

**ERGOCERT**<sup>©</sup>  
ERGONOMICS CERTIFYING INSTITUTE

## ***PROOF REPORT***

**Evaluation and certification of 2 series  
of pillows produced by Sleepit.com**

**RPE 19052 – 23/07/2019**

Accreditato dalla Regione

Friuli Venezia Giulia



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## COMPANY IDENTIFICATION

<b>Company name</b>	Sleepit.com
<b>Company referent</b>	Renato

## AUDIT EXECUTION

<b>Company name</b>	<b>“Morpheus Spring” Pillow Serie</b> <b>“ Sleepit ” Pillow Serie</b>	
<b>Place and Date</b>	Udine – 17-07-2019 Udine – 25-07-2019	
<b>Audit Group (GdA)</b>	<b>Lead auditor:</b> Marco Bordignon M.Sc. (European Certified Ergonomist - Eur.Erg) <b>GdA member:</b> Dr. Giovanni Pischiottin B.Sc. (Junior Ergonomist)	
<b>Requested Certification Level</b>	<b>“Morpheus Spring”</b> <b>ErgoCert Certified ★★★★★</b> <input checked="" type="checkbox"/> POLYTECHNICAL AREA <input checked="" type="checkbox"/> BIOMEDICAL AREA <input checked="" type="checkbox"/> PSYCHOSOCIAL AREA: USABILITY <input checked="" type="checkbox"/> SUSTENABILITY	<b>“ Sleepit ”</b> <b>ErgoCert Certified ★★★★★</b> <input checked="" type="checkbox"/> POLYTECHNICAL AREA <input checked="" type="checkbox"/> BIOMEDICAL AREA <input checked="" type="checkbox"/> PSYCHOSOCIAL AREA: USABILITY <input checked="" type="checkbox"/> SUSTENABILITY <input checked="" type="checkbox"/> PSYCHOSOCIAL AREA: USER EXPERIENCE (UX)
<b>Versions</b>	<input type="radio"/> Soft <input type="radio"/> Medium <input type="radio"/> Sustained	<input type="radio"/> Soft <input type="radio"/> Medium <input type="radio"/> Sustained

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## 1. INTRODUCTION

ErgoCert – Ergonomics Certifying Institute – was tasked by Sleepit.com . with evaluating and certifying the ergonomic characteristics of the “Morpheus Spring” line of pillows. We were also requested to extend the current certification for the “ Sleepit ” (\*\*\*) serie, carrying on with tests concerning these areas: environmental sustainability, usability, and user experience. This report shows the results of the ergonomic assessments and the product technical compliance level.


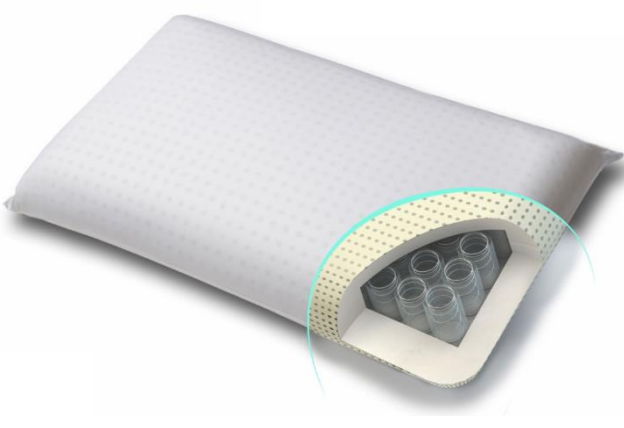
The ST02.02 Technical Specification requires the pillows, in order to be certified as ergonomic, to be subjected to tests and assessments regarding the three reference macro-areas of ergonomics: polytechnical, biomedical, and usability. For the ergonomic requirements see paragraph 4.

## 2. EVALUATION TEAM

The evaluation team was made up of the following experts:

- Dr. Marco Bordignon (*Certified European Ergonomist – ErgoCert Technical Manager*)
- Dr. Giovanni Pischiottin (Junior Ergonomist)

## 3. EVALUATED MODELS

Morpheus Spring Serie	Sleepit
	
<b>Thickness</b>	
12 cm	
<b>Inner core materials</b>	
<ul style="list-style-type: none"> <li>- 100% polyester fiber</li> <li>- Polyurethane insulating plate</li> <li>- 60 independent phosphated harmonic steel springs</li> </ul>	<ul style="list-style-type: none"> <li>- Visco-elastic polyurethane</li> <li>- 60 independent phosphated harmonic steel springs</li> </ul>
<b>Pillowcase</b>	
100% Cotton	

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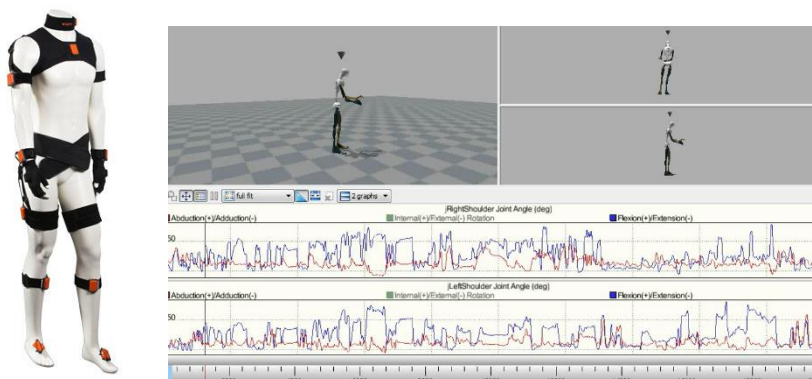
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#### 4. GENERAL ERGONOMIC REQUIREMENTS

##### *“Morpheus Spring” serie:*

- Regarding **the polytechnical area**, we carried out a document review of compliance with the non-toxicity of the product materials and with environmental sustainability.
- Regarding **the biomedical area**, the ErgoCert specification requires the performing of particular instrumental evaluations involving 6 subjects, selected depending on their height, weight, neck and shoulder length. In the instrumental detections we used the “MVN Biomech Awinda” movement analysis inertial system (X-Sens, NL): the system is made up of 17 suitably positioned (“dressing”) integrated sensors (accelerometers, gyroscopes, etc.) - as can be seen from the following picture - which ensure a subsequent accurate reconstruction of the postures adopted by the operators during the whole acquisition time.

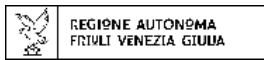


- Regarding **the usability area**, we carried out tests to check the ease (putting on and taking off the pillowcase) and satisfaction of use.

##### *“ Sleepit ” serie:*

- Regarding **the polytechnical area**, we carried out a document review of compliance with the non-toxicity of the product materials and with environmental sustainability.
- Regarding **the usability area**, we carried out tests to check the ease (putting on and taking off the pillowcase) and satisfaction of use.
- Regarding **the user experience area**, we analyzed the scientific evidence with regard to the evaluations on user experience with satisfaction levels not less than 70%.

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## 5. POLYTECHNICAL AREA: NON-TOXICITY AND ENVIRONMENTAL SUSTAINABILITY

On the basis of the collected evidence, the constituent materials of the “Morpheus Spring” and “ Sleepit ” pillows were awarded the “Öko-tex 100” quality mark. Moreover, the companies supplying the raw materials comply with the requirements contained in the Regulation (EC) No. 1907/2006 (REACH REGULATION), which means that the pillows are free from harmful substances.

On the basis of the documentation provided by Sleepit , the “Morpheus Spring” and “ Sleepit ” pillow lines come with the Simpes Srl test report, which guarantees the products as special and non-hazardous waste, showing NO potentially hazardous property.

 <p>Simpes Srl Via A. Bartocci, 33 - 05100 Terni Tel. 0744/424830 2 linee E-mail: info@simpes.it Web: www.simpes.it P.IVA: 00094710559</p>  <p>SISTEMA DI GESTIONE QUALITÀ CERTIFICATO</p> <p><b>Rapporto di prova n° 1594/2019 pag. 10 di 10</b></p> <p>In considerazione della tipologia del rifiuto e delle informazioni ricevute dal produttore (inerenti i processi produttivi di provenienza che hanno generato i rifiuti e le materie prime utilizzate), valutando il suo comportamento durante tutte le operazioni analitiche (contatto con acqua ed acidi, essiccamento, ecc), possiamo considerare quanto segue:</p> <ul style="list-style-type: none"> <li>• non si evidenzia la necessità / opportunità di considerare le classi di pericolo HP1, HP2, HP12, HP15 poiché non sussistono indicazioni tali per cui ci sia il sospetto che debbano essere attribuite al rifiuto in analisi</li> <li>• non si hanno indicazioni tali per cui ci sia il sospetto che il rifiuto risulti essere infiammabile (HP3)</li> <li>• non si hanno indicazioni tali per cui ci sia il sospetto che il rifiuto risulti essere infettivo (HP9)</li> </ul> <p>Quindi, in accordo al <b>Reg. UE 1357/2014 e alla legislatura precedentemente riportata</b>, in riferimento ai codici di pericolosità da HP4 a HP8 e per i codici HP10, HP11, HP13, HP14, il campione in esame risulta: <b>RIFIUTO SPECIALE NON PERICOLOSO</b></p> <p><b>Indicazione delle eventuali caratteristiche di pericolo: nessuna</b></p> <p>Data di emissione: 11 luglio 2019</p> <p>Il Responsabile del Laboratorio Ordine dei chimici del Lazio Umbria Abruzzo Molise n° 2890 Dott. Daniele Paolemili</p> <p>Firmato digitalmente Analisi effettuate presso i laboratori Simpes S.r.l di Terni - Via A. Bartocci, 33 - Terni Operante con sistema Qualità conforme alla norma UNI-EN ISO 9001 - Certificato Certiquality n° 10963 Certificato di analisi valido ai sensi della Legge n. 679 del 19/07/1975 e successive modifiche ed integrazioni (art. 1 della Legge del 28/02/1975 n. 56 - DM del 22/03/1986). Il presente certificato è valido esclusivamente per il campione esaminato. Riproduzione vietata.</p> 	 <p>Simpes Srl Via A. Bartocci, 33 - 05100 Terni Tel. 0744/424830 2 linee E-mail: info@simpes.it Web: www.simpes.it P.IVA: 00094710559</p>  <p>SISTEMA DI GESTIONE QUALITÀ CERTIFICATO</p> <p><b>Rapporto di prova n° 1595/2019 pag. 10 di 10</b></p> <p>In considerazione della tipologia del rifiuto e delle informazioni ricevute dal produttore (inerenti i processi produttivi di provenienza che hanno generato i rifiuti e le materie prime utilizzate), valutando il suo comportamento durante tutte le operazioni analitiche (contatto con acqua ed acidi, essiccamento, ecc), possiamo considerare quanto segue:</p> <ul style="list-style-type: none"> <li>• non si evidenzia la necessità / opportunità di considerare le classi di pericolo HP1, HP2, HP12, HP15 poiché non sussistono indicazioni tali per cui ci sia il sospetto che debbano essere attribuite al rifiuto in analisi</li> <li>• non si hanno indicazioni tali per cui ci sia il sospetto che il rifiuto risulti essere infiammabile (HP3)</li> <li>• non si hanno indicazioni tali per cui ci sia il sospetto che il rifiuto risulti essere infettivo (HP9)</li> </ul> <p>Quindi, in accordo al <b>Reg. UE 1357/2014 e alla legislatura precedentemente riportata</b>, in riferimento ai codici di pericolosità da HP4 a HP8 e per i codici HP10, HP11, HP13, HP14, il campione in esame risulta: <b>RIFIUTO SPECIALE NON PERICOLOSO</b></p> <p><b>Indicazione delle eventuali caratteristiche di pericolo: nessuna</b></p> <p>Data di emissione: 11 luglio 2019</p> <p>Il Responsabile del Laboratorio Ordine dei chimici del Lazio Umbria Abruzzo Molise n° 2890 Dott. Daniele Paolemili</p> <p>Firmato digitalmente Analisi effettuate presso i laboratori Simpes S.r.l di Terni - Via A. Bartocci, 33 - Terni Operante con sistema Qualità conforme alla norma UNI-EN ISO 9001 - Certificato Certiquality n° 10963 Certificato di analisi valido ai sensi della Legge n. 679 del 19/07/1975 e successive modifiche ed integrazioni (art. 1 della Legge del 28/02/1975 n. 56 - DM del 22/03/1986). Il presente certificato è valido esclusivamente per il campione esaminato. Riproduzione vietata.</p> 
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**LAREG 2 Srl** di Di Maurizio Edmondo e Di Maurizio Renato  
Località Stazione Zona Industriale  
64023 MOSCIANO S.ANGELO (TE)  
Telefono 085.8071000 - Fax 085.8071312

E-mail: [lareg2vendite@lareg2.it](mailto:lareg2vendite@lareg2.it)

**C.A.: Sig.Sellani**

**Mosciano Sant'Angelo Li, 18.06.2018**

**In relazione alla Vs. richiesta di conformità alle prescrizioni previste dal regolamento CE N.1907/2006 (REGOLAMENTO REACH ) siamo in grado di assicurare che tutti in ns. fornitori di materie prime di base hanno effettuato la preregistrazione delle sostanze chimiche.**

**Per quanto riguarda gli ulteriori adempimenti da mettere in atto nelle prossime scadenze abbiamo avuto assicurazione del loro assoluto interessamento.**

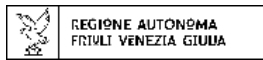
**Quindi allo stato attuale siamo in grado di assicurare i nostri clienti di essere in regola con le prescrizioni alle normative Europee in materia di prodotti chimici del tipo "polimero" (come il nostro).**

**Distinti Saluti**

**LAREG 2 SRL**

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Due Carrare, 26/06/18

**OGGETTO: Regolamento (CE) n. 1907/2006 REACH (European regulation for Registration, Evaluation and Authorisation of Chemicals)**

La nostra azienda non produce né importa sostanze chimiche primarie (in quanto tali o componenti di preparati o articoli), ed utilizzerà materie prime e prodotti composti esclusivamente da sostanze chimiche pre-registrate e poi registrate, secondo le scadenze previste dal Regolamento REACH.

A questo fine sono stati contattati tutti i nostri fornitori e la Supply Chain viene controllata attraverso le Loro risposte, dichiarazioni e aggiornamenti delle Schede di Sicurezza.

A tutt'oggi nessun fornitore ha espresso l'intenzione di non pre-registare e registrare il prodotto fornito.

I polimeri e miscele a base di polimeri sono esclusi dall'obbligo di registrazione secondo il Regolamento.

Gli aggiornamenti della Candidate List sono oggetto di costante attenzione da parte di Giancol spa. Per quanto di nostra conoscenza nel prodotto:

GIANMELT HM/2471

non compare, in quantità superiore allo 0.1% (w/w), nessuna delle sostanze chimiche SVHC né per addizione intenzionale né per composizione delle materie prime da noi utilizzate.

E' in atto comunque un continuo interscambio di informazioni con i nostri fornitori per avere formale conferma dell'assenza di tali sostanze nei loro prodotti.

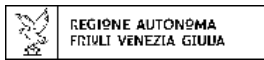
Restiamo a disposizione per ogni chiarimento e con l'occasione inviamo cordiali saluti.

GIANCOL S.p.A.  
*Referente REACH- Tognon Matteo*

Quanto contenuto nella presente è basato sullo stato attuale delle nostre conoscenze con lo scopo di fornire note generali sui nostri prodotti e i loro possibili utilizzi. Non deve pertanto essere interpretato come garanzia espressa o implicita delle proprietà specifiche del prodotto o dell'idoneità per un uso particolare. In ogni caso l'utilizzo di qualsiasi prodotto avviene sotto la responsabilità dell'acquirente, se necessario in seguito a test, per determinarne l'idoneità alle sue lavorazioni e condizioni applicative, e la conformità ad ogni Legge o Regolamento. Ricordiamo comunque che Giancol Spa garantisce un'assistenza continua al cliente per ottimizzare l'uso e l'impiego degli adesivi forniti. Tutti i diritti di proprietà industriale devono essere rispettati

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**E. PONZIANI s.p.a. INDUSTRIA ACCIAI TRAFILATI**

23844 **SIRONE** (Lc) - Via B. Buozzi, 2 - Tel. 031 850050 - Fax 031 852305 - Cap. Soc. € 224.976,00 int.vers.  
Registro Imprese Lecco 00903170132 - R.E.A. Lecco 174351 - M. LC003189 - Codice Fiscale e Partita I.V.A. IT 00903170132  
<http://www.ponziani.it> - E-mail: info@ponziani.it



Sirone  
18/06/2018

#### DICHIARAZIONE REACH:

Con la presente la E.Ponziani S.p.a. dichiara che:

- I prodotti da noi forniti non contengono SVHC ( Substance Very High Concern).
- I prodotti da noi forniti non contengono Sostanze incluse nella Candidate List, aggiornamento Gennaio 2018.
- I prodotti da noi forniti rispettano la direttiva REACH allegato XVII.

Distinti Saluti  
RGQ E. Ponziani S.p.a.  
Lionello Giuseppe



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TESSA S.R.L.  
Via Isonzo 6  
21063 CASTELLANZA (VA)  
Tel. 0331 500110 – Fax 0331 505768  
C.F. / P. IVA 03365420128

#### **Oggetto: Dichiarazione di conformità**

In relazione alla vostra richiesta Vi informiamo che i prodotti, utilizzati nelle nostre lavorazioni, non contengono:

PFOS (perfluorottanosulfonati) Direttiva Europea 2006/122/CE

Phatalate (DHEP, DBP, DINP, DODP, DOP, BBP)

Nonylphenolo

Benzo(A)pirene

PAK (EPA) Idrocarburi aromatici policiclici

Non sono classificate come CMR, cancerogene (categoria 1e2), mutagene (categoria 1 e 2), e tossiche per la riproduzione ( categoria 1 e 2 ).

Non sono classificate come PBT, persistenti, bio-accumulabili e tossiche

Non sono classificate come vPvB, molto persistenti e molto bio-accumulabili.

Non sono sostanze con proprietà in grado di modificare il sistema endocrino.

NON contengono ( in base allo stato attuale delle ns. conoscenze e alle informazioni dei

ns. fornitori ) nessuna delle sostanze inserite nella lista delle “sostanze candidate all’Autorizzazione “ (SVHC : Substances of Very High Concern ) pubblicata dall’ECHA

**(aggiornamento del ( 10/07/2017) .**

**Tale lista , in conformità all’articolo 59 del Regolamento**

**1907/2006/EC è stata pubblicata sul**

**sito dell’ECHA :**

[http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

Soggiacciono alle regole della legislazione europea vigente, o dei singoli stati della CEE

Così come da dichiarazione delle nostre aziende fornitrici

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## ERGONOMIC CERTIFICATION REQUIREMENTS

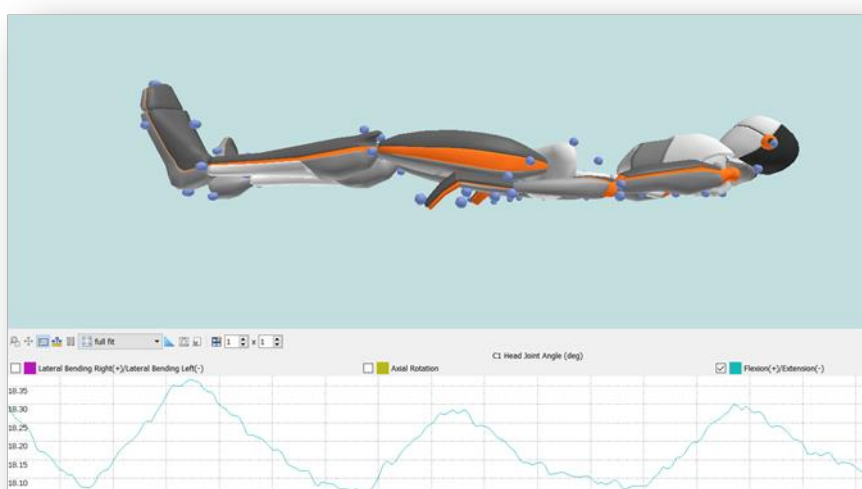
In order to acquire the certification, it is required that:

1. A dimensional variation of the products (different versions) has to be available to ensure an high **adequacy and anthropometric adaptability** for all the possible users, in the inner of the 5<sup>th</sup> percentile F/ 95 percentile M. If that did not happen, it is required that the version produced has to be in accord at least with the medium anthropometric data of the reference population (shoulder length).
2. AT LEAST ONE of the pillows variations being evaluating, for the subject tested, generate deviations of cervical rachis, fully within the limit of acceptability (**full compliance**), BOTH IN SUPINE POSITION AND LATERAL POSITION, or fully conformed in a sleep position and partially conformed in the other.
3. If the in the second requirement **2 partial non compliances** will emerge, than the certifiability of the product will depend on the fully or less compliance regard to the first requirement.
4. Requirement 2 occurs at least for the 2/3 of the tested subjects.

## 6.2 CERVICAL RACHIS

### SUPINE POSITION: DEVIATION C7 – C1

The following figure shows the angle included between the Cervical Vertebrae C7 and C1 in relation to supine position.





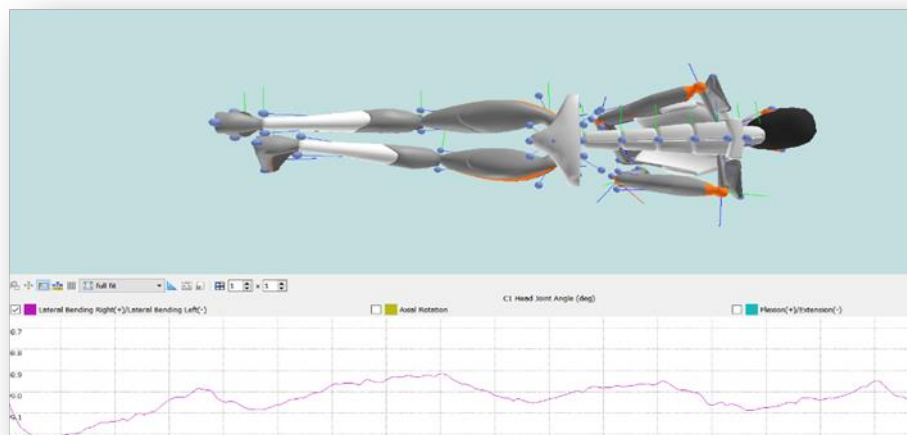
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#### LATERAL POSITION: DEVIATION C7 – HEAD

In the following figure is shown the calculated angle within the segment between the Cervical Vertebrae C7 and the vertex of the head, in relation to lateral position.

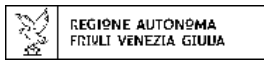


#### CERVICAL RACHIS DEVIATIONS: ACCEPTABILITY LIMITS

Movement	Image	Range of motion (ROM)	Ergocert Limit (1/3 of ROM)	COMPLIANCY
<b>Ventral Decrease (B)</b>  <b>DEVIATION C1 – C7</b>		$\pm 60^\circ$	$\pm 20^\circ$	<b>ACCORDANT</b> Deviation $\leq 20^\circ$
				<b>PARTIALLY ACCORDANT</b> $21^\circ < \text{Deviation} > 25^\circ$
				<b>NOT ACCORDANT</b> Deviation $\geq 26^\circ$
<b>Lateral Decrease (A e B)</b>  <b>DEVIATION C7 - CAPO</b>		$\pm 41^\circ$	$\pm 14^\circ$	<b>ACCORDANT</b> Deviation $\leq 14^\circ$
				<b>PARTIALLY ACCORDANT</b> $15^\circ < \text{Deviation} > 19^\circ$
				<b>NOT ACCORDANT</b> Deviation $\geq 20^\circ$

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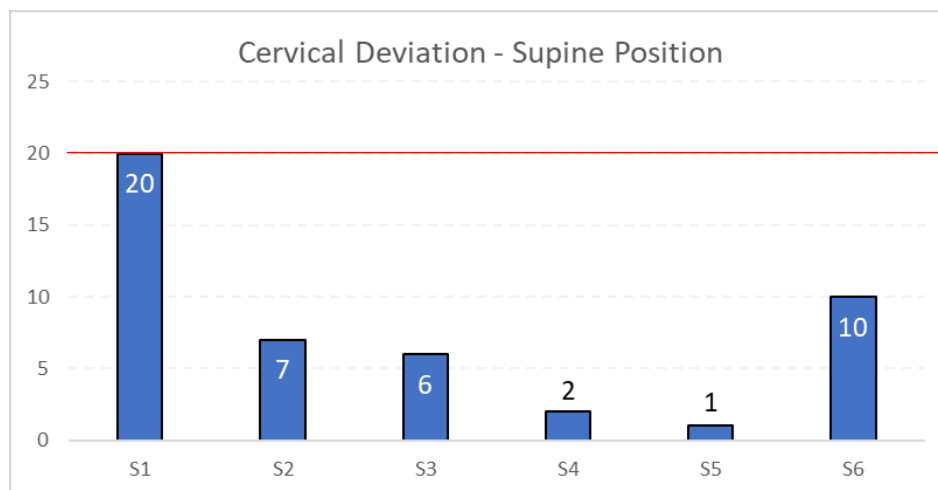
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## 6.3 RESULTS

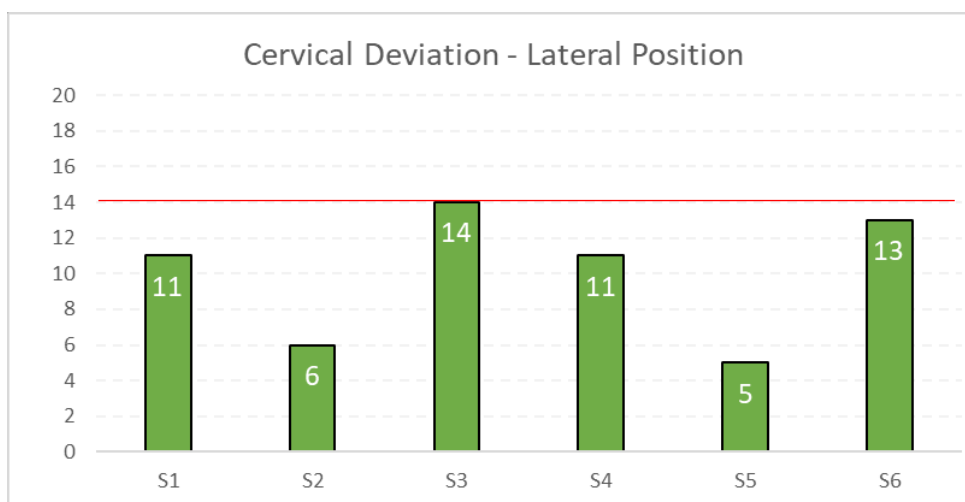
### “Morpheus Spring - SOFT” Pillow

	SUPINE POSITION	LATERAL POSITION
	C7 - C1	C7 - HEAD
User 1 - M - 180 cm - B.M.I. 17,0	20°	11°
User 2 - M - 182 cm - B.M.I. 25,1	7°	6°
User 3 - F - 168 cm - B.M.I. 23,0	6°	14°
User 4 - F - 164 cm - B.M.I. 21,0	2°	11°
User 5 - M - 171 cm - B.M.I. 22,3	1°	5°
User 6 - F - 170 cm - B.M.I. 19,4	10°	13°

### SUPINE POSITION



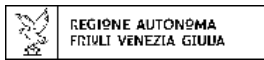
### LATERAL POSITION



The “Morpheus Spring SOFT” pillows resulted conformed,  
both in supine position like lateral, for every user

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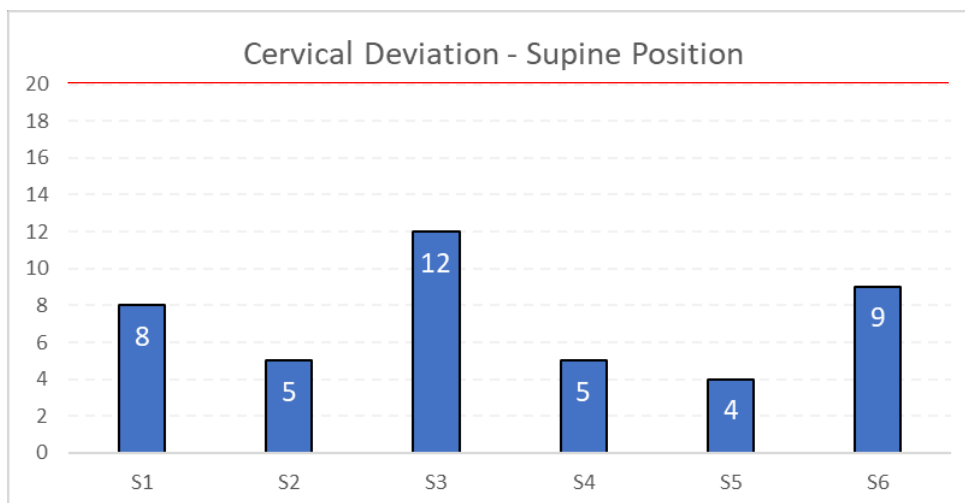
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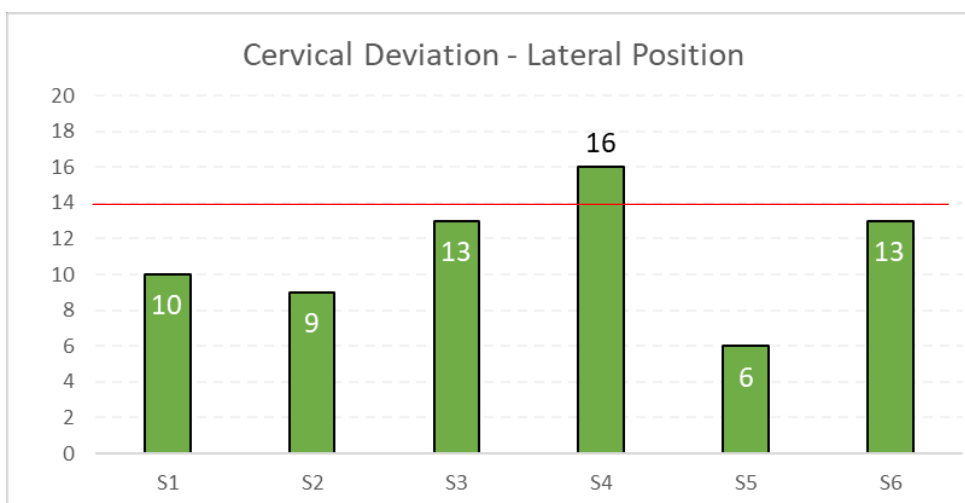
### “Morpheus Spring – MEDIUM” Pillow

	SUPINE POSITION	LATERAL POSITION
	C7 - C1	C7 - HEAD
User 1 - M - 180 cm - B.M.I. 17,0	8°	10°
User 2 - M - 182 cm - B.M.I. 25,1	5°	9°
User 3 - F - 168 cm - B.M.I. 23,0	12°	13°
User 4 - F - 164 cm - B.M.I. 21,0	5°	16°
User 5 - M - 171 cm - B.M.I. 22,3	4°	6°
User 6 - F - 170 cm - B.M.I. 19,4	9°	13°

### SUPINE POSITION



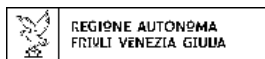
### LATERAL POSITION



The “Morpheus Spring MEDIUM” pillows were conformed in supine position for every user. In the lateral position there is a partially accordant for the user 4

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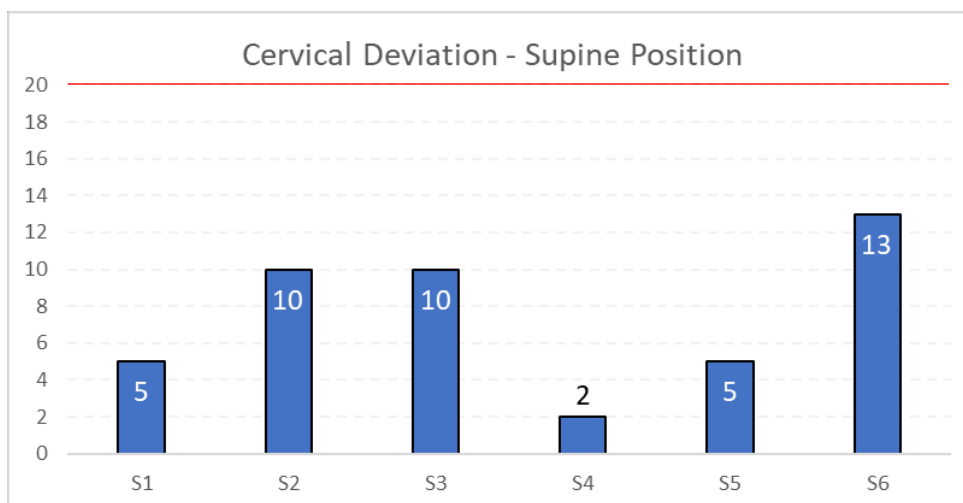
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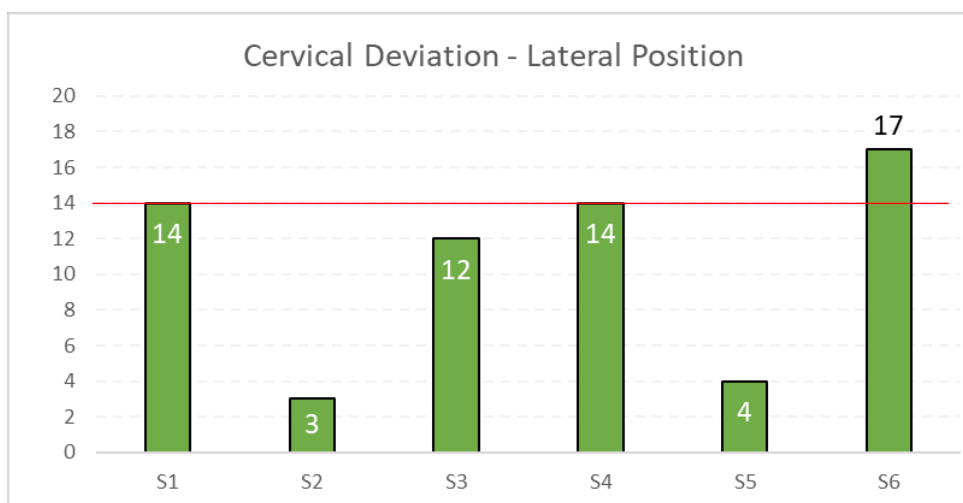
### “Morpheus Spring – SUSTAINED” Pillow

	SUPINE POSITION	LATERAL POSITION
	C7 - C1	C7 - HEAD
User 1 - M - 180 cm - B.M.I. 17,0	5°	14°
User 2 - M - 182 cm - B.M.I. 25,1	10°	3°
User 3 - F - 168 cm - B.M.I. 23,0	10°	12°
User 4 - F - 164 cm - B.M.I. 21,0	2°	14°
User 5 - M - 171 cm - B.M.I. 22,3	5°	4°
User 6 - F - 170 cm - B.M.I. 19,4	13°	17°

### SUPINE POSITION



### LATERAL POSITION



The “Morpheus Spring SUSTAINED” pillows were conformed in supine position for every user. In the lateral position there is a partially accordant for the user 17.


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#### 6.4 ERGONOMIC CERTIFIABILITY OF THE PILLOW

- 1) The qualitative evaluation carried out pointed out the variable softness of the pillow variations “Soft”, “Medium”, “Sustained”, all of them 12 cm height. This thickness is to be considered adequate for the majority of reference population in relation to the anthropometric parameter “shoulder length”. Moreover, the different softness levels provided meets largely the user requirement.
- 2) The following table reports the compliance, obtained with instrumental analysis, with the requirements 2 and 3:

<b>“MORPHEUS SPRING SOFT” PILLOW</b>				
	<b>SUPINE POSITION Compliance</b>	<b>LATERAL POSITION Compliance</b>	<b>Requirement 2 Compliance</b>	<b>Requirement 3 Compliance</b>
User 1	OK	OK	✓	 <b>CERTIFICABLE</b>
User 2	OK	OK	✓	
User 3	OK	OK	✓	
User 4	OK	OK	✓	
User 5	OK	OK	✓	
User 6	OK	OK	✓	

<b>“MORPHEUS SPRING MEDIUM” PILLOW</b>				
	<b>SUPINE POSITION Compliance</b>	<b>LATERAL POSITION Compliance</b>	<b>Requirement 2 Compliance</b>	<b>Requirement 3 Compliance</b>
User 1	OK	OK	✓	 <b>CERTIFICABLE</b>
User 2	OK	OK	✓	
User 3	OK	OK	✓	
User 4	OK	PARTIAL	✓	
User 5	OK	OK	✓	
User 6	OK	OK	✓	

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<b>“MORPHEUS SPRING SUSTAINED” PILLOW</b>				
	<b>SUPINE POSITION Compliance</b>	<b>LATERAL POSITION Compliance</b>	<b>Requirement 2 Compliance</b>	<b>Requirement 3 Compliance</b>
<b>User 1</b>	<b>OK</b>	<b>OK</b>	✓	 <b>CERTIFICABLE</b>
<b>User 2</b>	<b>OK</b>	<b>OK</b>	✓	
<b>User 3</b>	<b>OK</b>	<b>OK</b>	✓	
<b>User 4</b>	<b>OK</b>	<b>OK</b>	✓	
<b>User 5</b>	<b>OK</b>	<b>OK</b>	✓	
<b>User 6</b>	<b>OK</b>	<b>PARTIAL</b>	✓	



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## 7. USABILITY AREA: USER TEST

### 7.1 PROTOCOL

The protocol required the participation of 12 testers, who were asked to carry out some typical tasks interacting with the pillows (e.g., putting on the pillowcase, taking it off, perceived weight, etc.). As required by the ISO standard 9241-11 (2018), we calculated the levels of effectiveness (target achievement), efficiency (trials/errors/time taken), and satisfaction (scale from 1 – difficult – to 7 – easy) associated to the different tasks.

### 7.2 RANDOMIZATION

As indicated in the evaluation protocol, the interaction order was randomized in order to reduce the serial position effect:

1	2	3	4	5	6
1-2-3-4-5-6-	2-4-6-5-3-1	6-4-3-1-5-2	4-3-2-1-6-5	3-1-5-4-6-2	3-2-1-5-6-4
7	8	9	10	11	12
5-2-3-4-1-6	5-6-2-3-1-4	3-6-2-4-5-1	2-3-1-4-6-5	2-5-6-4-1-3	5-1-6-4-3-2

### 7.3 PROCEDURE

Each tester was welcomed in a specially reserved area, where each session was carried out following this procedure:

- Welcome, introduction to the test
- Informed consent
- 1<sup>st</sup> pillow test
- 2<sup>nd</sup> pillow test
- 3<sup>rd</sup> pillow test
- 4<sup>th</sup> pillow test
- 5<sup>th</sup> pillow test
- 6<sup>th</sup> pillow test
- Thank-yous and leave-taking.

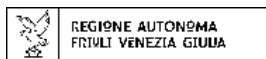
The subjects were filmed for the whole test duration for the purposes of the data analysis.

### 7.4 USER SAMPLE

The sample was made up of 12 users, 6 men and 6 women, with good age distribution.

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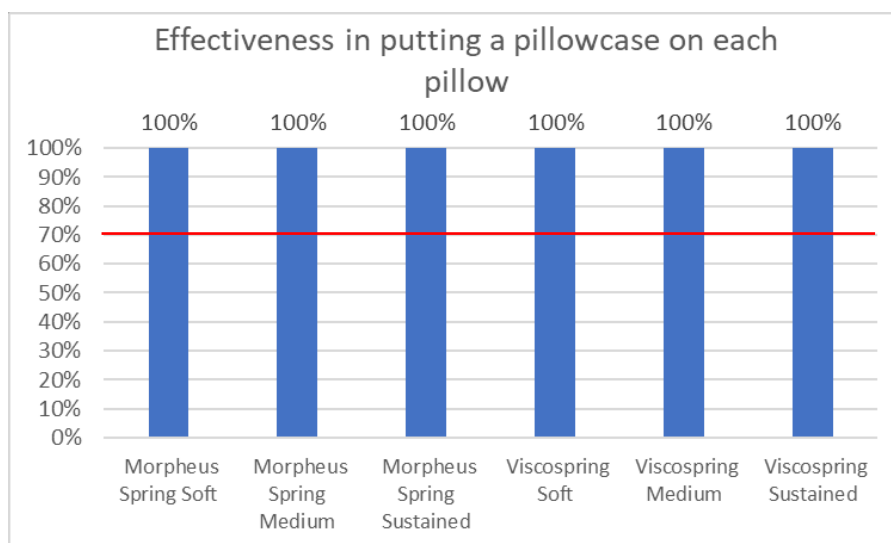
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## 7.5 RESULTS

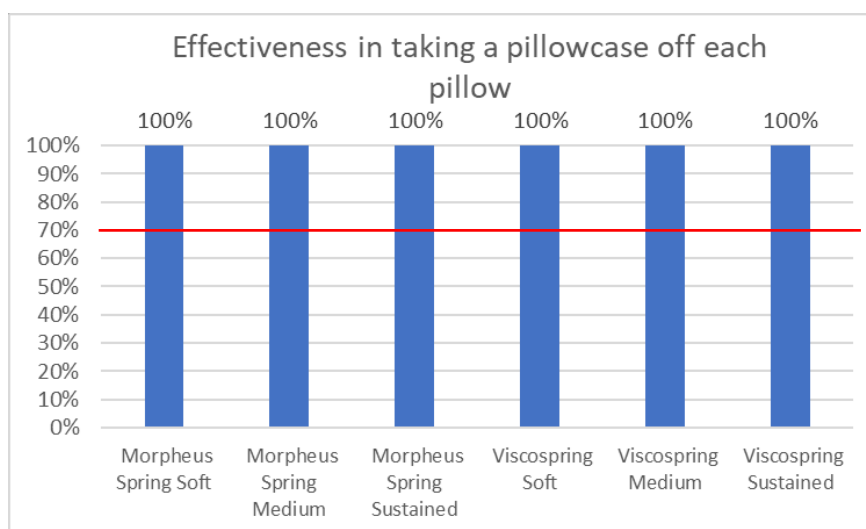
### 7.5.1 EFFECTIVENESS

The level of effectiveness is acceptable only if the given task is completed at least by 70% of the users.

The following figure shows the average value of the effectiveness in putting a pillowcase on each pillow.

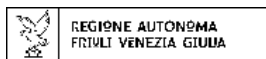


The following figure shows the average value of the effectiveness in taking a pillowcase off each pillow.



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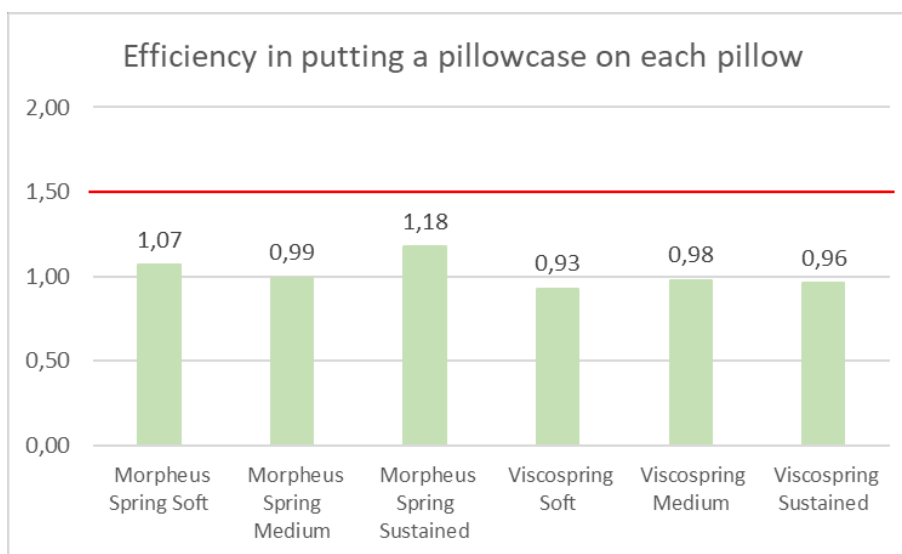
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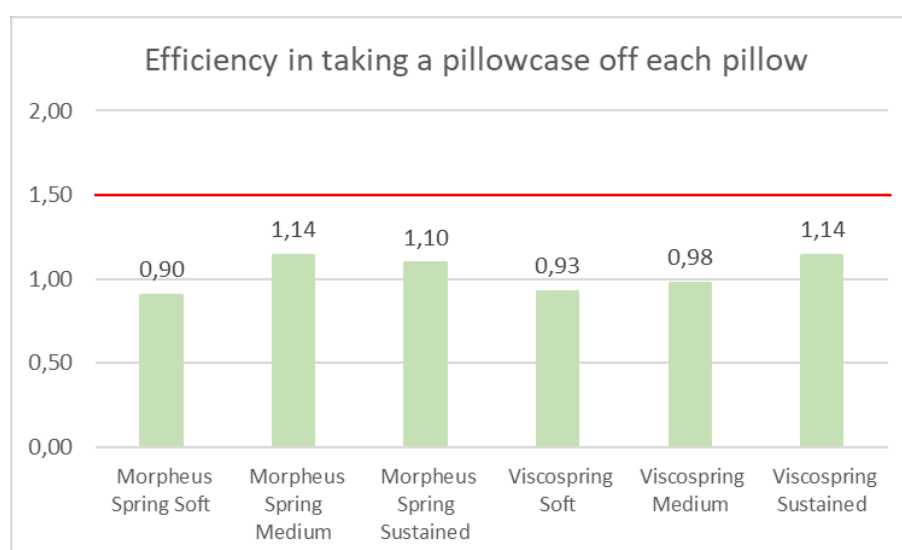
#### 7.5.2 EFFICIENCY

The level of efficiency is calculated as the ratio between the actual interaction time (time taken) and the expected time. The efficiency is considered acceptable when such ratio is not above 1.5.

The following figure shows the average value of the efficiency in putting a pillowcase on each pillow.



The following figure shows the average value of the efficiency in taking a pillowcase off each pillow.



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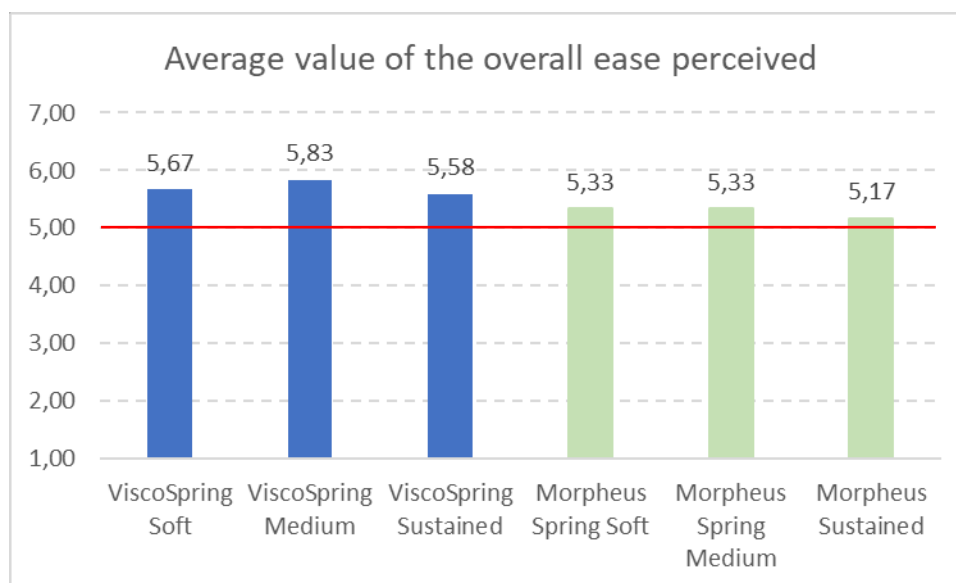
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#### 7.5.3 OVERALL EASE IN PUTTING ON THE PILLOWCASE

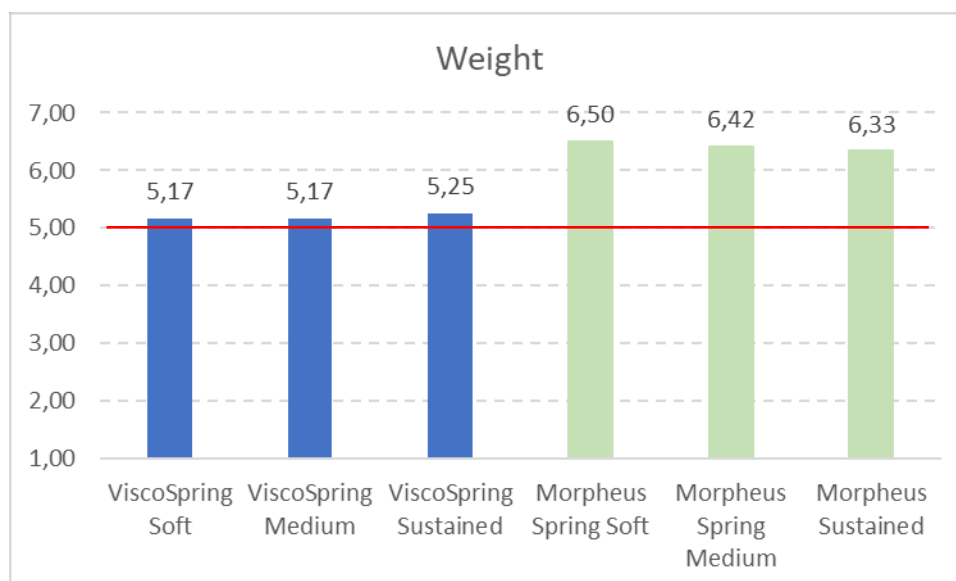
The following figure shows the average value of the overall ease perceived while putting a pillowcase on each pillow:



The table shows that all the average values are above the acceptability limit (5.00).

#### 7.5.4 PERCEIVED WEIGHT

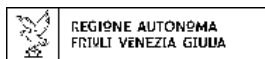
The following figure shows the average value of the perceived weight of each pillow (1 heavy – 7 light):



Although all the pillows are above the acceptability limit, there is a difference between the two lines, as the Morpheus Spring line turned out to be lighter.

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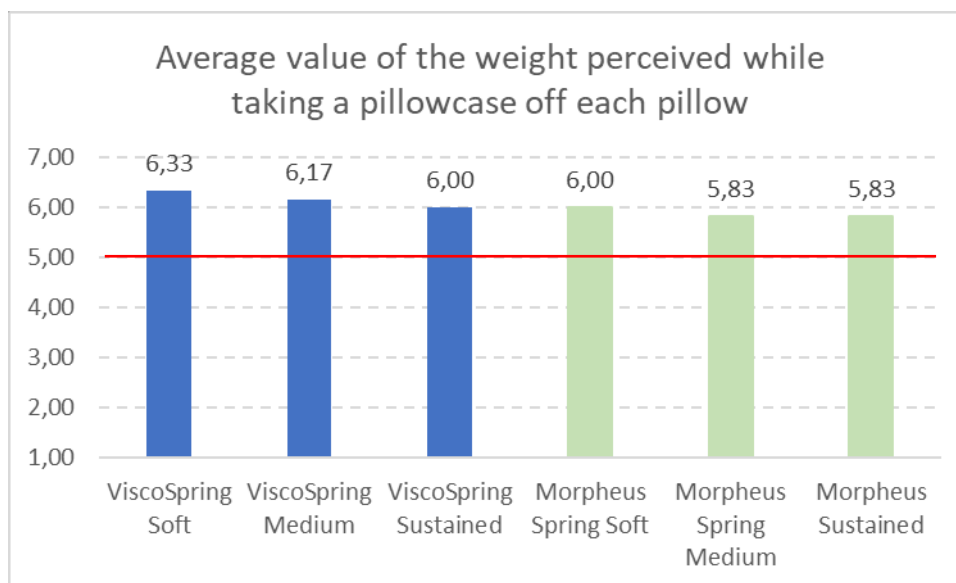
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#### 7.5.5 OVERALL EASE IN TAKING OUT THE PILLOWCASE

The following figure shows the average value of the weight perceived while taking a pillowcase off each pillow.



Owing to its greater firmness, the ViscoSpring line pillow turned out to be heavier than the Morpheus Spring line pillows; conversely, this makes it easier to take a pillowcase off it.

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#### Statistical validation of results: YES

Table 2. Outcome measurements across study time points

	Time 0				Time 1				Time 2				Time 3			
	SP -> EI (n = 35)		EI -> SP (n = 35)		SP -> EI (n = 34)		EI -> SP (n = 33)		SP -> EI (n = 33)		EI -> SP (n = 31)		SP -> EI (n = 33)		EI -> SP (n = 31)	
	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd	mean	sd
Neck NRS	40.8	27.3	47.0	22.9	26.1	22.3	37.8	21.4	31.5	29.2	40.8	23.7	32.3	27.2	28.3	22.4
Shoulder NRS	40.3	32.7	41.8	27.6	24.1	23.8	34.6	28.2	30.4	30.0	35.0	27.3	30.1	26.4	27.6	25.1
Thoracic NRS	27.7	30.9	27.3	25.6	19.5	21.0	25.5	24.1	22.7	24.1	26.7	23.7	28.4	26.5	18.7	20.1
Head NRS	39.1	34.8	30.7	29.9	23.8	23.9	33.7	27.5	25.7	30.6	32.2	26.4	32.9	31.8	18.5	24.4
NDI-I	12.9	7.4	13.8	5.6	8.7	5.2	12.7	4.4	8.9	6.3	11.9	6.0	11.2	6.7	9.5	6.0
PSQI	10.3	3.2	9.7	2.9	9.1	3.0	9.7	2.5	9.2	3.1	8.6	2.4	9.8	2.7	7.9	2.4

EI = Educational Intervention; NDI-I = Neck Disability Index-Italian Version; NRS = Numerical Rating Scale; PSQI = Pittsburg Sleep Quality Index; SP = Spring Pillow (intervention).

#### Appendix 4. Global Perceived Effect and Neck Pillow Satisfaction results.

		SP		EI	
		n	%	n	%
GPE	1. Recovered	0	0.0%	0	0.0%
	2. Much improved	12	18.5%	1	1.5%
	3. A little improved	33	50.8%	25	37.9%
	4. Not changed	16	24.6%	38	57.6%
	5. A little worse	2	3.1%	1	1.5%
	6. Much worse	1	1.5%	1	1.5%
	7. Worst ever	1	1.5%	0	0.0%
NPS	1. Perfectly comfortable	15	23.1%	1	1.5%
	2. Very comfortable	25	38.5%	10	15.2%
	3. Quite comfortable	14	21.5%	18	27.3%
	4. Neither comfortable nor uncomfortable	6	9.2%	23	34.8%
	5. Quite uncomfortable	2	3.1%	10	15.2%
	6. Very uncomfortable	2	3.1%	3	4.5%
	7. Perfectly uncomfortable	1	1.5%	1	1.5%

GPE= Global Perceived Effect; NPS = Neck Pillow Satisfaction.

#### Tested pillow effectiveness: YES

After dichotomizing GPE into “improved” (a score of 1 to 3 on the GPE) and “worsened” (a score of 5 to 7 on the GPE), we observed that 70.3% of the patients improved after SP, and 40.6% after EI, whereas 6.2% worsened after SP, and 3.1% after EI.

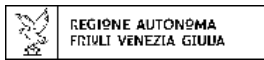
In relation to the comfort of the SP compared to the usual pillow, after a similar dichotomization, 84.3% of the patients judged the SR to be comfortable, whereas 45.3% of them attributed this score to their own pillow. The pillow was evaluated as 1 – uncomfortable - by 7.8% of the subjects following SP intervention, and by 21.8% of the subjects following EI and the use of their own pillow (see Appendix 4).

#### DISCUSSION

The results of this RCT crossover showed that SP was more effective than EI combined with the usual standard pillows for reducing cervical and referred pain, and decreasing disability at short-term follow-up in chronic NP. In addition, sleep quality, subjective improvement, and the evaluation of the pillow as comfortable were also superior in the SP group. These results concern both side sleepers and supine sleepers. A high percentage of subjects using SP reached clinically significant reduction of pain and disability.

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## 8. CONCLUSIONS

According to the outcomes of the current evaluation, the Lead Auditor proposes to the ErgoCert Certification Committee that the Certification is issued with the following level:

- Serie “Morpheus Spring” - > “Ergonomics Certified\*\*\*\*\*”



- Serie “ Sleepit ” - > “Ergonomics Certified\*\*\*\*\*”.



Udine, July 25th, 2019

Audit Group: M. Bordignon, G. Pischiottin

Lead Auditor: Dr. Marco Bordignon