

User Manual & Installer Guide

B-941 Electric Folding Bed



Version : 01

Publication date : 06/2022

B-941 Electric Folding bed

Company : Sigma Care Development Co., Ltd

Website :www.sigmabed.com

Version : 01

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General

The electric bed is classified as a Medical Device Class 1 in accordance with the European Medical Device Directive 93/42/EEC.

1. Symbols and Definitions

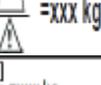
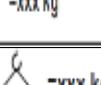
Warning Notices

Types of Warning Notices

Warning notices are differentiated by the type of danger using the following key words:

1. CAUTION warns about the risk of material damage.
2. WARNING warns about the risk of physical injury.
3. DANGER warns about the risk of fatal injury.

Symbols on the Bed and package

| | |
|---|--|
|  | READ INSTRUCTIONS FOR USE |
|  | WARNING |
|  | ONLY SUITABLE FOR INDOOR USE |
|  | APPLIED PARTS TYPE B |
|  | CE Mark Complies with the European Medical Device Directive 93/42/EEC |
|  | Manufacturer |
|  | Manufacture date |
|  | Use the mattress recommended by the manufacturer |
|  | Safe working load |
|  | Maximum patient weight |
|  | WEIGHT OF BED |
| Duty Cycle. : 10%,Max. 2min/18 min | When the movable part works continuously for 2 minutes, it should be stopped for 18 minutes before operation |



Product Label:

SIGMA-CARE DEVELOPMENT CO., LTD

UDI 471987461884114342

Electric Folding Bed

Model: B-941

Lot No.:

Serial No.:

PI NO:

Power Supply: 100-240VAC,50-60HZ

Duty cycle:10% max. 2 min./ 18 min.



2022.06

MADE IN TAIWAN

No AP/APG Protection

IPX 4

+40°C

+50°C



**SIGMA-CARE
DEVELOPMENT CO.,
LTD.
No. 5, Dapumeiyuanqu
20th Rd.,Dalin
Township, Chiayi County
622**

+10°C

-15°C

Operating

Storage

2. Safety and Caution

2.1 Safety instruction

1. Follow the instructions carefully.
2. Any non-observance of this manual may lead to injuries or damage of property.
3. Exclusively use the bed if it is in perfect working order.
4. If necessary, check the bed functions daily or at each shift change.
5. Use the bed exclusively in its original condition.
6. Use the bed exclusively with the correct mains supply.
7. Ensure that the bed is exclusively operated by qualified personnel.
8. Ensure that the patient (health permitting) has been informed about the operation of the bed and all applicable safety instructions.
9. Move the bed exclusively on even, hard-surfaced floors.
10. Replace any damaged parts immediately with original spare parts.
11. Ensure that maintenance and installation are performed exclusively by qualified personnel who have been trained by the manufacturer.
12. Do not apply excess weight or loads to the bed according to SWL (Safe Working Load).
13. Ensure that only one adult patient uses the bed at any time.
14. Take care to avoid squeezing when operating moving parts.
15. When using lifting poles or infusion stands, ensure that nothing will be damaged when you move or adjust the bed.
16. Ensure that the castors are braked when the bed is occupied or not being moved, regardless of whether it is occupied or empty.
17. Keep the mattress platform in the lowest position at any time when the healthcare personnel are not treating the patient in order to prevent the patient from falling or injuries.
18. Never use the bed in areas where there is a hazard of explosion.
19. Enable or disable functions on the handset using the supervisor panel as appropriate for the patient's physical and mental state. Verify that the function is actually disabled.
20. Never handle the mains plug with wet hands.
21. Remove the mains cable exclusively by pulling on the plug.
22. Position the mains cable so that there are no loops or bends in the cable; protect the cable from mechanical wear and tear.
23. Improper handling of mains cable can cause an electric shock hazard, other serious injuries or damage the bed.
24. Ensure that the moving parts of the bed are not blocked.
25. To prevent failures, use exclusively the manufacturer's original accessories and mattresses.
26. Ensure that the stipulated safe working load is not exceeded.
27. If the patient's condition could lead to an entrapment, leave the mattress support platform in the flat position whilst unattended.
28. Adjust bed height to approx. 20 cm below maximum height when transporting the bed in order to facilitate overcoming possible obstacles.
29. Ensure there is no danger of crushing or otherwise injuring the patient's limbs (e.g. between side rails and mattress platform, between movable parts etc.) before positioning the bed or collapsing the siderails.
30. Do not put any objects (e.g. accessories, cables) between or on side rails and movable parts.
31. Always set mattress platform to its lowest position and single parts of mattress

Platform to horizontal position in case the patient is left on the bed without supervision of personnel and if his health and mental status may indicate increased risk of falling out of the bed or entrapment.

32. When malfunction occurred, unplugging to prevent more damage.
33. Use the bed after adjusting to an appropriate height, we recommend using the bed at a height that allows the user to take a sitting position on the edge of the bed or at a low position.
34. If there is no attendant, we recommend using the bed at the lowest position for safety.
35. Be careful not to place heavy objects on the power cable, and not to crush the power with the bed. The cable may be damaged, resulting in fire or electric shock. Insert the power plug directly into the cable power outlet.
36. Neither use the extension cable, nor connect other electrical products into the same power outlet. It may exceed the capacity of the power outlet (Avoid connecting multiple cables to a single outlet). Fire may occur.
37. Use with another company's products may cause damage that results in injury. Furthermore, a serious injury may occur due to the unexpected enlargement of gaps.
38. If a lifting pole or IV pole is fixed to the bed, increased attention must be taken during movement, lifting or tipping, to the space around the lifting pole and infusion stand, so that the equipment is not damaged.
39. Before cleaning the bed, the electrical supply must be disconnected.
40. When repairing the bed, only original materials and components may be used, otherwise the manufacturer cannot guarantee against any damage that might occur.



Warning

The bed should be left in its lowest position with the mattress base in a flat profile when **the patient is** unattended in order to reduce the risk of patient injury due to falls while getting into or out of the bed, or whilst lying on the bed.

2.2 Conditions of use:

This bed is intended for use in the following application environments only:

1. Application Environment 3 - Long-term care in a medical area where medical supervision is required and monitoring is provided if necessary and ME EQUIPMENT used in medical procedures may be provided to help maintain or improve the condition of the patient, this includes use in nursing homes and in rehabilitation and geriatric facilities.
2. Application Environment 4 - Care provided in a domestic area where ME equipment is used to alleviate or compensate for an injury, disability or disease.

Suitable for:

- Patients
 - With weight ≥ 40 kg
 - With height ≥ 146 cm
 - With BMI ≥ 17
 - Whose weight (including mattress and accessories) does not exceed the SWL
- Personnel
 - Qualified medical staff
 - Any person familiar with the manual
 - Patient (condition permitting)

This bed can be used and stored in the following indoor environments

- Ambient temperature range: $+10$ °C to $+40$ °C
- Relative temperature: 30% to 75%

This bed can not be used and stored in the following indoor environments

- Dangerous places
- Where there are flammable anesthetics

3. Standard language specification:

The manufacturer follows a certified quality management system that meets the following standards:

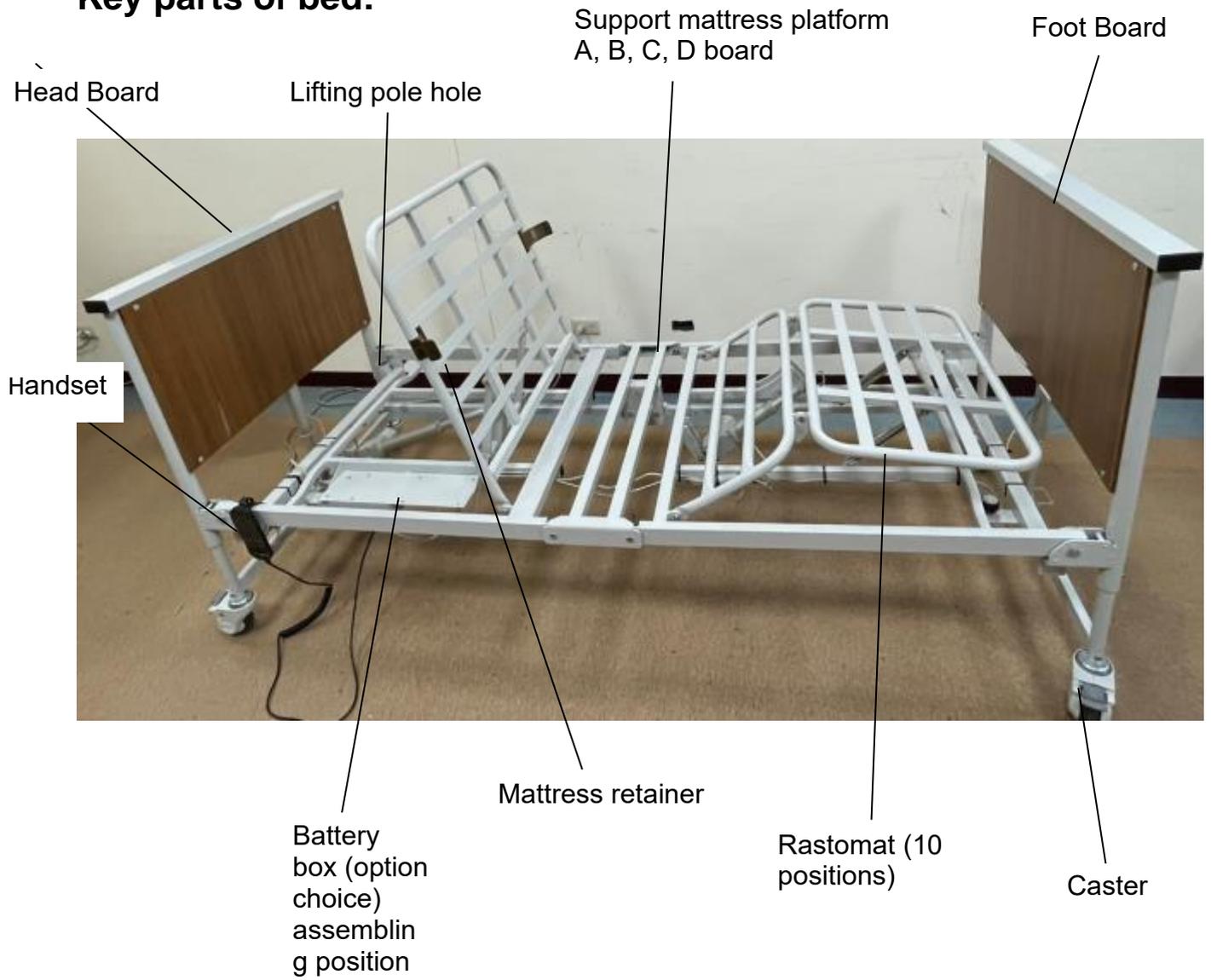
- EN 60601-1:2006/A1:2013
- EN 60601-1-2:2015
- 93/42/EEC

The manufacturer adheres to a certified quality management system in compliance with the following standards:

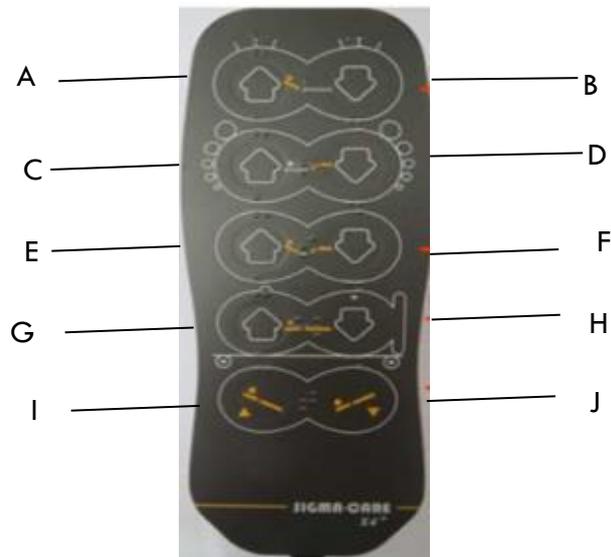
- EN ISO 13485:2016.
- EN ISO 14971

4. Product Description

Key parts of bed:



4.1 Handset

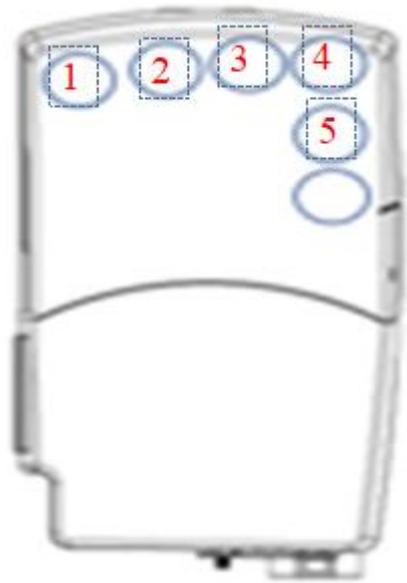


| | Function | Description |
|----------|--|---|
| A | Folding Backrest up | Press to fold the bed Press to raise the backrest position |
| B | Extension Backrest down | Press to extend the bed Press to lower the backrest position |
| C | Leg rest up | Press to raise the leg position |
| D | Leg rest down | Press to lower the leg position |
| E | Back and leg up simultaneously | Raise Back and Leg section in the same time |
| F | Back and leg down simultaneously | Lower back and legs section in the same time |
| G | Bed height up | Raise whole bed height |
| H | Bed height down | Lower whole bed height |
| I | Anti- Trendelenburg | Press to do Anti-Trendelenburg position |
| J | Trendelenburg | Press to do Trendelenburg position |

4.2 Actuator System



Control box



| Number | Function | Description |
|--------|--|---------------------------------------|
| 1 | Headrest Motor | Control headrest up and down |
| 2 | Footrest Motor | Control footrest up and down |
| 3 | High-low motor locates in Headboard position | Control High-low of backrest position |
| 4 | High-low motor locates in footboard position | Control High-low of footrest position |
| 5 | Handset | Operating all functions |

4.3. Operation

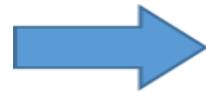
Extension operation

| | |
|---|--|
| <p>1.  Warning Before making extension, must make sure the folded bed is in the lowest height.</p> |  |
| <p>2. Lock the head board caster before starting extension. Caution : Always lock both castors locate below head board position before making extension movement.</p> |  |
| <p>3. Before starting the extension movement, must lock the red locking bar.</p> |  |
| <p>4. Unlock the black knocking knob from the locking position.</p> |  |

5. Push the footboard to let the bed open a little bit.



6. Press Backrest Down (Extension) position
Keep pressing backrest down(extension) position, then the bed will keep extending gradually.



Folding operation

| | |
|--|--|
| <p>1.</p>  <p>Warning</p> <p>Before folding, must lower the bed to the lowest height</p> |  |
| <p>2. Locking the casters before starting folding movement.</p> <p>Caution:</p> <p>Always lock both castors locate below headboard position before making movement.</p> |  |
| <p>3. Locking the red locking bar.</p> |  |
| <p>4. Press Backrest up (folding) button, keep pressing backrest up(folding) position, then the bed will keep folding up gradually.</p> |  |

5. When folding almost completed, manually push the footboard toward headboard position to make it completed folded.

 **Warning** During folding process, can only pressing the backrest up(folding) button, not to press any other function buttons, or it will causing the damage to the bed.



6. Moving the black knocking knob back to the lock position



7. Then the folding process completed.



Functions Operation

Backrest up and down buttons



Warning

Before pressing backrest up button, must release the red locking bar, or it will cause damage to the frame.



Backrest up can up to 73°



Kneerest up and down buttons



Knee rest up can up to 35°



Backrest and Kneerest up and down simultaneously.



Bed Height up and down



Anti-Trendelenburg and Trendelenburg



Caution :
Always lock both castors locate below head board position before making trendelenburg movement or it will cause the bed moving danger.

Trendelenburg can up to 10°





5. Technical specifications

■ ± 5%

| | |
|--|-------------------|
| Overall size | L2300mm x W1000mm |
| Surface size(Measure up to mattress retainer inner space) | L1986mm x W835mm |
| Minimum height (mm) (from the support mattress platform to floor) | 300mm |
| Maximum height (mm) (from the support mattress platform to floor) | 700mm |
| Folding up size | W 558mm x H1200mm |
| Backrest angle (°) | 0°- 73° |
| Footrest angle (°) | 0°-35° |
| Trendelenburg Angle | ±10° |
| Power Condition (Four Motor + Control Box) | 380W |
| Safe working load (including mattress) | 200 kg |
| Maximum patient weight | 135 kg |

6. Electrical specifications

| | |
|--------------------------------|---|
| Input Voltage | 100~240VAC, 50/60HZ 2000MA |
| Rating | 110-110V 55W-60W 200-230V 90W |
| Maximum Power Input | 32V 80VA |
| Ingress Protection | IP54 |
| Protection Class Applied parts | Class I Type B |
| Electrical Motor Duty Cycle | max. 2 min ON / 18 min OFF |
| Battery(option choice) | One 24V sealed lead battery (15 A fuse) When the capacity is 1.2 A. |
| Power cord length | 2 Meters 5 |
| Measured sound pressure level | 52dB(A) |

7. Cleaning/disinfection

In order to ensure safety and cause damage, please pay attention to the following when cleaning the bed:

- Disconnect power to the bed.
- Do not use any strong acid and strong alkali products (the optimal PH value range is 6-8).
- Still use cleaning agents suitable for cleaning medical equipment.
- Do not use abrasive powder, wire brush or other materials and cleaning agents that may damage the surface of the instrument.
- Do not use any corrosive cleaning agents.
- Do not use detergents with calcium carbonate precipitation.
- Do not use cleaning agents (such as benzene, toluene, acetone, etc.) that have the ability to dissolve and may affect the structure and characteristics of the plastic.
- Use an easy-to-wipe cloth to clean the bed.
- Clean the electronic components carefully and let them dry completely.

8. Troubleshooting

| Problem | Possible Cause | Solution |
|---|--|--|
| Adjusting with position buttons not possible | Handset is damaged | Notify the service department. |
| | Defective drive motors Defective battery | Check the mains connection. Notify the service department. |
| | Plug inserted incorrectly | Insert the mains plug correctly. |
| | Faulty powder cord | Notify the service department. |
| | Faulty control box | Notify the service department. |
| Faulty mattress platform height/tilt adjustment | There is an object on the undercarriage cover | Remove the object. |
| | Function disabled on supervisor panel | Enable disabled function. |
| | Drive motors have no power Defective drive motors Defective battery | Check the mains connection. Notify the service department. |
| | Plug inserted incorrectly | Insert the mains plug correctly. |
| | Faulty control box | Notify the service department. |
| | Faulty control element | Notify the service department. |
| | Faulty brakes | The brakes are blocked by dirt |
| The brake mechanism is defective | | Notify the service department. |
| The head and foot boards cannot be inserted | The head or foot board is in the wrong position | Check locking mechanism. Position head or foot board correctly. |
| | Defective mechanism | Notify service department. |
| Bed does not function at all | Power Cord not connected to Socket or to Controller Actuator plugs are not connected To controller Handset is not connected | Check handset connection to the controller. Check cable integrity Check that all Actuator plugs are connected well in the controller socket. Check connection of both sides of Power cable. Check if Socket has electric power |
| Handset not functioning | Lose connection to Controller Program Failure | Check connection of Handset wire to controller Call Technician |



9.Preventive Maintenance

| Actions to be done by care person | Daily | Weekly |
|--|-------|--------|
| Check patient handset and cable | | √ |
| Visually check castors | | √ |
| Visually check power supply cord and mains plug | | √ |
| Check that all bed adjustments able to function smoothly | | √ |
| Check the plug connectors with power cord are properly secured in the electric storage hook if not using for long time | | √ |

If you discover a problem while using or inspecting the bed, immediately stop using the bed and promptly contact your dealer or our customer service center and request repair. Never carry out replacement, repairs without engineer staff.

| Actions to be done by qualified personnel | Yearly |
|--|--------|
| Carry out a full test of all electrical bed positioning functions maximum position | √ |
| Check operation of the castors, paying Special attention to braking function | √ |
| Check the calf section latches securely in the horizontal position when manually raised | √ |
| Examine the power supply cord and mains plug, if damaged, replace the complete assembly, do not use a rewirable plug | √ |
| Examine all accessible flexible cables for damage and deterioration | √ |
| Check all accessible nuts, bolts and other fasteners are present and correctly tightened. | √ |

11.Spares Parts List

| Item | Part No. | Description | Picture |
|------|----------|-----------------------------------|---|
| 1 | GA0089 | Head Rest actuator |  |
| 2 | GA0360 | Knee Break actuator |  |
| 3 | GA0106 | Hi-Lo Actuator |  |
| 4 | GA0085 | Control box |  |
| 5 | FA0109 | SIGMA- CARE Handset |  |
| 6 | ZA1709 | Support mattress platform A Board |  |
| 7 | ZA1710 | Support mattress platform C Board |  |
| 8 | ZA1711 | Support mattress platform D Board |  |
| 9 | JA0656 | Castor with Peak Care mark |  |



SIGMA-CARE DEVELOPMENT CO., LTD.

