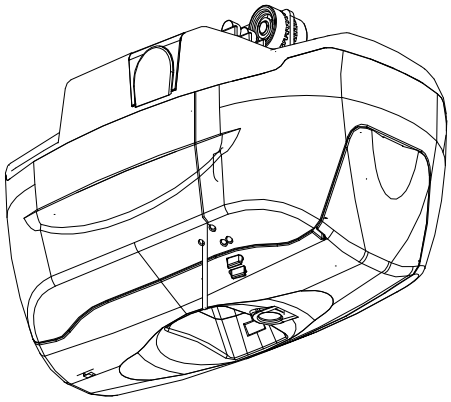
LIFTING DEVICES FOR PERSONS

V4

Ceiling Lift



TECHNICAL DOCUMENTATION

2001 Tanguay Street
Magog, Quebec, Canada
J1X 5Y5
Tel.: (819) 868-0441
Fax: (819) 868-2249

Revised: August 2003

Technical file content

1 Introduction

1.1 Product identification

General names:	420PLUS / V4
Serial name:	Voyager
Family name	Ceiling lift

1.2 Manufacturer and location

BHM Medical Inc
2001 Tanguay Street
Magog, Quebec, Canada, J1X 5Y5

How to contact us (North America):

BHM Medical Inc.
2001 Tanguay Street
Magog (Quebec)
Canada J1X 5Y5

Phone: (819) 868-0441
? service calls during business hours -
(8:00-12:00 and 1:00-5:00 p.m. E.S.T.)

? service calls outside regular business hours
Extension #6199 (you must press the pound key)

Fax: (819) 868-2249
Web site: www.bhm-medical.com
E-mail: bhm@bhm-medical.com

1.3 Subcontractors and location

BHM Medical designs all parts in Quebec, Canada, except of batteries and motor

Subcontractors manufacture majority of parts in Quebec, Canada.

Elvi manufactures motor in Italy.

Batteries and some electronic parts are manufactured in Asia. For more information, see annex 2.5.2 b)

BHM Medical assembles lift and accessories in Quebec, Canada.

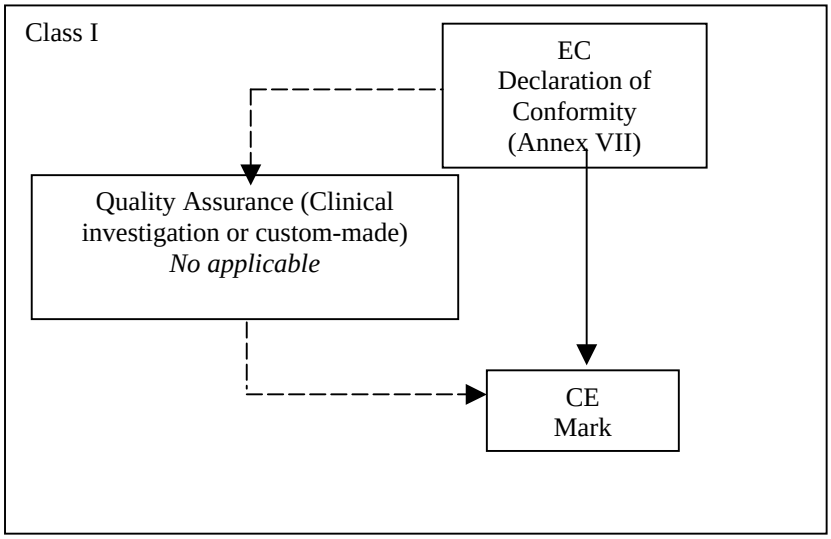
More information on suppliers and subcontractors are available.

2 Standards procedure

2.1 CE Marking procedure

2.1.1 Route of compliance

According to the Council Directive 93/42/EEC Article 11.5 “The manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on market”.



2.1.2 Declaration of conformity

See annex 2.1.2: Declaration of conformity

2.1.3 National and European device classification (annex IX)

See annex 2.1.3: Directive 93/42/EEC annex IX

2.2 European Directives and Standards:

2.2.1 Directive Medical Devices 93/42/EEC

See annex 2.2.1: Directive 93/42/EEC Annex I Essential Requirements

2.2.2 Directive 73/23/EEC Electrical Equipment

See annex 2.2.2: Directive 73/23/EEC Annex 1

2.2.3 European Standard: 89/336/EEC

See annex 2.2.3: Directive 89/336/EEC

2.2.4 Risk Analysis (EN 1441 for Europe): security and performance

See annex 2.2.4: Risk Analysis

2.3 Authorized European Union representation

BHM Medical general representative for Europe:

EHS European Healthcare Solutions
14 Cross Street.
Barnes
London
SW13 0PS
United Kingdom

BHM Medical authorized distributors for Europe (partial list):

Sunrise Medical Ltd
High Street Wollaston
West Midlands
DY8 4PS
England

RMT Reha Med Technology
63322 RODERMARK
Germany

2.4 Specific standards

2.4.1 ISO 10535

Test report available.

2.4.2 CSA 601.1 (EN 60601.1, UL 2601.1)

See appendix 2.4.2 a) CSA Certificate of Compliance V4
See appendix 2.4.2 b) CSA report V4

2.4.3 CSA Z323.5-1998

Test report available.

2.5 Lifetime of products

These product are designed, manufactured and tested for a lifetime corresponding at 10 000 cycles of use. The mechanism shall be maintained according to manufacturer instructions. The lifetime of batteries depend on the duty cycle of use, see “Technical specifications of batteries” section 4.2.1.

The lifetime may be more if a general maintenance and inspection, according to the manufacturer instructions, at 10 000 cycles permit this. 10 000 cycles usually correspond at 3 years of normal use.

2.6 Quality Assurance, procedures and certificate

See annex 2.6: SGS Certificate of ISO 9001-1994 accreditation.

2.7 Post-Market Surveillance

2.7.1 Complaints and incidents reported

Available at BHM Medical.

2.7.2 Advisory notices and recalls

Available at BHM Medical.

2.7.3 Competent authorities

See annex 2.7.3: Competent authorities for Europe

3 Description of Product

3.1 General Description

3.1.1 Description of product

TRACK LIFT SPECIFICATIONS	V4
CHARACTERISTICS	
* Weight – kg	11.5 kg (batteries include)
* Lifting capacity – kg	200 kg (440 lbs.)
* Soft start & stop movement	YES
SAFETY FEATURES	
* Emergency lowering device	Manual & electric
* Current limiter & emergency stopping device	YES
* Emergency brake	Centrifugal
TECHNICAL SPECIFICATIONS	
* CSA, UL & CE approved & respect EMI standards	YES
* Frame	Steel, 1000kg tested
* Vertical displacement speed	60 mm/sec, (40mm/s at 200kg)
* Vertical axis motor	24 VDC, 1/12 HP
* Horizontal displacement speed	150 mm/s
* Horizontal programmable speeds	100mm/s, 150mm/s, 200mm/s, 250mm/s
* Horizontal axis motor	24 VDC, 1/12 HP
BATTERY MODEL SPECIFICATIONS	
* Rechargeable sealed lead acid	2X12VDC, 4.5Ah
* Clip on charging system	YES
* Battery autonomy with load of 75 kg)	Up to 100 transfers
* Visual & audible low battery indicator	YES
* Battery protection function	YES
* Charge input	0.5 A max, 100 to 240 Vac, 50 to 60 HZ
* Lift cannot return to charger with load	YES
* Return to charge function on handset	Optional
STRAP SPECIFICATIONS	
* Length	2.3 m, 1500kg tested
* Automatically stops unit if twisted	YES
UNIT COMPOSITES	
* Mechanical structure – high strength steel	YES, 1000kg tested

* Dimensions	Length 38 cm, Width 25 cm, Height 18 cm
* Cab –VO plastic – fire retardant	YES
* Rail –T66081-T5 high extruded aluminium & baked paint coated.	YES

DESCRIPTION OF EQUPMENT – V4

Lift Unit

The lift unit is a steel frame based system driven by a gear reduced high torque motor.

OPERATING FEATURES :

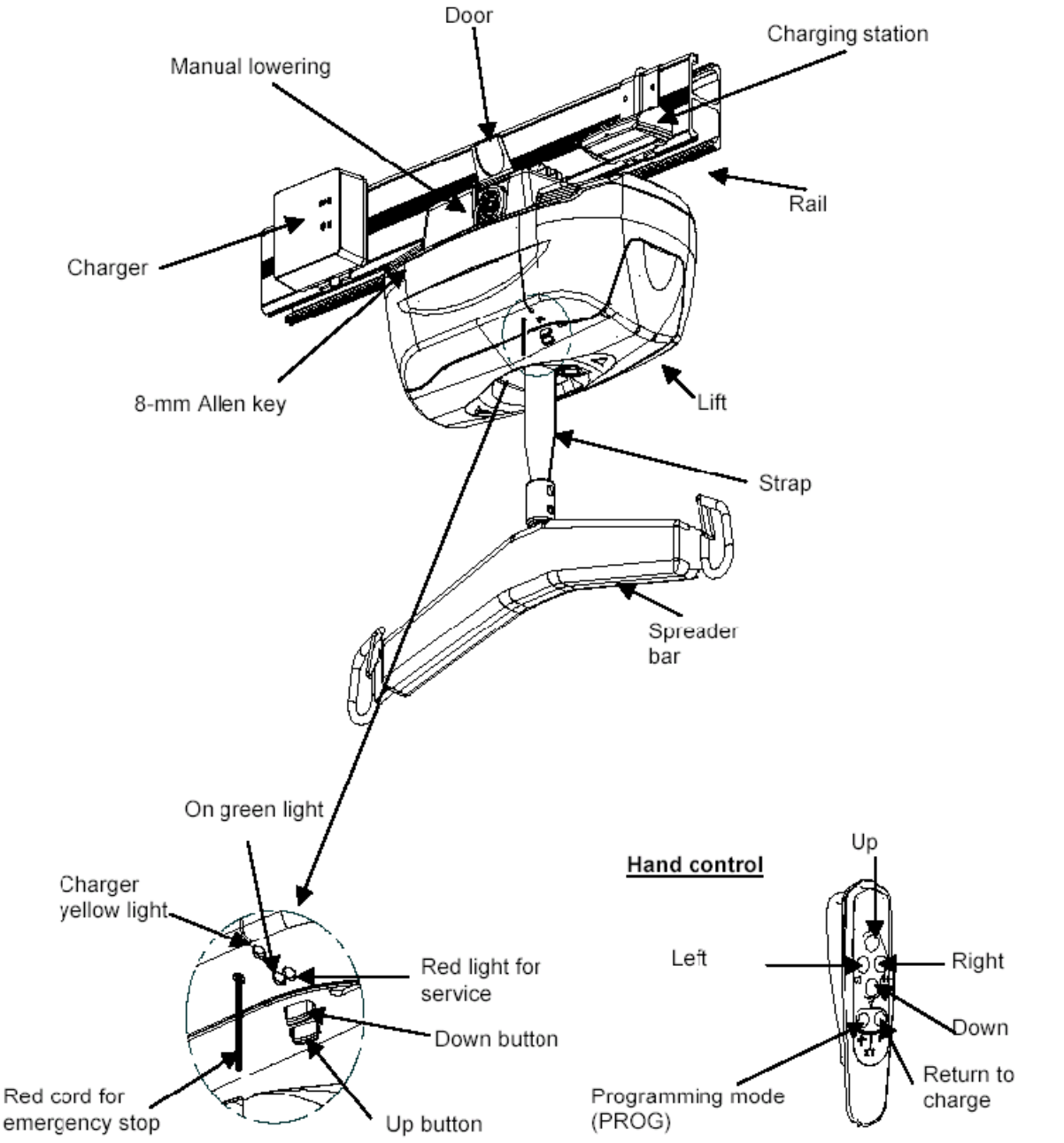
- Lifting capacity : 200 kg (440 lbs).
- Average weight: 11,5 kg (25 lbs) batteries included.
- Electronic soft-start and soft-stop motor control.
- Emergency lowering device
- Emergency stopping device.
- Current limiter for circuit protection in case of overload.
- Safety device that stops the motor to lift when batteries are too low.
- Lifting speed : 6 cm/s (2.3in/s), 3.5cm/s (1.6in/s) in full capacity.
- Horizontal displacement speeds : 10, 15, 20 and 25 cm/s. Speed by default 20cm/s (6in/s).
- Horizontal axis motor : 24VDC at 62 watts and vertical axis motor at 110w.
- Emergency brake (in case of mechanical failure). Operates on the same principle as a car safety belt mechanism.
- Strap length up to 2.3m (90in) tested for 1360kg (2998).
- CSA No. 601.1, UL No 2601-1 and CE conformity.
- Respect EMI standards
- ISO 10535.

What's included

ITEM	QTY
V4 Lift	*1*
Batteries (inside unit)	*2*
Clip on charging station	*1*
Hand control	*1*
Spreader bar	*1*
Power cord	*1*
8 mm Allen key	*1*
User Manual	*1*

3.1.2 Parts description

Part description

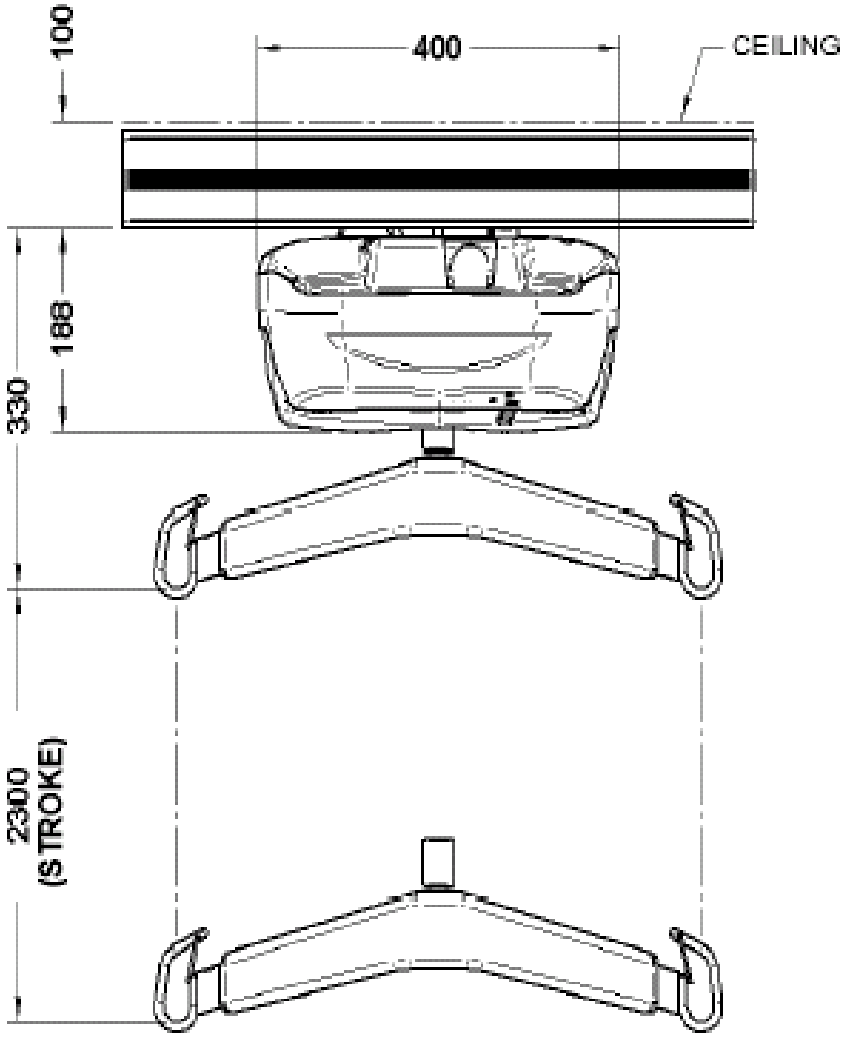


Notes:

- the yellow light "charger" flashes while charging and illuminates when charge is finished;
- the green light "on" illuminates once the lift is on and ready for use; the green light flashes when the batteries are low.
- The red light "service" flashes when servicing is required (contact customer service);
- The button "Programming mode" allows you to modify the functions of the product.

3.1.3 Dimensions

(In millimetres)



TOTAL STRAP LENGTH

3.1.4 Definition of product family

Family: Voyager Ceiling Lift:

Voyager:	BHM serial name (trade mark)
Lift:	Equipment for transferring by lifting and moving a disabled person in an area limited by the system.
Ceiling:	Stationary hoists using a ceiling support, a ceiling rail or a freestanding support.

3.1.5 Functional purpose of the device (intended use)

Lifting and moving a disabled person.

3.1.6 Variants of the device

Voyager 420PLUS or V420PLUS

Name:

The trade name “Voyager V420PLUS” or “V420PLUS” is used in some parts of North-America. The major difference is the safe working load indicated on V420PLUS is 190kg/420lbs for reason commercial only.

Conception and fabrication:

All Voyager 420PLUS have the same conception and fabrication for mechanism and control than V4. The most frequent variation is optional features and cabin.

3.1.7 Records of significant changes to the device design

No major modification was made to the product. None are concerning critical, safety or subjected part to the standards.

3.2 Use information

3.2.1 Advertising/Warning

See annex 3.3.1: Advertising (more advertising available in user manual).

3.2.2 Intended patient population and medical condition

For handicapped, disabled, people in loss of independence and senior citizen without wound.

3.2.3 The reasonably foreseeable medical conditions is not be used

People with wound or spasm (medical guidance),
People without muscular tonus (vigilance and precaution).

3.3 Market information

3.3.1 Warranty

WARRANTY (extract)

This warranty is extended only to the original purchaser/user of BHM products.

BHM Medical Inc. warrants its products to be free from defects in material under normal use and service, within the periods stated below from the date of purchase. If within such warranty period any such product shall be proven to be defective, such product shall be repaired or replaced at BHM Medical's option. This warranty does not include any labour or shipping charges incurred in replacement part installation or repair of any such product. BHM Medical's sole obligation and your exclusive remedy under this warranty shall be limited to such repair and/or replacement.

Patient Lifter	1 year
Tracks and installation	Life time warranty*
Weighing Devices	1 year
Accessories on Lifter	1 year
Slings	1 year
Batteries - All other lifts	1 year
Easytrack System	1 year

For warranty service, please contact the dealer from whom you purchased the BHM Medical product. [In the event that you do not receive satisfactory warranty service, please contact BHM Medical (see contact information in Table of Contents).]

Do not return products to our factory without prior authorization. BHM Medical will issue a Return Merchandise Authorization (RMA) Number. C.O.D. shipments will be refused; all shipments to BHM Medical must be prepaid. For this warranty to be valid, the purchaser must present its original proof of purchase at the moment of the claim. The defective unit, assembly or part must be returned to BHM Medical for inspection. The part or components repaired or replaced are guaranteed for the remaining period of the initial warranty.

Limitations and Exclusions:

The warranty above does not apply to serial numbered products if the serial number has been removed or defaced.

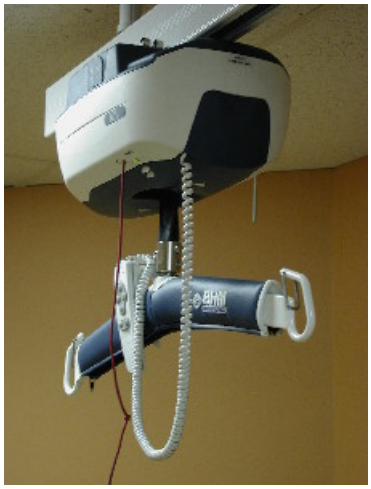
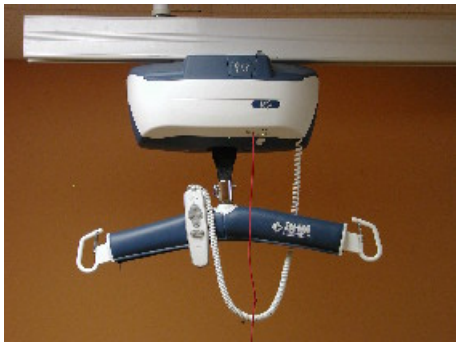
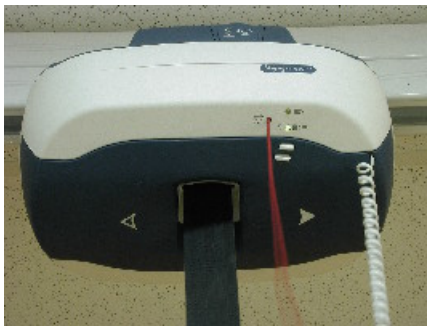
No warranty claim shall apply where the product or any other part thereof has been altered, varied, modified, or damaged; either accidentally or through improper or negligent use and storage. Warranty does not apply to products modified without BHM Medical's express written consent, (including but not limited to products modified with unauthorized parts or attachments); products damaged by reason of repairs made to any component without the specific consent of BHM Medical, or to products damaged by circumstances beyond BHM Medical's control. BHM Medical will solely determine evaluation of warranty claim. The warranty does not apply to problems arising from normal wear or failure to adhere to the instructions in this manual. BHM Medical Inc. slings are void of warranty if not laundered as per instructions on the Sling Label.

BHM Medical Inc. shall not be liable for damages losses or inconveniences caused by a carrier.

This warranty replaces any other warranty expressed or implicit and constitutes BHM Medical Inc. only obligation towards the purchaser. BHM Medical shall not be liable for any consequential or incidental damages whatsoever.

* Valid only if BHM Medical did the original installation. Guarantee void if tracks/installation have been modified.

3.3.2 Photograph of product and use

See also user and technical manuals.

3.3.3 Brochure, advertising, marketing claims

See annex 3.3.3

Also available at BHM Medical or ask your local representative.

3.3.4 Packaging specifications, transport and storage conditions

Duration: Not exceeding 15 weeks for transport and storage.

Handling: Do not drop de product.

Environmental conditions:

Ambient temperature range of –40°C to +70°C
Relative humidity range of 10% to 100%
Atmospheric pressure range of 50 to 106 Kpa

BHM Medical recommends charging of batteries at least every two weeks even if the lift is not used. This will prevent premature aging of batteries.

3.3.5 Details of product labelling, instructions for use and other literature

Ask your local representative for national specific labelling.

3.3.6 User and Technical Manuals

See your local representative for national version.

4 Product Specification

4.1 General description of each of the functional parts/components

4.1.1 Bill of Materials

See annex 4.1.1

4.1.2 Mechanism

Model consists of a 24Vdc battery operated patient lifter module installed on a rail. All components are enclosed in on-combustible enclosure without ventilation opening. Lifter can be displaced manually or it is moved by a motor on the rail.

Flame class rating for both plastic parts white and blue (plastic cab):

Material:	V-0 Class Rating
Test method:	UL 94

All electrical parts are enclosed in non-combustible V-0 plastic enclosure and metal chassis without ventilation opening.

Emergency Switch S5 Certified CSA*/UR* type pullchain switch.

DC Motor (vertical movement):

Manufaturer:	ELVI MOTORI ELETTRICI SRL
Type:	Fully enclosed, no ventilation opening permanent magnet, class A
Rating:	24Vdc, 1.1A, 110W, 4000RPM, 0.3N-m
Mounting:	Secured by screws and lock-washer to chassis.

DC Motor (Horizontal movement):

Manufaturer:	ELVI MOTORI ELETTRICI SRL
Type:	Fully enclosed, no ventilation opening permanent magnet, provided with integral reducer
Rating:	24Vdc, 1.8A, 30W, 260RPM, 1.0N-m
Mounting:	Secured by screws and lock-washer to chassis.

Frame: Frame is made of steel, 2.64mm thick. The structure forms a box, 164mm x 140mm wide by 124mm high. Other mechanical parts are fixed to this frame.
The frame and steel parts are protected against rust by a zinc plated treatment. Aluminium parts are protected by “heredite” or “anodize” plated treatment.

Displacement: Vertical (up/down), drum
The motor (ELVI without gearbox) drives a 30 teeth worm gear, double tread. The worm gear drives a shaft on which lies a worm. This worm drives a second worm gear directly attached to the drum. The total obtained ratio is 375:1.

Strap: The strap is a threaded nylon that can hold up to 2727kg (6000lbs).
Section: 49mm x 1.2mm thick.

Displacement: Horizontal (left/right).
The motor (ELVI with integrated gear box) drives a spur gear that drives two idlers. Those idlers directly drive the wheel. The wheels are made of plastic over-molded on ball bearings. Wheels are fixed on trolley with spring pins.
Steel trolley is fixed to the frame by three interlocks and secured with another interlock and a M5 screw.

End of strap stopper: (Up/down)
In the unit, a limit switch is attached on a steel blade, sensing the double thickness of the strap. This indicateds the higher position of the strap. The lower limit is sensed when the drum tries to roll the strap into the wrong direction. This will activate the switch and stops the motor.

4.1.3 Accessories and other devices or equipment

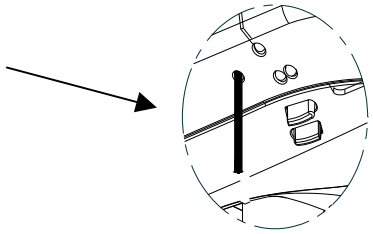
See annex 4.1.3

4.1.4 Functional characteristics and technical specifications for the device

HOW A VOYAGER SERIES IMPROVES EFFICIENCY AND CARE

Emergency Stop (Red Cord)

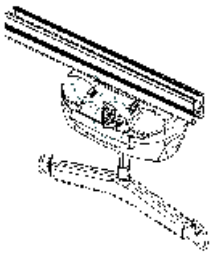
The emergency stop can be activated at any time to stop the functioning of the lift.

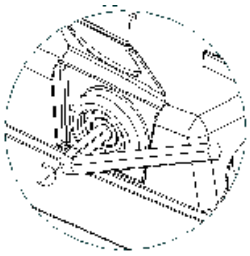


Emergency Lowering Feature

In the event of an electrical or functional failure, the V4 has an emergency manual lowering feature.

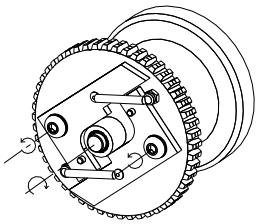
If the lift malfunctions when a patient is being transferred, the emergency lower device provices a safe way of lowering the patient onto a chair or a bed.





Emergency Brake

The emergency brake is made of a metal bar fixed to the drum.



In case of gear or motor breakage, the centrifugal force created will block the bar against the frame.

Programmable Lift

Mode Program

The speed and height of the lift can be easily adjusted by the user while in the Program « Service » Mode.

Use the « UP » button on the hand control to select the parameters wanted. Each push of the button will bring you to a different selection :

1 beep = Speed displacement

2 beeps = Length of the strap

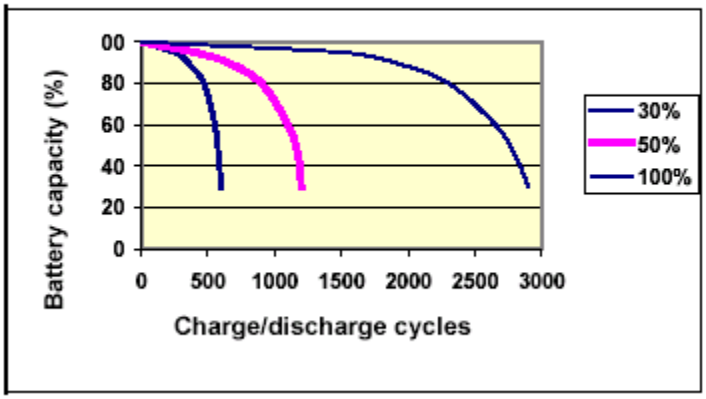
4.2 General Description of electrical components:

4.2.1 Technical specifications of batteries

- 2 rechargeable batteries of 12 Vdc, 5 Ah.
- Provides up to 120 transfers with a load of 74kg (200lb.) and up to 70 transfers with its maximum load of 200kg (440lb).

Life cycle (number of charging cycles) of the batteries is largely dependant on the depth of discharge in each cycle. More the batteries are drained, the shorter their life span. The lifte of the batteries is also related to such factors as varying temperatures and rest periods between charge and discharge.

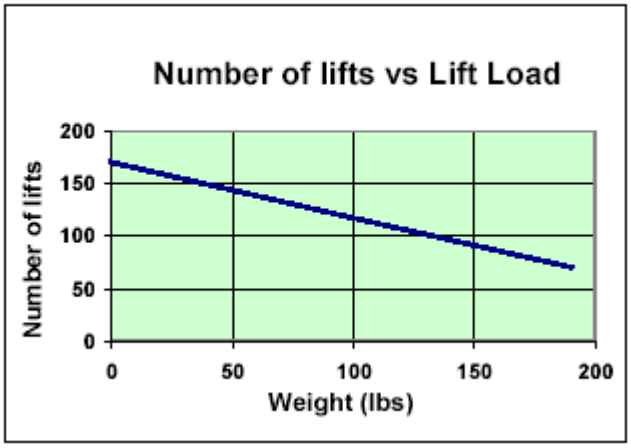
Graph 1: Number of recharges vs. Depth of discharge



Graph 1 illlustrates the relationship between the discharging depth and expected battery life.

If you drain the batteries until they beep every time, you can expect the batteries to fully charge only 600 times.

Graph 2: Number of lifts vs. lift load



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Indicator Lights

The lift and the charging system have many indicator lights. It important to understand their significance for use and comprehension of the lift.

Green light	Operating the lift	
	----------	Low batteries
	▬▬▬▬	The lift is on and ready to use.
Yellow light	States of batteries	
	----------	In process of charging batteries
	▬▬▬▬	Charging done, batteries charged.
Red light	Maintenance	
	----------	Maintenance required by your local representative
	▬▬▬▬	Lift started by service mode

Charging indicator green light	Turn on	Charger on
Clip on charging station indicator green light	Turn on	Clip on charging station on.

4.2.2 Technical specifications of charger

- Charger input : 100-240 Vac, 50/60 Hz.
- Charger output : 27 Vdc, 1 A max.
- Charger clip on the rail.
- Charging station clip on the rail.

See appendix 2.4.2 b) for more details.

4.2.3 Technical specifications of motors

DC Motor (vertical movement)

Manufacturer : ELVI
Type : Fully enclosed, no ventilation opening, permanent magnet, without gearbox.
Part # : 100.462/FC (BHM Part number = #400.14000)
Rating : 24 Vdc, 1.1A, 110 Watts, 4000 RPM, 0.3 N-m
Overall dim. : ø77mm x 131.5mm long (without worm shaft)
Mounting : Secured by screws and lockwasher to chassis.

A) Rotor : Laminated steel, 55 mm dia by 38 mm high
Mounting : Crimp to the shaft

B) Rotor Winding : Enamelled copper wire, class H- UL (see enclosed sheet)

C) Rotor to winding insulation : 1 layer of Isotherm, 0.25 mm thick, Class F 145°C

D) Spacer material : PSU 2010 (see enclosed sheet)

F) Collector : Copper 23 diam. long, (see enclosed sheet)

G) Brush : Carbon composition mounted on spring
Dimensions : 5 x 8 x 12 mm

H) Brush holder : Later 4 G/30 (see enclosed sheet)

I) Motor leads : Certified, TEW 105°C, N° 18AWG, connected by certified 2 pins AMP connector.

J) Motor leads connection to windings : crimping

DC Motor (horizontal movement)

Manufacturer : ELVI
Type : Fully enclosed, no ventilation opening, permanent magnet, with integral reducer.
Part # : 101.663/FC (BHM Part number = #E0006)
Rating : 24 Vdc, 1.8A, 30 Watts, 260 RPM, 1.0 N-m
Overall dim. : ø63mm x 114mm long (without reducer)
Mounting : Secured by screws and lockwasher to chassis.

A) Rotor : Laminated steel, 42 mm dia by 32 mm high
Mounting : Crimp to the shaft

B) Rotor Winding : Enamelled copper wire, class H- UL (see enclosed sheet)

D) Rotor to winding insulation : 1 layer of Isotherm, 0.25 mm thick, Class F 145°C

D) Spacer material : PSU 2010 (see enclosed sheet)

F) Collector : Copper 19 mm diam. (see enclosed sheet)

G) Brush : Carbon composition mounted on spring
Dimensions : 6.5x4.5x10 mm

K) Brush holder : Later 4 G/30 (see enclosed sheet)

L) Motor leads : Certified, TEW 105°C, N° 18AWG, connected by certified 2 pins AMP connector.

M) Motor leads connection to windings : crimping

4.2.4 Control circuit plans

See CSA report in appendix 2.4.2 b)

4.3 Design and production documentation

4.3.1 Calculation notes-scoop of work

Available

4.3.2 Bibliography and references

Available

4.3.3 Material safety data description and physical properties of the materials

Available

4.3.4 Specifications, instructions and fabrication process

Available

4.3.5 Special process instructions and inspections

Available

5 Verification of product

BHM Medical Inc. Credentials

- FDA Registration # 9681684
- CE mark (European Union Listing)
- Each finished Voyager Portable is individually tested in our laboratory.
- Lifting Capacity 200 kg/440 lbs. Engineering safety factor exceeds European Standards.
- Complete range of patient lift slings and supports designed and manufactured by BHM Medical Inc. using medical quality materials and fabrics.
- ISO 9001
- Voyager is a registered trademark of BHM Medical Inc.

APPROVALS:

CSA 601.1
UL 2601.1
EN 60601.1

5.1 Test records:

5.1.1 Internal, laboratory and engineering tests

Internal conception and development information are available

5.1.2 Records, methods and tests localization

See section 2 for certificates and reports.

Appendix 2.1.2: Directive 93/42/EEC Annex VII

Directive 93/42/CEE Concerning Medical Devices (June 1994)
Annex VII: Declaration of Conformity

Product: V4

Clause	Requirement	Notes	Verdict
2	The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorized representative established in the Community must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured.		Yes
3	The technical documentation must allow assessment of the conformity of the product with the requirements of the Directive. It must include in particular: - A general description of the product, including any variants planned, - Design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc., - The descriptions and explanations necessary to understand the above mentioned drawings and diagrams and the operations of the product, - The results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full, - In the case of products placed on the market in a sterile condition, description of the methods used, - The results of the design calculations and of the inspections carried out, etc.; if the device is to he connected to other device(s) in order to operate as intended, proof must he provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer, - The test reports and, where appropriate, clinical data in accordance with Annex X, - The label and instructions for use.	*Requirements of EN 1441 Risks analysis applied*	Yes Yes Yes Yes N/A Yes Yes Yes
4	The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He shall notify the competent authorities of the following incidents immediately on learning of them: - Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his stare of health; - Any technical or medical reason connected with the	Procedure previous	Yes

	characteristics on the performance of a device for the reasons referred to in subparagraph (I) leading to systematic recall of devices of the same type by the manufacturer.		
5	With products placed on the market in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Annex but also one of the procedures.		N/A
6.1	Where this Annex is applied in conjunction with the procedure referred to in Annex IV, V or VI, the declaration of conformity referred to in the abovementioned Annexes forms a single declaration. As regards the declaration based on this Annex, the manufacturer must ensure and declare that the product design meets the provisions of this Directive which apply to it.		Yes

This text don't reproduce the directive but to do refer at this

Appendix 2.1.3: CE Declaration of conformity

BHM MEDICAL INC.

CE DECLARATION OF CONFORMITY

COMPANY : BHM MEDICAL INC.
ADDRESS : 2001 Tanguay
Magog, Qc, Canada, J1X 5Y5

TELEPHONE 819-868-0441
FAX : 819-868-2249

HEREBY DECLARE THAT:

PRODUCT: Voyager V4 Patient Ceiling Lift
MODEL: Voyager 420PLUS, V420PLUS, V4

ARE ACCORDING TO THE STANDARDS LISTED BELOW AMONG OTHERS:

NUMBER	TITLE
CAN/CSA-C22.2	Medical Electrical Equipment
No.601.1-94	Part 1: General Requirements for Safety
No.601.2-94	Part 2: Collateral Standard: Electromagnetic Compatibility
CISPR 11:19990	Limits and Methods of Measurements of Electromagnetic (Radio) Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment
IEC 60601-1	Medical Electrical Equipment: General Requirements For Safety
IEC 801-2:1991	Electrostatic Discharge
IEC 801-4:1988	Electrical Fast Transients
EN 61000-4-3:1997	Radiated RF Immunity
EN 1041	Terminology and Symbols
EN 1441	Medical Apparatus - Risk Analysis
EN 12182	Technical Aids for Disabled Persons

AND IS ACCORDING TO THE FOLLOWING RULES AND GUIDE LINES:

NUMBER	TITLE
93/42/CEE	Medical Rules and Guide Lines
93/68/CEE	C.E. Marking Guide Lines

SIGNATURE:
DATE: 5/8/2003
NAME: BERNARD J. HAMEL, c.a.
VICE-PRESIDENT

MADE IN:
MAGOG, QUEBEC, CANADA

Appendix 2.1.4: Directive 93/42/EEC Annex IX

Directive 93/42/EEC Concerning Medical Devices (June 1994)
Annex IX: CLASSIFICATION CRITERIA

Product: V4

III. Classification

Rules	#	Devices concerned	Verdict
1.1	1	All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.	Class 1 Applied
1.2	2	All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa: - If they may be connected to an active medical device in Class IIa or a higher class, - If they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues, In all other cases they are in Class 1.	Class 1 Applied
1.3	3	All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class llb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.	N/A
1.4	4	All non-invasive devices which come into contact with injured skin: - Are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates, - Are in Class Ilb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, - Are in Class Ila in all other cases, including devices principally intended to manage the microenvironment of a wound.	Non invasive
2.1	5	All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device: - Are in Class I if they are intended for transient use, - Are in Class lla if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an car canal up to the car drum or in a nasal cavity, in which case they are in Class I, - Are in Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the car drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa. All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class lla or a higher class, are in Class IIa.	Non invasive
2.2	6	All surgically invasive devices intended for transient use are in Class lIa unless they arc: - Intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III, - Reusable surgical instruments, in which case they are in Class I, - Intended to supply energy in the form of ionizing radiation in which case they are in Class llb, - Intended to have a biological effect or to he wholly or mainly absorbed in which case they are in Class IIb,	Non invasive

		- Intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class IIb.	
2.3	7	All surgically invasive devices intended for short-term use are in Class IIa unless they are intended: - Either specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III, - Or specifically for use in direct contact with the central nervous system, in which case they are in Class III, - Or to supply energy in the form of ionizing radiation in which case they are in Class Ibis, - Or to have a biological effect or to be wholly or mainly absorbed in which cast they are in Class III, - Or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class lIb.	Non invasive
2.4	8	All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended: - To be placed in the teeth, in which cast they are in Class IIa, - To be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class Ill, - To have a biological effect or to be wholly or mainly absorbed, in which cast they are in Class Ill, - Or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class 111.	N/A
3.1	9	All active therapeutic devices intended to administer or exchange energy are in Class lIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which cast they are in Class lIb. All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class llb.	Non active
3.2	10	Active devices intended for diagnosis are in Class IIa: - If they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum, - If they are intended to image in vivo distribution of radiopharrnaceuticals, - If they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb. Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class lIb.	Non active
3.2	11	All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class lIa, unless this is done in a manner: - That is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of	Non active

		application in which case they are in Class IIb.	
3.3	12	All other active devices are in Class I.	Non active
4.1	13	All devices incorporating, as an integral part, a substance which, if used separately, can he considered to be a medicinal product, as defined in Article 1 of Directive 65165/EEC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class Ill.	N/A
4.2	14	All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class lIb, unless they are implantable or long term invasive devices, in which case they are in Class III.	N/A
4.3	15	All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb. All devices intended specifically to be used for disinfecting medical devices are in Class IIa. This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.	N/A
4.4	16	Non-active devices specifically intended for recording of X-ray diagnostic images are in Class Ila.	N/A
4.5	17	All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class 111 except where such devices are intended to come into contact with intact skin only.	N/A
5	18	By derogation from other rules, blood bags are in Class Ilb.	N/A

No other rules supersede de rule 1 and 2 than the device is Class 1.

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Appendix 2.2.1. Directive 93/42/EEC Annex I Essential requirements

Directive 93/42/EEC Concerning Medical Devices (June 1994)

Annex I: ESSENTIAL REQUIREMENTS

Product: V4

Clause	Requirements	Notes	Verdict
	I General requirements		
1	The devices must be designed and manufactured in such a way that, when used under the conditions and for the-purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Requirements of EN 1441 Risks analysis applied	Yes
2	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - Eliminate or reduce risks as far as possible (inherently safe design and construction), - Where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, - Inform users of the residual risks due to any shortcomings of the protection measures adopted.	Requirements of EN 1441 Risks analysis applied	 Yes Yes Yes
3	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.		Yes
4	The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	Requirements of EN 1441 Risks analysis applied	OK
5	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.		OK
6	Any undesirable side effect must constitute an acceptable risk when weighed against the performances intended.		Yes
	II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION		
7	***Chemical, physical and biological properties***		
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to: - The choice of materials used, particularly as regards toxicity	Requirements of EN 1441 Risks analysis applied	

	and, where appropriate, flammability, - The compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.		Yes N/A
7.2	The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.		N/A
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use		N/A
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC.		N/A
7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.		N/A
7.6	Devices must he designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	See Risk Analysis	Yes
8	**Infection and microbial contamination**	**N/A**	
9	**Construction and environmental properties**		
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	See Instructions manual for use accessories	Yes
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: - The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features, - The risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, - The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, - The risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	Requirements of EN 1441 Risks analysis applied	 Yes Yes N/A Yes
9.3	Devices must be designed and manufactured in such a way as to		Yes

	minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.		
10	**Devices with a measuring function**	**N/A**	
11	**Protection against radiation**	**N/A**	
12	**Requirements for medical devices connected to or equipped with an energy source**		
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	Requirements of EN 1441 Risks analysis applied	Yes
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	Requirements of EN 1441 Risks analysis applied	Yes
12.3	Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	Requirements of EN 1441 Risks analysis applied	Yes
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.		N/A
12.5	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	CSA C22.2 no601.1 approved	Yes
12.6	Protection against electrical risks Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	Requirements of EN 1441 Risks analysis applied	Yes
12.7	Protection against mechanical and thermal risks 1- Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts. 2- Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance. 3- Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance. 4- Terminals and connectors to the electricity, gas or hydraulic	Requirements of EN 1441 Risks analysis applied	Yes Yes Yes

	and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks. 5- Accessible parts of the devices (excluding the parts or areas intended to supply beat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal Use.		Yes N/A
12.8	Protection against the risks posed to the patient by energy supplies or substances		N/A
12.9	The function of the controls and indicators must be clearly specified on the devices.		Yes
13	**Information supplied by the manufacturer**		
13.1	Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set our on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set our in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	See labels and manuals	Yes
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	Symbols conform with medical standards	Yes
13.3	The label must bear the following particulars: a) The name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14 (2) or of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate; b) The details strictly necessary for the user to identify the device and the contents of the packaging; c) Where appropriate, the word 'STERILE'; d) Where appropriate, the batch code, preceded by the word 'LOT', or the serial number; e) Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; f) Where appropriate, an indication that the device is for single use; g) If the device is custom-made, the words 'custom-made device'; h) If the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	See labels	Yes Yes N/A N/A N/A N/A N/A N/A

	i) Any special storage and/or handling conditions; j) Any special operating instructions; k) Any warnings and/or precautions to take; l) Year of manufacture for active devices other than those covered by (c). This indication may be included in the batch or serial number; m) Where applicable, method of sterilization.		N/A N/A Yes N/A N/A
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	See labels and manuals	Yes
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.		Yes
13.6	Where appropriate, the instructions for use must contain the following particulars: a) The details referred to in Section 13.3, with the exception of (d) and (c); b) The performances referred to in Section 3 and any undesirable side-effects; c) If the device must he installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; d) All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; e) Where appropriate, information to avoid certain risks in connection with implantation of the device; f) Information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; g) The necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization; h) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they are sterilized before. Use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I; i) Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.); j) In the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:		 Yes Yes N/A Yes N/A N/A N/A N/A N/A

	k) Precautions to be taken in the event of changes in the performance of the device; l) Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; m) Adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice 'of substances to be delivered; n) Precautions to be taken against any special, unusual risks related to the disposal of the device; o) Medicinal substances incorporated into the device as an integral part in accordance with Section 7.4; p) Degree of accuracy claimed for devices with a measuring function.		OUI N/A N/A N/A N/A N/A
14	Where conformity with the essential requirements must be based on clinical data, as in Section I (6), such data must be established in accordance with Annex X.		N/A

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Appendix 2.2.2: Directive 73/23/EEC

Directive 73/23/EEC Electrical Equipment, Voltage Limits (February 1973) Annex I: Principal Elements of the Safety Objectives for Electrical Equipment Designed for Use Within Certain Voltage Limits

Product: V4

Clause	Requirements	Notes	Verdict
1	General conditions: a) The essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the equipment, or, if this is not possible, on an accompanying notice. b) The manufacturers or brand name or trademark should be clearly printed on the electrical equipment or, where that is not possible, on the packaging. c) The electrical equipment, together with its component parts should be made in such a way as to ensure that it can be safely and properly assembled and connected. d) The electrical equipment should be so designed and manufactured as to ensure that protection against the hazards set out in points 2 and 3 of this Annex is assured providing that the equipment is used in applications for which it was made and is adequately maintained.	CSA C22.2 no601.1 approved, see certificate	 Yes Yes Yes Yes
2	Protection against hazards arising from the electrical equipment Measures of a technical nature should be prescribed in accordance with point 1, in order to ensure: a) That persons and domestic animals are adequately protected against danger of physical injury or other harm which might be caused by electrical contact direct or indirect; b) That temperatures, arcs or radiation which would cause a danger, are not produced; c) That persons, domestic animals and property are adequately protected against non-electrical dangers caused by the electrical equipment which are revealed by experience; d) That the insulation must be suitable for foreseeable conditions.	CSA C22.2 no601.1 approved, see certificate	 Yes Yes Yes Yes
3	Protection against hazards which may be caused by external influences on the electrical equipment Technical measures are to be laid down in accordance with point 1, in order to ensure: a) That the electrical equipment meets the expected mechanical requirements in such a way that persons, domestic animals and property are not endangered; b) That the electrical equipment shall be resistant to non-mechanical influences in expected environmental conditions, in such a way that persons, domestic animals and property are not endangered; c) That the electrical equipment shall not endanger persons, domestic animals and property in foreseeable conditions of overload.	See CSA Certification	 Yes Yes Yes

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Appendix 2.2.3 a): Directive 89/336/EEC:

Directive 89/336/EEC Electromagnetic Compatibility (May 1989)

Product: V4

Clause	Requirements	Notes	Verdicts
4	The apparatus referred to in Article 2 shall be so constructed that: a) The electromagnetic disturbance it generates does not exceed a level allowing radio and telecommunications equipment and other apparatus to operate as intended; b) The apparatus has an adequate level of intrinsic immunity to electromagnetic disturbance to enable it to operate as intended. The principal protection requirements are set out in Annex III.	See requirements annex III	 Yes Yes
10.1	The conformity of apparatus with this Directive shall be certified by an EC declaration of conformity issued by the manufacturer or his authorized representative established within the Community. The manufacturer or his authorized representative established within the Community should also affix the CE conformity mark to the apparatus or else to the packaging, instructions for use or guarantee certificate.		 Yes Yes
10.2	The manufacturer or his authorized representative established within the Community shall hold at the disposal of the relevant competent authorities, as soon as the apparatus is placed on the market, a technical construction file. This file shall: - Describe the apparatus, - Set out the procedures used to ensure conformity of the apparatus with the protection requirements referred to in Article 4 - Include a technical report or certificate, one or other obtained from a competent body.		 Yes Yes Yes
Annexe I	EC declaration of conformity 1- The EC declaration of conformity contain the description and information to ensure the conformity of the apparatus 2- The CE conformity marking		 Yes Yes
Annexe II	Criteria for the assessment of the bodies to be notified.		N/A
Annex III	List of the principal protection requirements	See CSA Certification	---

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Appendix 2.2.3 b): Standard EN 12182

Standard EN 12182 Devices for Disable Persons
General Requirements and Test Methods (December 1999)

Product: V4

Clause	Requirements	Notes	Verdict
4	**General requirements**		
4.1	Risks analysis	Requirements of EN 1441 Risks analysis applied	Yes
4.2	Researched performance and technical file: a) Resistance and durability appropriate with previous the load b) Resistance, durability and stability describe in the technical file c) Technical file make references at books, calculations, tests and standards		Yes Yes Yes
4.3	Clinical evaluation shall be in accordance with EN 540		N/A
4.4	The device shall be not possible to assemble in an unsafe method		Yes
4.5	These fixation shall be reusable		Yes
4.6	(No exigencies about user weight)	N/A	N/A
5	Materials	Requirements of EN 1441 Risks analysis applied	-
6	Noise and vibration: shall be evaluated in risks analysis	Requirements of EN 1441 Risks analysis applied	-
7	Electromagnetic compatibility	CSA C22.2 no601.1 approved, see certificate	-
8	Electrical safety	CSA C22.2 no601.1 approved, see certificate	-
9	Leak and liquid penetration	Requirements of EN 1441 Risks analysis applied	-
10	Surface temp.	N/A	-
11	Sterility	N/A	-
12	Mobile parts safety	Requirements of EN 1441 Risks analysis applied	-
13	Entrapment prevention	Requirements of EN 1441 Risks analysis applied	-
14	Mechanism hazards	Requirements of EN 1441 Risks analysis applied	N/A
15	Transportation handles: shall be resist at the test 15.2		OK
16	Hoist for support user: resist at the strength and stability test in 16.2		Yes
17	Portable hoist: no standard exigencies	N/A	
18	Surfaces, corners and sides shall be smooth and burrs		Yes

	exempt		
19	Manual portable device: no standard requirement	N/A	-
20	Manipulation handles	N/A	-
21	Human tissues tense	N/A	-
22	The ergonomics of the hoists shall bee based on the requirements of EN 614-1		Yes
23	Information giving par the manufacturer, conform to the EN 1041 and have: 1) Security and devices combination recommendation 2) Information comprehensible by person with reading difficulties 3) Maintenance and cleaning instruction 4) Maximum load 5) In flammability information 6) Electromagnetic compatibility recommendation 7) Description of the maintenance and maintenance product if washable 8) Description of the disinfections method 9) Noise risks warning	 Symbols N/A N/A N/A N/A N/A	 Yes Yes Yes Yes - - - - -
24	Risks analysis of storage	Requirements of EN 1441 Risks analysis applied	-

This text don't reproduce the directive but to refer at this

Appendix 2.2.4: Standard EN 1441 Risk Analysis

Standard EN 1441 Medical Devices
Risks Analysis (April 1998)

Product: V4

Clause	Requirements	Notes	Verdict
3	Procedure		
3.1	General: the analysis requires a) Devices and accessories risks description and identification b) List of eventual risk identification in 3.3 c) An indication of the reduction risk method at acceptable levels d) An identification that who made the risks analysis	Risks analysis: BHM Medical inc, see tables; CSA (Canadian Standards Association)	 Yes Yes Yes Yes
3.2	Qualitative and quantitative characteristics identification (stage 2). For the device or the accessories, make a list of all characteristics could affect the security. a) Previsible using b) Patient contact c) Material d) Energy e) Substances f) Biological g) Sterile h) Patient environment i) Measuring j) Data k) Others dispositifs or drugs l) Energy emissivity m) Environment sensibility n) Accessories o) Maintenance p) Computer program q) Stock condition r) Long term utilisation s) Mechanical load t) Life time factors u) One use or reutilisable device	Made, See: Use and maintenance manual, See: Technical manual See accessories See Technical manual See manual Reutilisable	Yes --- No No No No No No No No No No No Yes Yes No No No --- N/A ---
3.3	Identification of possible dangers (stage 3): List of potential dangers, in normal condition or by fault (annex C).	Made, annex C used	Yes
3.4	Identification of relative risk for any danger (stage 4): For any identification dangers, to estimate risks with available information	Made	Yes
3.5	Risk acceptability (stage 5): For any risks, to determine if it is acceptable or unacceptable according to the standards	Made	Yes

3.6	Risk reduction (stage 6): To reduce the risk by security measures: a) Directs (conception) b) Indirects (protection) c) Descriptives d) By redefinition of the previous use	Made Intrinsic Protection Notice Notice	 Yes Yes Yes Yes
3.7	Others dangers generation (stage 7): To determine if the reduction had introduce new risks	Made	No
3.8	Verification if all danger evaluated	Made	Yes
3.9	Results of the risks analysis (on table)	In technical file	Yes
4	Revision of the risks analysis if new facts	In the conception procedure	Yes

This text don't reproduce the directive but to refer at this

Risk analysis

Characteristics Identification

Product: Ceiling Lift Family : Voyager Model : V4 Version : V4 and V420PLUS	By (presences): Fonction: - Réal Pedneault, ing. Jun. R&D - Equip R&D - _____	Date: 5 août 2002 Place: BHM No: V4 rev 2

Envisaged use:

- User: Medical personnel and residents
- Necessary Formation: BHM Medical formation
- Utilisation Environment: Institutionnal and residential
- Installation carried out by: User

The device is it in liaison with the patient or another person?: Patient (sling) and user
Which are the materials and the components of the device?: Plastic and aluminium

Influences of the environnement on:

- Transportation:
- Storage:
- Aspersion:
- Electrical alimentation: Batterie device

Ambient temperature range of –40°C to +70°C
Relative humidity range of 10% to 100%
Atmospheric pressure range of 50 to 106 Kpa

Which are the specification and the restrictions of the accessories available:
Use in combination with medical accessories BHM only

Maintenance carried out by:

- The user: Visual inspection and batterie recharge
- Tthe specialist/technician: Full maintenance by BHM or autorised technician.

With which forces mechanics the device will be used? 440lbs / 200Kg

Which is the lifespan estimated of the device?
10 000 cycles / 3 years by respecting preventive maintenance.

Risk Parameters

Parameters	Level	Weighting
Effect (E	Small wounds Serious wounds Death	1 5 9
Probability of event (P)	Improbable Low (will probably not occur) Average (can occur) Will frequently occur	0 1 3 5
Averting Danger (A)	Possible under certain circumstances Barely possible	0 1

Risk Evaluation TAble

		Probability					
Effect	0 Improbable	1 Low		3 Average		5 Frequently	
1 Small	1	2	3	4	5	6	7
5 Serious	5	6	7	8	9	10	11
9 Death	9	10	11	12	13	14	15
		0 Circumstance	1 Barely	0 Circumstance	1 Barely	0 Circumstance	1 BArely
		Averting Danger					

Risk Criticity

2 – 3	Low risk
4 à 10	Medium size risk
11 à 13	High risk
14 - 15	Very high risk

Acceptable

Risk Analysis Table

	Danger source identification		Risk evaluation				Corrective mesure	Risk revaluation			
	Situation risk / Dangerous phenomene	Possible damage	Effect	Occurrence probability	Possibility of avoidance	Risk level	Correction measurement	Effect	Occurrence probability	Possibility of avoidance	Risk level
1	Lifting internal mecanism failure	Patient fall	9	3	1	13	Inertial emergency brake on the sling's drum	5	1	1	7
2	Defective circuit	Throttling	9	1	1	11	Emergency stop device	1	1	1	3
3	Defective circuit	Fire, burn	5	1	1	7	Pastic V0 (flame retardant)	1	1	1	3
4	Defective circuit	Mechanical fail (see #1)									
5	Defective circuit or battery supply	Discomfort of the patient, suspended in the airs	1	5	1	7	Advertising low battery device, manual lowering device	1	1	0	2
6	Sling failure	Patient fall	9	5	0	14	Preventive maintenance, storage procedure (manual)	9	1	0	10
7	Device sales without handset or buttons failure	Disconfort of the patient	1	5	1	7	Manual lowering device	1	1	0	2
8	Unhooking of the fabric at the time of the patient deposit (exit of the arm)	Patient fall	9	5	0	14	Addition claplets of safety on the arms, advertising in the manual	9	1	0	10
9	Fixing of the fabric on the locket, if the locket is outwards	Patient fall	9	5	0	14	Modification of the clapet, adverstising in the manual	9	1	0	10
10	Patient crushing	Wounds	1	5	0	6	No load detector device	1	1	0	2
11	Battery: acid, emanation	Burn, turbid respiratory	5	5	1	11	Acid-plomb gel scelled battery, fuse	5	1	1	7
12	Overload	Mechanical breaking, fall	9	5	1	15	Oveload detector, emergency break high capacity	5	1	1	7

Appendix 2.5.2 a) CSA Certificate V4

CSA INTERNATIONAL

Certificate of Compliance

Certificate: 1329600 **Master Contract:** 184445

Project: 1329600 **Date Issued:** October 4, 2002

Issued to: **BHM MEDICAL INC.**
2001 Tanguay
Magog, QC J1X 5Y5
CANADA

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US'

C US

Issued by: M. Brossoit, Eng.

Authorized by: Alain Ste-Marie
Operations Manager

PRODUCTS

CLASS 8750 01 - MEDICAL ELECTRICAL EQUIPMENT
CLASS 8750 81 - MEDICAL ELECTRICAL EQUIPMENT - CERTIFIED TO U.S. STANDARDS

Part A:

Patient lifter on ceiling track, battery operated, cord connected via battery charger, VOYAGER series model: V4 rated: 24Vdc,15A, maximum load: 273 kg (600lbs) and
model : V420 PLUS, rated: 24Vdc,15A maximum load: 190 kg (420lbs).

1. Type of protection against electric shock: Internally Powered (Battery)
2. Degree of protection against electric shock: BF
3. Degree of protection against ingress of water: IP21.
4. Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous, Duty Cycle 10 % (6min/hour)

The 'C' and 'US' indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the U.S., respectively. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL, i.e. National Recognized Testing Laboratory, is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.

DQD 507WD 2002/04/30

CSA INTERNATIONAL

Certificate: 1329600 **Master Contract:** 184445
Project: 1329600 **Date:** October 4, 2002

Part B:

Universal battery charger used to recharge 24Vdc Sealed Lead Acid Batteries, Model: 700.15550, rated input: 100-240Vac, 50/60 Hz, rated output: 26-30Vdc at 27VA max, cord connected, transportable or desktop unit.

1. Type of protection against electric shock: Class II
2. Degree of protection against electric shock: Not Classified
3. Degree of protection against ingress of water: IP20.
4. Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 0-M91	-	General Requirements - Canadian Electrical Code, Part II
CAN/CSA-C22.2 No. 601.1-M90	-	Medical Electrical Equipment Part I: General Requirements for Safety
CAN/CSA-C22.2 No. 601.1S1-94	-	Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90--Medical Electrical Equipment--Part 1: General Requirements for Safety
CAN/CSA-C22.2 No 601.1:1998	-	Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90 Medical Electrical Equipment Part I: General Requirements for Safety

IEC Standards:

IEC 60601-1: 1988	-	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1:1991 Amendment No 1: 1991	-	Amendment 1 to 60601-1:1988
IEC 60601-1:1995 Amendment No 2: 1995	-	Amendment 2 to 60601-1:1988

UL Standards:

UL Standard No 2601-1-97(2nd Edition)	-	Medical Electrical Equipment Part I: General Requirements for Safety

Subject to the following conditions:

(1) The equipment has not been investigated for the protection against hazards of explosions in medically used rooms.

(2) Units provided with other than CSA Certified power supply cord sets are Certified without the power supply cord set as components only.

(3) Evaluated to IEC/CSA 601-1 Amendment 2 excluding requirements for, Biocompatibility (Clause 48) and Programmable Electronic Systems (IEC 60601-1-4 referenced in sub-clause 52.1).

DQD 507WD 2002/04/30

CSA INTERNATIONAL

Supplement to Certificate of Compliance

Certificate: 1329600 **Master Contract:** 184445

The products listed, including the latest revision described below, are eligible to be marked in accordance with the referenced Certificate.

Product Certification History

Project	Date	Description
1329600	October 4, 2002	Original Certification.

DQD 507WD 2002/04/30

Appendix 2.5.2 b) CSA Report V4

CSA INTERNATIONAL

Descriptive and Test Report

MASTER CONTRACT: 184145
REPORT: 1329600
PROJECT: 1329600

Edition 1: October 4, 2002; Project 1329600 - Montreal
Issued by M. Brossoit, Eng.

Contents: Certificate of Compliance - Pages 1 to 2
Supplement to Certificate of Compliance – Page 1
Description and Tests – Pages 1 to 15
Electrical Schematics - 1 to 4
Mechanical Drawing - 1 to 10
Photograph - 1 to 12

Copy for CSA Montreal Office only:
Annexe #1: Guide de l'utilisateur (Juillet 2002)

PRODUCTS

CLASS 8750 01 - MEDICAL ELECTRICAL EQUIPMENT
CLASS 8750 81 - MEDICAL ELECTRICAL EQUIPMENT - CERTIFIED TO U.S. STANDARDS

Part A:

Patient lifter on ceiling track, battery operated, cord connected via battery charger, VOYAGER series
model: V4 rated: 24Vdc,15A, maximum load: 273 kg (600lbs) and
model : 420 PLUS, rated: 24Vdc,15A maximum load: 190 kg (420lbs).

1. Type of protection against electric shock: Internally Powered (Battery)
2. Degree of protection against electric shock: BF
3. Degree of protection against ingress of water: IP21.
4. Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous, Duty Cycle 10 % (6min/hour)

865 Ellingham Street, Pointe-Claire, Québec, Canada H9R 5E8
Telephone: 514.694.8110 1.800.463.6727 Fax: 514.694.5001 www.csa-international.org

MASTER CONTRACT: 184445
REPORT: 1329600
PROJECT: 1329600

Date Issued: October 4, 2002

Part B:

Universal battery charger used to recharge 24Vdc Sealed Lead Acid Batteries, Model: 700.15550, rated input: 100-240Vac, 50/60 Hz, rated output: 26-30Vdc at 27VA max, cord connected, transportable or desktop unit.

1. Type of protection against electric shock: Class II
2. Degree of protection against electric shock: Not Classified
3. Degree of protection against ingress of water: IP20.
4. Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 0-M91	-	General Requirements - Canadian Electrical Code, Part II
CAN/CSA-C22.2 No. 601.1-M90	-	Medical Electrical Equipment Part I: General Requirements for Safety
CAN/CSA-C22.2 No. 601.1S1-94	-	Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90--Medical Electrical Equipment--Part 1: General Requirements for Safety
CAN/CSA-C22.2 No 601.1:1998	-	Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90 Medical Electrical Equipment Part I: General Requirements for Safety

IEC Standards:

IEC 60601-1: 1988	-	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1:1991 Amendment No 1: 1991	-	Amendment 1 to 60601-1:1988
IEC 60601-1:1995 Amendment No 2: 1995	-	Amendment 2 to 60601-1:1988

UL Standards:

UL Standard No 2601-1-97(2nd Edition)	-	Medical Electrical Equipment Part I: General Requirements for Safety

Subject to the following conditions:

(1) The equipment has not been investigated for the protection against hazards of explosions in medically used rooms.

(2) Units provided with other than CSA Certified power supply cord sets are Certified without the power supply cord set as components only.

(3) Evaluated to IEC/CSA 601-1 Amendment 2 excluding requirements for, Biocompatibility (Clause 48) and Programmable Electronic Systems (IEC 60601-1-4 referenced in sub-clause 52.1).

1329600/2/cd

MASTER CONTRACT: 184445
REPORT: 1329600
PROJECT: 1329600

Date Issued: October 4, 2002

ACCOMPANYING DOCUMENTS:

An operating manual is provided that specifies proper operating procedures for the equipment, recommended accessories, proper cleaning and operator maintenance procedures, maintenance information and particular technical characteristics.

For UL 2601-1: Multiple voltage cord-connected equipment shall be provided with instructions to indicate the type of attachment plug that should be used for connection to the alternate voltage.

SPECIAL ADVICE FOR FIELD REPRESENTATIVES

(a) Markings as above shall appear on each unit.

(b) The operator's manual shall contain instructions for replacement of parts subject to deterioration.

(c) Insulated conductors of the primary circuit and safety extra low voltage circuits shall be secured and separated.

(d) There shall be no indicator lights that are red in color except to indicate a warning of danger or need for urgent action.

(e) The shipping package shall be marked with the allowable transport and storage environmental conditions such as humidity range, atmospheric pressure range and temperature range. This shall also be listed in the manual.

Temperature:	Operating:	10 to 40°C
	Storage:	-40 to +70°C
Relative Humidity:	Operating:	30 to 75%
	Storage:	10 to100%
Pressure:	Operating:	700 hPa to 1060 hPa (2000 m Max)
	Storage:	500 hPa to 1060 hPa (2000 m Max)

(f) The accompanying documents include a glossary of symbols used on the product and in accompanying documents. The following symbols are explained in the accompanying documents: Alternating Current, Direct current and Attention Consult Accompanying Documents.

(g) All markings, symbols and warning statements appearing on the equipment appear in each of the accompanying documents.

(h) The technical description includes a statement that the supplier will make available on request circuit diagrams, component part lists, etc.

ALTERATIONS

1. The units are marked as noted under "MARKINGS" above.

1329600/4/ad

MASTER CONTRACT: 184445
REPORT: 1329600
PROJECT: 1329600

Date Issued: October 4, 2002

FACTORY TESTS REQUIRED

The equipment at the conclusion of manufacture, before shipment, shall be subjected to the following tests which may be made at room temperature.

1-DIELECTRIC STRENGTH

Equipment: The equipment at the conclusion of manufacture, before shipment, shall withstand for one minute, without breakdown, the application of 1500V ac between the mains part and body of the equipment.

Note: Although AC voltages are quoted above, coupling components within the product may require the tests be conducted using DC voltages. Where DC voltages are used, the test values are increased by 1.414 times the AC voltages. The test period may be shortened by using a potential 20 percent higher for one second.

Transformers Connected to AC Supply: Each transformer before assembly into the equipment shall be subjected to the following dielectric strength tests for a period of one minute, without breakdown:

An AC potential applied between each winding and the core and metal enclosure, with all other windings grounded to the core and metal enclosure. The test potential shall be:

(a) For Primary Windings to Core - 1500 V ac.

(b) For Primary Windings to SELV Secondary Windings - 4000 V ac.

(c) For Secondary Windings to Core - 1000 V ac.

The test period may be shortened by using a potential 20 percent higher for one second.
Transformer manufacturer's written agreement to conduct transformer dielectric strength test on 100 percent production will be acceptable. The power supplies employed in the subject equipment are CSA Certified/UL Recognized. Therefore the system component and power supply manufacturer is responsible for production-line dielectric voltage withstand tests on power supply isolating transformers. For this reason, such tests for the final product have been waived.

2-LEAKAGE CURRENT

Measurement of the earth leakage current according to CAN/CSA C22.2 No 601.1, Cl 19 and Fig 16 using the measuring supply circuit of Fig 10, at ambient temperature but without a preceding moisture preconditioning treatment.

In cases where the number of settings of parameters of the equipment or of switches of the measuring supply circuit or of the application of a metal foil or the application of the measuring device, to be performed during the test would be unacceptable and the results of certain tests would indicate the highest value(s), then the routine tests may be restricted to the setting(s) provoking these values.
Warning: The factory test(s) specified may present a hazard of injury to personnel and/or property and should only be performed by persons knowledgeable of such hazards and under conditions designed to minimize the possibility of injury.

1329600S/ad

MASTER CONTRACT: 184445
REPORT: 1329600
PROJECT: 1329600

Date Issued: October 4, 2002

INTRODUCTION:

Notes: Unless stated otherwise:

Agency Approvals: " C" or "CSA" or "Certified" – CSA Certified, "UR" = UL Recognized, "UL" = UL Listed, "CUL" = UL Listed to Canadian Standards.

: The asterisk "" adjacent to "C" or "L" indicates the Agency Mark appears on the component. An asterisk behind any other test house's name denotes that their monogram appears on the component.

+: The "+" preceding the "manufacturer's name" denotes a Certified component that can be interchanged for one from another Certified source provided that it has an equivalent or better electrical rating, the same terminal orientation, and that 3mm (120V) or 4mm (240V) min spacing is maintained from live parts to protectively earthed parts.

Asterisk: An asterisk "*" denotes that the agency logo appears on the component.

ELV: All references to "ELV" denote Extra Low Voltage (less then 42.4 V pk) secondary circuits.

SELV: All references to "SELV" denote Extra Low Voltage secondary circuits or components operating at less than 30V rms or 42.4V p-p.

Metal: All references to "metal" denote painted or plated steel min 0.78 mm (No 20 MSG).

Dimensions: (dim) All dimensions specified are approximations only, and shown in millimeters (mm).

Internal Wiring: All pri, SEC and grounding circuit conductors are certified, Type TEW, TR-64, TR-32, AWM SR-PVC or AWM XL-PVC and UL listed, rated min 80C, 300V ac. All wiring is suitably routed and secured away from sharp edges and moving parts to prevent chafing of the insulation. Alternatively, additional insulation is provided where the wiring passes over sharp edges and through holes.

Sleeving: All thermoplastic and other insulating tubing used in pri and SEC circuits are certified, UL Recognized and rated min 105EC, 300V ac; or teflon, rated min 200EC, 300V.

Crimp Connectors: All crimp-type connectors used in pri, SEC and grounding circuits are certified, UL Recognized, and appropriately sized for the gauge of conductors used, vinyl insulated (optional for grounding), rated min 90EC, 250V ac.

Connectors: All connectors used in pri and SEC circuits are certified, UL Recognized, and appropriately sized for the number and gauge of conductors used, rated min 250V ac.

Printed Wiring Boards (PWB): All pwb's are UL Recognized and are made of paper phenolic, paper epoxy or glass epoxy, min 1.6 mm thick, flammability rated 94V-1 or better.

Bonding: All accessible metal parts liable to become energized are acceptably connected together, and to the grounding means, by straps and/or conductors, bolts, screws and starwashers (to ensure surface coating penetration, Paint is masked.), in conformance to Clause 3.4 of CSA Standard C22.2 No. 0.4 .

1329600/6/ad

MASTER CONTRACT: 184445
REPORT: 1329600
PROJECT: 1329600

Date Issued: October 4, 2002

DESCRIPTION:
PART A:

The only difference between models is that V420 PLUS is limited electronically to lift 420 lbs and model V4 is limited electronically to lift 600lbs. Each model consists of a 24V dc battery or electrically operated patient lifter module installed on a rail. All components are enclosed in non-combustible enclosure without ventilation opening. Lifter can be displaced manually or it is moved by a motor on the rail.

Major primary components

1. Enclosure: : Overall dimensions: 400x260x170. (parts white and blue)
Unit cab is made of Bayblend, FR-2000, white #WH010639. This material is used for injection molding thickness of 2.70mm. White part dimensions: 400x260x170mm by 2.70 mm thick

2. Part of the Enclosure: Unit cab is consisted also of Magnum 5200, blue color added, #04MBS7047 BLUE 4% LDR, This material is used for injection molding thickness of 2.0mm
Blue part dimensions: 400x260x55mm by 2.0 mm thick

Flame class rating for both plastic parts white and blue(plastic cab):
Material: V-0 Class Rating
Test method: UL 94

All electrical parts are enclosed in non-combustible V-0 plastic enclosure and metal chassis without ventilation opening as per attached photograph.

3. Printed Circuit Board: (1 used)
Material: Fiberglass, 1.6 mm thiok, rated V-0
Dimensions: 88 mm by 146 mm
Mounting: Vertically mounted and secured to the chassis by 3 screws

4. Batteries: (2 used) Power Backup Batteries (optional)
Manufacturer: Wuhan Sota Enertech Inc..
Type: Rechargeable gel cell, sealed
Cat. N°: SA1250
Rating: 12V dc, 5Ah
Connection: Both connected in series

5. Fuse: F1 (INT) Certified* /UR
Manufacturer: Buss
Type: Glass cartridge 5 x 20 mm
Cat. N°: GMA15
Rating: 15A @ 125Vac
Mounting: inserted into fuse clip on pcb

6. Battery Blocking Diode: D11
Type: Silicon, phenolic body
Cat. N°: 1N5401
Rating: 3A, 100V
Mounting: Soldered to pcb

1329600/7/ad

7. PCB Connector J4: Certified*UR(INT)
   Manufacturer: AMP
   Cat. N°: 350764-4 / 1-480708-0
   Rating: 30A, 240Vac
   Mounting: Soldered to pcb

8. Relay K1-A, K2-A, K3-A, K4-A: (INT) Certified*, CSA*/UR*/TUV*
   Manufacturer: Hasco
   Type: Enclosed, SPDT
   Cat. N°: KLT1C15DC12
   Rating: Coil: 12Vdc Contacts: 28Vdc, 10A
   Mounting: Soldered to pcb

9. Motor Drive Transistors: Q9 and Q10 (INT)
   Manufacturer: International Rectifier
   Type: Silicon, plastic body, TO-220AB case
   Cat. N°: IRLZ44N
   Rating: 60V, 30A
   Mounting: Soldered to pcb and secured to 35 x 25 x 13 mm aluminum heat sink

10. Internal Wiring: (INT) Certified*, CSA/UL
    Type: TEW, 105°C, 16 or 18AWG

11. Switch S3-S6: Certified* (INT)
    Manufacturer: Omron
    Type: Tactile Switch
    Cat. N°: B3S-1002
    Rating: 50mA, 24Vdc.

12. Emergency Switch S5: Certified CSA*/UR*
    Manufacturer: Zingear, SPC
    Type: Pullchain switch
    Cat. N°: ZE-109 / 16N902
    Rating: 125/250Vac, 6/3A

13. DC Motor (vertical movement): Accepted
    Manufacturer: ELVI MOTORI ELETTRICI SRL
    Type: Fully enclosed, no ventilation opening permanent magnet, class A
    Cat. N°: 100.462/FC (BHM Part number = #400.14000)
    Rating: 24 Vdc, 1.1A, 110 Watts, 4000 RPM, 0.3 N-m
    Overall Dimensions: ø77mm x 131.5mm long (without worm shaft)
    Mounting: Secured by screws and lock-washer to chassis.

    A) Rotor : Laminated steel, 55 mm dia by 38 mm high
       Mounting : Crimp to the shaft
    B) Rotor Winding : Enamelled copper wire, class H- UL
    C) Rotor to winding insulation : 1 layer of Isotherm, 0.25 mm thick, Class F 145°C
    D) Spacer material : PSU 2010

1329600/3/ad

MASTER CONTRACT: 184445
REPORT: 1329600
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E) Collector : Copper 23 diam. long,
F) Brush : Carbon composition mounted on spring
Dimensions : 5 x 8 x 12 mm
G) Brush holder : Later 4 C/30
H) Motor leads : Certified, TEW 105°C, N° 18AWG, connected by certified 2 pins AMP connector.
I) Motor leads connection to windings : crimping

MATERIAL DESCRIPTION	TYPE	SUPPLIER	CERTIFICATION	CLASS OF TEMPERATURE
WINDING : COOPER WIRE	THENVEX	INVEX	CEI UL E45523	H
ROTOR WINDING INSULATION	ISOTERM	(ISOCOM) DUPONT	PETP MYLAR E93687 POLYESTER FILM E93687	F
BRUSHHOLDER	LATER 4 G/30	LATI EXPORT	LATER UL E54080	F
SPACER	POLYSULFONE RESIN PSU2010	BASF	PSU 2010 E41871	H
CABLE	PVC	ROTA CAVI	ACCORDING TO THE CEI NORM 2020 DAT A1225	
ISULATION OF THE COMMUTATOR	PHENOL RESIN WITH GLASS		ACCORDING TO UL VO	

14. DC Motor. Accepted (Horizontal Motor)
Manufacturer: ELVI MOTORI ELETTRICI SRL
Type: Fully enclosed, no ventilation opening, permanent magnet, provided with integral reducer
Cat. N°: 101.663/FC (BHM Part number = #E0006)
Rating: 24Vdc, 1.8A, 30 Watts, 260 RPM, 1.0 N-m
Overall Dimension: Secured by screws and lockwasher to chassis.
Mounting: Secured by screws to chassis

A) Rotor : Laminated steel, 42 mm dia by 32 mm high
Mounting : Crimp to the shaft
B) Rotor Winding : Enamelled copper wire, class H- UL
C) Rotor to winding insulation : 1 layer of Isotherm, 0.25 mm thick, Class F 145°C
D) Spacer material : PSU 2010
E) Collector : Copper 19 mm diam.
F) Brush : Carbon composition mounted on spring
Dimensions : 6.5x4.5x10 mm
G) Brush holder : Later 4 G/30
H) Motor leads : Certified, TEW 105°C, N° 18AWG, connected by certified 2 pins AMP connector.
I) Motor leads connection to windings :crimping

MATERIAL DESCRIPTION	TYPE	SUPPLIER	CERTIFICATION	CLASS OF TEMPERATURE
WINDING : COOPER WIRE	THENVEX	INVEX	CEI UL E45523	H
ROTOR WINDING INSULATION	ISOTERM	(ISOCOM) DUPONT	PETP MYLAR E93687 POLYESTER FILM E93687	F

MASTER CONTRACT: 184445
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Date Issued: October 4, 2002

BRUSHHOLDER	LATER 4 G/30	LATI EXPORT	LATER UL E54080	F
SPACER	POLYSULFONE RESIN PSU2010	BASF	PSU 2010 E41871	H
CABLE	PVC	ROTA CAVI	ACCORDING TO THE CEI NORM 2020 DAT A1225	
ISULATION OF THE COMMUTATOR	PHENOL RESIN WITH GLASS		ACCORDING TO UL VO	

15. Limit Switch S1, S2: (INT) Certified*UR,cUR
    Manufacturer: Cherry, TLS Entreprise
    Type: SPDT
    Rating: 10A, 125/250V ac / 3A 125/250Vac
    Cat. N°: DB2CC1AA / SM-00-3A-P

16. Frame: (Alternative) Frame is made of steel, 2.64 mm thick. The structure forms a box, 164 mm x 140 mm wide by 124 mm high. Other mechanical parts are fixed to this frame.

    N.B.: The frame and steel parts are protected against rust by a zinc plated treatment. Aluminum parts are protected by "heredite" or "anodize" plated treatment.

17. Displacement: Vertical (up / down), drum

    The motor (ELVI without gearbox) drives a 30 teeth worm gear, double tread. The worm gear drives a shaft on which lies a worm. This worm drives a second worm gear directly attached to the drum. The total obtained ratio is 375:1

18. Strap: The strap is a threaded nylon that can hold up to 2727 kg (6000 lb).

    Brand: La Gran
    Pattern: # 26472
    Section: 49 mm x 1.2 mm thick

19. Displacement: Horizontal (left / right). The motor (ELVI with integrated gear-box) drives a spur gear that drives two idlers. Those idlers directly drive the wheel. The wheels are made of plastic over-molded on ball bearings. Wheels are fixed on trolley with spring pins.

    Steel trolley is fixed to the frame by three interlocks and secured with another interlock and a M5 screw.

20. End of strap stopper: (up / down). In the unit, a limit switch is attached on a steel blade, sensing the double thickness of the strap. This indicates the higher position of the strap. The lower limit is sensed when the drum tries to roll the strap into the wrong direction. This will activate the switch and stops the motor.

21. End of rail stopper: (left / right). Both ends of the rails are closed by stoppers.

22. Rail and rail support: The rail and supports are made of aluminum 66081-T5.

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PART B:
DESCRIPTION

Universal battery charger model: 700.15500 is used to recharge a 24 Vdc Sealed Lead Acid Batteries for usage with BHM patient lifters series.

a)Type of Equipment: Portable equipment.

b)Class of Equipment: Class II

c)Type of Power system: Switching power supply, cord connected: rated input: 100-240 Vac, 50/60 Hz, rated output: 26-30 Vdc at 27VA max,

d)Weight of equipment: approx 0.5 kg.

1. Main Enclosure: Accepted
   Manufacturer (mold): MI Plastech (Moules Industriels)
   Model: 200-15500/200.15510/200.15520/200.15530/200.15535
   Dimensions: 110x90x55 by 1.8 mm thick
   Material Manufacturer: Bayer Plastics
   Material: Bayblend FR-2000
   Ratings: V-0 at 1.6 mm min
   Mounting: Top and bottom parts assembled by 2 torx screws.

   Ventilation Openings:
   - top openings: none
   - Back openings: none
   - Side openings: none
   - Bottom openings: none

   Refer to photographs for more details

2. Power Supply Cord Set: Certified*CSA
   Manufacturer: Wellshin
   Model:WS004
   Type: SPT-2
   Attachment Plug: Type 1-15P moulded-on attachment plug cap at one end
   Main power Cord: No 18/2 AWG, FT2, VW-1
   End Plug: Type IEC 320 C7 female connector body at other end terminates in a moulded-on.
   Ratings: 2.5A@125Vac
   Mounting: Inserted into male IEC320 coupler which is securely maintained on enclosure.

3. AC Input Appliance Coupler Inlet: Certified* CSA/ UR/VDE/S/N
   Manufacturer: Schurter
   Model No: 4300.0097
   Type: Class II (2 pin)
   Rating: 2.5A, 250Vac.
   Mounting: Secured soldered to pc-board and retained by plastic enclosure.

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4. + Fuse Main Input: Certified* cUR/UR/VDE/S/F
   Manufacturer: Wickmann
   Model: 1100, Series 181 or 195
   Type: Type T Glass or ceramic cartridge, 5 mm x 20 mm
   Rating: 1A@250V ac
   Mounting: Inserted into the metal fuseholder, requires a tool to replace.

5. PC-Board: Accepted
   Manufacturer: BHM
   Type: Epoxy Wafer, multi-layer
   Model: 492.00031
   Flammability Rating: V 0 at 1.5 mm min
   Dimensions: 102x87 mm by 1,5 mm thick
   Mountings: Mounted on spacers and securely mounted to enclosure by the means of clips.

6. ↓ Diodes (D1-D4, D5): Accepted
   Manufacturer: FAIRCHILD SEMICONDUCTOR
   Model: 1N4007
   Type: Axial DO-41
   Rating: 1A@ 700Vac. PRV=1000V
   Mounting: Securely soldered to pc-board.

7. + Capacitor (C1): Accepted
   Manufacturer: DAEWOO or Panasonic or Mallory
   Model: 22 , ECA2VHG220, SK220M350ST SEK220M350ST
   Type: Electrolytic
   Ratings: 22uFd@350Vdc, 105°C (M)
   Mountings: Securely soldered to pc-board.

8. + Inductance(T2): Accepted
   Manufacturer: ATC-Frost
   Model: S6575 (FFT209)
   Type: Vertically mounted
   Rating: 27mH@0.4A
   Mounting: Securely soldered to pc-board.

9. ↓ Capacitor (C2): Certified CSA/UR
   Manufacturer: STK, Nichicon
   Model: MM35D1004K00, QXJ2G105KTP
   Type: Metallized Polyester Film Capacitor PEMR series
   Ratings: 1uFd@400Vdc
   Mountings: Securely soldered to pc-board

10. ↓ Capacitor (C3): Accepted
    Manufacturer: Prm-Cap
    Model: MAI206CGJ222
    Type: Ceramic Chip
    Ratings: 2.2 nF@50V
    Mountings: Securely soldered to pc-board.

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11. + Transistor (Q4): Accepted
    Manufacturer: Zetex
    Model: FMMT458
    Type: NPN
    Ratings: Ic=225 mA, Vce=400V, Vcb=400V
    Mountings: Securely soldered to pc-board.

12. + Zener diode (D7): Accepted
    Manufacturer: Fairchild Semiconductor
    Model: 1N5240B
    Ratings: Vz= 10V, Iz= 20mA, Po= 500mW
    Mountings: Securely soldered to pc-board.

13. Transistor (Q1): Accepted
    Manufacturer: International Rectifier
    Model: IRFI820G
    Type: Power MOSFET
    Ratings: Vdss=500V, Rds=3.0 ohms, Id=2.1A
    Mountings: Securely soldered to pc-board.

14. + Opto-coupler (O2): CSA/UL/VDE/F/S/N/D
    Manufacturer: LITEON
    Model: CNY17F-3
    Type: High Collector Emitter Voltage
    Ratings: Isolation 5000 Vac, BVCEO = 70V
    Mountings: Securely soldered to pc-board.

15. Main Transformer (T1): Certified CSA/UR
    Manufacturer: ATC-Frost
    Designation: S6567C (FFS13)
    Type: Split bobbin, dual primary, thermally protected, open core and coil
    Rating:
        Primary: 90-260 Vac, 50/60 Hz, 27VA
        Secondary: 27 Vac@1A
    Windings: Enamelled copper wire
        Primary: Pin 2-7 (90-260 50/60 Hz), 34 AWG, single poly, NYLEZE magnet wire, MW80-C or equivalent 120 turns
        Secondary: Pin 4-9 (27Vac @ 1.0 A, 50/60 Hz), #26 AWG, single poly, NYLEZE magnet wire, MW80-C or equivalent 30 turns
    Core: Ferrite Core, approx 25 mm by 25 mm by 7.2 mm
    Mounting: Secured soldered to pc-board.
    General Insulation: Class A, 105°C, per UL 1446 Insulation system.
    Bobbin: Glass fiber reinforced GF Nylon 6/6, 0.8 mm thick min 2 flanges.
        Manufacturer: Dupont :
        Designation: Dupont Rynite, FR-530
        Insulation: Class B 130°C, V0 PET
    Bobbin Shroud: Glass fiber reinforced GF Nylon 6/6 , 0.8 mm thick min.
        Manufacturer: Dupont :
        Designation: Dupont Rynite, FR-530
        Insulation: Class B 130°C, V0 PET

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Material

Primary to core	
(a) Under winding	Polyester tape 130°C, 0.457 mm
(b) Flange	Polyester tape 130°C, 0.457 mm 2 layers.
(c) Core window (outerwrap)	Glass Cloth Tape 130°C, 0.063 mm 1 layer.
Primary to secondary	Polyester tape 130°C, 0.063 mm 2 layers.
Crossover Insulation	Polyester tape 130°C, 0.457 mm 2 layers.
Margin Tape	Polyester tape 130°C, 0.457 mm 2 layers.

Impregnation Compound: Any dry varnish or equivalent
Temperature rating: 180°C, Class II

Thermal protection: None

16. + Diode (D9, D10, D11): Accepted
Manufacturer: Fairchild Semiconductor
Model: 1N4935
Type: Fast Recovery
Ratings: 1A@250V, Po=2.5W
Mountings: securely soldered to pc-board

17. + Diode (D13): Accepted
Manufacturer. Fairchild Semiconductor
Model: 1N5401
Type: General Purpose
Ratings: 3A@100V, Po=6.25W
Mountings: securely soldered to pc-board.

18. + Capacitor (C12): Accepted
Manufacturer. Phillips
Model: SME63VB471M12X25LL
Type: Electrolytic
Ratings: 470uFd@63Vdc, 85°C (M)
Mountings: Securely soldered to pc-board.

19. – Inverter Circuits : Accepted
Manufacturer: Philips
Model: HEF4069UB
Type: I.C. Six inverter circuits
Ratings: 3-15Vdc
Mountings: Securely soldered to pc-board.

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TESTS REPORT

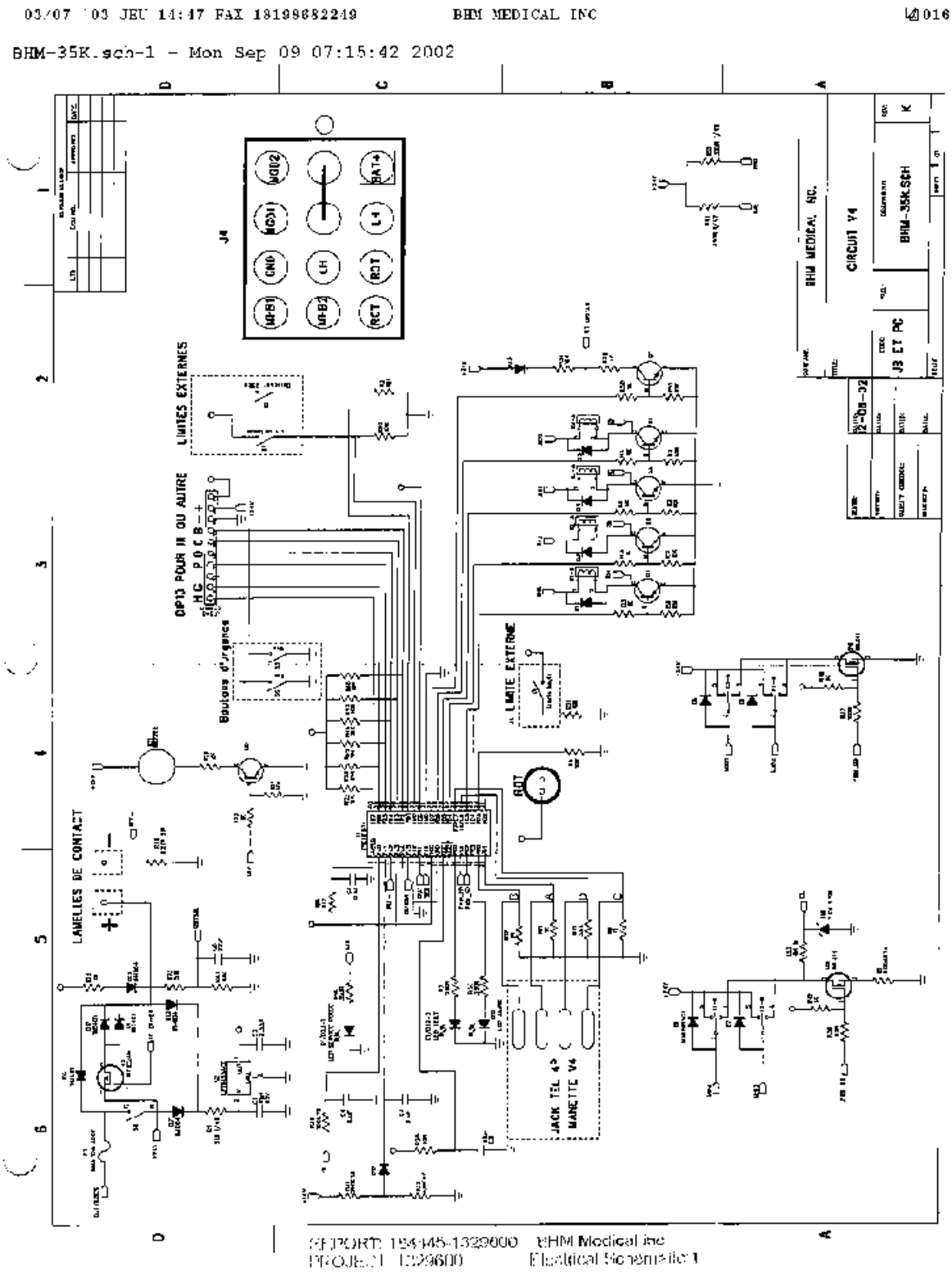
Edition 1 - Project 1329600

The following tests were performed on VOYAGER model:V420 and battery Charger model: 700.15500 the sample was configured for the worst conditions. Tests were performed according to the test requirements of IEC 601-1:1988, CAN/CSA C22.2 No 601-1-M90 (AM1+AM2), UL Standard 2601-97

The following tests have been performed with satisfactory results as per Std. C22.2 No. 601.1 and UL 2601.1 Details of these results are kept in the CSA Eastern Region Principal file:

General Requirements, Cl. 3
Humidity, Clause 4.10
Classification, Cl, 5
Marking, Cl. 6
Label Rub Test, Clause 6.1(z)
Power Input, Cl. 7
Requirements Related to Classification Cl. 14
Enclosures and Protective Covers Cl. 16
Separation Cl. 17
Continuous Leakage Current, Cl. 19
Dielectric Strength, Cl. 20
Mechanical Strength, Cl. 21
Rough Handling of Transportable Equipment, Clause 21.6
Surfaces, Corners and Edges, Cl. 23
Stability, Cl. 24
Excessive Temperature, Cl. 42
Fire Prevention, Cl. 43
Overflow, Spillage, Leakage, Humidity, Ingress of Liquids, Cleaning, Sterilization, Disinfection, Cl. 44
Interruption of The Power Supply, Cl. 49
Abnormal Operation Fault Condition, Cl. 52
Impact, Cl. 55
Components and General Assembly, Cl. 56
Overheating Test, Cl. 57.9.1
Induced Dielectric Strength Test on Transformer, Clauses 57.9.2
Creepage Distance and Air Clearance, Cl. 57.10
Construction and Layout Cl. 59
Enclosure Ball Pressure Test, Clause 59.2(b)

1329600/15/ad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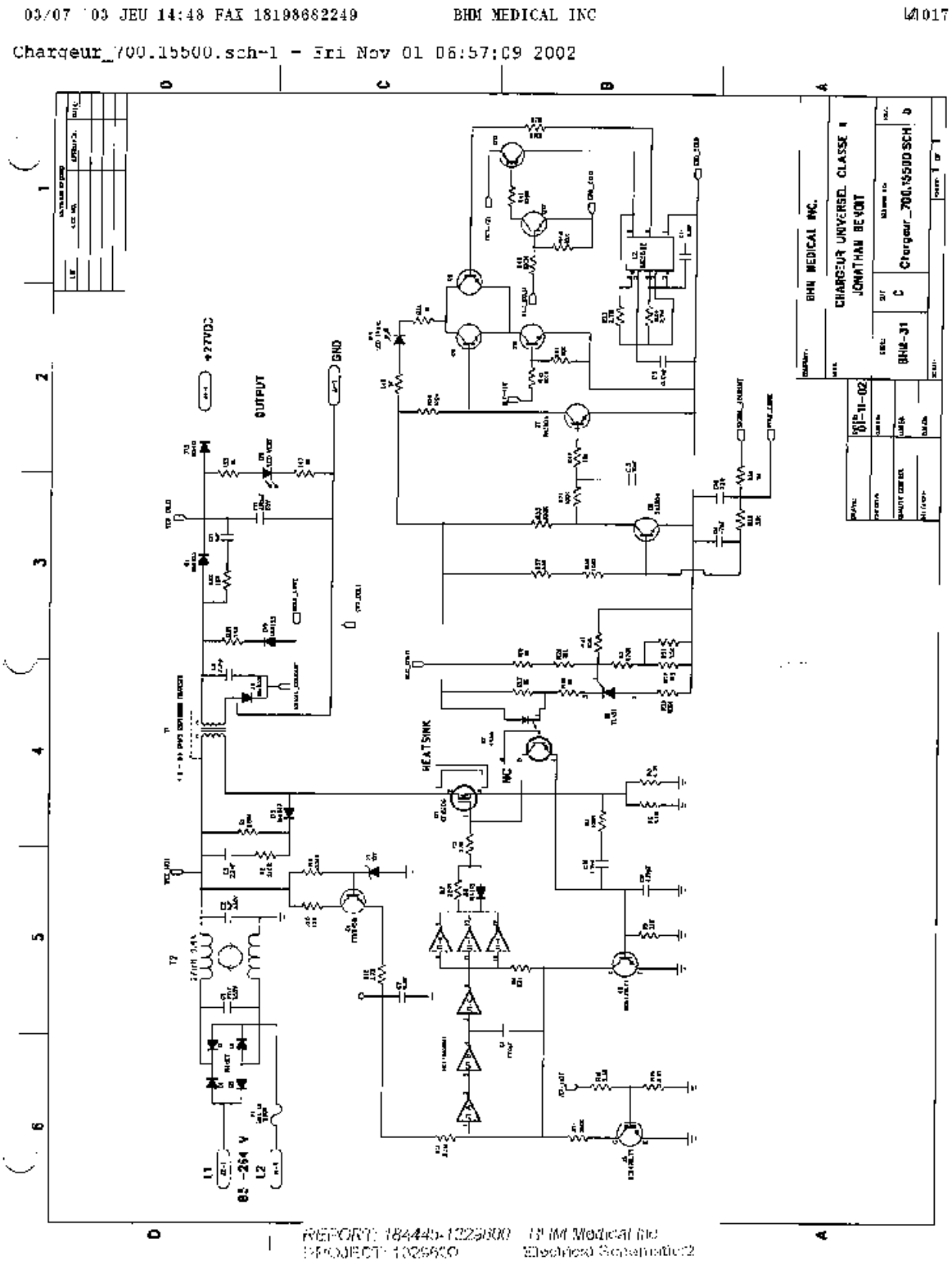
LIMITES EXTERNES
OPTO POUR IN OU AUTRE
HC P O C B - +
Boutons d'urgence
LIMITE EXTERNE
LAMELLES DE CONTACT
JACK TEL 4>
MANETTE V4
BHM MEDICAL INC.
CIRCUIT V4
BHM-35K.SCH
REPORT: 154145-1329600 BHM Medical Inc
PROJECT: 1329600 Electrical Schematic 1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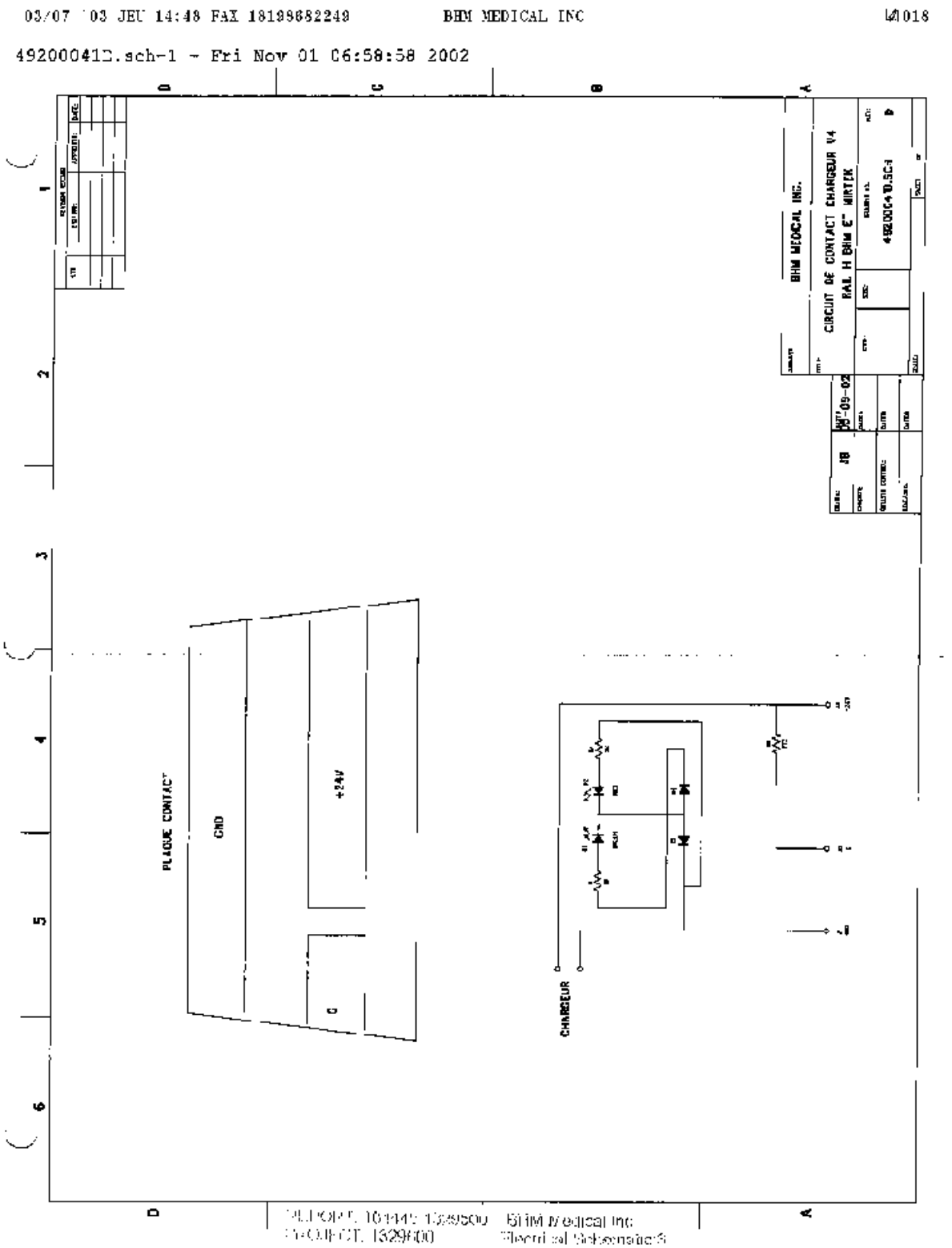
+27VDC
OUTPUT
GND
HEATSINK
CHARGEUR UNIVERSEL CLASSE I
JONATHAN BEVOIT
BHM MEDICAL INC.
BHM-31
Chargeur_700.15500.SCH
01-11-02
REPORT: 18448-122900 BHM Medical Inc
PROJECT: 122900 Electrical Schematics2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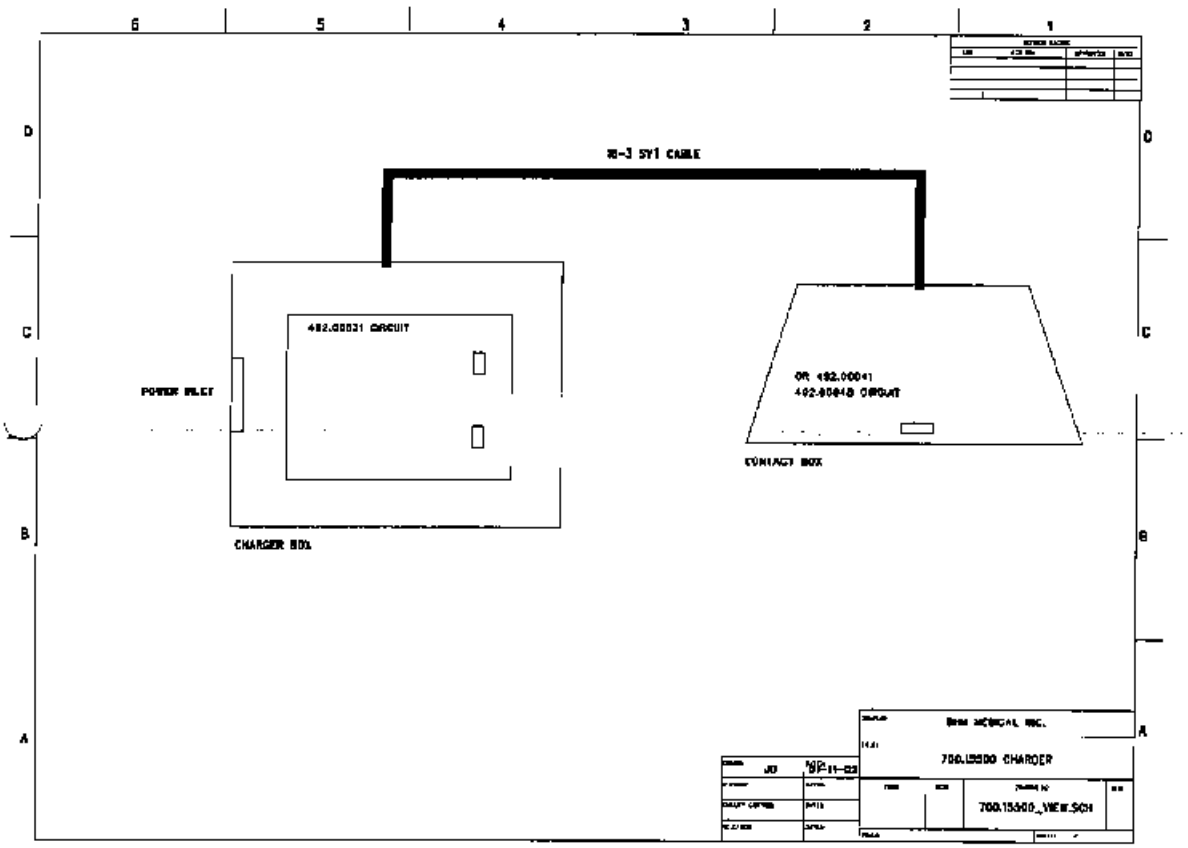
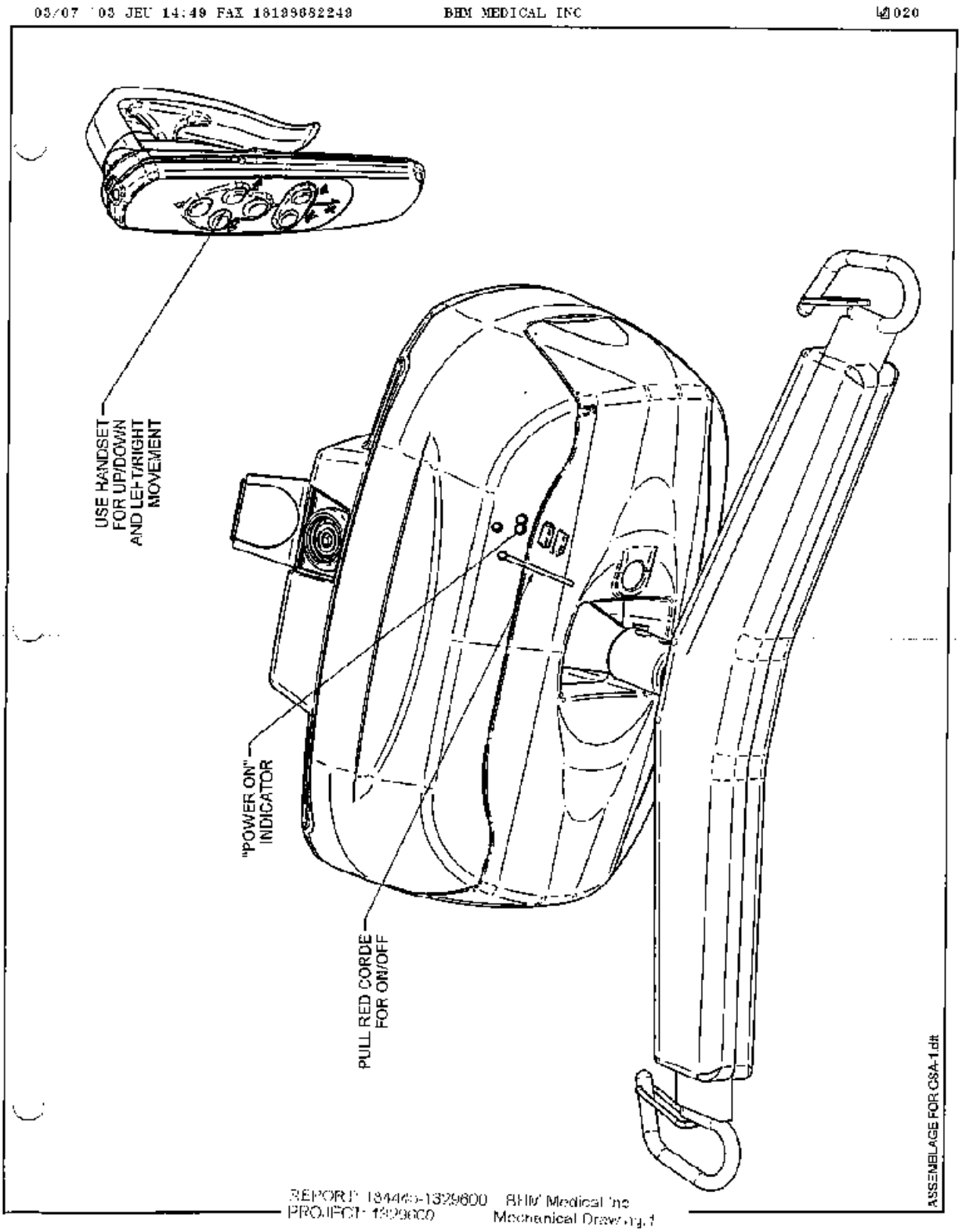
CIRCUIT DE CONTACT CHARGEUR V4
PLAQUE CONTACT
GND
+24V
CHARGEUR
BHM Medical Inc.
Electrical Schematics

03/07 '03 JEU 14:48 FAX 18199882249 BHM MEDICAL INC 019

700.15500_VIEW.sch-1 - Fri Nov 01 07:08:55 2002



MAJOR: 1394445-1329800 BHM Medical Inc.
PROJECT: 1329800 Electrical Schematics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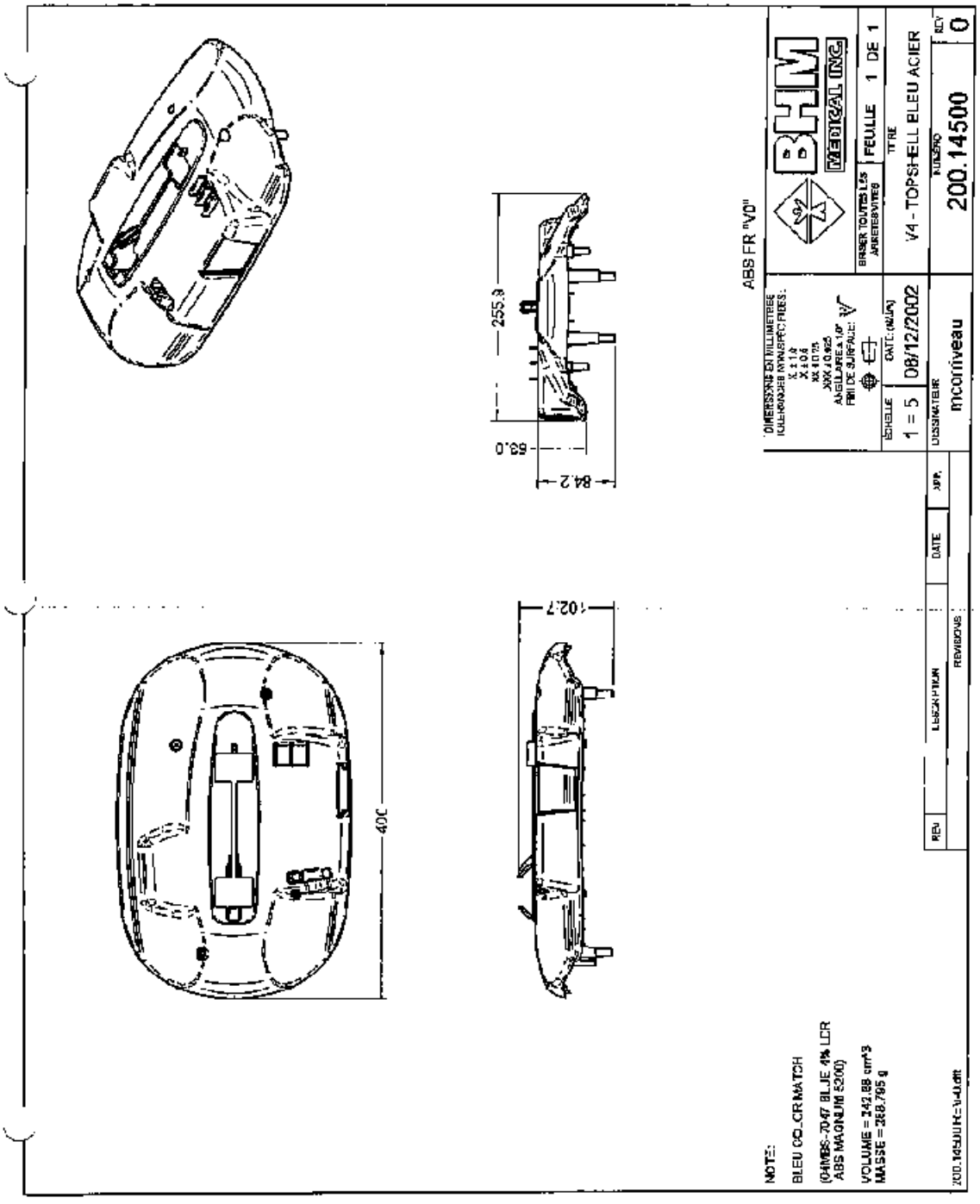
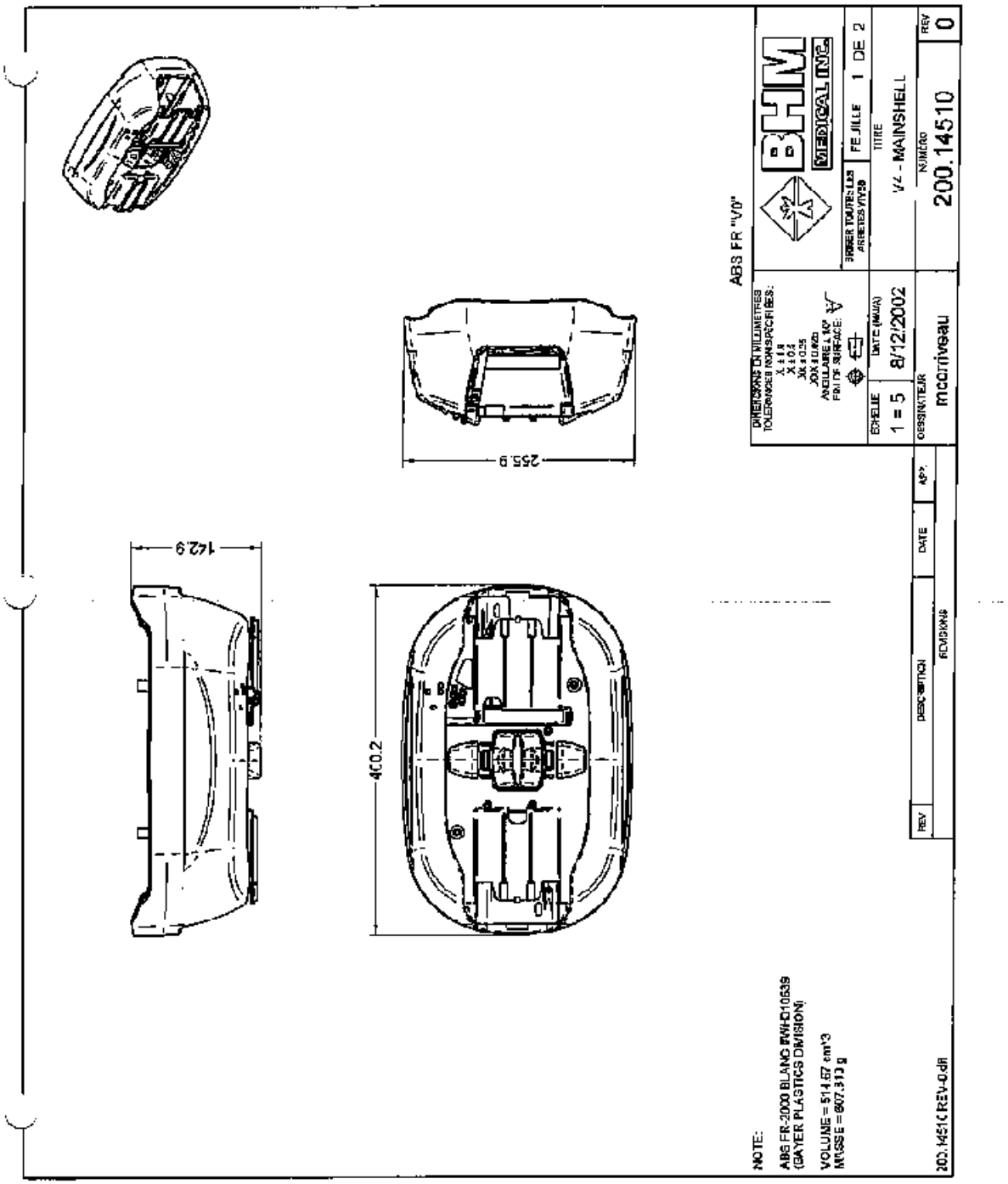
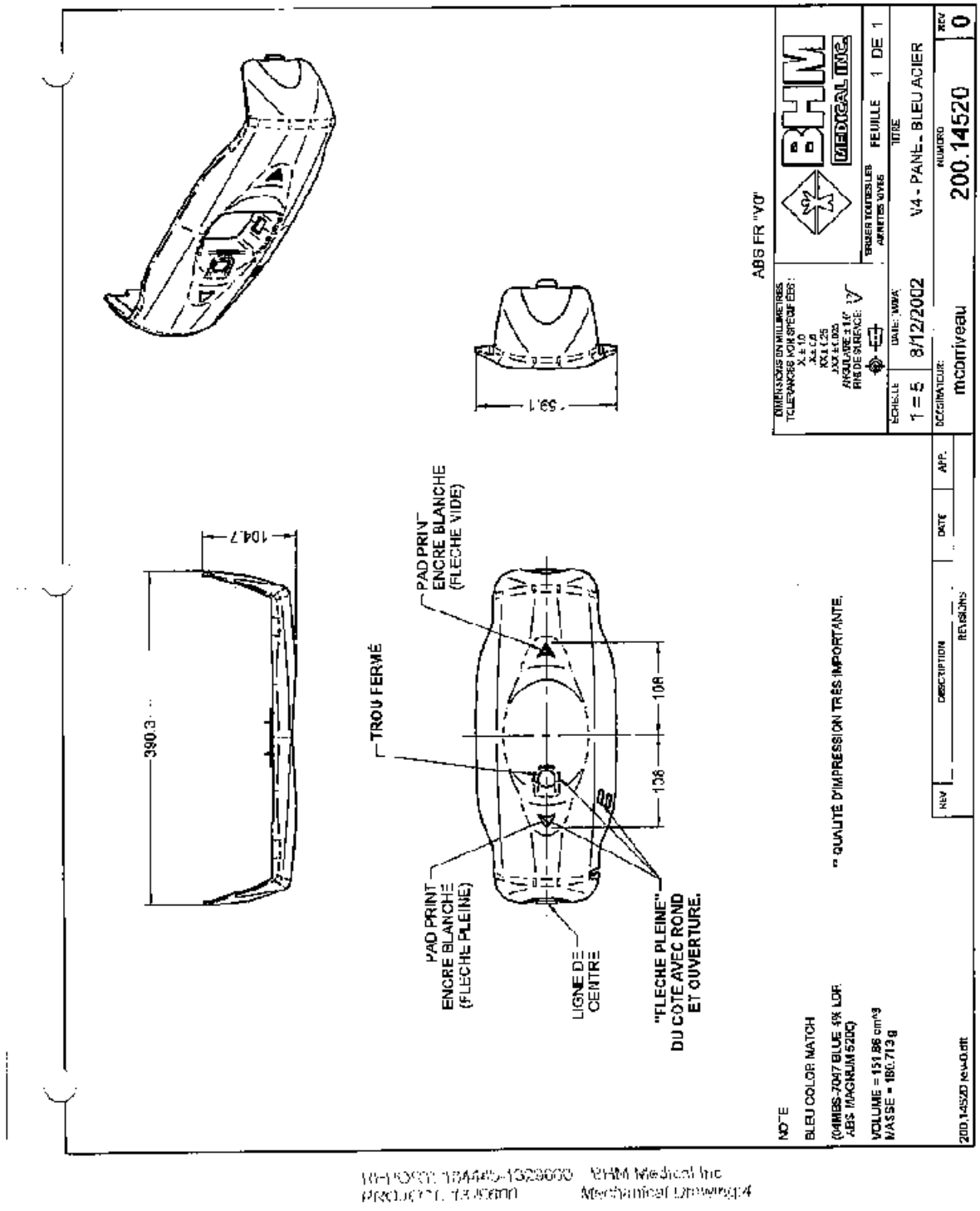
USE HANDSET FOR UP/DOWN AND LEFT/RIGHT MOVEMENT
"POWER ON" INDICATOR
PULL RED CORDE FOR ON/OFF
ASSEMBLAGE FOR C8A-1.dft
REPORT: 18444s-1329800 BHM Medical Inc
PROJECT: 1329800 Mechanical Drawing 1


ABS FR "V0"
255.3
68.0
84.2
102.7
400
BHM MEDICAL INC.
DIMENSIONS EN MILLIMETRES
TOLERANCES NON SPECIFIEES:
ANGULAIRE ± 1/2°
ÉCHELLE
1 = 5
DATE (AAAA/MM/JJ)
08/12/2002
DESSINATEUR
mcorriveau
BRISER TOUTES LES ARÊTES VIVES
FEUILLE 1 DE 1
TITRE
V4 - TOPSHELL BLEU ACIER
NUMÉRO
200.14500
REV
0
REV
DATE
APP.
REVISIONS
NOTE:
BLEU COLOR MATCH
(04W86-7047 BLUE 4% LDR
ABS MAGNUM 5200)
VOLUME = 342.88 cm^3
MASSE = 368.705 g
200.14500-V4.dft



PROJECT: 1329200 BHM Medical Inc
PROJECT: 1329200 Mechanical Drawing 3


ABS FR "V0"
BHM MEDICAL INC.
DIMENSIONS EN MILLIMETRES
TOLERANCES NON SPECIFIEES:
X ± 1.0
XX ± 0.5
XXX ± 0.25
ANGULAIRE ± 1/4°
ECHELLE
1 = 5
DATE: MMM/
8/12/2002
TRACER TOUTES LES ARETES VIVES
FEUILLE 1 DE 1
TITRE
V4 - PANEL BLEU ACIER
DESSINATEUR:
mcontreau
NUMERO
200.14520
REV
0
REV
DESCRIPTION
DATE
APP.
REVISIONS
NOTE
BLEU COLOR MATCH
(04MBS-7047 BLUE 4% LDR
ABS MAGNUM 5200)
VOLUME = 151.86 cm^3
MASSE = 180.713 g
200.14520 rev-0.dft
* QUALITÉ D'IMPRESSION TRÈS IMPORTANTE.
TROU FERMÉ
PAD PRINT
ENCRE BLANCHE
(FLECHE VIDE)
PAD PRINT
ENCRE BLANCHE
(FLECHE PLEINE)
LIGNE DE
CENTRE
"FLECHE PLEINE"
DU CÔTE AVEC ROND
ET OUVERTURE.
104.7
390.3
59.1
108
136

Appendix 2.6: SGS Certificate ISO 9001-1994

SGS International Certification Services Canada, Inc.
SGS Services de Certification Internationale Canada Inc.

Certificate Number/Numéro de certificat

2418/00

This is to certify that the Quality Management System of:
Le présent certifie que le système de gestion de la qualité de:

BHM Medical inc.
2001 Tanguay
Magog, Québec
J1X 5Y5

Has been assessed and registered as meeting the requirements of ISO 9001:1994.
The scope of registration is as follows:
A été évalué et enregistré conformément à la norme ISO 9001:1994. Le domaine d'enregistrement est présenté ci-dessous:

Design, production, sales, installation and servicing of mobile patient transfer, motorized ceiling lifts and related accessories.

Conception, production, ventes, installation et service de lève personne, levier sur rail et accessoires connexes.

Signed for and on behalf of SGS International Certification Services Canada Inc.
Document signé pour et au nom de SGS Services de Certification Internationale Canada Inc.

December 5, 2000 ***le 5 decembre, 2000***

This certificate remains valid subject to satisfactory maintenance of the system.
Certificat valide sous réserve du maintien satisfaisant du système.

SGS International Certification Services Canada Inc.
SGS Services de Certification Internationale Canada Inc.
Unit 2, 6275 Northam Drive, Mississauga, Ontario, Canada L4V 1Y8

REGISTERED COMPANY • SOCIÉTÉ ENREGISTRÉE ISO 9001 SGS

This is not a legal document and cannot be used as such. This certificate remains the property of SGS ICS to whom it must be returned upon request.
Ce document n'est pas légal et ne peut être utilisé à cette fin. Ce certificat demeure la propriété de SGS SCI, à qui il doit être renvoyé sur demande.

Standards Council of Canada Accredited Registrar
Conseil canadien des normes Registraire accrédité
TM

Member of the SGS Group (Société Générale de Surveillance)

Appendix 2.7.3: National authority

COUNTRIES		NAMES	E-mail/ Web site	ADDRESSES	PHONE FAX
AUSTRIA Federal Ministry of Social Security and Generations	AIMD MDD IVD	Dr. W Ecker Dr. Renhardt Ing. Gutruf	Nihil	Abt. VIII/A/22-Medical Devices/Medizinprodukte Radetzkystrasse 2A-1031 Vienna	Ph: +43 1 711 00 4206 Ph: +43 1 711 00 4487 Ph: +43 1 711 00 4492 Fax: +43 1 711 00 4217 Fax: +43 1 715 73 12
BELGIUM Federal Public Service Health, Food Chain Safety and Environment. Directorate General Public Health Protection: Medicinal Products Medical Devices Unit	AIMD MDD	Mr. P. Bauwin, Mrs. S. Mignon	meddev@afigp.fgov.be www.afigp.fgov.be	Vesalius Building – Rijksadministratief Centrum B- 1010 Brussels	Ph: +32-2 210.63.58 Fax: +32-2 210.49.01
BELGIUM Institut Scientifique de Santé Publique	IVD	Dr. JL Libeer	Jean-Claude.Libeer@ipf.fgov.be	Louis Pasteur Rue Juliette Wytsman 14 1050 Bruxelles	Ph: +32-2 642 55 27 Fax: +32-2 642 56 45
DENMARK Danish Medicines Agency		Mr H-K Andersen	hka@dkma.dk	Frederikssundsvej 378DK- 2700 Brønshøj	Ph. : +45-4488 9111 Ph. : +45-4488 9265 Fax: +45-4488 9314
FINLAND Medical Devices Centre National Agency For Medicines	AIMD MDD IVD	Mr Petri Pommelin	Nihil	Mannerheimintie 166 – PO Box 55 FIN- 00301 Helsinki	Ph: +358-9 4733-4249 Fax: +358-9 4733-4266
	IVD	Dr Jarkko Ihalainen	jarkko.ihalainen@nam.fi		Ph: +358-9-4733 42 64
	AIMD MDD	Mr Harry Sievänen	harry.sievanen@nam.fi		Fax: +358-9-4733 41
FRANCE Agence Française de Sécurité Sanitaire des Produits de Santé	MDD IVD	Dr J-C Ghislain jean-	claude.ghislain@afssaps.sante.fr, www.afssaps.sante.fr	AFSSAPS 143 / 147 Boulevard Anatole France F-93285 Saint - Denis Cedex	Ph: +33 1 55 87 37 47 Fax: +33 1 55 87 37 42
GERMANY Bundesinstitut für Arzneimittel und Medizin-produkte	AIMD MDD	Dr. E. Stößlein	e.stoesslein@bfarm.de	Geschäftsstelle Medizinprodukte (BfArM) Friedrich-Ebert-Allee 38 D-53113 Bonn	Ph: +49-228 207.53.84 Fax: +49-228 207.53.00
	IVD	Dr. R. Siekmeir	r.siekmeir@bfarm.de		Ph: +49-228 207 53 60 Fax: +49-228 207 53 00
	IVD	Dr. J.Halbauer	s-ivd@pei.de	Paul-Ehrlich-Institute (PEI) Paul-Ehrlich-Strasse 51-5963225 Langen	Ph: +49- 6103 77 7000 or .....77 3114 Fax: +49- 6103 77 1268

GREECE Ministry of Health, Welfare and Social		Dr. G.P. Demagos	Nihil	Services National Organization for Medicines 284 Messogion Avenue 15562 Holargos Attikis	Ph: +30- 1 65 07 380 Fax: +30-1 65 49 585
IRELAND Irish Medicines Board		Ms. Ann O'Connor	medicaldevices@imb.ie www.imb.ie	Irish Medicines Board Earlsford Centre Ealsfort Terrace Dublin 2 Ireland	Ph.: +353-1-67 64 971 Fax: +353-1-67 67 836
ICELAND Ministry of Health and Social Service		Mrs. Vilborg Ingolfsdottir	vilborg@landlaeknir	Laugavegur 116 IS- 150 Reykjavik	Ph: +35-45 609.700 Fax: +35-45 519.165
ITALY Ministry of Health		Dr. M. Marletta	Nihil	Dipartimento II Piazza Industria, 20 I-00144 ROMA	Ph: +39-6 59 94.2423 Fax: +39-6 59 94.2111
	IVD	Dr. Mirella Colella	Nihil	Dipartimento per la Valutazione dei Medicinali Farmacovigilanza Ufficio IX, Via della Civiltà Romana ,7 I-00144 Roma	Ph: +39-06 59 94 37 22 Fax: +39-6 59 94 32 85
LUXEMBOURG Ministère de la Santé. Direction de la Santé		Dr. G Scharll	gerard.scharll@ms.etat.lu	villa Louvigny - Allée Marconi L-2120 Luxembourg	Ph: + 352- 478 56 34 Fax: +352-262 03296
NETHERLANDS Health Care Inspectorate	MDD IVD	Mr. J. Moleveld	medtech.higz@igz.nl	Cluster Medical Technology PO Box 16119 NL-2500 BC Den Haag	Ph: +31-70 340 74 36 Fax: +31-70 340 71 59
NORWAY Norwegian Directorate for Health and Social Welfare		Mrs. I. Hagerup-Jenssen	ingeborg.hagerup-jenssen@shdir.no	PO Box 8054 Dep. N-0031 Oslo	Ph: +47-24 16 31 76 Fax: +47-24 16 30 21
		Mrs. Tove Farstad	tove.farstad@shdir.no		Ph: +47-24 16 31 72 Fax: +47-24 16 30 21
	IVD	Mrs. S. Dyrnes	sissel.dyrnes@shdir.no		Ph: +47-24 17 31 67 Fax: +47-24 16 30 21
PORTUGAL Direcção Operacional de Farmacogivilância e Segurança de Medicamentos e Produtos de Saúde do INFARMED	MDD IVD	Mr.Miguel Antunes	miguel.antunes@infarmed.pt adriana.gamboa@infarmed.pt dvps@infarmed.pt	Parque de Saúde de Lisboa; Av. do Brasil, 53, Pav. 241749 - 004 Lisboa	Ph: +351-21 798 71 79 Ph: +351-21 798 71 51 Ph: +351-21 798 71 45 Fax: +351-21 798 71 55
Instituto Nacional de Saúde (INSA) Dr. Ricardo Jorge	AIMD	Dr João Lavinha	Nihil	Av. Padre Cruz P-1649-016 Lisboa Codex	Ph: +351-21-751 92 00 Fax: +351-21-752 64 00

SPAIN Ministerio de Sanidad y Consumo		Mrs. C. Abad Luna Mrs. C. Valls	cabad@msc.es cvalls@msc.es www.msc.es	Dirección General de Farmacia y Productos Sanitarios Paseo del Prado 18/20 E-28014 Madrid	Ph: +34-91 596 43 48 Fax: +34-91 596 44 00 Ph: +34-91 596 43 48 Fax: +34-91 596 44 00
SWEDEN MPA - Medical Products Agency Medical Devices	AIMD MDD IVD	Mr Lennart Philipson Mr Lars Johansson	www.sos.se lennart.philipson@mpa.se lars.johansson@mpa.se	Box 26, SE - 751 03 UPPSALA	Ph: +46-18 17 46 00 Fax: +46-18 50 31 15
SWITZERLAND Swissmedic Swiss Agency For Therapeutic Products		Mr A Sparti	medical.devices@swissmedic.ch	Medical Devices Division Erlachstrasse 8 CH-3000 Bern 9	Ph: +41-31 323 22 51 Fax: +41-31 322 76 46
UNITED KINGDOM Medical Devices Agency		Mr A. Sant	mb-mda-aic@doh.gsi.gov.uk	Adverse Incident Center Hannibal House, Elephant and Castle UK-London SE1 6TQ	Ph: +44-171 972 80 80 Fax: +44-171 972 8109

Appendix 3.1.4: Identical models

Declaration of Identical models

COMPANY: BHM MEDICAL INC.
ADDRESS : 2001 Tanguay
Magog Qc (Canada)
J1X 5Y5

TELEPHONE : 819-868-0441
FAX : 819-868-2249

PRODUCT : CEILING

PRODUCT : V4

MODELS : VOYAGER 420PLUS, V420PLUS, VOYGAER V4, V4

Declares that the product(s) name “V420PLUS” is exactly the same component assembly then the V4 at exception:

- the “V420PLUS” the safe working load indicated is 190kg/420lbs.

It is brand name only for different market(s).

MADE IN: ***MAGOG, QUEBEC***
CANADA

BY: **Réal Pedneault**
Research and Development Department
DATE : ***August 2nd, 2003***

Appendix 3.2.1 Extract of safety instructions, advertisings and warnings

General

DO NO ATTEMPTS TO USE THIS EQUIPMEENT WITHOUT UNDERSTANDING THIS MANUEL

To ensure safe operation, read the entire manual carefully, especially the section on "Safety Instruction and Warnings", before installing, operating, or servicing this equipment.

If anything is not completely understood, please contact your supplier for more details. Failure to comply with warnings in this manual may result in injury.

Keep this manual with the lift and refer to it as required. Contents of this manual are subject to change without prior notice to users.

WARNING: this symbol is intented to alert the user to hazards or unsafe pratices, which could result in serious bodily harm.

CAUTION: this symbol is intented to alert the user of the presence of important operating and maintenance instructions, which could prevent product damage or possible personal injury.

NOTE: this symbol offers helpful information concerning certain operating procedures.

SAFETY INSTRUCTIONS AND WARNINGS

A. GENERAL

- **IMPORTANT – READ THESE INSTRUCTIONS CAREFULLY OR SERIOUS UNJURY MAY RESULT.**
- **KEEP THESE INSTRUCTIONS AND THE KEY PROVIDED WITH THE LIFT AT ALL TIMES**
- **READ OPERATION AND MAINTENANCE INSTRUCTIONS IN THIS MANUAL BEFORE INSTALLING, OPERATING, OR SERVICING THIS EQUIPEMENT**
- **BHM Medical ceiling lifts must be installed by an authorized contractor or installer.**
- **YOUR LIFT is for transferring patients only. Do not use the lift for any other purpose.**
- **ALWAYS carry out the daily checklist before using the lift.**
- **BHM Medical ceiling lifts are specifically designed for BHM Medical ceiling rail systems, slings and accessories. Slings and accessories designed by any other manufacturer are prohibited and will void BHM Medical warranty. Use only Ergofit slings and accessories to maintain patient safety and product utility.**

- **BHM Medical ceiling lifts are intented to be used for patients within the specified weight limit indicated for the lift. Do not attempt to lift more than the weight limit indicated.**
- **Before attempting to transfer, the patient must be assessed by a qualified professional.**
- **BHM Medical ceiling lifts must be used by a caregiver with proper training to work with the patient to be transferred.**
- **ONLY trained and qualified caregivers should transfer a patient. DO NOT attempt to use the lift if you have not been properly trained to do so.**
- **ALWAYS be prepared before attempting to transfer a patient.**
- **DO NOT use a sling that is not recommanded for the lift.**
- **NEVER use a damaged, torn or frayed sling.**
- **ALWAYS place the sling around the patient according to the instructions enclosed.**
- **FOLLOW lifting procedures outlined in this manual.**
- **USE all controls and safety features only according to the rules specified in this manual. Never attempt to force a control or button on the lift.**
- **DO NOT store the charger in a shoer, bath or other areas with high humidity.**
- **DO NOT drop the patient lift or batteries. Dropping the lift or batteries may cause internal damage that is not easily seen. If lift is suspected to be damaged, take to an authorized technician for servicing.**
- **IMPORTANT : Keep all components of the lift clean and dry, and have electrical and mechanical safety checkpoints done as instructed in the Maintenance section of this manual.**
- **Replace any precautionary or instruction labels that cannot be easily read.**
- **Avoid violent shock during transportation.**

B. SHOCK PREVENTION

- **DO NOT touch or use a lift with bare conductors or a damaged power cord. Electrically live equipment can electrocute a patient. If hte lift or charger has any exposed or damaged wires contact your local dealer immediately.**
- **DO NOT splash or expose electric parts of the device to water or moisture.**
- **CHECK nameplate for voltage and cycle requirements. These requirements differ by country. Do not attempt to use the lift in an area that has a different voltage and cycle requirement.**
- **DO NOT attempt to expose, service or repair the lift, battery or charger. If any unit is malfunctioning, contact your local dealer.**
- **READ batteries and charger instructions thoroughly before using or storing them.**

C. FIRE AND EXPLOSION PREVENTION

- **Batteries may explode, leak and cause personal injury if no disposed of properly.**
  - **Do not place or store the battery under direct sunlight or near a heat source**
  - **Do not dispose of in fire.**
  - **Do not short the battery terminals.**
  - **Flush with water if electrolyte (Acid) comes in contact with skin or eyes.**

- **Batteries must be recycled, disposed of according to local law regulations. When returning batteries, insulate their terminals with adhesive tape, etc. Otherwise, the residual electricity in used batteries may cause fire or explosion.**

D. EQUIPMENT WARNING LABELS

- **INSPECT all precautionary labels on the equipment. Order and replace all labels that cannot be easily read.**

Operation

READ « SAFETY INSTRUCTIONS AND WARNING » BEFORE ATTEMPTING TO USE THE V4.

The unit will not lift or lower when in contact with the charger.

If the lift does not work, gently pull on the red cord until you hear a click. The green light should illuminate.

.

Hold the lift spreader bar with one hand at all times when near a patient.

BEFORE LIFTING THE PATIENT :

1. **Make sure the patient is confortable;**
2. **Make sure the sling is not caught on any obstruction (wheelchair brake or arm of the chair).**
3. **If any of the above occurs – lower the patient immediately and correct the problem.**

Hold the lift spreader bar with one hand at all times when near a patient.

.Emergency Stop (Red Cord)

Do not pull red cord forcefully. If the cord is pulled too forcefully, the lift may becom inoperable.

Emergency Lowering Feature

Only to be used in case of an emergency.

Chargement de la batterie

DO NOT operate the charger unit with a damaged cord or if the unit has been dropped or damaged.

DO NOT forcibly bend the power cord or place a heavy object on it. This will damage the cord and may cause fire or electrical shock.

DO NOT pour liquid on or near the charger.

Do not place the unit in locations that are :

- **Extremely hot**
- **Dusty or dirty**
- **Very humid**
- **Moving or vibrating.**

DO NOT SLIDE THE LIFT TO THE CHARGER FORCEFULLY OR QUICKLY. CHARGER MAY BECOME DAMAGED.

Whenever possible, leave the lift on the charger when the lift is not in use. At minimum, charge the battery until the light is green before using it again. This will extend the life of the battery.

Maintenance

ALWAYS CARRY OUT THE DAILY CHECKLIST BEFORE EACH LIFT USE.

Alterations made to the V4 by someone other than a certified technician may cause serious injury and voids the warranty.

The V4 and accessories must be inspected ANNUALLY by a certified technician in addition to the daily and other periodic visual checks done by the user specified in this section.

Preventive maintenance specified in this manual can prevent accidents and reduce repair costs.

Note all services or repairs to the V4 or its accessories in the log book at the end of this manual. Have the document signed by the certified technician.

Do not immerse lift in watter.

Always reinstall the rail end stopper (if it has been removed) after servicing.

Strap

If there is any sign of wear as indicated here or other visual defects, strap should be changed immediately. By continuing to use the lift without changing the strap, caregiver and patient safety is greatly compromised.

In any case, the manufacturer recommends changing the strap at leat every two years. By continuing to use the lift without changing the strap, caregiver and patient safety is greatly compromised.

Take note of inspection results in the logbook at the end of this manual.

Handling and storage

BHM Medical recommends charging of batteries at least every two weeks even if the lift is not used. This will prevent premature ageing of batteries.

DO NOT ATTEMPT TO USE A BATTERY NOT AUTHORIZED BY BHM MEDICAL.

BHM batteries are specially designed for BHM charging systems. Attempting to use an unauthorized battery may seriously damage the lift and/or the charger.

V4 AND ACCESSORIES MUST BE SERVICED EVERY 12 MONTHS AS A MINIMUM REQUIREMENT.

Do not attempt to do the inspectionunless you are certified to do so.

As part of the annual inspection, an anual load test with the safe working load must be performed on the V4 as required for CE MARK MAINTENANCE.

After annual inspection, have the logbook signed by the certified technician.

Appendix 3.3.3 Brochure, advertising, marketing claims

NEW DESIGN IMPROVEMENTS , NEW SAFETY FEATURES, NEW "KWIKtrak" RAIL SYSTEM WITH PATENTED CEILING ATTACHMENTS, NEW CLIP ON CHARGING STATION

- **AESTHETICALLY PLEASING DESIGN**: The V4 will be the best looking piece of equipment in the room!

- **EASIER TO MAINTAIN**:
  - **Maintenance Light tells you when the lift needs service:** No more guesswork!
  - **Modular Design:** Remove the lift cover without tools to gain easy access to the batteries. The main circuit board has a single plug-in connector.
  - **Lightweight construction:** Moving or removing the lift is easier while the lifting capacity of 200 kg (440 lbs) remains the same.

- **PROGRAMMABLE FUNCTIONS**: Use the handset to program lateral speed adjustments, or the carry bar position after the return to charge function is completed.

- **SAFETY FEATURES**:
  - **New safety belt type lift strap** for proven strength and durability is tested to 2727 kg (6000 lbs)
  - **Power Emergency UP and DOWN** with an easily accessible MANUAL emergency down.
  - **Weight Sensor on Return to Charge Function** automatically shuts the lift off if it senses a weight of 9 kg (20 lbs) or more. No risk of the carry bar pulling trapezes, furniture or loaded IV poles on the way to the charger.
  - **No welds or chains to fail.** Components are press fitted with mechanically interlocking parts. Strong, direct drive nylatron gears power the lift.
  - **Soft start and stop** mechanisms smooth the transition between lift functions.
  - **Dual emergency (centrifugal) brake system** eliminate any free-fall potential
  - **Current limiting device will shut the lift off if** an over-weight lift is attempted

- **CLIP ON CHARGER**: Attaches without tools and can be placed anywhere along the track. An added convenience in multi-bed rooms. Allows you to reposition the charger to suit a changing furniture layout.

- **NEW COMFORTABLE HANDSET**: Its ergonomic design snugly fits the hand and does not restrict the caregiver during transfers.

- **NEW KWIKtrak RAIL SYSTEM**: Uses a revolutionary patented bracket that is 40% faster to install than conventional brackets. Its unique locking device keeps the track securely fastened.
  - **KWIKtrak's slim design permits a tight** 595 mm (23 in.) turning radius on curves.
  - **Smooth, Seamless joints** using a unique pin locking system improves lateral movement and finished appearance.

SPECS AT A GLANCE

- Lifting capacity: 200 kg (440 lbs.).
- Return to charge function initiated by user: weight sensor cut-out 9 kg (20 lbs.).
- Unit weight: 11.5 kg (28 lbs.) batteries included.
- Power on indicator.
- LED indicator for maintenance required.
- Electronic microprocessor soft-start and stop motor control.
- Manual emergency lowering device (located on the motor cab).
- Electrical up and down emergency buttons.
- Emergency stopping device (pull cord) accessible from the ground.
- Overload circuit protection current limiter.
- Low battery disconnect system.
- Low battery indicator (audible and visual LED).
- Charging indicators
  - blinking yellow – charging
  - full yellow – charging completed
- ABS FR casing (fire retardant).
- Double centrifugal emergency brake system (in case of mechanical failure).
- Strap length up to 2.3 m (90 in.) tested for 2727 kg (6000 lbs.).
- Lifting speed: 6 cm/sec. (2.4 in./sec.).
- Batteries: 2 X 5 Ah will average 150 cycles (loaded at 75 kg / 165 lbs.).
- Adjustable horizontal displacement speeds: 10, 15, 20, 25 cm/sec.(4, 6, 8, 10 in./sec.). Speed set by default 20 cm/sec (8 in/sec.).
- CSA No 601.1, UL No 2601-1 certifications.
- CE marked.
- Respects EMI standards (electromagnetic interference).
- ISO 10535

CHARGER UNIT

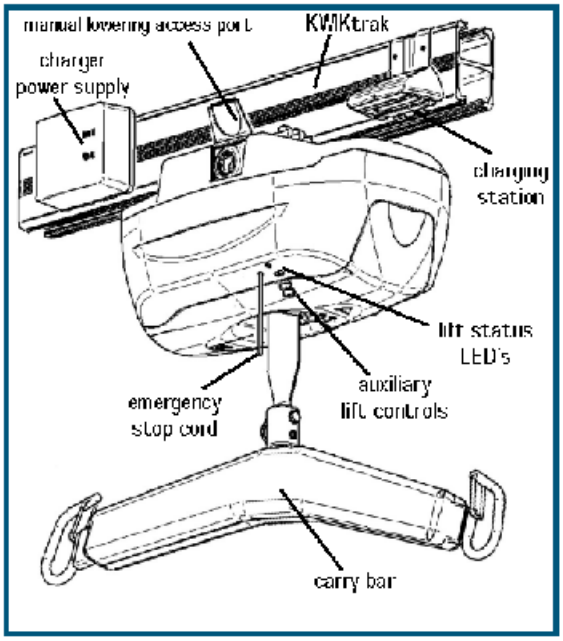
- Power indicator on charging module.
- Clip on charger any where on the track.
- 120-240 Vac / 50-60 Hz / 27 Va.
- Class 2 insulated
- CSA no. 601.1 and UL No. 2601-1 certifications.
- CE marked.
- Respects EMI standards (electromagnetic interference).
- ISO 10535.

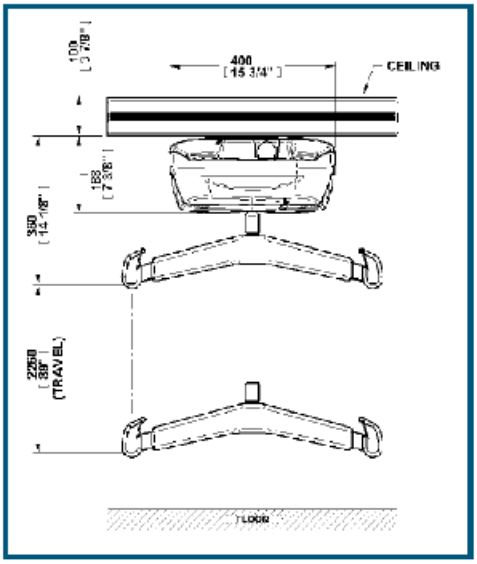
HANDSET

- ABS fire retardant
- Santopren tactile buttons
- IP44
- Infrared remote control (optional)

V4

the next generation in ceiling mounted patient lifts





2001 Tanguay St., Magog, Quebec, Canada J1X 5Y5
1-800-868-0441, Fax:(819) 868-2249 www.bhm-medical.com

designed for use with the revolutionary new track system

KWIKtrak

- a configuration to suit every need
- easier & faster to install
- a system of components
- aesthetically pleasing
- reduces space required for curves by 1/3
- ideally suited for use in confined areas
- uses the patented KWIKtrak bracket

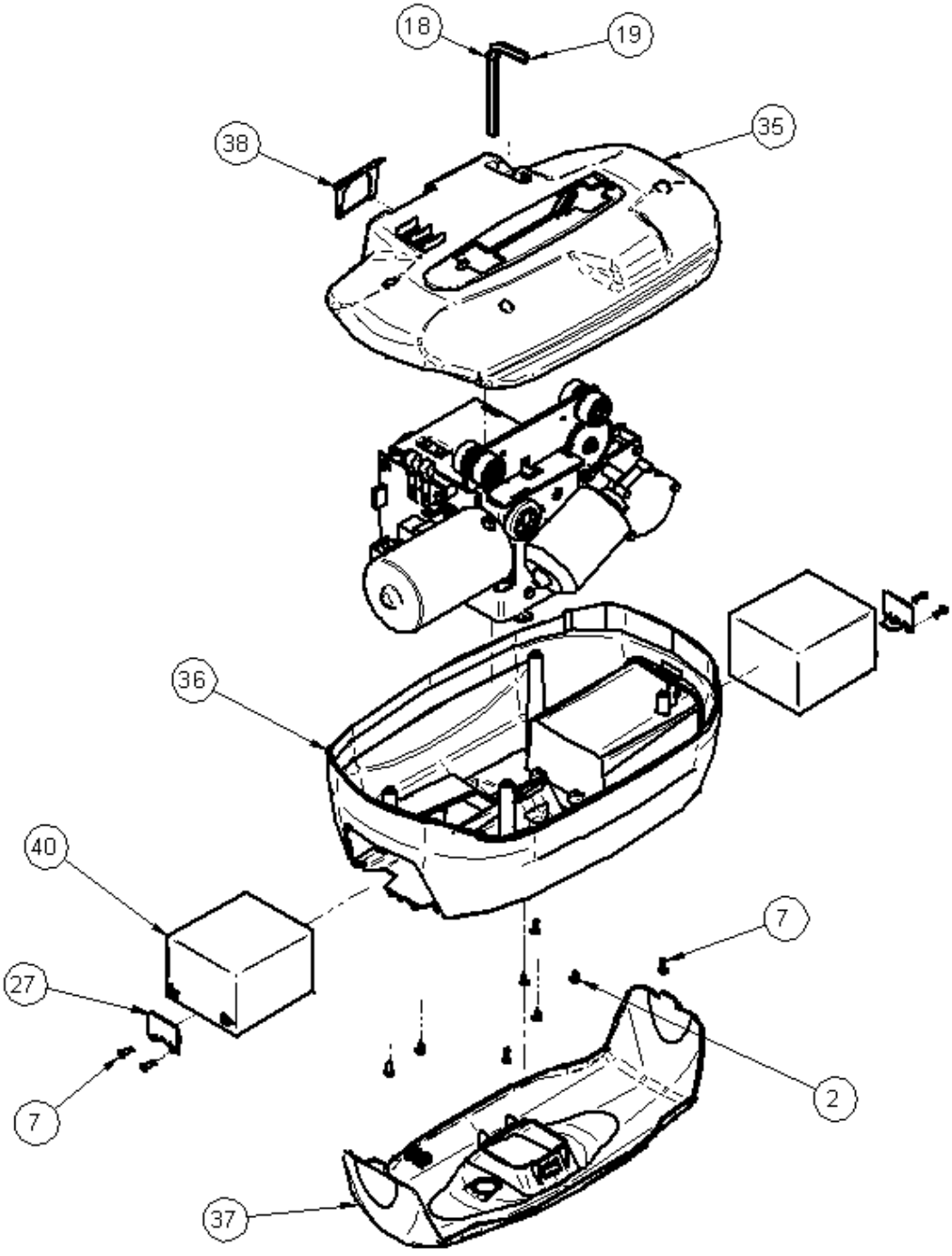
the V4 & KWIKtrak system at work

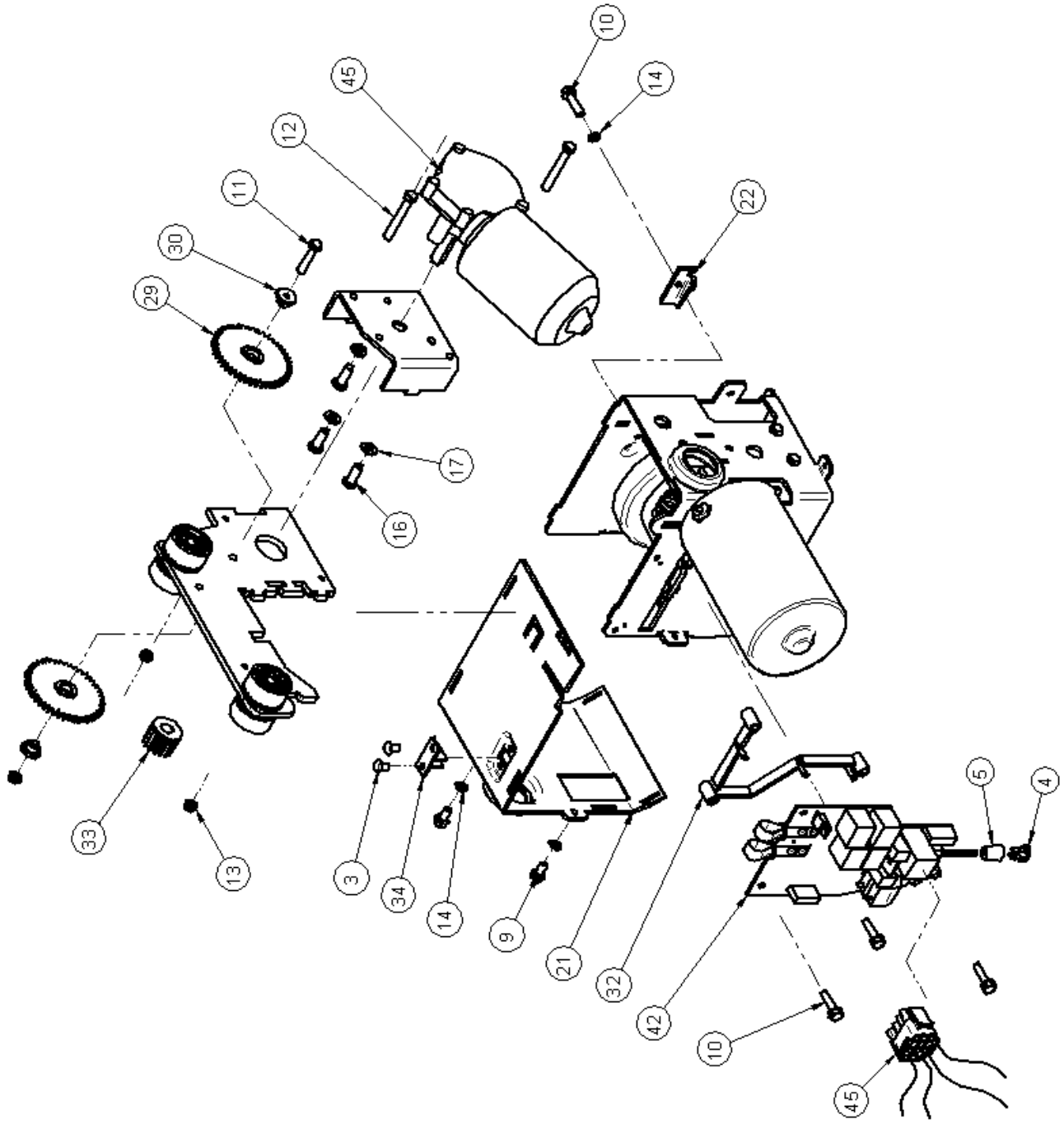
1. X-Y layout in the ICU
2. in a physical therapy facility
3. down the hallway for gait training
4. branched layout with track exchanger
5. private room installation
6. in a semi-private room

BHM MÉDICAL INC.
2001 Tanguay St.
Magog, Quebec,
Canada J1X 5Y5
1-800-868-0441
Fax:(819) 868-2249
bhm-medical.com

Appendix 4.1.1 : V4 part list

EXPLODED VIEW OF PRODUCT AND PARTS LIST

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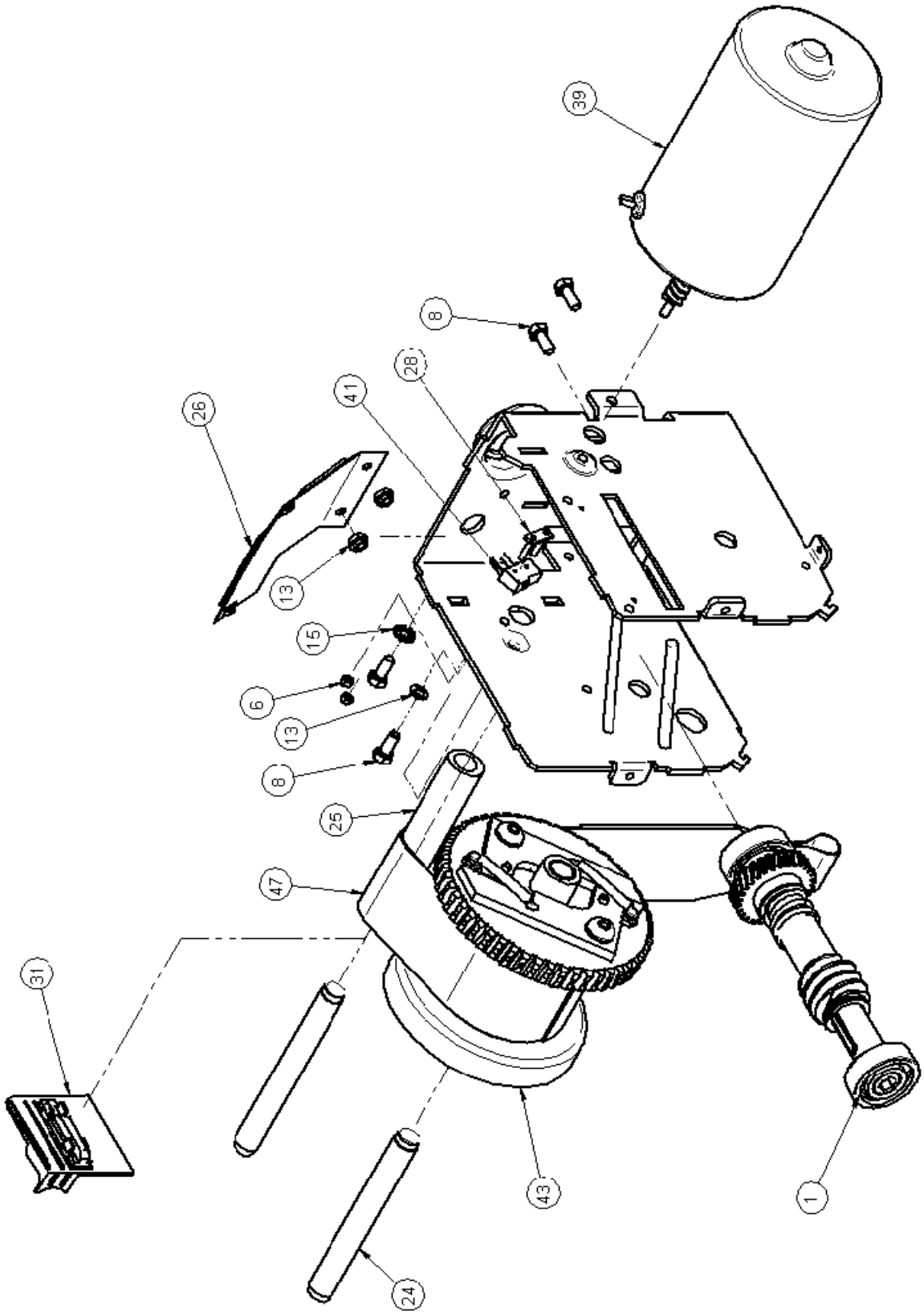
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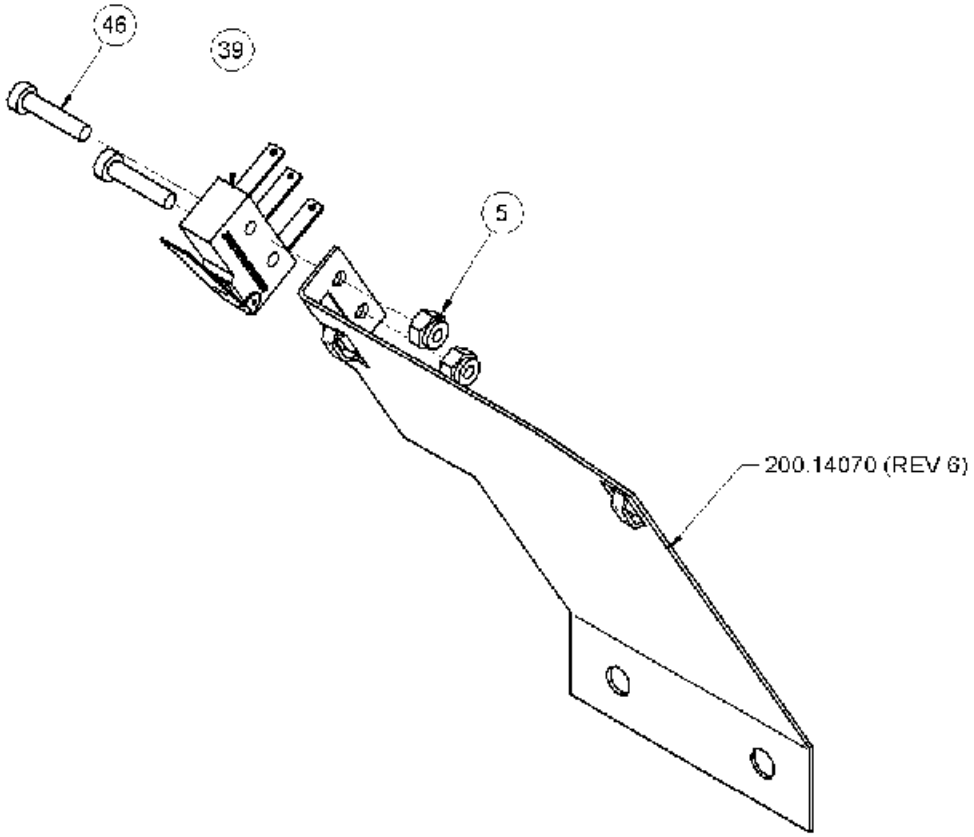


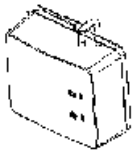
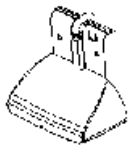
Item #	Part Number	*5.1.2.1 Description*	Qty
1	700.14100	SUB ASSY SHAFT V4	1
2	000.00635	TAP SCREW M4.2 x 9.5	4
3	000.00890	ALUM RIVET 3/16 0-1/8	2
4	000.01370	CORD END “INSERT”	1
5	000.01375	CORD END “SHEATH”	1
6	000.01970	LOCK NUT M2.5	2
7	000.02480	TAP PLASTIC SCREW 4.0 X 12	8
8	000.02550	SCREW M5 X 12 HEX ZINC	4
9	000.02562	SCREW M5 X 10 TAPTITE	2
10	000.02590	SCREW M5 X 20 TAPTITE	4
11	000.02610	SCREW M5 X 25 HEX ZINC	1
12	000.02655	SCREW M5 X 40 HEX ZINC	2
13	000.02800	LOCKNUT M5	5
14	000.02900	LOCKWASHER M5	4
15	000.02915	STARWASHER M5	1
16	000.03105	SCREW M6 X 16 ZINC STUD	3
17	000.03420	LOCKWASHER M6	3
18	000.03950	O-RING 8MM – 2MM CORE	1
19	000.03975	ALLEN KEY 8MM SHORT	1

Item #	Part Number	*5.1.2.1 Description*	Qty
20	200.14000	FRAME “U” SHAPE	1
21	200.14010	FRAME “TOP” PART	1
22	200.14030	LOCK TROLLEY	1
23	200.14040	LR MOTOR PLATE	1
24	200.14050	SHAFT 12MM	2
25	200.14060	STRAP GUIDE ROLL	1
26	200.14070	HIGH LIMIT PLATE	1
27	200.14080	BATTERY SUPPORT	2
28	200.14090	LIMIT SWITCH SUPPORT	1
29	200.14210	GEAR (46 TOOTH)	2
30	200.14220	BUSHING IDLER	2
31	200.14230	CBLM BLOCK PLATE	1
32	200.14240	MAIN PCB SUPPORT	1
33	200.14250	LR MOTOR GEAR	1
34	200.14260	V4 – SSRS *ENABLER*	1
35	200.14500	"UPPER SHELL " STEEL-BLUE	1
36	200.14510	"MAIN SHELL "	1
37	200.14520	STEEL-BLUE PANEL	1
38	200.14530	"TOOL DOOR"	1
39	400.14000	VERTICAL MOTOR	1
40	403.10500	BATTERY12V 5Ah	2
41	460.00005	SWITCH DB2 TERMINAL 0.110	1
42	492.00035-1	MAIN CIRCUIT BOARD	1
43	700.13300	DRUM SUB ASSY	1
44	700.14020	TROLLEY SUB ASSY	1
45	E0006	MOTOR	1
46	000.01960	SCREW M2.5 X 12 ZINC	2
47	362.14000	V4 – BLACK STRAP	1

Appendix 4.1.3 a): Accessories

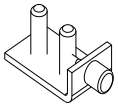
ACCESSOIRES

CLIP ON CHARGER AND CHARGING STATION
Product No 700.15500

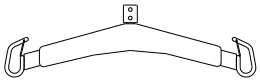



RAIL STOPPER

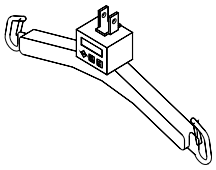
Product No 700.05430



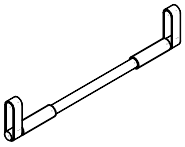
SPREADER BAR
Product No 700.05490



ERGOSCALE - WEIGHING DEVICE
Product No 700.14800

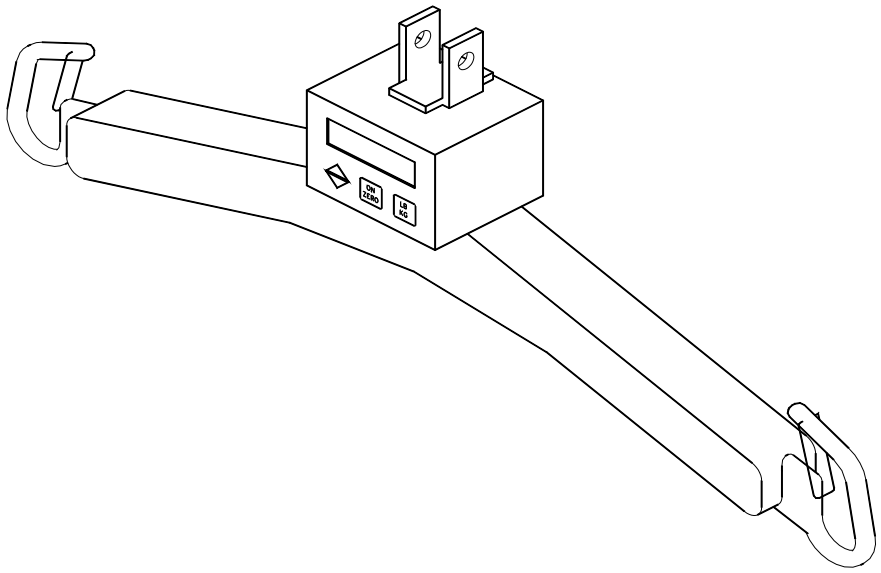


TRAPEZE BAR
Product No A5700



HAND CONTROL FOR V4
6 buttons - Product No 700.13650

THE ERGOSCALE



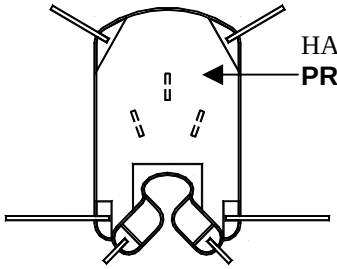
The Ergoscale is a compact precision scale system designed specifically for use with BHM's patient lifts. Completely self-contained, the Ergoscale combines the latest in precision strain gauge technology and microprocessor signal conditioning to provide stable, accurate and repeatable weight data.

One button Auto-Zero Electronics makes patient weighing quick and easy.

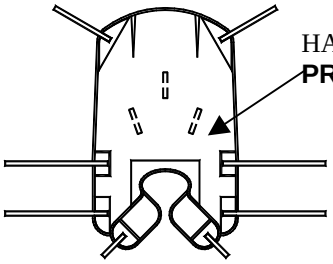
TECHNICAL SPECIFICATIONS	
Weight range	350 kg (770 lbs.)
Display resolution	0.2 kg (0.5 lbs.)
Accuracy	±1.0%
Display type	Liquid crystal with 0.60" high characters
Size	95 mm (3.75") x 70 mm (2.75") x 80 m (3.15")
Weight	0.6 kg (1.3 lbs)
Power Supply	9 volts standard battery
Batteries Life	App. 3000 readings
Modes	Kg or lbs
Enclosure	Powder coated stainless steel

Appendix 4.1.3 b): Slings

THE HAMMOCK SLING



HAMMOCK
PRODUCT #
THA-S
THA-M
THA-L



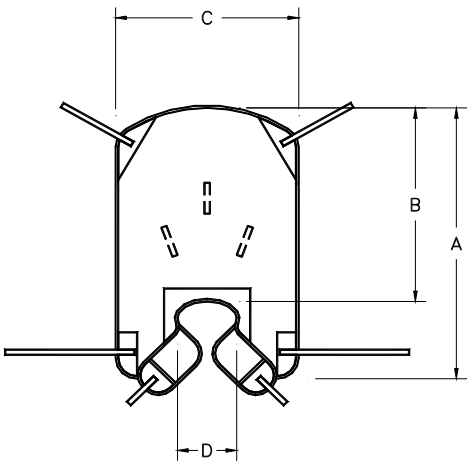
HAMMOCK 6
PRODUCT #THA6-S
THA6-M
THA6-L

THE HAMMOCK SLING IS IDEAL FOR MOST TRANSFERS; WHICH CORRESPONDS TO THE NEED OF ABOUT 80% OF ALL PATIENTS. THE HAMMOCK 6 HAS SIDE STRAPS FOR ADDED SECURITY AND TIGHTENED HEAD SUPPORT AREA. BOTH HAMMOCK SLINGS ARE EXCELLENT FOR BATHING.

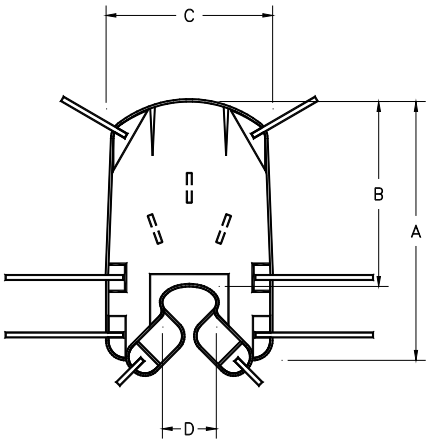
Our most universal sling, the Hammock sling, is a mesh type material that dries quickly but is soft and pliable. The sling has an incorporated head support and a unique strap system that keeps the patient secure in the sling. A special polyester fabric in the seat area helps to reduce friction and makes the sling easy to place around a patient in a chair without lifting or remove the patient. The patient may be transferred in a seated, semi-reclined or fully reclined position. Best choice for most situations – including bathing. Fits all BHM ceiling lift models as well as the Ergolift Mobile Lift. Available in sizes S, M & L. Weight capacity is 250 kg (550 lbs.)

Almost identical to the Hammock sling above, this sling provides extra security and a tighter fit for patients who are low-tone or who would prefer a more secure feeling. The head support is tighter and the extra straps on the side provide more lateral support. The patient may be transferred in a seated, semi-reclined or fully reclined position. Fits all BHM ceiling lift models as well as the Ergolift mobile lift. Available in sizes S, M & L. Weight capacity is 250 kg (550 lbs.).

SLING DIMENSIONS



HAMMOCK
PRODUCT #THA



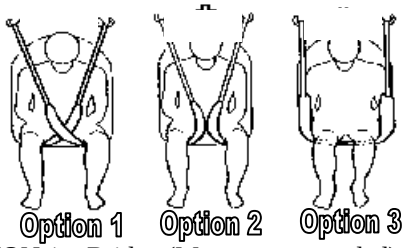
HAMMOCK 6
PRODUIT #THA6

SIZE	A (CM/IN)	B (CM/IN)	C (CM/IN)	D (CM/IN)
HAMMOCK SMALL	106.68/42	76.2/30	66.04/26	22.86/9
HAMMOCK 6 SMALL	106.68/42	76.2/30	66.04/26	22.86/9
HAMMOCK MEDIUM	124.46/49	93.98/37	86.36/34	27.94/11
HAMMOCK 6 MEDIUM	124.46/49	93.98/37	86.36/34	27.94/11
HAMMOCK LARGE	144.78/57	106.68/42	96.52/38	27.94/11
HAMMOCK 6 LARGE	144.78/57	106.68/42	96.52/38	27.94.11

SLING SIZES AND PRODUCT NUMBERS:

	SMALL	**MEDIUM**	**LARGE**
Approximate weight:	20-46 kg (45-100 lbs.)	46-95 kg (100-210 lbs.)	95-250 kg (210-550 lbs.)
Approximate height:	120-150 cm (4'-4'11"')	151-180 cm (5'-5'11")	181 cm + (6' +)
Colour Code	Red	Yellow	Green
Hammock Product #	THA-S	THA-M	THA-L
Hammock 6Product #	THA6-S	THA6-M	THA6-L

Sling Attachment Options



OPTION 1 – Bridge (Most recommended)

OPTION 2 – Leg Separation

Using this method of sling placement will pull the patient's legs apart. Check with the patient's physician, nurse or medical specialist before attempting this method.

OPTION 3 – Amputee

Do not use this method of sling placement for a patient who is agitated or spastic.

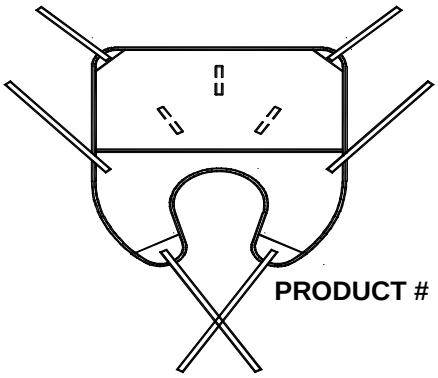
Sling attachment to Carry Bar

Sling position		
		
	BLACK	BLUE
	GREY	BLUE
	BLUE	BLUE
	BLUE	GREY

Always use the same colour loop on the rear shoulder straps for both sides of the sling.
Use the same colour loop on the leg straps for both sides of the sling.
Use the same colour loop on the hip straps for both sides of the Hammock 6-strap sling.

CHARACTERISTICS	BENEFITS
➢ Soft Polyester/Nylon net	+ Specially designed fabric is ultra-soft and long lasting / dries quickly – excellent for bath transfers / gently "hugs " the patient / fabric is easy to move – easy to install in bed.
➢ Ultra smooth Polyester leg area	+ Easy to install on a seated patient / patient never has to sit on the sling / slides without irritation to the patient's skin.
➢ Strong Nylon straps with positioning loops	+ Patient can be seated, semi-reclined and fully reclined / provides flexibility for many types of patients.
➢ Weight-distribution inserts	+ Distributes the weight evenly throughout the sling / no pinching or pressure points.
➢ Special Leg Strap design	+ Ensures the security of the patient / extremely mobile patients cannot fall out / leg can be positioned.
➢ Head Support	+ Excellent for most general transfers – suitable for 80% of patients / ensures that the patient is fully supported.
➢ Positioning Handles	+ Patient can be transferred to any position from any position / positions patient properly in the chair – no second adjustment needed / transferring from lying position to seated position fast and easy / provides a safe place for caregiver to turn the patient.
➢ 550 lbs lifting capacity	+ Very strong and durable / ensures patient safety.
➢ Single Solid Piece Construction	+ No skin irritation from seams / increases sling strength and safety
➢ Machine washable	+ Easy to clean and care for.
➢ S, M, L Sizes	+ Medium fits most patients/small sizes fit most paediatric patients / large fits tall patients.
Hammock 6 Strap additional features	
➢ Additional straps at the hip	+ Provides a more secure feeling for the patient / prevent low-tone patients from leaning to the side.
➢ Tightened Head Support	+ Provides additional support for the head/sling gently support more of the upper body.

THE QUICK-FIT SLING



THE QUICK-FIT SLIG IS PERFECTLY SUITED FOR STOCKY OR OBESE PATIENTS WITH LARGE HIPS OR THIGHS. USED FOR GENERAL TRANSFERS.

PRODUCT # TIR-S
TIR-M
TIR-L

Specially designed for patients who are stocky or obese, especially in the midsection. Padding around the buttock and leg area helps to provide extra support. Upper portion of the sling is a mesh type material that dries quickly but is soft and pliable. This sling does not provide head support. The patient may be lifted in a seated, semi-reclined or fully reclined position. Fits all BHM ceiling lift models as well as the Ergolift mobile lift. Available in sizes S, M & L. Weight capacity is 250 kg (550 lbs.)

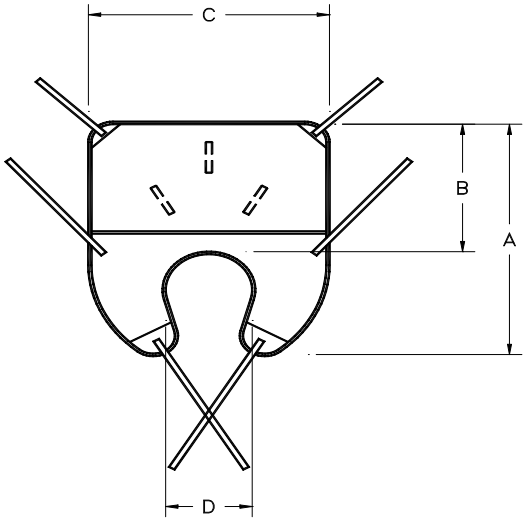
Do not use the Quick-Fit sling on a patient who cannot support his or her own head.

SLING SIZES AND PRODUCT NUMBERS:

	SMALL	MEDIUM	LARGE
Approximate weight:	20-46 kg (45-100 lbs.)	46-95 kg (100-210 lbs.)	95-250 kg (210-550 lbs.)
Approximate height:	120-150 cm (4'-4'11"')	151-180 cm (5'-5'11")	181 cm + (6' +)
Colour Code	Red	Yellow	Green
Quick-fit	TIR-S	TIR-M	TIR-L

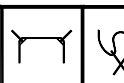
SLING DIMENSIONS

QUICK-FIT SLING PRODUCT #TIR



SIZE	A (CM/IN)	B (CM/IN)	C (CM/IN)	D (CM/IN)
SMALL	101.6/40	55.88/22	88.9/35	30.48/12
MEDIUM	116.84/46	66.04/26	99.06/39	35.56/14
LARGE	127.0/50	71.12/28	109.22/43	35.56/14

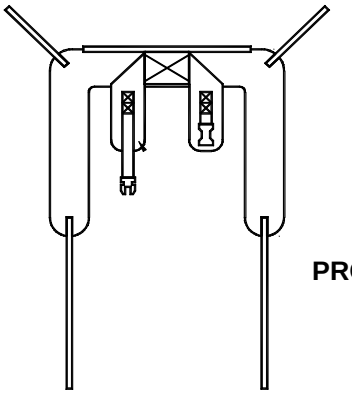
Sling attachment to Carry Bar

Sling position		
		
	BLACK	BLUE
	GREY	BLUE
	BLUE	BLUE

Always use the same colour loop on the rear shoulder straps for both sides of the sling.
Use the same colour loop on the hip straps for both sides of the sling.

CHARACTERISTICS	BENEFITS
➢ Soft Polyester / Nylon net upper	+ Specially designed fabric is ultra-soft and long lasting / gently "hugs" the patient / fabric is easy to move – easy to install in bed.
➢ Soft Padded leg area	+ Easy to install on a seated patient / patient never has to sit on the sling / slides without irritation to the patient's skin.
➢ Strong Nylon straps with positioning loops	+ Patient can be seated and semi-reclined / provides flexibility for many types of patients.
➢ Special Leg Strap Design	+ Ensures the security of the patient / legs can be positioned together, semi-open and open.
➢ Extra Sturdy	+ Excellent for obese and stocky patients / extra room for tights and hips / hip strap to support weight on the sides.
➢ Positioning Handles	+ Patient can be transferred to any position from any position / positions patient properly in the chair – no second adjustment needed / transferring from lying position to seated position is fast and easy / provides a safe place for caregiver to turn the patient.
➢ 550 lbs. Lifting capacity	+ Very strong and durable / ensures patient safety
➢ Machine washable	+ Easy to clean and care for.
➢ S, M, L Sizes	+ Medium fits most patients / small sizes fit most paediatric patients / large fits tall or very stocky patients.

THE HYGIENIC SLING



THE HYGIENIC SLING IS IDEAL FOR TRANSFERRING TO THE TOILET. IT ALSO PROVIDES AN EASY WAY TO CHANGE DIAPERS.

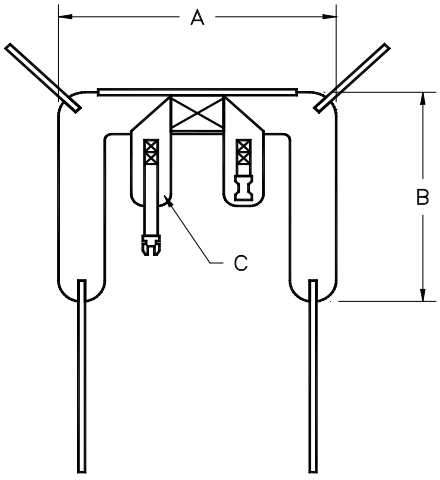
PRODUCT #THY-S
THY-M
THY-L

This sling is excellent for changing incontinence pads or to transfer onto a toilet as it provides an open area from the middle of the back to the middle of the thigh. The padding wraps around the patient's midsection and under each leg. In order to use this sling, the patient must have good muscle-tone in their shoulders and upper body. Fits all BHM ceiling lift models as well as the Ergolift mobile lift and Ergostand stand-assist. Available in sizes S, M & L. Weight capacity is 250 kg (550 lbs.)

Do not use Hygienic sling on a patient who does not have good muscle-tone in their shoulders and neck. Check with the patient's physician, nurse or medical specialist before using this sling.

SLING DIMENSIONS

HYGIENIC SLING PRODUCT #THY

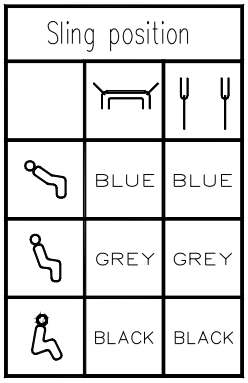


SIZE	A (CM/IN)	B (CM/IN)	C (CM/IN)
SMALL	96.52/38	83.82/33	88.9/35
MEDIUM	106.68/42	88.9/35	106.68/42
LARGE	116.84/46	93.98/37	124.46/49

SLING SIZES AND PRODUCT NUMBERS

	SMALL	MEDIUM	LARGE
CHEST SIZE	68-89 cm (27-35”)	89-107 cm (35-42”)	107-125 cm (42-49”)
PRODUCT #	THY-S	THY-M	THY-L
COLOR CODE	Red	Yellow	Green

Sling attachment to Carry Bar

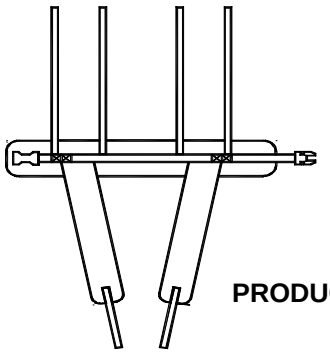


Always use the same colour loop on the shoulder straps for both sides of the sling.
Use the same colour loop on the leg straps for both sides of the sling.

CHARACTERISTICS	BENEFITS
➢ Open area from above waist to thighs.	+ Excellent for toileting / easy access to pants, diapers or for cleaning / sling supports from both the upper body and lower body.
➢ Padded and quilted Polyester Nylon	+ Specially designed fabric is ultra-soft and long lasting / provides extra comfort for the patient / fabric is easy to move.
➢ Padded waist band with belt	+ Easy to install on a seated patient / extra padding under the arms keeps the patient comfortable during the transfer / padding around entire waist reduce pressure.
➢ Strong Nylon straps with positioning loops	+ Patient can be seated forward, straight or semi-reclined and fully reclined / legs can be raised or lowered slightly / provides flexibility for many types of patients / excellent for ERGOSTAND lift.
➢ Special Leg Strap design	+ Leg straps are fully padded to reduce pressure / legs can be positioned together, semi-open and open.
➢ Positioning Handles	+ Patient can be transferred to any position from any position/positions patient properly in the chair – no second adjustment needed/transferring from lying position to seated position is fast and easy/provides a safe place for caregiver to turn the patient.
➢ 550 lbs. Lifting capacity	+ Very strong and durable/ensures patient safety.
➢ Machine washable	+ Easy to clean and care for
➢ S, M, L Sizes	+ Medium fits most patients / small sizes fit most paediatric patients large fits tall or very stocky patients.

***Patient must have muscle-tone in upper body to use this sling.**

THE WALKING SLING



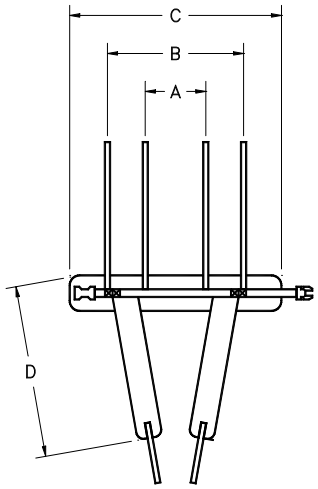
PRODUCT #TEM-S
TEM-M
TEM-L

THE WALKING SLING HELPS TO HOLD PATIENTS IN A STANDING POSITION. DURING WALKING EXERCISES, IT CAN PROVIDE COMPLETE OR PARTIAL SUPPORT.

Designed to assist people with limited ability to walk, this sling helps support and assist in rehabilitation. Fully padded with a security buckle, the sling is comfortable and simple to use. The user must have some weight bearing ability. Fits all BHM ceiling lift models as well as the Ergolift mobile lift. Available in sizes S, M & L. Weight capacity is 250 kg (550 lbs.)

Do not use the Walking sling on a patient who does not have weight bearing ability and good muscle-tone in their shoulders and neck.
Check with the patient's physician, nurse or medical specialist before using this sling.

SLING DIMENSIONS WALKING SLING PRODUCT#TEM



SIZE	A (CM/IN)	B (CM/IN)	C (CM/IN)
SMALL	25.4/10	50.8/20	73.66/29.7
MEDIUM	30.48/12	68.58/27	91.44/36
LARGE	30.48/12	86.36/34	111.76/44

SLING SIZES AND PRODUCT NUMBERS

	SMALL	MEDIUM	LARGE
CHEST SIZE	68-89 cm (27-35”)	89-107 cm (35-42”)	107-125 cm (42-49”)
PRODUCT #	TEM-S	TEM-M	TEM-L
COLOR CODE	Red	Yellow	Green

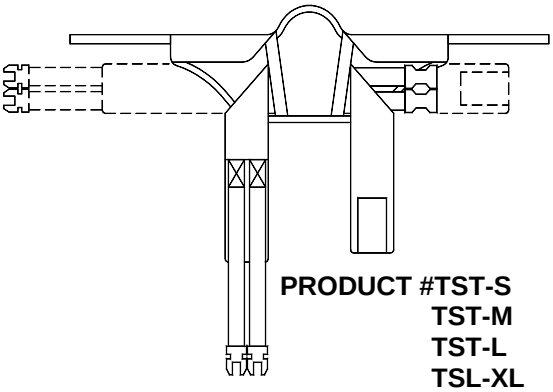
Sling attachment to Carry Bar

Sling position		
	FRONT	BACK
	SAME COLOR FOR ALL 4 STRAPS	
	BLUE	BLACK
	BLACK	BLUE

Always use the same colour loop on the rear shoulder straps for both sides of the sling.
Use the same colour loop on the chest straps for both sides of the sling.

CHARACTERISTICS	BENEFITS
➢ Waist band and leg straps	+ Excellent for rehab uses / narrow, padded strap support through the legs / enables patient to walk with the security of knowing they are fully supported.
➢ Padded and quilted Polyester/Nylon	+ Specially designed fabric is ultra-soft and long lasting / provides extra comfort for the patient/fabric is easy to move.
➢ Padded waist band with belt	+ Easy to install on a seated patient /m padding around entire waist reduces pressure.
➢ Strong Nylon straps with positioning loops	+ Patient can be positioned forward, straight or slightly backward / adjustable straps allow for patients with a large midsection / provides flexibility for many types of patients.
➢ Special Leg Strap design	+ Leg straps are fully padded to reduce pressure / straps are adjustable to patient size.
➢ 550 lbs listing capacity	+ Very strong and durable / ensure patient safety.
➢ Machine washable	+ Easy to clean and care for
➢ S, M, L Sizes	+ Medium fits most patients / small sizes fit most paediatric patients / large fits tall or very stocky patients

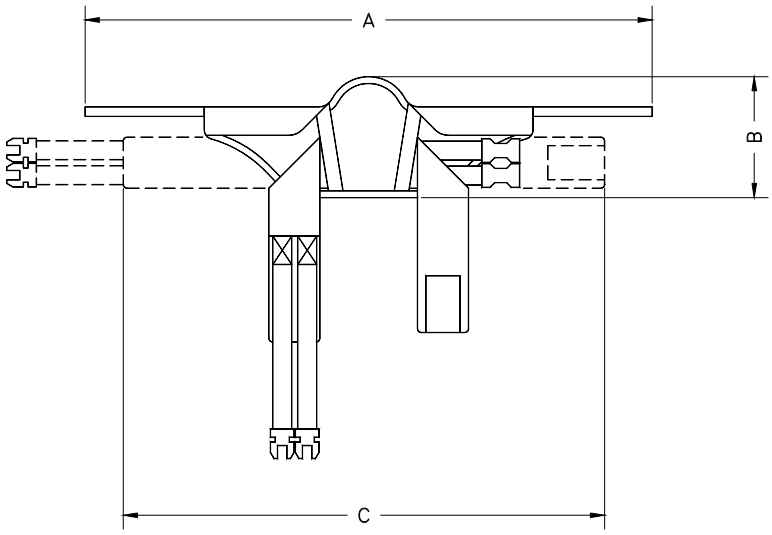
THE BAND SLING



PRODUCT #TST-S
TST-M
TST-L
TSL-XL

THE BAND SLING IS PERFECT FOR THE ERGOSTAND. IT HAS A VELCRO WAIST WITH 2 ADDITIONAL BELTS, BACK SUPPORTS AND ANTI-SLIP MATERIAL FOR THE BACK.

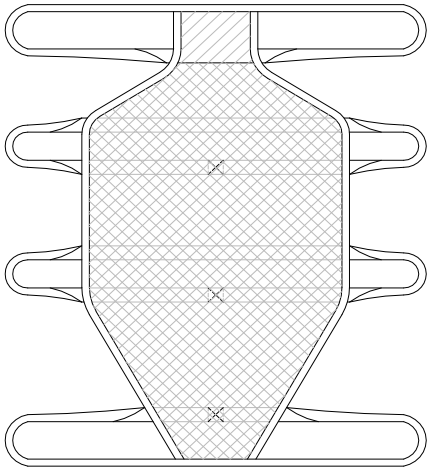
SLING DIMENSIONS BAND SLING PRODUCT#TST



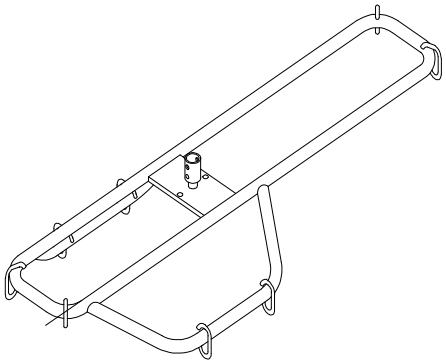
SIZE	A (CM/IN)	B (CM/IN)	C (CM/IN)
SMALL	149.86/59	28.96/11.4	107.95/42.5
MEDIUM	149.86/59	32.0/12.6	121.92/48
LARGE	157.99/62.2	35.05/13.8	144.78/57
X-LARGE	162.56/64	36.83/14.5	166.37/65.5

CHARACTERISTICS	BENEFITS
➢ Velcro & Double belted waist band	+ Use only with Ergostand / Velcro closure adjusts to size differences / double belted waistband secures patient in sling / enables patient to stand with the security of knowing they are fully supported / easy to install on a seated patient.
➢ Padded and quilted Polyester Nylon	+ Specially designed fabric is ultra-soft and long lasting / provides extra comfort for the patient/ fabric is easy to move.
➢ Extra padding under arms	+ Provides additional cushion for the patient / flexible and gentle.
➢ PVC netting	+ Sure-grip material keeps the sling in place/ soft material is gentle to skin.
➢ Back support strips	+ Distributes the weight evenly throughout the sling / covers a wide area of the back for support / reduces pressure under the arms.
➢ Strong nylon straps with positioning loops.	+ Adjustable straps allows for patients with a large midsection / provides flexibility for many types of patients.
➢ 400 lbs lifting capacity	+ Very strong and durable / ensure patient safety
➢ Machine washable	+ Easy to clean and care for.
➢ S, M, L, XL Sizes	+ Medium fits most patients / small sizes fit most paediatric patients / large fits tall or very stocky patient

THE SOFT STRETCHER SLING



Product #
Sling: TOC-L
TOC-M

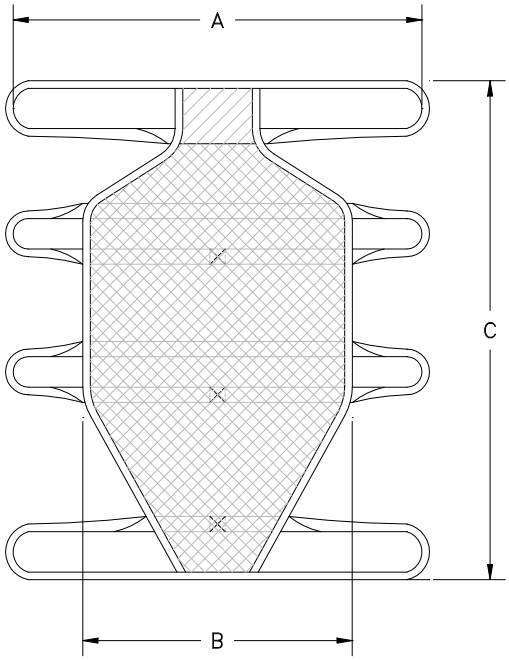


Frame: #A5515

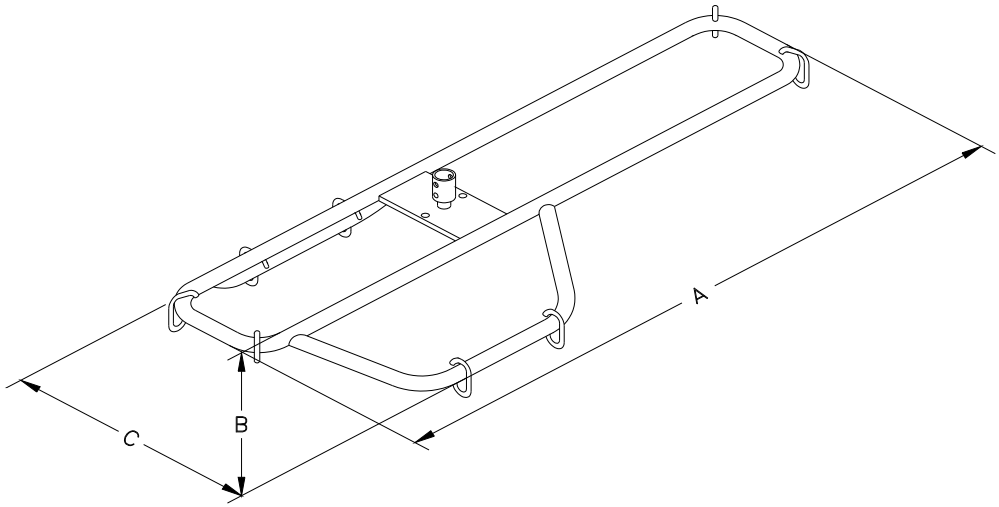
The soft stretcher sling was designed to make prone transfers simple and efficient. The sling itself is made from a polyester/nylon net material that is pliable breathable and easy to use. Eight sturdy straps support the length of the body and connect to specialized frame for the soft stretcher. Because the frame is attached to the lift and not the sling, it is faster and easier to install. The straps also ensure the patient safety by ensuring the person cannot fall out of the sling. Fits to Voyager Series ceiling lifts and the Ergolift mobile lift.

SLING DIMENSIONS

SOFT STRETCHER SLING PRODUCT #TOC



SOFT STRETCHER FRAME PRODUCT #A5515



SIZE	A (CM/IN)	B (CM/IN)	C (CM/IN)
MEDIUM	140/55.1	49/19.3	136/53.5
LARGE	140/55.1	89/35	164/64.6
FRAME	120/47	20/8	63/25

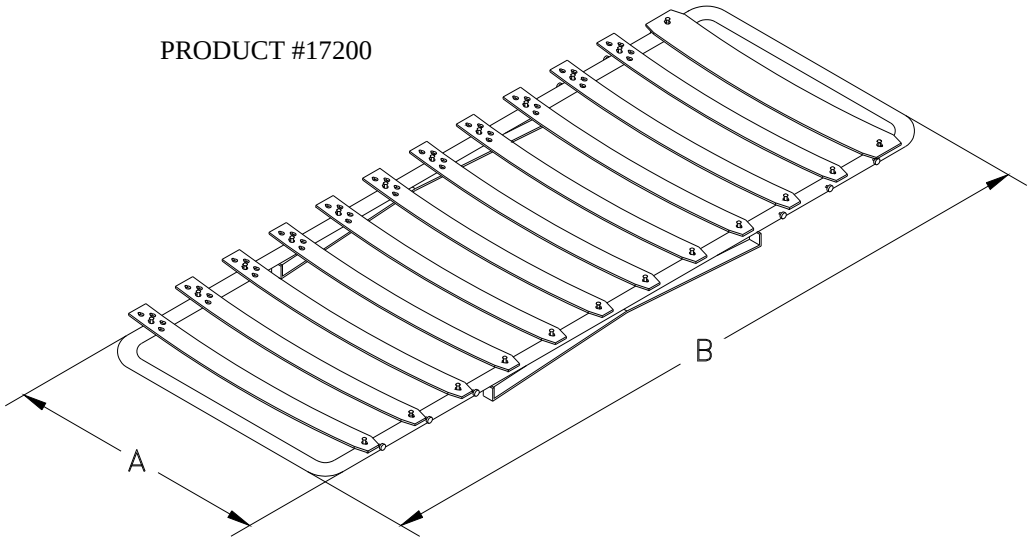
CHARACTERISTICS	BENEFITS
➢ Soft Polyester/Nylon net	+ Specially designed fabric is ultra-soft and long lasting / dries quickly – excellent for bath transfers / gently "hugs" the patient / fabric is easy to move – easy to install in bed.
➢ Strong Nylon straps for support	+ Wide straps positioned at the head, shoulders, hips and legs to provide through support. / Aids in ensuring the patient is secure in the sling. / Allows for one-person transfer.
➢ Head Support	+ Two straps support the head to ensure the patient is comfortable and safe. Excellent for most supine transfers – suitable for 80% of patients / ensures that the patient is fully supported.
➢ White powder coated steel frame	+ Strong and durable – powder coat resist rust.
➢ Frame attached to lift	+ Easy to place sling around patient and attach to frame / Frame need to be stored away from the lift.
➢ 550 lbs. Lifting capacity	+ Very strong and durable / ensures patient safety.
➢ Single Solid Piece Construction	+ Reduces skin irritation from seams/ increases sling strength and safety.
➢ Machine washable	+ Easy to clean and care for
➢ M & L Sizes	+ Medium fits most patients / large fits broad patients

FRAMED SLAT STRETCHER

The frame slat stretcher is ideal for prone position transfers where the person should bot are disturbed during manual or lifter transfers. The frame can be assembled around and injured or immobilized patient. The patient is supported by a series of semi-rigid cross support slats which are individually inserted beneath the patient's limbs and body. Ideal for spinal or postoperative orthopaedic care. Can be used with both the Voyager Series and the Ergolift Mobile Floor Lift.

SLING DIMENSIONS FRAME SLAT STRETCHER

PRODUCT #17200



SIZE	A (CM/IN)	B (CM/IN)
ONE SIZE	71/27.9	190/74.8

CHARACTERISTICS	BENEFITS
➢ Semi Rigid Cross Support Straps (Polypropylene)	+ Specially design to be easily inserted under patient.
	+ Can be used anywhere.
	+ Gliders can be fitted diagonally to avoid injured areas.
	+ Each slat is adjustable to allow for desired tension under patient.
	+ A glider can be left out for toileting or mound dressing.
➢ White powder coated steel frame	+ Can be assembled around injured or immobilized patient.
	+ Easy to use plastic locking clip makes assembly easy and secure
➢ 230 kg (500 lbs.) lifting capacity.	+ Very strong
➢ Sturdy nylon straps in positioning loops	+ The loops offer the flexibility of adjusting the frame to the required height.
	+ Great for high lifts manoeuvres example: bed to bed
➢ Versatile	+ Can be used in any situation from operative room, spinal or postoperative orthopaedic care to fallen injured patient – Clinical pathology.
➢ Sanitary	+ Easy to clean + disinfect

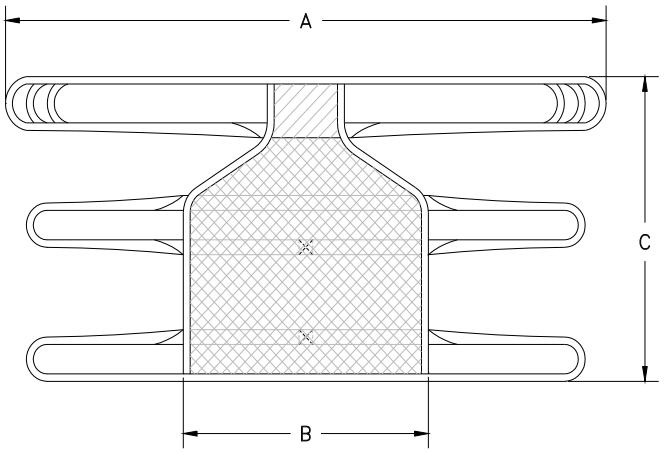
THE BED POSITIONING SLING

This sling is designed to reduce the risk of injury to caregivers by assisting with patient positioning and adjustments in bed. The sling is placed in bed as part of the bedding. The straps allow the caregiver to easily lift the patient just enough to reposition and lower. The polyester net material breathes easily while is soft to the touch. Loops on the straps near the head provide adjustment for head position. May also be used for lateral transfers. Fits all BHM ceiling lift models as well as Ergolift mobile list. One size only. Weight capacity 250 kg (550 lbs).

SLING DIMENSIONS

BED POSITIONING SLING PRODUCT#TPO

PRODUCT #
SLING : TPO



SIZE	A (CM/IN)	B (CM/IN)	C (CM/IN)
ONE SIZE	218/85	89/35	103/40

CHARACTERISTICS	BENEFITS
➢ Soft Polyester / Nylon net	+ Specially designed fabric is ultra-soft and long lasting / gently "hugs" the patient / fabric is easy to move – easy to install in bed.
➢ Strong Nylon straps with positioning loops	+ Patient position can be adjusted slightly depending on need / provides flexibility for comfort.
➢ Extra Sturdy	+ Excellent for heavy patients/extra room for thighs and hips.
➢ Positioning Handles	+ Positions patient properly in a chair – no manual positioning needed / provides a safe way for caregiver to turn the patient.
➢ White powder coated steel frame	+ Strong and durable / umbrella shape with 4 hooks provides ample room for the patient.

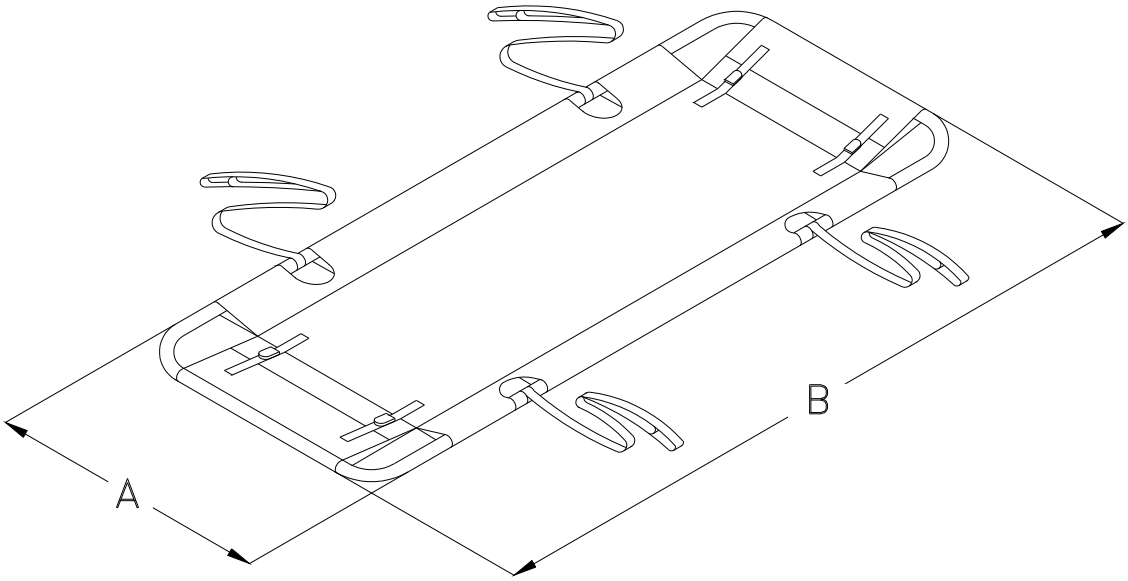
➢ 250 kg (550 lbs.) lifting capacity	+ Very strong and durable / ensures patient safety.
➢ Machine washable	+ Easy to clean and care for.
➢ One size	+ Fits 95% of patients.

THE UNIVERSAL STRETCHER

The Universal stretcher sling is specifically designed to transfer a person in a prone position. The sling is made of polyester / nylon, net material that is easy to manipulates and allows for air circulation. The frame can be assembled around the patient once the sling has been installed, which makes the installation faster and easier. The buckles at the headrest and footrest offer the flexibility to adjust to the patient's comfort level. Can be used with Voyager Portable, Voyager Series and the Ergolift Mobile Floor Lift.

SLING DIMENSIONS UNIVERSAL STRETCHER

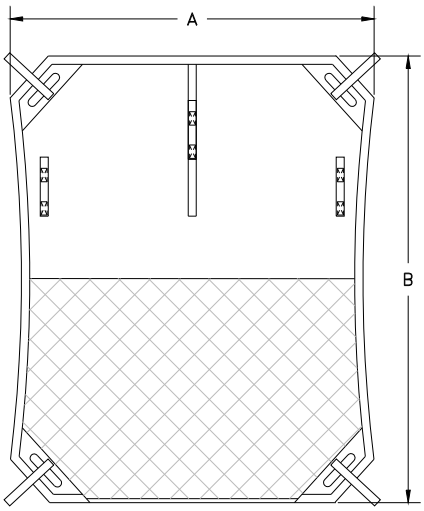
PRODUCT #A3500

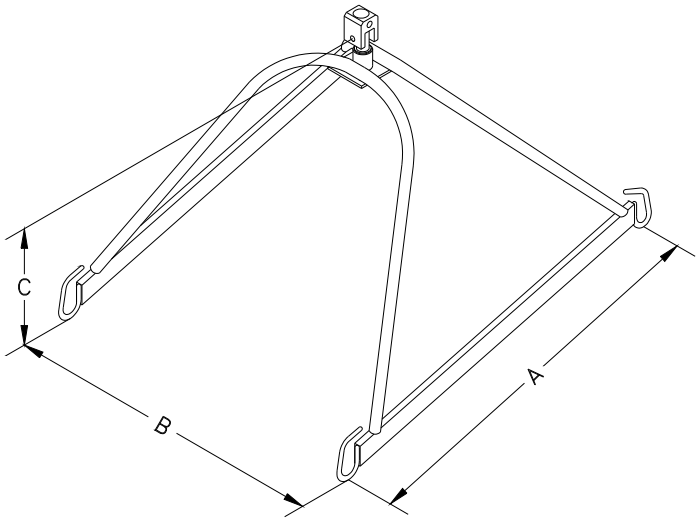


SIZE	A (CM/IN)	B (CM/IN)
ONE SIZE	73.6/29	190/74.8

CHARACTERISTICS	BENEFITS
➢ Soft polyester / nylon net	+ Specially designed fabric is ultra-soft / dries quickly fabric gently hugs the patients / fabric is easy to move.
	+ Easy to manipulate: easy to install
	+ Adjustable headrest and footrest.
➢ Stainless Steel Frame	+ Easily assembled around patient by slipping frame parts into loops of sling.
	+ Frame is rust resistant so can be submerged in water.
	+ Rust resistant.
➢ 240 kg (550 lbs.) lifting capacity	+ Very strong and durable /ensures patient safety.
➢ Machine washable	+ Easy to clean and care for.

THE ERGOFIT PLUS SLING





PRODUCT #

TOILE: TOB-HA

FRAME: PRODUCT #700.05550

Our truly bariatic size sling is designed for the special needs of a bariatric patient weighing from 182-455 kg (400 to 1000 lbs.). Polyester/nylon material moves easily to reduce friction on tender skin. The area around the legs and buttocks is padded, adding additional support and comfort. Positioning loops and handles allow you to adjust the position the person is transferred in as well as position the person properly into a chair. The Ergofit Plus sling is designed to be used only in conjunction with the Ergofit Plus 4-point frame. The frame fits all Voyager Series overhead ceiling lifts and the Ergolift mobile lift.

SLING DIMENSIONS

ERGOFIT PLUS SLING PRODUCT #TOB-HA
ERGOFIT PLUS FRAME PRODUCT #700.05550

SIZE	A (CM/IN)	B (CM/IN)	C (CM/IN)
SLING (ONE SIZE)	109.5/43	134/53	N/A
FRAME	66/26	63/25	49/19

CHARACTERISTICS	BENEFITS
➢ Soft Polyester/Nylon upper	+ Specially designed fabric is ultra-soft and long lasting / fabric is easy to move – easy to install in bed.
➢ Soft Padded leg area	+ Provides additional support and strength to the buttocks and leg area. / ¨Padding protects the tender skin.
➢ Strong Nylon straps with positioning loops	+ Patient position can be adjusted slightly depending on need / provides flexibility for comfort.
➢ Extra Sturdy	+ Excellent for heavy patients / extra room for thighs and hips.

➢ Positioning Handles	+ Positions patient properly in a chair – no manual positioning needed/ provides a safe way for caregiver turn the patient.
➢ White powder coated steel frame	+ Strong and durable / Umbrella shape with 4 hooks provides ample room for the patient.
➢ 455 kg (1000 lbs.) lifting capacity	+ Very strong and durable / ensures patient safety.
➢ Machine washable	+ Easy to clean and care for.
➢ One XXL Size	+ Fits most bar iatric patients

*TOB SLING MUST BE USED ONLY WITH SPECIAL CARRY BAR.

QUICK STEP STAND AID

Product # 96500

Sling :	SMALL	96600
	MEDIUM	96610
	LARGE	96620

Quick Step provides weight-bearing transfers for patients/residents with the Ergolift or Voyager ceiling lifts.

CHARACTERISTICS	BENEFITS
➢ Standing transfer	+ Encourages ongoing weight-bearing capability. + Provides resident/patient with increased participation. + *Patient/Resident must be assessed by a nurse or doctor as physically capable of using the Quick Step.
➢ Versatile	+ Easily attaches to the Ergolift, Voyager Portable or the Voyager Series lifts. + Simple to use. + Easier to access small rooms or tight areas.
➢ Lightweight 8 kg (18 lbs.)	+ Easy to move from room to room.
➢ 170 kg (374 lbs.) capacity	+ Easily transfers 95% of your patients.
➢ Cost efficient	+ Can be use with you standard ceiling or mobile lift. + Purchase of stand assist lift not necessary. + Reduces back injuries from pivot transfers.
➢ Thick knee pad	+ Comfortable for the patient. + Provides support for patients of all heights. + Removes for easy laundering.
➢ Padded arm bar	+ Patient has a secure grip to help himself or herself. + Encourages participation of the patient/resident.
➢ Specially designed polyester band sling	+ Easy clean and very comfortable, durable – lasts a long time. + Band sling covers 90% of patients. + Slings are quickly and easily installed and removed + Fastest and safest methods of transferring to a chair or toilet.
➢ Ergonomic easy to manoeuvre	+ Designed to pivot easily in tight spaces. + The caregiver can walk behind the lift easily no matter what height.

SLING SPECIFICATION

SLING SIZING

	SMALL	**MEDIUM**	**LARGE**
SUGGESTED WEIGHT	20 – 46 kg (45-100 lbs.)	46-95 kg (100-240 lbs.)	95-250 kg (240-550 lbs.)
SUGGESTED HEIGHT	120 – 150 cm (4’ – 4’ 11")	151-180 cm (5’ – 5’ 11")	181 cm + (6’)

PRODUCT NUMBERS

TYPE OF SLING						
	HAMMOCK	**HAMMOCK6**	**QUICKFIT**	**HYGIENIC**	**WALKING**	**BAND**
	THA-S	THA6-S	TIR-S	THY-S	TEM-S	TST-S
M	THA-M	THA6-M	TIR-M	THY-M	TEM-M	TST-M
L	THA-L	THA6-L	TIR-L	THY-L	TEM-L	TST-L
XL	-	-	-	-	-	TST-XL

SLING CARE

- Wash and dry at medium temperature (maximum 60^{o} Celsius)
- Use mild soap
- Do not bleach

SLING SPECIFICATIONS (SPECIAL)

SLING SIZING

	SMALL	**MEDIUM**	**LARGE**	**BARIATRIC**
SUGGESTED WEIGHT	20 – 46 kg (45-100 lbs.)	46-95 kg (100-240 lbs.)	95-250 kg (240-550 lbs.)	453 kg (1000 lbs.)
SUGGESTED HEIGHT	120 – 150 cm (4’ – 4’ 11")	151-180 cm (5’ – 5’ 11")	181 cm + (6’)	

PRODUCT NUMBERS

	TYPE OF SLING				
	STRETCHER	FRAME SLAT STRETCHER	REPOSITIONING SLING	UNIVERSAL STRETCHER	BARIATRIC SLING
S	-	-	-	-	-
M	TOC-M	ONE SIZE	ONE SIZE	ONE SIZE	-
L	TOC-L	-	-	-	ONE SIZE (XL)

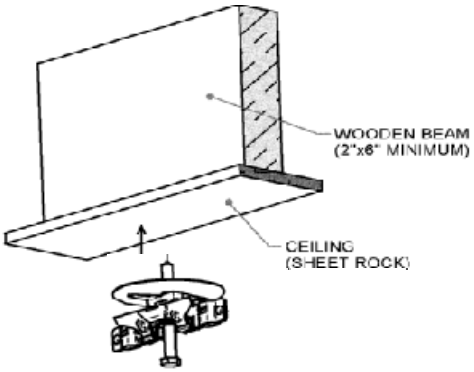
SLING CARE

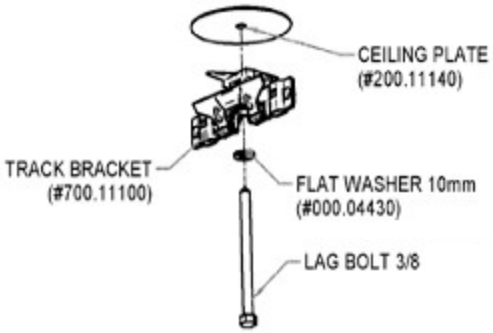
- Wash and dry at medium temperature (maximum 60^{o} Celsius)
- Use mild soap
- Do not bleach
- Do not dry clean

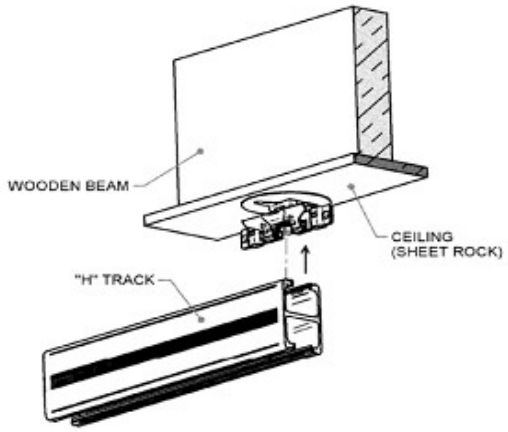
Appendix 4.1.3 c) KWIKtrak

For more information, consult the “Kwiktrak Installation Guide” of BHM Medical.

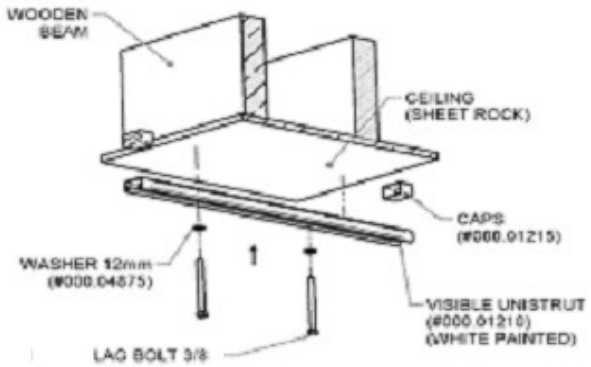
WOOD BEAM INSTALLATION (2 X 6”)

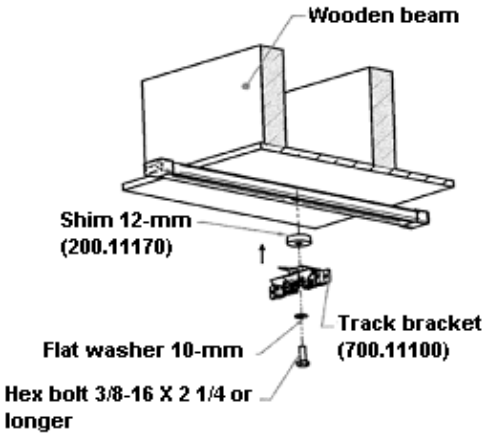


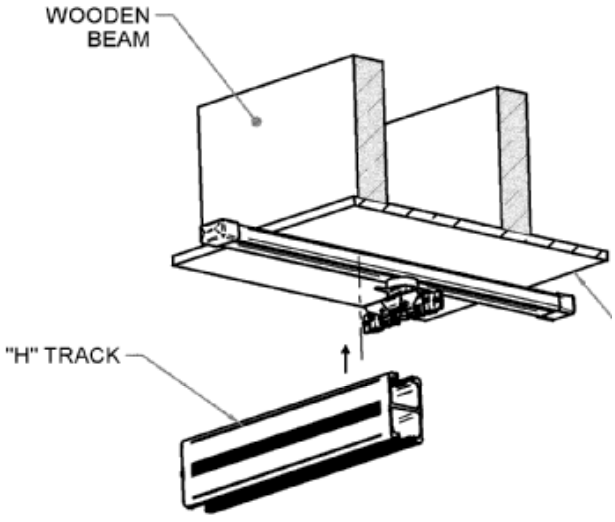




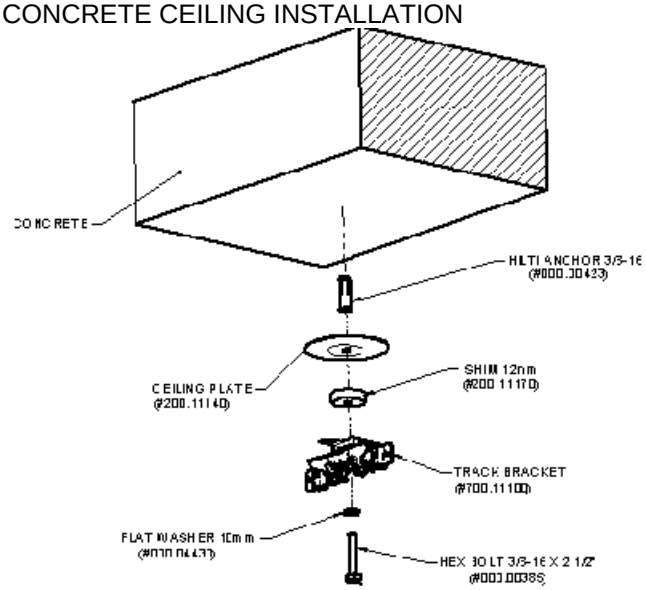
WOOD BEAM INSTALLATION (2 X 6”) - BETWEEN BEAMS



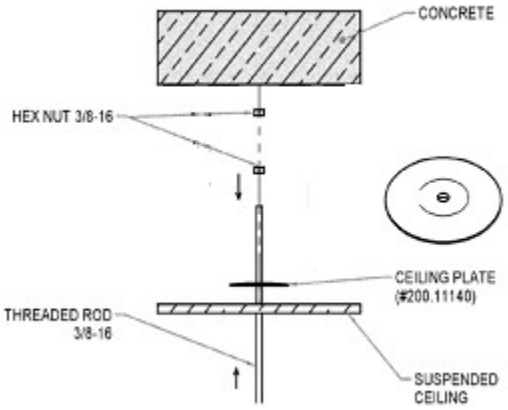




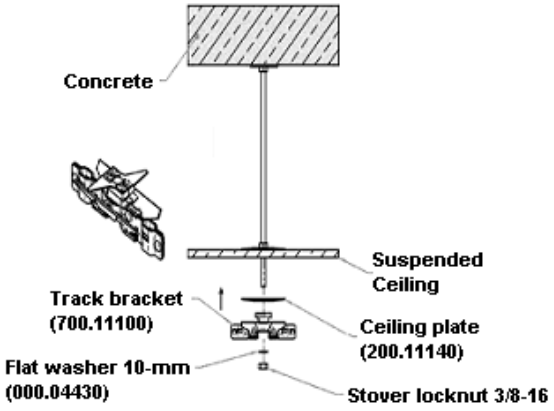
CONCRETE CEILING INSTALLATION

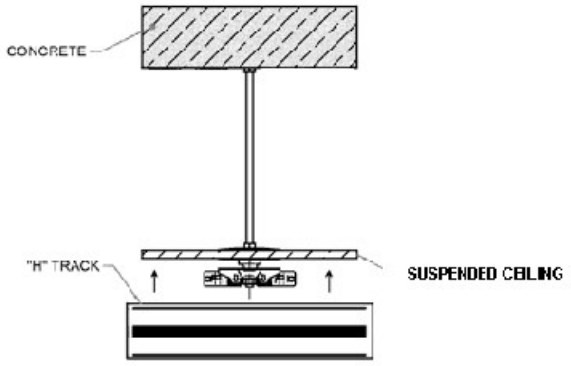


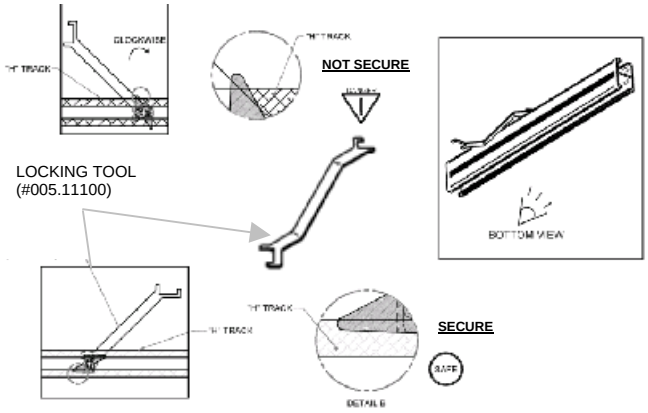
SUSPENDED CEILING WITH CONCRETE STRUCTURE



Insert a ceiling plate.
Install track brackets as shown on diagram below.



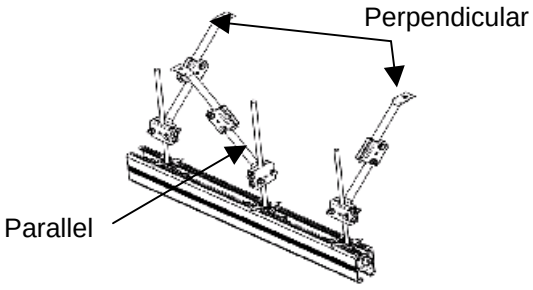


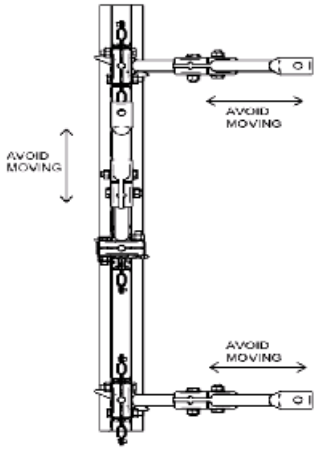


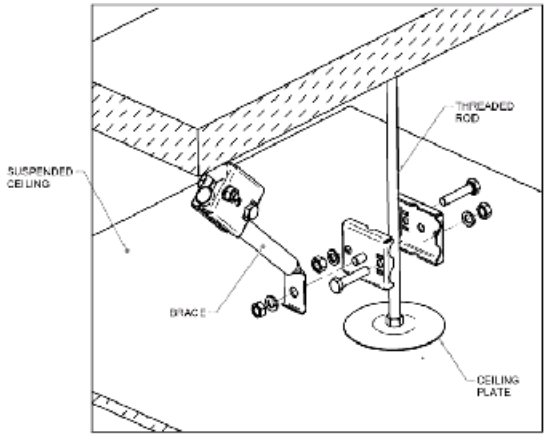
Make sure that brackets are properly locked. Check the strength of the installation.

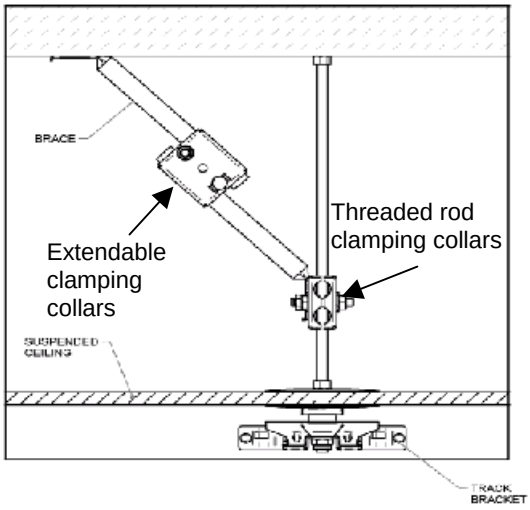
Lateral Brace (#700.11350) Installation

> We recommend the usage of lateral braces if the distance between the suspended ceiling and anchors are more than 18 inches.

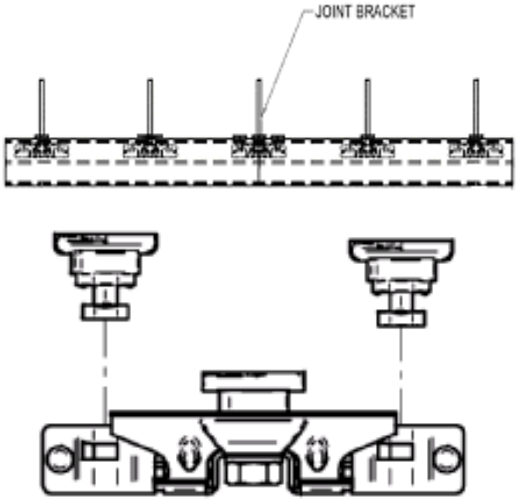








JOINT BETWEEN TWO TRACKS



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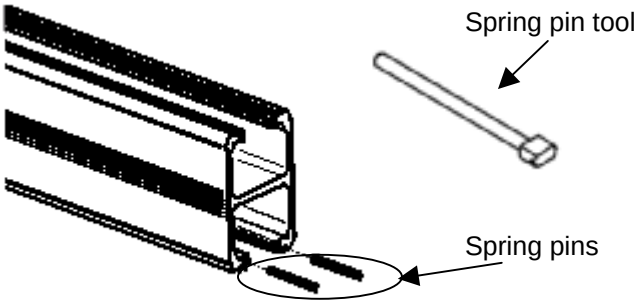
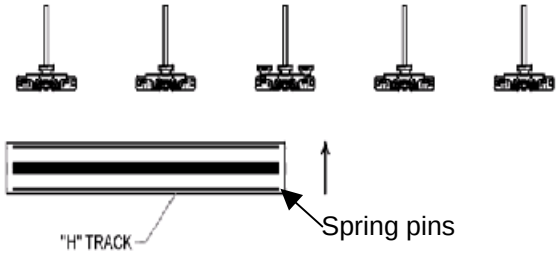
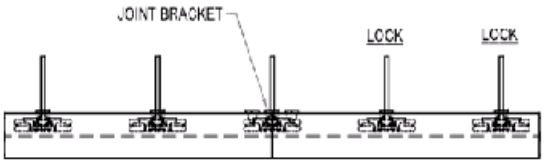
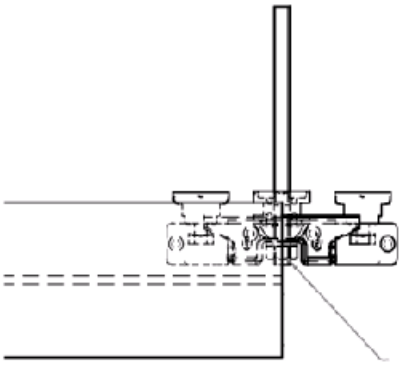
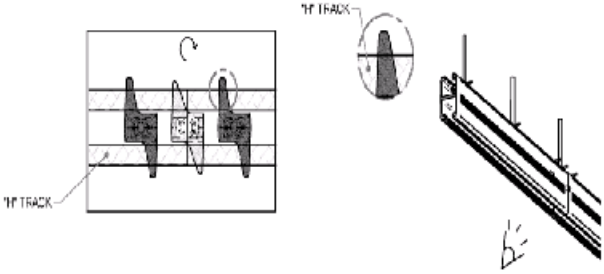


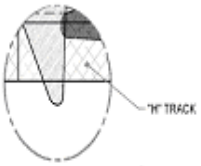


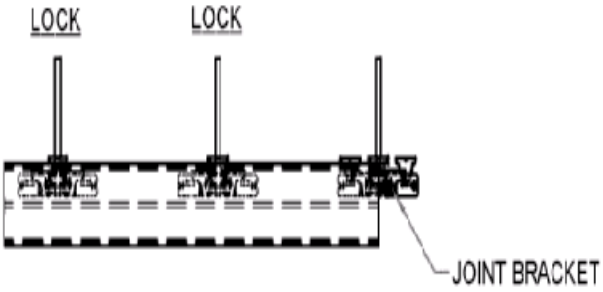


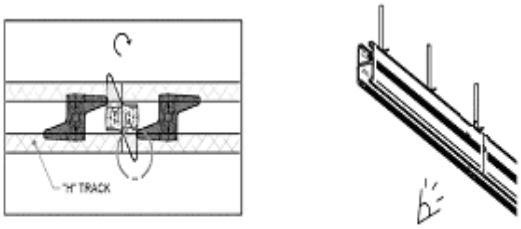


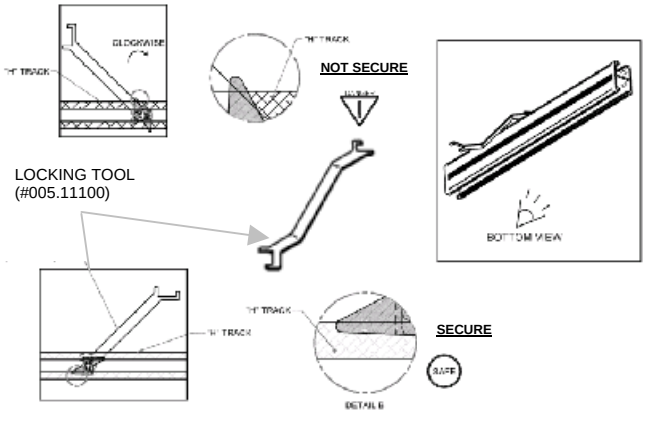
MIDDLE OF THE JOINT BRACKET



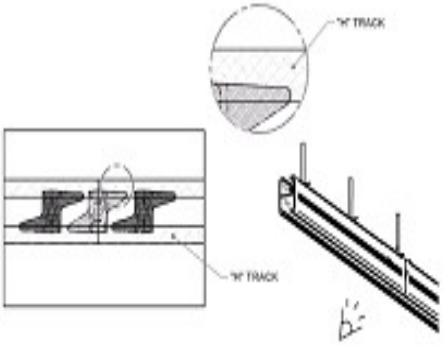


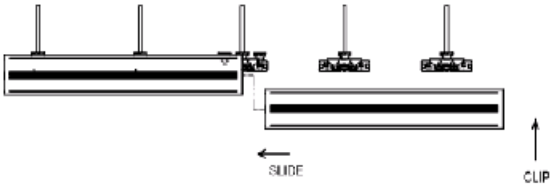


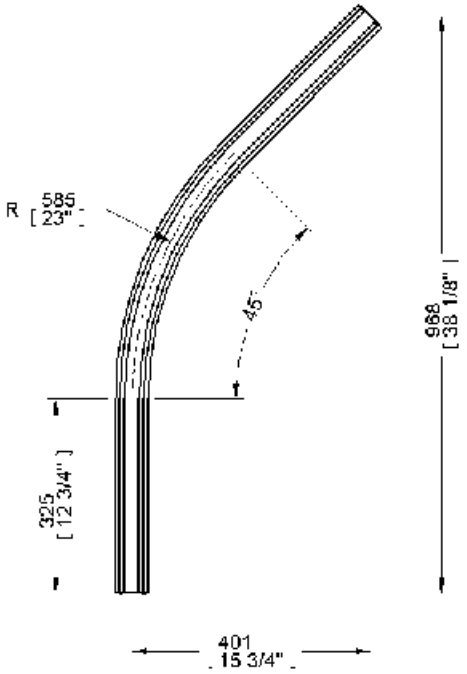




SECURE



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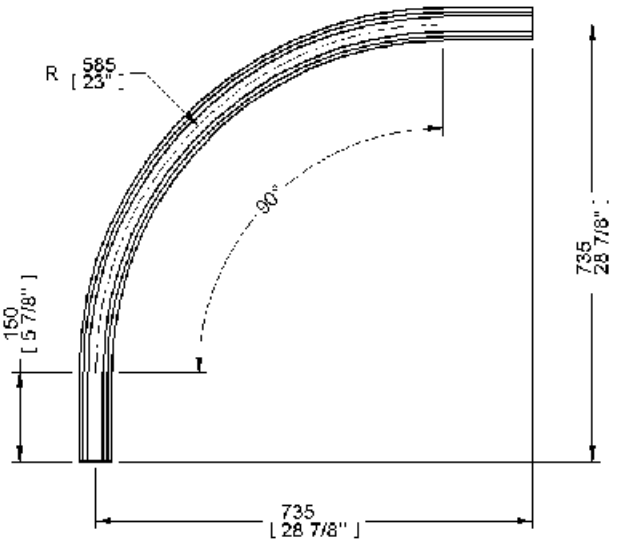
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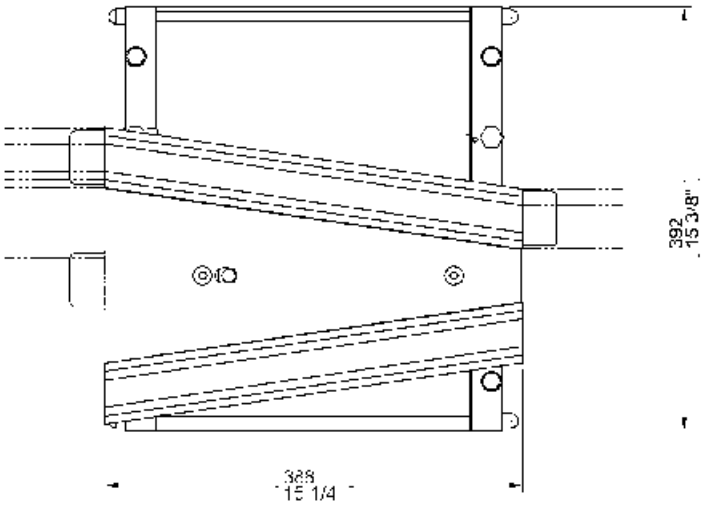
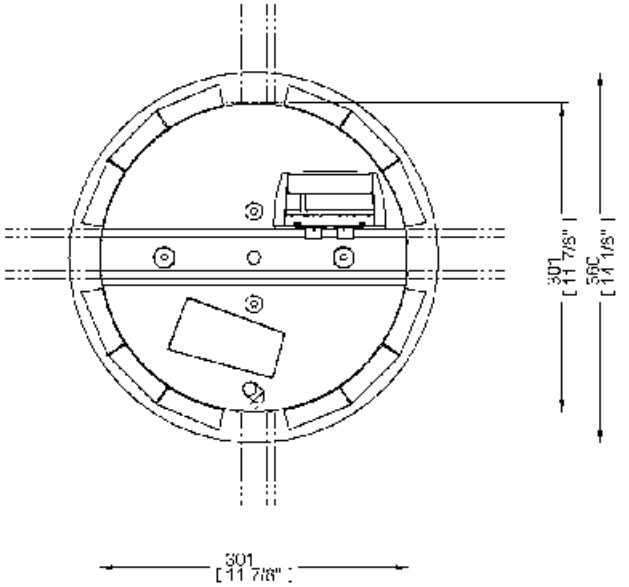


Exchanger



Turntable