

Invacare[®] Alegio™

- User Manual (EN)
- Bruksanvisning (SV)
- Gebruiksaanwijzing (NL)
- Manuel d'utilisation (FR)
- Manual del usuario (ES)
 - Manuale d'uso (IT)
- Manual de Utilização (PT)





Quality Declaration

Congratulations with your new bed Invacare®Alegio[™] from Invacare®.

Your new bed is **((**-marked in accordance with directive 93/42/EEC concerning medical devices. Invacare®Alegio[™] is developed and constructed with consideration for the user and others handling or assisting at the bed.

Furthermore, the bed is developed in accordance with the European Standard EN 1970/A1.

Invacare®Alegio™ is supervised and quality controlled throughout the entire production process, and the finished bed is inspected by our finished goods control.

Identification label are located on the bed confirming that the finished goods control has approved the bed. Please read the entire user's manual before using the bed.

Invacare®France Operation SAS is certified according to ISO 9001 and ISO 13485.

DK

KVALITETSDEKLARATION

Tillykke med Deres nye seng Invacare®Alegio™ fra Invacare® France Operation SAS.

Deres nye seng er CE - mærket og lever op til alle krav i henhold til direktiv 93/42/EØF om medicinske anordninger.

Sengen er udviklet og konstrueret under størst mulig hensyntagen til brugeren samt alle andre, der enten håndterer sengen eller hiælper til ved sengen. Invacare*Alegio** er udviklet under hensyntagen til de sikkerhedsmæssige krav i den Europæiske Standard EN 1970/A l. Hver seng har gennem hele produktionsforløbet været overvåget og

kontrolleret, og den færdige seng er blevet inspiceret af vores færdigvarekontrol. Typeskilt påsættes sengen som dokumentation for, at færdigvare kontrollen har godkendt sengen. For ibrugtagning af Deres seng skal De gennemlæse brugermanualen grundigt. Invacare® France Operation SAS er certificeret i henhold til ISO 9001 og ISO 13485.

DE

NL

QUALITETSDEKLARATION

Herzlichen Glückwunsch zu Ihrem neuen Pflegebett Invocare³ Alegio⁷⁴⁴ von Invocare⁴ France Operation SAS. Ihr neuer Pflegebett ist gemäß der Richtline 39/4/2FVG für Medizinprodukte CE-gekennzeichnet. Der Invocare⁴ Alegio⁷⁴⁴ wurde unter Berücksichtigung der Bedürfinste von Beruzer um Mittegepersonal entwickelt und in Übereinstimmung mit der Europäischen Norm EN 1970/AI.

konzipiert und hergestellt.

Während des gesamten Herstellungsprozesses unterliegt der Invacare® Alegio 7th einer ständigen Qualitätskontrolle und wird im Anschluss nochmals durch unsere Endkontrolle geprüft. Das Typenschild sind am Bett angebracht, um die Abnahme durch unsere Qualitätskontrolle zu bestätigen. Bitte lesen die gesamte Bedienungsanleitung, bevor Sie den Bett in Gebrauch nehmen.

Invacare® France Operation SAS ist zertifiziert nach ISO 9001 und ISO 13485.

KWALITEITSGARANTIE

Gefeliciteerd met de aanschaf van uw nieuwe bed **Alegio**TM van Invacare®</sup> France Operation SAS

Invacare® Alegio™ is CE - gecertificeerd en goedgekeurd conform richtlijn 93/42/EEC betreffende medische hulpmiddelen.

Invacare®AlegioTM is ontwikkeld en geconstrueerd met inachtneming van de behoeften van de gebruiker en verzorgers.

imoute **Arego**¹ is oriented in geoma bed men includering and e beneficient and e geoma for error geos. Imoute² Arego¹⁰ is ontwikkel in overenstemming mer de Europes Standard EN 1970/A1. Gedurende het gehele productieproces is het **Alegio¹⁰** bed geontroleerd op kwaliteitsaspecten en het complete bed is na productie zorgvuldig geontroleerd. Het productabel zijn op het bed bevestigd om aan te tonen dat de bedden zijn gecontroleerd en goed zijn bevonden door de afdeling productcontrole. Wij verzoeken u vriendelijk de gehele gebruikershandleiding te lezen voordat u

het bed in gebruik neemt. Invacare® France Operation SAS is ISO 9001 en ISO 13485 gecertificeerd.

IT

DICHIARAZIONE DI OUALITÀ

Complimenti per aver scelto il letto Invocare®AlegioTM prodotto da Invacare® France Operation SAS. Il vostro nuovo letto è marcato CE - ai sensi della Direttiva 93/42/EEC relativa ai dispositivi medici.

Il letto è stato progettato e costruito con un occhio di riguardo per gli utilizzatori e per i loro assistenti. Invacare®Alegio™ è stato realizzato nel rispetto della Normativa Europea EN 1970/A1.

Il letto è stato oggetto di accurate verifiche qualitative durante l'intero processo produttivo; una volta completato è stato controllato dal nostro servizio prodotti finiti.

Un'apposita targhetta sono state apposte sul letto a conferma dell'avvenuta verifica e accettazione del prodotto da parte del servizio qualità. Prima di utilizzare il letto vi invitiamo a leggere

integralmente il manuale d'uso. Invocare® France Operation SAS è un'azienda certificata ai sensi della Normativa ISO 9001 e ISO 13485.

FS

FR

DECLARACIÓN DE CALIDAD

Enhorabuena por su nueva cama Invacare® Alegio™ de Invacare® France Operation SAS.

Su nueva cama cuenta con el marcaje CE - de acuerdo a la directiva 93/42/EOF que hace referencia a los aparatos médicos.

Invacare®Alegio™ ha sido diseñada y fabricada teniendo en cuenta a los usuarios y las personas que los asisten. La cama Invocare[®]Alegio[™] ha sido diseñada de acuerdo a la normativa Europea EN 1970/AI.

El proceso de producción del modelo Invacare® Alegio^{7M} ha sido supervisado en su totalidad y su calidad inspeccionada, por nuestro control de producto acabado.

La cama cuenta con una placa y marca CE que confirma que la misma ha sido inspeccionada por el control de producto acabado. Por favor lea el manual antes de utilizar la cama. Invocare® France Operation SAS es una empresa certificada ISO 9001 e ISO 13485

DÉCLARATION DE QUALITÉ

Félicitations! Vous avez choisi votre nouveau lit Invacare® Alegio*

Votre nouveau lit est marqué CE conformément à la directive 93/42/EEC concernant les dispositifs médicaux.

Invacare® Alegio™ a été développé et construit en considérant systématiquement les besoins de l'utilisateur et des tierces personnes lors de la manipulation du lit ou de son utilisation.

Invacare®Alegio™ a été développé conformément au Standard Européen NF EN 1970/A1.

Innocare Alegior a été supervisé et contrôlé tout au long du process de fabrication et le lit achevé a été inspecté par le contrôle des produits finis. La plaque d'identification sur le lit attestant que le contrôle des produits finis a approuvé le lit. Le lit répond aux exigences de l'analyse de risques de la norme NF EN 14971.

Nous vous remercions de lire le Manuel de l'Utilisateur dans son intégralité avant d'utiliser le lit Invacare®est certifiée ISO 9001 et ISO 13485.

PT

DECLARAÇÃO DE OUALIDADE

Parabéns pela sua nova cama Invacare® Alegio[™] da Invacare® France Operation SAS. A cama tem a marca CE - em conformidade com a directiva 93/42/EEC referente a aparelhos médicos.

A cama foi concebida e desenhada, tendo em consideração o seu utilizador e o seu(s) assistente(s), que o ajudarão a manipular a cama. A cama foi concebida em conformidade com o Standard Europeu EN 1970/A1.

Durante todo o processo de fabrico e produção, a cama Invacare® AlegioTM foi supervisionada e a sua qualidade controlada, sendo o produto final inspeccionado e testado pelo nosso controlo de qualidade. As etiquetas são colocadas na cama, após a aprovação final da cama, confirmando e garantindo a conformidade com o nosso controlo de qualidade. Por Favor, leia atentamente este manual de utilizador antes de utilizar a sua cama.

A Invacare® France Operation SAS está certificada em conformidade com ISO 9001 e ISO 13485.

| USER MANUAL (EN) | Z |
|---------------------------|--------|
| BRUKSANVISNING (SV) | SV |
| gebruiksaanwijzing (nl) | Z |
| MANUEL D'UTILISATION (FR) | L L |
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User's part

Congratulations with your choice of the *Invacare*[®] **Alegio**[™] nursing bed.

- The Invacare® Alegio™ is designed for patients over the age of 12 years especially for home care.
- The Invacare[®] Alegio[™] combines excellent stability and ergonomic design with easy disassembly and operation.
- Max. weight: 170 kg.

Max. patient weight: 135 kg (provided that the weight of the mattress and the accessories do not exceed 35 kg).

Important! The max. load of the bed must not be exceeded.

In order to optimise the patient's comfort, Invacare® France Operation SAS recommends using a 16 cm mattress.

I. In general

Please read the entire User's part carefully before using the bed. All indications of right and left are based on a patient lying on the back in the bed.

| \triangle | Check whether the bed shows any signs of damage. If the bed is damaged, see terms of delivery. |
|-------------|---|
| \triangle | Please contact your <i>Invacare®</i> supplier if, contrary to our expectations, a problem should arise in connection with the delivered product. |
| \triangle | <i>Invacare®</i> France Operation SAS accepts no liability for any use, change or assembly of the product other than as stated in this User's Manual. |
| \triangle | The bed must not be used by patients under 12 years of age, or by patients with body size equivalent to an average 12-year-old or smaller. |
| | Electromagnetic interference between the bed and other electrical products can occur. To reduce or eliminate such electromagnetic interference, increase the distance between the bed and the products or switch them off. This medical bed can be used together with medical electrical equipment connected to the heart (intracardially) or the blood vessels (intravascularly), provided that following points are respected: - The medical bed should be equipped with means for potential equalization connection marked out by a symbol shown in the back of this manual. - Medical electrical equipment should not be fixed on the bed's metallic accessories such as side rails, lifting pole, drip rod, bed ends ect. In addition, the medical electrical equipment power supply cord should be kept clear of the accessories or any other moving part of the bed. |
| \triangle | If the bed is used by restless (spasms) or confused persons, an ACP box can be used for blocking the hand control functions. |
| \triangle | Ensure the bed is adjusted to it's lowest position before leaving the bed unattended - thereby the effect of fall-down / entrapment accidents is reduced. |
| \triangle | Always apply the brakes when there is no need for moving the bed, to avoid accidents during entering or exiting the bed, and during handling of the patient. |
| \triangle | Disconnect the plug from the mains before moving the bed. The cable must be kept clear off the floor and the castors during transport. Make sure that the mains cord cannot be jammed or in any other way damaged, when the bed is used. |
| \triangle | Always leave the bed in the lowest position. Otherwise there is a risk of entrapment due to accidental lowering of the mattress support. A person under the bed can be seriously injured during height adjustments. |

- The Invacare[®] Alegio[™] is CE- marked in accordance with directive 93/42/EEC concerning Medical Apparatus.
- The motors and the control box of the Invacare[®] Alegio[™] are approved according to EN 60601:1996-03.
- The Invacare[®] Alegio[™] has undergone a risk analysis according to EN 14971.

•

The control unit, motors and hand control are protected according to IP 66.A lock cam **must** be used on the control unit, otherwise *Invacare*[®] France Operation SAS cannot guarantee the protection.

Max. load: 170 kg - max. patient weight: 135 kg. Max. load is stated on the identification label.

NOTE! The max. load of the bed must not be exceeded.

Operating the hand control



2. Operating the Invacare[®] Alegio[™]

Adjustment of leg section (only on 3-sectioned beds)

Operate the leg section by lifting the mattress handle.

Up: Lift the mattress handle on the leg section. **Down:** Lift the mattress handle on the leg section all the way up and then lower the leg section.



Operating the braking castors

| Operating castors without central braking system When the bed is positioned correctly, at least one castor at the head end and one castor at the foot end must be locked. I) Braking: Step on the pedal. 2) Releasing the brake: Step on the release pedal. | 2) |
|--|----|
| Operating castors with central braking system When the bed is positioned correctly, the castors must be locked. I) Braking: Step on the bow. 2) Releasing the brake: Lift the bow, until the brake is released. | |
| Operating the steerable castor The Alegio[™] with central braking system may be equipped with a steerable castor: The steerable castor is operated by means of the central braking pedal. I) Activating the steering: If the brake is in neutral, step on the green pedal. 2) Deactivating the steering: Step on the red pedal, until the brake is in neutral position. | |

Set-off from the castors might under special conditions appear at different types of absorbing floor covering including untreated or badly treated floors. In matters of doubt, *Invacare®* recommends to place a suitable kind of protection between the castors and the floor.

3. Safety guidelines

Disconnect the plug from the mains before moving the bed. The cables must be kept clear off the floor and the castors during transport.

Make sure that the mains cord cannot be jammed or in any other way damaged, when the bed is used.



The brakes of the bed must be activated during nursing of a patient in the bed and when the bed is adjusted.



The main plug must be accessible any time to disconnect the device from mains missing. We recommend to mount the mains cable on the hook for this purpose, see following picture.



Adjust all mattress support sections to a horizontal position before transporting an assembled bed. Hold the top of the bed end with both hands while the bed is pushed/pulled.



Caution! Please ensure that the pipe pins are fully inserted through both holes of the tubular section, and that the spring clip is fully engaged prior to operating the lifting mechanism on the bed. Furthermore, please ensure that all four plastic bushings are intact and located correctly between shear arm/base and shear arm/top frame.

NB! Do not pull the clamp part of the pipe pin during dismantling – the clamp may be deformed, thus being unable to lock properly.



Risk of entrapment of fingers during assembly and operation of the bed end and side rail.



A minimum of 2 persons are required to release a mattress support.



There is a risk of entrapment while operating the side rails.



Position the lifting pole in such a way that the handle extends inwards across the bed. If the handle has been turned away from the bed while the lifting pole is being used, the bed can tip.



We recommend to mount the mains cable on the hook for this purpose, see picture below.



Adjust all mattress support sections to a horizontal position before transporting an assembled bed. Hold the top of the bed end with both hands while the bed is pushed/pulled.

Only personnel who have been trained or instructed by *Invacare®* may perform the service work described in this manual in the chapters 12 and 13.

If the functions of the bed change, check the bed according to chapter 13.

The Invacare[®] Alegio[™] must be stored in a room with a humidity of 10 - 80%, RH within a temperature of < 0 - 50°C.

4. Dismounting/mounting the Invacare[®]Alegio[™]

Dismounting the Invacare[®]Alegio[™]

- I. Brake the bed and bring it to its lowest position and then about 5 cm up.
- 2. Remove the accessories: Siderails, bed ends and lifting pole.
- 3. Dismount the finger screws at both sides (see illustration A).
- 4. Dismount the cable from the backrest/leg section (see illustration B).
- 5. Dismount the top frame at the head end and place it in a vertical position (see illustration C and D).
- 6. Lift the leg section and dismount the pipe pins (see illustration E).
- 7. Dismount the top frame at the foot end and place it in a vertical position (see illustration F).
- 8. Dismount the shear arm (see illustration G, H, I, J and K).





























L)



Mounting the Invacare[®]Alegio[™]

- I. Mount the shear arm (see illustration K, J, I, H and G).
- 2. Mount the leg section and the pipe pins, ensuring that the spring clip is securely latched over the end of the pin (see illustration F and E).
- 3. Mount the head section (see illustration D and C).
- 4. Push the head section into the leg section (see illustration L).
- 5. Mount the cable for the backrest motor/leg section (see illustration B).
- 6. Mount the finger screws in both sides (see illustration A).
- 7. Mount the accessories: Siderails, bed ends and lifting pole.



Caution! Please ensure that the pipe pins are fully inserted through both holes of the tubular section, and that the spring clip is fully engaged prior to operating the lifting mechanism on the bed. Furthermore, please ensure that all four plastic bushings are intact and located correctly between shear arm/base and shear arm/top frame. **NB!** Do not pull the clamp part of the pipe pin during dismantling – the clamp may be deformed,

thus being unable to lock properly.

Mounting of the pipe pin between shear arm and base

The pipe pin must be mounted with the opening upwards and locked.



5. Removal of cables from the control unit

Raise the bed to highest position and remove the mains cord from the socket outlet.



Use a small tool (such as screwdriver) to release the pawl on the locking cam.

Hold the locking cam while releasing the remaining pawls. With all pawls released, the locking cam can be removed from the control unit.





Motor connections are indicated on the label behind the cables.

6. Mounting/dismounting the accessories

Risk of entrapment of fingers during assembly and operation of the bed end and side rail.

Mounting the Vibeke bed end and Verso side rail

- I. Lower the bed ends into the U-profiles.
- 2. Place the side rail with the release system in the leg end, and tighten both finger screws.





0-6 cm

Mounting the Kirsty bed end and Nina side rail

1. The bed end is mounted as shown on illustration A - push the bed end all the way down, and secure it with the two finger screws (see illustration B).



- 2. Raise the mattress support to approximately 1/3 from lowest position.
- 3. Remove the side rail stopping bracket and finger screws (see illustration C).
- 4. Remove the protective tape from the locking dowels in each end of the side rail.
- Install one end at a time. Lift the lower wooden rail with one hand while guiding the metal bow into the bed end bar (see illustration D).
- 6. Press the locking pin of the side rail with one finger.
- 7. Raise the side rail until the locking pin engages with an audible click, thus preventing the side rail from falling down.
- 8. Re-install the side rail stopping bracket and finger screws (see illustration C).





Mounting the lifting pole

Lower the lifting pole into the lifting pole tube. The lifting pole MUST be fastened with a finger screw.

7. Emergency lowering of the backrest and/or thigh section

A minimum of 2 persons are required to release a mattress support.

Remove the plug from the mains before emergency lowering of the mattress support. In an emergency, the mattress sections are released by pulling out the cotter pin from the motors.

Two persons hold the mattress section in locked position. One of them pulls out the cotter pin. Both slowly lower the mattress section until it is complete down.



8. Operating the accessories

To open (fold the siderail):

Pull the locking button and start the folding movement with one hand on the upper horizontal bar. Release the locking button during the folding movement and handling the siderail until its lower position (under the mattress).





Take care to don't squeeze body of patient during this step. To avoid all finger pinch out during the manipulation, fingers must be positioned in the two lateral dug areas designed for that purpose, in locking button (grey zone, next page).

To close (unfold the siderail): Pull the siderail by the upper bar and rising until it engage in the locking system.



Take care to don't squeeze body of patient during this step.

Operating the Nina side rail

Up: Pull up the top wooden siderail bar, until the locking pins engages with an audible click. **Down:** Lift the top wooden siderail bar while pressing the two locking pins together. Lower the siderail.

Operating Line and Britt side rail

The bed end may be equipped to lock the siderail at half height as well as in the top position. Normally the side rail can only be locked in top position.

Up: Pull up the top wooden side rail bar, until the locking pin locks with an audible click.

Down: Lift the top wooden side rail bar and press the two locking rings together. Lower the side rail.



Raise



Release



Lower

The The

There is a risk of entrapment while operating the side rails.

Adjusting the height of the lifting pole handle

Loosen the cord as shown in ill.A.The lifting handle can now be adjusted to the desired height. Press the cord together as shown in ill. B and check that the cord is secured in the cord lock by pulling the handle.



Position the lifting pole in such a way that the handle extends inwards across the bed. If the handle has been turned away from the bed while the lifting pole is being used, the bed can tip.





Max. load of the lifting pole: 80 kg.

А

В

9. Accessories

| Article | |
|---|--|
| Nina wooden side rail - I pair Britt wooden side rail - I pair Line wooden side rail - I pair | |
| Verso II steel side rail - 1 pair | |
| Kirsty wooden bed end with slide bars - I pair | |
| Kirsty wooden bed end - I pair | |
| Vibeke wooden bed end (high) - I pair | |
| Lifting pole | |
| Hand control support | |
| IV drip rod | |
| Support for IV drip rod | |
| IR handset | |

Please only use original spare parts.

Spare parts lists and extra user manuals for the *Invacare*[®] **Alegio**[™] can be ordered from *Invacare*[®].

10. Cleaning

The *Invacare*[®] **Alegio**[™] does not tolerate cleaning in automatic washing plants or using water jet based cleaning equipment.

The bed is washed down using a sponge, cloth or brush. Use ordinary disinfectioning detergents. Dry the bed after cleaning.

Never use acids, alkalines or solvents such as acetone or cellulose thinner.

The hand control, motors and the control box can be wiped with a moist cloth

(the water temperature must be below 30° C).

When cleaning: Bring the backrest to its top position. Bring the bed to its top position. Disconnect the power cord by pulling the plug from the socket outlet before cleaning the bed. The risk of entrapment of fingers is minimised, as accidental elevation of parts of the bed is not possible.

II. Maintenance and check-ups

Only personnel who have received the necessary instruction or training may perform service and maintenance on the *Invacare*[®] **Alegio**TM.

After 3 months of use the following must be checked:

- Tightening of the finger screws at the inserts in the middle of the bed.
- Fastening of the side rail locking system and moving system.

With normal operation, the first service inspection is required after 2 years and thereafter every second year, according to the maintenance chart shown in chapter 12.

Please note:

The mattress support must be supported during service inspections to prevent accidental lowering.

Motors, control unit and hand control

These parts are serviced by exchanging the faulty part.

Motors, control unit and hand control must be regularly cleaned from dust and dirt and must be inspected for mechanical damage or breakage.

Inspect anchor points, cables, piston rod, casing and plugs and check the correct functioning of the motor.

12. Maintenance chart

| Only personnel who have received the necessary instruction or training may perform service and maintenance on the <i>Invacare® Alegio™</i> | | | | |
|--|--|---|--|--|
| S/N (located on mattress support): | | _ | | |
| What to check for: Date: | | | | |
| Electrical safety check in accordance with the values in the standard EN 60601-1 | | | | |
| Check the side rails' mounting and locking/movement. | | | | |
| Check mounting and braking of wheels. | | | | |
| Check height adjustment motor - suspension, and performance. | | | | |
| Check backrest and leg rest motor - suspension and performance. | | | | |
| Check that cables and plugs are undamaged. | | | | |
| Check rastofix fitting and its function. | | | | |
| Check weldings. | | | | |
| Have damaged coating repaired. | | | | |
| Lubrication performed: I. Points of rotation in mattress support and base frame, with oil. 2.All of the motors' tension rods, with oil. | | | | |
| Lubricate with medically clean oil, e.g. KEN-WO 50, order no.: 813239. NB! The wooden side rails´ gliding system must not be lubricated with oil - otherwise the wooden bars will move sluggishly. | | | | |

A service contract can be made in countries where $Invacare^{\otimes}$ has its own sales company. Furthermore, $Invacare^{\otimes}$ offers courses in service and maintenance of the $Invacare^{\otimes}$ **Alegio**TM.

13. Disposal

This product has been supplied from an environmentally aware manufacturer that complies with the Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/CE.

This product may contain substances that could be harmful to the environment if disposed of in places (landfills) that are not appropriate according to legislation.

The 'crossed out wheelie bin' symbol is placed on this product to encourage you to recycle wherever possible.

Please be environmentally responsible and recycle this product through your recycling facility at its end of life.

14. Trouble-shooting the electrical system

Only personnel who have received the necessary instruction or training may perform service and maintenance on the *Invacare*[®] **Alegio**TM.



15. Technical specifications

All measurements are given in cm.All angles are stated in degrees.All measurements and angles are stated without tolerances.

Invacare® reserves the right to change the stated measurements and angles.



Temperature between -30° and 40° C Humidity between 10 and 80 % RH Pressure between 700 and 1.100 hPa

16. Electrical data

Voltage supply: 230 V. Max. current input: I A. Motor voltage: 24 V. Intermittent (periodic motor operation): 2/18 minutes. Protection class: IP 66. Insulation class: II, type B.

Alternating current: 🔨

Direct current:

Sound level < 45 dB.

The bed is not provided with a mains switch, so the mains plug is the only separation from the mains.

The patient is not separated from the ground and the chassis.

★

Double insulated.



Max. load (SWL) (Patient + mattress + side rail + lifting pole + other equipment).

The product should be reused where possible.

Equipotentiality localisation





17. Weights

| Mattress support 3-section |
|--|
| Mattress support 4-section |
| Top frame – head section 3-4-section |
| Top frame – leg section 3-4-section |
| Top frame – leg section 4-section 16.5 kg |
| Base and shear arm |
| |
| Base |
| Base |
| |
| Shear arm 15,0 kg |
| Shear arm 15,0 kg Bed ends Vibeke (per pcs.) 6,0 kg |

18. Electro Magnetic Compliance (EMC)

| The Medical Bed is intended for use in the electromagnetic environment specified below. The user of the Medical bed should assure that it is used in such an environment. | | | | | |
|---|------------|--|--|--|--|
| Emissions test | Compliance | Electromagnetic environment – guidance | | | |
| RF emissions CISPR 11 | Group I | The Medical Bed uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. | | | |
| RF emissions CISPR | Class B | The Medical Bed is suitable for use in all | | | |
| Harmonic emissions IEC 61000-3-2 | Class A | establishments, including domestic establishments and those directly connected to the public low-voltage | | | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | power supply network that supplies buildings user for domestic purposes. | | | |

Guidance and manufacturer's declaration - electromagnetic immunity

The Medical Bed is intended for use in the electromagnetic environment specified below. The user of the Medical should assure that it is used in such an environment.

| IMMUNITY test | IEC 6060 I test level | Compliance level | Electromagnetic environment guidance | |
|--|---|---|---|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact ± 8 kV air | ± 6 kV contact ± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. | |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines ± I kV for input/ output lines | ± 2 kV for power supply lines ± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. | |
| Surge IEC 61000-4-5 | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | ± I kV differential mode ± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. | |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s | <5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Medical bed Alegio requires continued operation during power mains interruptions, it is recommended that the Medical Bed Alegio be powered from an uninterruptible power supply or a battery. | |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 0,3 A/m | The power frequency magnetic field should be at a characteristic level of a typical commercial or hospital environment. | |

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The Medical bed is intended for use in the electromagnetic environment specified below. The user of the Medical Bed should assure that it is used in such an electromagnetic environment.

| IMMUNITY test | IEC 60601 TEST LEVEL | Compliance level | Electromagnetic environment – guidance |
|---|--|---|--|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the Medical Bed, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | Recommended separation distance |
| Conducted RF | 3 Vrms | l Vrms | $d = 3,5\sqrt{P}$ |
| IEC 61000-4-6 | 150 kHz to 80 MHz outside ISM bandsª | | |
| | 10 Vrms | l Vrms | $d = 12\sqrt{P}$ |
| | I 50 kHz to 80 MHz in ISM bandsª | | |
| Radiated RF | 10 V/m | 10 V/m | d = 1,2 \sqrt{P} 80 MHz to 800 MHz |
| IEC 61000-4-3 | 80 MHz to 2,5 GHz | | |
| | | | d = 2,3 \sqrt{P} 800 MHz to 2,5 GHz |
| | | | where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). ^b |
| | | | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^c should be less than the compliance level in each frequency range. ^d |
| | | | Interference may occur in the vicinity of equipment marked with the following symbol: $\left(\begin{pmatrix} (\bullet) \\ \bullet \end{pmatrix} \right)$ |
| | I Iz and 800 MHz, the highe delines may not apply in a | | I pplies. magnetic propagation is affected by absorption and reflection |
| | ctures, objects and people | | |
| 13,553 MHz to 13 ^b The compliance le 80 MHz to 2,5 GF could cause interf 10/3 has been incompliance | 8,567 MHz; 26,957 MHz to wels in the ISM frequency Hz are intended to decrea erence if it is inadvertent | o 27,283 MHz; and 4 bands between 150 se the likelihood tha y brought into patie | Hz and 80 MHz are 6,765 MHz to 6,795 MHz; 0,66 MHz to 40,70 MHz. kHz and 80 MHz and in the frequency range at mobile/portable communications equipment nt areas. For this reason, an additional factor of og the recommended separation distance for |
| ^c Field strengths fro mobile radios, am with accuracy. To a survey should be exceeds the applie | m fixed transmitters, such ateur radio, AM and FM ra assess the electromagnetic considered. If the measure cable RF compliance level rmal performance is obse | adio broadcast and T c environment due t ed field strength in t above, the Medcial B | radio (cellular/cordless) telephones and land V broadcast cannot be predicted theoretically o fixed RF transmitters, an electromagnetic site he location in which the Medical Bed is used Bed should be observed to verify normal sures may be necessary, such as re-orienting or |

 $^{\rm d}$ Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Model 006

The Medical Bed is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Medical Bed can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Medical Bed

as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power | Separation distance according to frequency of transmitter | | | |
|----------------------------|---|----------------------|-----------------------|--|
| of transmitter W | l 50 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2,5 GHz | |
| | d = 1,2√P | d = 1,2√P | d = 2,3√P | |
| 0,01 | 0,12 | 0,12 | 0,23 | |
| 0,1 | 0,38 | 0,38 | 0,73 | |
| 1 | 1,2 | 1,2 | 2,3 | |
| 10 | 3,8 | 3,8 | 7,3 | |
| 100 | 12 | 12 | 23 | |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE I At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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