

使用说明书

INSTRUCTIONS FOR USE

Sara Flex



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arjo
with people in mind

警告

为避免受到伤害，在使用产品前，必须阅读本《使用说明书》以及产品随附的文档。



请务必阅读本《使用说明书》。

WARNING

To avoid injury, always read this *Instructions for Use* and accompanied documents before using the product.



Mandatory to read the *Instructions for Use*.

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前言

感谢您购买 Arjo 设备。

如果您在 Arjo 设备的使用或维护过程中遇到任何问题, 请随时联系我们。

请在使用 *Sara® Flex* 之前请仔细阅读本《使用说明书》(IFU) 并充分理解其中的内容。

如果发生与该医疗器械相关并影响用户或患者的严重事件, 则用户或患者应将该严重事件报告给医疗器械制造商或分销商。在欧盟, 用户还应向其所在成员国的主管当局报告该严重事件。

本 IFU 中包含的信息对正确操作与维护设备至关重要。可帮助您保护产品并确保您获得令人满意的使用效果。本 IFU 中包含的信息对于保证患者与护理人员的安全非常重要, 必须阅读并理解以防止可能发生的人身伤害。

任何对 Arjo 设备未经授权的改变都会影响其安全性。Arjo 对任何因未经授权改动产品而导致的意外、事故或性能丧失均不承担任何责任。

严重事件

如果发生与该医疗器械相关并影响用户或患者的严重事件, 则用户或患者应将该严重事件报告给医疗器械制造商或分销商。在欧盟, 用户还应向其所在成员国的主管当局报告该严重事件。

服务和支持

必须对 *Sara Flex* 进行常规维护, 以保持设备的安全性和可靠性。请参阅第 30 页的“保养与防护性维护”部分。

如果需要了解更多信息, 请联系您当地的 Arjo 工作人员以获取更换的部件。本 IFU 末页提供了联系信息。

本 IFU 中的定义

警告

表示: 安全性警告。如不理解并且不遵守该警告可能会对您或他人造成人身伤害。

注意事项

表示: 如不遵守这些说明可能导致整个系统或设备或其中部分部件的损坏。

注意

表示: 这些是正确使用本系统或设备的重要信息。



表示: 制造商的名称和地址。

既定用途

在使用设备时,必须遵守这些安全说明。使用本设备的任何人员都必须阅读并理解使用说明书(IFU)中的说明。

如果有任何不明确之处,请联系您的 Arjo 工作人员。

Sara Flex 产品用途

Sara Flex 是一款移动式站立和提升辅助设备, 安全承重为 200 kg (440 lb), 旨在帮助医院、长期护理机构、疗养院以及家庭护理环境(包括私人住宅)的护理人员将病人/患者抬起并将其从一个地方转移至另一个地方, 例如从椅子、轮椅、床侧、浴缸、淋浴/坐厕椅或马桶抬起并转移到另一个椅子、轮椅、床侧、浴缸、淋浴/坐厕椅或马桶。

本设备仅供经过适当培训的护理人员使用, 而且护理人员应对护理环境、常用做法和步骤有充分了解, 并遵守本《使用说明书(IFU)》中的指导说明。

Sara Flex 只能用于本 IFU 中指定的用途。禁止用于其他目的。

患者/病人评估

我们建议使用机构建立日常评估程序, 以确保护理人员能够在使用前对每位病人/患者进行评估。

使用前, 护理人员要始终考虑到病人/患者的医疗条件、身体和心理状况。

此外, 病人/患者必须满足下述条件

- 至少能够承受一条腿的重量并且躯干有一定稳定性
- 能够坐在床边
- 最大体重为 200 kg (440 lb)
- 身高范围为 145 至 195 cm (4'8" - 6'4")

如果病人不能满足这些条件, 应使用其他的设备/系统产品。

注意事项

为了避免产品损坏, 请勿在户外使用 Sara Flex。本产品适合与经过特殊设计的吊兜配合使用。

预计使用寿命

预期使用寿命是制造商规定的最长使用寿命。考虑到产品已按照“护理和预防性维护”部分的说明进行维修和维护, Sara Flex 的预期使用寿命为十 (10) 年。

实际使用寿命可能因使用频率和条件而异。

考虑到设备的使用寿命, IFU 应在合理需要的时间内提供。

其他耗材(例如电池、吊兜等)也会出现磨损, 因此其预期寿命取决于使用情况。

安全说明

警告

为避免人身伤害,应始终有专人看护患者。

警告

本设备包含细小部件,如被儿童吸入或吞食可能会造成窒息危险。

避免儿童与宠物接触本设备。

手持控制器电线可能造成窒息;采取一切必要的预防措施防止出现这种情况。

警告

为了避免受伤,在尝试使用 *Sara Flex* 之前,必须由合格的人员对病人的状况和适用性进行全面的临床评估。

警告

为了避免受伤,施加在产品上的负荷不得超出所用产品及附件的安全承重。

注意事项

为了避免产品腐蚀,不得在潮湿区域中长期使用或放置 *Sara Flex* 及其附件。

有关转运病人所需的护理人员数量的规定

一位护理人员即可安全使用 Arjo 的地面移位机。护理人员负责根据以下情况确定转运时需要一位还是两位人员:

- 患者状况
- 任务
- 病人体重
- 环境
- 容量
- 护理人员的技能水平

请尽管与您的医护人员联系以获得指导。

使用准备

初次使用前的准备措施(6个步骤)

1. 目视检查外包装是否损坏。如果由于运输原因导致产品看起来有损坏,请联系运输公司。请勿使用该产品。
2. 包装材料应依照当地相关规定进行回收。
3. 阅读本使用说明书 (IFU)。
4. 在指定位置妥善存放 IFU,以便随时取阅。
5. 检查确认各项功能(上-下、开-合移位机支腿)。
6. 启动紧急降低功能,检查其是否工作正常。具体操作是:将红色紧急降低手柄拉起来,拉住手柄的同时向下推升降臂,直到它开始往下降。

注意

初始激活时可能需要对升降臂施加外力。建议由两个人执行该项检查,一人负责激活手柄,另一人往下按升降臂。

每次使用前的准备措施(2个步骤)

1. 目视检查 *Sara Flex*。如果任何部件损坏 - 不得使用本产品。
2. 检查电池电量。

使用前后

按照第 27 页的“清洁和消毒指示”对产品进行清洁和消毒。

Sara Flex 方向说明

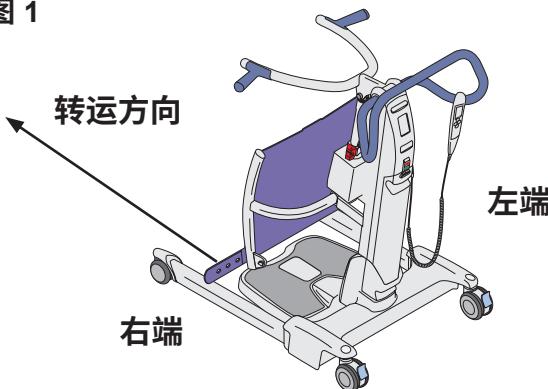
左侧和右侧

Sara Flex 分左右两侧。(请见图 1)

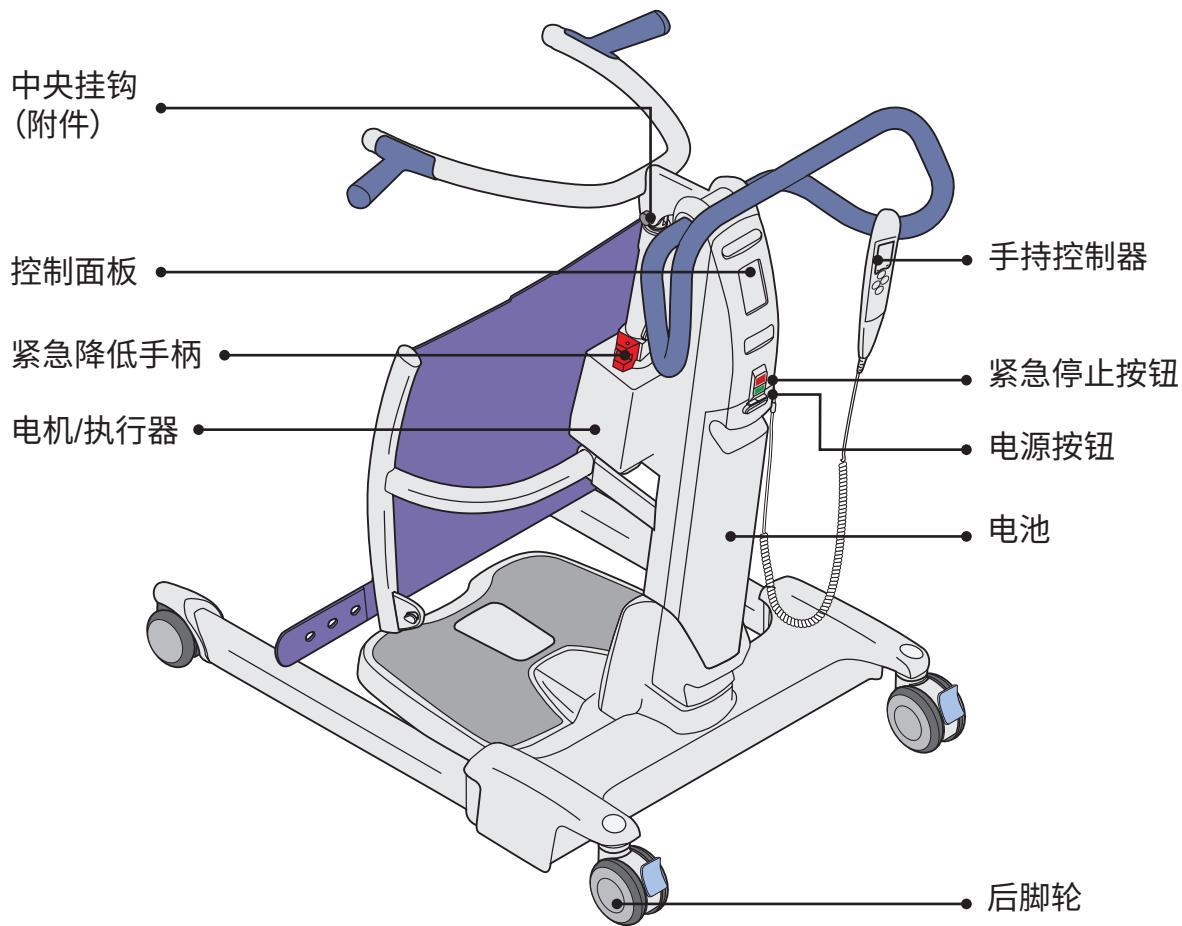
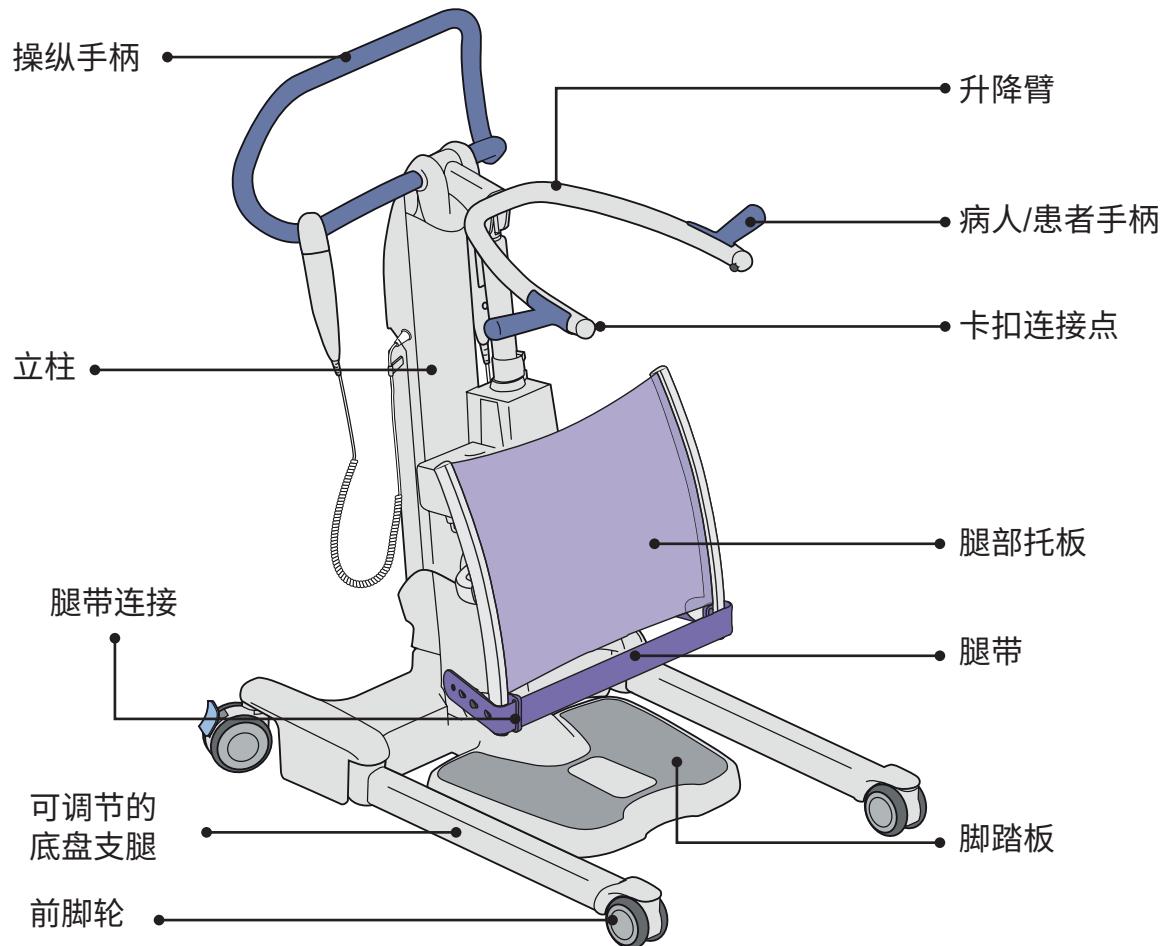
转运方向

转运期间,护理人员必须位于 *Sara Flex* 的后面。

图 1

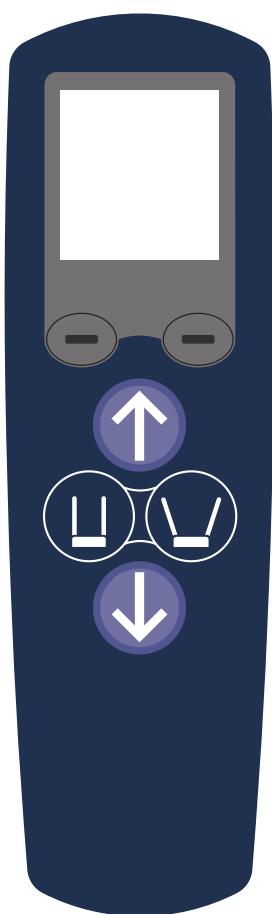


部件名称



产品描述/功能

图 2



控制器和功能

手持控制器 (请见图 2)

使用手持控制器：

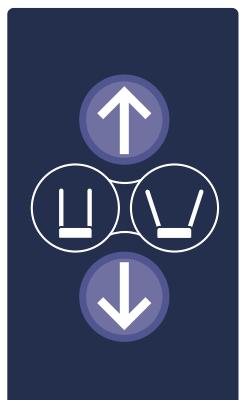
- 升高/降低 *Sara Flex* 上的升降臂。
- 打开/合拢 *Sara Flex* 底盘支腿。
- 短横线按钮用于菜单操作。

按钮功能：

	向上
	向下
	合拢移位机支腿
	打开移位机支腿
	右短横线
	左短横线

如果松开按下的按钮，则会立即停止其功能。

图 3



控制面板 (请见图 3)

安装在立柱上的控制面板可与手持控制器并行操作。也可以通过立柱对 *Sara Flex* 进行控制。

按钮功能：

	向上
	向下
	合拢移位机支腿
	打开移位机支腿

图 4



液晶显示屏

(请见图 4)

电池电量 - 请参阅第 25 页的“电池说明”。

0.0 工作时间记录器

维护符号

0.0 患者体重 - 请参阅第 20 页的“称重器(可选附件)”。

启动时, 显示屏要显示如图 4 所示的画面需要花一点时间。只有按下按钮时, 液晶显示屏才会亮起。

工作时间记录器

工作时间记录器显示移位机的升降臂已升起或降下的总时间(以小时计)。

设备每使用 6 分钟, 工作时间记录器就递增 0.1 小时。

注意

工作时间记录器只有在升降臂移动时才进行记录。

维护符号

维护符号提醒用户每年对产品进行维护。

在设备使用 125 小时后, 会显示维护符号。这是移位机一年内的平均使用时间。维护符号会闪烁(1 秒显示和 1 秒消失)。

维护符号出现时, 设备仍可安全使用, 但应尽快安排年度维护。

注意

进行年度检查时, 技术人员必须将显示屏重置为“0.0”小时。这样做是为了可以直观地看到进行下一次检查的时间。

制动脚轮

后脚轮制动器可以用脚控制, 使 *Sara Flex* 保持在某个位置

启用制动器(请见图 5):

按下灰色的脚轮制动杆 (A)。

释放制动器(请见图 5):

轻轻地抬起灰色的脚轮制动杆 (B)。

图 5

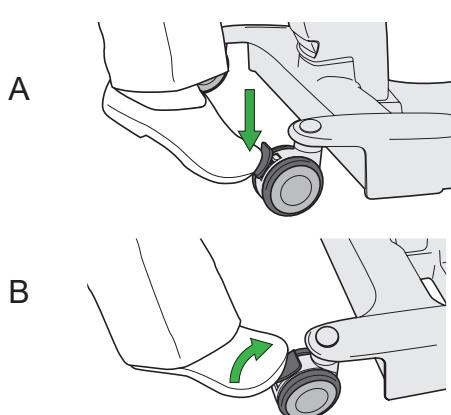


图 6

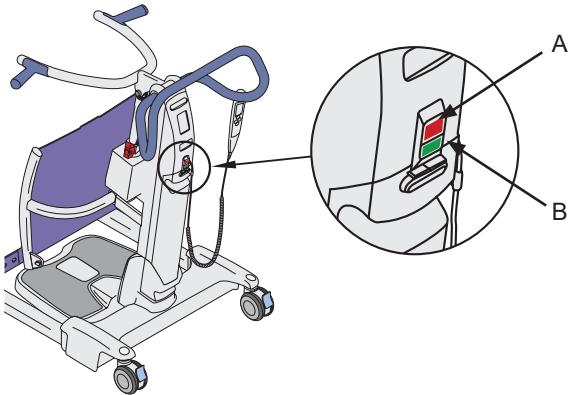


图 7

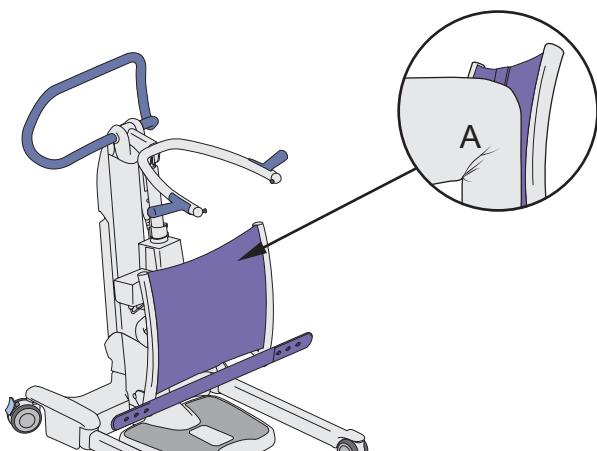
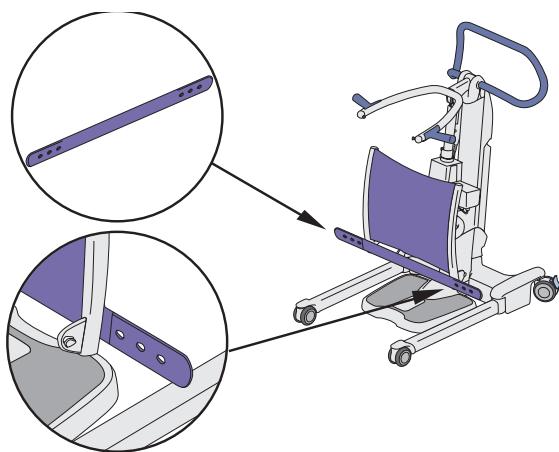


图 8



紧急停止按钮

激活

按下红色紧急停止按钮 (A) 可切断所有电气部件的所有电源。(请见图 6)

取消激活

按下绿色电源按钮 (B) 再次接通设备电源。
(请见图 6)

电源按钮

绿色电源按钮 (B) 紧挨着紧急停止按钮。按下电源按钮开启 *Sara Flex*。(请见图 6)

腿部托板

腿部托板由硅胶制成。(请见图 7)

这种材料可以根据病人膝盖 (A) 施加的压力进行自我调整。

腿带

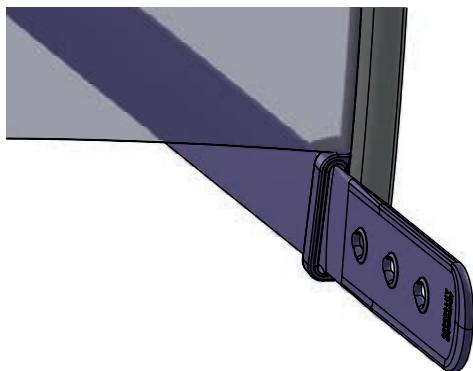
腿带位于硅胶腿部托板的下方。(请见图 8)

腿带用于确保病人的腿紧贴腿部托板。

将腿带固定在腿部托板两侧的连接点上以将其固定。

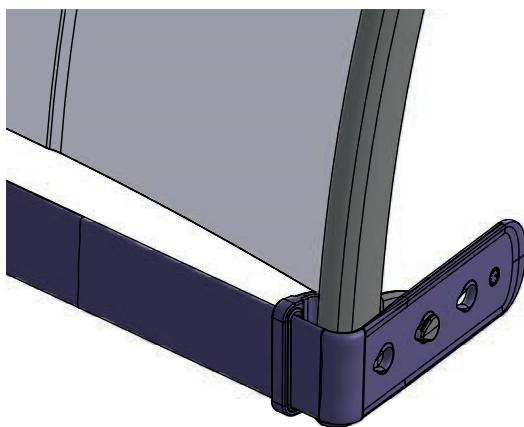
腿带连接(可选)

图 9



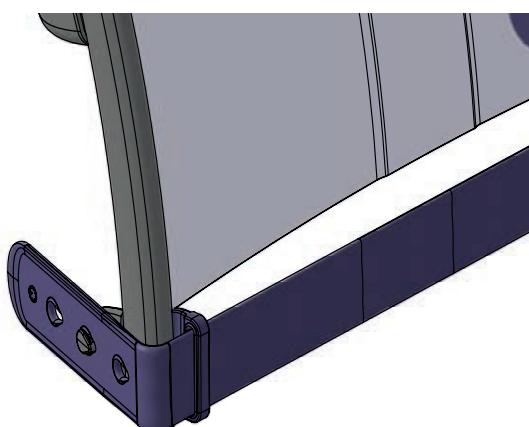
将腿带从腿带连接处插入。
(请见图 9)

图 10



将腿带固定在腿部托板上。
(请见图 10)

图 11

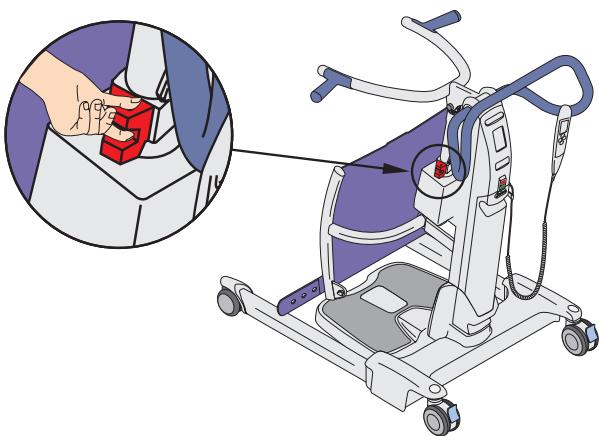


如有需要, 在另一侧重复。
(请见图 11)

图 12



图 13



紧急降低

如果需要激活紧急降低功能, *Sara Flex* 所在的位置应该能够方便患者降到椅子、病床等适当的平面上。站在 *Sara Flex* 边上, 与红色紧急降低手柄同侧。(请见图 12)

一只手慢慢地向上拉紧急降低手柄(拉住), 此时升降臂会将患者降到相应的平面上。下降到位后, 松开紧急降低手柄, 它将自动回到正确位置。
(请见图 13)

注意

如果在紧急降低手柄拉起来时, 升降臂并不往下降, 可用手向下推升降臂, 同时仍然向上拉住紧急降低手柄, 直到升降臂开始往下降。(如果升降臂完全竖直, 可能有助于您面向患者站立, 将升降臂推开)。紧急降低手柄应该一直完全拉起来, 直到患者降至所需的平面上。

超安全承重自动切断装置

这并不是操作人员的控制器, 而是 *Sara Flex* 电子系统中的一项内置功能。

若无意中使升降机过载(如提升或降低超过额定承重的病人), 自动“切断”功能就会启动以防止移位机吊升超过安全承重(SWL)的重量。这将会自动停止移位机的操作。

出现这种情况时, 松开手持控制器或控制面板上的“升高”按键。请勿继续增加负荷。确保 *Sara Flex* 只在其安全承重范围内工作。

下降遇障碍自动停机安全装置

这并不是操作人员的控制器,而是 *Sara Flex* 电子系统中的一项内置功能。

使用时应格外小心,不要将升降臂降到病人身上或碰到任何其他障碍物。如果出现了这种情况, *Sara Flex* 下降遇障碍自动停机安全装置将开始工作,发动机被停机,所有向下的运动被停止。出现这种情况时,立即松开“降低”按键并按下“升高”按键,以抬高升降臂直至移位机与障碍物完全脱离。

然后移走障碍物。

***Sara Flex* 兼容的吊兜**

下列吊兜可兼容 *Sara Flex*。

主动式吊兜 (请见图 14)

- TSS.500 (S)
- TSS.501 (M)
- TSS.502 (L)
- TSS.503 (XL)
- TSS.504 (XXL)

Flites

- MFA3000 (Flite)

转运吊兜 (请见图 15)

- TSS.511(转运吊兜型号,仅与中央挂钩一起使用)

有关吊兜选型,请参阅相关吊兜的 *IFU*。

图 14

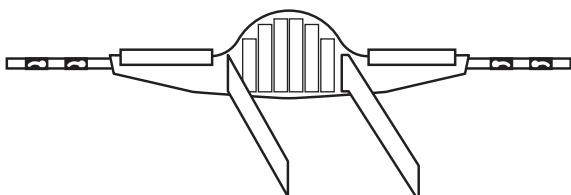


图 15

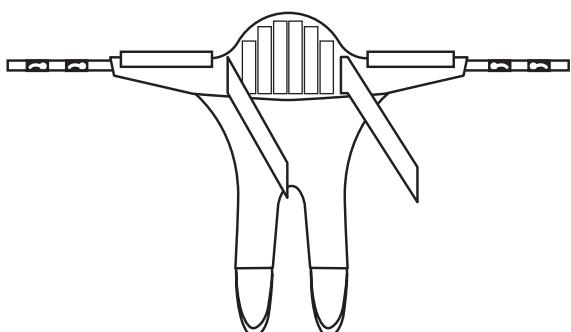
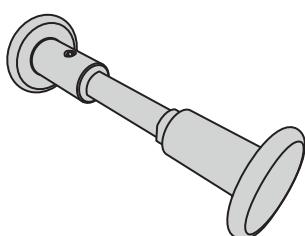


图 16



中央挂钩 (附件)

仅与转运吊兜一起使用。仅由合格的工作人员将中央挂钩(请见图 16)安装在升降臂正下方。

从轮椅转移到 Sara Flex

将 Sara Flex 和病人准备好

- 有关吊兜的说明,请参阅相关吊兜的使用说明书 (IFU) 和吊兜标签。
- 确定 *Sara Flex* 是否适合病人使用,请参阅第 5 页的“既定用途”。
- 将 *Sara Flex* 升降臂降低至其最低位置。
- 告知病人要进行转运了(比如转运至卫生间)。
- 选择和使用吊兜,请参阅相关吊兜的使用说明书 (IFU)。
- 对轮椅施加制动(如适用)。

将病人放入 *Sara Flex*

(8 个步骤)

- 需要时打开底盘支腿以适应椅子、床等的宽度。

注意
如果底盘支腿可以放入家具下面,则不要打开底盘支腿
- 请求或协助病人将他/她的双脚放在脚踏板上。(请见图 17)

图 17



图 18



图 19

- 将 *Sara Flex* 推向病人直至轻触患者的小腿。(请见图 18)

- 请求或协助病人将他/她的双手放在病人/患者手柄上。(请见图 19)



图 20

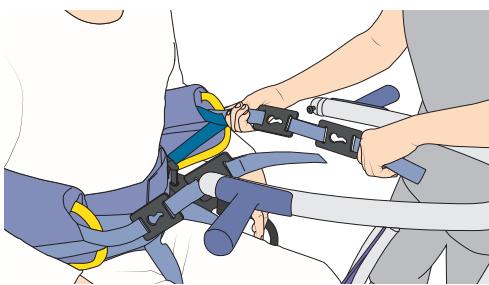


图 21

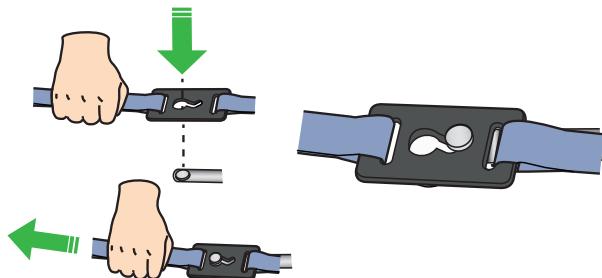


图 22

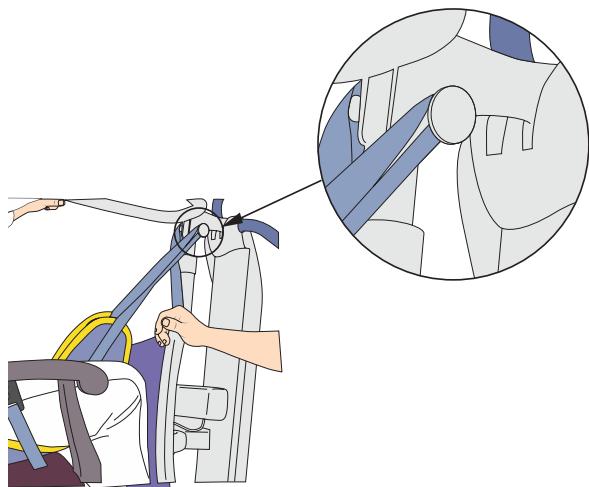
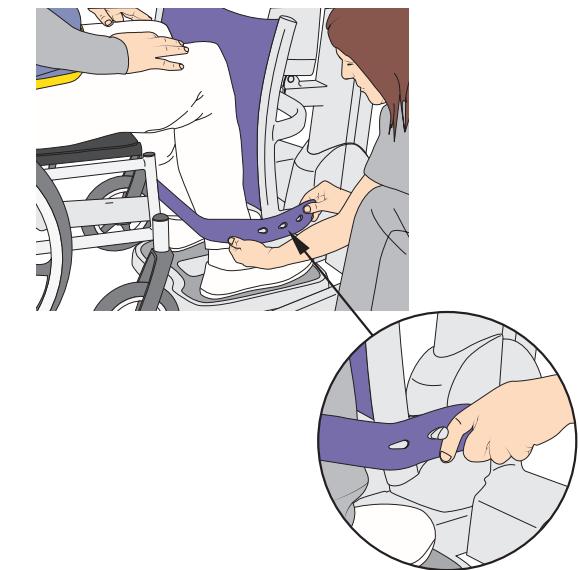


图 23



5. 将吊兜卡扣连接至 *Sara Flex* 升降臂上的连接点。(请见图 20)

6. 确保卡扣连接牢固。(请见图 21)

7. 使用转运吊兜时, 还要将吊带连接至升降臂正下方的中央吊钩(附件)上。(请见图 22)

8. 必要时可用腿带支撑患者的双腿。(请见图 23)

图 24



将病人提升到站立位置

注意

- 如果使用转运吊兜提升病人，在提升期间，他/她应该无需帮助。
- 使用转运吊兜时，请勿将病人提升至高于坐立位置。位置太高对病人来说会不舒服。

(5 个步骤)

1. 站在病人旁边并告诉他/她 *Sara Flex* 会升高至站立位置。
2. 检查各连接点，确保 *Sara Flex* 准备就绪。

警告

为避免受伤，请确保让病人参与其中。如果无法参与，则要考虑结束转运，将病人恢复坐姿并重新评估设备的选择。

3. 使用手持控制器将病人从坐立位置升高至站立位置。(请见图 24)
4. 病人站立时，请检查各支撑物。
5. 如有必要，系紧腹部的安全带。

转运病人

(2 个步骤) (请见图 25)

1. 使用操纵手柄，将 *Sara Flex* 推离轮椅。
2. 必要时合拢底盘支腿。



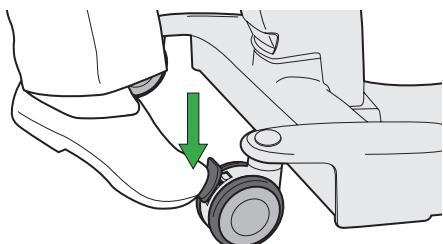
图 25

从 Sara Flex 上转移至马桶上

图 26



图 27



(18 个步骤)

1. 使用操纵手柄, 将病人推至马桶前面或病人要坐的设备前。(请见图 26)
2. 必要时调节底盘支腿。
3. 当病人站立时, 护理人员可以帮助病人更衣(即, 穿衣、脱衣或上厕所等)。
4. 将病人放置至马桶上方。按手持控制器上的向下箭头, 将病人降低到坐立位置。
5. 降低病人时站在他/她身边。

警告

为了避免挤压生殖器和皮肤, 要确保移动过程中留有足够的间隙。

6. 病人坐上马桶后, 使用脚轮制动器以使 *Sara Flex* 保持原位不动。(请见图 27)
7. 从 *Sara Flex* 上拆除吊兜卡扣。
8. 让病人把手从病人/患者手柄上松开。
9. 如果可以, 拆下腿带。
10. 必要时取下吊兜。
11. 应让病人保留隐私, 但要确保病人有专人看护。
12. 完成个人卫生护理后, 将取下的吊兜重新安装好。
13. 请求或协助病人将他/她的双手放在病人/患者手柄上。(请见图 19)
14. 将吊兜卡扣连接至 *Sara Flex* 升降臂上的连接点。(请见图 20)
15. 确保卡扣连接牢固。(请见图 21)
16. 轻轻抬起病人, 必要时使用失禁产品, 并整理好衣服。
17. 释放制动装置。
18. 从马桶上转移离开之前, 请重复第 17 页的“将病人提升到站立位置”中的步骤。

从 Sara Flex 转移至病床/椅子上

(11 个步骤)

图 28



图 29



1. 如适用, 对轮椅施加制动。
2. 必要时调整底盘支腿, 以纳入病床或椅子。
(请见图 28)
3. 将病人降低至病床/椅子上。
(请见图 29)
4. 确保将病人正确放置在病床/椅子上。
5. 将吊兜从 *Sara Flex* 解开。
6. 让病人把手从病人/患者手柄上松开。
7. 如果可以, 拆下腿带。
8. 让病人将脚从脚踏板上抬起来, 必要时给予帮助。
9. 将 *Sara Flex* 从病人处推开。
10. 将吊兜从病人身上取下
11. 转运完成后, 按照第 27 页的“清洁和消毒指示”或本地的指导原则清洁 *Sara Flex*。

称重器(可选附件)

警告

为避免受伤,仅在护理人员和医疗保健专业人士的监督下使用称重器对医院或护理机构的病人进行称重。

注意事项

必须先将称重器稳固地置于平坦表面,然后才能启动,以执行自动零位复位。

在称重器显示“0.0”之前,请勿操纵移位机或其任何组件。如果不这样做,将导致称重器的重量读数不准确。

显示符号/功能

手持控制器上的液晶显示屏可以以千克(kg) (或在特定市场以磅(lb)为单位)为单位显示重量。

如果显示减号(-),则表示所显示的体重为负值(参阅第 23 页的“方法 B - 为病人称量体重,含吊兜重量”)。

超安全承重警告符号

病人体重超出称重器的安全工作承重(SWL) 200 kg (440 lb)时,显示最大重量警告符号。(请见图 30)

如果称重器过载,该装置将发出 2 声蜂鸣音,显示屏交替显示称重器符号和最大重量警告符号。立即降低病人,以消除过载的重量。

在最大重量警告符号消失之前,请勿操纵称重器/移位机。

图 30



称重器符号



最大重量警告符号

图 31



净重

病人不带任何配件(如吊兜)的“净”体重。
(请见图 31)

如何获得患者“净”体重的说明, 见第 22 页的“方法 A - 为病人称量体重, 不含吊兜重量”部分。

图 32



保存重量值

要使用“保存”功能, 按左横线按键 (A) 以保存称重器上的重量值。(请见图 32)

此功能将保存屏幕上显示的称量结果。当显示的测量值被保存时, 会出现两条蓝线 (B)。

注意

在称重过程中, 病人应尽可能保持不动。病人动来动去会造成读数不正确

图 33



倾斜(仅适用于 III 级称重器)

显示屏交替显示倾斜的称重器符号和称重器符号。

注意

对于仅限于 III 级的称重器,
如果屏幕交替显示更大的“TILT”(倾斜)符号和称重器符号, 则应将 *Sara Flex* 重新移至水平地面,
以便称重器能够正常工作。(请见图 33)

Sara Flex 倾斜时, 不显示任何重量读数。

如果在移动或操纵移位机时, 显示屏偶尔显示“Tilt”(倾斜)符号, 属于正常现象。

使用称重器 - 为病人称量体重

方法 A - 为病人称量体重, 不含吊兜重量

图 34



图 35

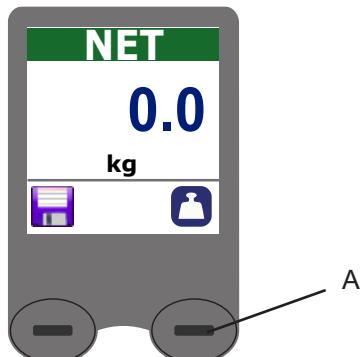


图 36



6. 移动患者位置。(请见图 36)

7. 这时显示病人的净体重。
(请见图 37)

8. 按下左横线按键 (A), 将“净”体重值保留在显示屏上。

注意

Sara Flex 进入休眠模式时, 显示屏上的重量值会消失。

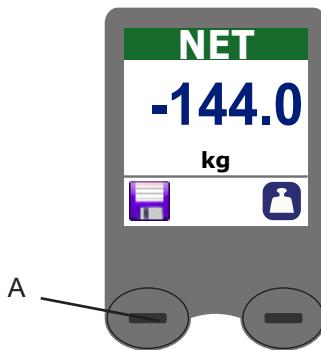


方法 B - 为病人称量体重, 含吊兜重量

图 38



图 39



(7 个步骤)

1. 将病人提升到站立位置。
2. 按右横线按键使显示屏读数归零。(请见图 38)
3. 完成转运并将病人从 *Sara Flex* 上放下。
4. 称重器将显示负值。
5. 将吊兜重新装回 *Sara Flex*。
6. 忽略屏幕上的减号。等重量读数稳定下来。所显示的重量即为病人的实际体重。(请见图 39)
7. 按左横线按键 (A), 将净体重值保留在显示屏上。

注意

Sara Flex 进入休眠模式时, 显示屏上的重量值会消失。

注意事项

如果患者仍在吊兜中时重置称重器, 将导致称重器跳出零范围并显示“8888.8”, 表示出现了错误状态。将患者从 *Sara Flex* 上放下并重置称重器。

更改称量单位

图 40

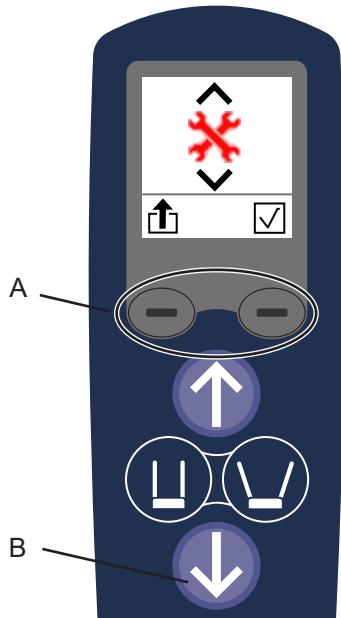
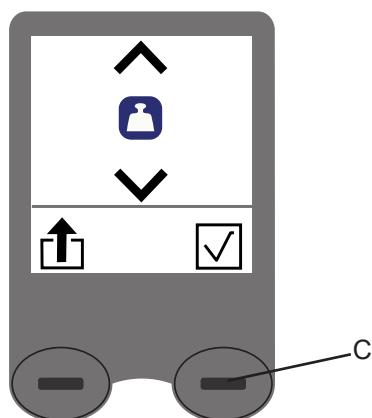
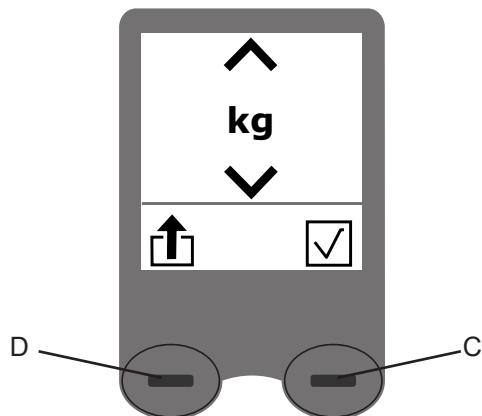


图 41



“重量单位”屏幕则会显示出来。
(请见图 41)

图 42



2. 要显示设置菜单, 可按手持控制器上的向下键 (B)。(请见图 40)
3. 按右横线按键 (C), 可进入称量单位选项菜单。
(请见图 42)
4. 要在 kg 和 lb 之间切换, 请按向下键 (B)。
5. 要保存设置并返回正常使用, 请按右横线按键 (C)。(请见图 42)
6. 按左横线按键 (D), 可退出而不保存更改。
(请见图 42)

注意

III 级称重器的质量单位是无法更改的。

电池说明

警告

为避免人身伤害,不得挤压、刺破、拆开、分解或以其它机械方式破坏电池。

- 如果电池外壳裂开,并导致内容物接触皮肤或衣物,应立即用清水冲洗。
- 如果内容物进入眼睛,立即用大量清水冲洗并迅速就医。
- 吸入内容物可能导致刺激呼吸道。请设法呼吸新鲜空气并立即就医。

注意事项

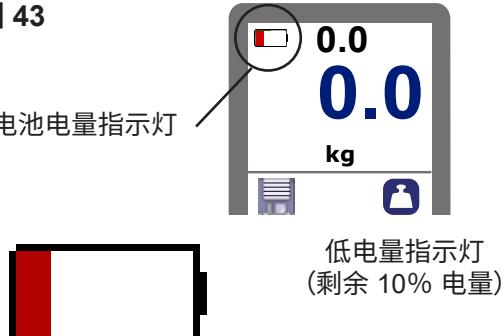
为避免电池过热和发生爆炸,不得将电池投入火中或使其受热过度。

Sara Flex 使用的密封铅酸电池装在控制面板的下方。待机仅 2 分钟后,液晶显示屏关闭。其余电子设备在待机 10 分钟后关闭,以防止移位机处于待机模式时损坏电池或耗光电池电量。

低电池电量警告

Sara Flex 的手持控制器上有一个电池电量指示灯。(请见图 43)

图 43



手持控制器上的电池指示灯将显示 *Sara Flex* 电池电量是否即将耗尽,并且每隔一分钟会发出两声蜂鸣音。完成转运并为电池充电。

如果电池电量即将耗尽,该设备会发出 3 声蜂鸣音,并且显示屏上只显示一个大的红色低电池电量指示灯,然后移位机进入休眠模式。

试图使用几乎耗尽电池电量的移位机时:

- 该设备会发出 3 声蜂鸣音。
- 手持控制器将短暂显示低电量图标。
- 设备将重新进入休眠模式。
- 在电池充电或更换之前,移位机将无法进行操作。

电池存放

- 尽管电池在出厂时已充满电,但由于存在缓慢的放电现象,建议您在到货之后再次对其进行充电。
- 在不使用的时候,电池会缓慢地放电。
- 应在 -0°C (32°F) 至 +30°C (86°F) 温度范围内储存不用的电池。
- 为了极大地提高电池性能,切勿在高于 50°C (122°F) 的温度下储存电池。

充电的间隔时间

- 为了延长电池的使用寿命,应定期(如:每天晚上)对其进行充电。
- 建议使用两个电池,这样可以在使用一个电池的同时,将另一个放入充电器中备用。
- 建议将未使用的电池放在充电器中。这样做不会发生过度充电的危险。
- 当长时间不使用时,建议将电池从 *Sara Flex* 中取出。
- 为了延长电池的使用寿命,应在电池电量较低之前对其进行充电。

插入/取出电池

在 *Sara Flex* 或充电器中插入/取出电池时, 采用同一方法。

图 44

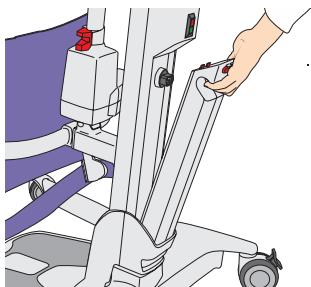


图 45

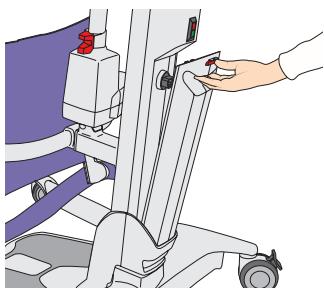
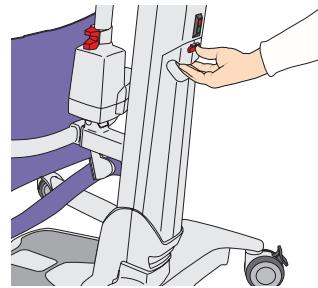


图 46



插入电池(2个步骤)

1. 将电池放入电池托架。(请见图 44)
2. 按电池顶部直到电池固定到位。(请见图 45)

取出电池(3个步骤)

1. 按释放按钮。(请见图 46)
2. 拉出电池。(请见图 45)
3. 提起电池, 将其从电池托架中拉出。
(请见图 44)

电池的使用寿命

根据充电情况及承重负荷, 电池的使用寿命大约为 2-5 年。

安装充电器

请参阅电池充电器使用说明书 (*IFU*)。

如何为电池充电

请参阅电池充电器使用说明书 (*IFU*)。

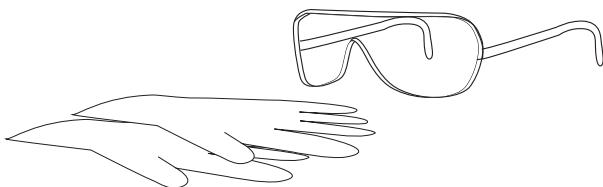
清洁和消毒指示

建议使用以下流程,但应予以调整以遵守当地或所在国家(关于医疗设备消毒的)指导原则,这些指导原则可能在医疗机构或使用国家内适用。如果不确定,应向当地感控专家寻求建议。

Sara Flex 应在更换病人时和使用期间定期进行常规清洁和消毒;这是对所有可重复使用的医疗设备的良好实践。

如果对设备清洁和消毒有任何疑问,或希望订购消毒剂,请联系 Arjo 客服人员。请参阅“部件和附件”一节。确保所使用的消毒剂有安全数据表(SDS)。

警告



为避免眼睛和皮肤受伤,请始终佩戴护目镜和手套。如果消毒剂接触皮肤或眼睛,请用大量清水进行冲洗。如果眼睛或皮肤有刺痛感,请立即就医。应始终查阅消毒剂的使用说明书和安全数据表。

警告

为了预防交叉感染,必须始终遵守本使用说明书中 的消毒说明。

警告

为避免眼睛或皮肤过敏,切勿在患者在场时消毒。

清洁剂/消毒剂

- 使用温和的中性清洁剂

消毒剂	Sara Flex	手持控制器
季铵 ≤ 0.28% (2,800 ppm)	X	X
异丙醇 ≤ 70%	X	X
酚醛 ≤ 1.56% (15,600 ppm)	X	X
过氧乙酸 ≤ 0.25% (2,500 ppm)	X	X
漂白剂(氯) ≤ 1% (10,000 ppm)	X	X*
过氧化氢 ≤ 4.5%	X	X*

*反复使用这些消毒剂后,产品可能会有褪色,表面会变的有点粘手。

清洁/消毒所需附件

- 护目镜
- 防护手套
- 装有水的喷雾瓶
- 一次性纸巾
- 刷子

清洁/消毒

每次使用前后都要遵循此程序。

遵照如下 14 个步骤

准备(步骤 1)

1. 将 *Sara Flex* 置于一个符合人体工程学的工作位置。

清除肉眼可见污染(步骤 2-3)

2. 用水沾湿一张一次性纸巾, 清除 *Sara Flex* 上肉眼可见污渍和灰尘。
3. 如果污染严重, 请使用刷子和抹布清除所有肉眼可见污染。

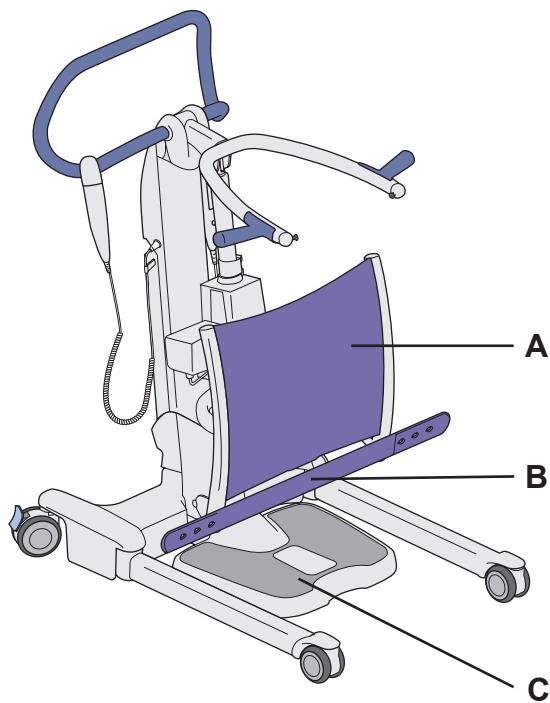
清洁(步骤 4-8)

4. 在 *Sara Flex* 所有部件和手持控制器上喷洒经过 Arjo 验证的清洁剂, 请参阅第 27 页的清洁剂/消毒剂。
5. 用水沾湿一张一次性纸巾, 清除所有清洁剂痕迹。对于腿部托板 (A) 和腿带 (B), 可使用一次性纸巾清除清洁剂, 而对于脚踏板 (C), 您可以使用刷子清除。(请见图 47)
6. 如果无法清除清洁剂, 则在沾有清洁剂的部件上喷水并用一次性纸巾擦掉。
7. 反复操作直到去掉所有的清洁剂。
8. 让所有部件干燥。

消毒(步骤 9-14)

9. 在所有部件和手持控制器上重复喷涂经过 Arjo 验证的消毒剂。
10. 让消毒剂保留在部件上, 时长为制造商建议的时间。
11. 使用新的浸湿一次性纸巾清除所有消毒剂痕迹。对于腿部托板 (A) 和腿带 (B), 可使用一次性纸巾清除清洁剂, 而对于脚踏板 (C), 您可以使用刷子清除。(请见图 47)
12. 如果无法清除消毒剂, 则对受影响部件喷水并用一次性纸巾擦掉。
13. 反复操作直到去掉所有的消毒剂。
14. 让所有部件干燥。

图 47



故障排除

问题描述	解决方案
手持控制器不响应	<ul style="list-style-type: none">• 检查主机控制器上的紧急停止按键是否未按下。• 检查手持控制器的电线插头。• 检查电池状况(更换成充满电的电池组)。
主机控制器上的“提升”和“降低”按键不响应	<ul style="list-style-type: none">• 检查主机控制器上的紧急停止按键是否未按下。• 检查电池状况(更换成充满电的电池组)。
主机控制器每隔 30 秒发出两声蜂鸣音,显示屏的左上角将显示红色电池电量耗尽的图标。	电量不足。用刚充满电的电池组替换。
主机控制器发出三声蜂鸣音,并且显示屏上只显示一个大的红色低电池电量指示灯,然后移位机关闭。	电量不足。用刚充满电的电池组替换。
主机控制器在非前述情况下发出三次以上的蜂鸣声。	联系 Arjo 安排维护。
操作时执行器停止工作。	电量不足。用刚充满电的电池替换。不得超过承重能力。

保养与防护性维护

Sara Flex 容易出现磨损和破损, 为确保产品保持其原始制造规格, 必须执行下列保养和维护措施。

警告

为避免因故障而导致伤害, 确保进行定期检查并遵循推荐的维护计划。在某些情况下, 由于产品频繁使用和暴露在恶劣环境下, 需要更经常地进行检查。

本地法规和标准可能比推荐的维护计划更严格。

警告

为避免伤害患者和护理人员, 切勿改装设备或使用不兼容的部件。

安排	每次 使用前后	每周 一次	每年
护理人员职责(措施/检查)			
清洁/消毒	x		
检查吊兜、吊带与卡扣是否损坏或磨损(必要时)。	x		
检查并确保病人/患者手柄牢固可靠	x		
目视检查暴露表面有无损坏、尖锐边缘等问题。		x	
目视检查吊兜连接点。如有损坏情况, 切勿使用。		x	
确保所有标签已粘贴。		x	
目视检查手持控制器和电缆有无损坏。		x	
执行 Sara Flex 上的完整功能测试。		x	
检查紧急停止/电源按钮和紧急降低手柄的运行情况。		x	
检查电池有无漏液和/或劣化情况。需要时更换。		x	
检查所有脚轮有无磨损。		x	
检查是否存在腐蚀现象。		x	
只能由合格的服务人员每年进行检查。			x

护理人员职责

每次使用前后

清洁和消毒

- *Sara Flex* 在使用后必须马上清洁和消毒。
- 有关更多消毒说明, 请参阅第 27 页的清洁和消毒指示。

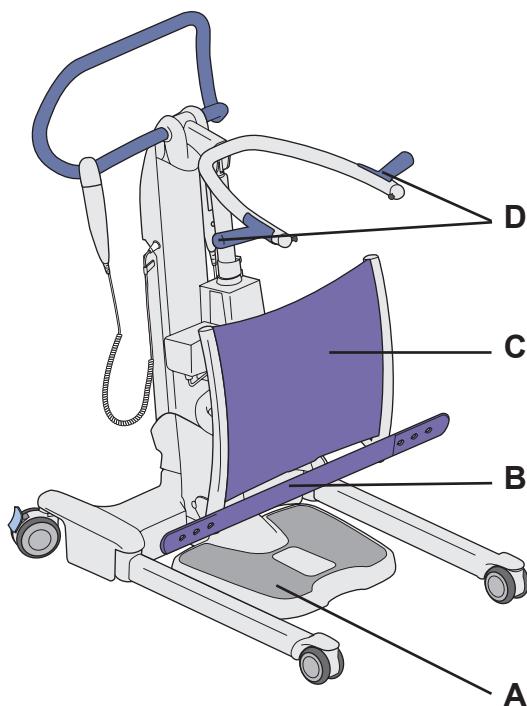
必要时检查吊兜、吊带与卡扣有无损坏或磨损。

- 请参阅相关吊兜的使用说明书 (*IFU*)。

检查并确保病人/患者手柄牢固可靠

- 用力抓住病人/居民手柄 (D), 转动手柄并将手柄向外拔。(请见图 48)

图 48



每周一次

目视检查暴露表面有无损坏、尖锐边缘等问题。

- 密切注意与病人接触的所有部件:脚踏板 (A)、腿带 (B)、腿部托板 (C)、病人/患者手柄 (D)。(请见图 48)
- 查看腿部托板和腿带有无开裂。
- 查看结构部件有无任何变形。

目视检查吊兜连接点。如有损坏情况, 切勿使用。

- 检查吊兜有无磨损、割裂和缝合松动等情况。

确保所有标签已粘贴。

- 检查所有标签是否按照第 37 页的“*Sara Flex* 上的标签”的要求粘贴在 *Sara Flex* 上。

目视检查手持控制器和电缆有无损坏

- 检查手持控制器屏幕有无坏点或任何其他显示缺陷。

执行 *Sara Flex* 上的完整功能测试

图 49

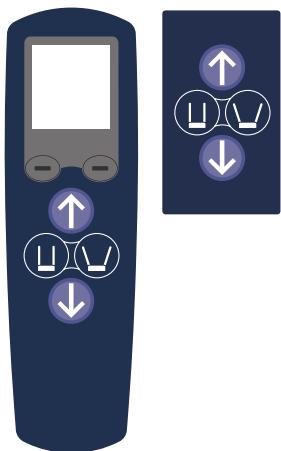


图 50

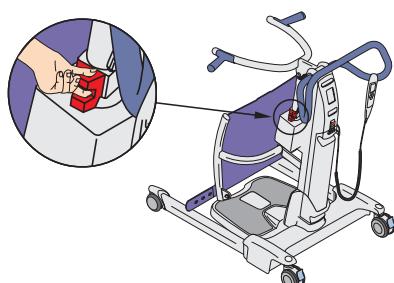
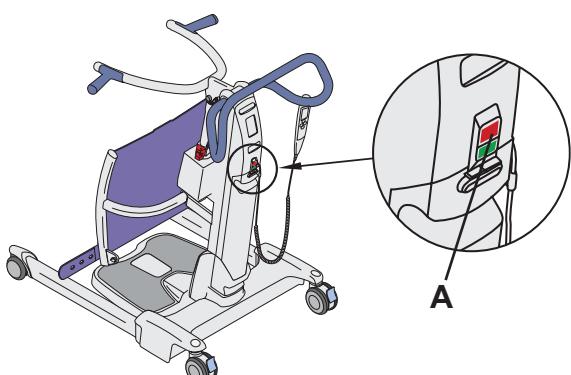


图 51



检查紧急停止/电源按钮和紧急降低手柄的运行情况

- 升高升降臂。
- 向上拉起紧急降低手柄的同时, 向下推升降臂。应缓慢降低升降臂。(请见图 50)
- 升高/降低升降臂或打开/合拢支腿时, 按下紧急停止/电源按钮 (A)。移位机的操作应立即停止。(请见图 51)

检查电池有无漏液和/或劣化情况。需要时更换

- 取下电池。
- 检查电池座连接器有无损坏。
- 目视检查电池，查看有无漏液和/或劣化情况。

检查所有脚轮有无磨损

- 用水清洗脚轮(肥皂、毛发、灰尘和清洁地面的化学品，可能影响其功能)。
- 检查脚轮能否灵活滚动和转向。

检查有无腐蚀现象

如果发现部件有任何明显的腐蚀或损坏，请联系您当地的 Arjo 工作人员以获得支持。

只能由合格的人员每年进行检查

Sara Flex 必须依照保养和维护手册一年维护一次。

警告

为避免伤害和/或使用不安全的产品，必须由对相应程序具备足够知识的授权人员使用适当工具和部件按适当的频率进行维护。授权人员必须具有本设备的培训和维护证书。

注意

在授权人员进行维护时，将检查全部的护理人员职责的完成情况。

有关详细信息，请参阅单独的服务说明。

技术规格

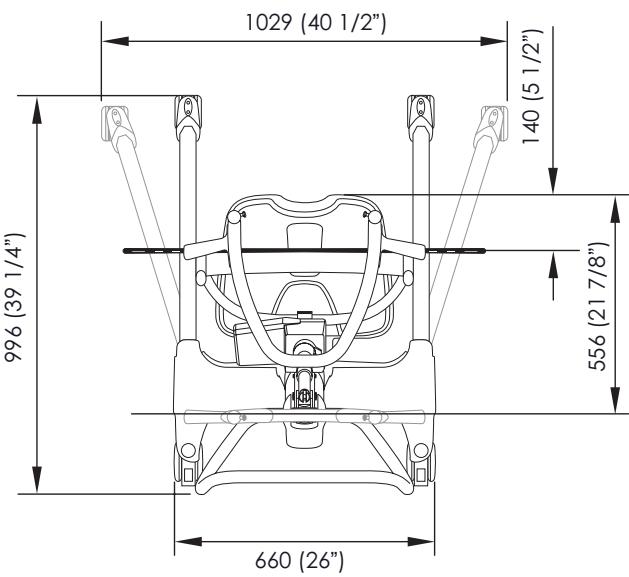
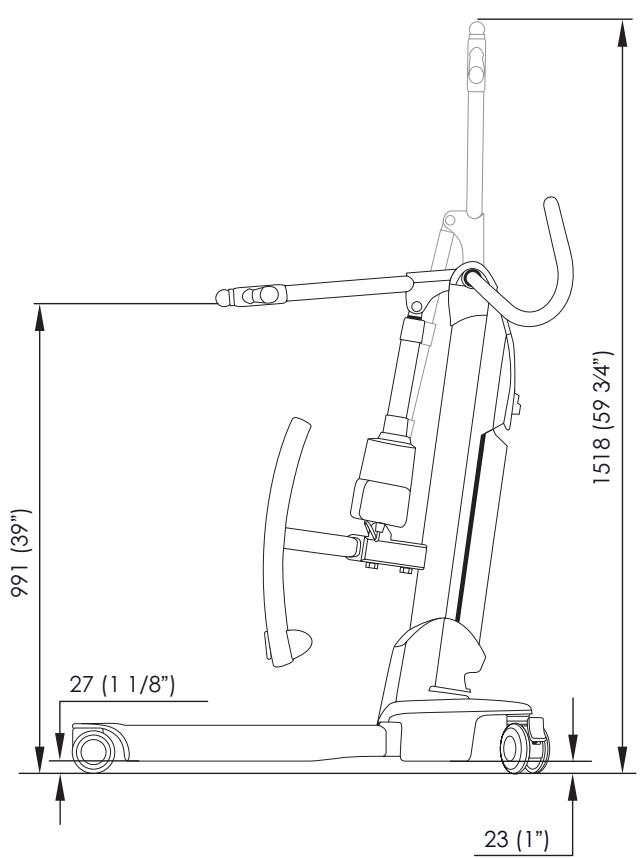
基本信息	
安全工作荷载 (SWL) <i>Sara Flex</i>	200 公斤/440 磅
部件重量 <i>Sara Flex</i> 总重	52 kg / 114.5 lb
电池组	3.8 kg / 8.4 lb
电气	
防护级别 - 防电击	BF 型 
移位机 - 防护级别	IP24
手持控制器 - 防护级别	IPX7
电池类型	可充电 - 密封铅酸电池
电池部件号	NDA0100-20
电池容量	24V DC 4Ah
充电器	NDA8200
移位机 - 防护等级 - 防止电击	内部供电设备
移位机额定电压	24V DC
保险丝	15A 型 AGC 保险丝
控制装置操作力	< 5 N
最大工作周期, 移位机执行器 最大工作周期, 腿部传动执行器	最大 10% (2 分钟开/18 分钟关) 最大 10% (2 分钟开/18 分钟关)
最大声功率级	50dB
称重器规格	
称重范围	200 公斤/440 磅
显示精度和显示器类型	0.2 kg / 0.5 lb, 液晶显示屏
工作电压	
环境温度	+10°C (50°F) 至 +40°C (104°F)
相对湿度范围	10% 到 80%
大气压力	700hPa 至 1060 hPa
运输和存储	
环境温度	-25°C (-13°F) 至 +70°C (158°F)
相对湿度范围	10% 到 80%
大气压力	700hPa 至 1060 hPa
将产品从一个机构运输到另一个机构时, 确保产品正确固定。	

安全处置	
电池	铅酸电池 不得丢弃；会危害环境。
包装	木质和瓦楞纸板，可回收。
产品	电气、金属和塑料部件应按设备标牌说明分类和回收。
电气和电子部件	移位机系统含有电气和电子部件或电线，应按照废弃电气和电子设备(WEEE) 或根据当地或国家法规进行拆卸和回收。
吊兜	吊兜含有加强筋/稳定器、填充材料、其他纺织品或聚合物或塑料等， 应归类为可燃废弃物。

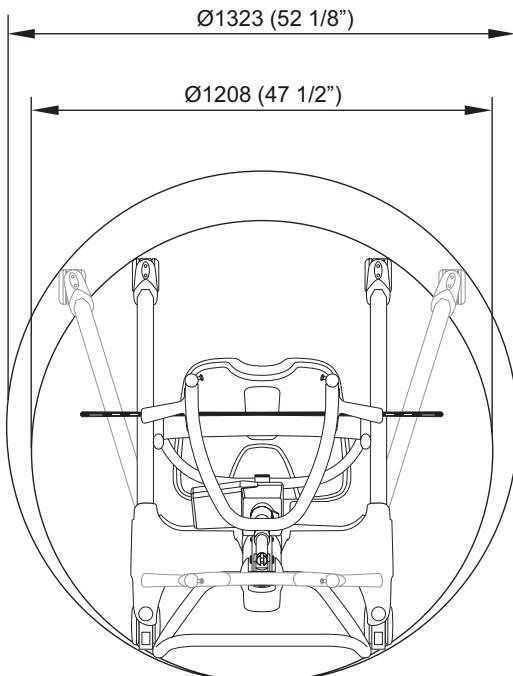
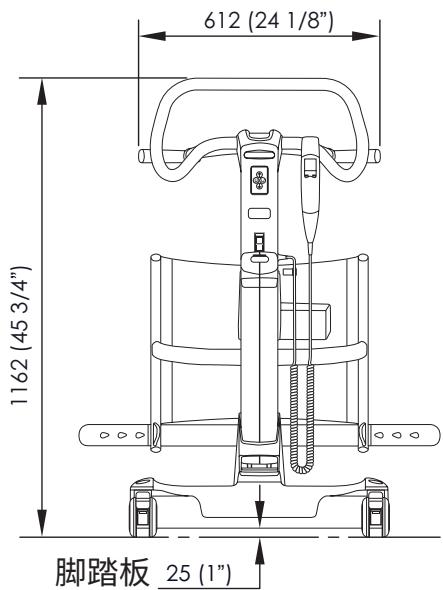
允许组合	
主动式吊兜	<ul style="list-style-type: none"> • TSS.500 (S) • TSS.501 (M) • TSS.502 (L) • TSS.503 (XL) • TSS.504 (XXL)
转运吊兜	<ul style="list-style-type: none"> • TSS.511 (仅与中央挂钩一起使用)
Flite	<ul style="list-style-type: none"> • MFA3000

尺寸

测量单位为 mm 和英寸 ("")



旋转半径



Sara Flex 上的标签

在标签上, 您可以找到以下符号/信息:

标签说明

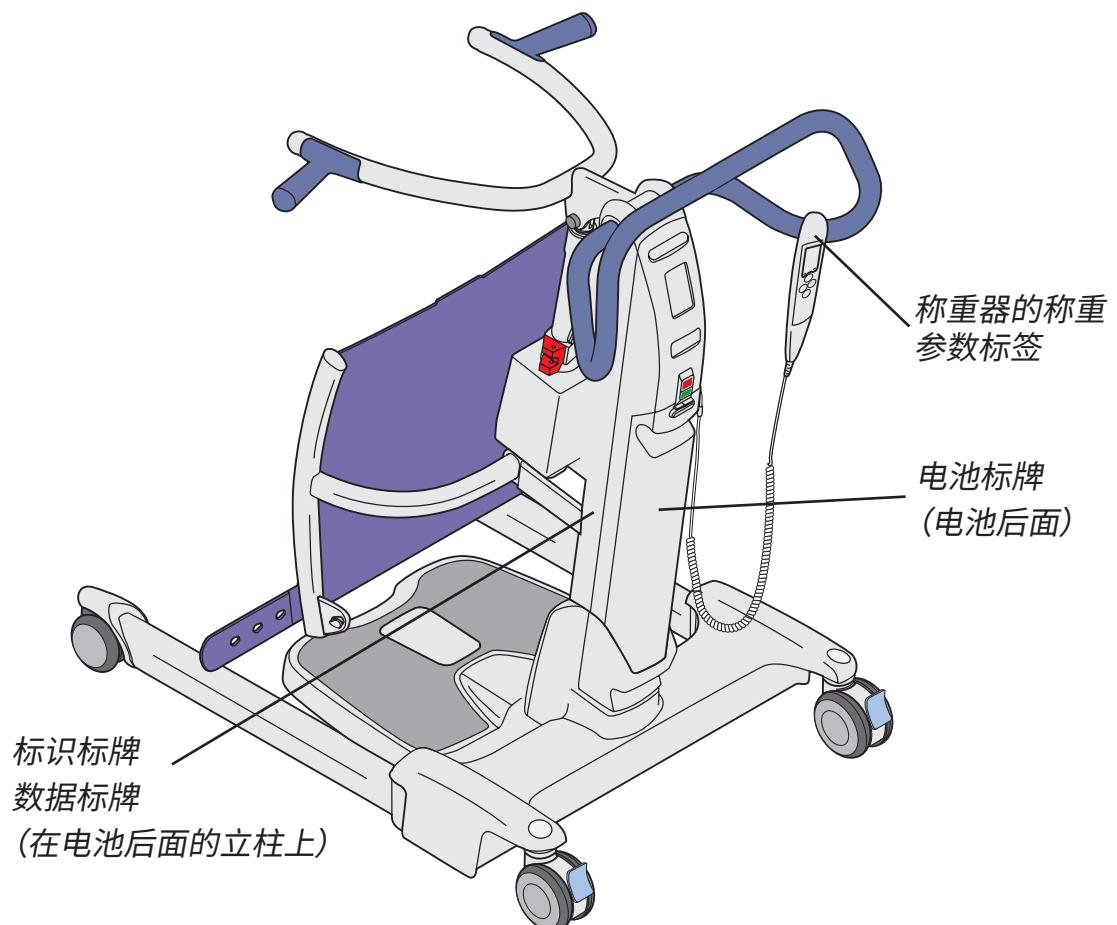
数据标签	描述技术性能与要求, 如: 输入功率、输入电压与病人最大体重等。
标识标签	描述产品标识、序列号和制造年份与月份。
SWL 标签	该标签表示 <i>Sara Flex</i> 的最大提升能力。
电池标牌	描述关于电池的安全与环保信息。
称重器的称重参数标签	该标签说明了称重器的称重参数。

符号说明

SWL	安全承重 定义了 <i>Sara Flex</i> 上患者和任何其他负载的最大总载重
IP24	防溅防护等级
24 V ——	电源电压(直流)
10 A	电流
	废弃电气电子设备 (WEEE) - 切勿将本产品丢弃到一般家庭或商业废弃物中。
REF	型号
SN	序列号
	制造商的名称和地址

	使用前阅读使用说明书 (IFU)
	BF 类, 符合 IEC 60601-1 的防电击保护标准
	符合医疗设备指令 93/42/EEC 的 CE 标志。
	经过认证, 符合 NRTL 到 TÜV SÜD。请参阅“标准与证书列表”部分。
	经过 TÜV SÜD 的认证。请参阅“标准与证书列表”。
	包括设备安全承重在内的总质量 ($52\text{kg}/116\text{lb}+200\text{kg}/440\text{lb}=252\text{kg}/556\text{lb}$)。
	SWL 额定值 表示移位机的最大提升能力。
	称重器符号。 如果移位机带有该符号, 则表示安装了称重功能。
Max	称重仪器的最大称重能力
Min	称重仪器的最小称重能力
e	称重器检验间隔时间
	请勿推拉执行器
	III 级非自动称重设备标签; yy = 年;XXXX = 公告机构编号。

MD	表示该产品是符合欧盟医疗器械法规 2017/745 的医疗器械
UDI	设备唯一标识符



电磁兼容性

经检测, *Sara Flex* 在拦截外部电磁干扰 (EMI) 的能力方面, 符合当前的监管标准。但仍可采用以下程序帮助降低电磁干扰:

- 确保其他患者监控或生命保障设备符合可接受的辐射标准。
- 最大限度地保持电子医疗设备之间的距离。高功率设备可能会产生电磁干扰 (EMI), 从而影响移位机。

有关如何管理此设备的射频 (RF) 电磁环境的更多信息, 请参考《AMI TIR 18-1997 - 适用于临床或生物医学工程师的医疗设备电磁合规性指南》。

Sara Flex 设计为在下面指定的电磁环境中使用。*Sara Flex* 的客户及用户务必在此类环境中使用该产品。

警告

对于便携式移动射频通信设备 (包括外围设备, 例如天线电缆和外置天线), 其使用位置应距离 *Sara Flex* 移位机任何部件 (包括制造商规定的电缆) 30 厘米以上。否则, 将会影响设备的性能。

警告

使用未经 Arjo 指定或提供的零配件、电缆和备件可能会导致电磁辐射增加或设备的电磁抗扰性降低, 从而导致操作不当。

警告

应避免邻近或堆叠在其他设备在使用本设备, 这可能造成工作不正常。如果必须这样使用, 应观察本设备和其他设备, 检查它们是否工作正常。

警告

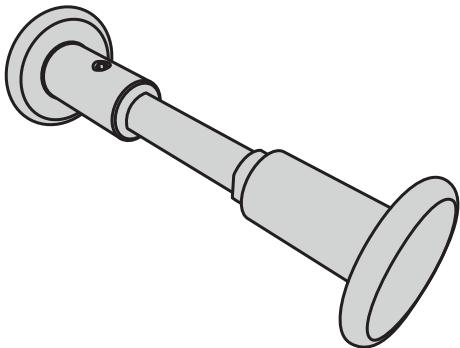
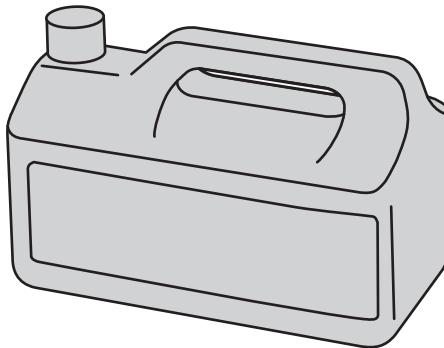
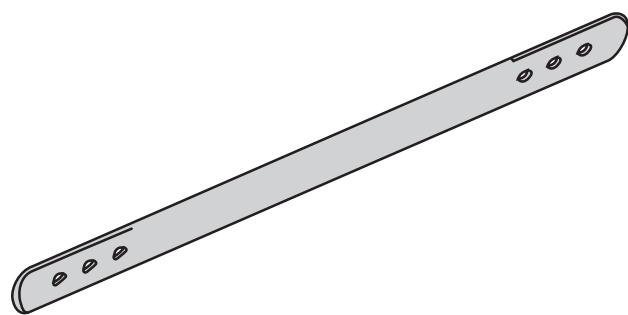
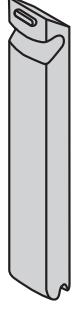
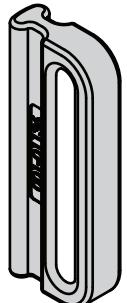
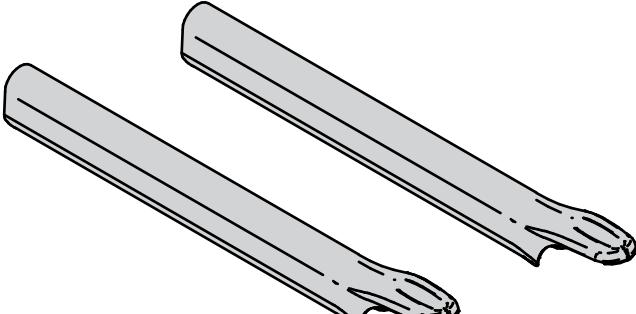
本设备可能会导致射频干扰或中断附近设备的操作。可能需要采取操作, 比如改变方向、重新放置设备或屏蔽位置。

指导和制造商声明: 电磁辐射

辐射测试	合规	电磁环境 - 指导
射频 (RF) 辐射 CISPR 11	组别 1	<i>Sara Flex</i> 仅对内部功能使用射频能量。因此, 其射频辐射非常低, 不太可能对附近的电子设备产生任何干扰。
射频 (RF) 辐射 CISPR 11	B级	<i>Sara Flex</i> 适用于各种建筑物, 其中包括民用建筑物和直接连接于公用低压电网 (此类电网旨在为民用建筑物供电) 的建筑物。

指南和制造商声明：电磁抗扰度			
抗扰性测试	IEC60601 试验电平	符合电平	电磁环境 - 指导
静电放电 (ESD) IEC 61000-4-2	±8kV 接触放电 ±2 kV、±4 kV、±8 kV ±15 kV 空气放电	±8kV 接触放电 ±2 kV、±4 kV、±8 kV ±15 kV 空气放电	地板应为木质、水泥或瓷砖。 如果地板上覆盖合成材料，则相对湿度应至少为 30%。
射频传导 IEC 61000-4-6	3V, ISM频段外 0.15-80 MHz	3V, ISM频段外 0.15-80 MHz	N/A
	6 V, ISM 之内, 0.15-80 MHz 业余无线频率	6 V, ISM 之内, 0.15-80 MHz 业余无线频率	
射频辐射 IEC 61000-4-3	10V/m 80MHz 至 2.7GHz	10V/m 80MHz 至 2.7GHz	
电快速瞬变/ 脉冲群 IEC 61000-4-4	±1 kV, 输入/输出端口 100 kHz 重复频率	±1 kV, 输入/输出端口 100 kHz 重复频率	主电源应符合一般商业或医院 环境的电源质量要求。
电源频率 (50/60 Hz) 磁场 IEC 61000-4-8	30 A/m 50/60 Hz)	30 A/m 50/60 Hz)	如果 <i>Sara Flex</i> 出现功能障 碍, 可能需要安装磁屏蔽。该工 频磁场应进行测量, 以确保它 足够低。
近场射频 (RF) 无线通信设备 IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz	380 - 390 MHz 27 V/m; PM 50%; 18 Hz	N/A
	430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz 正弦波) PM; 18 Hz	430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz 正弦波) PM; 18 Hz	
	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	
	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	
	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	
	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	
	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	

部件和附件

	
中央挂钩 700-27041	消毒剂 如需订购,请联系当地的工作人员
	
腿带 AH1003006	电池 NDA0100-20
	
腿带连接 700-27044	充电器 NDA8200
	
腿部护罩套件 700-27034	

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Foreword

Thank you for purchasing Arjo equipment.

Please contact us if you have any questions about the operation or maintenance of your Arjo equipment.

Please read and fully understand these *Instructions for Use (IFU)* before using Sara® Flex.

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

Information in this *IFU* is necessary to perform the operation and maintenance of the equipment. It will help to protect your product and make sure that the equipment performs to your satisfaction. The information in this *IFU* is important for the safety of both patient and caregiver and must be read and understood to help prevent possible injury.

Unauthorized modifications on any Arjo equipment can affect safety. Arjo will not be held responsible for any accidents, incidents or lack of performance that occur as a result of any unauthorized modification to its products.

Serious incident

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

Service and Support

Routine maintenance must be performed on *Sara Flex* to maintain safety and reliability of the equipment. See section “*Care and Preventive Maintenance*” on page 70.

If further information is needed, contact your local Arjo representative for replacement parts. The contact information appear on the last page of this *IFU*.

Definitions in this *IFU*

WARNING

Means: Safety warning. Failure to understand and obey this warning may result in injury to you or to others.

CAUTION

Means: Failure to follow these instructions may cause damage to all or parts of the system or equipment.

NOTE

Means: This is important information for the correct use of this system or equipment.



Means: The name and address of the manufacturer.

Intended Use

This equipment must be used in accordance with these safety instructions. Anyone using this equipment must also have read and understood the instructions in these *IFU*.

If there is anything that remains unclear, contact your Arjo representative.

Intended Use for *Sara Flex*

Sara Flex is a mobile standing and raising aid, with a Safe Working Load of 200kg (440 lb), intended to assist caregivers in hospitals, long-term care, nursing homes and home care environments, including private homes, to lift and transfer patients/residents from one place to another e.g. to and/or from a chair, wheelchair, bed side, bath, shower/commode chair or toilet.

The equipment must be used by appropriately trained caregivers with adequate knowledge of the care environment, its common practice and procedures and according to guidelines in this *IFU*.

Sara Flex should only be used for the purpose specified in this *IFU*. Any other use is prohibited.

Patient/Resident Assessment

It is recommended that facilities establish regular assessment routines to make sure that caregivers are assessing each patients/residents prior to use.

Before use the caregiver should always consider the patients/residents medical condition, physical and mental capabilities.

In addition the patient/resident must

- be able to bear weight on at least one leg and have some trunk stability
- be able to sit on the edge of the bed
- have a maximum weight of 200 kg (440 lb)
- have a height within the range of 145 to 195 cm (4'8" – 6'4").

If the patient does not meet these criteria an alternative equipment/system shall be used.

CAUTION

To avoid product damage do not use *Sara Flex* outdoors. The product is intended to be used with specifically designed slings.

Expected Service Life

The expected service life is the maximum period of useful life as defined by the manufacturer.

The expected service life for *Sara Flex* is ten (10) years considering the product has been serviced and maintained as indicated in the Care and Preventive Maintenance section.

Actual service life may vary depending on the frequency of use and conditions.

The *IFU* shall be available as long as reasonably necessary, taking the lifetime of the device into consideration.

Other consumable parts, e.g. batteries, sling, etc. are also subject to wear and their expected operational life is dependent on usage.

Safety Instructions

WARNING

To avoid injury, make sure that the patient is not left unattended at any time.

WARNING

This equipment includes small parts that may present a choking hazard to small children if inhaled or swallowed.

Keep children and pets away from the equipment.

The hand control cable presents a strangulation risk; take all precautions necessary to prevent this.

WARNING

To avoid injury, a full clinical assessment of the patient's condition, and suitability must be carried out by qualified personnel, before attempting to use *Sara Flex*.

WARNING

To avoid injury, make sure that the applied load is lower than the safe working load for all products or accessories being used.

CAUTION

To avoid corrosion on the product do not leave *Sara Flex* and its accessories for extended periods in humid or wet areas.

Policy on Number of Staff Members Required for Patient Transfer

Arjo's floor lifts are designed for safe usage with one caregiver. It is the responsibility of the caregiver to determine if a one or two person transfer is more appropriate, based on the following:

- Patient's condition
- The task
- Patient's weight
- Environment
- Capability
- Skill level of the caregiver

Do not hesitate to contact your medical professional for guidance.

Preparations

Actions Before First Use (6 steps)

1. Visually check the package for damage. If the product looks damaged due to freight, contact the transport agency.
Do NOT use the product.
2. The packaging should be recycled according to local regulations.
3. Read this *IFU*.
4. Choose a designated area, where this *IFU* should be kept and is easily accessible at all times.
5. Verify each functions (Up-Down, Open-Close lift legs)
6. Initiate the emergency lowering function to check it is working correctly. To do this, pull up the red emergency lowering handle and keep it pulled up, whilst at the same time, push down on the lifting arm until it starts lowering.

NOTE

Initial activation may require additional amount of load on the lifting arm. It may be helpful if two people perform this check, one to activate the handle and the other to push down the lift arm.

Actions Before Every Use (2 steps)

1. Visually inspect *Sara Flex*. If any part is damaged - do NOT use the product.
2. Check the battery level.

In between Use

Clean and disinfect the product according to the “*Cleaning and Disinfection Instructions*” on page 67.

Sara Flex Directions

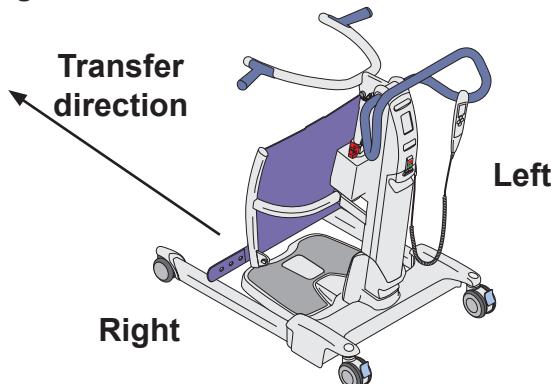
Left and right

Sara Flex has a left and right side. (See Fig. 1)

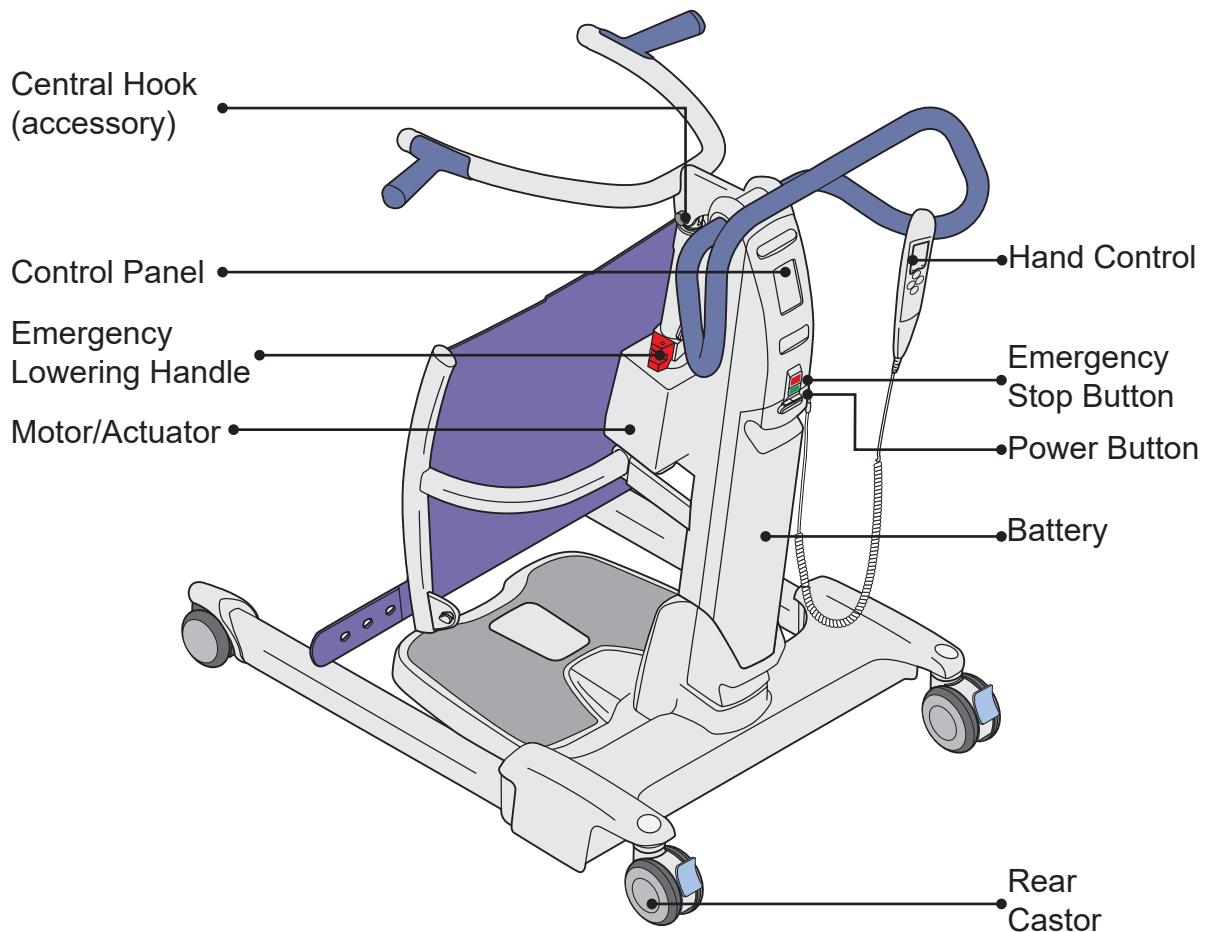
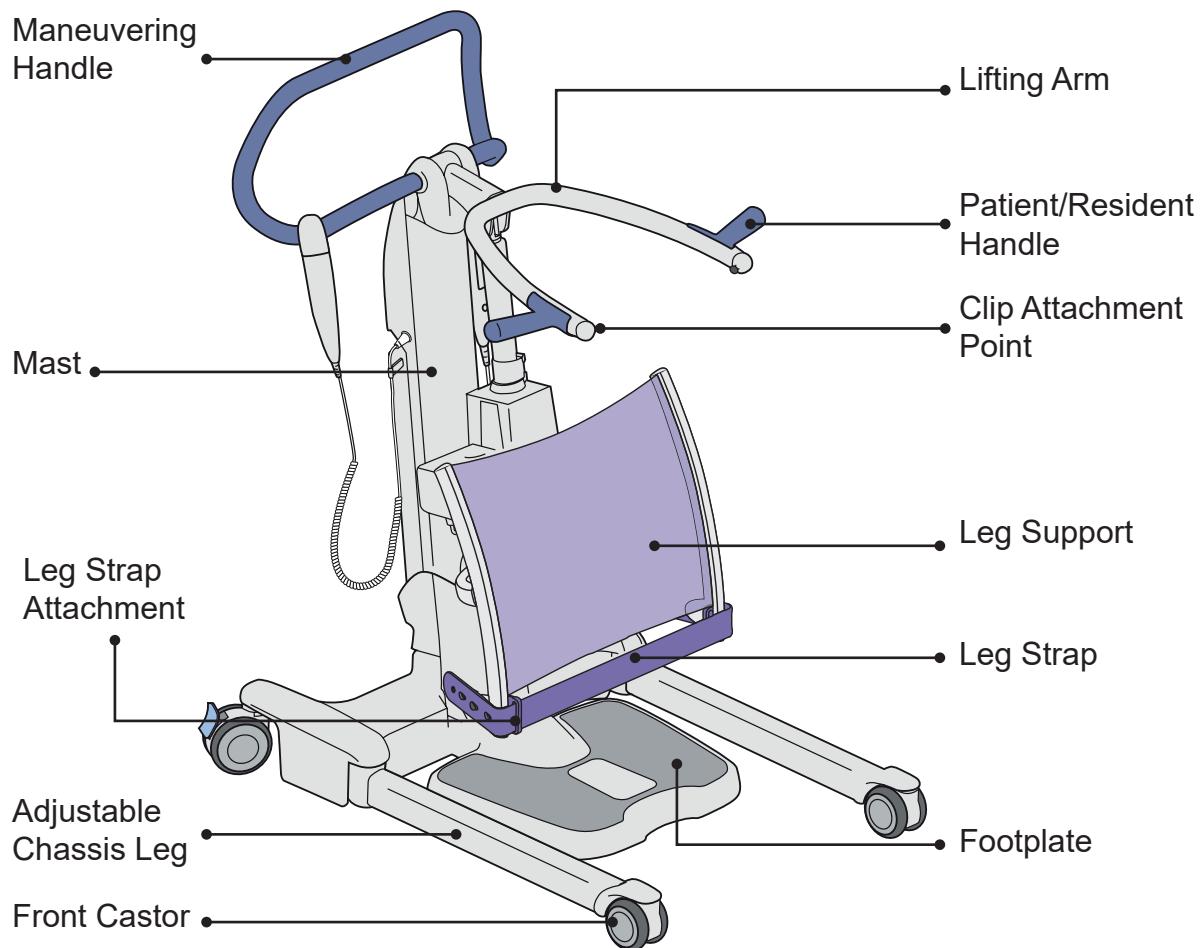
Transfer direction

The caregiver must be positioned behind *Sara Flex* during transfers.

Fig. 1

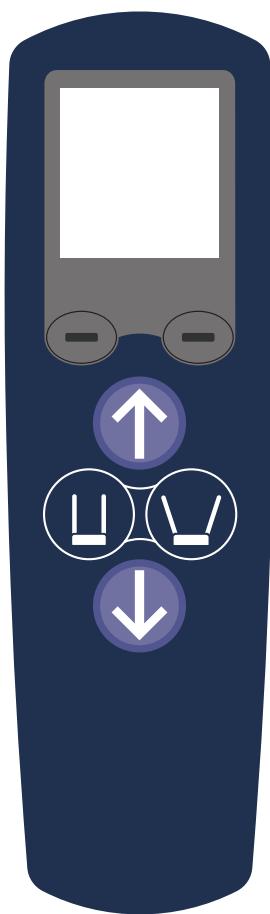


Parts Designation



Product Description / Functions

Fig. 2



Controls and Features

Hand control (See Fig. 2)

Use the hand control to:

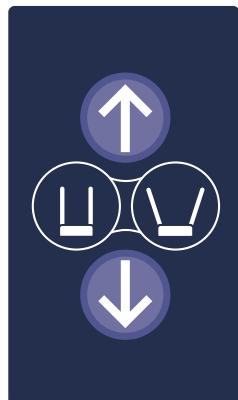
- Raise/lower the lifting arm on *Sara Flex*.
- Open/close the chassis legs on *Sara Flex*.
- The dash buttons are used for menu operations.

Button Functions:

	Up
	Down
	Close lift legs
	Open lift legs
	Right Dash
	Left Dash

If a pressed button is released, it will stop its function immediately.

Fig. 3



Control Panel (See Fig. 3)

The mast-mounted control panel operates in parallel with the hand control. *Sara Flex* can also be controlled from the mast.

Button Functions:

	Up
	Down
	Close lift legs
	Open lift legs

Fig. 4



LCD Display

(See Fig. 4)

Battery Level - see "Battery Instructions" on page 65.

0.0 Usage counter

Maintenance symbol

0.0 Patient's weight - see "Scale (Optional)" on page 60.

At start up it takes a little time before the display looks as shown in **Fig. 4**. The LCD display will only light up when a button is pressed.

Usage counter

The usage counter shows the total added amount of time (in hours) that the lift's lifting arm has been raised or lowered.

The usage counter will increase in increments of 0.1 hours whenever an additional six minutes have been added.

NOTE

The usage counter only records during movement of the lifting arm.

Maintenance symbol

The maintenance symbol is a reminder for the yearly maintenance requirements for the product.

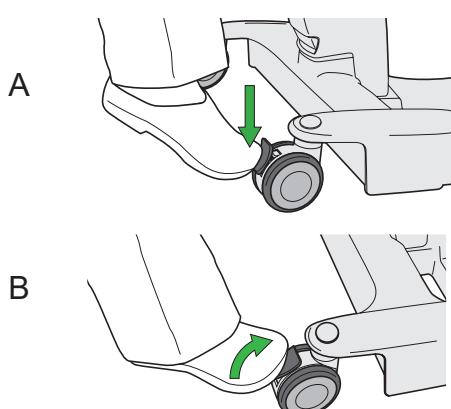
The maintenance symbol is shown after a 125 hours of usage. This is the average time a lift is used during one year. the maintenance symbol will flash (1 sec ON and 1 sec OFF).

When the maintenance symbol appears, the unit will still be safe to use, but the yearly maintenance should be performed as soon as possible.

NOTE

The technician must reset the display to "0.0" hours when the annual inspection is performed. This is done to visually see when next inspection is due.

Fig. 5



Castor Brakes

The rear castors brakes are foot operated to keep *Sara Flex* in position.

Apply the brakes (See Fig. 5):

Press down on the gray castor brake lever (A).

Release the brakes (See Fig. 5):

Slightly kick up the gray castor brake lever (B).

Fig. 6

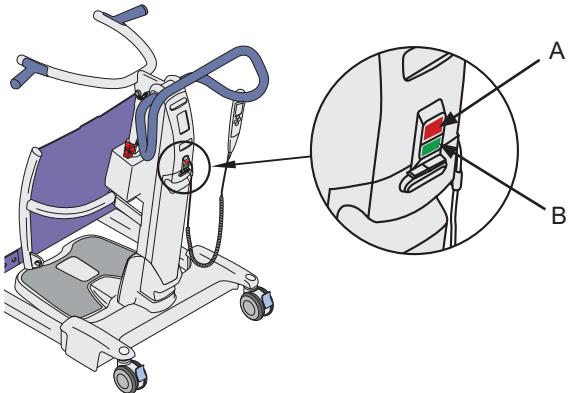


Fig. 7

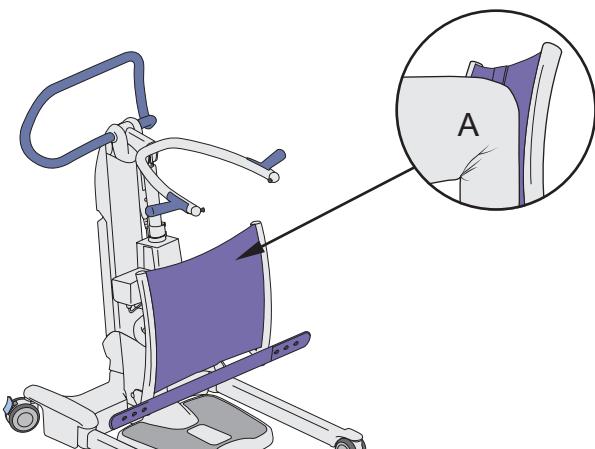
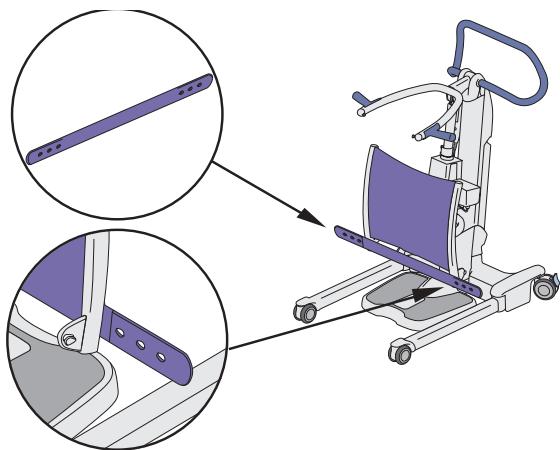


Fig. 8



Emergency Stop Button

To Activate

Press the red emergency stop button (**A**) to cut all power to all electrical components. (See Fig. 6)

To Deactivate

Press the green power button (**B**) to power on the equipment again. (See Fig. 6)

Power Button

The green power button (**B**) is located next to the stop button. Press the power button to switch on *Sara Flex*. (See Fig. 6)

Leg Support

The leg support is made out of silicone. (See Fig. 7)

This material adjusts itself based on the pressure applied by the patient knees (**A**).

Leg Strap

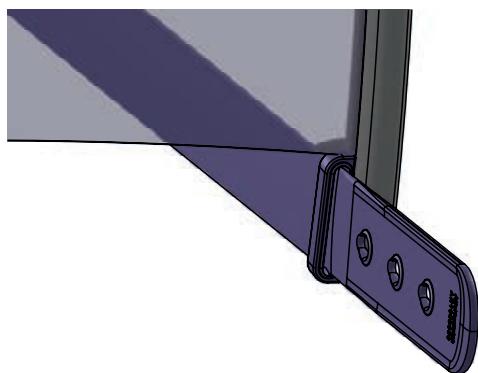
The leg strap is located under the silicone leg support. (See Fig. 8)

The leg strap is used to make sure that the patient's legs stay close to the leg support.

To fasten the leg strap, attach it to the attachment point on either side of the leg support.

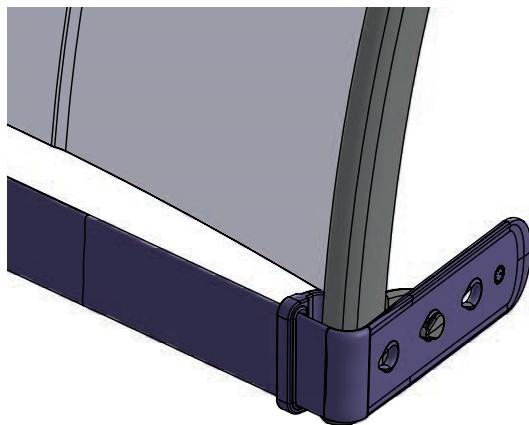
Leg Strap attachment (optional)

Fig. 9



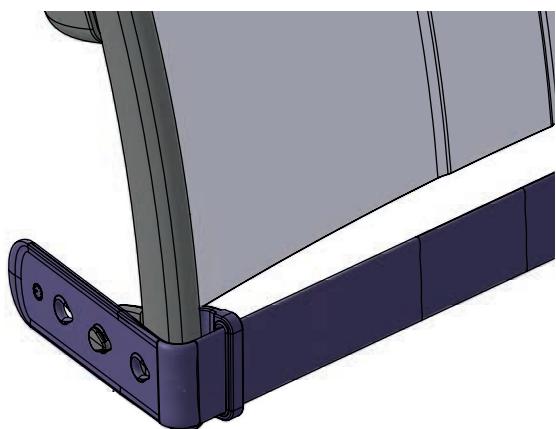
Insert strap through the leg strap attachment.
(See Fig. 9)

Fig. 10



Fasten strap to the leg pad support.
(See Fig. 10)

Fig. 11

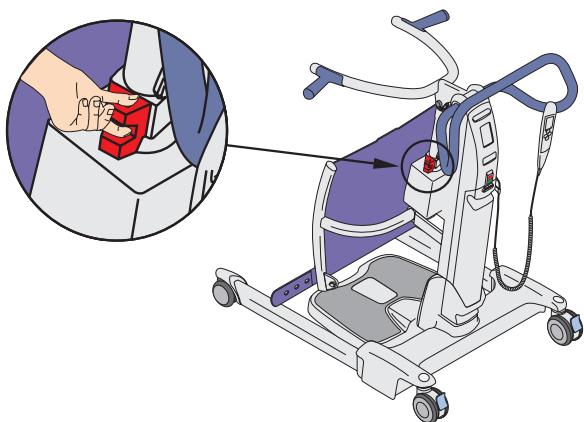


Repeat on the other side, if needed.
(See Fig. 11)

Fig. 12



Fig. 13



Emergency Lowering

In the event that the emergency lowering function needs to be activated, position the *Sara Flex* so that the patient can be lowered on to an appropriate surface such as a chair or bed. Stand close to the *Sara Flex*, on the same side as the red emergency lowering handle. (See Fig. 12)

Use one hand to gradually pull up the emergency lowering handle (and keep it there), allowing the lifting arm to lower the patient onto the surface. Once lowered, let go of the emergency lowering handle and it will return to its correct position. (See Fig. 13)

NOTE

If the lifting arm does not start to lower when the emergency lowering handle is pulled up, use your other hand to push down on the lifting arm whilst still pulling up on the emergency lowering handle, until the lifting arm begins to lower. (If the lifting arm is in the fully upright position, it may help to stand facing the patient and push the lifting arm away from you). Keep the emergency lowering handle pulled up fully until the patient is lowered on to the receiving surface.

Automatic Cut-Out

This is not an operator control but a function built into the *Sara Flex* electronics.

If the lift is inadvertently overloaded by trying to raise or lower a load heavier than permitted, an automatic “cut-out” function operates to prevent the lift from raising a weight in excess of the safe working load (SWL). This will stop the lift’s motion automatically.

If this occurs, release the “up” button on the hand control or the control panel. Do not continue to raise the load. Make sure that the *Sara Flex* operates only within its safe working load.

Anti-Crush System

This is not an operator control but a function built into the *Sara Flex* electronics.

Great care should be taken not to lower the lifting arm onto the patient or any other obstruction. If this should happen, the *Sara Flex* “anti-crush” system will engage, stop the motor and all downward movement will cease. If this occurs, release the “down” button immediately and press the “up” button to raise the lifting arm until the lift is clear.

Then remove the obstruction.

Allowed Slings with *Sara Flex*

The following slings are compatible with *Sara Flex*.

Active Slings (See Fig. 14)

- TSS.500 (S)
- TSS.501 (M)
- TSS.502 (L)
- TSS.503 (XL)
- TSS.504 (XXL)

Flites

- MFA3000 (Flite)

Transfer Sling (See Fig. 15)

- TSS.511 (Transfer Sling Model, only to be used with Central Hook)

For sling selections see respective sling *IFU*.

Fig. 14

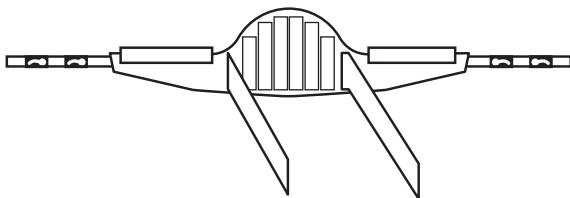


Fig. 15

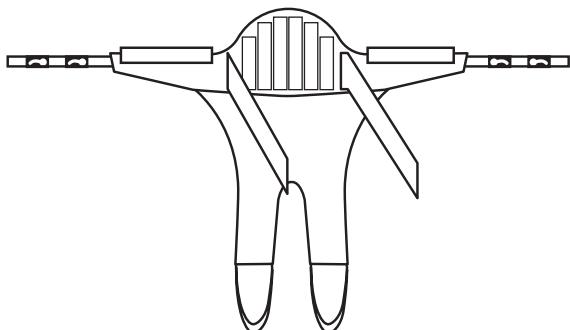
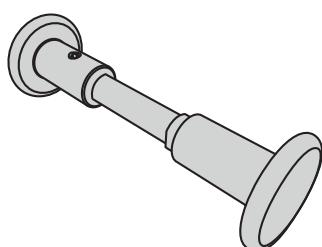


Fig. 16



Central Hook (Accessory)

Only to be used with the transfer sling. The central hook (**See Fig. 16**) is to be installed right under the lifting arm by qualified personnel only.

Transfer from Wheelchair to Sara Flex

Prepare Sara Flex and Patient

- For sling instructions, see respective sling *IFU* and the sling label.
- Determine if *Sara Flex* is the appropriate equipment to use for the patient, see “*Intended Use*” on page 45.
- Lower the *Sara Flex* lifting arm to its lowest position.
- Inform the patient about the transfer (e.g. transfer to bathroom).
- Select and apply sling, see respective sling *IFU*.
- Apply brakes to the wheelchair (if applicable).

Place Patient in *Sara Flex*

(8 Steps)

1. Open chassis legs if needed to accommodate the width of the chair, bed, etc.

NOTE

If the chassis legs can fit underneath the furniture, do not open the chassis legs

2. Ask or assist the patient to place his/her feet on the foot plate. (See Fig. 17)

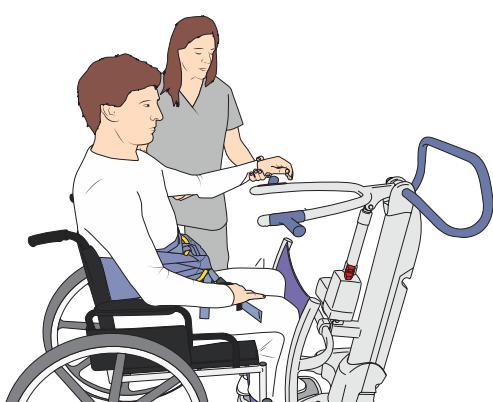
Fig. 17



Fig. 18



Fig. 19



3. Push *Sara Flex* towards the patient until it gently touches the patient’s shins. (See Fig. 18)

4. Ask or assist patient to place his/her hands on the patient/resident handles.(See Fig. 19)

Fig. 20

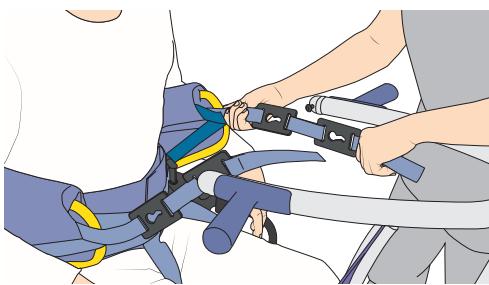


Fig. 21

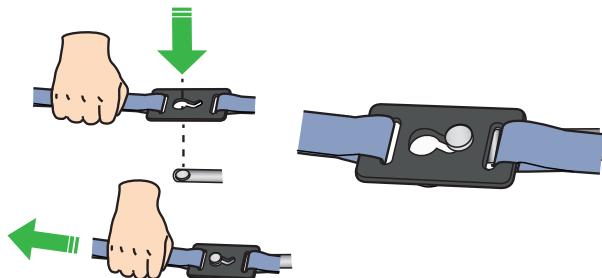
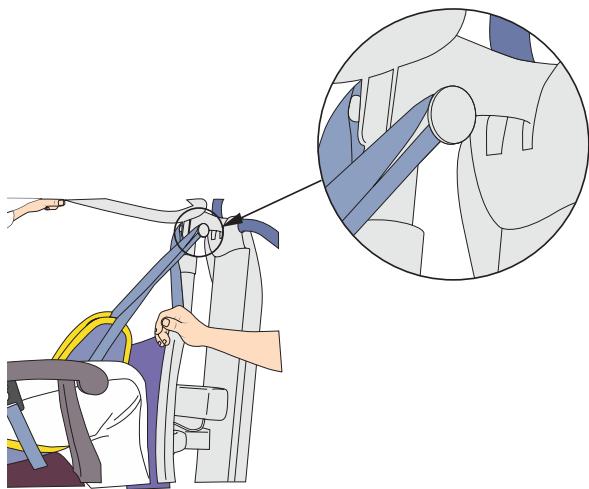


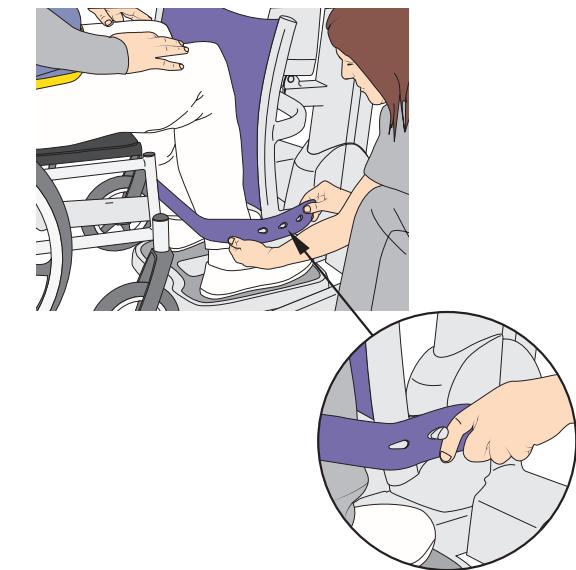
Fig. 22



5. Attach sling clips to attachment points on the *Sara Flex* lifting arm. (See Fig. 20)

6. Make sure the clips are attached securely. (See Fig. 21)

Fig. 23



7. When using a transfer sling, also attach the loops on the central hook (accessory) located right under the lifting arm. (See Fig. 22)

8. Attach the leg strap to support the patient's legs, if needed. (See Fig. 23)

Fig. 24



Raise a Patient to Standing Position

NOTE

- When raising the patient with transfer sling, he/she should not help out while being raised.
- When using the transfer sling, do not raise the patient higher than seating position. A higher position will not be comfortable for the patient.

(5 Steps)

1. Stand next to the patient and inform him/her that the *Sara Flex* will be raised to a standing position.
2. Check attachment points to make sure the *Sara Flex* is ready.
3. Use the hand control to raise patient from sitting position to standing position. (See Fig. 24)
4. While the patient is standing, check the supports.
5. Tighten safety straps around the abdomen, if needed.

WARNING

To avoid injury make sure the patient is participating. If not, consider to end the transfer, return the patient to a sitting position and reevaluate the choice of equipment.

Fig. 25



Patient Transfer

(2 Steps) (See Fig. 25)

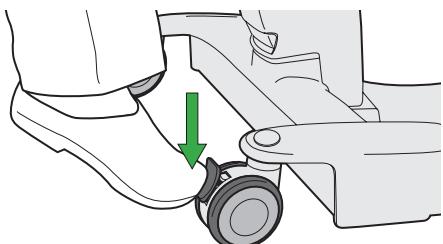
1. Pull *Sara Flex* away from the wheelchair, using the maneuvering handle.
2. Close the chassis legs if needed.

Transfer from Sara Flex to Toilet

Fig. 26



Fig. 27



(18 Steps)

1. Using the maneuvering handle, position patient in front of the toilet/commode or device that patient will sit on. (See Fig. 26)
2. Adjust chassis legs if needed.
3. While the patient is standing caregiver can help with the patient's clothing (i.e., dressing, undressing or toileting tasks etc.).
4. Position the patient over the toilet/commode. Press the down arrow on the hand control to lower the patient to a sitting position.
5. Stand next to the patient while he/she is being lowered.

WARNING

To avoid pinching of genitals and skin, make sure there is enough clearance during movement.

6. Apply the castor brakes to keep *Sara Flex* in position once the patient is sitting on the toilet. (See Fig. 27)
7. Remove sling clips from *Sara Flex*.
8. Have the patient release their hands from the patient/resident handles.
9. Detach leg straps, if applicable.
10. Remove sling, if needed.
11. Allow privacy for the patient, but make sure the patient is not left unattended.
12. After providing personal hygiene care, reapply sling, if removed.
13. Ask or assist patient to place his/her hands on the patient/resident handles.(See Fig. 19)
14. Attach sling clips to attachment points on the *Sara Flex* lifting arm. (See Fig. 20)
15. Make sure the clips are attached securely. (See Fig. 21)
16. Raise the patient slightly and apply any necessary incontinent products and adjust clothing.
17. Release the brakes.
18. Before transfer from the toilet, repeat the steps in "Raise a Patient to Standing Position" on page 57.

Transfer from *Sara Flex* to Bed/Chair

Fig. 28



Fig. 29



(11 Steps)

1. Apply the brakes on the wheelchair, if applicable.
2. Adjust chassis legs if needed to go around bed/chair. (See Fig. 28)
3. Lower the patient onto the surface of bed/chair. (See Fig. 29)
4. Make sure the patient is positioned correctly on the bed/chair.
5. Detach the sling from *Sara Flex*.
6. Have the patient release their hands from patient/resident handles.
7. Detach leg straps, if applicable.
8. Have the patient lift his/her feet off the footplate, assist if needed.
9. Pull the *Sara Flex* away from the patient.
10. Remove the sling from the patient
11. Clean the *Sara Flex* after the transfer is complete, according to “*Cleaning and Disinfection Instructions*” on page 67 or according to local guidelines.

Scale (Optional)

WARNING

To avoid injury, only use the scale to weigh hospital or care facility patients under the supervision of Nursing staff and healthcare professionals.

CAUTION

The unit must be stationary on a flat level surface when it is powered up, to allow the scale to perform an automatic zero reset. Do not touch the lift or any of its components until the scale displays “0.0”. Failure to do so may result in inaccurate reading of the weight on the scale.

Display Symbols/Functions

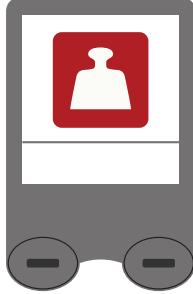
The LCD screen on the hand control can display weight in kilograms (kg) (or pounds (lb) in specific markets).

The minus sign (-) appears when the weight is negative (see “*Method B - Weigh Patient with Sling* on page 63”).

Fig. 30



Scale Symbol



Maximum Weight
Warning Symbol

Overload Warning Symbol

The maximum weight warning symbol appears when the patient weight exceeds the Safe Working Load (SWL) 200 kg (440 lb). (See Fig. 30)

If the scale is overloaded, the unit will beep 2 times and the display will switch between the scale symbol and the maximum weight warning symbol. Remove the overload weight by lowering the patient immediately.

Do not touch the scale/lift until the symbol is switched off.

Fig. 31



Net weight

This is the Net weight of the patient without any accessories e.g. sling. (**See Fig. 31**)

For instruction on how to get the Net weight of the patient, see “*Method A - Weigh the Patient without Sling Weight*” on page 62

Fig. 32



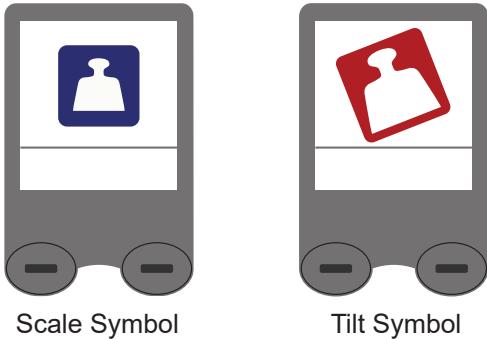
Save weight

To use the Save function, press the left dash button (**A**), to store the weight on the scale. (**See Fig. 32**) This will save the displayed measurement on the screen. Two blue lines will be displayed when the displayed measurement is saved (**B**).

NOTE

Patient should be as still as possible during the weighing procedure. Too much movement by the patient may cause an incorrect reading

Fig. 33



Tilt (for class III scale only)

The display will switch between the scale symbol with a tilted symbol.

NOTE

FOR CLASS III SCALE ONLY,
If the display shows the larger “TILT” symbol alternating with the scale symbol, relocate *Sara Flex* to a level position so that the scale can be operated correctly (**See Fig. 33**).

When the *Sara Flex* is tilted, no weight reading will be available.

It is normal that the display occasionally shows a “Tilt” symbol when the lift is being moved or touched.

Using the Scale - Weigh the Patient

Fig. 34



Fig. 35

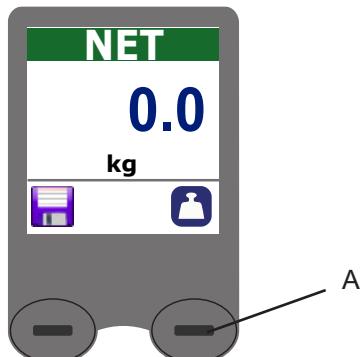
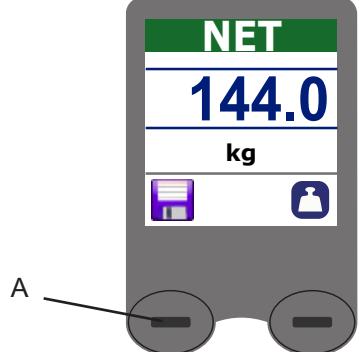


Fig. 36



Fig. 37



Method A - Weigh the Patient without Sling Weight

(8 Steps)

1. Use the power button to power on the *Sara Flex*.
2. If the sling is already installed on the *Sara Flex* it has already zeroed the scale weight automatically. (See Fig. 34)
Move ahead to step 5.
3. If the sling isn't already installed on the lift, install the sling. The scale will now show the weight of the sling on the screen.
4. To use the Scale function, press the right dash button (A) to zero the scale. Now the display will show a zero weight with a NET symbol. (See Fig. 35)
5. Apply the sling on the patient, see respective Sling *IFU*. Place the patient safely onto *Sara Flex*.

6. Lift the patient. (See Fig. 36)

7. The net weight of the patient is now displayed. (See Fig. 37)
8. Press the left dash button (A) to keep the Net weight text on the display.

NOTE

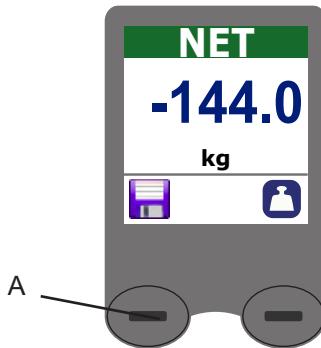
When the *Sara Flex* goes into sleep mode the weight text on the display will disappear.

Method B - Weigh Patient with Sling

Fig. 38



Fig. 39



(7 Steps)

1. Raise the patient to a standing position.
2. Press the right dash button to obtain a zero reading on the display. (See Fig. 38)
3. Complete the patient transfer and remove him/her from the *Sara Flex*.
4. The scale will display a negative number.
5. Attach the sling back on *Sara Flex*.
6. Ignore the minus sign on the screen. Allow the weight reading to stabilize. The weight shown is the patient's actual weight. (See Fig. 39)
7. Press the left dash button (A) to save the net weight text on the display.

NOTE

When the *Sara Flex* goes into sleep mode the weight text on the display will disappear.

CAUTION

If the unit is reset while the patient is still suspended in the sling, the scale will move out of its zero range and display "8888.8" to indicate an error status. Remove the patient from the *Sara Flex* and reset the unit.

Changing the Units of Measure

Fig. 40

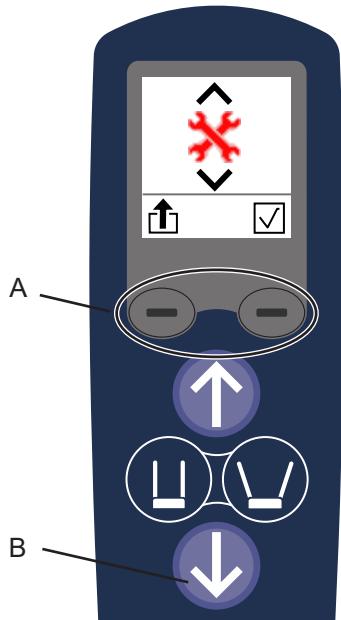


Fig. 41

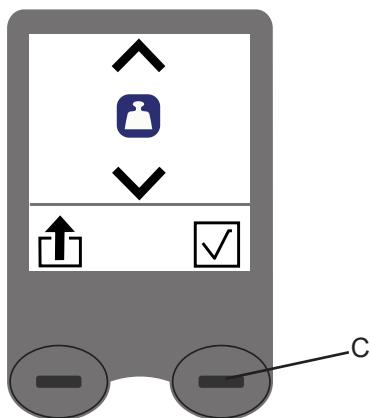
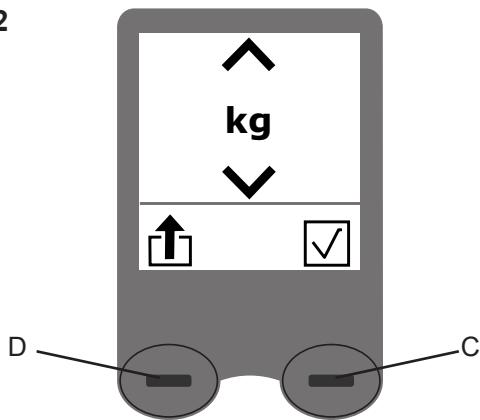


Fig. 42



(6 Steps)

1. To display the Lift Status Screen, press both dash buttons (A) at the same time. (See Fig. 40)
2. To access the configuration screen, press the down button (B) on the hand control. (See Fig. 40)

The Weight Unit screen will be displayed. (See Fig. 41)

3. Press the right dash button (C) to access the units of measurement option. (See Fig. 42)
4. To switch between kg and lb, press the down button (B).
5. To save the settings and return to normal use, press the right dash button (C). (See Fig. 42)
6. Press the left dash button (D) to exit without saving changes. (See Fig. 42)

NOTE

It is not possible to change the units of mass on the Class III scale.

Battery Instructions

WARNING

To avoid bodily injury, do NOT crush, puncture, open, dismantle or otherwise mechanically interfere with the battery.

- Should the battery casing crack and cause contents to come in contact with skin or clothing, rinse immediately with plenty of water.
- If contents come in contact with the eyes, rinse immediately with plenty of water and seek medical attention.
- Inhalation of the contents can cause respiratory irritation. Seek fresh air and medical attention.

CAUTION

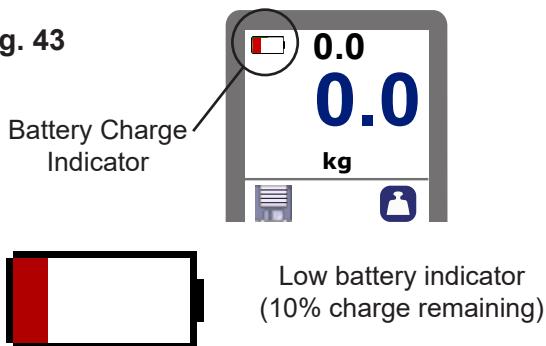
To avoid the battery from overheating and exploding, do NOT expose the battery to flames or excessive heat.

Sara Flex uses sealed lead-acid batteries mounted below the control panel. The LCD screen only shuts down after 2 minutes of inactivity. The rest of the electronics shuts down after 10 minutes of inactivity, to prevent battery damage or drainage while the lift is in the stand-by mode.

Low Battery Warning

Sara Flex has a battery charge indicator on the hand control. (See Fig. 43)

Fig. 43



The battery indicator on the hand control will show if the batteries for *Sara Flex* are close to being empty and it will beep two times every minute. Complete the transfer and charge the battery.

If the battery is close to being empty, the unit will beep 3 times and only a large red low battery indicator will show on the display, then the lift will go into sleep mode.

When trying to use the lift with an almost empty battery:

- The unit will beep 3 times.
- The hand control will briefly display the low battery icon.
- The unit will go back to sleep mode.
- The lift will not be operable until the battery is recharged or replaced.

Battery Storage

- The battery is delivered charged but it's recommended to recharge the battery when received, due to a slow discharge.
- The battery will slowly discharge when not used.
- A battery not in use should be stored in a temperature range of -0°C (32°F) to + 30°C (86°F).
- For maximum battery performance do not store the battery above 50°C (122°F).

Charging Intervals

- To prolong the life of the battery, charge it at regular intervals, e.g. every night.
- It is recommended to use two batteries, one in operation and one as a stand-by in the charger.
- It is recommended that the battery not in use is left in the charger. There is no risk of overcharging the battery.
- It is recommended to remove the battery from the *Sara Flex* when it is not to be used for an extended period of time.
- To prolong the life of the battery, recharge it before it reaches a low level charge.

Inserting/Removing the Battery

The same method applies for inserting/removing the battery on the *Sara Flex* or the charger.

Fig. 44

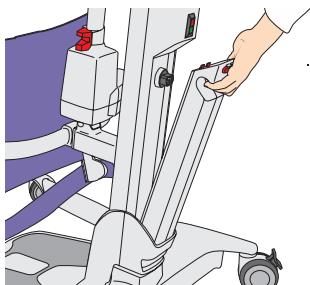


Fig. 45

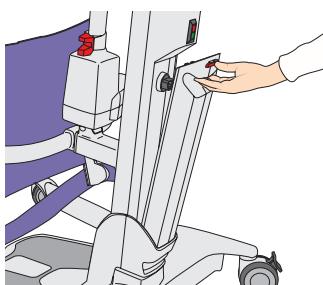
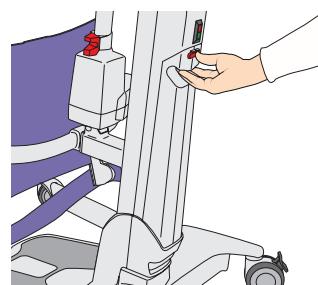


Fig. 46



Inserting the Battery (2 Steps)

1. Place the battery in the battery rack. (See Fig. 44)
2. Push the top of the battery until it is in position. (See Fig. 45)

Removing the Battery (3 steps)

1. Push the release button. (See Fig. 46)
2. Pull the battery out. (See Fig. 45)
3. Lift the battery to detach it from the battery rack. (See Fig. 44)

Battery Service Life

The battery life is around 2-5 years and is affected by charging practices and load exertion.

Installation of Charger

See respective *Battery Charger IFU*.

How to Charge the Battery

See respective *Battery Charger IFU*.

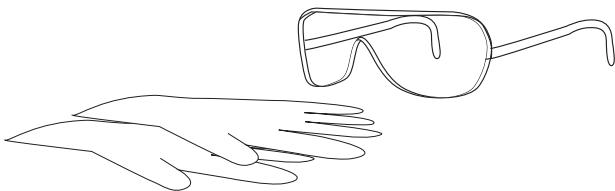
Cleaning and Disinfection Instructions

The following processes are recommended, but should be adapted to comply with the local or national guidelines (Decontamination of Medical Devices) which may apply within the Healthcare Facility or the country of use. If uncertain, seek advice from the local Infection Control Specialist.

Sara Flex should be routinely cleaned and disinfected between patients and at regular intervals while in use; as is good practice for all reusable medical devices.

If there are any questions regarding cleaning and disinfecting the equipment, or wish to order disinfectant fluid, contact Arjo Customer Service. See section, Parts and Accessories. Make sure to have the Safety Data Sheets (SDS) available for the disinfectants being used.

WARNING



To avoid eye and skin damage, always use protective glasses and gloves. If contact occurs, rinse with plenty of water. If eyes or skin becomes irritated, contact a physician. Always read the instructions for use and material safety data sheet of the disinfectant.

WARNING

To prevent cross-contamination, always follow the disinfection instructions in this Instructions for Use.

WARNING

To avoid eye or skin irritation, never disinfect in the presence of a patient.

Detergents/Disinfectants

- Use a mild, neutral detergent

Disinfectant	Sara Flex	Hand control
Quaternary Ammonium ≤ 0.28% (2,800 ppm)	X	X
Isopropyl Alcohol ≤ 70%	X	X
Phenolic ≤ 1.56% (15,600 ppm)	X	X
Peracetic Acid ≤ 0.25% (2,500 ppm)	X	X
Bleach (Chlorine) ≤ 1% (10,000 ppm)	X	X*
Hydrogen Peroxide ≤ 4.5%	X	X*

*Repeated use of these disinfectants may lead to discoloration and cause surfaces to become slightly sticky.

Accessories Needed for Cleaning/Disinfection

- Protective glasses
- Protective gloves
- Spray bottle with water
- Disposable towels
- Brush

Cleaning/Disinfection

Follow this procedure between every use.

Follow these 14 steps

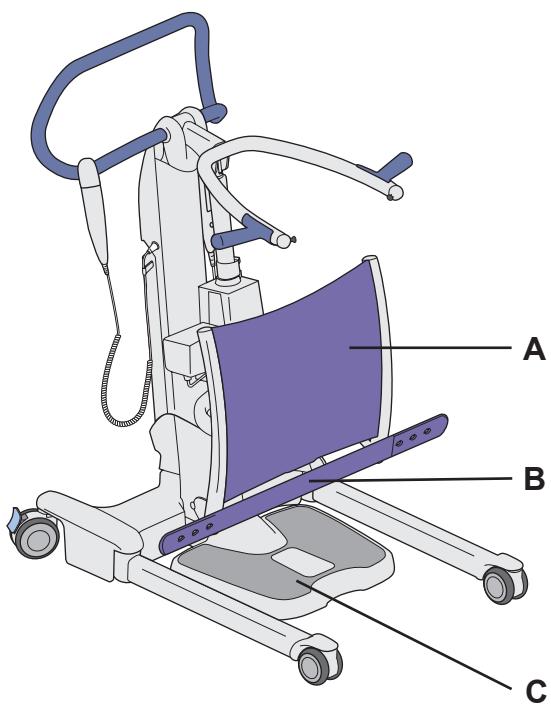
Preparation (step 1)

1. Place *Sara Flex* in an ergonomic working position.

Removal of visible contamination (step 2-3)

2. Wet a disposable towel with water and remove visible stains and soil on *Sara Flex*.
3. If heavily contaminated, please use brush and towels to remove all visible contamination.

Fig. 47



Cleaning (step 4-8)

4. Spray with Arjo verified detergent (see "Detergents/Disinfectants" on page 67) on all parts of *Sara Flex* and on the hand control.
5. Wet a disposable towel with water and remove all traces of the detergent. For the leg support (A) and leg strap (B), use a disposable towel to remove the detergent and for the footplate (C), you may need a brush. (See Fig. 47)
6. If the detergent cannot be removed, spray water on the affected part and then wipe it off with disposable towels.
7. Repeat until all of the detergent has been removed.
8. Let all parts dry.

Disinfection (step 9-14)

9. Repeat spraying with the Arjo verified disinfectant on all parts and on the hand control.
10. Allow the disinfectant to stay on the parts according to manufacturer's recommendation.
11. Remove all traces of disinfectant, using new wet disposable towels. For the leg support (A) and leg strap (B), use a disposable towel to remove the disinfectant and for the footplate (C), you may need a brush. (See Fig. 47)
12. If the disinfectant cannot be removed, spray with water on the affected part and wipe it off with disposable towels.
13. Repeat until all of the disinfectant has been removed.
14. Let all parts dry.

Troubleshooting

Problem Description	Solution
Hand control does not respond	<ul style="list-style-type: none"> Check that the Emergency stop button on the control box is not pushed. Check the connector on hand control cord. Check the battery condition (replace with a fully charged battery pack).
UP and DOWN buttons on control box do not respond	<ul style="list-style-type: none"> Check that the Emergency stop button on the control box is not pushed. Check the battery condition (replace with a fully charged battery pack).
The control box beeps two times every 30 seconds and the red empty battery icon will show in the upper left corner of the display	Battery is low. Replace with a freshly charged battery pack.
The control box beeps three times and only a large red low battery indicator will show on the display and then the lift shuts-off.	Battery is low. Replace with a freshly charged battery pack.
The control box beeps more than three times in conditions other than those mentioned above.	Call Arjo for service.
Actuators "stalls" during operation	Battery is low. Replace with a freshly charged battery. Do not exceed the lifting capacity.

Care and Preventive Maintenance

Sara Flex is subject to wear and tear, and the following actions must be performed when specified to make sure that the product remains within its original manufacturing specification.

WARNING

To avoid malfunction resulting in injury, make sure to conduct regular inspections and follow the recommended maintenance schedule. In some cases, due to heavy use of the product and exposure to aggressive environment, more frequent inspections should be carried out.

Local regulations and standards may be more stringent than the recommended maintenance schedule.

WARNING

To avoid injury to both the patient and the caregiver, never modify the equipment or use incompatible parts.

SCHEDULE	Between Every Use	Every Week	Every Year
Caregiver Obligations Action/Check			
Cleaning/Disinfection	x		
Examine the sling, straps and clips for damage or fraying as required.	x		
Check to make sure the patient/resident handles are secure.	x		
Visually check exposed surfaces for damage, sharp edges, etc.		x	
Visually check sling attachment points. Do not use if damaged.		x	
Make sure all labels are attached.		x	
Visually check the hand control and cable for damage.		x	
Perform a full functionality test on <i>Sara Flex</i> .		x	
Check operation of the Emergency Stop/Power Button and the Emergency Lowering Handle		x	
Check battery for leakage and/or deterioration. Replace if needed.		x	
Check all castors for wear.		x	
Check for evidence of corrosion.		x	
Yearly checks by qualified service personnel only.			x

Caregiver Obligations

Between Every Use

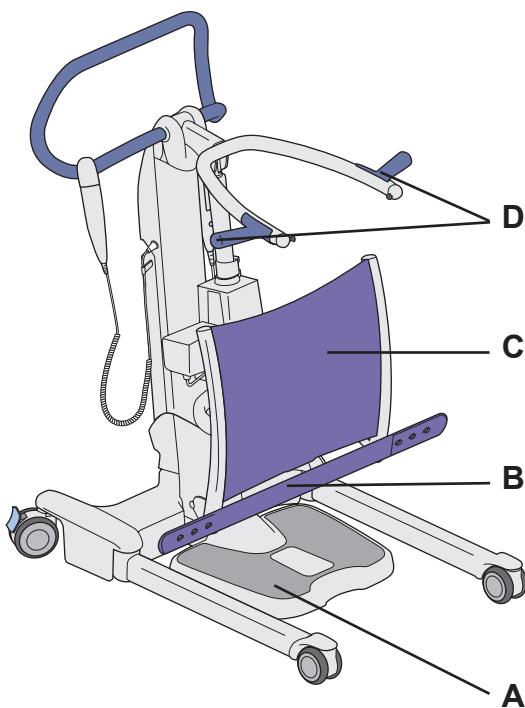
Cleaning and disinfection

- *Sara Flex* has to be cleaned and disinfected immediately after usage
- For further disinfecting instructions, refer to the “*Cleaning and Disinfection Instructions*” on page 67.

Examine the sling, strap and clips for damage or fraying as required

- See respective sling *IFU*.

Fig. 48



Check to make sure the patient/resident handles are secure

- Grab the patient/resident handles (D) firmly, rotate them and push them outward. (See Fig. 48)

Every Week

Visually check exposed surfaces for damage, sharp edges, etc.

- Pay close attention to all the parts that are in contact with the patient: foot plate (A), leg strap (B), leg support (C), patient/resident handles (D). (See Fig. 48)
- Look for tears in the leg support and leg strap.
- Look for any deformation in structural parts.

Visually check sling attachment points. Do not use if damaged

- Check the slings for fraying, cuts or loose stitching.

Make sure all labels are attached

- Check if all labels are attached on the *Sara Flex* according to “Labels on *Sara Flex*” on page 77.

Visually check the hand control and cable for damage

- Check the hand control screen for dead pixels or any other display defects.

Fig. 49

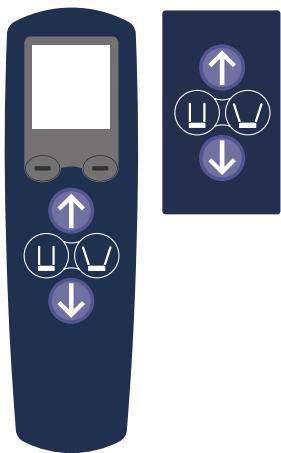


Fig. 50

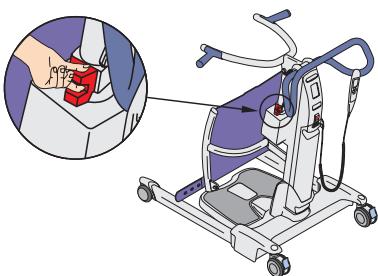
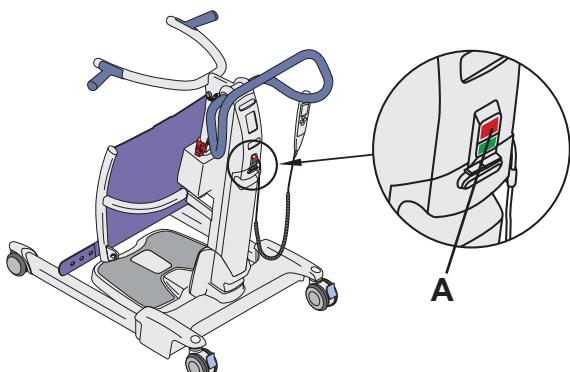


Fig. 51



Perform a full functionality test on *Sara Flex*

- Raise the lifting arm to its highest position using the hand control or the control panel.
- Lower the lifting arm to its lowest position using the hand control or the control panel.
- Test every button on the hand control and the control panel. (See Fig. 49)
All buttons must be working according to “Controls and Features” on page 49.
- Move the *Sara Flex* around on a flat surface and make sure that the four castors are in contact with the ground.
- Make sure to test the brakes. Activate the brakes and try to move the *Sara Flex* around.
- Check for abnormal sounds during movements.

Check operation of the Emergency Stop/Power Button and the Emergency Lowering Handle

- Raise the lifting arm.
- Push the lifting arm down while pulling up the Emergency Lowering handle. The lifting arm should lower slowly. (See Fig. 50)
- While raising/lowering the lifting arm or opening/closing the legs, press the Emergency Stop/Power Button (A). The lift movement should stop immediately. (See Fig. 51)

Check battery for leakage and/or deterioration. Replace if needed

- Remove the battery.
- Check the battery connector for any damage.
- Visually inspect the battery and look for leakage and/or deterioration.

Check all castors for wear

- Clean the castors with water (their functionality can be affected by soap, hair, dust and chemicals from floor cleaning).
- Check that the castors are rolling and swiveling freely.

Check for evidence of corrosion

If there is any visible corrosion or damage on parts, contact your local Arjo representative for support.

Yearly Checks by Qualified Personnel only

Sara Flex must be serviced once a year in accordance with the Maintenance and Repair Manual.

WARNING

To avoid injury and/or unsafe product, the maintenance activities must be carried out at the correct frequency by qualified personnel using correct tools, parts and knowledge of procedures. Qualified personnel must have documented training in maintenance of this device.

NOTE

All Caregiver Obligations are to be checked when performing the Qualified Personnel Service.

For details, see separate service instructions.

Technical Specifications

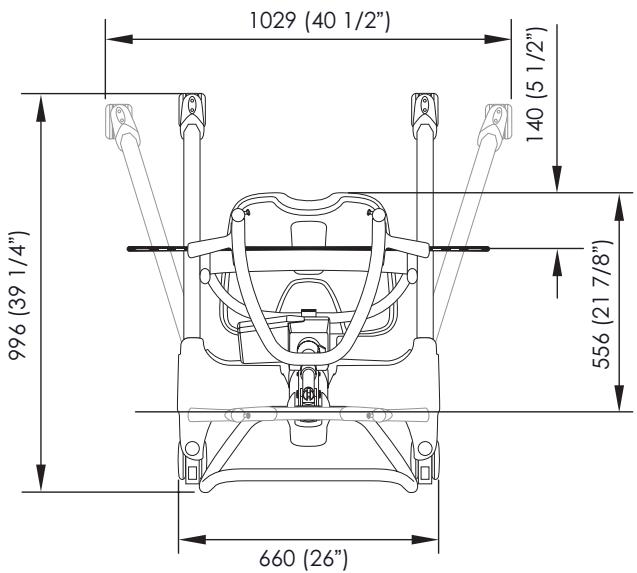
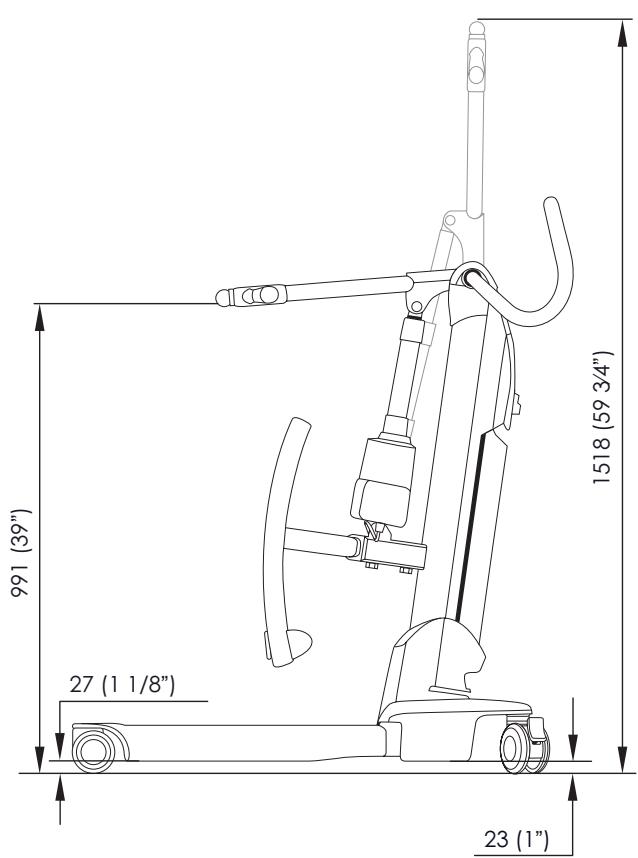
General	
Safe working load (SWL) <i>Sara Flex</i>	200 kg / 440 lb
Component Weight <i>Sara Flex</i> complete	52 kg / 114.5 lb
Battery Pack	3.8 kg / 8.4 lb
Electrical	
Degree of protection - Electrical Shock	Type BF 
Lift - Protection Class	IP24
Hand Control - Protection Class	IPX7
Battery Type	Rechargeable - sealed lead acid
Battery Part Number	NDA0100-20
Battery capacity	24V DC 4Ah
Battery Charger	NDA8200
Lift - Protection Class - shock protection	Internally powered equipment
Lift nominal voltage	24V DC
Fuse	15A type AGC fuse
Operating force of controls	< 5 N
Max Duty Cycle, Lift Actuator	10% MAX (2 min ON / 18 min OFF)
Max Duty Cycle, Leg Spread Actuator	10% MAX (2 min ON / 18 min OFF)
Maximum sound power level	50dB
Scale specification	
Weight range	200 kg / 440 lb
Display resolution and type	0.2 kg / 0.5 lb, liquid crystal display
Operating conditions	
Ambient temperature	+10°C (50°F) to +40°C (104°F)
Relative humidity range	10% to 80%
Atmospheric Pressure	700 hPa to 1060 hPa
Transport and Storage	
Ambient temperature	-25°C (-13°F) to +70°C (158°F)
Relative humidity range	10% to 80%
Atmospheric Pressure	700 hPa to 1060 hPa
When transporting the product from one facility to another, make sure the product is properly secured.	

Safe Disposal	
Battery	Lead-Acid Not for disposal. Environmental danger.
Package	Wood and corrugated cardboard, recyclable.
Product	Electric, Metal and Plastic Parts shall be separated and recycled according to marking on the unit.
Electrical and electronic components	Lift systems having electrical and electronic components or an electrical cord should be disassembled and recycled per Waste of Electrical and Electronic Equipment (WEEE) or in accordance with local or national regulation.
Slings	Slings including stiffeners/ stabilizers, padding material, any other textiles or polymers or plastic materials etc. should be sorted as combustible waste.

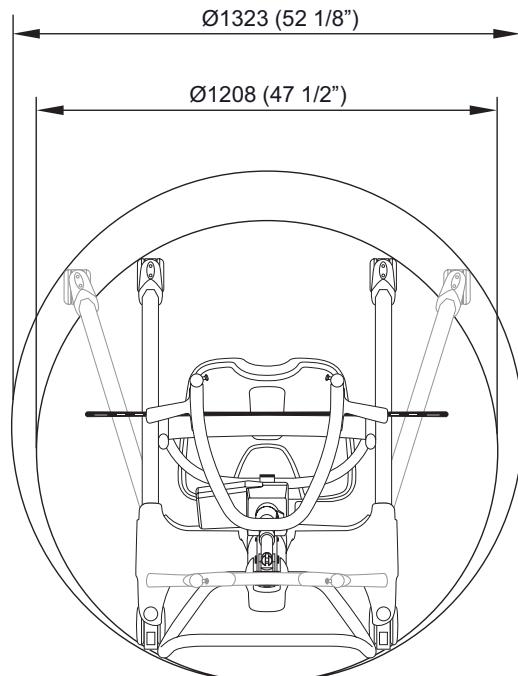
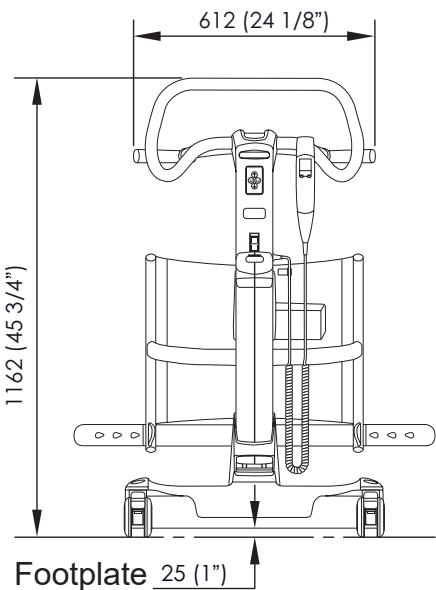
Allowed Combinations	
Active Sling	<ul style="list-style-type: none"> • TSS.500 (S) • TSS.501 (M) • TSS.502 (L) • TSS.503 (XL) • TSS.504 (XXL)
Transfer Sling	<ul style="list-style-type: none"> • TSS.511 (Only to be used with Central Hook)
Flite	<ul style="list-style-type: none"> • MFA3000

Dimensions

Measurements in mm and inches ("")



Turning radius



Labels on Sara Flex

On the labels you can find the following symbols / information:

Label explanation

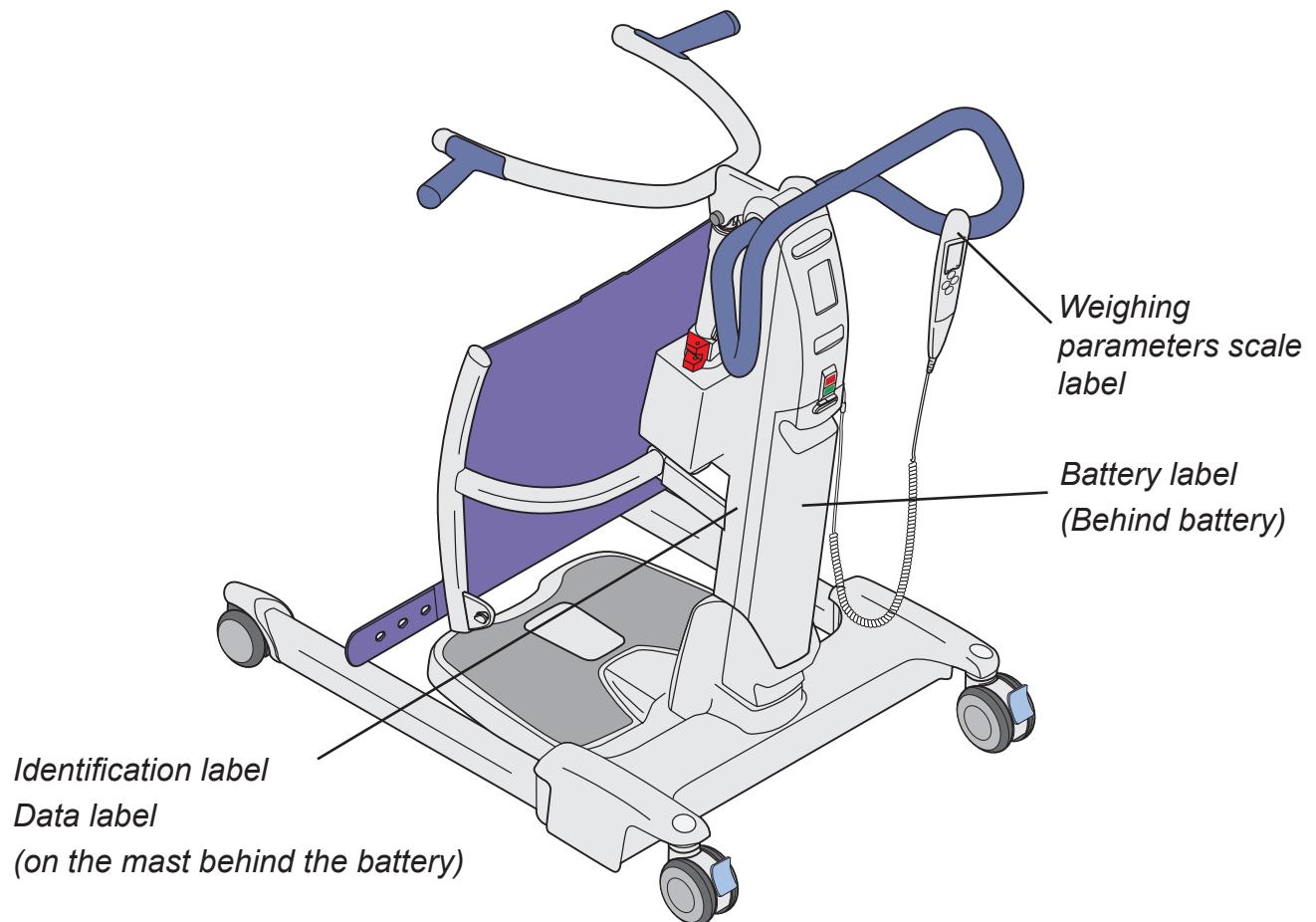
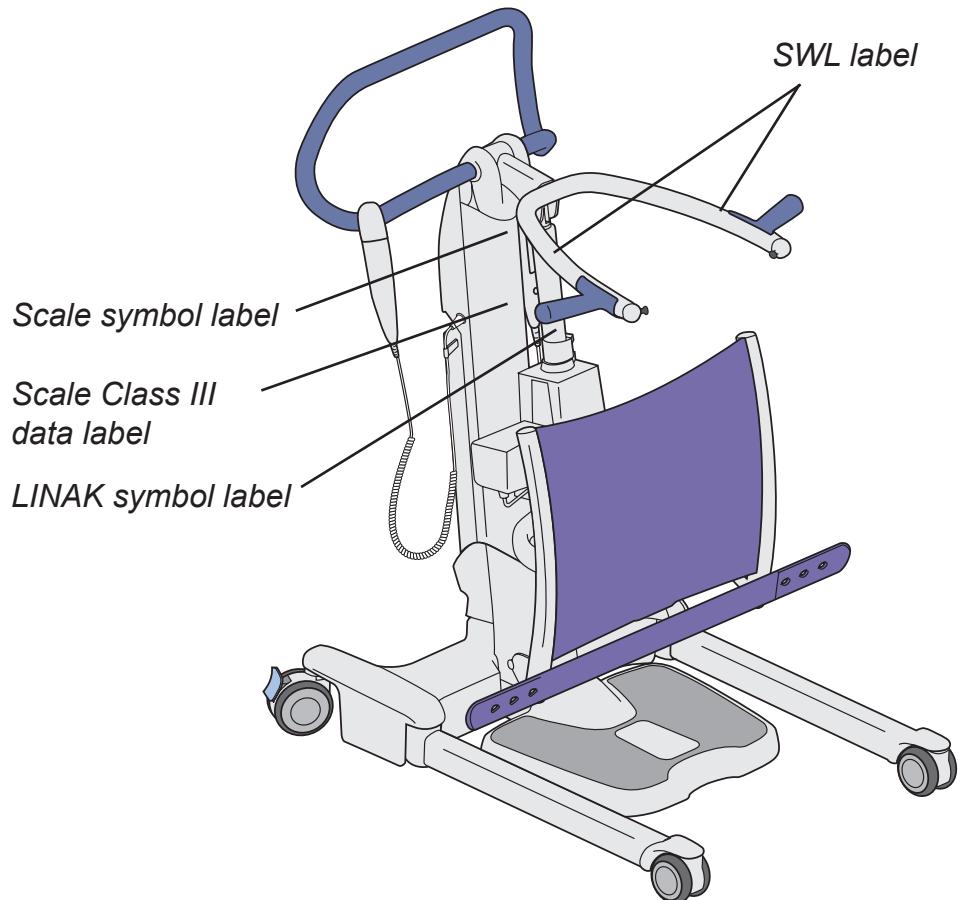
Data Label	States technical performance and requirements, e.g. Input Power, Input Voltage and maximum patient Weight etc.
Identification Label	States the product identification, serial number and year and month of manufacturing.
SWL Label	This label indicates the maximum lifting capacity of <i>Sara Flex</i>
Battery Label	States safety and environmental information for the battery.
Weighing Parameters Scale Label	This label states the weighing parameters for the scale.

Symbol explanation

SWL	Safe Working Load Defines the maximum total load of patient or any other load that may be on <i>Sara Flex</i>
IP24	Degree of protection against splashing water
24 V ——	Supply voltage (DC)
10 A	Current
	Waste Electrical and Electronic Equipment (WEEE) - do not dispose of this product in general household or commercial waste.
REF	Model number
SN	Serial number
	Manufacturer name and address

	Read the <i>IFU</i> before use
	Type BF protection against electrical shock in accordance with IEC 60601-1
	CE marking in accordance with The Medical Devices Directive 93/42/EEC.
	Certified according to NRTL through TÜV SÜD. See section, List of Standards and Certificates..
	Certified through TÜV SÜD. See section, List of Standards and Certificates.
	Total mass of equipment including its safe working load (52kg/116lb+200kg/440lb =252kg / 556lb).
	SWL Indicates the maximum lifting capacity of the lift.
	Scale symbol. If the lift has this symbol, the scale function is installed.
Max	Maximum capacity of the weighing instrument
Min	Minimum capacity of the weighing instrument
e	Verification scale interval
	Do not push or pull on the actuator
	Non-automatic weighing instrument label Class III; yy = year; XXXX = Notified Body Number.
	Non-automatic weighing instrument label Class III; yy = year; XXXX= Approved Body Number.

	Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745
	Unique Device Identifier



Electromagnetic Compatibility

Sara Flex has been tested for compliance with current regulatory standards regarding its capacity to block EMI (electromagnetic interference) from external sources. Nonetheless, some procedures can help reduce electromagnetic interferences:

- Ensure that other devices in patient-monitoring and/or life-support areas comply to accepted emissions standards.
- Maximize the distance between electro-medical devices. High-powered devices may produce EMI that can affect the lift.

For more information on how to manage the unit's RF electromagnetic environment, please consult the AMI TIR 18-1997 - Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers.

Sara Flex is intended for the use in the electromagnetic environment specified below. The customer or the user of *Sara Flex* should assure that it is used in such an environment.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the *Sara Flex* including cables specified by the manufacturer. Otherwise, performance degradation of this equipment could result.

WARNING

Use of accessories, cables and spare parts other than those specified or provided by Arjo could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING

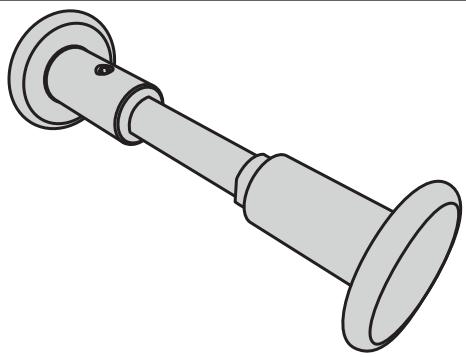
The equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take action, such as reorienting, relocating the equipment or shielding the location.

Guidance and manufacturer's declaration: electromagnetic emissions

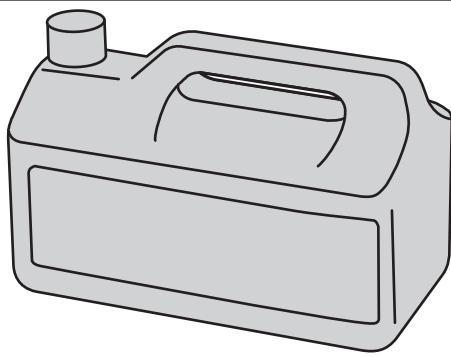
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	<i>Sara Flex</i> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	<i>Sara Flex</i> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration: electromagnetic immunity			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV Contact ±2 kV, ±4 kV, ±8 kV ±15 kV Air	±8 kV Contact ±2 kV, ±4 kV, ±8 kV ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity level should be at least 30%
Conducted RF IEC 61000-4-6	3 V outside ISM bands between 0.15-80 MHz 6 V inside ISM and amateur radio bands between 0.15 - 80 MHz	3 V outside ISM bands between 0.15-80 MHz 6 V inside ISM and amateur radio bands between 0.15 - 80 MHz	N/A
Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7GHz	10V/m 80MHz to 2.7GHz	
Electrical fast transient/burst IEC 61000-4-4	±1 kV, I/O Ports 100 kHz repetition frequency	±1 kV, I/O Ports 100 kHz repetition frequency	Mains power supply should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	If functional disturbance occurs on <i>Sara Flex</i> it may be necessary to install magnetic shielding. The power frequency magnetic field should be measured prior to installation to assure that it is sufficiently low.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	N/A

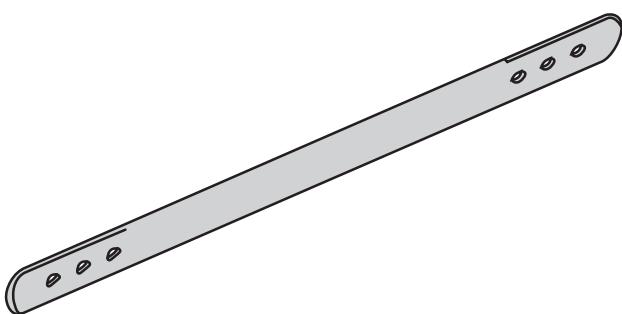
Parts and Accessories



Central Hook
700-27041



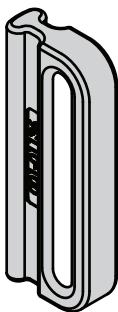
Disinfectant
To order, contact local representative



Leg Strap
AH1003006



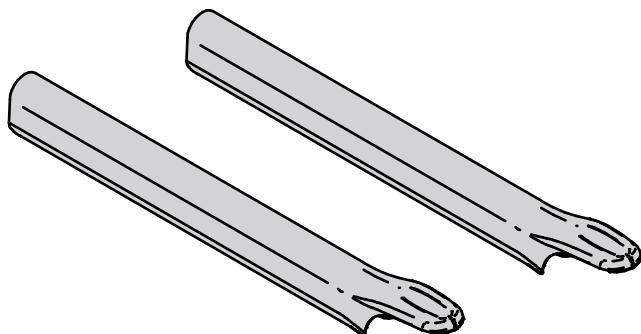
Battery
NDA0100-20



Leg Strap Attachment
700-27044



Battery Charger
NDA8200



Leg Cover Kit
700-27034

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产品名称:电动移位机

型号:见标签

产品描述:该产品由支架、脚轮、底座支腿、控制器组件和扶手等组成。该产品含电池组件。

预期用途:用于医疗机构转运、移动患者用。

医疗器械备案编号:国械备20200703号

产品技术要求编号:国械备20200703号

生产日期:见标签

备案人/生产企业名称:ArjoHuntleigh AB 而久亨特利瑞典

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代理人名称:安捷祐(苏州)医疗设备贸易有限公司

代理人住所:苏州工业园区方洲路158路

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修订日期:2022年5月16日

此册子是从 Sara Flex 使用说明书 04.KL.00 版本7 创建

This booklet was created from 04.KL.00 revision 7 of the Sara Flex Instructions
for Use (IFU).

At Arjo, we are committed to improving the everyday lives of people affected by reduced mobility and age-related health challenges. With products and solutions that ensure ergonomic patient handling, personal hygiene, disinfection, diagnostics, and the effective prevention of pressure ulcers and venous thromboembolism, we help professionals across care environments to continually raise the standard of safe and dignified care. Everything we do, we do with people in mind.



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