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ASSESS HEALTH TECHNOLOGIES

SHEET

Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care

Validated by the HAS Board on 4 February 2021

Digital technology is becoming an integral part of our health system. Moreover, the current health context highlights the potential offered by digital solutions in addressing the adaptations to the healthcare system needed during a crisis situation.

Public policies have measured the importance of this digital process, both nationally and on a European level. The French Ministry of Solidarity and Health has presented its roadmap for digital policy in the field of health within the framework of the health system transformation strategy, and an action plan has been defined. On an EU level, the European Commission has adopted an action plan detailing the resources that Europe should deploy to encourage the "*Transformation of Health and Care in the Digital Single Market*". As regards artificial intelligence, on 19 February 2020, it adopted a White Paper[1] and the European Parliament subsequently adopted three resolutions on 20 October 2020 containing recommendations for the Commission including the resolution on a civil liability regime for artificial intelligence[2].

For its part, HAS dedicated its 2019 prospective analysis[3] to the digital (r)evolution and formulated 29 proposals to ensure that digital technology is a tool serving all stakeholders.

Why a classification grid?

Existing and future "digital solutions" cover an extensive and highly diversified field. This extraordinary heterogeneity may stem from their technological nature or from their operating principles and their

[1] European Commission. White Paper. On Artificial Intelligence - A European approach to excellence and trust. (COM(2020)0065). 2020. https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf

[2] European Parliament. Civil liability regime for artificial intelligence. 2020/2014(INL). 2020. https://www.europarl.europa.eu/doceo/document/TA-9-2020-0276_EN.html

[3] HAS. 2019 prospective analysis report - Digital technology: what (R)evolution? 2019. https://www.has-sante.fr/upload/docs/application/pdf/2019-07/rapport_analyse_prospective_20191.pdf

associated functions, the assessment procedures required, and/or potential funding methods. For example, some are intended to be used by users/patients/caregivers, while others are aimed at healthcare professionals and/or facilities. Some are medical devices, while others are not. Some are assessed, certified, in compliance with standards, guidelines, while others are not. Some are funded by the healthcare system, while others are not, etc.

Furthermore, two "ecosystems" (healthcare/digital development) interplay, without mutual knowledge of the specific aspects of each. As such, mention can be made of the National Office for Innovation and eHealth Practices: gnius.esante.gouv.fr. Indeed, to save businesses time and speed up the introduction of their innovations onto the market, G_NIUS (the French National Office for Innovation and eHealth Practices) has an approach based on the type of regulations, stakeholders, and funding sources.

In addition, to facilitate and structure interactions between the various stakeholders further, in view of the wide range of differences mentioned above, HAS is proposing a digital solution classification grid based on their intended use supplemented by:

- the capacity of the digital solution to take into account user/patient parameters (capable of resulting in personalisation of the response),
- the autonomous[4] or non-autonomous[5] nature of the digital solution in terms of human intervention.

Four increasing levels (from A to D) of patient/caregiver/user personalisation and autonomy of the digital solution are thus proposed[6]. It is understood that where a digital solution includes several functions characterised by different intended uses, it may fall under several classification categories in view of each of its functions. Moreover, at this stage, no subcategory has been formed to separate digital solutions including or not including embedded decision-making systems based on "artificial intelligence".

[4] An autonomous solution refers to a technology operating in a closed circuit, i.e. an active therapeutic device having an embedded or incorporated diagnostic function which determines patient management by the device. As such, an autonomous digital solution generates a therapeutic, screening or diagnostic action on its own, without prior human intervention.

[5] A non-autonomous solution refers to a technology operating in an open circuit, i.e. a solution that will not carry out any therapeutic, screening, or diagnostic action without prior human intervention.

[6] This grid does not cover all fields of digital solutions (for example those used for purposes other than routine care (clinical trial support software, order management software, etc.), those relating to data warehouses, and software used to query databases, etc.). It will need to be supplemented if stakeholders deem it necessary.

Table: Simplified classification

	Description	Number of categories	Personalisation	Autonomy
Level A	System services for patients, caregivers or healthcare professionals within the scope of care or care pathway optimisation or medical/socio-administrative management with no direct action on patient health.	1 category		
Level B	General non-personalised user information on living conditions, healthy living, diseases/disabilities or any health state (in the broad sense of the term), health, care or life pathways, etc. Also provides training materials or tools.	1 category		
Level C	Aid for living, for prevention, screening, diagnosis, compliance, monitoring or treatment of a disease, health state, or in the context of a disability. No autonomy of the digital solution in care pathway management.	8 categories		
Level D	Autonomous decision management after data analysis and diagnosis with a view to automatically adjusting the treatment to be administered, without human intervention.	1 category		

As regards the preliminary information of the status (MD, IVDMD or not) of the different categories proposed, according to the ANSM, *"it can currently not be envisaged to incorporate this information in this classification without further details on the intended purpose (or claim) established by the manufacturer of the digital solution.*

Indeed, not all the software and applications used in the field of health have MD or IVDMD status. The qualification of a digital solution requires a case-by-case assessment based on the intended purpose and its specific features to characterise the medical intended use of the product[7]*.*

For a digital solution equipped with several functions or modules, the analysis to establish MD/IVDMD status or not will be carried out for each of the functions, in view of the intended use of each.

Moreover, the risk associated with the use of a digital solution is not a qualification criterion. However, this risk for a digital solution assigned MD or IVDMD status shall be a classification criterion as per annexes VIII of MD Regulation 2017/745 and IVDMD Regulation 2017/746."

[7] By way of reminder, in order to be awarded MD or IVDMD status, the digital solution must have the following cumulative criteria:
– be intended for use for medical purposes in accordance with the MD or IVDMD definition. For example, it should enable diagnosis, diagnostic assistance, treatment, or treatment assistance,
– provide a specific result for the benefit of a single patient,
– carry out an action on input data, such as an analysis with a view to providing new medical information. For example, a data analysis application in respect of a patient's specific physiological signals and equipped with alert functions for medical intended use will be deemed to have MD status. This action must be different from storage, communication, or merely a search such as a database or a digital library incorporating data solely for the purposes of archival, without processing the data.

Is it necessary to create subcategories for artificial intelligence systems?

The European Parliament defines an "***AI system***" as "*a system that is either software-based or embedded in hardware devices, and that displays behaviour simulating intelligence by, inter alia, collecting and processing data, analysing and interpreting its environment, and by taking action, with some degree of autonomy, to achieve specific goals*"

For AI technologies, it also defines an "***autonomous***" system as "*an AI system that operates by interpreting certain input, and by using a set of predetermined instructions, without being limited to such instructions, despite the system's behaviour being constrained by and targeted at fulfilling the goal it was given and other relevant design choices made by its developer*".

The European Parliament stipulates that "*the operator of a high-risk AI-system shall be strictly liable for any harm or damage that was caused by a physical or virtual activity, device or process driven by that AI-system*", the term operator being defined in section 12 of its resolution[2].

High-risk "*AI-systems*, and all critical sectors where they are used shall be listed in the Annex of the European Regulation announced for 2021.

Although the approach of the following classification grid is based on increasing levels in terms of patient/caregiver/user personalisation and autonomy of the digital solution, at this stage, no subcategory has been established to separate digital solutions with or without embedded artificial intelligence-based decision-making systems.

What does the future hold for such a classification grid?

The high level of feedback from the public consultation held to help build the grid (76 responses, including 46 collective responses, and 30 individual responses) confirmed the level of interest in the approach as over 90% (Appendix 1).

However, from the point of view of HAS, this function-based approach will only be beneficial if, over time and according to its use, it is accompanied by developments of matrix approaches including other aspects. For example:

- applicable regulations: technology falling under MD, IVDMD status or not (if yes, which risk class), subject (or not) to confidentiality/personal data protection regulations (GDPR) or health data hosting regulations (L.1111-8 CSP), considered as high-risk or not (according to the upcoming European Regulation), etc.,
- technical guidelines: need for interoperability or not, etc.,
- possible funding models: assessment with a view to funding or not? by HAS or by other stakeholders?, etc.

This will require in-depth research by the stakeholders concerned in a given field to potentially link this grid with one or more maps of the characteristics of their field. For HAS, this is a *sine qua non* condition for facilitating the understanding of each party (competent authorities and companies seeking a better

understanding of their expectations, users, etc.). All this work will be fully coordinated with the work of the Digital Health Council.

Under these conditions, this grid will reach its full potential.

An example of possible use of the classification would be to link it with a risk matrix. To this end, in 2016[8], HAS previously published best practice guidelines aimed at developers of health apps and smart devices proposing a modulation of the level of best practices to be taken into consideration according to the risk, based on a risk matrix accounting for the target user and the intended use of the solution.

This risk level-based approach has also been adopted in the upcoming European regulations (MD and IVDMD and that planned for the civil liability regime for artificial intelligence).

To summarise, by proposing a function-based approach supplemented by increasing levels in terms of patient/caregiver/user personalisation and autonomy of the digital solution, this classification grid, subject to further work on matrixes, should, if taken onboard by stakeholders, help structure their interactions (regulatory/technical/clinical/economic/assessment-related) and ultimately help increase effective integration of digital solutions in the healthcare system, including the medico-social sector.

[8] HAS. Good practice guidelines on Health Apps and Smart Devices (*Mobile Health or mHealth*). 2016. https://www.has-sante.fr/jcms/c_2681915/fr/referentiel-de-bonnes-pratiques-sur-les-applications-et-les-objets-connectes-en-sante-mobile-health-ou-mhealth [in French]
https://www.has-sante.fr/upload/docs/application/pdf/2017-03/dir1/good_practice_guidelines_on_health_apps_and_smart_devices_mobile_health_or_mhealth.pdf [English translation]

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Table 1: Full classification grid

Category	Functional classification	Intended use	Potential users	Technologies not included in scope	Examples[9]
Level A					
A1	**System service**	Used for: – technical support for patients, caregivers or healthcare professionals in the context of care or care pathway optimisation, – or medico-administrative facility management with no direct action on patient health.	Depending on the technologies: – Patient – Healthcare professional – Facility – Home healthcare provider – Caregiver	This category does not include systems performing automatic health data transmission to a third party for telehealth purposes	– Tool for administrative management, storage, archival, such as a database or digital library including data and information, including those containing the patient's personal data or health data • For example: medical transportation order and management platform, hospital product management or storage software, material order software – Software for sharing patient data. • For example: Shared medical record (SMR), Pharmaceutical Record (PR) – Instant messaging app – Communication software used for example for medical telemonitoring or video transmission telecare, with no automatic transmission function to a third party and with no patient data processing – Platform for communication between and with healthcare professionals – Online appointment or care pathway optimisation software – Geolocation app for public health purposes. – Electronic personal tracking record (symptoms, health state, etc.) without automatic data transmission to a third party and without patient data processing – …

[9] The examples provided are not exhaustive. They are intended to illustrate the type of technologies potentially falling under each category. Many other technologies could be inserted in this column.

Category	Functional classification	Intended use	Potential users	Technologies not included in scope	Examples[9]
Level B					
B1	**General information** for the user	Provides the user with: – general non-personalised information on living conditions, lifestyle and dietary measures, diseases/disabilities or any health state, standard care protocols, – or training materials or tools.	Depending on the technologies: – Patient – Healthcare professional – Facility – Home healthcare provider – User	This category does not include systems used for entering personal data and transmitting such data to a third party	– System offering lifestyle and dietary advice (diet, smoking cessation, sports or physical activities, skin protection, etc.) – Healthcare professional training material or tool – …
Level C					
C1	**Living aid** in the context of a disability or loss of autonomy without autonomy of the digital solution[5]	Aims to mitigate disability by providing personalised information or assistance.	User	This category does not include systems providing general non-personalised information	– Smartphone app enabling persons with a disability to request assistance in solving an occasional problem from volunteer caregivers connected to the app (directions in a geographic area, reading a document, etc.) – Audio description app intended for the visually impaired – Connected emergency service alert wristband for elderly persons – Fall detection activity sensor for elderly persons – …
C2	**Preventive actions related to behaviour** without autonomy of the digital solution[5]	Aims to provide lifestyle and dietary /physiological information: – tailored to the user's profile (whether they have a disease or not), – so that they adapt their lifestyle / behaviour.	Depending on the technologies: – Patient – Healthcare professional	This category does not include systems that make a diagnosis and suggest screening or treatments	– Systems offering targeted lifestyle and dietary advice (smoking, diet, alcohol, physical exercise) on the basis of the user's data, for the purposes of preventing/managing chronic illnesses/addictions/health states – Ovulation phase prediction tool – Connected pedometer – …
C3	**Self-monitoring** **Self-treatment**	Aims to help people with a diagnosed and treated condition to manage their treatment autonomously.	Patient	This category does not include systems enabling: – diagnosis	– System used by patients for self-monitoring or self-treatment purposes, essentially in the context of chronic, somatic or psychiatric illnesses

Category	Functional classification	Intended use	Potential users	Technologies not included in scope	Examples[9]
	without autonomy of the digital solution[5]	This may concern: – self-monitoring when tracking by the patient will result in them recontacting the healthcare professional to adapt their treatment. – self-treatment when monitoring will: • result in the patient adapting their treatment according to the medical prescription and to achieve the care objectives defined with the healthcare professional, • help optimise treatment compliance by the patient.		– autonomous treatment initiation – automatic data transmission by the system for telemonitoring purposes	The system may also be used for managing a non-pathological health state or be used for rehabilitation by the patient themselves in presence of a professional or not. The system enables patients to receive alerts/advice so that they can improve the management of their condition, these alerts/this advice being managed by the patients themselves. For example: • Continuous interstitial glucose monitoring system coupled with an insulin pump or not • External neurostimulator for managing pain and epileptic seizures, etc. • Gamification solution applied to the treatment of psychiatric illnesses • App proposing physiotherapy exercises • 3D simulation headset for rehabilitation (for example for balance, treating phobias, etc.) • Eye or musculoskeletal disorder rehabilitation/prevention/treatment app • Wrist blood pressure monitor connected to the patient's smartphone only • System that can be used to record patient compliance data (duration of use via periodic reports) and send the patient alerts/advice to encourage better compliance or shared between the patient and the healthcare professional at follow-up visits – …
C4	**Telehealth** with automatic analysis of data transmitted for alert purposes without autonomy of the digital solution[5] in relation to managing these	Enables a healthcare professional to: – interpret the patient's data remotely, via alerts sent based on the data collected at the patient's home, – and manage these data to optimise patient care and treatment management.	Depending on the technologies: – Patient – Healthcare professional	This category does not include systems enabling: – initial diagnosis – autonomous treatment initiation – autonomous treatment management without human	– Medical telemonitoring system such as an app, web platform or other, optionally connected to a tool or an MD having a measuring function, and which sends data or alerts according to the thresholds or criteria established by the professional user for medical telemonitoring purposes For example: • eHealth app intended for home-based medical follow-up of patients, with no signs of severity, suffering from or suspected of suffering from a disease via medical questionnaires proposed

Category	Functional classification	Intended use	Potential users	Technologies not included in scope	Examples[9]
	alerts in terms of diagnosis or treatment/care	This may concern: – medical telemonitoring when tracking by the doctor will result in them recontacting the patient to adapt their treatment, – telecare when a pharmacist or a medical auxiliary will be placed in contact with the patient for remote care.		intervention (by the patient or the professional)	one or more times daily. The app generates alerts based on the response to the questionnaire to provide suitable medical care if symptoms worsen. • Heart failure tracking software with cardiac alert sent to doctor in the event of decompensation • App for tracking the mood of patients with depression sending an alert to the healthcare professional if any issue is detected. • Upper arm blood pressure monitor connected to a telemonitoring platform and coordination of care – System used in the context of medical telemonitoring including software such as an app, web platform or other based on an expert system processing the data recorded collected by the system itself or which are obtained from technologies with which it is connected or which are input by the patient, to analyse them and send the professional information to assist with diagnosis or prognostic information other than that obtained directly by reading the data collected. Unlike the previous example, these systems produce new data from the data collected. For example: • Web-app type software equipped with an expert system analysing the patient's data to produce a risk score used in the context of medical telemonitoring for the purposes of early detection of recurrence among cancer patients in remission – …
C5	**Screening aid** without autonomy of the digital solution[5]	Offers a disease or impairment screening aid via the production of options proposed to the patient or healthcare professional. The digital solutions concerned are intended to be used in a large population and involve	Depending on the technologies: – Patient – Healthcare professional	This category does not include systems providing general non-personalised health advice	– Diabetic retinopathy screening software – Connected genetic disease or cancer detection system – …

Category	Functional classification	Intended use	Potential users	Technologies not included in scope	Examples[9]
		diagnostic confirmation, where applicable.[10]			
C6	**Diagnostic aid** without autonomy of the digital solution[5]	Offers a personalised disease or health state diagnostic aid via the production of diagnostic options or prognostic information intended for the healthcare professional.	Healthcare professional	This category does not include systems that only provide a non-personalised list of symptoms and signs of a disease	– System using patient data to assist a healthcare professional in diagnosing a disease (e.g. cancer) or health state (e.g. pregnancy confirmation and dating). Systems providing prognostic information fall under this category. For example: • Software for detecting tumours using imaging techniques • Software associated with a chest band to detect breathing pauses with a view to diagnosing sleep apnoea • Medical pathology result-based diagnostic aid software – …
C7	**Treatment aid** without autonomy of the digital solution[5]	Enables treatment, determination of parameters for implementation or guidance of the medical decision. The technology is used during care provision or beforehand to optimise implementation.	Depending on the technologies: – Patient – Healthcare professional	This category does not include systems intended for therapeutic decision-making	– System that uses the patient's clinical data to calculate treatment parameters (for example in radiotherapy) or treatment administration methods (infusion rate, dilutions, etc.) directly. Depending on the circumstances, the users may be those implementing the treatment, i.e. patients or prescribers, those dispensing it (pharmacists, assistants) or those administering it (nurse). For example: • App calculating insulin dose based on blood glucose data • Dosage adaptation software based on kidney function – System used by healthcare professionals for the purposes of aiding treatment, regardless of type (surgical, rehabilitation, etc.). For example: • Surgical robot

[10] Digital solutions falling under this category can also be classified as diagnostic aids if they are envisaged to be used for diagnostic purposes.

Category	Functional classification	Intended use	Potential users	Technologies not included in scope	Examples[9]
					• Gamification solution used during care provision in the presence of a healthcare professional (for example, app in the context of locomotor or oculomotor rehabilitation) • Pelvic floor rehabilitation solution used in the context of sessions conducted in the presence of a healthcare professional • Orthopaedic surgery guidance solution – …
C8	**Therapeutic decision-making aid** without autonomy of the digital solution[5]	– Suggests, based on the patient's data, one or more options to the professional to help them make therapeutic decisions relative to a diagnosed condition.. Or – Identifies medicinal product interactions, contraindications and pharmacovigilance.	Healthcare professional	This category does not include systems that provide non-personalised general health advice or systems intended to improve the care pathway	– System that uses the patient's data in order to propose the various possible treatment options to healthcare professionals (for example, in oncology). The users are those who prescribe and dispense the treatment. For example: • Prescription aid software • Dispensing aid software • Drug interactions calculation software • – … This category includes devices also incorporating the functions of C7.

Level D

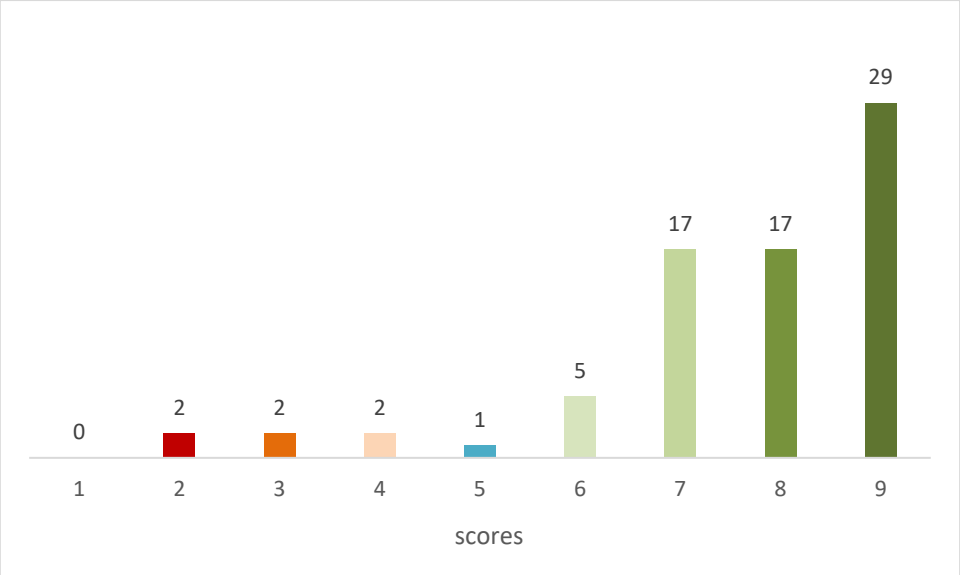
Category	Functional classification	Intended use	Potential users	Technologies not included in scope	Examples[9]
D1	Autonomous decision management[5]	Analyses data, establishes the diagnosis then automatically and autonomously adjusts the treatment to be administered or implemented.	Depending on the technologies: – Healthcare professional – Patient	This category does not include systems incorporating the functions of this category but operating in an open circuit	– System that uses the patient's data with a view to diagnosing a disease status and subsequently automatically modifying, without prior human intervention, the parameters of a treatment. At the present time, the examples of this type of fully autonomous technologies appear to be limited. For example: • System that analyses data from a continuous glucose monitor used by a patient with diabetes and that will automatically adjust the basal rate or administer a bolus dose without the need for patient intervention (artificial pancreas, also known as closed loop), • Implantable cardiac defibrillator with a remote monitoring solution that analyses data from a heart monitor, delivers a shock in the event of cardiac arrest, and can transmit alerts to the healthcare professional responsible for the patient's care. – …

Appendix:1 Breakdown of scores awarded to the draft functional classification of digital solutions according to their intended use in the public consultation by HAS.

From 22 April to 30 June 2020, the French National Authority for Health submitted its draft grid to public consultation in order to obtain the opinions of stakeholders in the sector, involved in developing and using digital solutions: accredited or non-accredited patient and healthcare user associations, national professional associations and learned societies, public institutions and agencies, unions, companies, developers, researchers, etc.

Through this public consultation, HAS sought to collect the expression of opinions on the draft classification and assess the clarity and exhaustive nature of the proposed categories.

Out of the 76 participants, 75 responded to the final question "Overall, what do you think of this draft functional classification of digital solutions on the basis of their intended use?", which suggested giving an overall score between 1 and 9. **The mean score of the draft version was 7.6/9, and the median corresponds to a score of 8/9**. **A score greater than or equal to 6 showed the participant's satisfaction with the draft: this was the case for 90.7% of the contributors' responses.**



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