Health Technology Review	
Technology Ref.:	HTA24030
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Technology Name/Version/Model:	Cardio Explorer / T – 200-2
Approvals by International Bodies (year):	Swissmedic and Europe (CE Mark) MoHaP
Manufacturer/ Company name, country of Origin	Exploris Health AG, Switzerland
Agent in UAE:	AlfaDiag
Class/ Type	Standalone software as a medical device (SaMD)
Licensed Indications	Diagnostic tool for coronary artery disease (CAD)
Cost and Comparisons with standard of Care	• Estimated contractual price: AED 1,518.80 • Replaces pre-test probability (PTP) with an algorithm comparable to CT scans and MRI analysis, reducing unnecessary referrals to specialists and hospitals, minimizing invasive tests.
Administration/ Use	• Non-invasive diagnostic tool using AI/ML algorithm and blood test results to evaluate patient data and compute a risk score for Cardio artery disease (CAD) likelihood.

Short Description of the Technology:	**Introduction** ○ Cardio Explorer aids in diagnosing coronary artery disease (CAD) using a cloud-based AI/ML algorithm. ○ It evaluates 32 input variables, including standard laboratory values, clinical findings, and medical history, to compute a risk score, categorizing patients into four risk classes for CAD likelihood. ○ Results are available on-screen and as a downloadable PDF report. ○ The algorithm is validated with high discriminative power in both low and high-prevalence CAD patient cohorts. ○ Cardio Explorer is a standalone software as a medical device (SaMD) that aids in diagnosing coronary artery disease (CAD). It uses a cloud-based AI/ML algorithm to evaluate patient data and compute a risk score for CAD likelihood. ○ It is an AI-based test for detecting significant coronary stenoses in primary diagnostic.

	○ 15-minute Cardio Explorer® check-up can be carried out anywhere and shows whether preventive measures or further examinations are advisable. **Clinical Evidence/ Efficacy:** ○ The Cardio Explorer has been validated in three clinical studies with over 4,500 patients, in high and low prevalence populations and showed an enormously high accuracy (AUC of 0.87) in all studies. The broad validation is a prerequisite for use in primary diagnostics and prevention. ○ In low-risk population for screening purposes the sensitivity and specificity of using this technology are 98% and 83% while in high-risk population the sensitivity and specificity are 75% and 83%. ○ Cardio Explorer enables precise risk stratification of patients with suspected CAD. Artificial intelligence (AI) allows efficient and personalized assessment. **Indication**: • Cardio Explorer is a standalone software as a medical device (SaMD) that aids in diagnosing coronary artery disease (CAD). It uses a cloud-based AI/ML algorithm to evaluate patient data and compute a risk score for CAD likelihood. **Safety/ Risk** • Risks associated with over-reliance on technology. Potential contraindications or risks to both patients and healthcare practitioners include reliance on algorithmic decisions without clinical judgment. **Place in Therapy/ diagnosis:** ○ An aid on diagnostic in the field of Non-invasive CAD evaluation minimizing the need for invasive tests by providing clearer non-invasive diagnostic outcomes. ○ Tailored diagnostics supporting a personalized approach to CAD diagnosis and treatment. ○ The software will not replace the clinical judgment and decision of the treating physician.

Health Technology Assessment Team Recommendation:	**Approve**
Summary of Review:	

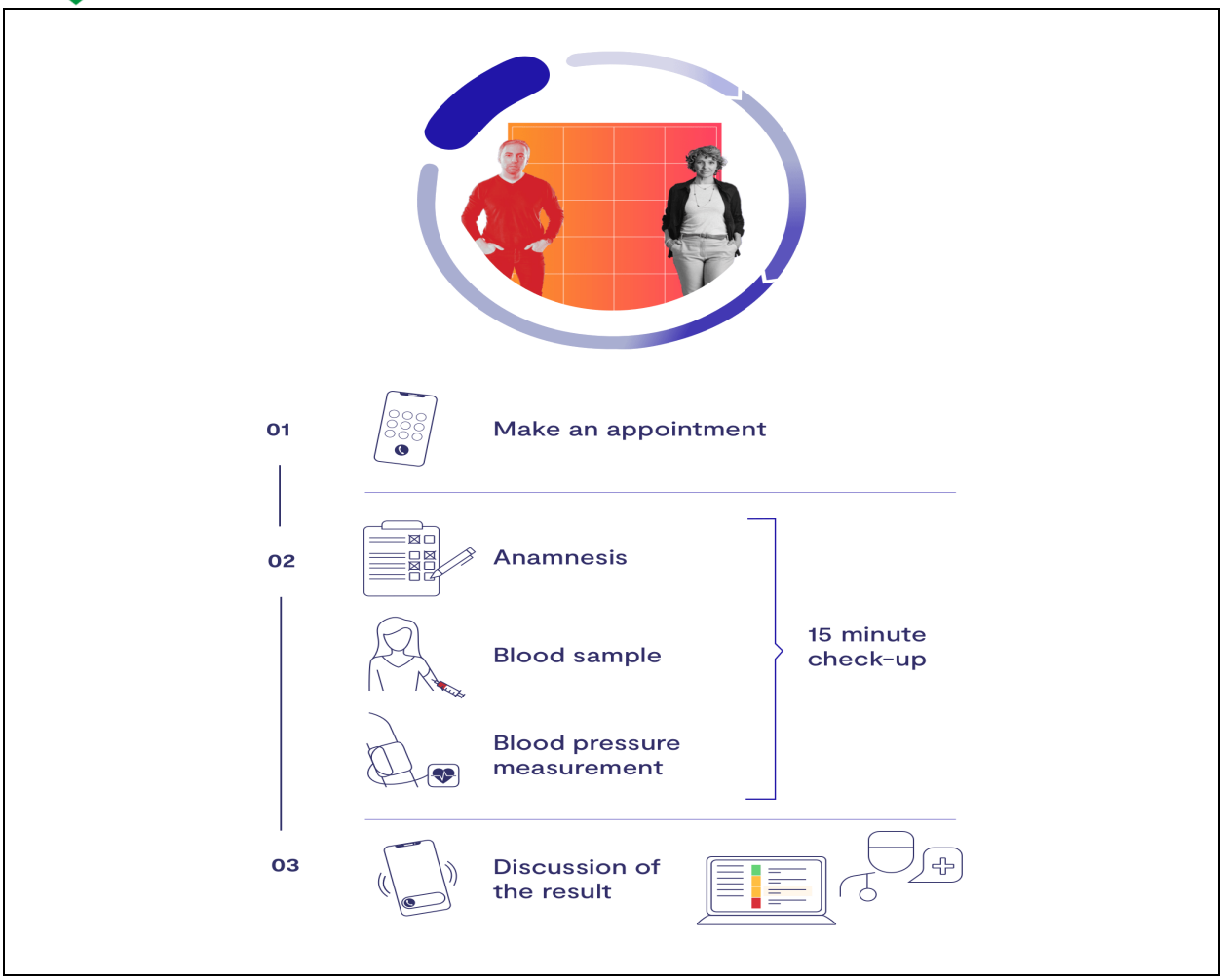
- Cardio Explorer introduces artificial intelligence to enhance the prediction and diagnosis of CAD, addressing limitations in current diagnostic models and minimizing invasive procedures. Its high accuracy and non-invasive nature make it a significant improvement over existing practice.

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. Approval on Cardio Explorer / T – 200-2
2. The software will not replace the clinical judgment and decision of the treating physician.
3. Prioritize transparency in AI decisions.
4. Ensure data privacy and integrity.
5. Require training for users for accurate data input and interpretation.
6. Monitor false positives and negatives.
7. Prioritize transparency in AI decisions.
8. Implement strict access controls.
9. Set up a feedback mechanism for continuous improvement.
10. Manufacturer to validate algorithm accuracy periodically.
11. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
12. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image



Population, setting and intended user for Technology "Cardio Explorer"

- **Population/ Intended User**:
  - Patients with cardiovascular symptoms, those with risk factors like smoking, diabetes, hypertension, high cholesterol, and family history of early heart disease.
- **To be performed by**:
  - Healthcare professionals are trained to use the Cardio Explorer interface and interpret results.
- **Clinical Setting:**
  - Outpatient clinics, primary care settings, and emergency rooms.
- **Condition of use:**
  - For non-invasive evaluation and diagnosis of CAD.
- **Exclusion criteria:**
  - Patients with severe non-cardiovascular comorbidities (e.g., advanced cancer, severe renal or liver disease) that might influence the diagnostic accuracy or the interpretation of results.
  - Patients who have already been diagnosed with advanced coronary artery disease and are undergoing treatment might not need additional risk stratification.
  - Patients with uncontrolled diabetes, hypertension, or hyperlipidemia might skew the results or require immediate intervention outside the scope of this diagnostic tool.

- Patients on medications that significantly alter cardiovascular parameters (e.g., certain anti-arrhythmic drugs, high-dose corticosteroids) might not be suitable candidates.