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AUdiTE – Decision Support System for Diabetologists
Automated diabetological diagnoses & therapy decisions

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Medical software for health care professionals

1 WHAT?

AUdiTE is an **automated support system for diabetological diagnoses and therapy decisions**. It helps health care professionals (HCP) such as **diabetologists, doctors** and **nurses**.

It is designed **for use in combination with diabetes data management systems** conceived by medical device manufacturers.

AUdiTE is a **valuable add-on product for medical device manufacturers**, as it allows them to bind doctors & clinics to their own data management systems by providing valuable and time saving therapy recommendations.

AUdiTE is a medical device class IIa. It was developed according to EN ISO 13485, EN ISO 27001, MDR, MDSAP, digital health applications (German DiGA) and has a CE mark as a standalone software.

OUR VISION: BETTER CONNECTIVITY, CARE & HEALTH

2 HOW?

A **doctor has got just 7 minutes to analyse patient data** and adjust therapy. This time covers analysing the patient data with statistics like general glucose profile graph (AGP), identifying relevant weak spots in the daily logbook, explaining and supporting the patient, prescriptions and so forth.

AUdiTE provides faster therapy recommendations than 7 minutes
- It gives relevant therapy recommendations within few seconds!

- The software identifies weak points based on rules with priorities.
- It helps avoiding critical situations like severe hypoglycemias, ketoacidosis or alcohol impact on hypoglycemias.
- It identifies inappropriate basal insulin amount, wrong insulin-carb ratios and correction rules.
- Moreover, it sees psychological issues like hypoglycemia anxiety, lack of motivation etc.
- Finally, it increases overall quality of therapy.

HOW DOES **AUdiTE** WORK FOR HEALTH CARE PROFESSIONALS?

HOW?

Decision Support based on underlying set of rules

The system has **over 100 underlying rules and algorithms** for examining the patient and making treatment recommendations. Those are for example:

- 20 specific rules & **recommendations just for AID** (automated insulin delivery)/loop patients,
- 29 specific rules with **recommendations just for patients on CSII/insulin pump patients**,
- 38 rules & **recommendations for avoiding hypoglycemia situations**,
- 24 rules & **recommendations for avoiding hyperglycemia situations**,
- 23 rules & **recommendations about high variability in patient data**,
- 4 rules & recommendations for upgrading therapy form or referral to a specialist.
- The system provides an integrated feedback loop for HCP users for additional machine learning on recommendations.

Understanding therapy data & recommendations

AUdiTE checks the **macro perspective** of patients' health situation based on cumulated data with patterns. It also checks the **micro perspective** with striking situations that can be improved or avoided.

- The system supports HCP for decisions about a **therapy upgrade**, in case that the current therapy does not show good results.
- Every recommendation can be verified with a detailed text to **explain, what has happened** or what has triggered this recommendation for increased confidence. This is easy to check by HCP.
- All rules are classified by type, e.g. macro perspective, single day hit or weekday patterns. As such the system can **show direct context for each specific recommendation and jump to the AGP** (ambulatory glucose profile) or a specific day in the logbook or calendar view.
- AUdiTE can be **easily and quickly updated** (e.g. add further rules) since the core engine is not using artificial intelligence (AI). There is no need to train the AI for new specific data situation and reliable outcome.

DIAGNOSIS & THERAPY RECOMMENDATIONS ARE BASED ON ...

- International and national guidelines (e.g. German Diabetes Association DDG, international consensus).
- Current publications on threshold and target values in the treatment of diabetes (2018–2024).

- SINOVOs own advisory board with German diabetologists, endocrinologists and sports & nutritional physicians.

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WHY? ③

ONE OF THE MAJOR MACRO PERSPECTIVE TRIGGER EXAMPLES

In case that patients with diabetes have a repetitive high glucose at night:

- Recommendation in case of multiple daily injection (MDI): Increase the basal insulin dose which covers the night. This might be depending on the used basal insulin and insulin profile for 12h / 24h with 2 or 1 basal injections.
- Recommendation for patients using an insulin pump: Increase the basal rate programming in a specific time window, e.g. max. time frame 10 pm – 5 am. However, it might be an even more precise window from the analysed data like just 1 am – 4 am.
- Recommendation for loop/AID: Increase the programmed fallback basal rate in time window but also check if the loop was running on that night.
- Additional hints given for all categories like if there are frequent fat protein meals at late evening which might have caused the high glucose at night or hints to double check for technical issues for pump & AID (catheter, low batteries, air bubbles in tube etc.).

MICRO PERSPECTIVE TRIGGER EXAMPLES

From a micro perspective, health care professionals will be supported with specific patterns on single days which are not obvious in statistics like AGP:

- A patient might have a good overall therapy quality with low A1c, good time in range but there was one critical situation which might have been close to a diabetic ketoacidosis.
- Another dangerous micro perspective example might be situations in combination with an alcohol situation and a severe power of hypoglycemia.
- A patient might use basal profiles that include a stand-up dose for the morning, which is causing hypoglycemias on weekends with longer sleeping hours.

WHY?

3

Certified quality management system according to ISO 13485.

The ISO 13485 standard defines the minimum requirements for the design and development, production, storage and maintenance of medical devices and the provision of accompanying services. **The standard is mandatory for medical device manufacturers.**

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11 STRONG ARGUMENTS FOR A PARTNERSHIP WITH US

1 Almost 20 years of experience
Collaborate with SINOVO, your experienced partner with outstanding practical knowledge in the medical sector.

2 App development
App development for smartphone (Android, iOS), tablet (iOS, Android, Windows), desktop (Windows, Mac OS, Linux) & interface programming (e.g. NFC, Bluetooth, USB).

3 Development of multilingual apps
21 languages, including English, French, German, Italian, Russian and Spanish.
On request, we can implement any other language for a customer project.

4 Creation of diverse medical software
SINOVO has marketed its own medical software products and developed software and web portals as medical products for various applications and customers.

5 Expert in interface programming for interoperability in medicine
In medicine, many electronic devices are used that cannot „talk" to each other, i.e. exchange data. However, interfaces, i.e. „electronic connection bridges", between the devices make this possible. SINOVO is an expert in programming interfaces to enable interoperability in medicine.

6 ISO 13485
Development of medical software in accordance with the highest quality standards, as our quality management system is certified in accordance with ISO 13485.

7 CE labelling
CE conformity in accordance with the quality management specification in order to be able to distribute medical software in Europe.

8 MDR
Technical documentation in accordance with the Medical Device Regulation.

9 FDA
Software development in accordance with the Code of Federal Regulations (CFR), Title 21, of the US Food and Drug Administration (FDA).

10 GDPR-compliant
- GDPR-compliant thanks to secure data encryption and encrypted data transmission.
- Data storage in strictly secured data centres in the EU in accordance with European directives.

11 Trend technologies
We offer state-of-the-art software development, including big data, the Internet of Things, serverless apps, cloud services, bots, deep learning, artificial intelligence (AI) and blockchain technology.
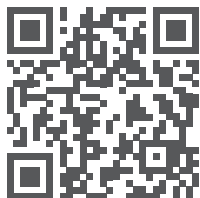
At a glance: Services, your advantages & contact persons

COMPANY NAME & LEGAL FORM:
SINOVO health solutions GmbH

HEADQUARTERS: Bad Vilbel, Germany
YEAR FOUNDED: 2005
NUMBER OF EMPLOYEES: >80

CUSTOMERS: Medical device manufacturers, pharmaceutical companies, health care professionals

AUdiTE at a glance:

- AUdiTE is an automated support system for diabetological diagnoses & therapy decisions.
- The goal of the system is to provide doctors with concrete recommendations for therapy improvements for people with diabetes.
- Machine support for rapid patient data analysis.
- Reliable recommendations based on international guidelines and medical publications.
- Designed to run invisible and can therefore be integrated with every diabetes care software (online, mobile, desktop).

WHY DO HEALTH CARE PROFESSIONALS NEED AUdiTE?

A doctor has got just 7 minutes to analyse patient data and adjust therapy. This time covers analysing the patient data with statistics like AGP graph, identifying relevant weak spots in the daily logbook, explaining and supporting the patient, prescriptions etc.

- **Excellent time saving for health care professionals:** This is to make good treatment decisions with therapy data provided in just a few seconds.
- **Better understandable recommendations for nurses:** This enables them to cover more patients by giving easy understandable recommendations.
- **Learning system for better results:** This is based on feedback provided by health care professionals.

CERTIFICATIONS

EN ISO 13485, EN ISO 27001, MDR, MDSAP

WHO?

CONTACT & POINT OF CONTACT

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