

MusiCure®

P I L L O W

Introduction & Manual

It is recommended to read this manual and user guide thoroughly before
The MusiCure Pillow is put into use.



Important information about the MusiCure Player

Always start by charging the included "MusiCure Player",

Use the enclosed USB charger cable, which is found in the Player's original packaging - a full charge will take approx. 2 hours.

Charging can be done using a 220v charger plug, or via USB input in a computer.

On the Player there is a pre-recorded MusiCure program
of one hour and 15 minutes by composer Niels Eje.

The program is copyright protected and may not be copied, passed on or transferred to other media.



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Video instructions for MusiCure Player: www.musicurepillow.com



MusiCure Pillow is CE marked - Registered and approved as class 1 medical device according to current EU MDR standards 2022

Produced by MusiCure in Healthcare ApS, CVR: 20292296 Virum, Denmark

MusiCure Pillow product catalog number: GFO 20178

MusiCure Player is not covered by the registration as a medical device.
The player is an accessory to the pillow, like other potential sound sources.

THE HEALTHY WAY OF LISTENING - About the MusiCure Pillow

MusiCure Pillow is a comfort memory-foam pillow with built-in speaker cabinets of high quality. The pillow is designed specifically for optimal private and intense listening to the evidence-based MusiCure music - but can also be used for playing audio books or other music. The pillow is also developed as a "healthy" alternative to headphones and earplugs. The listening experience is concentrated and personal, and when listening, one does not get shut out from the outside world, as can be the case with headphones/earplugs.

The texture of the ergonomic and viscoelastic foam pillow material is pleasantly supportive and comfortable for both head and neck. The built-in speakers are passive and require no power, batteries or the like. All you need is connecting an external audio source, such as MP3 player, iPod, smartphone, CD disc player etc. The pillow is also suitable for listening to TV, radio, audio books or your mobile phone (on speaker), as well as any other audio source with possibility for mini-jack connection.

Product specifications for the pillow: The MusiCure Pillow is made of high quality Visco Elastic Memory Foam, which ensures maximum comfort and optimal head and neck support. There are two layers of cover where the outermost cover is the hospital-approved "Techmaflex" hygiene cover, removable and washable at 95 degrees.

All materials contained in the pillow, as well as cover and cable, are approved and CE marked according to current EU standards, and the total product is registered and approved as a class 1 medical device.

With the pillow comes a convenient travel and storage bag that protects the pillow effectively, and it is always recommended to store the pillow in the bag when not in use.



Correct positioning of the head on the pillow

MusiCure Pillow is designed as an ergonomic viscoelastic foam pillow, that provides maximum head and neck support. Therefore, it is important to position your head correctly on the pillow in order to get the best relax and sleep comfort and optimum sound from the built-in speakers:

The optimal positioning is lying or sitting with the head located at the center of the high part of the pillow, so the cord and the MP3 player are located at the left side of the pillow.

Important!

Although the ear is not directly affected, as is the case with e.g. headphones. or ear-plugs, you should as private user or healthcare professional, always be aware if the sound level is appropriate. Never set the volume higher than what is equal to normal conversation level (50-60 dB).

Temperature sensitivity and general advice

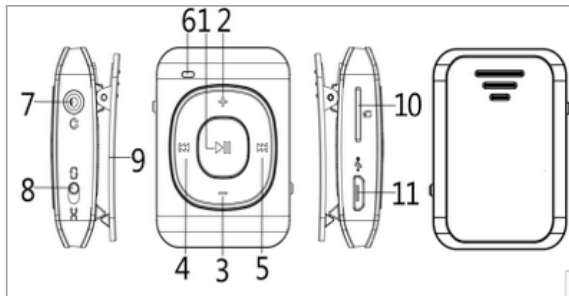
The pillow's foam material is temperature sensitive and can feel hard if stored cold, even though it quickly becomes 'normal' again upon contact with ordinary body temperature. The pillow should also be placed away from heat sources such as direct sunlight, radiators, cookers or other heat-producing appliances. The pillow must not come into contact with water in any way or be used outdoors in the rain. Pay special attention to the fact that the mini-jack cable is always free and not in contact with the head and neck - take special care with this if children use the pillow.

DIMENSIONS AND WEIGHT OF THE PILLOW:

The extent of the pillow = 50 x 30 x 10/7 cm. Weight 870 g

MusiCure[®] PLAYER

Appearance and controls




1. Power/Play/Stop/Pause - on/off
2. Volume +
3. Volume -
4. Previous/Fast rewind
5. Next/Fast forward
6. Indicator light
7. 3.5mm earphone jack
8. Sequential/Shuffle play mode switch
9. Rear clip
10. SD/TF card slot
11. USB socket

MusiCure[®] PLAYER

Operating instructions - MusiCure Player

*Technical Specifications

Dimensions/weight	34*43*17.5mm, weight 17g
Memory	No internal memory, Supports TF card up to 64GB
Music Formats	MP3, WMA, 32Kbps – 320kbps
USB	USB 2.0 (High speed)
Power supply (charging)	5V  500mAh
Battery duration	8-10 hrs music (Max. volume)
Battery recharging	Around 2 hours
Working temperature	0°-40° C



*LED Indication

Status	LED Indication
Power off	LED off
No TF card or No files in TF card	Pink LED flashes for 11 times and player will auto turn off
Playing	Sequential mode: Blue LED flashes slowly, Shuffle mode: Blue LED flashes quickly.
Pause	Constant blue
Low power	Blue & red LED flashes alternately
Battery recharging	Red LED flashes
Battery charged	Constant red

MusiCure[®] PLAYER

Basic operation

Charging the player Important: Charge the player fully before using it for the first time. Use the enclosed USB charger cable and connect the player to a USB charger socket (220v) or computer USB port. The status light flashes red on/off. Charging takes approximately 2 hours, and when fully charged, the status light will be steady red. When the USB cable is disconnected, the LED lights continuously red, and then the player automatically turns off after about 3 seconds. Recharge the player when it shows signs of low battery status.

Saving music to the player

The UX-500 is an external SD/TF card based player device with no additional built-in memory. The music is stored on the Micro SD card which is inserted in the player upon delivery. The card contains an evidence-based and specially composed MusiCure program by Niels Eje, which has a documented calming and positive relaxing effect.



Listen to the music

Press the round 'Play Button' for 2 seconds to turn on/off the player. When the player is turned on, the blue LED light is on and the music starts playing and the blue LED light flashes. Briefly press the start playback button to pause, and briefly press again to resume playing. If the music is paused for up to 2 minutes, the player turns off automatically.

NB: It is recommended to place the player in the pocket on the left side of the pillow during playback.

Volume adjustment

Press the '+' / '-' button to stepwise increase/decrease the volume level. Previous/fast back, next/fast forward Briefly press the 'previous button' to play the MusiCure program from the beginning. Press and hold the same button for fast rewind. Press 'next/fast forward' and hold to fast forward.

To pause press short on the Play button, and press short again to resume playing.

Sequential/shuffle playback Slide the switch to position to play music in sequential mode. Slide the switch to position to play music in shuffle mode.

It is recommended that the 'Sequential playback' option be set permanently.

THE HEALTHY WAY OF LISTENING

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What is special about the MusiCure music?

The pillow is always delivered together with a special program containing the evidence-based MusiCure music, embedded on the supplied MusiCure Player. The foundation for the MusiCure compositions has its basis in more than 20 years of independent research, direct feedback from patients and staff in hospitals, as well as from elderly care centers in Scandinavia and abroad. MusiCure music is composed and produced especially for stress reduction and treatment purposes within the entire health sector.



USER GUIDE - HOW THE MUSICURE PILLOW WORKS

1. The included MusiCure Player must be fully charged
2. Insert the jack plug from the cable on the left side of the pillow, into the player's round headphone entrance
3. Switch on the player by pressing the start/play button for 2 seconds.
4. Set the desired volume using the volume up/down (+ /-) buttons at the grey ring on the player front
5. Place the head in the middle of the high part of the pillow, with the cable for the player on the left side of the pillow

**Reference list of departments and areas,
where the MusiCure Pillow is implemented in Denmark and Scandinavia**

Hospital departments:

- Psychiatry
- Cardiac patients - Cardiology Laboratory
- Delirium patients
- Emergency Patients (ER)
- Oncology
- Day surgery and Recovery
- Epilepsy treatment
- Pulmonary Outpatient Clinic
- Colonoscopy
- Pain management
- Palliative care



Care centers and institutions

- Occupational therapy for children and young people
- Elderly care and dementia/Alzheimer's patients
- Danish Refugee Council (traumatized refugees) and
- Rehabilitation Center for Torture Victims

Warranty and complaint

MusiCure in Healthcare ApS guarantees that you will receive a first-class product. If, contrary to expectations, there are errors or defects in the product, we offer a 2-year warranty.

In the event of a fault, we must ask for the damaged product to be sent, with a description of the fault and documentation of the purchase - together with the following information:

- ◆ Name of Institution - department and contact person.
- ◆ Order date
- ◆ Address
- ◆ Telephone number - email address
- ◆ Reason for returning the product

Right of complaint: In case of any complaints, we offer repair of the product, or exchange for a new product in the event that the fault cannot be repaired. In connection with complaints, we ask that the defective product be sent for inspection and testing, after which we assess, whether it can be repaired or replaced with a new product.



Technische gegevens
Fiche technique
Technical specifications
Technische daten
Ficha tecnica

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Kwaliteit Qualité Quality Qualität Calidad	: TECHMAFLEX BIPE FRC (T116)
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Gewicht ISO 3801 Poids Weight Gewicht Largo	: 190 GR/M ² +/- 10 GR/M ²
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Breedte ISO 3932 Largeur Width Breite Anchura	: 110 CM 150 CM 220 CM
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Samenstelling Composition Composition Zusammensetzung Composición	: 54% POLYESTER - 46 % PU FR COATING
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Treksterkte ISO 13934-1 Resistance à la traction Tensile strength Zugfestigkeit Resistencia a la tracción	: Ketting - Chaîne - Warp - Kette - Cadena : 350 N Inslag - Trame - Weft - Schuss - Trama : 200 N
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Scheursterkte ISO 13937-1 Résistance à la déchirure Tearing strength Weiterreisfestigkeit Resistencia rasgao	: Ketting - Chaîne - Warp - Kette - Cadena : 20 N Inslag - Trame - Weft - Schuss - Trama : 30 N
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Waterdichtheid ISO 811 Imperméabilité Waterproofness Wasserdichtheit Impermeabilidad	: > 3 m
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Wassen Lavage Wash Waschen Lavar	: 95 °C
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Droogklus Nettoyage à sec Dry cleaning Reinigungstrocknen Limpieza a seco	: OK
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Waterdampdoorlaatbaarheid DIN 53122 Klima B Perméabilité à la vapeur d'eau Breathability Wasserdampfdurchlässigkeit Permeabilidad	: +/- 600 GR/M ² /24H
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Brandnorm Norme de feu Fire Standard Brennorm Norma de inflamabilidad	: BS 6807 CRIB 5 : OK BS 7175 CRIB 5 : OK
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WASVOORSCHRIFTEN - PRESCRIPTIONS DE LAVAGE - WASHING PRESCRIPTIONS - PFLERGE

Cleaning and maintenance



Additional instructions for treating the pillow's Techmaflex Polyurethane cover

Techmaflex covers must be treated with care when the surface is cleaned.

The normal maintenance instructions include wiping the surface with a sponge or cloth with warm soapy water.

- Techmaflex can be washed with hot water up to 95 degrees C
- Do not use solvents or bleaches on Techmaflex
- Techmaflex can be cleaned in an autoclave at a temperature of 134 degrees C for 3 minutes
- Techmaflex can be chemically cleaned with suitable liquids except trichlorethylene

Other means for disinfecting and cleaning pillow covers - recommended by Techmaflex:

- Hand sanitizer gel Abena 5000 ml 85%
- Alcohol wipes for surface disinfection Bactitox 80% - 100 pcs.
- Cleaning tissue Plum WipeClean Ethanol alcohol 80% mini 1200 pcs
- Surface disinfection Wet Wipe 97%
- Refill bottle, Suma Bac D10, for Divermite/DQFM dispenser, 750 ml
- It is not permitted to twist Techmaflex
- It is not permitted to iron Techmaflex

Storage

- Store Techmaflex in a cool, dry environment
- Avoid excessive pressure and contact with non-colorfast materials

Music as Medicine* as a complementary treatment method for hospital patients with delirium

Camilla Engelstoft Hess, Clinical nursing specialist, MSc (Nursing)
Department of Nephrology and Endocrinology – H0842, North Zealand Hospital, Hillerød Denmark

Background and Aim

Delirium is a commonly occurring, serious neuropsychiatric complication associated with acute somatic illness. Delirium is most common in patients who are elderly, have dementia or are chronically ill. The condition can be extremely distressing for the patient and may cause some patients to act aggressively or experience anxiety. North Zealand Hospital's department of Nephrology and Endocrinology, H0842, treat a large number of patients with delirium.

An alternative to medical treatment could be a non-pharmacological intervention in the form of music. Several Danish and international studies suggest that music from MusiCure and the specially developed MusiCure Pillow*, can be successfully used in the treatment of delirium.

This quality improvement project was to test the efficacy of the MusiCure pillows as a complementary treatment method for patients, who become delirious during hospitalisation. The primary goal was to replace medical treatment for delirium with music. The secondary goal of the project was to make the patients feel more secure, and to reduce stress, side effects, mental illness and mortality resulting from delirium.



Design and Procedure

The retrospective design of the project involved gathering six months of data on the ward's use of extra 1:1 carers and Serenase and Stesolid medication. The prospective part of the project consisted of a four-month intervention using MusiCure pillows. The aim of this approach was to test and detect any issues or barriers, so that it was possible to modify and revise the intervention before implementation.

The intervention was carried out at the Department of Nephrology and Endocrinology, H0842. The intervention started when an inpatient became delirious. Patients who became delirious were identified and CAM screening was performed. If the patient had a positive CAM score, they were included in the study with the music pillow. The intervention was carried out in the patient's room, where they lay in their bed. The music played for over an hour and often repeated for several hours or days, and the nursing staff completed the attached registration form to measure the effect of the music.

Method and Results

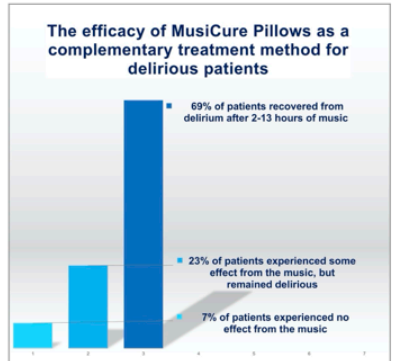
The quality improvement project was based on a scientific hermeneutical approach. This is reflected in the project's combination of qualitative and quantitative data collection. The project's quantitative component consisted of collecting data on patients' behaviour before, during and after the music, and any use of sedatives. The ward's use of extra 1:1 carers was also registered. The music pillows were tested on 13 patients over a period of four months. The results from the registration forms showed that patients recovered from delirium more quickly, when they listened to the music:

- 7% of patients experienced no effect from the music
- 23% of patients experienced some effect from the music, but remained delirious
- 69% of patients recovered from delirium after 2-13 hours of music.

33% of these patients received Serenase in connection with their delirium. The results also showed that no extra 1:1 carers were used during the intervention period. In the period prior to the intervention, an average of 11.5 extra 1:1 carers per month were used in the ward. A review of the ward's use of Serenase and Stesolid also showed that during the intervention period, 0.12 less packets of Serenase and 0.62 less packets of Stesolid were used compared to the remaining months in 2019.

MusiCure Pillow

The MusiCure pillow is an ergonomic, memory-foam pillow with a built-in sound system. The pillow comes with a rechargeable MP3 player loaded with one hour of specially designed music. Studies have shown that it increases the body's oxytocin level and lowers the cortisol level. The pillow's cover can be easily cleaned using sanitiser wipes. The pillow is also CE marked and EU approved as a class 1 medical device.



Conclusion

The aim of the quality improvement project was to test the efficacy of MusiCure pillows as a complementary treatment method for delirious patients.

It was found that patients who received music and other non-pharmacological treatments recovered from delirium faster and needed less sedation. It can therefore be argued that the music pillows can beneficially be used as a first priority before any sedatives are used for the treatment of delirium. The use of the music pillows also resulted in there being no need for extra 1:1 carers when the patients were listening to the music. The ward's costs associated with the use of extra 1:1 carers were therefore much reduced during the intervention period.

After publication of the positive results with delirium patients from both Hvidovre and North Zealand Hospitals, a number of other Danish hospitals have introduced the same procedures with the MusiCure pillows to delirium patients, and achieved similar results.

* Music as Medicine is a part of the original MusiCure® International Trademark.

Randomized clinical trial examining the effect of soothing music in response to relaxation during bed rest after open-heart surgery

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Örebro University Hospital and School of Health, Örebro University, Sweden

Background

Music interventions have been evaluated as an appropriate intervention to reduce pain, stress and anxiety in a number of clinical settings. A new challenge is to study if music can influence the relaxation system, which incorporates oxytocin which is a hormone synthesised in the hypothalamus.

Aim

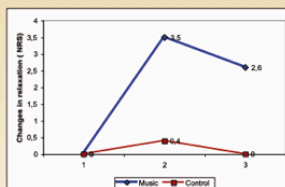
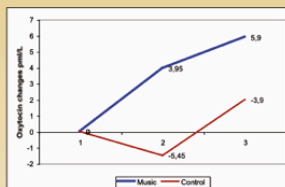
To evaluate the effect of bed rest with music on relaxation for patients who had undergone heart surgery on postoperative day one.

Method

A randomised controlled trial with 40 patients undergoing open coronary artery bypass grafting and/or aortic valve replacement surgery randomly allocated to either music listening during bed rest or bed rest only. The music was distributed through a music pillow connected to a MP3 player (Wellness Musicpillow) and the music, MusiCure, (MusiCure) was soft, relaxing, and included different melodies of 60 to 80 beats per minute (bpm) and was played for 30 minutes with a volume of 50-60 dB. Relaxation was assessed during bed rest the day after surgery by determining serum oxytocin, heart rate, mean arterial blood pressure (MAP), arterial oxygen tension (PaO₂), arterial oxygen saturation (SaO₂) and subjective relaxation levels.

Results

In the music group levels of oxytocin increased significantly in contrast to the control group for which the trend over time was negative i.e. decreasing values. Subjective relaxation levels increased significantly more and there were also a significant higher levels of PaO₂ in the music group compared to the control group. There was no difference in MAP, heart rate and SaO₂ between the groups.



Conclusion

Listening to music during bed rest after open-heart surgery has some effects on the relaxation system as regards s-oxytocin and subjective relaxations levels. This effect seems to have a causal relation from the psychological (music makes patients relaxed) to the physical (oxytocin release). Music intervention should be used as an integral part of the multimodal regime administered to the patients that have undergone cardiovascular surgery. It is a supportive source that increases relaxation.