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Towards a Health 4.0 Framework for the Design of Wearables: Leveraging Human-Centered and Robust Design

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Abstract

With the introduction of Health 4.0 we face a new era in healthcare and notice the disruption of delivery, adoption and use through newly introduced technology. Wearables have become increasingly important in the medical sector and their remote application and widespread use are significant to the development of technology in healthcare today and the future. The implementation of wearables requires regulations and clinical approval when intended to use for health tracking and monitoring. Within this process designers play a crucial role. Design methodologies are the guideline to accomplish a successful path towards the creation of a new product. In this paper the authors explore and draw from established design methodologies to support the creation of a framework for design of wearables in a health 4.0 context. Identifying the positions of design practices and analyzing the correlations in the context of Health 4.0 is therefore presented within this paper.

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Keywords: Health 4.0, inclusive design, mental health, user-friendly, user-centred design, wearable technology

1. Introduction

Driven by networked Electronic Health Record systems, Artificial Intelligence, real-time data from wearable devices with an overlay of invisible user interfaces and improved analytics, a revolution is afoot in the healthcare industry. Over the next few years, it is likely to fundamentally change how healthcare is delivered and how the outcomes are measured. The focus on collaboration, coherence, and convergence will make healthcare more predictive and personalised. This revolution is called Health 4.0. Data portability allows patients and their physicians to access it anytime anywhere and enhanced analytics allows for differential diagnosis and medical responses that can be predictive, timely, and innovative. Health 4.0 allows the value of data more consistently and effectively. It can pinpoint areas of improvement and enable decisions that are more informed. It also helps move the entire healthcare industry from a system that is reactive and focused on fee-for-service to a system that is value-based, which measures outcomes and ensures proactive prevention [1].

In this context, the overarching research aim is to investigate and understand how smart healthcare systems of the future (products or product-service-systems) can be designed effectively and efficiently. To be more specific, our focus is on the design of digital wearables for monitoring and managing health conditions remotely, and potentially for detecting developing health conditions and thus preventing medical emergencies. To achieve this aim, we intend to devise a design framework to aid the design process of such products. In this context, the research question addressed in this paper is “How can existing design methodologies support the creation of such a framework for the design of wearables for Health 4.0 applications”.

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Wearables have become increasingly important in the medical sector and their remote application and widespread use are significant to the changing healthcare landscape. Despite their importance, there is limited guidance for designers seeking to produce new wearable devices in the context of Health 4.0. In this paper, existing design methodologies, and their associated standards and practices, are reviewed for use in a new design framework for wearable design in the context of Health 4.0. In this section, tangible differences between Health 3.0 and Health 4.0 are considered in the wearable design context, existing literature in this sector is discussed and the research questions, to be addressed by this paper, is identified.

1.1. Designing for Health 3.0 vs. Health 4.0

Health 4.0 represents the ongoing results of a significant technological revolution in healthcare. Technologies such as MioT (medical Internet of Things), AI (Artificial Intelligence), VR (Virtual Reality), ML (Machine Learning), Big Data, Deep Learning and NLP (Natural Language Processing), are now integrated within healthcare systems and have significantly altered the way care is given and received.

Designers play a vital role in bridging the gap between disciplines and in understanding the needs of stakeholders within the healthcare system. As problem solvers they help to design products, services and systems for and with people. The changes resulting in the Health 4.0 era, however, have resulted in tangible changes to the way designers must approach new projects. Table 1 below gives an example of these tangible changes and how they may influence the design of wearables.

Table 1: Designing for Health 4.0

Tangible changes from 3.0 to Health 4.0	Implication on Wearable Design Health Process
Shift from point of care to point of need (shift away from hospitals/institutions)	Quality expectations and requirements should be clearly defined as part of the problem definition. [2]
Virtual delivery of care outside of hospitals [2]	In any decision-making stage, implications on quality should be considered and heavily weighted as part of the decision-making process.
Management and processing of data: services tailored to individuals rather than designed by statistical averages [2]	Quality should be defined quantitatively in problem definition and in the context of the problem. For example, in the Health 4.0 context, deviations from ergonomic standards, should be recognised as the number of excluded patients.
Interactive pharmaceuticals: A more reactive pharmaceutical industry [2]	Wearable devices allow pharmaceuticals and other health stakeholders to be more reactive but only if there is adequate feedback from individuals to stakeholders. Designers must consider how their device supports other stakeholders and provides the right information in a timely manner.

1.2. Existing Literature on Wearable Design in Health 4.0 era

For wearable design in a Health 4.0 era, existing literature exclusively includes design approaches for the use and application of wearables. Literature can therefore be categorised according to the application domain. Existing literature, set in the context of Health 4.0, addresses either the use of wearables for specific medical conditions, use of wearables for a specific user group or use of wearables for a specific medical unit, such as cardiology. Use of the term "Health 4.0" is still emerging, so search terms such as "smart healthcare" and "digital healthcare" were also considered and yielded the same results.

The first sector of literature considers the use of wearables, in the context of Health 4.0, for specific medical conditions such as multiple sclerosis. Golab et al. [3] present an approach to design for a "wearable headset for monitoring electromyography responses within spinal surgery". They find that the design process must place emphasis on "improving efficiency of the device" with regards to ease of use. Grigoriadis et al. [4] present a Health 4.0 approach for the design of wearables for the "management of multiple sclerosis". They find that as a consequence of the "chronic and variable" nature of the disease, designers must recognise the need for "flexibility" in the final design.

The second sector of literature considers the use of wearables in the context of Health 4.0, for specific user groups. Terroso et al. [5] present a wearable for active fall detection for the elderly, Dong et al. [6] evaluate consumer attitudes towards wearable in China and Petrie et al. [7] discuss lifecycle design in the context of wearables for those with disabilities. These and other authors, offer some insight for an approach to design but all insights are very specific to the user group. Furthermore, this literature is predominantly in the field of health, as opposed to design, and therefore does not leverage existing design research or methodologies.

The final sector is the design of wearables, in a Health 4.0 context, for specific medical units. Park et al. [8] discuss the "design and control of a bio-inspired soft wearable robotic device for ankle–foot rehabilitation". They find that bioinspired design methodologies can support the design of wearables for healthcare applications. This is a concept echoed by Pevnick et al. [9] who considers wearable technology for cardiology. They "also offer several frameworks to classify and better understand wearable devices" in the context of digital health. These frameworks can be described as micro-abstract design methods and are therefore "not appropriate for guiding the full design process" [10]. As a consequence, there is still a need for holistic design framework for guiding wearable design in the context of Health 4.0.

Existing literature offers many insights into design approaches for a Health 4.0 context but since these insights are founded on specific application domains, they are not clearly applicable for general use.

1.3. Literature Gap and Research Aim

Tangible differences in Health 3.0 and Health 4.0, and the implications on the design process (Table 1), results in a need to devise new approaches to design in the Health 4.0 era. In the context of wearable design, existing literature is yet to present a holistic framework to guide the design of wearables. To begin to address this literature gap and devise a design framework, the authors consider what existing design methodologies can provide. The research question to be addressed in this paper is therefore:

How can existing design methodologies support the creation of a framework for the design of wearables in a Health 4.0 context?

The following section first includes a discussion on which existing design methodologies to consider. Inclusive design, emotional design, robust design and participatory design are then reviewed for their use in the context of wearable design in the Health 4.0 era. Following this section, a consolidation of the findings is presented, followed by future research directions and conclusions.

2. Design Methodologies

In this section, four design methodologies, and how they can support wearable design in a Health 4.0 context, are presented. Distilling the design requirements in Table 1, demonstrates the need for patient understanding and stakeholder management in the Health 4.0 era. By shifting from point of care to point of need, further emphasis is placed on the requirement of the individual and, as a consequence, stakeholder requirements are more numerous and diverse to fulfil customisation. With regards to delivery of virtual care and the consideration of access, emphasis on individuals as stakeholders means consideration of a range of levels of accessibility and a range of types of accessibility (such as technical savviness, access to the internet, motor skills and other physical access). Management of data and information flow requires significant collaboration of stakeholders, and further emphasises the need to consider stakeholder management in the design process. Inclusive and emotional design are chosen to reflect both the needs and feelings of patients, while robust and participatory design have been considered due to the significance of stakeholder management for designers in the context of Health 4.0.

2.1. Inclusive Design

"The British Standards Institute (2005) definition of inclusive design is: "The design of mainstream products and/or services that are accessible to, and usable by, as many people as reasonably possible ... without the need for special adaptation or specialized design." [11].

Organizations such as SCOPE focus on the independence of disabled people and argue that medical interventions focus on what is "wrong" rather than on what is "needed" (SCOPE, 2019). Designers in this case, and this should be applied broadly in healthcare, are the middle man or better said the mediator between the "medical model of disability" and aforementioned charitable organization. Functioning in a pool of cross-disciplinary interaction [12]. The "BS 7000-6:2005 Guide to managing inclusive design", released by the bsi in 2005, is out there but progress is stagnating. The guidelines address the need of inclusive design and "disabled people's needs are considered throughout the lifecycle of a product or service."

We can agree upon one fairly in common sense understandable fact that is that we are all different from each other, this is expressed in size, shape and form. And the aim of inclusive design is to take down the barriers of separation and move towards empowerment of an equal, independent and confident lifestyle without limitations in the built environment. This is where the design of wearables for healthcare 'in its infancy' should focus on, the benefits in designing universally creates the aforementioned viewpoint (equality). Following up on the empowerment of inclusive design in context with wearables for the use of monitoring, gathering data and evaluation. The main stakeholders involved are the user/patient and the clinician/ practitioner. But as researchers from the Berkeley University of California have accurately illustrated, these are not the only parties involved in the process of accumulating big data (Fig. 1). Although primarily information on vital signals is send to the practitioner for evaluation and diagnosis. In later stages it surpasses the payer (insurance companies) and pharma companies.

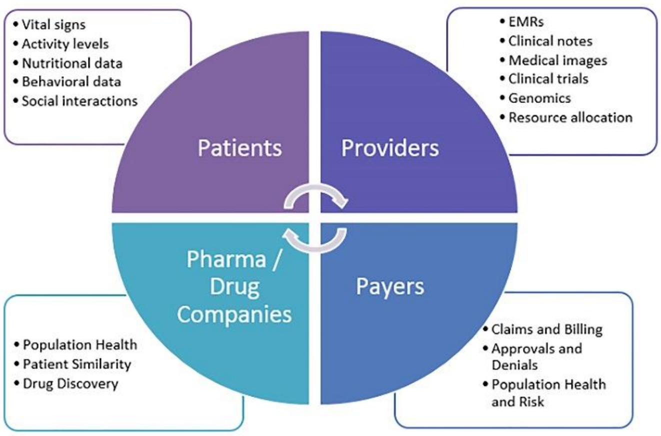

Figure 1: Source ELPP 2016. [13]

Inclusivity plays a role here too by bridging the gap between stakeholders it can create services, systems and products that operate on an interconnected level. An example would be the Remote Care Monitoring (Preparation) Scheme introduced by the NHS in 2013/14 for GP's to remotely follow up on patients with long-term conditions that do not need hospitalisation. This scheme is designed to support GP's with identifying "… the ongoing tests or bodily measurements required to support the stable management of the chosen condition and how those tests and measurements will be accessed or fed in by patients with the condition." (p.2/10b) [12]. Further it allows patients to participate in "the monitoring of results from such tests or measurements other than by face to face consultation (e.g. video call, telephone, text, email or letter) and the governance arrangements to support these including safe and confidential exchange of information." [14]. This is happening today and will be accessible for the wider mass rather than 'just' to patients with long-term conditions. Which draws us back to inclusive design that is engraved in the aforementioned examples and analysis. Thus far we have understood that the method of inclusive design is to be able to widen the focal area with a design approach aiming at including people and to attain information from multiple perspectives. Other than 'User centred Design' and 'Participatory Design' as well as similar design approaches that are rather mainstream focused, Inclusive Design aims at including the generality; "Universal Design", "Inclusive Design" and "Design for All" movements have encouraged designers to extend their design briefs to include older and disabled people."[15].

To include the different stakeholders displayed in Berkeley's research example, designers need to consider the significance of the solid system and provide inclusivity for all parties involved in the circle. In the context of Health 4.0 it can establish an opportune stage for universal applicable devices, systems and services.

2.2. Emotional Design

Design is key in shaping the lifes of individuals. This part of the paper deals with the emotional aspect in designing wearable technology in Health 4.0. D. Norman in his book Emotional Design states: "*The problem is that we still let logic make decisions for us, even though our emotions are telling us otherwise. Business has come to be ruled by logical, rational decision makers, by business models and accountants, with no room for emotion. Pity!*" [16]. To his understanding rational thinking rules out emotional response. The design of wearables within the context of emotional design faces challenges since these products are attached to the body or embedded. An online database search on 'emotional design and wearables' lacks of in depth research and design methods. Most articles are concerned with studying how to detect emotions with sensors and computing systems. In emotional design we analyze the responds of individuals to the form, shape, surface and look of products in order to consider reactions for the design process and create a positive experience for the consumer. D. Norman's Three Level of Design concept is displayed in Figure 2 which consists of three different parts that are interconnected and form a method to the practice of emotional design.

Visceral Design – "Concerns itself with appearances".
Behavioural Design – "...has to do with the pleasure and effectiveness of use."
Reflective Design – "...considers the rationalization and intellectualization of a product. Can I tell a story about it? Does it appeal to my self-image, to my pride?" [16].

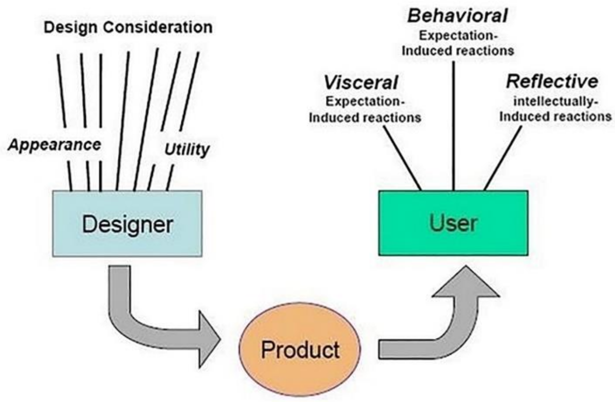

Figure 2: Norman's Three Levels of Design [15]

What we see is translated into our senses and Norman's emotional system describes the three different areas in our minds that are responsible for it, as mentioned above. All dimensions are separated into three areas of design that together are the sum of emotional design. In regard to designing wearables for healthcare it is vital to understand the difference of these levels, as their methods are applicable in different areas, i.e. commercial use, business interest or to suite companies' objectives (visceral design) [17]. Especially designing for healthcare requires to set new rules for quantitate, content focused environment. Though designers will face limitations in ethical concerns, healthcare norms and regulations. This part of the paper gave a brief example of a method to apply when designing wearables provided by Donald Norman. Reference aimed specifically at designing wearables for Health 4.0 have been mentioned earlier in this paper and appear to be a gap when exploring online. Designers are challenged to apply these methods to a field of product design and engineering where the primary focus is held on form, function and performance. Clearly defining how emotional design contributes to the process in the context of Health 4.0.

2.3. Robust Design

Having established the importance of stakeholder management for design in the context of Health 4.0, robust design is the first design methodology considered. Robust design is a group of methods implemented to limit deviations from original function [18]. This methodology may provide insight for wearable design by ensuring multiple stakeholder inputs are a consideration but not a distraction from fulfilling the design problem. Unlike other design methodologies included in this paper, robust design is centred in increasing performance. In robust design, associated with each quality characteristic, the design objective often involves multiple aspects such as "bringing the mean of performance on target" and "minimizing the variations" [19]. In this section, the authors specifically consider the Taguchi method and identify theories transferrable to the creation of a framework for wearable design in a Health 4.0 context.

The Taguchi method is classified as a significant aspect of robust design methodology [20]. The Taguchi method is a concept that has produced a unique and powerful quality improvement discipline that differs from traditional practises [21]. It is considered a powerful tool for design optimization for quality [22]. The Taguchi method is defined by three principles which each have implications on the product development process, as shown in Table 2 below.

Table 2. The Three Taguchi Principles and their Implication on the Design Process

Three Principles for the Taguchi method	Implication on Design Process
Quality should be designed into the product and not inspected into it [21].	Quality expectations and requirements should be clearly defined as part of the problem definition.
Quality is best achieved by minimizing the deviation from a target. The product should be so designed that it is immune to uncontrollable environmental factors [21].	In any decision-making stage, implications on quality should be considered and heavily weighted as part of the decision-making process.
The cost of quality should be measured as a function of deviation from the standard, and the losses should be measured system wide. [21]	Quality should be defined quantitatively in problem definition and in the context of the problem. For example, in the Health 4.0 context, deviations from ergonomic standards, should be recognised as the number of excluded patients.

To obey the principles of the Taguchi method, designers, most fundamentally, need to place significant consideration on quality throughout the product development process. This means incorporating feedback loops and stage-gates throughout the process to consider how decisions influence the quality of the wearable. Furthermore, this means placing importance on clearly defining what quality means, in the context of the product and Health 4.0, in the problem definition phase.

Taguchi also proposes a prescriptive approach to applying robust design as shown in Figure 3. These stages are not defined according to product development phases and are therefore phase agnostic. They also may be repeated within product development phases or considered on a macro level.

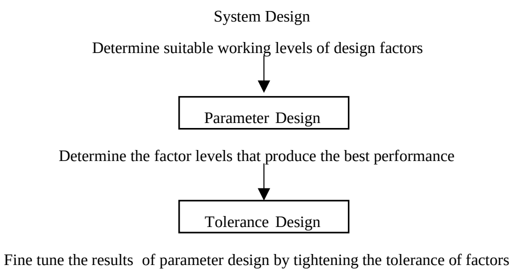

Fig. 3. Three-stages of Robust Design

In Table 3 below these stages are considered in the context of wearable design and Health 4.0

Table 3. The Three Taguchi Stages and an example in the context of Health 4.0

Three Stages for the Taguchi method	Example in Context of Health 4.0
System Design	Consider dimension range for optimal ergonomics suitable for patients.
Parameter Design	Assign range within which the device dimensions can differ.
Tolerance Design	Consider how movement with this ranged can be recognised quantitatively. For example, deviations from ergonomic standards, should be recognised as the number of excluded patients.

In summary, robust design has been developed to improve product quality and reliability in industrial engineering [18]. This is applied through methods such as the Taguchi method which is defined by three principles and a three-stage prescriptive approach. In this section, this methodology has been considered in the context of wearable design for Health 4.0. Findings show that the following could be included in a framework for wearable design in the context of Health 4.0:

- Clearly defined requirements of quality
- Consideration of these quality requirements and how they are impacted, with all key decisions
- Assignment of quantitative measure of quality such as patients impacted

The purpose of robust design is to limit the design process to deviation due to external factors [23]. In the context of Health 4.0, this means fulfilling functional requirements despite demands from several and multiple stakeholders. Using the Taguchi method could allow incorporation of stakeholder input while ensuring performance. Furthermore, by assigning a quantitative consideration of quality, such as patient impact, the robust design methodology centres the design process on the needs of the patient, mirroring the existing shift in healthcare as a consequence of Health 4.0 technologies.

2.4. Participatory Design

In robust design, the risk of distraction from stakeholder involvement is mediated. In participatory design, involvement of stakeholders is expanded to create a collaborative relationship between designers and stakeholders. While robust design views stakeholder involvement as a challenge, participatory design views stakeholder involvement as an opportunity. Considering both of these perspectives is valuable for yielding balanced insights for future work.

Participatory design is "not defined by the type of work supported, nor by the technologies developed, but instead by a commitment to worker participation in design" [25]. It is an "attitude from designing for users to one of designing with users" [27] and an attempt to "rebalance the power relations" between designers and users [25]. Participatory design attempts to steer a course "between tradition and transcendence" that is, between participants' tacit knowledge and researchers' more abstract, analytical knowledge [26, 28, 30]. In the context of Heath 4.0, participatory design means recognising the vital involvement of patients, health professionals and health institutions in the design process.

This attitude is realised in the form of several techniques and activities to ensure collaboration with users. Activities for applying participatory design include workshops, stories, creation of shared languages, descriptive artefacts and working prototypes [24]. Table 4 considers the prescriptive design process [29] in the context of wearable design for Health 4.0, how users can contribute and through which participatory design activities they could be involved.

Table 4. Participatory Design Activities for wearable design in Health 4.0 context

Product Development Process	Value of User Input	Participatory Design Activity
Problem Definition: What problem is this wearable device addressing?	Validation that problem is the right problem Understanding of how the problem impacts the user	Interviews with users Focus groups with users Brainstorming workshop to encourage suggested problems from users
Requirements Elicitation and Analysis: What do users require from this device?	Feature suggestions Understanding of physical constraints Understanding of nonphysical constraints	User scenario mapping Interviews with users Focus groups with users Brainstorming on feature list Observational studies for understanding of lived experience
Concept Generation	Diverse ideas from new and user perspective More numerous ideas	Crowdsourcing activity seeking idea submissions Brainstorming session with users
Concept Evaluation	Early testing of ideas Refinement of features within boundary of existing ideas Weighted input from users in selection process	Group interviews gaging interest on individual concepts Individual interviews for each concept Collaborative creation of weighted selection tool
Embodiment Design	Regular feedback from users	Open design tools to allow read access for group of users
Detailed Design	Regular feedback from users	Open design tools to allow read access for group of users
Testing and Validation: Has this design addressed the problem?	Understanding of use in real environment Understanding of use in reality	Observational studies with use of prototypes

A framework for the design of wearables in a Health 4.0 context can use participatory design techniques, to ensure stakeholder input is placed at the centre of the design process. Designers essentially must engage and involve users in each design phase and in important design decisions. This can be done by using several of the participatory design techniques listed above, and by adopting the participatory design mindset. In the context of Health 4.0, the participatory design mindset means understanding that patients, health professionals and health institutions should have as much, if not more, ownership of the device than researchers and designers, and their input must be treated with upmost importance in design decision making.

3. Conclusions

This paper addresses the research question: how can existing design methodologies support the creation of a framework for the design of wearables in a Health 4.0 context?

Four design methodologies were considered inclusive design, emotional design, robust design and, participatory design, to yield insight for framework development. From robust design, the authors recognize a need for clearly defined quality requirements, consideration of quality as part of all design decision making and a quantitative assessment of quality to leverage as part of design decisions. From participatory design, authors recognize a need to adopt a mind-set that places user input as highest in a hierarchy of decision influencers. From inclusive design, the authors recognize a need to, not only include users, but make user involving activities accessible to all user groups, especially vulnerable users such as those with disabilities or the elderly. Finally, emotional design highlights the need to assess the visceral, behavioural and reflective impact on users, throughout the design process.

In summary, the authors will incorporate the following into a framework for wearable design in the context of Health 4.0:

- Varying techniques of user involvement to ensure inclusivity
- Recognition of different user needs and adoption of new approaches to include all users
- Identification of user responses to design on the three emotional levels
- Robust design methods to ensure user involvement does not distract designers from performance and quality requirements.

Future research directions, suggested by the authors, include consideration of software, as well as hardware, design methodologies, ethnographic studies to assess user involvement in the design of wearables, and extensive consideration of the ethics associated with the involvement of vulnerable people in design.

4. Discussion of Future Research Directions

To leverage these findings and continue towards a framework for the design of wearables in a Health 4.0 context, several future research directions have been identified.

Firstly, additional design methodologies must be considered. Methodologies such as interface design, interactive design and functional design may provide further insights to support framework development. Furthermore, analysis in this paper has been biased towards hardware design but software design methods must also be incorporated into a future design framework. Methodologies derived from software such as user interface design, user experience design and agile, should be considered as part of framework development.

In addition, further consideration of the design of wearables, outside of the context of Health 4.0 should be included in framework development. The authors consider the implications of the context of wearable design and the context of Health 4.0, as equally important. This paper considers Health 4.0 in more detail, and therefore the wearable design sector should feature more significantly in future research.

User involvement has been shown to be key in the development of a future design framework. Further research in this area is a vital research direction. Researchers should seek insight from user involvement in previous wearable projects and should also seek to understand how vulnerable users have been previously involved in product development. Furthermore, the ethics associated with vulnerable user involvement will significantly impact this work and should be extensively considered by future researchers.

Finally, the authors suggest future work includes observational studies. Existing literature includes limited use of ethnographical studies and, based on the importance of addressing user needs, observational studies could be a method to extract new findings in this field.

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