EU. On the basis of the referenced test reports, the samples of the listed product were found to comply with the essential requirements of the above mentioned directive as implemented in the standards used valid at the time the tests were carried out. For the requirements of the Article(s) 3(2) and 3(3) only harmonized standards valid at the moment of issuing where used. The used standards completely cover all essential requirements of the Radio Equipment Directive applicable to this product. The manufacturer must ensure compliance of the manufactured products with the technical documentation and other requirements of the Radio Equipment Directive that apply to them. National legal requirements have to be considered before bringing the product to the market. For details see: www.tuvsud.com/pe-cert

Test report no.: 4842020214500

Date: 2020-06-23


(Ming Gu)

Page 1 of 2
After preparation of the necessary documentation and establishing compliance to requirements of all applicable directives the manufacturer may sign a Declaration of Conformity and apply the CE-marking.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

CE

Attestation of Conformity
No. T8A 107911 0003 Rev. 00

Model(s): FC-286X3B2/4/6, FC-287X5B4/6


Parameters:

Ratings: DC 3.6V, 500mA
Test report no.: 4842020214500A/EN 55032, EN 55035, EN 61000-3-2, EN 61000-3-3, EN 301 489-1, EN 301489-17, 4842020214500B/EN 300 328, EN 50663, 70-420.20.441.07/EN 62368-1

Tested according to: EN 55032:2012
EN 55032:2015
EN 55035:2017
EN 61000-3-2:2014
EN 61000-3-3:2013
EN 301 489-1 V2.2.3:2019
Draft EN 301 489-17 V3.2.2:2019
EN 300 328 V2.2.2:2019
EN 50663:2017
EN 62368-1:2014/A11:2017

Page 2 of 2
After preparation of the necessary documentation and establishing compliance to requirements of all applicable directives the manufacturer may sign a Declaration of Conformity and apply the CE-marking.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

6.1.3. Stability, including shelf life

Planning and overview of performed tests

Because of the structural similarity between the Corsano SmarWatch 287-1 and the Frédérique Constant Smartwatch Vitality FC-287™ no dedicated stability tests are deemed necessary. Use is made of the experience of Frédérique Constant with storing, shipping and servicing of watches.

Storage stability

For the storage stability of the Corsano SmartWatch 287-1 use is made of the experience of Frédérique Constant, who produces and stores an identical product, the Frédérique Constant Smartwatch Vitality FC-287™, under the same storage conditions (based on normal conditions for electronic devices):

- Temperature -20°C/+60°C
- Humidity 40-80% RH

The experience from Frédérique Constant provides evidence of excellent storage stability of watches under these circumstances.

Transport stability

Watches are stored and shipped in special transportation modus, where hands of watches are at 10:10 and CPU is put in sleep state. In this modus, watches can easily be stored for 4-5 years.

Watches are usually securely shipped with reputable transporting companies. Corsano will insure its shipments. The experience of Frédérique Constant is that damaged or stolen shipments are very rare.

In-use stability

For the in-use stability of the Corsano CardioWatch 287-1 reference is made to the warranty data of the Frédérique Constant Smartwatch Vitality FC-287™.

Evaluation of data and test results

The structural similarity of the Corsano CardioWatch 287-1 with the Frédérique Constant Smartwatch Vitality FC-287™ provides the confidence that the Corsano CardioWatch 287 will also perform stable and reliably.

Other pre-clinical tests


Based on the risk assessment of the Corsano CardioWatch 287-1 [Ref. REC-73-2 Risk Management File CardioWatch 287-1] no additional tests were necessary to warrant reliable performance.

6.1.4. Clinical evaluation

To provide evidence of the effectiveness of the CardioWatch 287-2 System a number of large-scale clinical evaluations have been completed.

Below an overview of the relevant evaluations on CW287-1 and CW287-2 products:

No.	Topic	Number of Participants	Study center	Start time, Duration
1	Pilot study MMT- Continuous Photoplethysmography (PPG) measurement in presumably healthy people/ non-clinical environment	30 presumable healthy people ≥ 18 years old in a non-clinical environment	Preventicus Jena (DE)	August / September 2020, 1 month
2	Validation of PPG Measured Heart Rate and RR-intervals with the Corsano CardioWatch 287-1 Module Compared with ECG	100 presumable healthy people ≥ 18 years old in a non-clinical environment	Cardiologie Centra Nederland, Amsterdam UMC, Location AMC (NL)	September 2020, 1 month
3	Determine Atrial Fibrillation (AF) Burden with PPG Trial – Detection and Quantification of Episodes of AF	100 patients ≥ 18 years old with known paroxysmal atrial fibrillation Excluded: • Cardiac implanted electronic device (Pacemaker, ICD)	Universitätsspital Basel (CH)	Q3 2020, 6 months

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

4	Monitoring of AF in Hospitalized Patients for Stroke Prevention	250 hospitalized patients with CHA ₂ DS ₂ -VASc Score ≥ 2 Excluded: • Current or prior diagnosis of AF • Chronic anticoagulation therapy for other reasons • Cardiac implanted electronic device (Pacemaker, ICD)	Universitätsspital Basel (CH)	Q1 2021, 1.5 years
5	Smart in OAC – AFNET 9, Feasibility study To demonstrate that patients with previously unknown atrial arrhythmias can be detected by a wearable in combination with Preventicus Heartbeats Core	2,000 Patients 65 years or older to be screened Excluded: • Known AF • Known OAC treatment	Germany: Hamburg UK: Birmingham Spain: Barcelona Poland: Krakow (or Katowice)	Start: Q4 2020, Total study duration: 12 months Duration per patient: 1 month
6	Smart in OAC -Main study To demonstrate that initiation of oral anticoagulation (OAC) with edoxaban after detection of atrial arrhythmias detected by a smartphone / smartwatch-based detection of arrhythmias is superior to usual care (i.e. initiation of anticoagulation after specialist referral and verification of the diagnosis of AF) in preventing stroke, systemic embolism, or cardiovascular death.	143,000 Patients > 60 years with at least two of the CHADSVA risk factors (heart failure, hypertension, diabetes, prior stroke, age >65 years, vascular disease) to be screened	?	Start: Q4 2021

Cardiologie Centra Nederland

Heart rate and RR-interval measurement accuracy were assessed in a clinical trial conducted by Cardiologie Centra Nederland (CCN). In this trial, the Corsano CardioWatch 287-1 was tested against ECG. 180 cardiology patients with the following characteristics were included:

- Age 60 ± 15
- BMI 27.0 ± 5.0
- Skin type I-VI


7'880 heart beats were recorded and included in the analysis.

Root mean squared error (RMSE) for heart rate (Figure 1 Accuracy of heart rate (HR) measurement by the Corsano CardioWatch 287-1 Figure 1) was 1.96 bpm. Limits of agreement were between -3.89 and 3.77 beats per minute.

RR-intervals (Figure 2) yielded a correlation of 0.891 (95%CI 0.886-0.895). 89.2% (95%CI 88.5-89.9) of the recorded RR-intervals were within ± 50 ms of the concurrent ECG RR-interval. 94.6% (95%CI 94.1-95.1) of the recorded RR-intervals were within ± 100 ms of the concurrent ECG RR-interval.

The results were published in the Journal of Electrocardiology:

<https://doi.org/10.1016/j.jelectrocard.2021.06.009>

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

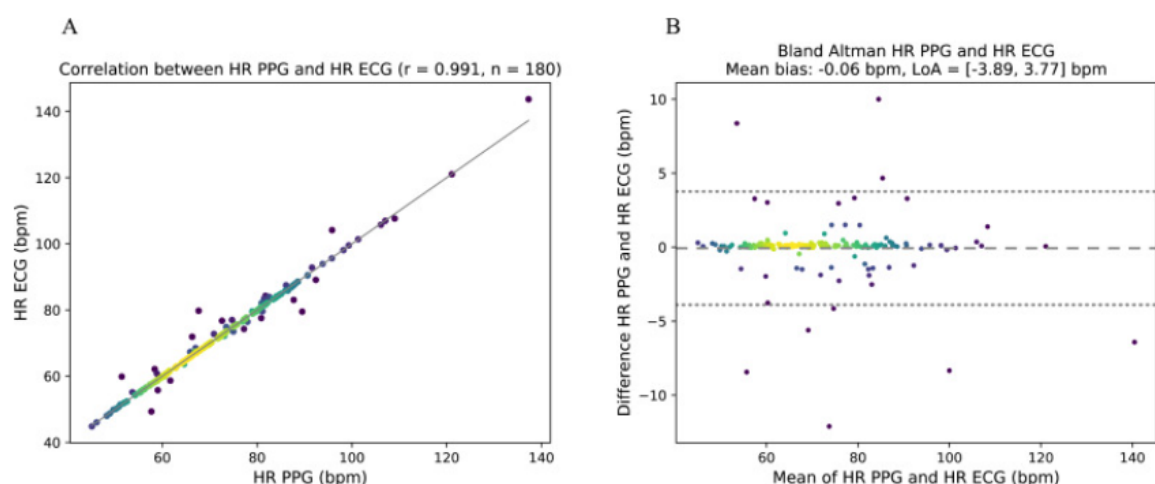


Figure 1 Accuracy of heart rate (HR) measurement by the Corsano CardioWatch 287-1

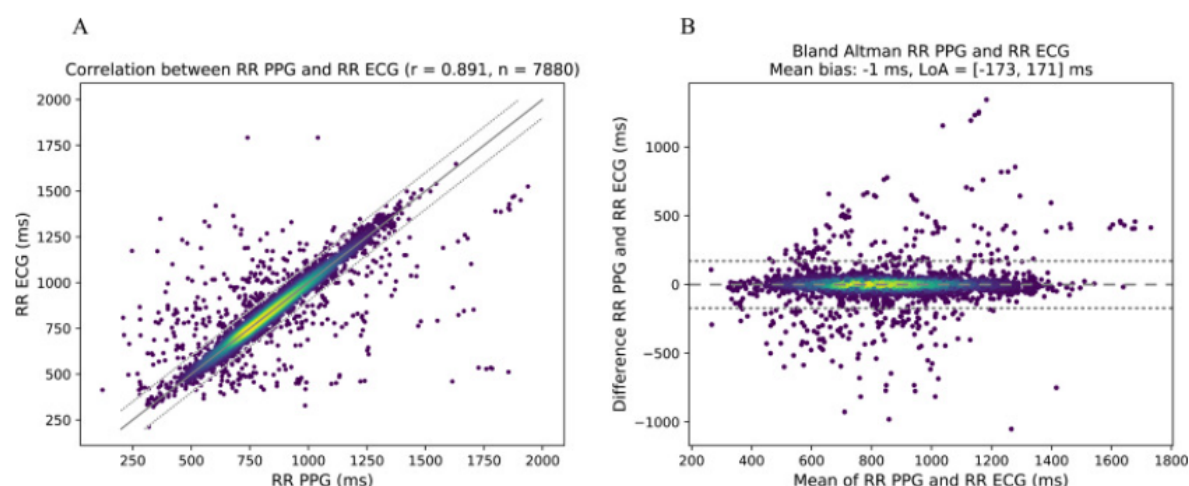


Figure 2 Accuracy of RR-interval measurement by the Corsano CardioWatch 287-1

Haaglanden clinics


Heart rate and respiration rate measurement accuracy was assessed in a clinical trial conducted by Haaglanden Clinics. In this trial, the Corsano CardioWatch 287-1 was tested against a pulse-oximeter for heart rate and a chest-worn belt for respiration rate. 26 patients were included, with the following characteristics:

- 18 suspected for Obstructive Sleep Apnea
- 8 healthy
- Age 47 ± 16 years old
- BMI 28.6 ± 7.4 kg/m²
- Skin type II-V

10'962 minutes were recorded, yielding 38'693 heart rate measurement pairs and 31'083 respiration rate pairs. Measurements were averaged over a window of 60 seconds.

Heart rate accuracy (Figure 3) was 0.95 bpm (RMSE). 95% Limits of Agreement were -2.09 to 1.17 bpm (mean bias -0.46 bpm).

Respiration rate accuracy (Figure 4) was 0.60 brpm (RMSE). 95% Limits of Agreement were -1.28 to 1.71 brpm (mean bias -0.14 brpm).

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

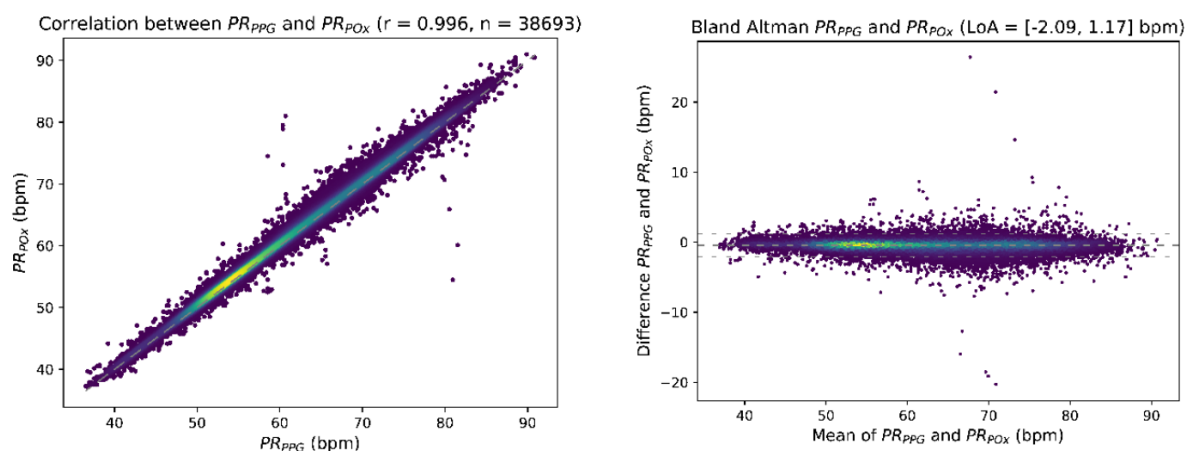


Figure 3 Accuracy of heart rate measurement by the Corsano CardioWatch 287-1. PR: pulse rate. PPG: photoplethysmography. POx: pulse-oximetry. bpm: beats per minute.

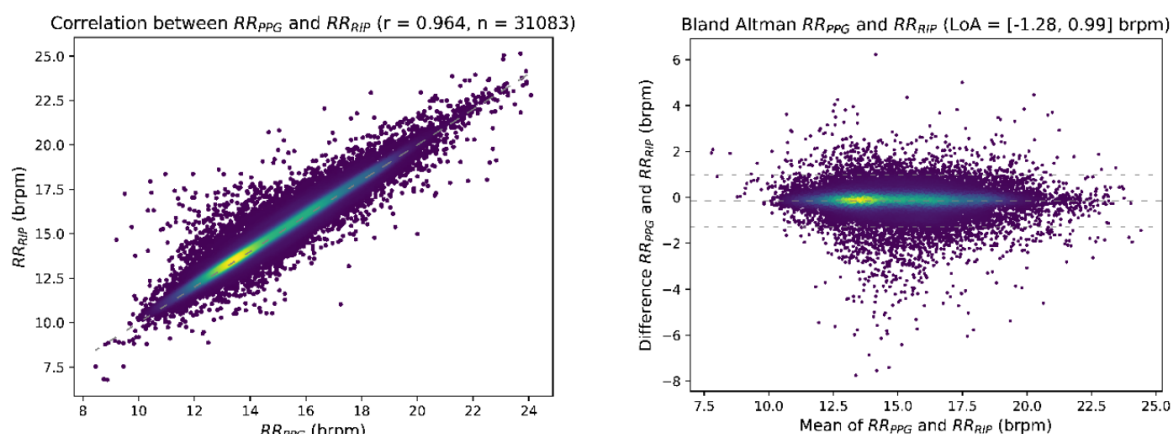



Figure 4 Accuracy of respiration rate measurement by the Corsano CardioWatch 287-1. RR: respiration rate. PPG: photoplethysmography. RIP: respiratory inductance plethysmography. brpm: breaths per minute.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

References

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[2] GHTF/SG1/N011:2008 Summary technical documentation for demonstrating conformity to the essential principles of safety and performance of medical devices (STED).

[3] EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

[4] ISO 14971:2019 Medical devices – Application of risk management to medical devices.

Note: at the time of publication of this version of the IMDD, the document was approved, the publication of the European version (EN) was pending.

[5] ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Note: during the development of this version of the IMDD, ISO 10993-1 was recently published and the European version (EN 10993-1) was not yet available.

[6] NEN-EN-IEC 62304; 2006 Medical device software - Software life-cycle processes

[7] NEN-EN-IEC 82304-1; 2017 Health software - Part 1: General requirements for product safety

[8] NEN-EN-IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

[9] EN ISO 11135: 2014 AMD 2018 Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.


[10] Atrial Fibrillation Detection Using a Novel Cardiac Ambulatory Monitor Based on Photo-Plethysmography at the Wrist, Alberto G. Bonomi, PhD, Fons Schipper, MSc, Linda M. Eerikainen, MSc, Jenny Margarito, MSc, Ralph van Dinther, PhD, Guido Muesch, MSc, Helma M. de Morree, PhD, Ronald M. Aarts, PhD, Saeed Babaeizadeh, PhD, David D. McManus, MD, Lukas R.C. Dekker, MD

[11] Smart detection of atrial fibrillation, Lian Krivoshei, Stefan Weber, Thilo Burkard, Anna Maseli, Noe Brasier, Michael Kuhne, DavidConen, Thomas Huebner, Andrea Seeck, and Jens Eckstein

[12] Clinical Evaluation of the Measurement Performance of the Philips Health Watch: A Within-Person Comparative Study, Jos Hendriks, MSc, Loes S Ruijs, MSc, PDEng, Lieke GE Cox, PhD, Paul MC Lemmens, PhD, Erik GP Schuijers, MSc, and Annelies HC Goris, PhD

[13] Apple Watch, Wearables, and Heart Rhythm: where do we stand? Joel M. Raja et al. Annals of translational medicine 2019

[14] Atrial fibrillation set to affect more than 14 million over-65s in the EU by 2060. European Society of Cardiology, 2019

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

Appendix: Corsano Privacy & Security

Corsano Privacy & Security - Introduction

CORSANO is medical orientated company and is dealing with sensitive patient-data. That is why the Health and User data have to be taken very seriously.

This document is discussing CORSANO's ongoing journey with the cloud and our innovative use of security offerings to reduce risks and improve the privacy of information. Here's an overview of how we have built security at CORSANO:

Proactive Security

We believe in taking a proactive stance on securing our systems and applications. We follow industry best practices, as well as our customers' recommendations, to harden our systems. When it comes to our application, our developers follow industry best practices during the software development lifecycle, including OWASP (Open Web Application Security Project) Top 10 and relevant technology specific guidelines. We rigorously test our code prior to and after the deployment to production. Preventative and corrective maintenance of the data center equipment is scheduled through a standard process according to documented procedures.

Data Center Security

CORSANO stores all production data in physically secure datacenters. We own and maintain the backend infrastructure where customer data is stored. We use data centers in various geographic locations for continuity and regulatory purposes, which are Tier III/Tier III+ and ISO 27001 certified. Our data centers have common security practices, including closed-circuit video monitoring and 24/7-manned guards and require the use of biometric access controls to our locked cages.

Data Security

Our customer's data – and the security of that data – is of utmost importance to us, which is why we provide our customers with complete control over their data. Our servers are encrypted using TLS. We employ multiple layers of network devices and intrusion detection to protect its external attack surface. And, our security architecture ensures segregation of customer data.

Continuous Monitoring


We utilize both internal and external services to perform continuous scanning and monitoring of our network and application. We also conduct regular vulnerability scans, risk assessments and penetration tests.

Compliance

We strive to be industry leaders in regulatory requirements and compliance. Our processes and controls are regularly audited by internal and external parties, including customers and independent assessors. Our datacenters are Tier III/Tier III+ and/or ISO 27001 certified. We have also successfully undergone audits and are compliant with General Data Protection Regulation (GDPR).

Located in Europe and NSA non-compatible

Europe is internationally recognized for data protection. CORSANO Health B.V. is a neutral, independent company incorporated in The Netherlands. Dutch law concerning data protection

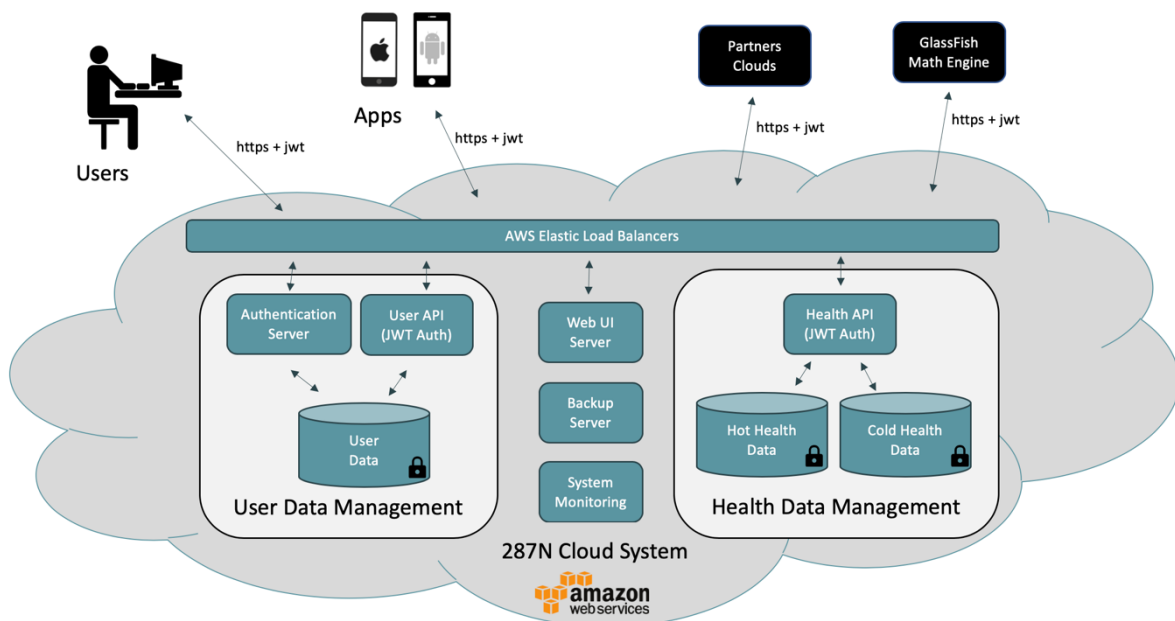
	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

ensures complete confidentiality both for businesses and for individuals, and no government can have access to personal information without the agreement of a judge.

General Data Protection Regulation (GDPR) Compliance


CORSANO is passionate about ensuring that our clients are able to comply with data privacy regulations, including the European Union's GDPR, which goes into effect in May 2018. We provide our clients with enterprise-grade controls to manage, govern access and ensure security of personal data housed in CORSANO Cloud. As required by GDPR, CORSANO allows our clients to correct, export, or permanently delete personal information. CORSANO also purges personal data from internal processing systems to minimize the data we retain per GDPR Article 5. More information on the GDPR compliance can be found further in this document.

In the following figure the Data Management is represented in a clear overview of the setup:



In this document we will be discussing more information on the following subjects:

- The European Union's General Data Protection Regulation (GDPR)
- Privacy Terms
- Terms of Use

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

General Data Protection Regulation (GDPR)

Ensure data privacy, security and accuracy

The European Union's General Data Protection Regulation ([GDPR](#)), which becomes effective in May 2018, requires companies to be accountable for how they use, manage and maintain the personal data of their customers and employees.

FIND OUT MORE [HERE](#).

Setting the bar for data protection

We provide our clients with enterprise-grade controls to manage, govern access and ensure security of personal data housed in the CORSANO Cloud.

Personal data privacy

All personal data or personally identifiable information (PII) in the CORSANO Cloud are stored securely in our datacenters in Switzerland. We use encryption to protect data in transit and at rest. Data in transit to our applications is protected using HTTPS. Our personnel are required to execute a confidentiality agreement and must acknowledge receipt of, and compliance with, CORSANO's confidentiality and privacy policies. Personnel handling Customer Personal Data are required to complete additional requirements appropriate to their role and will not process Customer Personal Data without authorization.

Full-service data management


CORSANO Cloud automates GDPR compliant deletion of customer data for customers requesting "right to be forgotten" requests. You can manage your personal data directly in our CORSANO cloud portal. We offer the possibility to directly delete your account and all your personal data. CORSANO's applications also provide data export and modification that comply with GDPR.

Data retention

CORSANO purges personal data from internal processing systems to minimize the data we retain per [GDPR Article 5](#). Our system retains customer data until our customers delete it or not use our service after a long period.

Got questions on GDPR?

Don't hesitate to contact us to find out more about how we're helping keep your data private, accurate and secure. Please contact us by email at privacy@corsano.com

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

Privacy Terms

The customer agreeing to these terms ("Customer"), and CORSANO Health B.V.

(as applicable, "CORSANO") have entered into an agreement under which CORSANO has agreed to provide the "CORSANO" products or services to Customer (as amended from time to time, the "Agreement").

These CORSANO Data Processing and Security Terms, including their appendices, (the "Terms") will be effective and replace any previously applicable data processing and security terms as from the Terms Effective Date (as defined below). These Terms supplement the Agreement.


1. Introduction

These Terms reflect the party's agreement with respect to the terms governing the processing and security of Customer Personal Data under the Agreement.

2. Definitions

2.1 Capitalized terms used but not defined in these Terms have the meanings set out in the Agreement. In these Terms, unless stated otherwise:

- Account has the meaning given in the Agreement or, if no such meaning is given, means Customer's account for the Services.
- Additional Product means a product, service or application provided by CORSANO or a third party that: (a) is not part of the Services; and (b) is accessible for use within the user interface of the Services or is otherwise integrated with the Services.
- Affiliate has the meaning given in the Agreement or, if not such meaning is given, means any entity that directly or indirectly controls, is controlled by, or is under common control with, a party.
- Alternative Transfer Solution means a solution, other than Privacy Shield, that enables the lawful transfer of personal data to a third country in accordance with Article 45 or 46 of the GDPR.
- Customer Personal Data means the personal data provided by or on behalf of Customer
- Data Incident means a breach of CORSANO's security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Customer Personal Data on systems managed by or otherwise controlled by CORSANO. "Data Incidents" will not include unsuccessful attempts or activities that do not compromise the security of Customer Personal Data, including unsuccessful log-in attempts, pings, port scans, denial of service attacks, and other network attacks on firewalls or networked systems.
- Data Protection Legislation means, as applicable: (a) the GDPR; and/or (b) the Federal Data Protection Act of 19 June 1992 (Switzerland).
- EEA means the European Economic Area.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

- GDPR means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.
- Notification Email Address means the email address(es) designated by Customer.
- Privacy Shield means the EU-U.S. Privacy Shield legal framework.
- Term means the period from the Terms Effective Date until the end of CORSANO's provision of the Services, including, if applicable, any period during which provision of the Services may be suspended and any post-termination period during which CORSANO may continue providing the Services for transitional purposes.
- Terms Effective Date means, as applicable:
 1. August 17, 2020, if the Customer agreed to these Terms prior to or on such date; or
 2. the date on which Customer agreed to these Terms, if such date is after August 17, 2020.

2.2 The terms “personal data”, “data subject”, “processing”, “controller”, “processor” and “supervisory authority” as used in these Terms have the meanings given in the GDPR.

3. Duration of these Terms

These Terms will take effect on the Terms Effective Date and, notwithstanding expiry of the Term, will remain in effect until, and automatically expire upon, deletion of all Customer Personal Data by CORSANO as described in these Terms.

4. Scope of Data Protection Legislation

4.1 Application of European Legislation. These Terms will only apply to the extent that the Data Protection Legislation applies to the processing of Customer Personal Data, including if:


1. the processing is carried out in the context of the activities of an establishment of Customer in the territory of the EEA; and/or
2. the Customer Personal Data is personal data relating to data subjects who are in the EEA and the processing relates to the offering to them of goods or services in the EEA or the monitoring of their behavior in the EEA.

5. Processing of Data

5.1 Roles and Regulatory Compliance; Authorization.

5.1.1 Processor and Controller Responsibilities. The parties acknowledge and agree that:

- the subject matter and details of the processing are described in Appendix 1;
- CORSANO is a processor of that Customer Personal Data under the Data Protection Legislation;

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

- Customer is a controller or processor, as applicable, of that Customer Personal Data under Data Protection Legislation; and
- each party will comply with the obligations applicable to it under the Data Protection Legislation with respect to the processing of that Customer Personal Data.

5.2 Scope of Processing.

5.2.1 Customer's Instructions. By entering into these Terms, Customer instructs CORSANO to process Customer Personal Data only in accordance with applicable law: to provide the Services; as further specified via Customer's use of the Services; as documented in the form of the Agreement, including these Terms; and as further documented in any other written instructions given by Customer and acknowledged by CORSANO as constituting instructions for purposes of these Terms.

5.2.2 CORSANO's Compliance with Instructions. CORSANO will comply with the instructions described in Section 5.2.1 (Customer's Instructions) (including with regard to data transfers) unless EU or EU Member State law to which CORSANO is subject requires other processing of Customer Personal Data by CORSANO, in which case CORSANO will inform Customer (unless that law prohibits CORSANO from doing so on important grounds of public interest) via the Notification Email Address.

5.3 Additional Products. If Customer uses an Additional Product, the Services may allow that Additional Product to access Customer Personal Data as required for the interoperation of the Additional Product with the Services. For clarity, these Terms do not apply to the processing of personal data in connection with the provision of any Additional Product used by Customer, including personal data transmitted to or from that Additional Product.


6. Data Deletion

6.1 Deletion by Customer. CORSANO will enable Customer to delete Customer Personal Data during the Term in a manner consistent with the functionality of the Services. If Customer uses the Services to delete any Customer Personal Data during the Term and that Customer Personal Data cannot be recovered by Customer, this use will constitute an instruction to CORSANO to delete the relevant Customer Personal Data from CORSANO's systems in accordance with applicable law. CORSANO will comply with this instruction as soon as reasonably practicable and within a maximum period of 180 days, unless EU or EU Member State law requires storage.

6.2 Deletion on Termination. On expiry of the Term, Customer instructs CORSANO to delete all Customer Personal Data (including existing copies) from CORSANO's systems in accordance with applicable law. CORSANO will, after a recovery period of up to 30 days following such expiry, comply with this instruction as soon as reasonably practicable and within a maximum period of 180 days, unless EU or EU Member State law requires storage. Without prejudice to Section 11.1 (Access; Rectification; Restricted Processing; Portability), Customer acknowledges and agrees that Customer will be responsible for exporting, before the Term expires, any Customer Personal Data it wishes to retain afterwards.

7. Data Security

7.1 CORSANO's Security Measures, Controls and Assistance.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

7.1.1 CORSANO's Security Measures. CORSANO will implement and maintain technical and organizational measures to protect Customer Personal Data against accidental or unlawful destruction, loss, alteration, unauthorized disclosure or access. The Security Measures include measures to help ensure ongoing confidentiality, integrity, availability and resilience of CORSANO's systems and services; to help restore timely access to personal data following an incident; and for regular testing of effectiveness. CORSANO may update or modify the Security Measures from time to time provided that such updates and modifications do not result in the degradation of the overall security of the Services.

7.1.2 Security Compliance by CORSANO Staff. CORSANO will take appropriate steps to ensure compliance with the Security Measures by its employees, contractors and Sub-processors to the extent applicable to their scope of performance, including ensuring that all persons authorized to process Customer Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

7.2. Data Incidents

7.2.1 Incident Notification. If CORSANO becomes aware of a Data Incident, CORSANO will: (a) notify Customer of the Data Incident promptly and without undue delay after becoming aware of the Data Incident; and (b) promptly take reasonable steps to minimize harm and secure Customer Personal Data.

7.2.2 Details of Data Incident. Notifications made pursuant to this section will describe, to the extent possible, details of the Data Incident, including steps taken to mitigate the potential risks and steps CORSANO recommends Customer take to address the Data Incident.

7.2.3 Delivery of Notification. Notification(s) of any Data Incident(s) will be delivered to the Notification Email Address or, at CORSANO's discretion, by direct communication (for example, by phone call or an in-person meeting). Customer is solely responsible for ensuring that the Notification Email Address is current and valid.


7.2.4 No Assessment of Customer Personal Data by CORSANO. CORSANO will not assess the contents of Customer Personal Data to identify information subject to any specific legal requirements. Customer is solely responsible for complying with incident notification laws applicable to Customer and fulfilling any third-party notification obligations related to any Data Incident(s).

7.2.5 No Acknowledgement of Fault by CORSANO. CORSANO's notification of or response to a Data Incident under this Section 7.2 (Data Incidents) will not be construed as an acknowledgement by CORSANO of any fault or liability with respect to the Data Incident.

7.3 Customer's Security Responsibilities and Assessment.

7.3.1 Customer's Security Responsibilities. Customer agrees that, without prejudice to CORSANO's obligations under Section 7.1 (CORSANO's Security Measures, Controls and Assistance) and Section 7.2 (Data Incidents):

1. Customer is solely responsible for its use of the Services, including:

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

- making appropriate use of the Services to ensure a level of security appropriate to the risk in respect of the Customer Personal Data;
 - securing the account authentication credentials, systems and devices Customer uses to access the Services;
 - backing up its Customer Personal Data; and
2. CORSANO has no obligation to protect Customer Personal Data that Customer elects to store or transfer outside of CORSANO's and its Sub-processors' systems (for example, offline or on-premise storage), or to protect Customer Personal Data by implementing or maintaining additional security controls except to the extent Customer has opted to use them.

7.3.2 Customer's Security Assessment.

1. Customer is solely responsible for reviewing the Security Documentation and evaluating for itself whether the Services, the Security Measures, the Additional Security Controls and CORSANO's commitments under this Section 7 (Data Security) will meet Customer's needs, including with respect to any security obligations of Customer under the Data Protection Legislation.
2. Customer acknowledges and agrees that (taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of the processing of Customer Personal Data as well as the risks to individuals) the Security Measures implemented and maintained by CORSANO as set out in Section 7.1.1 (CORSANO's Security Measures) provide a level of security appropriate to the risk in respect of the Customer Personal Data.

8. Data storage and processing locations

CORSANO may process and store your data in Europe and Switzerland.


9. Security information

9.1 Data encryption.

- CORSANO services encrypt data in transit using HTTPS and logically isolate customer data. In addition, several CORSANO services may also encrypt their data at rest.
- Redundancy: Infrastructure systems have been designed to eliminate single points of failure and minimize the impact of anticipated environmental risks. Dual circuits, switches, networks or other necessary devices help provide this redundancy.

9.2 Networks and Transmission.

- Data centers are typically connected via high-speed private links to provide secure and fast data transfer between data centers. This is designed to prevent data from being read, copied, altered or removed without authorization during electronic transfer or transport or while being recorded onto data storage media.
- CORSANO employs multiple layers of network devices and intrusion detection to protect its external attack surface.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

- Intrusion detection is intended to provide insight into ongoing attack activities and provide adequate information to respond to incidents
- Incident Response. CORSANO monitors a variety of communication channels for security incidents, and CORSANO's security personnel will react promptly to known incidents.

9.3 Security practices. To keep personal data safe, CORSANO employs extensive security measures to minimize access:

1. CORSANO restricts access to a select employees who have a business purpose to access personal data.
2. CORSANO employees are required to conduct themselves in a manner consistent with the company's guidelines regarding confidentiality, business ethics, appropriate usage, and professional standards.

10. Impact Assessments and Consultations

Customer agrees that CORSANO will (taking into account the nature of the processing and the information available to CORSANO) assist Customer in ensuring compliance with any obligations of Customer in respect of data protection impact assessments and prior consultation, including if applicable Customer's obligations pursuant to Articles 35 and 36 of the GDPR, by providing the information contained in the Agreement including these Terms.

11. Data Subject Rights; Data Export

11.1 Access; Rectification; Restricted Processing; Portability. During the Term, CORSANO will, in a manner consistent with the functionality of the Services, enable Customer to access, rectify and restrict processing of Customer Personal Data, including via the deletion functionality provided by CORSANO as described in Section 6.1 (Deletion by Customer), and to export Customer Personal Data.


11.2 Data Subject Requests

11.2.1 Customer's Responsibility for Requests. During the Term, if CORSANO receives any request from a data subject in relation to Customer Personal Data, CORSANO will advise the data subject to submit their request to Customer and Customer will be responsible for responding to any such request including, where necessary, by using the functionality of the Services.

11.2.2 CORSANO's Data Subject Request Assistance. Customer agrees that CORSANO will (taking into account the nature of the processing of Customer Personal Data) assist Customer in fulfilling any obligation to respond to requests by data subjects, including if applicable Customer's obligation to respond to requests for exercising the data subject's rights laid down in Chapter III of the GDPR, by complying with the commitments set out in Section 11.1 (Access; Rectification; Restricted Processing; Portability) and Section 11.2.1 (Customer's Responsibility for Requests).

12. CORSANO Data Protection Team; Processing Records

12.1 CORSANO Representative. Customer may contact a CORSANO representative in relation to the exercise of its rights under these Terms via email to support@Corsano.com

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

12.2 CORSANO's Processing Records. Customer acknowledges that CORSANO is required under the GDPR to: (a) collect and maintain records of certain information, including the name and contact details of each processor and/or controller on behalf of which CORSANO is acting and, where applicable, of such processor's or controller's local representative and data protection officer; and (b) make such information available to the supervisory authorities. Accordingly Customer will, where requested, provide such information to CORSANO via the SwissCloudPortal or other means provided by CORSANO, and will use the SwissCloudPortal or such other means to ensure that all information provided is kept accurate and up-to-date.

13. Liability

The jurisdiction of any disputes will be established in Switzerland. This Agreement shall be governed by and construed in accordance with the laws of Switzerland.

Any and all disputes and legal actions arising out of the interpretation or application of this Agreement shall be disputes resolved by and brought exclusively in the courts of The Netherlands. This Agreement shall be interpreted and enforced in accordance with the laws of The Netherlands.

In the event that any portion of this Agreement is held unenforceable, the unenforceable portion shall be construed in accordance with applicable law as nearly as possible to reflect the original intentions of the parties, and the remainder of the provisions shall remain in full force and effect.

15. Legal Disclaimer

Though we make every effort to preserve user privacy, we may need to disclose personal information when required by law wherein we have good-faith belief that such action is necessary to comply with a current judicial proceeding, a court order or legal process served on our website.

16. Attorney fees

In any litigation, arbitration, or other proceeding by which one party either seeks to enforce its rights under this Agreement (whether in contract, tort, or both), or seeks a declaration of any rights or obligations under this Agreement, the prevailing party shall be awarded its reasonable attorney fees and costs and expenses incurred.

17. Effect of these Terms


Notwithstanding anything to the contrary in the Agreement, to the extent of any conflict or inconsistency between these Terms and the remaining terms of the Agreement, these Terms will govern.

Appendix 1: Subject Matter and Details of the Data Processing

1. Subject Matter

CORSANO's provision of the Services to Customer.

2. Duration of the Processing

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

The Term plus the period from the expiry of the Term until deletion of all Customer Personal Data by CORSANO in accordance with these Terms. We will retain your personal data as long as your CORSANO account is considered to be active.

3. Nature and Purpose of the Processing

CORSANO will process Customer Personal Data for the purposes of providing the Services to Customer in accordance with these Terms.

Personal data that is processed when you create a CORSANO account:

When you create a CORSANO account, we ask you to provide your email address and name. You can choose to provide only your first name or a nickname instead of your full name if you wish.

Purposes and Legal Ground:

CORSANO processes your email address because you use your email address and your password to sign in to your account. The legal ground for processing your email address for this purpose is based on CORSANO's legitimate interest in protecting the security of your account.

CORSANO also processes your email address for the purpose of sending you important information about your CORSANO products, apps or account, such as important safety information or material changes to this Privacy Policy. The legal ground for processing your email address and name for these purposes is CORSANO's legitimate interest in providing you important safety or other information about your CORSANO products, apps or account or material changes to this Privacy Policy

If you provide your opt-in consent to receiving marketing information from CORSANO or one of our partners, CORSANO will also process your email address for the purpose of sending you marketing information about CORSANO products and apps. The legal ground for processing your email address for this purpose is your consent. You may withdraw your consent at any time by changing your preferences in your CORSANO account or through the unsubscribe link at the bottom of our marketing emails.


Additional personal data that is processed if you choose to provide it when you create a CORSANO account:

You can add additional information to your profile, such as your gender, birthdate, height and weight.

Purposes and Legal Ground:

This information is used to calculate the calories you burn during an activity and to enable you to show the types of activities you participate in if you wish. The legal ground for processing this information for these purposes is your consent. You can withdraw your consent by deleting this information from your account profile.

Personal data that is processed when you choose to upload your workouts, activity data to CORSANO:

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

You can choose to upload workouts, activity data (e.g., steps, distance, activity time, calories burned, heart rate, sleep, location, temperature, barometer, altitude, UV index...) from your device to your CORSANO account.

Purposes and Legal Ground:

CORSANO processes your activity and sleep data, if you choose to upload it to CORSANO, to enable you to analyze your activity data, see your location on your activity workout and segment maps, see your heart rate related metrics, sleep data, altitude, temperature, barometer, UV index...

If you choose to upload activity data (such as steps, distance, activity time, calories burned, heart rate, sleep, etc.) from your CORSANO device to your CORSANO account and you choose to participate in Insights, then you will be presented with an Insights section in your CORSANO account in which you will be provided with recommendations and motivational messages, information and links to articles that may be of interest to you based upon your activity data, and a comparison of your activity data with anonymous aggregated activity data of others in the CORSANO community.

Personal data that is processed when you sync your CORSANO device (bracelet, watch, ...):

When you sync your device through one of our CORSANO applications we may upload information concerning the device, such as brand name, manufacturer, serial number, model, battery level, the sync time and date, crash/diagnostic logs.

Purposes and Legal Ground:

We process this information to help identify and resolve errors or syncing issues. The legal ground for processing this information for this purpose is CORSANO's legitimate interest in resolving errors or syncing issues and providing quality product support.

4. Categories of Data

Data relating to individuals provided to CORSANO via the Services, by (or at the direction of) Customer or by Customer End Users.


5. Data Subjects

Data subjects include the individuals about whom data is provided to CORSANO via the Services by (or at the direction of) Customer or by Customer End Users.

6. Cookies and Similar Technologies

Websites

To help analyze how you and other visitors navigate CORSANO websites, and compile aggregate statistics about site usage and response rates, we, with assistance from third-party analytics service providers, collect certain information when you visit our site. This information may include IP address, geographic location of the device, browser type, browser language, date and time of your request, time(s) of your visit(s), page views and page elements (e.g., links) that you click. We may use cookies, pixel tags, web beacons, clear GIFs or other similar tools on our site or in our email messages to assist us in collecting and analyzing such information. We use this information to provide better, more relevant content on our site, to measure the effectiveness of advertisements, to identify and fix

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

problems, and to improve your overall experience on our site. If you do not want information collected through the use of these technologies, there is a simple procedure in most browsers that allows you to automatically decline many of these technologies, or to be given the choice of declining or accepting them.

If you reside in the European Union or other jurisdiction that requires us to obtain your consent to use cookies on our sites, then you will have an opportunity to manage your cookie preferences on the sites; except that certain cookies are required to enable core site functionality, and you cannot choose to disable those cookies.

CORSANO Mobile apps

We also collect data from users about their usage of CORSANO mobile apps. The types of analytical information that are collected may include the date and time the app accesses our servers, app version, the location of the device, language setting, what information and files have been downloaded to the app, user behavior (e.g., features used, frequency of use), device state information, device model, hardware and operating system information, and information relating to how the app functions. CORSANO uses this data to improve the quality and functionality of our mobile apps to develop and market products and features that best serve you and other users and to help identify and fix app stability issues and other usability problems as quickly as possible.


The legal ground for processing this analytical information is our legitimate interest in understanding how our customers interact with our products, apps and websites so we can enhance the user experience and functionality of our products, apps and websites.

Here are examples of third-party providers of analytics and similar services we currently use:

- **Google Analytics** is used to track site statistics and user demographics, interests and behavior on websites. We also use Google Search Console to help understand how our website visitors find our website and to improve our search engine optimization. Find out more information about how this analytics information may be used, how to control the use of your information, and how to opt-out of having your data used by Google Analytics.
- **Crashlytics and Answers (Fabric)** are used to help us better understand usage of the CORSANO Mobile applications to improve user experience and to identify and resolve the root causes of app crashes.

Social Networks

Third-party social networks that provide interactive plug-ins or social networking features (e.g., to allow you to connect to Facebook, Google or Twitter to find friends to add as connections or to “Like” a page) on CORSANO websites or mobile apps, may use cookies or other methods (e.g., web beacons) to gather information regarding your use of our websites and apps. The use of such information by a third party depends on the privacy policy available on that social network’s website, which we encourage you to carefully review. Such third parties may use these cookies or other tracking methods for their own purposes by relating information about your use of our site with any of your Personal Information that they may have. We may also obtain analytics information from social networks that help us measure the effectiveness of our content and advertisements on social networks (e.g., impressions and clicks).

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

7. Children

We request individuals under 16 not provide personal data to CORSANO. If we learn that we have collected the personal data from a child under 16, we will take steps to delete the information as soon as possible.

8. Data Controller and Data Protection Officer

Your personal data collected by CORSANO is controlled by CORSANO B.V., which is located at Molengraaffsingel 12, 2629JD Delft, the Netherlands. CORSANO's Data Protection Officer is located at the same address and can also be reached by email at privacy@corsano.com

9. Your Rights

If you reside in the EEA, you have the right under the General Data Protection Regulation to request from CORSANO access to and rectification or erasure of your personal data, data portability, restriction of processing of your personal data, the right to object to processing of your personal data, and the right to lodge a complaint with a supervisory authority. If you reside outside of the European Union, you may have similar rights under your local laws.

To request access to or rectification, portability or erasure of your personal data, or to delete your CORSANO account, visit <http://corsanocloud.com> and use our export or delete data tool.

If you live in the EEA and you wish to exercise your right to restriction of processing or your right to object to processing, contact CORSANO Data Protection Officer at Corsano Health B.V., Molengraaffsingel 12, 2629 JD Delft, the Netherlands or by email at privacy@corsano.com. If you do not live in the EEA but you believe you have a right to restriction of processing or a right to object to processing under your local laws, please contact us using the address or email above.

Appendix 2: Security Measures

As from the Terms Effective Date, CORSANO will implement and maintain the Security Measures set out in this Appendix 2. CORSANO may update or modify such Security Measures from time to time, provided that such updates and modifications do not result in the degradation of the overall security of the Processor Services.


1. Data Center & Network Security

Data Centers.

Infrastructure. CORSANO stores all production data in physically secure data centers.

Redundancy. Infrastructure systems have been designed to eliminate single points of failure and minimise the impact of anticipated environmental risks. Dual circuits, switches, networks or other necessary devices help provide this redundancy. Preventative and corrective maintenance of the data center equipment is scheduled through a standard process according to documented procedures.

Power. The data center electrical power systems are designed to be redundant and maintainable without impact to continuous operations, 24 hours a day, and 7 days a week. In most cases, a

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

primary as well as an alternate power source, each with equal capacity, is provided for critical infrastructure components in the data center.

Server Operating Systems. CORSANO servers use hardened operating systems which are customised for the unique server needs of the business. Data is stored using proprietary algorithms to augment data security and redundancy. CORSANO employs a code review process to increase the security of the code used to provide the Processor Services and enhance the security products in production environments.

Businesses Continuity. CORSANO replicates data over multiple systems to help to protect against accidental destruction or loss.

Networks & Transmission.

Data Transmission. Data centers are typically connected via high-speed private links to provide secure and fast data transfer between data centers. This is designed to prevent data from being read, copied, altered or removed without authorization during electronic transfer or transport or while being recorded onto data storage media. CORSANO transfers data via Internet standard protocols.

External Attack Surface. CORSANO employs multiple layers of network devices and intrusion detection to protect its external attack surface. CORSANO considers potential attack vectors and incorporates appropriate purpose-built technologies into external facing systems.

Intrusion Detection. Intrusion detection is intended to provide insight into ongoing attack activities and provide adequate information to respond to incidents. CORSANO's intrusion detection involves:

1. Tightly controlling the size and make-up of CORSANO's attack surface through preventative measures;
2. Employing intelligent detection controls at data entry points; and
3. Employing technologies that automatically remedy certain dangerous situations.


Incident Response. CORSANO monitors a variety of communication channels for security incidents, and CORSANO's security personnel will react promptly to known incidents.

Encryption Technologies. CORSANO makes HTTPS encryption (also referred to as SSL or TLS connection) available. CORSANO servers support ephemeral elliptic curve Diffie Hellman cryptographic key exchange signed with RSA and ECDSA. These perfect forward secrecy (PFS) methods help protect traffic and minimize the impact of a compromised key, or a cryptographic breakthrough.

2. Access and Site Controls

3. Site Controls

On-site Data Center Security Operation. CORSANO's data centers maintain an on-site security operation responsible for all physical data center security functions 24 hours a day, 7 days a week. The on-site security operation personnel monitor Closed Circuit TV ("CCTV") cameras and all alarm systems. On-site security operation personnel perform internal and external patrols of the data center regularly.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

Data Center Access Procedures. CORSANO maintains formal access procedures for allowing physical access to the data centers. The data centers are housed in facilities that require electronic card key access, with alarms that are linked to the on-site security operation. All entrants to the data center are required to identify themselves as well as show proof of identity to on-site security operations. Only authorized employees, contractors and visitors are allowed entry to the data centers. Only authorized employees and contractors are permitted to request electronic card key access to these facilities. Data center electronic card key access requests must be made in advance and in writing and require the approval of the requestor's manager and the data center director. All other entrants requiring temporary data center access must: (i) obtain approval in advance from the data center managers for the specific data center and internal areas they wish to visit; (ii) sign in at on-site security operations; and (iii) reference an approved data center access record identifying the individual as approved.


On-site Data Center Security Devices. CORSANO's data centers employ an electronic card key and biometric access control system that is linked to a system alarm. The access control system monitors and records each individual's electronic card key and when they access perimeter doors, shipping and receiving, and other critical areas. Unauthorized activity and failed access attempts are logged by the access control system and investigated, as appropriate. Authorized access throughout the business operations and data centers is restricted based on zones and the individual's job responsibilities. The fire doors at the data centers are alarmed. CCTV cameras are in operation both inside and outside the data centers. The positioning of the cameras has been designed to cover strategic areas including, among others, the perimeter, doors to the data center building, and shipping/receiving. On-site security operations personnel manage the CCTV monitoring, recording and control equipment. Secure cables throughout the data centers connect the CCTV equipment. Cameras record on-site via digital video recorders 24 hours a day, 7 days a week. The surveillance records are retained for at least 7 days based on activity.

2. Access Control

Infrastructure Security Personnel. CORSANO has, and maintains, a security policy for its personnel, and requires security training as part of the training package for its personnel. CORSANO's infrastructure security personnel are responsible for the ongoing monitoring of CORSANO's security infrastructure, the review of the Processor Services, and responding to security incidents.

Access Control and Privilege Management. Customer's administrators and users must authenticate themselves via a central authentication system in order to use the Processor Services.

Internal Data Access Processes and Policies – Access Policy. CORSANO's internal data access processes and policies are designed to prevent unauthorized persons and/or systems from gaining access to systems used to process personal data. CORSANO aims to design its systems to: (i) only allow authorized persons to access data they are authorized to access; and (ii) ensure that personal data cannot be read, copied, altered or removed without authorization during processing, use and after recording. The systems are designed to detect any inappropriate access. CORSANO employs a centralised access management system to control personnel access to production servers, and only provides access to a limited number of authorized personnel. LDAP, Kerberos and SSH certificates are designed to provide CORSANO with secure and flexible access mechanisms. These mechanisms are designed to grant only approved access rights to site hosts, logs, data and configuration information.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

CORSANO requires the use of unique user IDs, strong passwords and carefully monitored access lists to minimize the potential for unauthorized account use. The granting or modification of access rights is based on: the authorized personnel's job responsibilities; job duty requirements necessary to perform authorized tasks; and a need to know basis. The granting or modification of access rights must also be in accordance with CORSANO's internal data access policies and training. Where passwords are employed for authentication (e.g. login to workstations), password policies that follow at least industry standard practices are implemented. These standards include restrictions on password reuse and sufficient password strength.

3. Data

Data Storage, Isolation & Authentication.

CORSANO stores data in a multi-tenant environment on CORSANO Data, the Processor Services database and file system architecture are replicated between multiple geographically dispersed data centers in Europe. CORSANO logically isolates each customer's data. A central authentication system is used across all Processor Services to increase uniform security of data.

Decommissioned Disks and Disk Destruction Guidelines.

Certain disks containing data may experience performance issues, errors or hardware failure that lead them to be decommissioned ("Decommissioned Disk"). Every Decommissioned Disk is subject to a series of data destruction processes (the "Data Destruction Guidelines") before leaving CORSANO's premises either for reuse or destruction. Decommissioned Disks are erased in a multi-step process and verified complete by at least two independent validators. If, due to hardware failure, the Decommissioned Disk cannot be erased, it is securely stored until it can be destroyed.


4. Personnel Security

CORSANO personnel are required to conduct themselves in a manner consistent with the company's guidelines regarding confidentiality, business ethics, appropriate usage, and professional standards. CORSANO conducts reasonably appropriate background checks to the extent legally permissible and in accordance with applicable local labor law and statutory regulations.

Personnel are required to execute a confidentiality agreement and must acknowledge receipt of, and compliance with, CORSANO's confidentiality and privacy policies. Personnel are provided with security training. Personnel handling Customer Personal Data are required to complete additional requirements appropriate to their role. CORSANO's personnel will not process Customer Personal Data without authorization.

5. Sub-processor Security

Before onboarding Sub-processors, CORSANO conducts an audit of the security and privacy practices of Sub-processors to ensure Sub-processors provide a level of security and privacy appropriate to their access to data and the scope of the services they are engaged to provide. Once CORSANO has assessed the risks presented by the Sub-processor the Sub-processor is required to enter into appropriate security, confidentiality and privacy contract terms.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

Terms of Use

Welcome to the internet sites of CORSANO Health B.V. (CORSANO).

“CORSANO sites” include

<https://Corsano.com>,

<https://CORSANOcloud.com>,

and other Internet sites on which these Terms of Use are posted. CORSANO is sometimes referred to herein as “we,” “us” or “our”.

PLEASE READ THESE TERMS OF USE CAREFULLY BEFORE USING ANY CORSANO SITE.

By using any CORSANO Site you signify your agreement to these Terms of Use. If you do not agree to these Terms of Use, you may not use the CORSANO Sites.


Note that special terms might apply to some services or features offered on certain CORSANO Sites. These terms are posted in connection with the applicable service or feature. Any such terms are in addition to these Terms of Use, and in the event of a conflict, prevail over these Terms of Use.

CORSANO may modify these Terms of Use at any time by updating this posting. You are bound by any such modification and should therefore visit this page periodically to review these Terms of Use. Your continued use of the CORSANO Sites after a modification signifies your agreement to the modification.

1. Use of Content

The content contained on CORSANO Sites, such as text, graphics, images, audio, video and other material, as well as the domain names, tagline, organization and user look-and-feel (collectively, the “Content”), is protected by copyright, trademark and other such laws in Switzerland and foreign countries, and is owned or controlled by CORSANO or by third parties that have licensed their Content to CORSANO. Unauthorized use of the Content may violate copyright, trademark, and other laws. Where a CORSANO Site is configured to enable the download of particular Content, you may download one copy of such Content to a single computer for your personal, noncommercial home use only, provided that (a) you retain all copyright and other proprietary notices contained in the original Content, (b) you may not sell or modify the Content or reproduce, display, publicly perform, distribute, or otherwise use the Content in any way for any public or commercial purpose without the prior written permission of CORSANO, and (c) you may not use the Content in a manner that suggests an association with any of our products, services or brands.

You may not, without the prior written permission of CORSANO, “mirror” on any other server any material contained on any CORSANO Site. The use of the Content on any other Web site or in a networked computer environment for any purpose is prohibited, without the express written permission of CORSANO. The trademarks, logos and service marks (the “Marks”) displayed on the CORSANO Sites are owned by CORSANO or third parties. You are prohibited from use of those Marks without the express, written permission of CORSANO or such third party. If you would like information about obtaining CORSANO’s permission to use the Content on your Web site, e-mail privacy@corsano.com.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

In the event that we offer downloads of software on a CORSANO Site and you download such software, the software, including without limitation any files, images incorporated in or generated by the software, and data accompanying the software (collectively, the “Software”) is licensed to you by us or third-party licensors for your personal, noncommercial home use only. We do not transfer title to the Software to you. You may not distribute or otherwise exploit the Software or decompile, reverse engineer, disassemble or otherwise reduce the Software to a human-readable form. Unless otherwise specifically and expressly stated elsewhere, CORSANO hereby disclaims all warranties with regard to the software, including without limitation all warranties of merchantability, fitness for a particular purpose, title and non-infringement, whether such warranties are express, implied or statutory.

CORSANO shall not be liable for (1) any inaccuracy, error in or failure of the software; (2) any loss or damage (including without limitation any consequential, indirect, incidental, special or exemplary damages) arising from any download or use made of the software, or occasioned by any such inaccuracy, error or failure of the software. If any of the above provisions are void under applicable law, CORSANO’s liability shall be limited to the full extent permitted by law.

2. Accounts

Some services on the CORSANO Sites permit or require you to create an account to participate or to secure additional benefits. You agree to provide, maintain and update true, accurate, current and complete information about yourself as prompted by our registration processes (the “Registration Data”). You agree not to impersonate any person or entity or misrepresent your identity or affiliation with any person or entity, including using another person’s username, password or other account information, or another person’s name, likeness, voice, image or photograph. You also agree to notify us promptly at privacy@corsano.com of any unauthorized use of your username, password, other account information, or any other breach of security that you become aware of involving or relating to any CORSANO Site.

We may suspend or terminate your account and your ability to use any CORSANO Site or portion thereof for failure to comply with these Terms of Use or any special terms related to a particular service.


3. Modifying and Terminating our Services

We are constantly changing and improving our Services. We may add or remove functionalities or features, and we may suspend or stop a Service altogether. You can stop using our Services at any time, although we’ll be sorry to see you go. CORSANO may also stop providing Services to you, or add or create new limits to our Services at any time.

We believe that you own your data and preserving your access to such data is important. If we discontinue a Service, where reasonably possible, we will give you reasonable advance notice and a chance to get information out of that Service.

4. Liability

CORSANO makes no representations or warranties about the accuracy, reliability, completeness, or timeliness of the Content or about the results to be obtained from using the CORSANO Sites and the Content. Any use of the CORSANO Sites and the Content is at your own risk. Changes are periodically made to CORSANO Sites and may be made at any time. Some Content on the CORSANO Sites may be

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

provided by third parties and CORSANO will not be held responsible for any such Content provided by third parties.

CORSANO does not warrant that the CORSANO sites will operate error-free or that the CORSANO sites or their servers are free of computer viruses or other harmful goods. If your use of the CORSANO sites or the content results in the need for servicing or replacing equipment or loss of profits or data, CORSANO will not be responsible for those costs.

The CORSANO sites and content are provided on an 'as is' basis without any warranties of any kind. CORSANO, to the fullest extent permitted by law, disclaims all warranties, including, but not limited to the warranty of merchantability, non-infringement of proprietary or third party rights, and the warranty of fitness for particular purpose.

5. Warranties and Disclaimers

Your use of the CORSANO Sites is at your own risk. If you are dissatisfied with any of the Content or other contents of the CORSANO Sites or with these Terms and Conditions, your sole remedy is to discontinue use of the CORSANO Sites. In no event will CORSANO or any third parties mentioned at the CORSANO sites be liable for any damages whatsoever (including, but not limited to, incidental, exemplary, and consequential damages, lost profits, or damages resulting from lost data or business interruption) resulting from the use or inability to use the CORSANO sites and the content, whether based on warranty, contract, tort, or any other legal theory, and whether or not CORSANO is advised of the possibility of such damages. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you, in which case such exclusion or limitation applies to the fullest extent allowable under the applicable law.

6. Links to Other Sites


The CORSANO Sites may contain links to third party Web sites that are maintained by others. Any such links are provided solely as a convenience to you and not as an endorsement by CORSANO of the contents on such third-party Web sites. CORSANO is not responsible for the content of linked third-party sites and does not make any representations or warranties regarding the content or accuracy of materials on such third-party Web sites or the privacy practices of such third parties. If you decide to access linked third-party Web sites, you do so at your own risk.

7. Third-party Applications

On CORSANO Sites you might have an opportunity to download applications that were developed by third-parties. CORSANO is not responsible for and makes no representations or warranties regarding the content or functionality of these third-party applications or the privacy practices of such third-party developers. If you decide to download and use any of these third-party applications, then you do so at your own risk.

8. Indemnity

You agree to defend, indemnify, and hold harmless CORSANO, its officers, directors, employees and agents, from and against any claims, actions or demands, including without limitation reasonable legal and accounting fees, alleging or resulting from your breach of these Terms of Use. This indemnification provision does not apply to intentional or reckless acts or gross negligence on the part of CORSANO.

	Investigational Medical Device Dossier (IMDD) CardioWatch 287 20200927	
	IMDD CardioWatch 287 20200927.docx	
	Reference: IMDD CardioWatch 287	Author T. van Deudekom Approval W. Baelde Date: 31-Okt-20

9. Copyright Policy

CORSANO respects the intellectual property rights of others. It is CORSANO's policy, at its discretion and when appropriate, to terminate the accounts of users who may infringe or repeatedly infringe the copyrights of third parties.

To submit a copyright infringement notification to CORSANO, please notify us:

By Email:

support@corsano.com

By Mail:

CORSANO Health B.V.
Isaac da Costalaan 20
1401BH Bussum
The Netherlands

10. Governing Law

The jurisdiction of any disputes will be established in Switzerland. This Agreement shall be governed by and construed in accordance with the laws of The Netherlands. Any and all disputes and legal actions arising out of the interpretation or application of this Agreement shall be disputes resolved by and brought exclusively in the courts of The Hague, The Netherlands. This Agreement shall be interpreted and enforced in accordance with the laws of The Netherlands.

In the event that any portion of this Agreement is held unenforceable, the unenforceable portion shall be construed in accordance with applicable law as nearly as possible to reflect the original intentions of the parties, and the remainder of the provisions shall remain in full force and effect.