



Medical Technology Company Specializing in Cardiology

Corporate presentation

Nov. 22, 2023

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Agenda

- 01** ABOUT MEDICALGORITHMICS SA
- 02** DEVELOPMENT STRATEGY
- 03** ECG AI ANALYSIS
- 04** VCAST AI IMAGING
- 05** APPENDIX

About us



Medicalgorithmics in numbers

The company was founded in

2005

8 k

Physicians is actively
using our products

767 k

Diagnostic reports generated
by our software in 2022

We employ

120+

RnD engineers

Our products are used by

170 k

patients

Presence in

22 Countries

Regulatory clearance to
enter 50+ countries

Who are we and what do we do?

01

We are a technology company that provides advanced software and AI algorithms for non-invasive cardiac diagnostics

02

We develop AI algorithms and software for arrhythmia diagnostics (first FDA approval in 2009)

03

Our software enables the detection of 26 types of cardiac rhythm disorders – highest in industry

04

We are in 4 continents, across 22 countries, including the USA since 2010, Canada, the EU, and Southeast Asia

05

We are developing VCAST technology based on AI, which has the potential to revolutionize the diagnosis of coronary artery disease

06

We have been listed on the Warsaw Stock Exchange (GPW) since 2014 and are included in the sWIG80 index



Milestones in MDG development

2005

Establishment of Medicalgorithmics company

2016

Acquisition of 75% stake in Medi-Lynx Cardiac Monitoring, LLC in the USA

2022

Investment in Biofund

2009

FDA clearance for the PocketECG system for sale in the USA

2022

FDA registration obtained for the DeepRhythmAI system

2022

Inclusion of Kardiolytics Inc. into the MDG Group

2014

Debut on the Main Market of the GPW

2022

Obtaining FDA registration for the QPatch device

2022

Sale of Medi-Lynx



The Management Board of Medicalgorithmics S.A.



MACIEJ GAMROT

CFO at Medicalgorithmics S.A.
CFO at Kardiolytics Inc.

Previously:
PwC, EY, Agora, Platige Image,
Audioteka, Dobroplast Fabryka Okien /
Arbonia AG

Education:
University of Lodz; ACCA, CIA

CFO of Medicalgorithmics since 2021.



JAROSŁAW JERZAKOWSKI

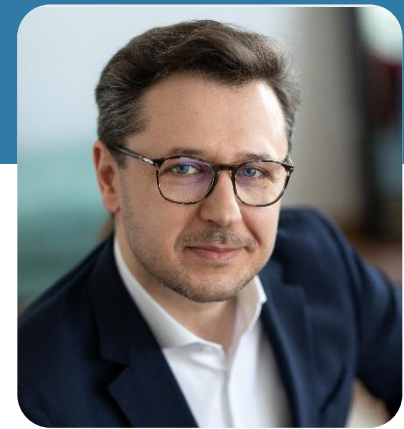
COO, Member of the Management
Board of Medicalgorithmics S.A.

Previously:
Konica Minolta Business Solutions, Adrem
Software

Education:
Cracow University of Economics -
International Trade and International
Business;

University of Mannheim - EMBS
17 years of experience in the IT industry,
responsible for global business
development and marketing.

With Medicalgorithmics since 2013.



PRZEMYSŁAW TADLA

CTO Member of the Management
Board of Medicalgorithmics S.A.
COO at Kardiolytics Inc.

Previously:
Kardiolytics Inc., Biometryks LLC,
Medicalgorithmics, UL International

Education:
Poznan University of Technology
(Automation and Management)
24 years of professional experience,
including over 15 years of experience in the
med-tech industry.

From 2013 to 2021 at Medicalgorithmics as
Director of Strategy and later as Chief
Operating Officer.

MDG Group structure

100%
of shares

100%
of shares

100%
of shares

97%
of shares



Kardiolytics

MEDICALgorithmics

US Holding
Corporation

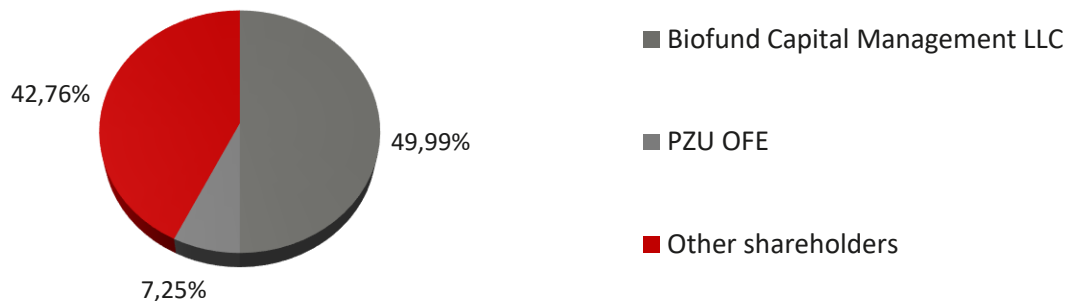


mobileHolter

MEDICALgorithmics

India Private
Limited

MDG shareholders structure, ownership and voting

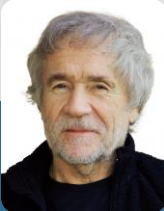


Kardiolytics and Biofund

BioFund's mission is to utilize cutting-edge artificial intelligence and advanced technologies to accelerate progress in medicine, provide advanced medical procedures to those who currently lack access to sophisticated care, and thus make the world a better place.

Kardiolytics Inc. is an artificial intelligence company based in Chicago specializing in cardiology. The company was founded in 2018 by Dr. Paul Lewicki, a pioneer in the field of Data Mining and Big Data Learning (founder of StatSoft and STATISTICA), and Dr. Kris Siemionow, a surgeon (founder of AI-based medtech companies HoloSurgical and Inteneural, both acquired). The company comprises a team of physicians, researchers, and AI software engineers. Its main headquarters and research and development center are located in the USA (Chicago), with two additional research and development centers in Poland (Poznań and Zabrze).

Our goal is to make advanced and highly accurate heart diagnostics affordable and widely accessible, even in parts of the world that currently have limited access to advanced medical diagnostics. The technology developed by Kardiolytics enables physicians to quickly analyze cardiac and vascular medical imaging data, allowing for effective treatment planning.



prof. dr hab. Paweł Lewicki



- He was a professor of psychology at UT
- Founder and CEO of StatSoft (acquired by Dell in 2014).
- A pioneer in Big Data
- An entrepreneur and CEO of a large international company (StatSoft had 30 foreign offices in major markets and over 1 million B2B users from various industries)
- Former director of a NASDAQ technology company.
- H-index of 22
- >8000 citations



dr n. med. Krzysztof Siemionow



- He was the former head of spine surgery and associate professor of orthopedic and neurosurgery at the University of Illinois
- Co-founder of HoloSurgical (AI in neurosurgery).
- Co-founder of Inteneural Networks (Brain MRI analysis); acquired
- Former medical director of a NASDAQ medtech company.
- Author of over 100 scientific publications
- Holder of over 50 patents
- H-index of 18



Strategy

04



Group Strategy 2023 -2026



A new business model based on offering products in a non-exclusive model. Additionally, PocketECG AI software is offered as a standalone product



Offering new VCAST cardiac imaging software. FDA approval and commencing commercialization from 2024



Development of modern software, AI/ML algorithms, and cloud-based solutions for the healthcare sector



Integration of proprietary software with third-party devices for cardiac diagnostics



Conducting scientific research to support the development of cutting-edge medical technologies



Building value through organic growth and valuable business and technological partnerships, including mergers and acquisitions

A global provider of non-invasive cardiac diagnostic technology, offering proprietary software for medical data analysis, AI/ML algorithms, and software for integration with third-party devices (a device-agnostic system)

Currently
2023



The future vision
2026

KPI

SALES (USA)

USA: ensure **growth in revenue** and number of daily examination* **from 2024 y/y**

SALES (OUS)

OUS: continued **growth in revenue** and number of daily examination of min. **15 - 20% on average per year**

OPERATING PROFITABILITY

Increase in operating profitability from 2H 2024 thanks to high operating leverage

R&D

R&D expenditures for cardiac rhythm analysis and cardiac imaging products at **12 - 15 million zloty per year.**

Offering a completely new type of VCAST cardiac imaging software.

FDA and start commercialization from 2024.

* **Daily examination** – equivalent to a 24-hour EKG signal analyzed by the Company's software. For example, 1 MCT study lasting 25 days, 7 24-hour Holter studies, and 3 days of EKG signal of an unspecified type as per reimbursement, would amount to a total of 35 examination

Summary of the most important developments

DEVELOPMENT STRATEGY	The new strategy announced in June this year brings results
ORGANIZATIONAL CHANGES	Commercial and operational optimization: Jarosław Jerzakowski was promoted to the position of COO, capitalizing on his extensive knowledge of the company and the industry
NEW CONTRACTS IN THE USA	Contracts: 3 with IDTF from the US: 2 for providing AI software, 1 for software with P4 devices. Technology evaluation, option for CE certification aiming at long term partnership with a TOP3 US player
VCAST TECHNOLOGY	On track: CE certification of VCAST cardiac imaging technology started October 2023 Kardiolytics obtained in August this year. 2 new European patents
HARDWARE DEVELOPMENT	Concluding an agreement in August this year with German medical device supplier livetec - new Patch
OUS (outside the US)	2 Integrations and pilots of software with leading global ECG device manufacturer and European leader in cardiac diagnostic services - the goal is partnership and reve share. Canada: contract extension for 4 years contract m- Health Solutions Inc. on soft AI and P4
POLAND - WON TENDERS	Tenders won in August this year for the delivery of solutions for remote cardiology diagnostics to medical facilities in Białystok and Katowice

Integration of proprietary software for important partnerships

Agreement with a TOP3 player from the USA, NASDAQ listed,

MOU agreement with leading ECG devices manufacturer

MOU with European leader in cardiac diagnostic services

Cooperation with livetec (Germany) – new Patch

- US Player Agreement: AI Software Integration with ECG patch recorder, evaluation, option for joint CE and significant collaboration
- 2 MOUs with device manufacturer and cardiac monitoring co.: always starts integration of AI software with partner's devices (some devices already integrated), commercial pilots for evaluating the effectiveness of MDG's AI software, the goal is partnership and cooperation based on the revenue share model.
- Agreement with the German supplier of livetec medical devices. In the first stage, the livetec recorder together with the Medicalgorithmics software will be available in the EU and in the UK, Canada and India
- Integrations with devices and systems of acquired partners: 3 IDTFs in the US

Expansion in North America

Signing of 3 agreements with American IDTFs (USA)

Extension of cooperation with m-Health Solutions Inc. (Canada)

- Agreements with 2 IDTFs (Independent Diagnostic Testing Facility) and 1 IDTF (in the organization) to provide software and algorithms for cardiology diagnostics - building a diversified portfolio of customers
- After successful completion of the integration process, Medicalgorithmics solutions are to be used to analyze ECG tests from US IDTF devices
- Annexing the contract with m-Health Solutions Inc. for the delivery of the PocketECG IV system with software
- The annex provides for the replacement of the older version of PocketECG with the latest version (PocketECG IV) by the end of 2023 and a 4-year contract on equipment leasing
- End cooperation with the former exclusive US distributor by Dec. 2023, as assumed in the MDG new strategy, to be replaced with new contracts



Strengthening the position on the Polish market

Winning tenders

- In August this year we won 2 tenders to provide a comprehensive ecosystem for diagnosing heart diseases for medical facilities (Katowice and Białystok)
- We were the only bidder that met the criteria in both tenders
- Total value of won tenders: PLN 2.5 million gross



Technology

- **ECG - arrhythmia diagnostics**
- **VCAST Autonomous CT analysis**

Scientific research

Scientific research has always been an integral part of the company's research and development activities. Since November 2022, Dr. Linda Johnson, a professor at Lund University, has taken over the supervision of clinical research work conducted in the company.



> **Atrial Fibrillation Prediction**

Project coordinated by Dr. Sanjeev Bhavnani, conducted by Scripps Clinic & Research Foundation, and supported by BMS (Bristol-Myers Squibb)

Main objective: Utilizing deep learning methods for precise prediction of atrial fibrillation morphology.

> **Monitoring after TAVI**

Project coordinated by Dr. Madhu K. Natarajan, conducted by PHRI (Population Health Research Institute, Hamilton Health Sciences)

Main objective: Remote monitoring of EKG to reduce complications following transcatheter aortic valve implantation (TAVI).

> **Monitoring after CABG Procedure**

Project led by Dr. Michael DiMaio, conducted by Cardiothoracic Surgical Trials Network in collaboration with the American College of Cardiology

Main objective: Determining the incidence of postoperative atrial fibrillation (POAF) 30 days after coronary artery bypass grafting (CABG) using continuous mobile cardiac telemetry.

> **Alternative to ILR Implantation**

Project coordinated by Dr. Andrea Russo (President of the Heart Rhythm Society), conducted by CUHC (Cooper University Health Care)

Main objective: Comparing implantable loop recorders (ILRs) and mobile telemetry monitoring for detecting silent atrial rhythm disorders in patients with cryptogenic stroke.

A leader in medical technology

AI/ML Algorithms

Research is being conducted on new algorithms for automatic analysis of EKG and CT data

Cloud Platforms

Currently, work is underway on a proprietary platform for EKG data analysis and a platform for CT data analysis

Medical software

The company offers and continuously improves software used in monitoring centers and hospitals

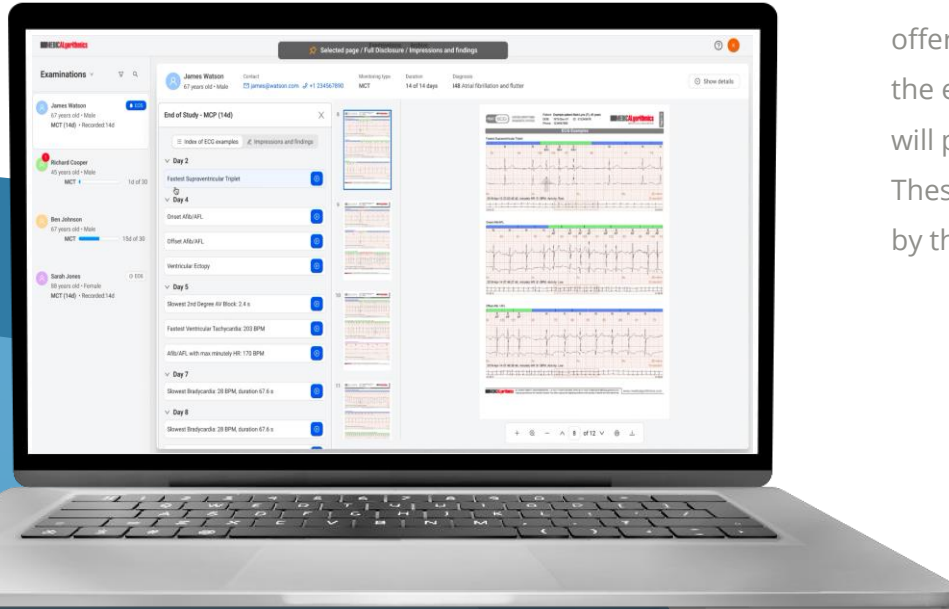
Collaboration with other MedTech companies

Active collaboration with other companies is carried out to jointly develop new medical products



DeepRhythm Platform

The new cloud platform will be an alternative to the currently offered ECG analysis software by the company. In addition to the existing functionalities available to customers, the platform will provide entirely new features utilizing predictive analytics. These will significantly enhance the quality of analysis provided by the platform.



- Cloud-based platform for ECG analysis
- Analytics using DRAI, state-of-the-art AI algorithms
- Can analyze signals recorded by Qpatch, PocketECG, and devices from other companies
- Designed for seamless integration with software and ECG monitoring devices from other companies
- Capable of generating automatically generated reports
- In FDA and CE certification processes

ECG Analysis workflow

An appointment in a physician's office for prescribing a 24-hour Holter or long-term ECG monitoring by a physician



Patient hook-up. Start of the ECG recording



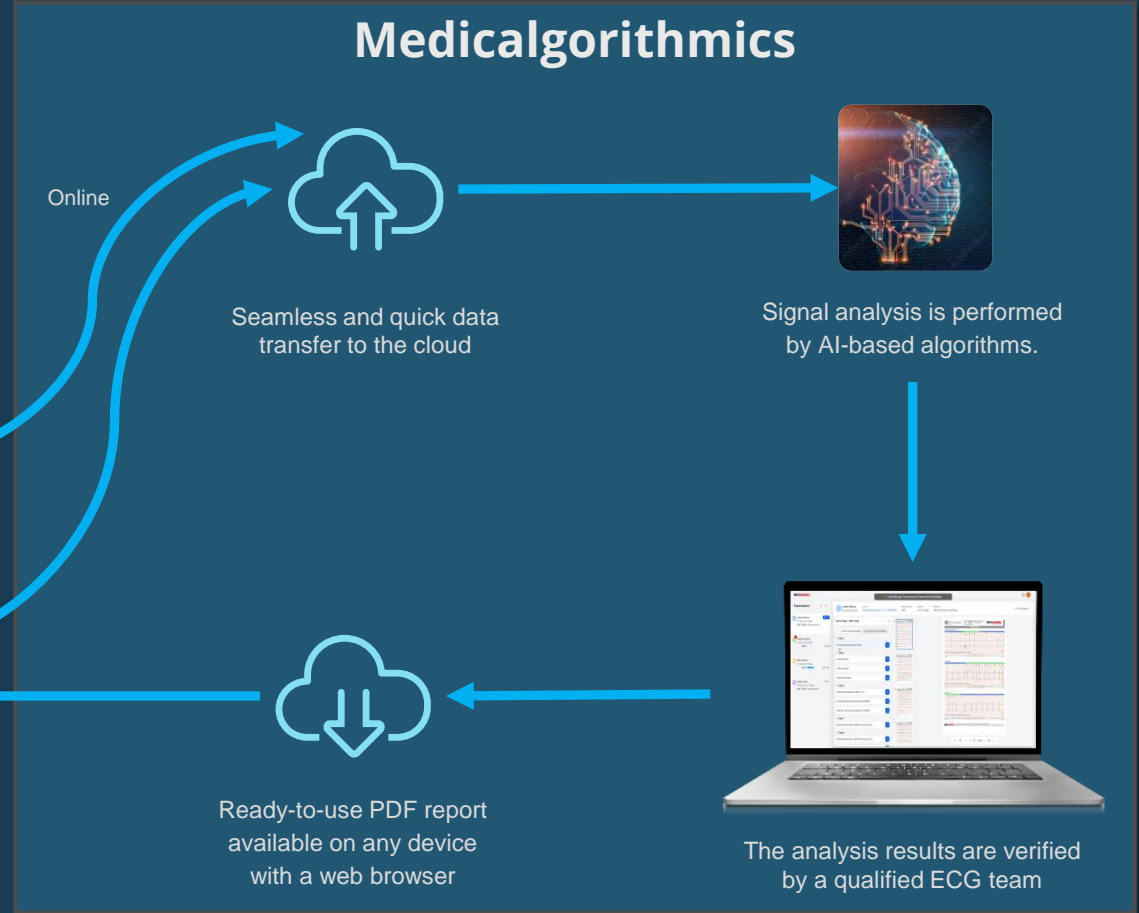
ECG Signal Recording Online download



End of the ECG signal recording. Data are uploaded to the cloud for signal analysis.



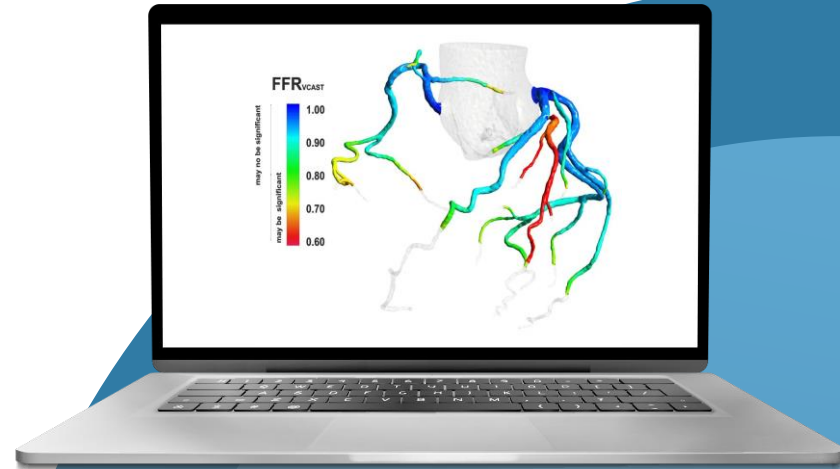
The report is delivered to the doctor, who can then make a decision regarding the next steps



VCAST – Autonomous CT analysis

VCAST is cloud-based software with a unique technological advantage of AI algorithms for segmentation and reconstruction of narrowed vessels. It provides personalized, color-coded 3D modeling of coronary arteries along with detailed functional diagnostic information related to blood flow. This includes calculated blood volumes, pressure, and velocity, aiming to assist the physician in both diagnosis and designing a treatment plan for coronary artery disease.

- AI-based coronary analysis for submitted computed tomography scans (3D model segmentation and vessel reconstruction using mesh models)
- Cloud-based numerical simulation
- Detection of plaque location and basic plaque classification - soft, calcified
- The user will have access to vessel parameters such as color-coded diameter and diameter in mm, degree of coronary vessel stenosis, and FFR value
- Automatically generated reports



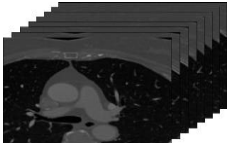
VCAST – Autonomous CT analysis



Computer Tomography



DICOM Data

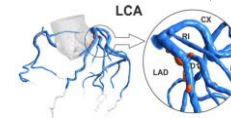


Cloud software for autonomous CT analysis

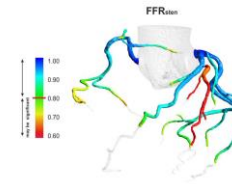
AI Powered
Vessel Segmentation
and Reconstruction

No CAD

Stenosis <50%



Stenosis >50%



Regular monitoring



Pharmacotherapy



Invasive therapy



VCAST – competitive landscape

	VCAST™	HeartFlow®	clearly
FFRct	✓	✓	—
RFR	✓	—	—
EFR	✓	—	—
Stenosis	✓	✓	✓
Plaque assessment	Full	Full	<ul style="list-style-type: none"> ● Non-Calcified Plaque (NCP) ● Calcified Plaque (CP) ● Low-Density Non- Calcified Plaque (LD- NCP)
Distance Measurements	✓	✓	✓
Segmentation of region of interest	Automatic	Manual and Semi-Automatic	Manual and Semi-Automatic
Turnaround time	< 2h	> 4h	> 2h
Product Approvals	USA, Europe (planned)	USA, Europe, Japan	USA
Amount Raised	-	\$682M	\$281M
Company Valuation	N/A	\$1.5b ¹	\$0.9–1.3b ²



Main directions of current research and development work



Research on the next generation of AI/ML algorithms for ECG and CT image analysis



Development of cloud platforms for ECG and CT data analysis



Development of software for ECG and CT data analysis centers



Development of middleware software enabling fast integration of applications



Integrations with devices for long-term patient monitoring offered by the third-party companies



Custom development for current customers

International team of sales leaders and clinicians



JAROSŁAW JERZAKOWSKI
Chief Operational Officer



JAROSŁAW JERZAKOWSKI
COO
Intedependent salesreps network
od c.35 salesman



COR JONGEN
Business Director
EMEA



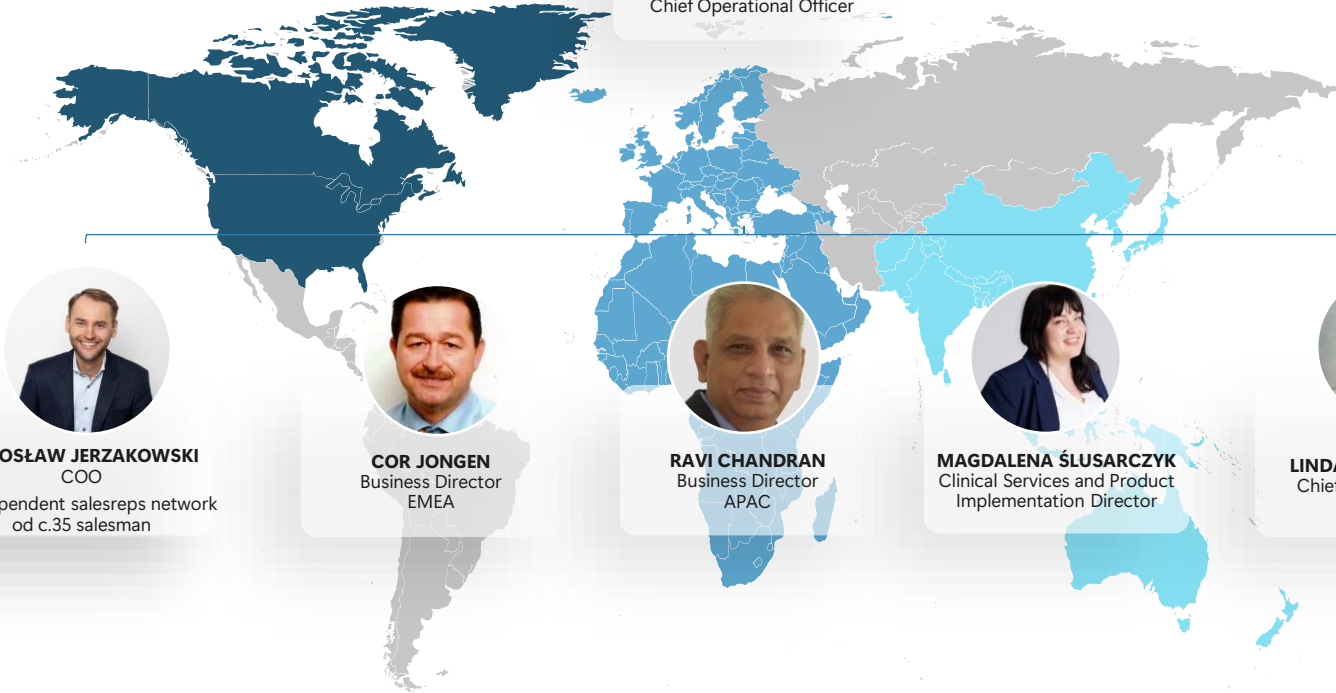
RAVI CHANDRAN
Business Director
APAC



MAGDALENA ŚLUSARCZYK
Clinical Services and Product
Implementation Director



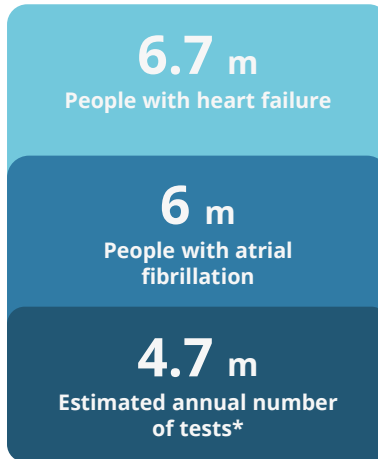
LINDA JOHNSON PHD
Chief Scientific Officer



USA: Market potential for arrhythmia diagnostics and coronary disease diagnostics (VCAST)



Market opportunities for arrhythmia diagnostics:



Reimbursement amount for:

- Holter - \$73,54
- Extended Holter - \$274,49
- Event - \$180,62
- MCT - \$874,97



Market opportunities for cardiac imaging



Reimbursement amount for:

- FFRCT - \$900,72
- Analysis of atherosclerotic plaque - \$950

All providers receive market rates of **10 to 20% reimbursement.**

*The given number includes Holter, Extended Holter, Event, and Mobile Cardiac Telemetry tests.

Strategy for international expansion OUS (arrhythmia and VCAST)

Focus on current OUS markets and new countries with the highest growth potential

NORTH AMERICA

Canada

Market potential

350 000

Patients with atrial fibrillation

2 600 000

Patients with coronary artery disease

Next steps

- Increasing business in additional key provinces in Canada outside of Ontario
- Introducing a new offering and monetizing our existing PocketECG software for client and AI analysis of EKG signals from third-party devices, and optionally selling pre-integrated EKG devices
- Preparing and commercializing VCAST technology through current and new sales channels

EMEA

UK, Switzerland, Austria, Sweden, Denmark, Israel

Market potential

2 627 377

Patients with atrial fibrillation

3 937 131

Patients with coronary artery disease

Next steps

- Supporting the commercialization of EKG diagnostics in newly contacted countries: United Kingdom, Switzerland, Austria, Israel, Sweden.
- Introducing a new offering and monetizing our existing PocketECG software for client and AI analysis of EKG signals from third-party devices, and optionally selling pre-integrated EKG devices
- Preparing for market entry in new markets: Germany, France, and Saudi Arabia
- Preparing and commercializing VCAST technology through current and new sales channels

APAC

Australia, India, Philippines, Indonesia

Market potential

10 718 113

Patients with atrial fibrillation

45 306 188

Patients with coronary artery disease

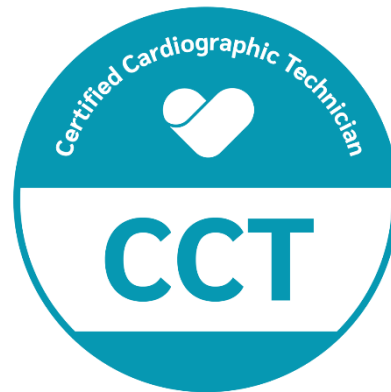
Next steps

- Supporting the commercialization of EKG diagnostics in newly contacted countries: Philippines and Indonesia
- Introducing a new offering and monetizing our existing PocketECG software for client and AI analysis of EKG signals from third-party devices, and optionally selling pre-integrated EKG devices
- Preparing for market entry in new markets: Japan and South Korea
- Preparing and commercializing VCAST technology through current and new sales channels

ECG Analysis services

Our ECG technicians hold the following certificates:

- US Certified Cardiographic Technicians (CCT)
- UK Certificate in Electrocardiography by Society for Cardiological Science and Technology (SCST)



We offer ECG over-reading services in two locations



In Poland for customers from Europe and North America



In India for customers from Asia and the Middle East

OUS: Current markets with the highest growth potential

UK

Population with AF*: 1,73 mln¹

Reimbursement: €215

CANADA

Population with AF: 350 tys.³

Reimbursement: €50 - €277

UEA

Population with AF: 180 tys.⁵

Reimbursement: €75 - €745

ISRAEL

Population with AF: 180 tys.⁷

Reimbursement: €120 - €163

SWEDEN

Population with AF: 305 tys.²

Reimbursement: €137 - €317

DENMARK

Population with AF: 178 tys.⁴

Reimbursement: €83 - €120

AUSTRALIA

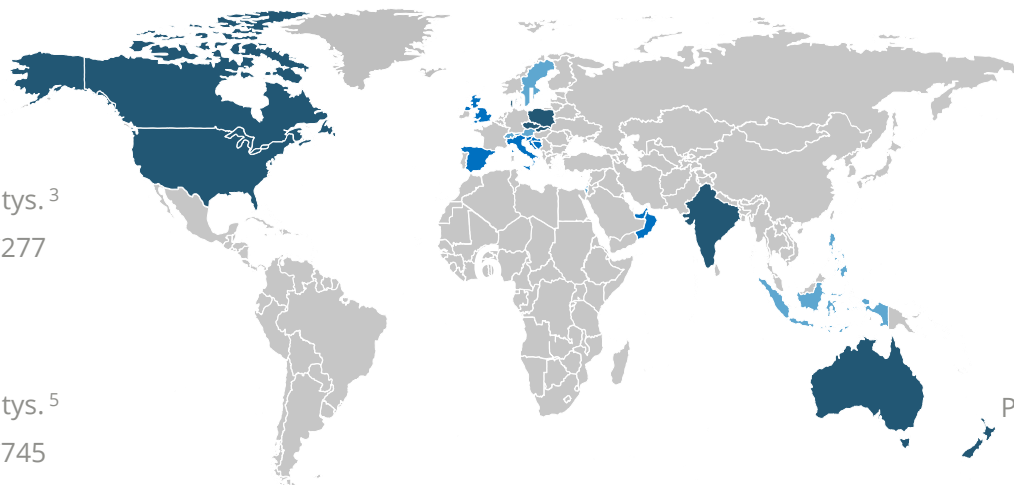
Population with AF: : 178 tys.⁶

Reimbursement: €85

SWITZERLAND

Population with AF: 0,94 tys.⁸

Reimbursement: €182 - €203



■ active and performing countries

■ markets we have recently entered

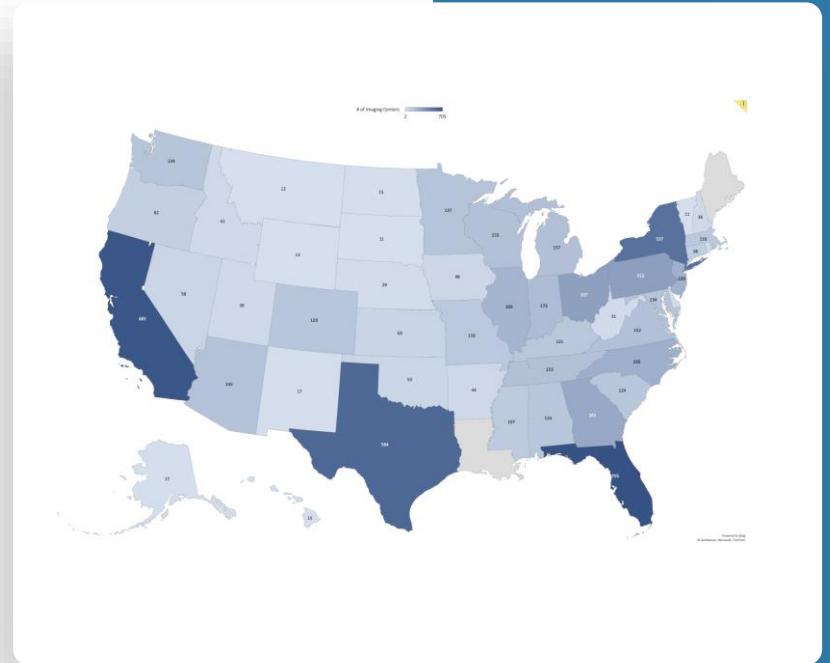
■ market penetration space

*AF (atrial fibrillation)

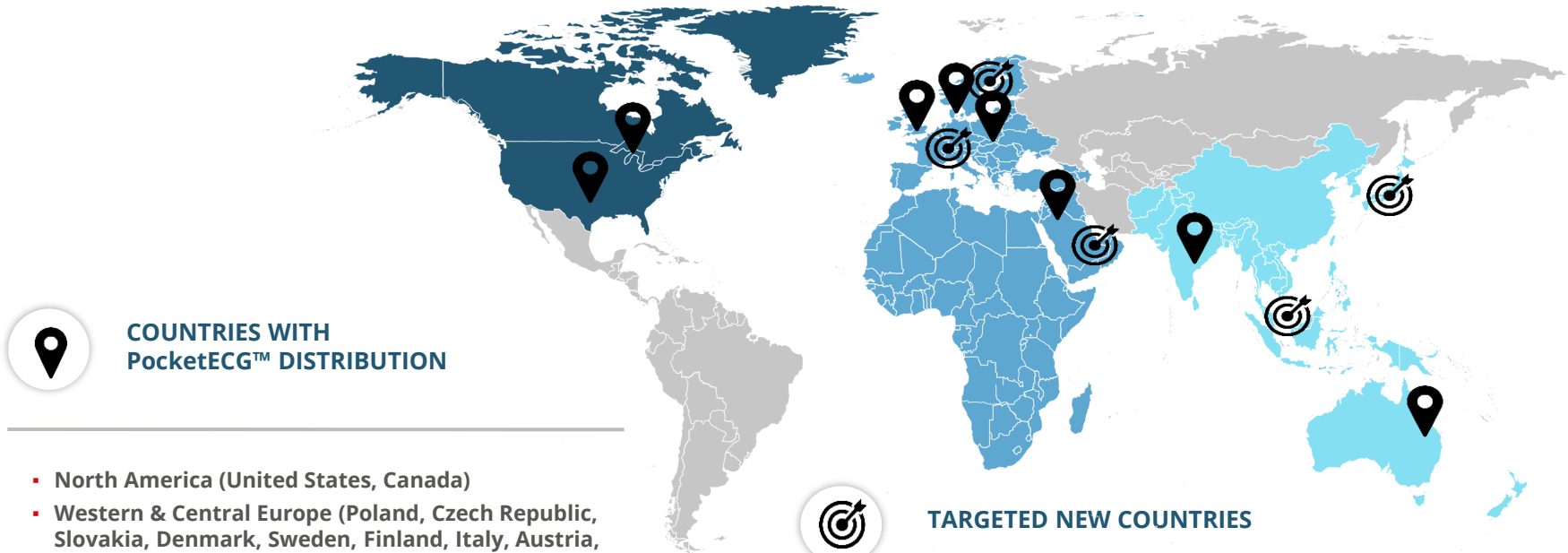
VCAST - STRATEGY for the USA:

Preparation and commercialization directed at key US states with the greatest potential.

- More than 20 million Americans have coronary artery disease (according to the CDC)
- VCAST will be offered to imaging facilities
- Currently, the company has identified 10,116 imaging facilities with the required accreditation and reimbursement agreements
- The four largest states in terms of the number of imaging facilities are California, Florida, New York, and Texas
- Interventional cardiologists, radiologists, and diagnostic radiologists have been identified as the primary users of VCAST
- In later stages of VCAST commercialization, the company will also target other cardiology specialties, as not all physicians actively use cCTA reports



Increasing Global Reach to Serve Growing Global Opportunity



COUNTRIES WITH PocketECG™ DISTRIBUTION

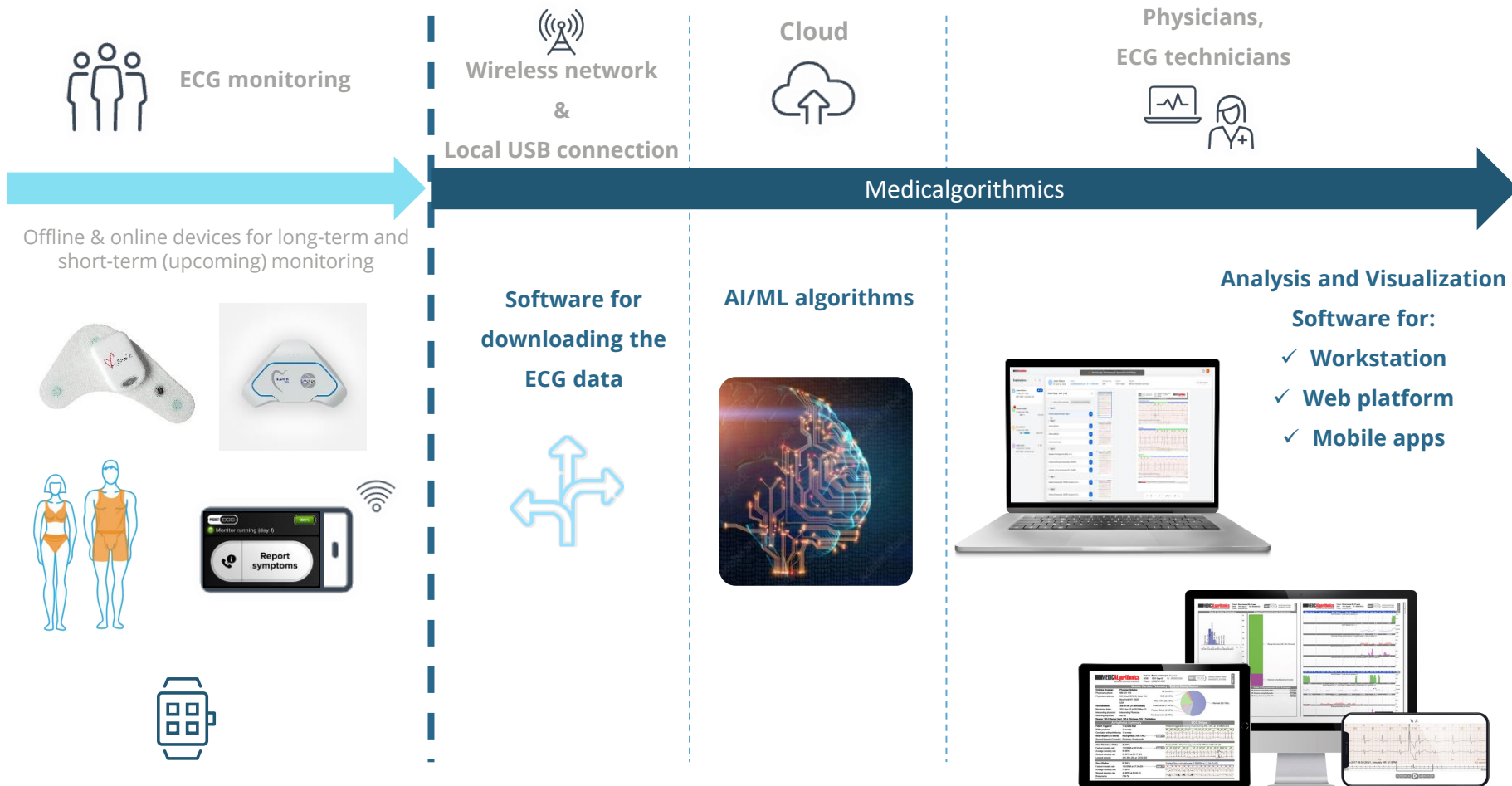
- North America (United States, Canada)
- Western & Central Europe (Poland, Czech Republic, Slovakia, Denmark, Sweden, Finland, Italy, Austria, Spain, Switzerland, Slovenia, UK)
- Middle East (United Arab Emirates, Oman)
- Israel
- APAC (India, Australia & New Zealand, Indonesia, Philippines)



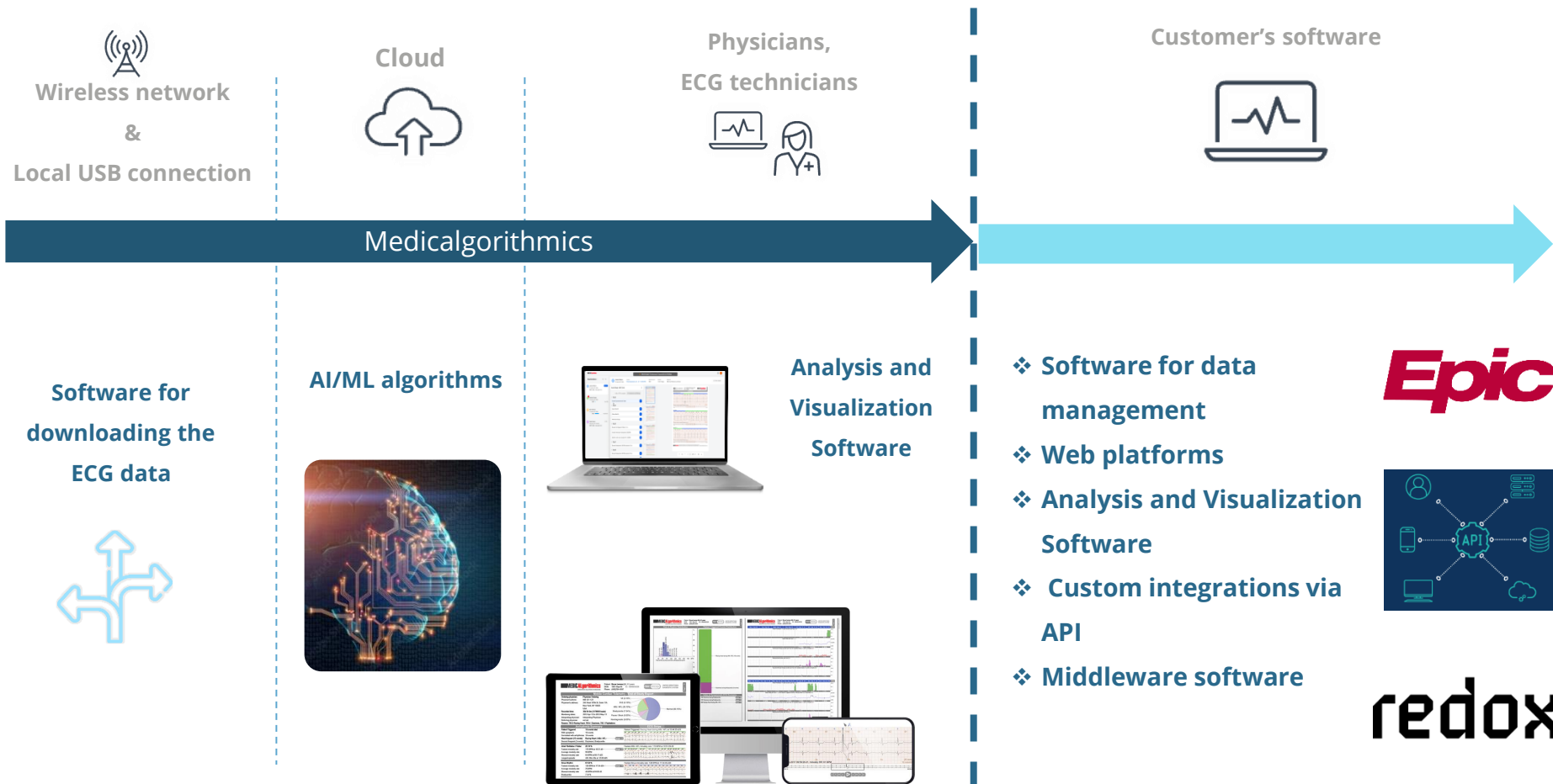
TARGETED NEW COUNTRIES

- Europe [Norway, Germany, France]
- Middle East (Kingdom of Saudi Arabia)
- APAC (Singapore, Vietnam, Malaysia, Thailand, Hong Kong, Taiwan, Japan, South Korea).

Integrations with Third-party Wearables



Integrations with Third-party Software



Integrations – Benefits for our customers



Customer 1

Medicalgorithmics software integrated with third-party ECG devices

- ✓ The PC Client software is integrated with MDG and third-party devices, which gives our customer great flexibility in tailoring their offerings to end customers.
- ✓ The PC Client offers the highest number of detected cardiac rhythm disorders (26).
- ✓ The PC Client provides the highest diagnostic accuracy through the utilization of AI algorithms for signal analysis.

Customer 2

Medicalgorithmics software integrated with external web platform and third-party ECG devices

- ✓ The PC Client software is integrated with MDG and third-party devices, giving our customer the ability to reach new market segments.
- ✓ The PC Client software optimizes the process of ECG data analysis, reducing it to a matter of minutes. This allows for the analysis of more data with the same workforce.
- ✓ The integration of MDG software into the customer's web platform for patient management resulted in cost savings. PC Client was integrated into the processes present in the company.

Summary

01

We are successfully executing a business model transformation and growing into a global provider of innovative solutions for the healthcare sector

02

We expect that the implementation of the strategy will positively affect the company's value and strengthen its market position in the long term

03

We are focusing on the US market, where we have the greatest potential for growth through our technology and with the support of a new strategic investor (Biofund)

04

Our technological advantages enable us to scale our solutions globally
We are well positioned to scale our operations in the US, Europe and Asia

05

Growing demand for diagnostics supported by AI algorithms and increase in number of patients requiring cardiac diagnostics



Outlook for the next quarters



Implementation of the new strategy and transformation of the business model



Ability to contract with new customers



Efforts to complete certification of VCAST technology in the EU



Preparations to begin certification of VCAST technology in the US



2023 is a transition year; we are building a solid base for further development



Expected demand for the company's software

A hand in a dark suit jacket and blue tie points towards a glowing white arrow that points upwards and to the right. The arrow is set against a digital dashboard background featuring a grid, a bar chart, and a line graph. The line graph shows a sharp upward trend, with a bright green light at the tip of the arrow. The dashboard includes a legend with the following items: EVOLUTION, METRIC, ACTUAL VS TARGET, REVENUE, PROFIT, ONTIME DELIVERY, AVG. ORDER SIZE, NEW CUSTOMERS, MARKET SHARE, and CUSTOMERS SATISFACTIONS. The word 'EVOLUTION' is also visible on the person's jacket. The overall color scheme is blue and green, with a large blue wave shape at the bottom left.

Finance

Appendix: Analyst coverage by Ipopema Securities Coverage

@ 29 Sept. 2023	PLNm	PLN/share
ECG business - DCF valuation (EV)	137.0	13.8
Kardiolytics - rNPV valuation (EV)	247.0	24.8
Enterprise value	383.9	38.6
Net cash (1Q23)	26.4	2.7
Fair value	410.3	41.2

Source: [analzy-medicalgorithmics-a-new-hope.pdf \(ipopemasecurities.pl\)](#)

Appendix: Stock performance



MEDICALG - company quotations

Reference rate:	PLN 7.1900 <small>(22/09/28)</small>
Starting date:	2022-09-29
End date:	2023-11-15
Change:	275.52%
Change:	PLN 19.8100
Minimum:	PLN 6.4000 <small>(22/09/30)</small>
Maximum:	PLN 46.8000 <small>(23/08/14)</small>
Mediocre:	PLN 21.3548
Trading volume:	13,908,937 pcs
Average volume:	48,975 pcs
Turnover:	298.691 million
Average revolutions:	1.052 million

Financing secured

MDG has secured funding secured to achieve strategic objectives until 2026

- ECG business delivers positive opex cashflows, new business will deliver increased revenues from mid 2024
- We have the support of a strategic investor (Biofund)
- We will consider supporting R&D projects with grants (e.g., NCBiR)
- We focus on organic growth through acquisition of new customers
- Capital expenditures mainly for further technological development
- We do not rule out potential M&A in the future to increase technological competence and geographic reach, beyond the current strategic plan and financing

Selected financial data (H1 2023)

Revenues yoy

PLN 20.1m

compared to PLN 26.7m a year earlier

Net profit yoy

PLN 0.3m

compared to PLN -48.5m loss a year earlier

Positive operating cash flow yoy

PLN 0.5m

compared to PLN -4.7m a year earlier

Increase in cash yoy (30.06.23)

PLN 33.3m

compared to PLN 8.7m a year earlier

Medicalgorithmics S.A. Group Consolidated P&Ls (extracts)

	000 PLN	2016	2017	2018	2019	2020	2021	2022	1Q23	2Q23
Sales revenue		127 921	203 354	199 404	173 870	111 734	120 563	62 719	11 290	9 705
Consumption of materials and energy		(3 328)	(6 250)	(9 085)	(8 303)	(8 542)	(7 394)	(12 354)	(750)	(2 009)
Employee benefits		(55 267)	(106 581)	(110 549)	(102 103)	(91 144)	(82 458)	(17 093)	(4 892)	(4 153)
Depreciation		(4 594)	(12 470)	(11 579)	(18 717)	(15 896)	(17 546)	(4 020)	(917)	(425)
External services		(41 443)	(30 411)	(33 831)	(37 648)	(30 629)	(33 163)	(12 218)	(2 774)	(3 147)
Other costs		(4 071)	(5 337)	(6 211)	(7 437)	(3 868)	(4 247)	(657)	(174)	(274)
Total operating expenses		(108 703)	(161 049)	(171 255)	(174 208)	(150 079)	(144 808)	(46 342)	(9 507)	(10 008)
Profit / (loss) on operating activities		46 530	41 820	24 724	(85)	(37 508)	(166 711)	17 212	1 899	(552)
Net profit / (loss) from continuing operations		42 004	33 653	18 948	(299)	(27 676)	(180 638)	18 088	1 519	(1 242)
Net profit/(loss) from discontinued operations		-	-	-	-	-	-	(48 492)	-	-

The presented financial data comes from published financial statements, which only in their entirety provide a complete picture of the results of the Medicalgorithmics S.A. Group

Financial reports can be downloaded at: <https://www.medicalgorithmics.com/investors/financial-reports/>

Medicalgorithmics S.A. Group Consolidated Balance Sheets (extracts)

000 PLN	31.12.2016	31.12.2017	31.12.2018	31.12.2019	31.12.2020	31.12.2021	31.12.2022	31.03.2023	30.06.2023
Intangible assets	237 383	196 900	210 454	209 717	201 767	50 571	63 920	65 325	67 471
Tangible fixed assets	22 112	17 249	14 685	31 705	23 535	26 996	2 003	1 740	2 014
Other financial assets	18 744	10 910	200	200	200	97	20	20	20
Deferred tax assets	2 085	3 514	1 831	5 240	17 161	-	-	-	-
Non-current assets	280 325	228 573	227 170	246 862	242 663	77 664	65 943	67 085	69 505
Inventory	-	-	-	-	-	-	8 771	9 898	10 179
Trade receivables	29 867	23 951	22 781	25 250	24 544	25 079	7 857	5 342	5 885
Cash and cash equivalents	47 540	32 531	60 189	11 150	16 197	11 667	26 165	39 059	33 276
Current assets	89 566	60 708	88 912	36 400	40 741	36 746	42 793	54 299	49 340
TOTAL ASSETS	369 891	289 281	316 082	283 262	283 404	114 410	108 736	121 384	118 845
Share capital	361	361	361	361	433	498	995	995	995
Reserve capital	124 622	124 622	124 622	124 622	137 129	148 123	210 982	210 982	210 982
Retained earnings	40 108	58 434	72 032	76 311	75 880	(104 758)	(135 340)	(133 821)	(116 523)
Foreign exchange differences	8 709	(19 816)	(7 151)	(5 454)	(6 087)	3 522	3 433	7 068	(1 580)
Equity attributable to equity holders of the parent company	176 970	168 913	189 864	195 840	207 355	47 385	80 070	85 224	93 874
Non-controlling interests	37 976	34 820	40 898	28 882	10	9	9	9	9
Provisions	414	1 170	1 790	2 023	2 973	105	191	234	182
Deferred income tax provision	3 659	2 250	3 306	3 343	5 331	4 378	8 293	9 181	8 071
Credits and loans	-	-	216	9 845	12 128	8 123	-	-	-
Other financial liabilities	76 961	63 794	7 479	14 394	17 182	10 784	4 244	3 029	2 407
Other liabilities	-	120	80	-	-	144	147	147	147
Accruals	629	315	386	1 026	1 279	3 227	4 178	4 178	4 719
Long-term liabilities	81 663	67 649	13 257	30 631	38 893	26 761	17 053	16 769	15 525
Credits and loans	69	873	111	3 057	2 928	1 519	9	-	1
Provisions	-	-	-	-	-	3 200	641	1 618	1 999
Other financial liabilities	10 511	7 887	58 399	13 015	7 144	8 008	5 006	4 916	4 505
Trade and other liabilities	61 752	7 522	10 717	9 444	13 588	18 416	5 788	5 409	2 739
Accruals	509	1 306	2 572	2 339	13 446	8 999	35	7 316	35
Current liabilities	73 282	17 899	72 063	27 909	37 146	40 255	11 604	19 382	9 437
Total liabilities	154 945	85 548	85 320	58 540	76 039	67 016	28 657	36 151	24 962
TOTAL LIABILITIES AND EQUITY	369 891	289 281	316 082	283 262	283 404	114 410	108 736	121 384	118 845

The presented financial data comes from published financial statements, which only in their entirety provide a complete picture of the results of the Medicalgorithmics S.A. Group. Financial reports can be downloaded at: <https://www.medicalgorithmics.com/investors/financial-reports/>

Medicalgorithmics S.A. Group Consolidated Cash Flows (extracts)

000 PLN	2016	2017	2018	2019	2020	2021	2022	1H 2023
Cash flows from operating activities								
Net profit (loss)	42 004	33 653	18 948	(299)	(27 676)	(180 638)	(30 404)	276
Depreciation of property, plant and equipment	2 932	5 481	4 969	11 061	8 157	10 396	1 482	612
Depreciation of intangible assets	1 662	6 989	6 610	7 656	7 739	7 137	2 741	729
Income tax	3 912	(594)	3 625	(2 076)	(12 208)	17 343	1 804	(99)
Change in inventory	-	-	-	-	-	-	(1 633)	(1 408)
Change in trade and other receivables	(16 033)	(5 725)	633	(1 664)	6 104	(2 889)	(36 290)	1 972
Change in prepayments and accruals	(1 008)	483	952	(64)	11 108	(2 499)	11	(638)
Change in trade and other liabilities	(1 171)	(14 265)	3 088	(1 288)	2 300	4 972	(51)	(3 048)
	35 477	28 611	44 232	13 499	(3 956)	(6 479)	6 331	458
Cash flows from investment activities								
Proceeds from the sale of investments	19 520	15 885	8 661	-	-	103	19 957	13 282
(Purchase)/sale of intangible assets	(3 108)	(35 652)	(5 050)	(4 923)	(4 590)	(5 969)	(12 374)	(4 533)
(Acquisition)/sale of other investments	-	(80)	346	5 952	-	-	-	-
Adjustment of cash on disposal of investments	-	-	-	-	-	-	(9 395)	-
	(80 702)	(22 026)	2 407	(2 793)	(5 005)	(15 776)	(1 812)	8 542
Cash flows from financial activities								
Inflows from credits and loans	-	804	-	19 000	2 807	(1 400)	-	-
Inflows from the issue of shares	32 186	-	-	-	12 578	11 447	13 870	-
Proceeds from subsidiaries received	-	-	-	-	16 533	15 087	-	-
Repayment of loan debt plus interest	-	-	-	(6 661)	(12 852)	(136)	(1 447)	-
Dividend payment	(6 392)	(11 565)	(5 121)	-	-	-	-	-
Repayment of financial liabilities	-	(8 080)	(8 069)	(8 113)	-	(2 040)	(1 651)	(1 910)
Payments of finance lease liabilities	-	-	-	(5 290)	(5 310)	(5 233)	-	(525)
	72 803	(21 594)	(18 981)	(59 745)	14 008	17 725	9 979	(1 889)
Total net cash flow	27 578	(15 009)	27 658	(49 039)	5 047	(4 530)	14 498	7 111
Cash opening balance	19 962	47 540	32 531	60 189	11 150	16 197	11 667	26 165
Closing balance of cash	47 540	32 531	60 189	11 150	16 197	11 667	26 165	33 276

The presented financial data comes from published financial statements, which only in their entirety provide a complete picture of the results of the Medicalgorithmics S.A. Group. Financial reports can be downloaded at: <https://www.medicalgorithmics.com/investors/financial-reports/>

Appendixes

US and EU Regulatory compliance

USA FDA 510k approvals

- Home
- Food
- Drugs
- Medical Devices
- Radiation-Emitting Products
- Vaccines, Blood & Biologics
- Animal & Veterinary
- Cosmetics
- To

510(k) Premarket Notification

FDA Home Medical Devices Databases


1 to 7 of 7 Results

Applicant: Medicalgorithmics **Decision**

Date To: 10/26/2023

Results per Page

New Search

 [Export to Excel](#) | [Download Files](#) | [More About 510\(k\)](#)

Device Name	Applicant	510(K) Number	Decision Date
Deeprhythmai	Medicalgorithmics S.A.	K210822	07/27/2022
Q Patch	Medicalgorithmics S.A.	K210758	06/02/2022
Unified Arrhythmia Diagnostic System Pocketecg Iv	Medicalgorithmics S.A.	K193104	04/09/2020
Medicalgorithmics Unified Cardiac Rehabilitation System	Medicalgorithmics S.A.	K173969	07/11/2018
Medicalgorithmics Unified Arrhythmia Diagnostic System	MEDICALGORITHMICS S.A.	K152550	10/08/2015
Medical Gorithmics Unified Arrhythmia Diagnostic System	MEDICALGORITHMICS S.A.	K124060	02/21/2013
Medicalgorithmics Real-Time Ecg Monitor And Arrhythmia Detector, Model Pocketecg	MEDICALGORITHMICS SP Z.O.O.	K090037	05/22/2009

Products Approved in Europe

Medicalgorithmics' products are CE certified as:

1. Software for the ECG data visualization, analysis and reporting (including cloud-based algorithms):
 - PocketECG PC Client (under MDR):
 - PocketECG PC Client (under MDD valid until 24 May, 2024)
2. The complete suite consisting software, algorithms, monitoring devices:
 - Unified Arrhythmia Diagnostic System PocketECG III (under MDD valid until 24 May, 2024)
 - Unified Arrhythmia Diagnostic System PocketECG IV (under MDR)

The conformity assessment of our products, including the safety of electrical and electronic components is certified under the IECEE CB scheme.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 1023833-1

Manufacturer: **MEDICALGORITHMICS S.A.**
Al. Jerozolimskie 81
02-001 Warszawa
Poland

EUDAMED Single Registration No.: PL-MF-000011413

Products: Products of class IIa:
Z129082 - VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS - SOFTWARE ACCESSORIES
Z12050403 - ECG HOLTER RECORDERS

Authorised representative(s): Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial Certification	2023-03-29
1	Scope extension	2023-05-05

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 84965710-40
Effective date: 2023-05-05
Expiry date: 2028-03-28
Issue date: 2023-05-05

 Member Association of
Notified Bodies for
the Assessment and
Certification of
BSI-MDR-091


Jarosław Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

1 of 1

Integrated QMS

The Integrated Management System at Medicalgorithmics is based on a process model. The system is certified by TUV Rheinland and audited on an annual basis, meeting the requirements defined in the following standards and regulations:

- EN ISO 13485:2016,
- ISO/IEC 27001:2013,
- Medical Device Single Audit Program:
 - United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D, 21 CFR 821
 - Australian Therapeutic Goods Regulations, 2002, Schedule 3 Part 1 (excluding 1.6) Full Quality Assurance Procedure,
 - Canadian Medical Devices Regulations - Part 1- SOR 98/282,
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR),
- The Polish law on medical devices Dz.U. 2022 item 974,
- Indian Drugs & Cosmetic Act 1940 & Rules 1945,



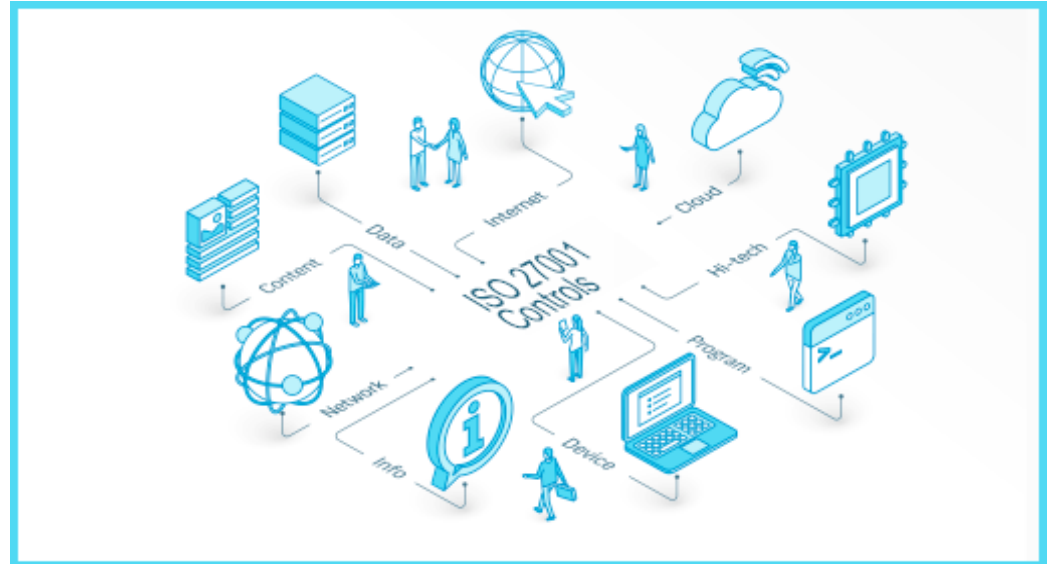
Data protection

ISO/IEC 27001

In 2019 company implemented Information Security Management system according to ISO 27001 requirements. System is certified by TUV Rheinland and audited on annual basis.

System covers the following areas:

- Company security policy
- Asset management
- Physical and environmental security
- Access control
- Incident management
- Regulatory compliance



Data protection

GDPR regulations at Medicalgorithmics:

- Personal data protection policy
- Response to security incidents
- Access instructions to video surveillance system
- Handling of data requests
- Verification during selection and monitoring of data processing entities
- Methodology for performing risk analysis
- Data retention policy
- Information clause and consent templates





Thank you!

Maciej Gamrot
CFO
Executive / Mgt. Board Member
mob: +48 507 095 201
e-mail: m.gamrot@medicalalgorithmics.com

Mateusz Paradowski
IR Manager
mob: +48 516 089 279
e-mail: m.paradowski@innervalue.pl

web: <http://www.medicalalgorithmics.com>