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Compass Flex

Operator's Manual

The text of this manual was originally written, approved, and published by the manufacturer in English.

Made in the USA

L280-1185 REV A

Overview

This manual pertains to the specified devices only and does not intend to replace or substitute for certified training in the application of this equipment. The device is intended for qualified medical personnel who have been trained in the use of medical equipment.

Owner Responsibilities

The owner of this device is responsible to ensure system compatibility, the qualifications of the operator and maintenance personnel. The operator must be properly trained and have obtained credentials from the appropriate authorities.

This equipment must be installed in an area provided with the proper electrical power.

The owner of this device is responsible for verifying continued compliance with all applicable regulations and standards. Consult local, state, federal and/or international agencies regarding specific requirements and regulations applicable to the use of this equipment.

Image Diagnostics, Inc. certifies only the equipment. After-sale operating practices and safety are the responsibility of the owner and operator. Image Diagnostics, Inc. assumes no liability or responsibility for after-sale operating or safety practices; nor can it be responsible for personal injury or damage resulting from misuse.

Never make modifications or adjustments to the equipment unless directed by a qualified Image Diagnostics representative. This equipment, when properly assembled, meets US federal regulations and standards. Unauthorized modifications to the equipment may impact adherence to these standards and make the equipment unsafe to operate.

Customer Support

Image Diagnostics will make available, on request, circuit diagrams, component part lists, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable.

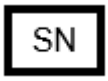
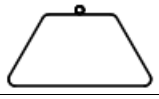
For technical assistance, call IDI at (978) 829-0009, and request service department. Be prepared to give the complete model and serial number found on the data plate on lower side of the monitor stand on the upper column assembly at the time of contact.

Image Diagnostics, Inc.
310 Authority Drive
Fitchburg, MA 01420 USA

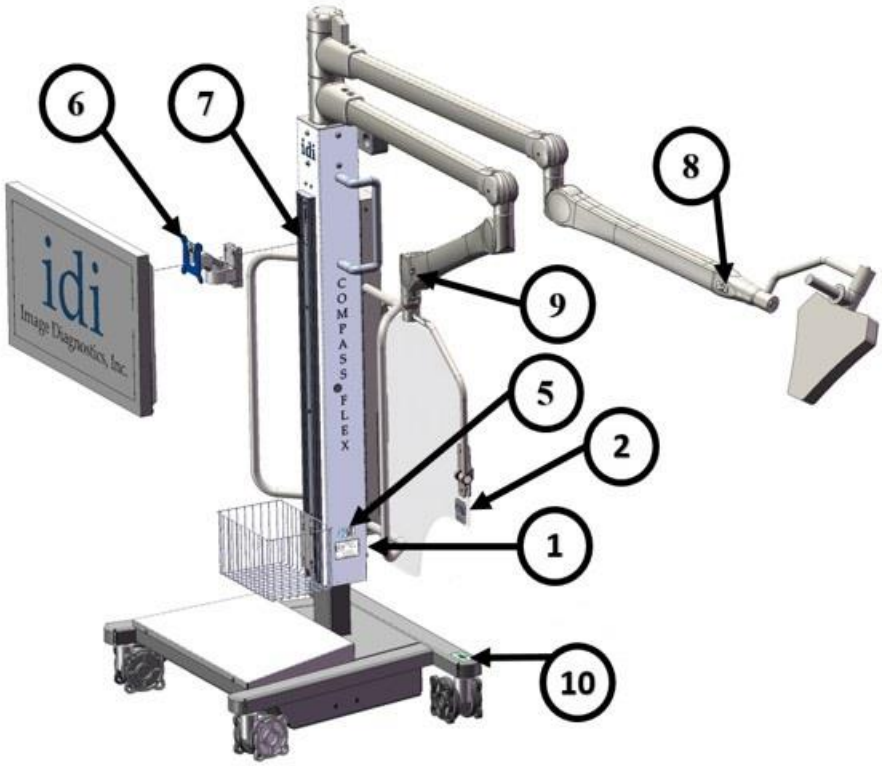
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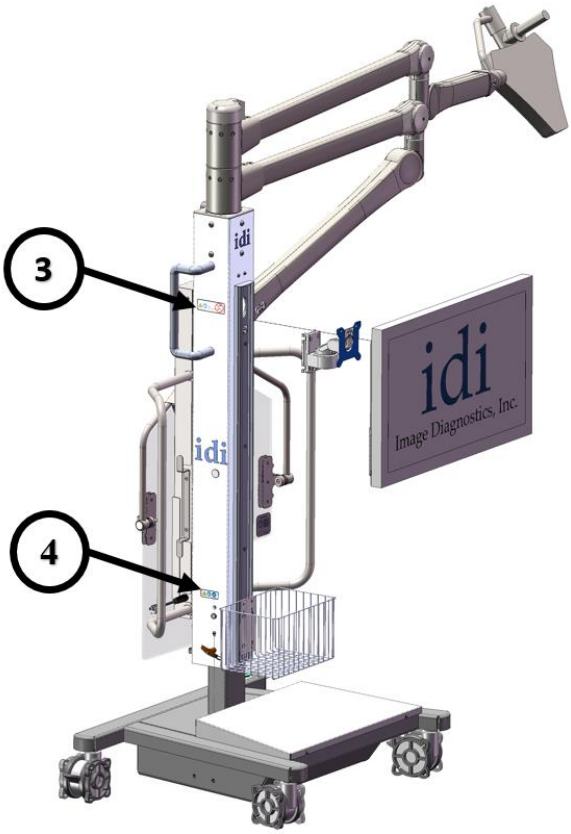
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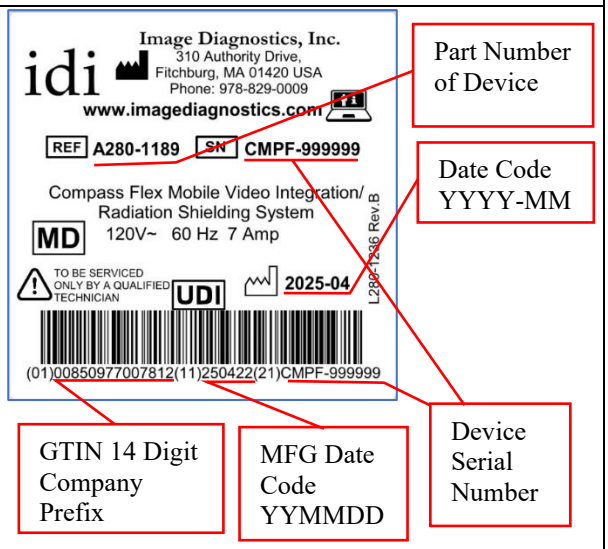
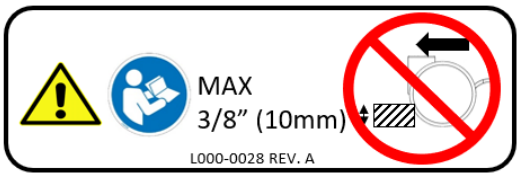
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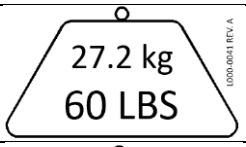
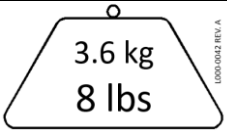
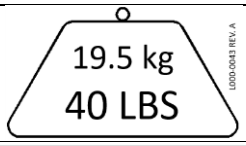
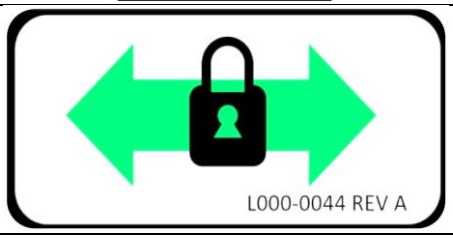
1. Symbol Identification	
	Attention! Consult accompanying documents. Failure to follow these instructions could cause serious personal injury or damage to equipment.
	Read the manual.
	Model of Compass Flex.
	Serial Number of Compass Flex.
	Date of manufacture of the device.
	Location where device was manufactured.
	Warning! Information or instructions shown near this symbol must be adhered to in order to prevent a potentially hazardous situation which if not avoided, could result in death, personal injury or damage to the equipment.
	Electric Shock hazard. Information or instructions shown near this symbol must be adhered to in order to prevent a potentially hazardous situation which if not avoided, could result in death, personal injury or damage to the equipment.
	Recyclable material, some material can be recycled rather than discarded.
	Maximum allowable Weight Limits.

2. Label Identification





Item No.	Part No.	Description	Qty.	Label
1	L280-1236	Serial Number Label with UDI Barcode	1	
2	L610-0224	Operator Manual QR code Scan with compatible device to view operator manual online. Will be linked to the current revision of the user manual.	1	
3	L000-0028	Warning Do not jump any steps or “Curbs” over 3/8” (10mm) in height with this equipment. Approach obstacles slowly. Operator must use a ramp to allow the casters to roll up and over the vertical edge.	1	
4	L000-0029	Connect to properly grounded hospital grade outlet. For safety and proper function of equipment, connect power cord to a properly grounded outlet.	1	
5	L000-0035	Operator Manual QR code Scan with compatible device to view operator manual online. Will be linked to the current revision of the user manual.	1	

6	L000-0040	Maximum load capacity for monitor. Do not exceed capacity. *Qty varies based on model	*0 *1 *2	
7	L000-0041	Weight Capacity of Front monitor rail	1	
8	L000-0042	Weight capacity of light head spring arm	1	
9	L000-0043	weight capacity of spring arm	1	
10	L000-0044	Steer lock Caster, caster identifier for steering device	1	

3. Intended Use

The intended use of the device is to provide a mobile device that houses a secondary video display, overhead light, and radiation shield for doctor. In most cases the device can be used by medical and hybrid professionals in various procedures, such as Vascular, Ortho, Trauma, Spine, GI, Urology, OBL Cath lab.

The Compass Flex is **NOT** intended to supply power to electrocautery equipment. The Compass Flex has not been tested in an oxygen rich environment and should **NOT** be used in such an environment. The Compass Flex has **NOT** been tested for use with HF surgical equipment, nor cardiac defibrillator. The Compass Flex device is **NOT** intended to contact patient; however, the compass shield may come in contact with the patient. When the radiation shield is being used, sterile drapes may be used depending on the hospital's operating procedures. Reference the Compass Radiation Shield's operator manual, L610-0220 for details.



Review the SAFETY HAZARDS and OPERATING INSTRUCTIONS before operating Compass Flex unit

4. Safety



- All persons using this equipment must fully understand its operation instructions, emergency procedures, capabilities, and be aware of all potential safety hazards.
- This manual should be accessible to all personnel installing, operating, or servicing this equipment.

- Only a qualified technician may install or service this equipment.



Failure to follow safety precautions may result in serious injury to patient or user or damage to equipment.

It is imperative that all personnel operating the Compass Flex be familiar with the equipment operation, transport and all documentation supplied by IDI.

- The Compass Flex is intended to be used in typical clinical or research environments in accordance with national standards.
- When transporting the Compass Flex from room to room, it is imperative that the device be moved in the transport position. Transport position is achieved by lowering the upper column assembly to its lowest point, inserting the safety pin and folding the spring arms and equipment into the column into their designated storage locations.
- When transporting Compass Flex, it is required that the device be moved by two personnel.
- To ensure proper grounding, a medical grade electrical outlet must be used to provide power to the monitor stand.
- The Compass Flex does not have any essential performance functions that pose a risk due to failure or degradation of the unit or any of its components.

Comments and questions regarding safety should be addressed to:

	Customer Support Image Diagnostics, Inc. 310 Authority Drive Fitchburg, MA 01420 USA		Or call IDI at (978) 829-0009

5. Safety Hazards

WARNING!
Do NOT jump any curbs or steps over 3/8" (10mm) in height with this equipment. Approach all obstacles slowly. Operator must use a ramp to allow the casters to roll up and over the vertical edge for over 3/8" (10mm).

WARNING!
It is the user's responsibility to make sure the equipment is safe and operates properly prior to use.

WARNING!
Do not modify this equipment without authorization of the manufacturer.

CAUTION!
Caution should be used when moving the system over uneven or sloped surfaces.

WARNING!
To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

WARNING!
Use caution when adjusting the height of the column. Verify no objects are under or above the monitor, light or shield when adjusting the column height.

EMC (Electromagnetic Compatibility) Statement

This equipment may generate and use radio frequency energy. The equipment must be installed and used according to this manual in order to avoid radio frequency interference.

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment including the Compass Flex. Use special precautions regarding EMC when these stands are installed with any external accessories, maintained or operated adjacent or stacked with other equipment. The equipment or system must be observed to verify normal operation in the final configuration in which it will be used.

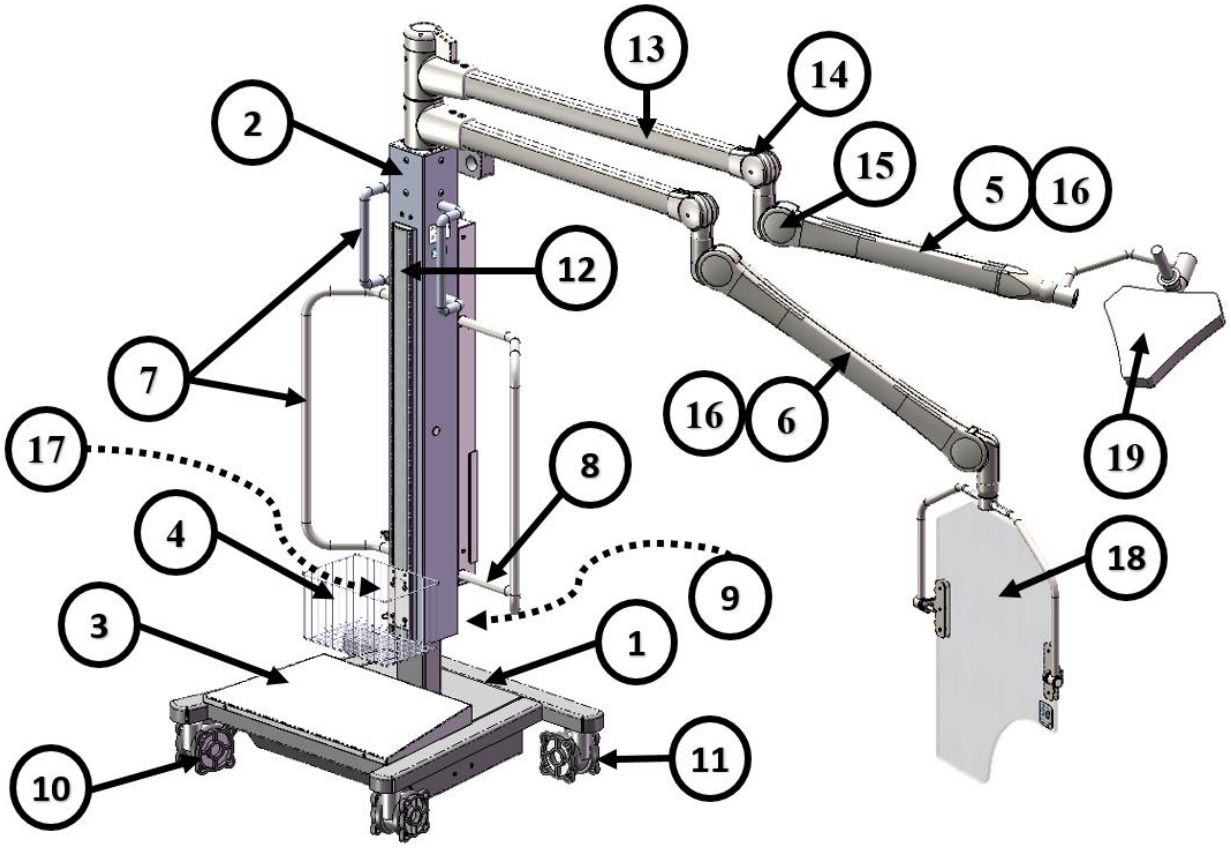
The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.



If this equipment generates or receives interference:

1. Verify that the equipment is the cause by turning the system off and on.

6. Basic Use Instructions



Item	Description	Qty
1	Base	1
2	Upper Column	1
3	Base Cover	1
4	Cable Storage	1
5	Light Head Spring Arm	1
6	Spring Arm	2
7	Push Handle	2
8	Lifting Handle	2
9	Brake Mechanism	1
10	Total Lock Casters	3

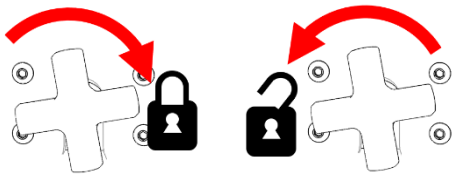
Item	Description	Qty
11	Steer Lock Caster	1
12	VESA Mount (not shown)	0,1,2*
13	Horizontal Arm	2
14	Clam Shell Cover	2
15	Circular Cover	6
16	Spring Arm Clam Shell	2
17	Safety Pin	1
18	Compass Contour Radiation Shield	1
19	Light Head	1

*Qty depends on model purchased

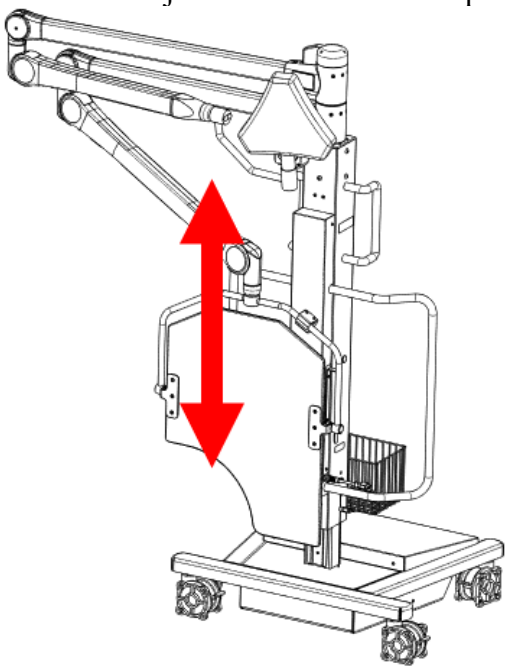
Power Cord

To ensure proper grounding, the power cord must be plugged into a hospital grade power outlet. Before plugging in cord, verify cord has no damage.

Column Height Adjustment



The height of the column can be adjusted with the assistance of the internal gas springs. A combination of brake pressure and lifting of the column is required to move the column up or down. A brake knob is equipped on the rear of the column to lock the column at a desired height. To tighten the brake, turn the knob in a clockwise motion until the column does not move. To unlock the brake, turn the knob in a counterclockwise position until the column is free to move. When adjusting the height of the column, ensure no devices or objects are below or above the column that my cause a collision. Occasionally the friction in the spring arm may require the user to push up to release the initial pressure, then the gas spring will assist with lowering or raising the entire column.
Each of the spring arms allows for additional height adjustments. These adjustments are manually done by pushing or pulling on the spring arms of the system. Take care not to crash into other objects in the room when positioning devices.



To move the column, loosen the brake mechanism and grasp the rear handle and either push up or pull down to desired height. Hold the column at the desired height and turn the brake handle clockwise to tighten and hold the column in position. To verify the column is tight, apply 10-20lbs of force to the lift handle, and ensure column does not move. This is equivalent of pushing down on the lift handle with an arm. If required tighten the knob in clockwise direction to fully secure the upper column assembly.

A safety pin is utilized for transportation mode. The safety pin is located on the right-hand side of the column as viewed from the rear of the device. The safety pin must be removed to adjust the height. When transporting device, the safety pin must be installed to move device to another location.

The recommended height for usage is between 88” and 98” (maximum system height) measured from the floor to the top of the column cap.



WARNING!
Use caution when adjusting the height of the system. Verify no collisions will occur while adjusting the height of the device.



WARNING! Verify brake mechanism is fully tightened and column is secured prior to moving arms or adjusting monitor.

Cable Management

A wire basket is provided to allow for storage of video and power cables. Use caution not to wrap cables too tight as this may damage cables. Cables should be stored prior to moving the unit.

Video Cables

If the Compass Flex is a model with video monitors, it will be equipped with industry standard HDMI, SDI, or DP cables. A few adapters are also provided to assist with connecting to proper video output cables. When connecting video cables do NOT use excessive force to join cables. If there is a large resistance when connecting then the connectors are not compatible, and a different connector or cable should be used. Cable terminations should be able to be connected properly with light finger pressure.

Monitors

Monitors may vary depending on configuration purchased, for exact specifications of the monitor please refer to instructions for use documentation from the monitor manufacturer. Each unit is shipped with instructions or can be obtained by contacting Image Diagnostics, Inc. Please have serial number available when calling. Serial number can be found on the bottom part of the column. Power switches on the monitor are either underneath or on the side of the monitor.

Each monitor has a variable height configuration. For adjusting the height of the monitor, a second person is required. To adjust the height of the monitor, one person should hold the monitor, while the second person loosens the four screws on the rail mount. Slide the monitor to the desired position and then retighten the four set screws to secure the monitor in place. The cover may need to be cut down if the monitor is moved more than 1”, this can be cut with a hacksaw.









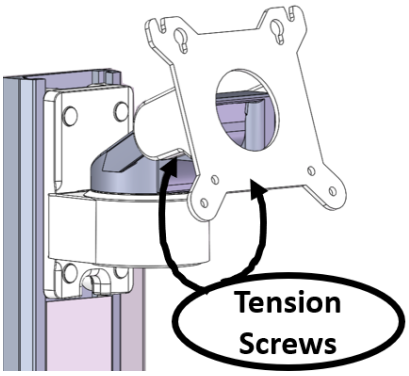


Monitor swivel and rotation

The device is equipped with a VESA mount plate (either 100mm x 100mm or 75mm x 75mm). The monitor is capable of tilting upward or downward. Additionally, the monitor is capable of rotating about its vertical axis. Some models do not have monitors and will not have this capability.

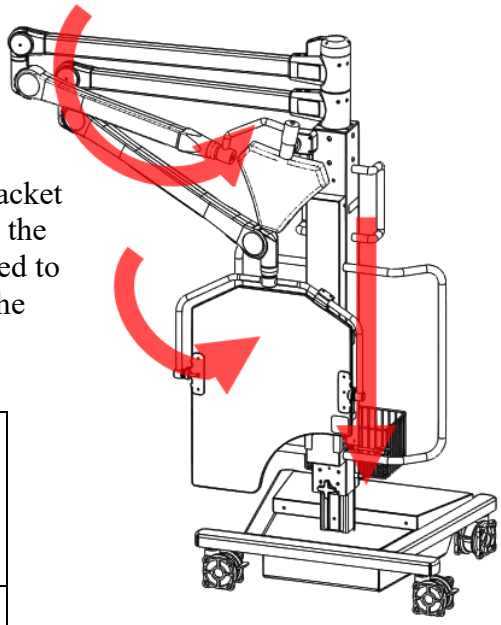
When adjusting the monitor, it is recommended to lock the casters in position so that the cart does not move inadvertently. To adjust the tilt of the monitor, grab the top and bottom of the monitor and gently tilt the monitor forward or backward to the desired position. To adjust the rotation of the monitor, grab the left and right side of the monitor simultaneously and gently adjust rotation to desired position.

Depending on monitor weight, the tension may need to be adjusted to allow for easier movement of the monitor. To adjust this, rotate the tension bolt clockwise to add tension, rotate counterclockwise to reduce tension. The tension must be enough to hold the monitor up by itself. Do NOT loosen the tension so that the monitor rotates down on its own. Move the cart around the room to verify the monitor still can hold itself up, otherwise add more tension to the bolts.



Transport Mode

The device must be placed in the transport mode prior to moving around the facility. Unit is in transport mode when the two spring arms are folded completely back in towards the column, with the shield's top tube is stored in the clip mechanism on the back of the column and the light's handle is stored in its bracket hole. The column must then be lowered to its lowest position, and the safety pin, located on the lower part of the column, must be inserted to ensure device is ready for transport. The device should look like the image to the left when ready for transport.

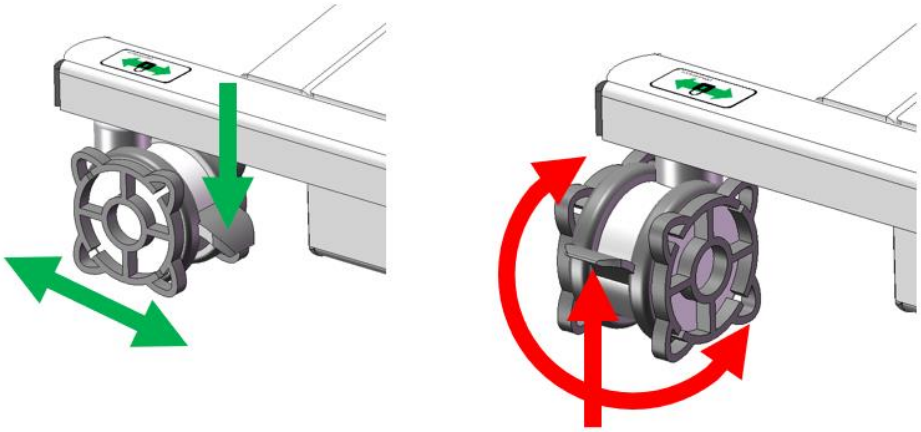


⚠	**Device must be in transport mode prior to moving. Failure to put device in transport mode may result in damage to equipment or injury to personnel.**
⚠	**When transporting Compass Flex, it is required that the device be moved by two personnel.**

Moving and Positioning the cart

For positioning and moving the device two personnel are required. The device is equipped with 3 locking casters that can be individually locked to prevent the device from moving. The fourth caster is a steer caster and is identified by the label on the rear channel. The device has push handle mounted on the rear of the upper column assemblies. The device should be pushed rather than pulled when transported around the facility. Verify the overall height of the device is less than 79.5" [200cm] prior to moving between rooms.

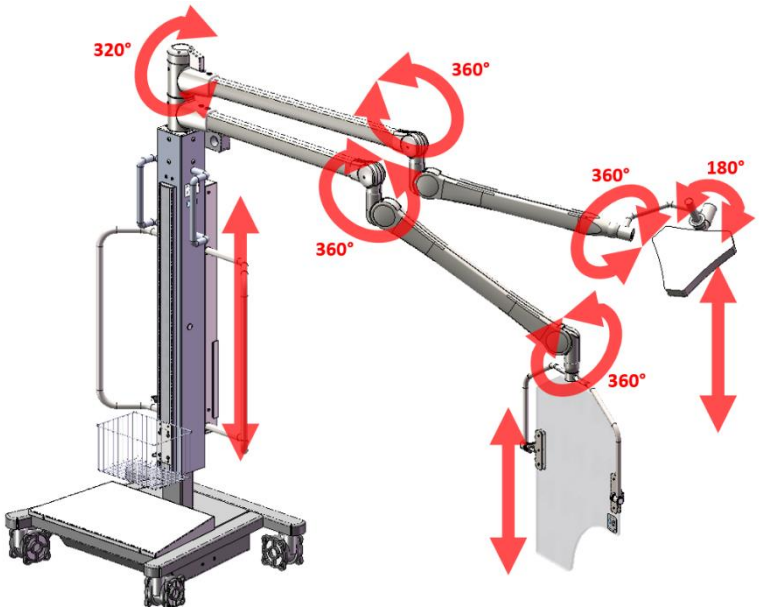
To move the device, unlock all 4 casters by gently pulling up on the lever of each caster with your foot. Locate the steer caster, marked with the label, and press the locking lever to lock in steer caster. The caster will rotate freely, until it becomes parallel with the rear channel. Once the caster gets aligned parallel with the rear channel, a click will occur and the caster will no longer rotate. The steer caster is capable of locking in two positions, both 180 degree from each other, and parallel to the rear channel of the base. Use the rear push handles to move the stand. The same handles may be used to move the device closer or further away from procedure table. Note: locking of the steer caster will only allow the device to move laterally. If required unlock the steer caster to move in any direction.



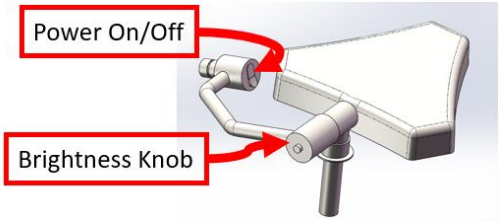
	**Do NOT use excessive force on steer lock caster lever. Moving the lever to the lowest position activates the steer functionality. Pressing down further does not lock the caster from moving, and can result in damaging the caster.**
	**Do NOT move cart over cords or uneven, soft or sloping surfaces. Failure to comply may result in cart instability leading to equipment damage or personal injury.**
	**Use handles to move cart with the help of an assistant to avoid collision with other equipment and walls**

Moving spring arms and accessories.

The spring arms have 320 degrees of rotation about the center axis. Each of the joints between the horizontal and spring arm has a rotation of 360 degrees. Spring arms are adjustable up and down 45 degrees. The shield can rotate 360 degrees about the connection joint. The shield has a pivot point on the acrylic to allow for more flexibility. The light has a 360 rotation about the connection joint. The light joint closest to the brightness knob has 180-degree rotation. A combination of rotating the connection joint and the brightness knob joint may be required to get the desired location of the light beam.



The light has an on/off switch, as well as a brightness knob to adjust brightness. Once the system is plugged in turn the switch on to turn on light. Adjust the brightness to desired setting by rotating the knob.



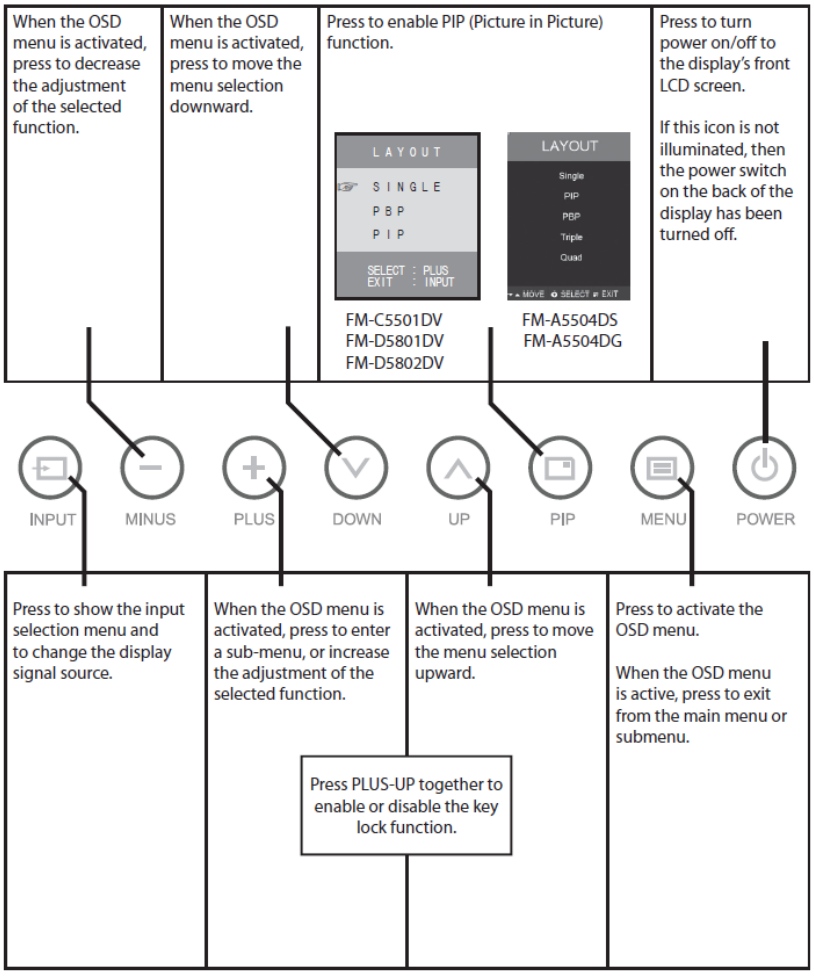
7. Monitor Setup

For devices with monitors, please refer to the manufacturer's instructions for use which are provided with the Compass Flex. To assist with determining which monitor is equipped locate the serial tag typically located on the rear of the monitor. Other quick references may include the following.

- FSN monitor will have menu buttons on the front bezel.
- Barco Monitor will have logo in the center part of the screen
- LG monitor will have logo in center part of screen

FSN Monitor

(from monitor's user guide, #FSN1995-10/2019), menu buttons on front panel of monitor.



For additional features and options, please consult monitor operator guide provided with the device, or contact IDI for further assistance.

8. General Cleaning

To clean the device please use the following procedure. For cleaning monitors please reference the manufacturers instructions for use for proper cleaning.

First unplug the device prior to cleaning process. Wipe clean the surfaces of the system, except the monitor screen, with a diluted mixture of mild detergent (Isoprotpyl alchol 70%, Enviorcide™, or 5.25% Sodium Hypochlorite sometimes refered to as household bleach diluted between 1:10 and 1:100 with water) and water using a soft cloth. Wipe off cleaner with another cloth with damp with just water. Let dry as needed, except on stainless steel parts use another soft cloth to dry completely.

Monitor Cleaning Only

Precautions

- Take care not to damage or scratch the front filter or LCD panel.
- Be careful with rings or other jewelry that can touch the front filter
- Do not apply pressure on the front filter or LCD panel.
- Do not apply or spray liquid directly to the front filter, panel or cabinet as excess liquid may cause damage to internal electronics. Instead, apply the liquid to the cleaning cloth.
- Follow your hospital or clinical institution protocol for the handling of blood and body fluids.
- The display is not disinfected or packed in sterile environment.
- Follow your hospital protocol in case the display needs to be disinfected prior to installation.
- The following products are tested and approved:

Bohle glass cleaner	Microzid
Household bleach (generic sodium hypochlorite, solutions of 5.25% sodium hypochlorite diluted with water between 1:10 and 1:100)	Mild detergent
Incidin Foam (Ecolab)	Misty Clear Lemon 10 Disinfectant
Isopropyl alcohol with concentration < 5%	Screen TFT (Kontakt Chemie)
Klear Screen	Zep Heavy-duty glass & all surface cleaner

DO NOT USE:

Alcohol/solvents at higher concentration > 5%	Sponge with abrasives
Acid	Steel blades
Cloth with steel thread	Steel wool
Detergents with abrasives	Strong solvents
Detergents with ammonia	Strong alkalis lye
Detergents with fluoride	

9. Service & Repair

On this device there are a few serviceable parts, the gas spring on the lift column and the gas spring in each of the spring arms. Servicing and replacing the gas spring should only be done by a qualified technician. Spring arms should be checked per manufacturers instruction, included with the device. Please contact Image Diagnostic for the most up to date Technical Service Instructions (TSI) on how to replace the gas spring if needed.

For repairs or replacement of components, please contact Image Diagnostics for Service and Repair at (978) 829-0009.

10. Maintenance

All maintenance procedures should be done by an experienced and qualified technician with demonstrated knowledge and skills (electrical and mechanical) in the service of medical equipment.

- ✓ This individual must have access to this manual and the proper tools.
- ✓ Lubrication of this device is *not* required.

RECOMMENDED PERIODIC PERFORMANCE CHECKS

Daily (Prior to use)	***Inspect all external cables, and casters. Replace damaged cables promptly.***
Semi Annual (Every 6 Months)	***Inspect spring arms per manufacturers instruction. Verify spring force is still consistent with the device attached to it.***
Biennial Year (Every other year)	***Inspect gas spring for loss of force. Contact Image Diagnostics to replace gas spring if column assembly is no longer assisting in lifting the column.***

11. Disposal of Components



The Compass Flex is constructed mostly of steel, aluminum and copper which are easily recycled. Components must be disassembled before recycling. Shielding material is considered a waste disposal product.
Disposal Considerations for shielding material – Waste Disposal: Classified in Europe as non-hazardous under EWC code 12.01.99. Should be disposed of in registered landfill sites in accordance with Local Authority regulations.

COMPONENT	ITEM	RECYCLING GROUP
Chassis	Column and base	Metal (Steel and Aluminum)
Casters	Locking caster	Metal and Plastic
Cables	Windings	Copper
Shield	Lead Acrylic Window	Lead Composites

12. Specifications

Mode of Operation

- For continuous use

Type of Equipment:

- Class I (as defined by IEC 60601-1, 3rd Edition)
- Monitor is 60601 listed
- Monitor stand tested to applicable 60601 standards

Electrical:

- Supply Voltage: 120v/230v Max amperage is 8 Amp/4 amp

Environmental:

- Operating Temperature Range: 41°F to 95°F (5°C to 35°C)
- Operating Humidity Range: 20% to 80% relative humidity, noncondensing.
- Operating Pressure Range: 700 hPa to 1010 hPa.
- Transport & Storage Temperature Range: +14°F to +122°F (-10°C to +50°C).
- Transport & Storage Humidity Range: 20% to 80% relative humidity, noncondensing.
- Transport & Storage Pressure Range: 700 hPa to 1010 hPa.
- **NOT suitable for oxygen rich environment**

Product features included with Compass Flex:

- Individual cables for monitor power and video input.
- Detachable AC power cord.

Physical Characteristics:

- Steel Frame with height adjustable monitor
- 35 5/8" (90.64cm) wide x 29 1/2" (74.8cm) deep footprint of the base.
- The height of the unit from the floor to the top of the column is 79 1/4" (201.3cm) at its lowest elevated position and up to 99 1/4" (252.1cm) at its highest elevated position.

Typical Positions of Operator during use:

- To move the device, the operator may push on the handles on the column.
- For transporting cart, the casters should be placed in the unlock positions, with the steer lock caster engaged for traveling in a straight line.

13. ME Equipment and Systems

For RF data on monitor please contact Image Diagnostics, please have Compass Flex serial number ready for quicker assistance. The serial number plaque is located on lower side of the upper column assembly.

14. Warranty

Warranty details for IDI Products can be obtained directly from Image Diagnostics, Inc.



Image Diagnostics, Inc.
310 Authority Drive
Fitchburg, MA 01420 USA



Or call IDI at (978) 829-0009.