

SCIENTIFIC OPINION ON I-CARE PLATFORM

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Introduction

I-Care has been presented as a comprehensive and innovative platform aimed at prevention and wellbeing management.

I-Care platform has been conceived to make available the most innovative, non-invasive screening technologies even for non medical health operators, such as pharmacists, nurses and/or other health-related professionals.

The platform is mainly focused on satisfying the need for wellbeing as well as guaranteeing support for the prevention of the so called “non communicable diseases”, such as cardiovascular diseases, diabetes mellitus, metabolic disorders and the metabolic syndrome, which account for 41 million deaths per year all over the world, according to WHO reports. The empowerment of customers’ awareness about the best possible strategies to self-prevent such diseases is also claimed to be another major goal of the I-Care platform.

It’s noteworthy that the platform does not have diagnostic and/or therapeutic purposes, but collects diagnostic and screening data provided by third parties, just representing them in an userfriendly way. With respect to this function, I-Care platform has obtained a CE Class I medical certification, which defines it as a tool for data storage and organization, though the platform collects measurements by means of specific CE Class II certified medical devices.

Therefore, different devices perform the measurement and process the result which is then represented on the I-Care platform in an easily comprehensible manner, according to the device’s manufacturer and/or according to the commonly used international standards.

A team of bioengineers, medical consultants, medical device partners/suppliers and multidisciplinary outstanding researchers has largely contributed to the elaboration, evaluation and testing of the algorithms for building scores for each kind of check up measurement, according to recommendations based on range/parameters defined by medical device CE certification, on international guidelines or professionals’ own know how.

The areas most developed in I-Care are:

- Nutrition

- Ageing
- Lifestyle
- Aesthetics
- Indicators of risk of developing chronic diseases.

Moreover, as I-CARE software has been developed through a Web Application, it allows continuous and automatic updates of the system and its features. The access to the platform is performed via the secure protocol https, which guarantees the encryption of the exchanged data, in order to protect them from possible interceptions. An ISO 27018 certified service also ensures secure storage and management of personal and sensitive data.

As the software program is not the object of this scientific report, I will not comment on this any further, given that the software has been developed by specifically skilled professionals and fully respects the last EU General Data Protection Regulation.

Medical Devices included

I-Care is considered an active medical Class I device, since it has not been conceived to provide diagnosis and/or therapy, rather to manage and monitor clinical/medical data of patients by means of a Web platform, in synergy with other devices. These, in turn, comply with the related CEE Directives and quality standard certifications; they are non invasive, do not need any specific environment for their use and no medical training is required. Moreover, they are designed and manufactured in order not to compromise the safety and the health of the patients nor those of the users.

Measurements performed

1) AGE CHECK

This measurement is performed by using a non invasive recent technique called skin autofluorescence, which has been reported to be a sensitive marker of the accumulation of advanced glycation end products, derived from glycemic and oxidative stress. An association between skin autofluorescence measure and type 2 diabetes micro- and cardio-vascular complications, as well as its independent predictive value for the aforementioned complications, has also been shown and reported in several valuable studies available in literature. More in details, the test is based on an autofluorescence reader that illuminates a small skin surface with a given excitation light intensity. This emission light and the reflected skin light are then measured with a spectrometer and the final result is provided by specific calculations and expressed in units.

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2) BODY CHECK

This test utilizes worldwide commonly used measurements such as waist circumference, waist/hip and waist/height ratios and body mass index. These clinical anthropometric parameters have been reported as predictive scores for the risk of developing metabolic syndrome, type 2 diabetes and cardiovascular diseases. Many scientific societies support their clinical use in the prevention and screening of non communicable diseases, together with the evaluation of other well known risk factors such as physical activity. A large number of studies have also been published in highly reputed international scientific journals.

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3) BODY COMPOSITION

The evaluation of body composition has become more and more common in clinical practice, especially when physicians seek for nutritional and metabolic parameters which may correlate with the development of non communicable diseases later in life. In this regard, its predictive value has been clarified and demonstrated in several well designed studies reported in literature, which support the percentage of body fat as a better and more reliable predictor than body mass index.

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4) CALORIMETRIC CHECK

In the field of clinical nutrition, physicians cannot avoid to check patients' energy expenditure in order to calculate their personal energy requirements and design a proper diet. With respect to this need, the calorimeter is the most utilized apparatus worldwide. There is a large consensus within the scientific community about the recommendation to prefer this method rather than other energy expenditure tests currently available.

References:

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5) DENSI CHECK

The estimation of bone density is of utmost importance for the evaluation of bone health and the prevention of osteoporosis. Its measure is also relevant for monitoring possible side effects of specific “by exclusion diets”, either in health or in disease related regimens, as well as those linked to the use of some specific drugs or subsequent to hormonal changes or to some inherited metabolic disorder. Therefore, it should be always assessed when evaluating the nutritional status of a subject presenting with risk factors for bone health. Many different methods are currently available to measure bone density. Among these, heel ultrasound densitometry has been demonstrated to be a quick, non invasive, safe, reliable, validated and easy to learn method, sometimes even more accurate than other techniques used for bone densitometry evaluation.

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6) FOOD DETECTIVE

This assay is claimed to be able to identify the presence of food intolerance to a large number of common foods, by measuring related IgG antibodies. As a matter of fact, the method is not validated by any international or national scientific society of Allergology or Nutrition, though it is supported by some papers published in literature.

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7) METABOLIC CHECK

The prevention of cardiovascular diseases must take into account the evaluation of specific metabolic biochemical parameters which have turned to be considered as major risk factors. The assessment of blood lipid profile, including total cholesterol, HDL and LDL cholesterol and triglycerides is the mainstay of cardiovascular and cardiometabolic risk evaluation, as recommended by many outstanding international scientific societies as well as by WHO. A huge amount of papers has been published to support the value of this check in prevention and/or in monitoring therapeutic interventions.

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8) SKIN AREA: SKIN CHECK, TRICO CHECK, NAIL CHECK, UV CHECK

As declared by the authors, these dermo-cosmetic checks have no diagnostic value for skin health or disease, rather they just represent an aesthetic evaluation. In this regard, the use of medical devices is not required, except for a digital microscope and a device for the detection of moisture and skin elasticity. Therefore, I have no further comment on this point.

9) PULMONARY CHECK

Spirometric pattern evaluation is of utmost importance in the assessment of lung functions, according to the international recommendations by different scientific societies of Pneumology and Allergology. The reference and cut-off values of the parameters to evaluate have been fully agreed and adopted worldwide. Should a subject need a pneumological evaluation, this must include the assessment of spirometric parameters to define pulmonary functions, obstruction or restriction severity scores and prescribe adequate therapeutic intervention. The check is also commonly used in the clinical follow up for monitoring drug efficacy and response and may also have predictive value for lung function later in life.

References:

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10) SAT CHECK

It's undisputed that oxidative stress plays a major role in determining many diseases affecting the whole body from the skin, to the brain and the heart, as well as a number of metabolic pathways and reactions. It may also have mutagenic effects on DNA, in turn involved in cancer onset and progression. Oxidative stress may affect protein and lipid metabolism as well as DNA via the deleterious effect of free radicals substances, which should be counteracted by a proper action of antioxidant compounds to maintain an healthy balance. The different harmful effect of oxidative stress may also underlie very common oral diseases, such as periodontitis, precancerous lesions and dental caries. As the latter is thought to be the most common, chronic, non communicable, preventable oral disease in the world, a number of studies have been designed to find adequate salivary markers of oxidative stress to prevent the onset of such and of other preventable oral diseases. As a diagnostic fluid, saliva has the advantage to allow non-invasive, easy collection and even repeated sampling. It has been assessed that saliva contains products of lipid and protein peroxidation and of DNA oxidation and fragmentation, which can be used for the assessment of oxidative stress. On the other hand, various antioxidant compounds are present in saliva including glutathione, ascorbic, and uric acid and some antioxidant enzymes such as superoxide dismutase, catalase, and glutathione peroxidase. A simple, non invasive test of the salivary "redox" status may therefore be considered as a useful tool in the prevention of common oral diseases, according to many scientific studies published in literature.

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11) VASCULAR AGE

Arterial stiffness, measured as pulse wave velocity, has been described as associated to brain lesions detected as white matter hyperintensities in nuclear magnetic resonance T2 imaging. More recently, it has been clarified that these lesions may be associated to the progression of cognitive decline and functional disabilities, which in turn are typical features of the so called geriatric syndrome. Evidence has been accumulating to suggest that diabetes mellitus may favour the progression of these brain lesions, in addition to other already known risk factors such as hypertension, dyslipidemia and old age. Given the above, it seems obvious that the periodical check of the vascular age and stiffness may represent a valuable preventive tool, especially in subjects with the aforementioned risk factors.

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12) VEIN CHECK

The measure of the elasticity of venous system, especially of leg veins, has been described as a useful tool to prevent venous insufficiency. Some studies have been carried out and published in literature so far, showing that reduced vein elasticity may predispose to varicose veins and precede valvular incompetence.

References:

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In conclusion, I-Care software provides a useful integration of different clinical and biochemical parameters, mostly supported by a robust scientific literature. As it is meant to be a screening and monitoring technology, addressed to non physicians and without diagnostic purposes, it seems to fully achieve its goals.

Piacenza, 10/01/2019

A handwritten signature in blue ink, enclosed in a thin black rectangular border. The signature is cursive and appears to read 'Giovanni...'.