Caso di studio: HTA per la Medicina Digitale

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HTA e Medicina Digitale

Consider the best available evidence

Studi

Dimensions of value

Framework - Valutazioni

The process is formal, systematic and transparent

Accesso al mercato

The purpose is to inform decision-making

Decisioni

STUDI

Validazione della digital health

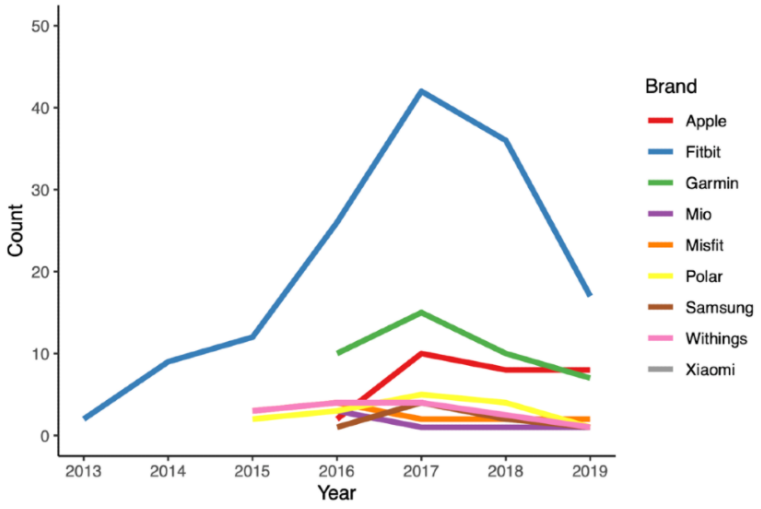
JMIR MHEALTH AND UHEALTH

Fuller et

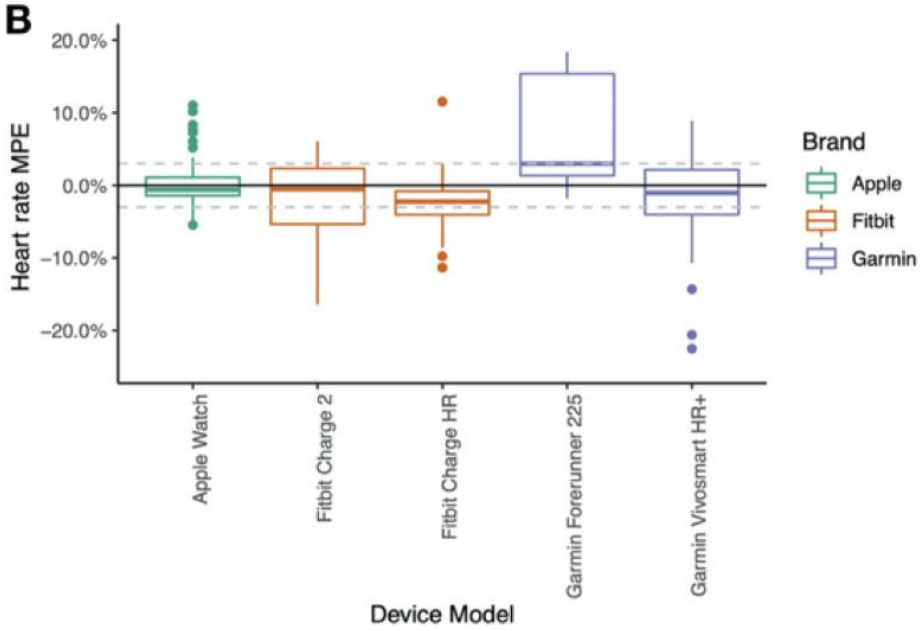
Review

Reliability and Validity of Commercially Available Wearable Devices for Measuring Steps, Energy Expenditure, and Heart Rate: Systematic Review

Numero di studi pubblicati



Box plots representing mean percentage error (MPE) for heart rate device brand and model for devices with 10 or more comparisons.



Studi

Centre for Innovative Medical Technology (CIMT) -Olanda

www.telemedicine.cimt.dk

Based on a literature study of over 300 studies (**randomised or with control groups**) the database lets you search using a number of filters and easily identify whether a solution has showed positive effects on clinical outcomes, patient experience and/or economic effects.

Technology

App

Video consultation

Phone consultation

Home monitoring

SMS / Mail

Website

Clinical Effect, Patient Experience, Economic Effect

No information

Positive effect

No effect

Negative effect

Implementation

A Requires cross-sector collaboration

B Requires new equipment

C Requires additional development

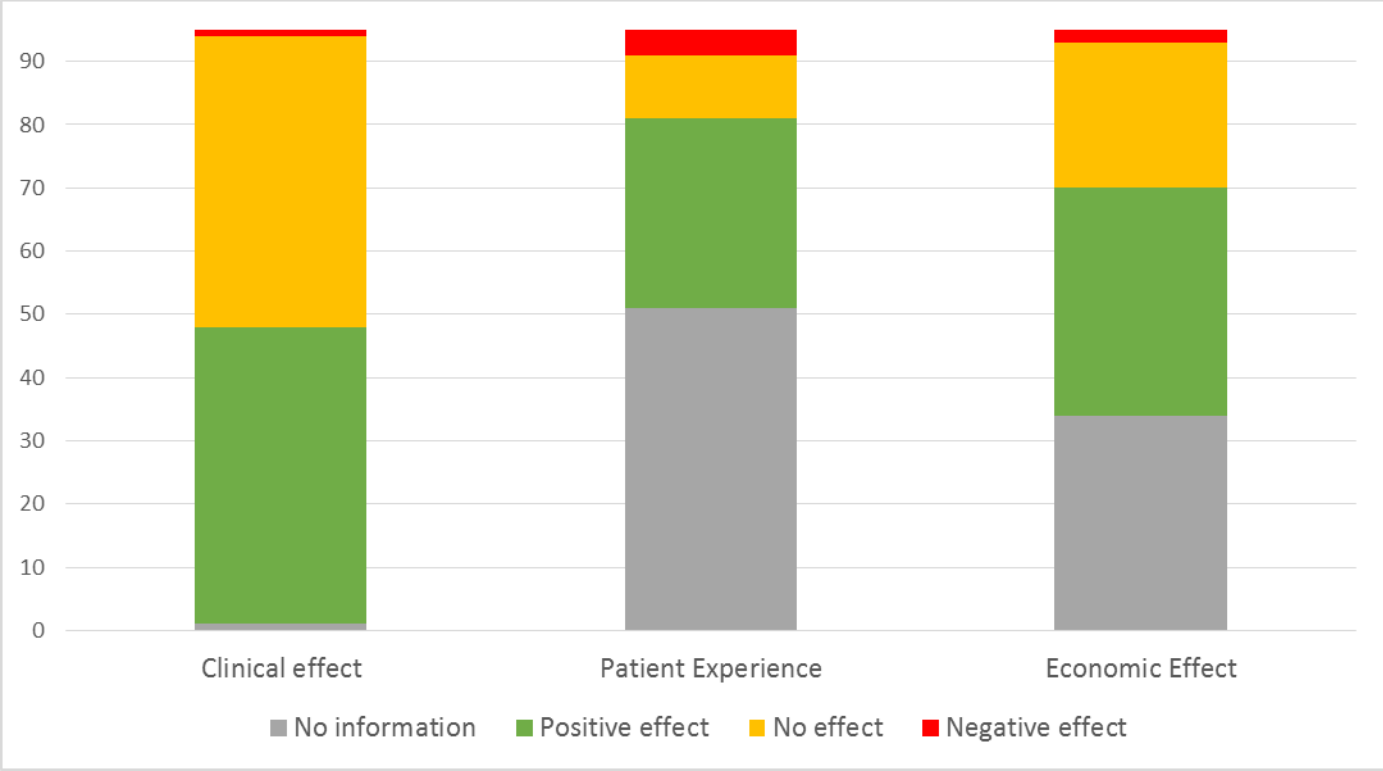
D Requires new skills, training or new tasks

E Is addition to usual treatment

F Requires integration with electronic patient record

Cardiologia

- 95 studi relativi a tecnologie digitali in cardiologia
- 55 studi condotti in Paesi Europei
- 12 studi hanno coinvolto l'Italia (il Paese con più studi assieme alla Spagna)



FRAMEWORK

Oltre il MAST: Model for Assessment of **Telemedicine**

- E' un framework di HTA realizzato per la telemedicina sviluppato all'interno dello studio europeo MethoTelemed (**2010**) da MedCom & the Norwegian Centre for Integrated Care and Telemedicine University of Stirling e il Knowledge Centre for the Health Services.
- E' stato creato per essere utilizzato a livello EU e nazionale.
- Lo scopo è valutare l'effectiveness e la qualità delle cure.

STEP 1: Preceding assessment:
- Purpose of the telemedicine application?
- Relevant alternatives?
- International, national, regional or local level of assessment?
- Maturity of the application?

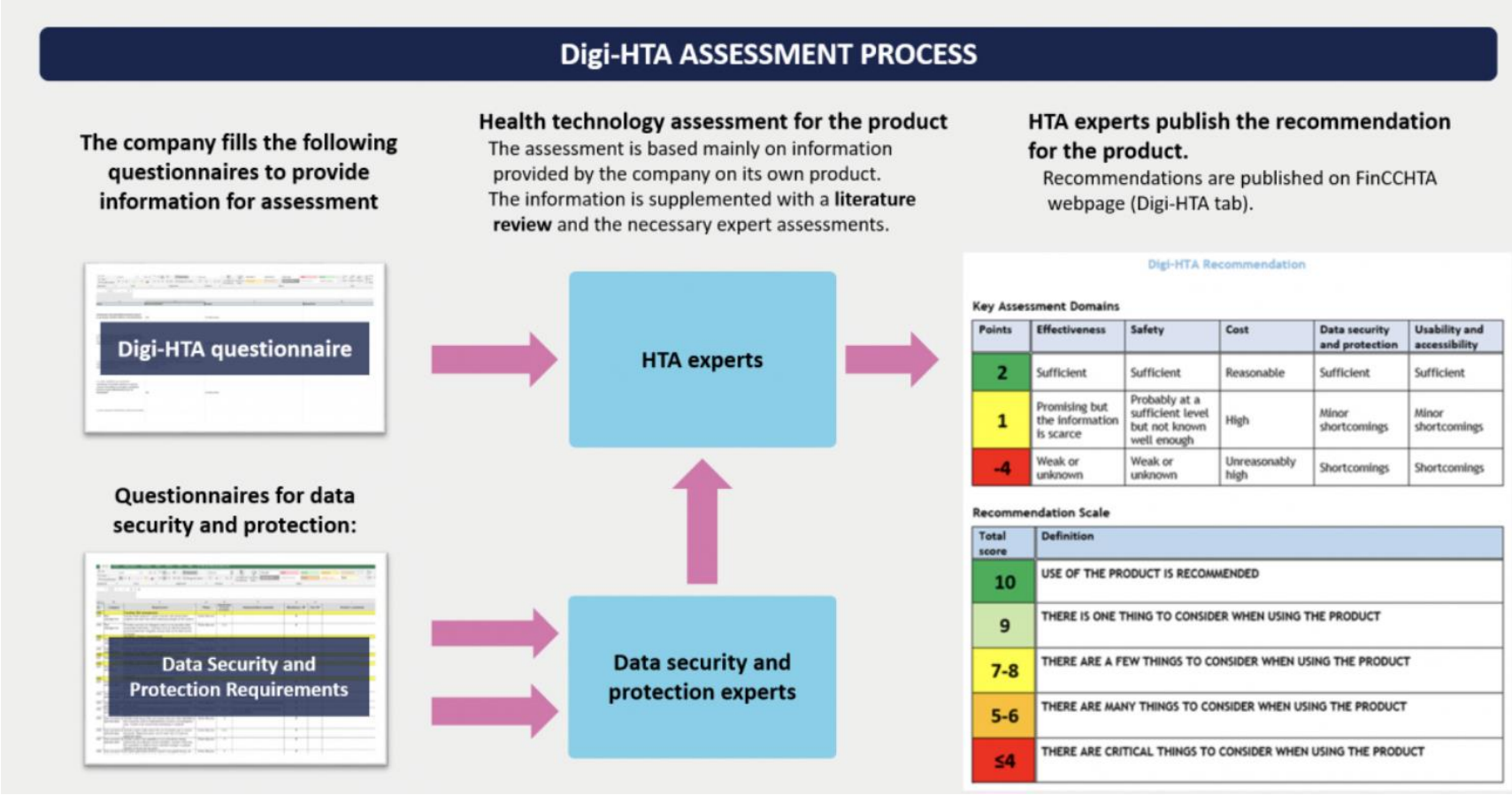
STEP 2: Multidisciplinary assessment:
1. Health problem and characteristics of the application
2. Safety
3. Clinical effectiveness (mortality, morbidity, HRQL, behavioural outcomes, utilization of health services
4. Patient perspectives
5. Economic aspects
6. Organisational aspects
7. Socio-cultural, ethical and legal aspects

STEP 3: Transferability assessment:
- Cross-border
- Scalability
- Generalizability

https://journals.sagepub.com/doi/pdf/10.1177/1357633X17721815

Digi-HTA: HTA framework for digital healthcare services

- E’ un framework specifico per la valutazione dei digital healthcare services applicabile al contesto della Finlandia.
- «Digi-HTA is an **assessment tool** that provides an opportunity for **objective analysis** about the product or service’s suitability for healthcare use based on information from **real-life operating environmen**t.»



Haverinen J et al (2019) Digi-HTA: Health technology assessment framework for digital healthcare services.
Finnish Journal of eHealth and eWelfare, 11(4), 326–341. https://doi.org/10.23996/fjhw.82538

Digi-HTA: **framework**

Domini di HTA	
Company information	Business model, quality management systems
Product information	Intended purpose and maturity level of the product, CE and/or FDA approvals, medical device classification, need for changes and training
Costs	Costs of using the product for healthcare customers and organization, initial and maintenance costs
Effectiveness	Clinical benefits, benefits for end-users and/or organization, evidence for the effectiveness claims
Safety	Risks, possible side effects, or other undesirable effects of using the product, reported or identified adverse events and how those are handled
Data security and protection	Guarantees of data security and protection in the technical and organizational implementation of the product, and during its lifecycle
Usability and accessibility	Considerations of and testing with different user groups, company process for evaluating and developing usability and accessibility, compatibility with available usability guidelines
Interoperability	Product interfaces into website, other software, healthcare services, electronic patient records, and/or to other companies' services; formats of data transfer and storage
Technical stability	Processes for testing and handling error messages, any previous reported downtime or impairment in the use of the product
Artificial intelligence	The problem that is being solved by the AI, machine learning or neural network, possibility for retraining and used data sources, AI solution decision logic transparency for healthcare personnel, are access rights in order for data in every use case?
Robotics	Any possibility for safety risks for healthcare personnel or customers of using the robot, and how those are avoided in the design, needed arrangements for teaching or programming the robot, battery-life of the robot

Digi-HTA: valutazioni

A Maggio 2021 il Digi-HTA è stato applicato a 4 digital healthcare services:

- **Evondos**- medication dispensing robot - Servizio di erogazione di farmaci
- **Indego** - Robot «da passeggio» esoscheletro per riabilitazione
- **Lokomat** - robot per la riabilitazione motoria
- **KaikuHealth** - per il monitoraggio/gestione dei sintomi dei pazienti oncologici aderenti

edito	raccomandazione	
11/2019		Servizio di dosing Evondos
2/2020		Robot da passeggio esoscheletro Indego
6/2020		Servizio sanitario kaiku
1/2020		Robot riabilitativo Lokomat Walking

Digi-HTA: valutazione The Kaiku Health service

"The Kaiku Health service is suitable for monitoring the well-being of a patient with cancer during and after active cancer treatments. The service can help the patient manage their symptoms and get treatment when severe symptoms occur".

Effectiveness	Five people participated in the pilot **study** from the Kaiku Health service. These participants had **head or neck cancer**. Based on the research, the Kaiku Health service is suitable for monitoring the side effects and quality of life of radiotherapy **during and after radiotherapy**. In addition to the pilot study, a few other studies have used the Kaiku Health service to monitor patients. The system was found to be easy to use when monitoring **multiple myeloma (MM) patients**. From the **patients' perspective**, different systems have been reported to improve communication between the patient and the health-care worker, helping patients treat their symptoms and increasing theDigi-HTA Recommendation patients' sense of safety when symptom monitoring is performed between appointments. For the **health-care organization**, the use of systems can be a cost effective way to monitor the symptoms and quality of life of cancer patients. During the assessment (June 2020), several studies were underway on Kaiku Health and **other similar systems**.
Safety	The safety of the Kaiku Health service is at a satisfactory level, although **end-user activity** can increase or decrease some risks. The company constantly **monitors error messages** and takes the necessary actions to improve safety. **No adverse events** related to the use of the product have been reported. The company's risk assessment report is comprehensive.
Cost	The use of the Kaiku Health service involves an **initial cost and a monthly usage fee**. The initial cost is reasonable and tied to the number of modules to be acquired. The monthly usage fee depends on the number of modules and patients. The manufacturer does not charge the end user. Presumably, customer organizations do not charge end users for using the system
Data security and protection	The Kaiku Health service fulfills the data security and protection requirements well. The service supports interfaces to several different systems.
Usability and accessibility	During the assessment (June 2020), the Kaiku Health service did not meet all the requirements set by the Act on the Provision of Digital Services (WCAG 2.1., level A ja AA). The regulations for websites will enter into force in September 2020 and for mobile applications in June 2021. Users with different kinds of disabilities have been considered in the product's design. The service has been tested with real users, and the company has a process in place that takes usability development needs identified based on customer feedback to become part of the product development process.
Other Things to Consider When Using This Product	**The Service Utilizes Artificial Intelligence** **Training and Product Support** **Widespread Use of the Service** The Kaiku Health service is used by more than forty oncology clinics in Finland, Sweden, Switzerland, Germany, Italy, and the Netherlands. The first version of the product was introduced in 2012. **Other Available Recommendations for the Product** When the COVID-19 pandemic spread in the spring of 2020, ESMO recommended the use of remote monitoring systems to monitor the well being of cancer patients to reduce exposure to COVID-19

Germania: Digital Care Act (Digitale-Versorgung-Gesetz)

Dal secondo quadrimestre del 2020, le **medical apps con marchio CE di Classe 1 e 2** a basso rischio medico possono accedere alla **procedura di fast track** per l'accesso al mercato in Germania.

I **requisiti** da rispettare sono sia quelli definiti dal digital healthcare application/act **(DiGA),** ma anche dal **Federal Institute for Drugs and Medical Devices** (BfArM).

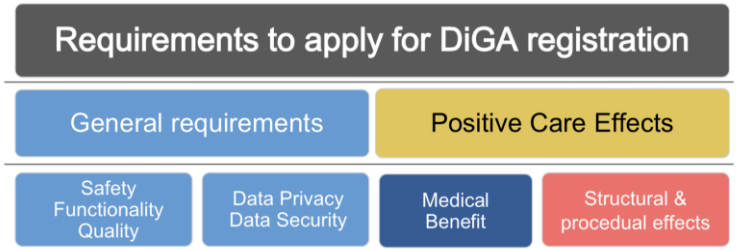
Inoltre, per la **negoziazione del prezzo** ci sono i requisiti del **National Association of Statutory Health Insurance Funds** (GKV-SV).

Germania: Digital Care Act (Digitale-Versorgung-Gesetz)

Avvio del processo

- Il processo si attiva per iniziativa del produttore.
- La valutazione per l'approvazione o meno si conclude **entro 3 mesi**.

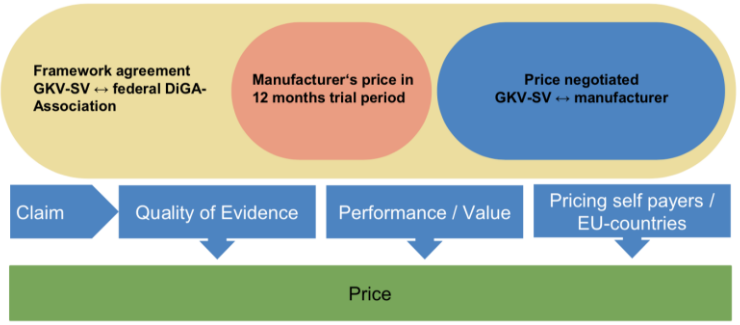
Requisiti da soddisfare



Accesso al mercato

- Se approvate, le app (e non solo) sono provvisoriamente **rimborsate** dall'assicurazione sanitaria pubblica per la **durata di 1 anno**.
- In questo periodo il produttore decide **il prezzo** liberamente.
- La app potrà essere prescritta da ogni clinico e psicoterapista con l'approvazione da parte del fondo assicurativo.
- Durante questo periodo, i produttori devono **dimostrare** all'Istituto Federale che la loro applicazione **migliora la salute dei pazienti.** Se provata, si ha l'inserimento officiale/finale nella lista DIGA.

Negoziazione del prezzo



Germania: Digital Care Act (Digitale-Versorgung-Gesetz)

App	Indicazione
Kalmeda	Acufene/tinnito comportamentale
Mindable	Agorafobia
Vivira	Artrosi dell'anca
Deprexis	Depressione
Selfapy	Depressione
Somnio	Disturbi del sonno
Invirto	Disturbi dell'umore
Velibra	Disturbi dell'umore
M-Sense	Emicrania
Rehappy	**Post ictus**
Elevida	Sclerosi Multipla
Zanadio	Sovrappeso
Velibra	Terapia del movimento per artrosi
Mika	Tumore maligno della cervice uterina
CANKADO PRO-React Onco	Tumore maligno al seno

15 soluzioni digitali valutate positivamente

\+ 10 in valutazione

Autorizzazione concessa con studio in corso.
E' richiesto 1 studio almeno per indicazione e che arruoli pazienti tedeschi.

Però, il prezzo potrà essere negoziato solo nel caso di beneficio addizionale dimostrato.
La negoziazione deve essere basata sugli *outcome-related component.*

P	Pazienti colpiti da ictus in cure ambulatoriali di follow-up
I	Supporto al paziente per la ripresa della sua vita quotidiana tramite un'app certificata, tracker di attività e portale web.
C	Pazienti in lista d'attesa per il follow-up tradizionale post ictus
O	Miglioramento dello stato di salute e della qualità della vita (prevenzione della depressione, prevenzione secondaria dopo l'ictus), supporto a livello emotivo e fisico), nonché miglioramento dell'aderenza

DiGA Directory -

https://diga.bfarm.de/de/verzeichnis

Germania: Digital Care Act (Digitale-Versorgung-Gesetz)

Accettabilità

Da un'indagine condotta a Dicembre 2020, dopo l'entrata in vigore del Digital Care Act, emerge che:

- Un medico su quattro (24%) vuole prescrivere applicazioni sanitarie digitali (DiGA);
- Però il 28% dei medici non vuole prescrivere un'app per la salute ai propri pazienti in futuro;

- Solo il 2% dei medici le ha già prescritte;
- Il 68% di chi ha già prescritto le applicazioni digitale le ritiene un'aggiunta utile all'offerta medica standard;

- Quasi 3 medici su 10 (29%) chiedono anche che la gamma di app per la salute venga ampliata rapidamente;
- Il 58% dei medici disposti a prescrivere tali soluzioni (ora o in futuro) richiede di avere una piattaforma centrale su cui medici e pazienti possano conoscere le applicazioni sanitarie digitali disponibili e rimborsate.

Prezzi «liberi»

App	Rimborso mensile
Kalmeda	*38,99 €* (116,97 € / 90 gg)
Somnio	164,67 €
Velibra	158,67 €
Vivira	79,99 €
Zanadio	166,67 € (500 €/ 90 gg)

A fine 2020 la National Association of Statutory Health Insurance Funds (National Association of Statutory Health Insurance Funds - GKV-Spitzenverband), in accordo con 13 produttori, ha deciso di determinare un **prezzo massimo** accettabile ai fini del rimborso.

https://www.bitkom-research.de/de/pressemitteilung/jeder-vierte-arzt-will-gesundheits-apps-verschreiben

DECISIONI

FDA- Software **precertification** Program

9 aziende sono state selezione a Settembre 2017 per testare Software Pre-Cert program lanciato dal FDA:

1. **Apple**
2. Fitbit
3. Johnson & Johnson
4. Pear Therapeutics
5. Phosphorus
6. Roche
7. Samsung
8. Tidepool
9. Verily

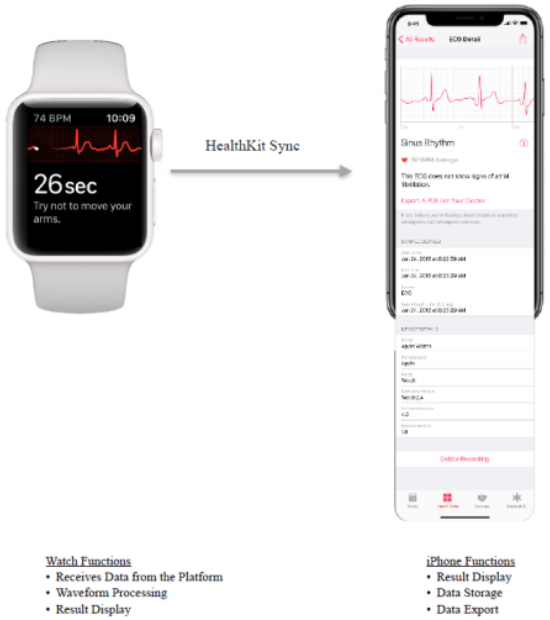
Why an Apple Watch with EKG matters

The FDA has approved the EKG feature, meaning the Watch can be used as a medical device

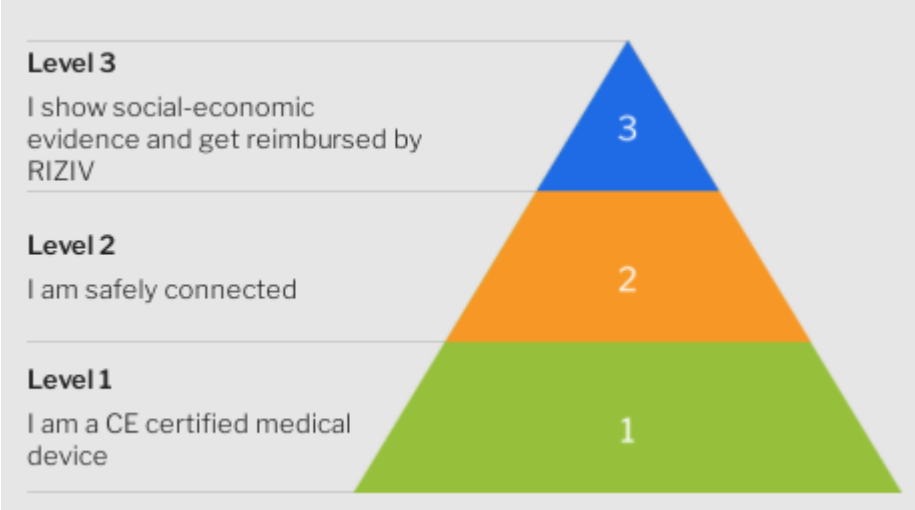
With the new FDA guidance**, healthcare providers** can access the expanded capability of noninvasive remote monitoring devices during the COVID-19 pandemic. … Providers can now use **Apple Watch and the ECG app for telemedicine and virtual care,** helping facilitate both patient care and social distancing to minimize potential exposure to COVID-19.

Table 6: Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Poor quality ECG signal resulting in failure to detect arrhythmia	Clinical performance testing Human factors testing Labeling
Misinterpretation and/or over-reliance on device output, leading to: • Failure to seek treatment despite acute symptoms • Discontinuing or modifying treatment for chronic heart condition	Human factors testing Labeling
False negative resulting in failure to identify arrhythmia and delay of further evaluation or treatment	Clinical performance testing Software verification, validation, and hazard analysis Non-clinical performance testing
False positive resulting in additional unnecessary medical procedures	Clinical performance testing Software verification, validation, and hazard analysis Non-clinical performance testing Labeling

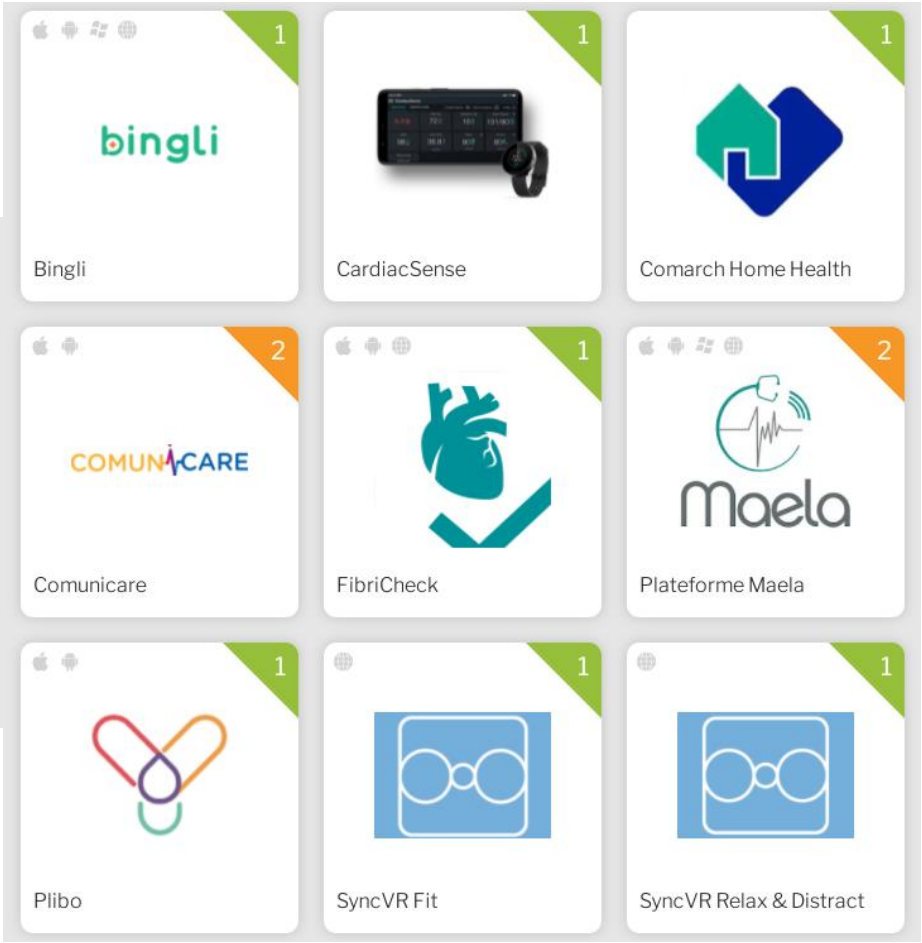


Il caso belga: mHealthBelgium, **rimborso**, cardiologia



31 app
Nessuna ha raggiunto il Livello 3

Heart / Blood Vessel



CONCLUSIONI

Conclusioni

- Il contenuto delle valutazione di HTA per le soluzioni digitali
- La qualità delle evidenze ed il ruolo dei RWD
- L’assenza di un modello condiviso

Grazie per l’attenzione

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