mHealthBelgium, an introduction

SMAV: 12 september 2020

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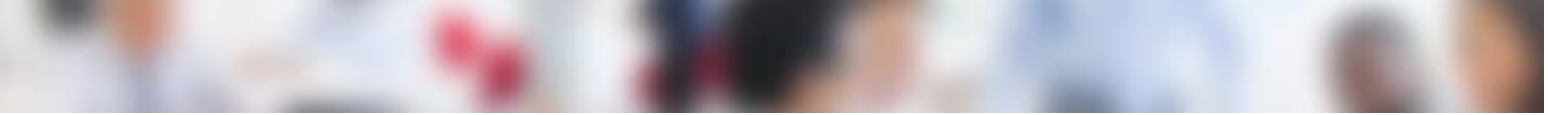
www.mhealthbelgium.be

Embracing technology
Embracing ambition

MHealth BELGIUM .AGORIA


MHealth
BELGIUM



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HET BELANG VAN LIMBURG
VRIJDAG 25 JANUARI 2019

Deze medische apps werken echt

Overheid geeft certificaat van betrouwbaarheid aan eerste vier gezondheidsapplicaties

HASSELT - Minister van Volksgezondheid Maggie De Block (Open Vld) promoot vanaf dit weekend medische apps op de website mhealthbelgium.be. Het platform moet op termijn dé referentie worden voor burgers die informatie zoeken over online gezondheidszorg. "Er is een gigantisch aanbod aan gezondheidsapps, waardoor de betrouwbaarheid ervan moeilijk te bepalen is", zegt De Block. "Wij willen burgers en hulpverleners daarmee helpen."

Aylin KOKSAL

FIBRICHECK

MOVEUP

REMECARE

AIRVIEW

Vous cherchez une application de santé fiable ? En voici quatre qui ont été validées

L. D. Publié le vendredi 25 janvier 2019 à 16h05 - Mis à jour le vendredi 25 janvier 2019 à 16h55

La Belgique doit rembourser au plus vite les applications médicales

TOM BRAEKELEIRS

Directeur du BioHealth Innovation Center (BHIC), un partenariat public-privé qui soutient la transformation numérique des soins de santé

Le potentiel de ces applications médicales est énorme. Cette technologie va permettre à la société d'économiser beaucoup d'argent, mais aussi d'améliorer la santé en général et de renforcer l'efficacité des prestataires de soins.

Procédures inadaptées

Potentiel énorme

Il est désormais possible de mesurer très facilement, via smartphone ou smartwatch, notre rythme cardiaque, tension, glycémie et même notre activité cérébrale.

Vinger op de camera en **Fibricheck meet uw hartritme.** © Raymond Lemmens

Nu **slechts vier**, andere zullen volgen

Overheid promoot eerste 'betrouwbare' medische apps

Minister van Volksgezondheid Maggie De Block (Open VLD) promoot vanaf zaterdag vier medische apps op mhealth-belgium.be.

BRUSSEL | De Block wil op termijn een overzicht bieden van alle apps die voldoen aan de medische en wettelijke vereisten. 'Je zult er informatie vinden over de werking en de voordelen van online toepassingen voor de patiënt of de zorgverlener', stelt haar kabinet. De minister werkt daarvoor samen met gezondheidsadministraties Agoria en beMedTech.

Fibricheck

Fibricheck kan hartritmestoornissen opsporen en voorkamerfibrillatie detecteren. U plaatst uw vinger op de camera van uw smartphone om uw hartritme te registeren. De gegevens worden automatisch gedeeld met een arts die meteen een diagnose kan stellen. Zo krijgt u sneller een aangepaste behandeling.

MoveUp

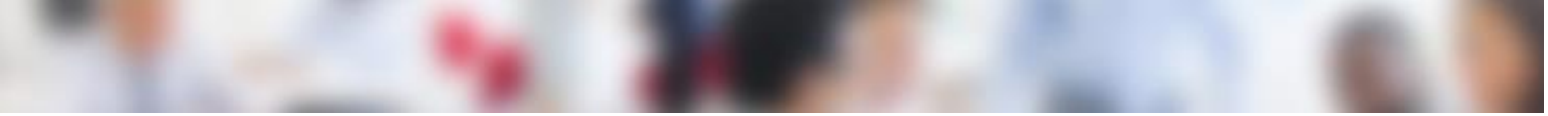
Een app die patiënten voor en na een heup- of knieoperatie helpt optimaal te revalideren. U krijgt aangepaste oefeningen, advies, informatie en coaching. Via een ingebouwde microfoon kunt u vragen stellen aan een therapeut.

RemeCare

Via de RemeCare Oncologie app kunnen zorgverleners en kankerpatiënten in hun thuisomgeving vlot met elkaar communiceren over hun chemobehandeling. U kunt registreren hoe ernstig de nevenwerkingen van de chemobehandeling zijn. Daardoor kan het ziekenhuisteam sneller ingrijpen en de medicatie optimaal doseren.

Airview

Hebt u slaap- of ademhalingsproblemen, dan kunt u deze app gebruiken voor een slaaptest bij u thuis. De app behandelingen en ondersteunt u met een screening, een diagnose en therapie-opvolging. (ak)



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History of mHealthBelgium

- Based on action item 19 of the federal e-health roadmap 2.0 consisting out of 20 e-health action items defined in **2015**
- In **September 2016**, 98 projects were submitted 24 were selected
- By **mid 2018** a follow-up structure was created: the validation pyramid
- Launched by the government after **summer 2018**
- Platform went live for the first time on **25 January 2019**

MHealth BELGIUM

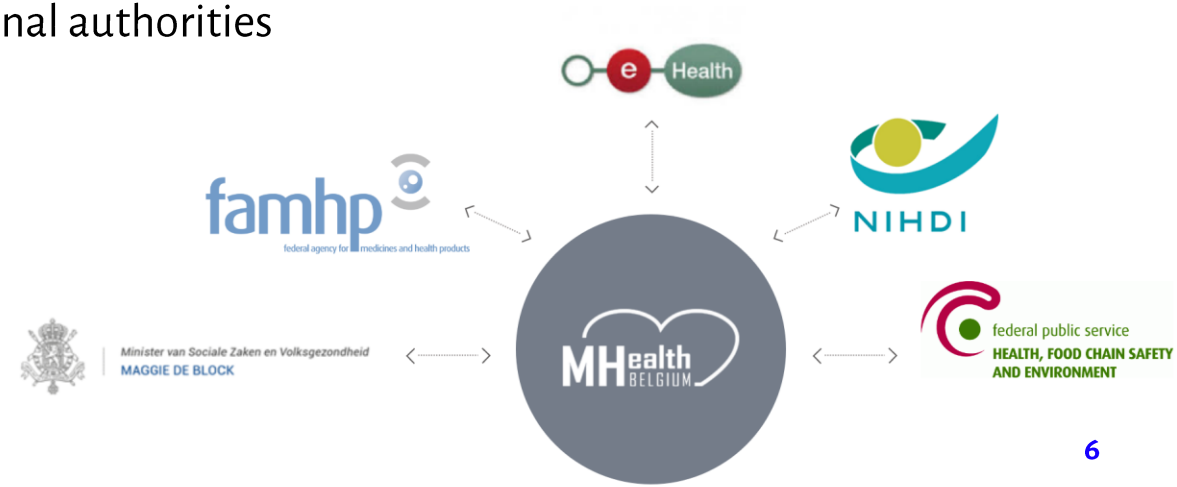
AP 19 = mHealth: why?

- Upcoming technology
- Need for new framework
  - Quality
  - Privacy
  - Evidence
- Goal = integrate mHealth applications in Belgian healthcare system

mHealthBelgium: the stakeholders

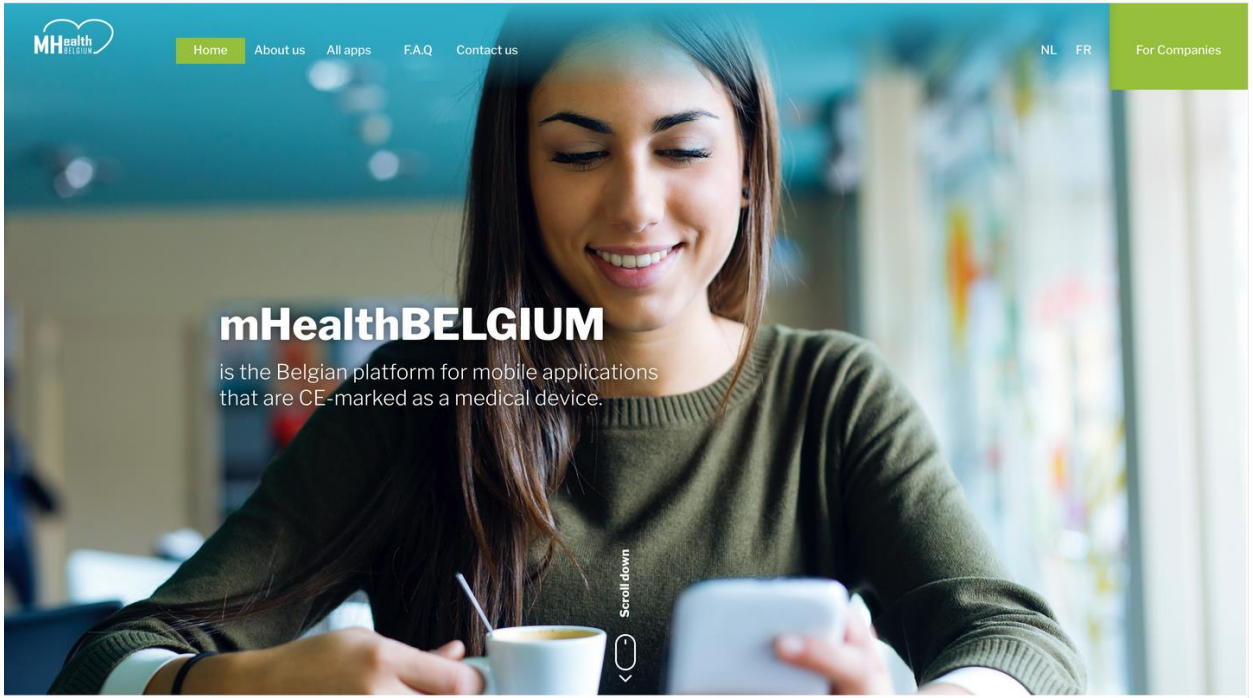
- mHealthBelgium is an initiative of the **Belgian Federal Government**.

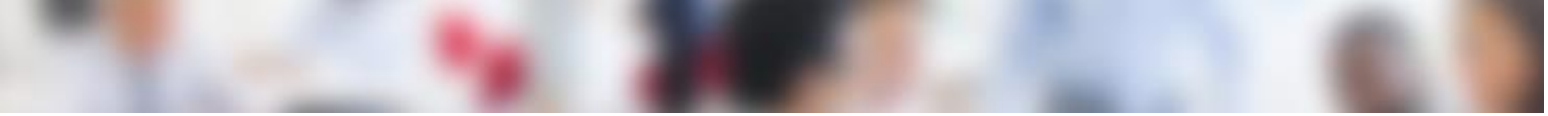
- This platform is managed by **beMedTech** (sector federation for industry of medical technologies) and **Agoria** (sector federation of technological industry), in close cooperation with three national authorities



The platform: what? Who?

- **www.mhealthbelgium.be**
- **In 3 languages: NL – FR – EN**
  (DE out of scope at this stage)
- **Information for**
  - Broad public
  - Patients
  - Healthcare professionals
  - Healthcare institutions
- **List of validated apps**
  - No full market scan
  - Company driven





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Objective of the platform mHealthBelgium

- Provide **an overview** to patients, healthcare providers and healthcare professionals of the various (CE-Marked as medical device) health-apps that wish to provide information around their status in the pyramid

  - It's the manufacturer who decides if the app is published or not
  - It's the manufacturer that informs mHealthBelgium of its status.
  - It's the manufacturer who is responsible of the quality of the information
  - mHealthBelgium does NOT "guarantee" or "validate" this information, but there are some built-in checks

MHealth BELGIUM

In 2018, the public authorities introduced the mHealth pyramid

Level 3

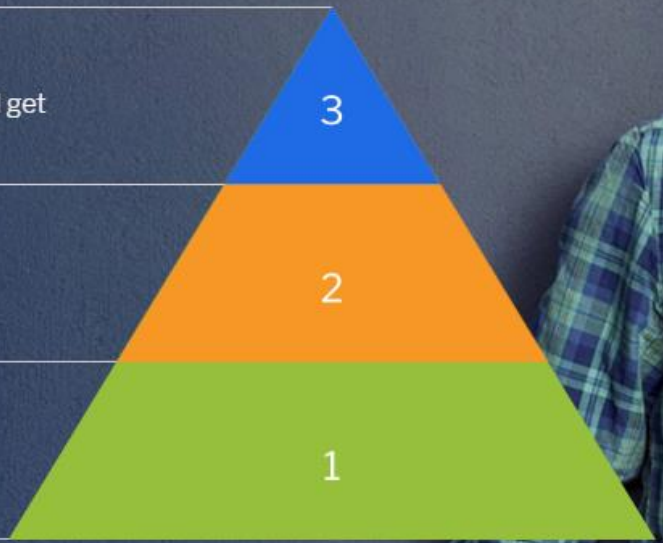
I show social-economic evidence and get reimbursed by RIZIV

Level 2

I am safely connected

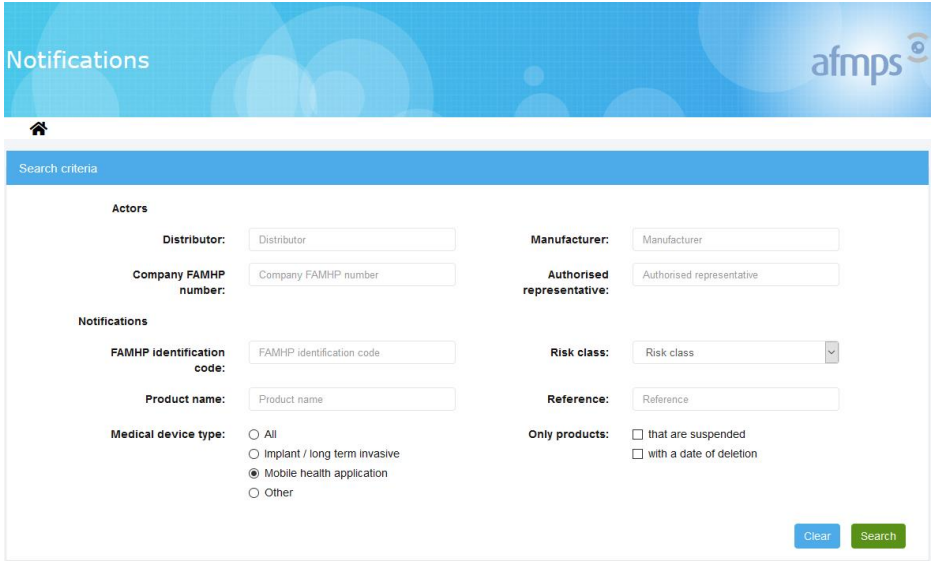
Level 1

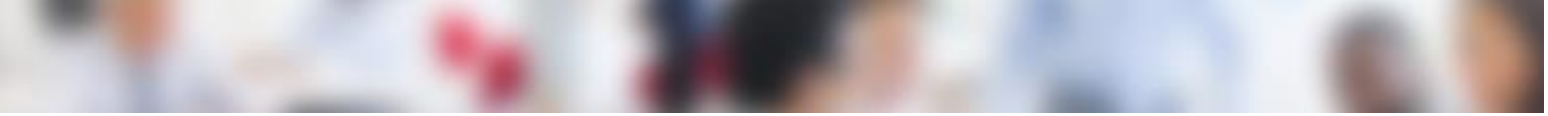
I am a CE certified medical device



Level 1 (M1): the basic criteria for an app.

- **CE declaration** as a medical device is submitted
- **Voluntary notification** of the mobile app to the **Federal Agency for Medicines and Health Products (FAMHP)** during which the CE marking and the compliance with the rules and regulations for medical devices are confirmed and can be checked.
- The app and the parent company declare that they comply with the EU **General Data Protection Regulation (GDPR)**.





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PACSONWEB

PACSonWEB

By Dobco Medical Systems

PACSonWEB is a platform based on pure HTML5 web technology that lends support to all scenarios for the secure delivery of medical images and reports to extramural recipients.

Level 1

I am a CE-certified medical device

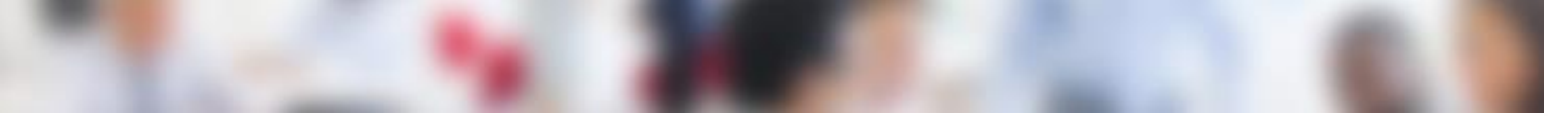
Downloads

Languages

DE EN ES FR IT NL

Visit website

Contact company



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General description | Additional info | Media

General description

Main purpose

The purpose of the application is to visualize medical imaging examinations and to share them between healthcare providers and with the patient.

Target audience

Patients and physicians

Approach

Images and reports of medical imaging are made available according to the authorization rules.

Connectivity to sensors and platforms

The platform is connected to the local systems of the medical imaging departments.

Financing and pricing model

This application is fee of charge for users.

Pathology

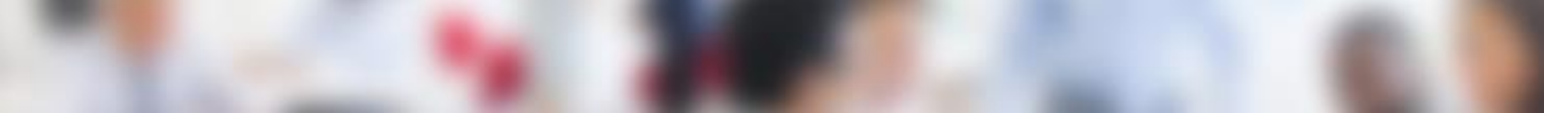
Other

Functions

Data Sharing
Diagnostics

Users

Everyone



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General description | Additional info | Media

Additional info

Compliance to M1 criteria

Data privacy (More info)

- Company declares to be compliant with GDPR rules
- Company declares that the data are stored in EU only

Class type of medical device (More info): 2A

ISO Standards

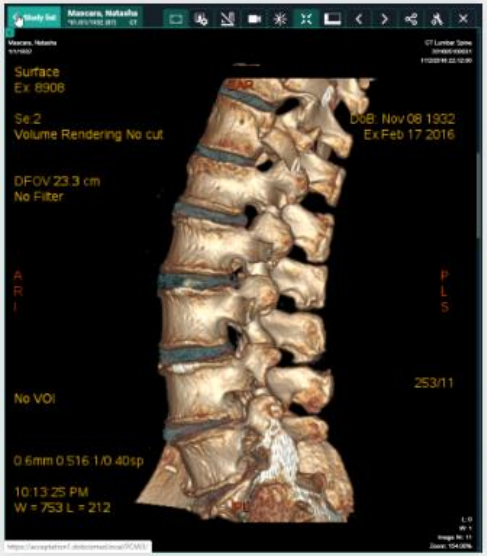
- ISO 13485 Quality Management Systems for Medical Devices (on company level)
- ISO 27000 series: Information Security Management Systems

FAMHP registration number: 08439

FAMHP product identification code: 123456

General description | Additional info | Media

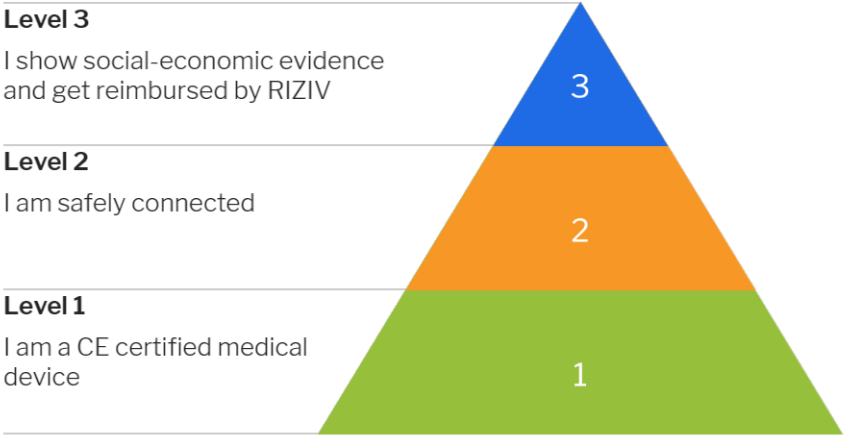
Media

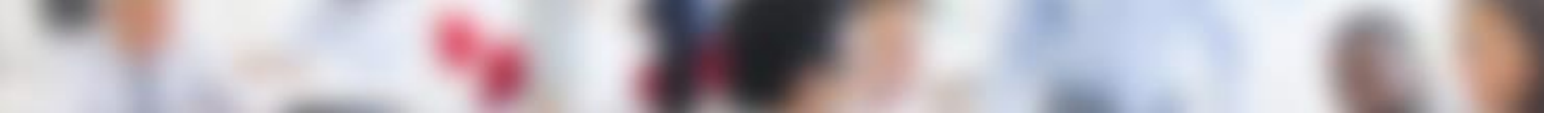


Level 2 (M2): connect with eHealth platform

- Meet the basic criteria of level 1

- Have submitted a risk assessment after which they have proven to meet all imposed criteria regarding:
  - Use of SSIN
  - Authentication: FAS or own system
  - Therapeutic relationship
  - Security
  - Use of local e-health services





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moveUP

moveUP Coach

By moveUP

Through the moveUP Coach App, patients are offered an optimal treatment and rehabilitation for hip and knee arthroplasty, both before and after surgery. Health care professionals get insights and control over the treatment of their patients to achieve higher patient satisfaction and better outcomes in an efficient way.

Level 2

I am a CE-certified medical device
I am safely connected

Downloads

Languages

EN FR NL

Visit website

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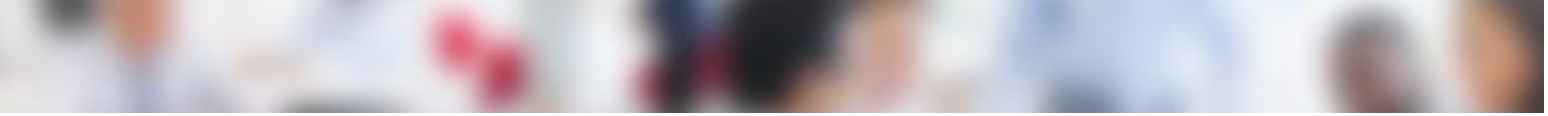

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Compliance to M2 criteria

GDPR app category

- 1 (no processing of personal data)
- 2 (processing of personal data)
- ✓ 3 (processing of sensitive personal data)

App user authentication

- not applicable (only for app category 1)
- via FAS level 400 (FAS = Federal Authentication Service, More info)
- ✓ company own authentication system fulfilling the M2 requirements (self-declared)

Verification of therapeutic relationship and informed consent

- ✓ not applicable
- via eHealth platform user and access management system IAM (More info)
- via company own database fulfilling the M2 requirements (self-declared)

Secured Messaging

- ✓ not applicable
- via eHealth platform's eHealth Box (More info)

Applied interoperability standards

- KMEHR (More info)
- HL7 CDA (More info)
- HL7 FHIR (More info)
- SNOMED-CT (More info)
- ✓ Other

Level 3 (M3): financing after approval NIHDI

- Meet the basic criteria of level 1 and level 2
- Have a demonstrated social-economic added value
- Expected by the end of the year
- Will provide information on the status of the financing request to the NIHDI and timeline
  - Submitted
  - Accepted for review
  - Approved
  - Rejected
- Note that mobile health apps can also be financed by other means
  - Own financing of hospitals
  - Health insurance companies
  - ..

M3: news on reimbursement

moveUP moveUP Coach

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Revalidatieapps vanaf oktober tijdelijk kosteloos

©katrijn van giel

PIETER HAECK | 14 juli 2020 13:11

Patiënten met een knie- of heupprothese die vanaf oktober willen revalideren met een smartphoneapp moeten daar in bepaalde ziekenhuizen tijdelijk niets voor betalen.

In 2018, the public authorities introduced the mHealth pyramid

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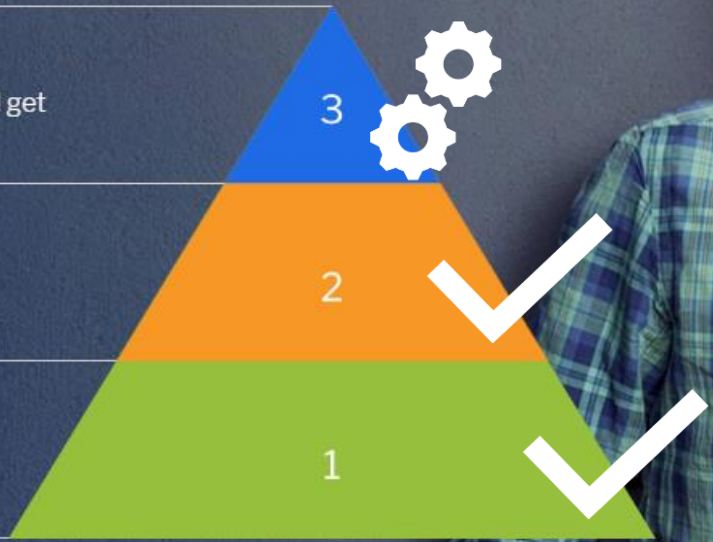

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Embracing ambition

Thank you

For your attention

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