

# Cub Product Information and Technical Data Sheet

Product Number	Product Description for Commercial Documents
Cub_SSA9A8	Cub_SS, Color: Aegean. Includes: 7 in. casters, Small 16" Rear Wheels, Flip Down Abductor, All Terrain Accessory, Cub Contour Cushion, and Activity Tray
Cub_SSA9A6	Cub_SS, Color: Aegean. Includes: 7 in. casters, Small 16" Rear Wheels, All Terrain Accessory, Cub Contour Cushion, and Activity Tray
Cub_SSA9A4	Cub_SS, Color: Aegean. Includes: 7 in. casters, Small 16" Rear Wheels, Flip Down Abductor, Cub Contour Cushion, and Activity Tray
Cub_SSA9AY	Cub_SS, Color: Aegean. Includes: 7 in. casters, Small 16" Rear Wheels, Cub Contour Cushion, and Activity Tray

- Supplier's Contact Details: Participant Assistive Products PO Box 156614 San Francisco, CA 94115, USA www.participant.life
- Contract Manufacturer's Contact Details: Zhongjin Medical Taizhou Co., Ltd. No. 88 Century Rd, Jiulong Town Hailing District, Taizhou City Jiangsu Province, China <u>http://www.zhjmedical.com</u> ISO 9001, 13485 Certified, JIS JE0409005
- Intended Use: The Cub mechanical wheelchair is intended to provide mobility to persons who are limited to a sitting position.
- Intellectual Property: Cub is patented. Patent USD951824, USD961464, and other patents are pending. Cub and Participant Assistive Products are registered trademarks in the USA and globally.
- Contact details for the person appointed for vigilance:

Keoke King CEO, Participant Assistive Products keoke@participant.life 01-415-323-5965

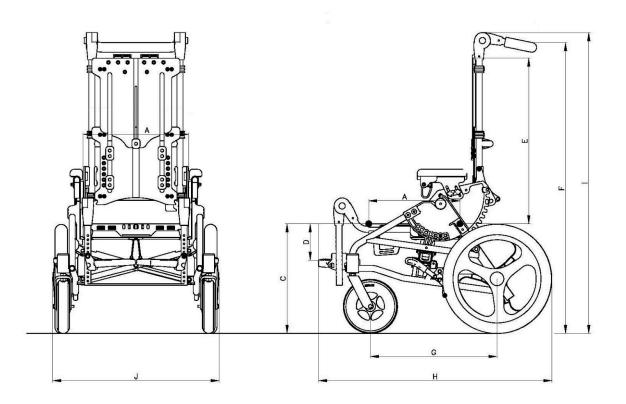
## **Product Technical Data Sheet**

- Class 1 Medical Device per the Food and Drug Administration (FDA) of the USA
- Regulatory requirements for marketing clearance:
  - Approved for marketing in Japan. JIS Certificate no.: JE0409005
  - Approved for marketing in the EU MDR Registration: 23/Oct/2021 Cert. No. R20211009
  - Applied to FDA for approval for marketing and has been assigned the number K203301. The application is submitted but not yet approved.
  - TGA is completed, ARTG:421976
  - INVIMA, ANVISA, and ANMAT are planned.
- Testing Standards:
  - The Cub wheelchair was tested by a third party test lab to comply with the following standards:
    - ISO 2014 7176 7, 8, 9, 10, 11, 13, 15
    - Biocompatibility
    - Flammability

Third party test report summaries, manufacturer quality certificates, and other supporting documents are available on request.

- Product Dimensions and Weight:
  - Overall Product Weight / Net Weight: 23.4 kg
  - Weight of Base: 10.1 kg
  - Weight of Seat: 13.3 kg
  - User weight capacity: 60 kg
  - This accurate weight measurement is for Cub S in the Standard Packaging as listed below.

• Device Diagrams and Photos:



### Dimensions

- A Seat Depth Range
- C Floor to Top of Seat Pan at 0°
- D Seat Pan to Footbed Range
- E Seat Pan to Top Back Range
- F Floor to Handle Range
- 225 360 mm 400 mm
- 89 368 mm
- 290 560 mm
- 914 1260 mm
- G Wheelbase
- H Overall Length
- I Overall Height
- J Overall Width

#### 540 mm 787 mm 1092 mm

635 mm



Cub with Activity Tray

Cub with maximum recline and tilt



Cub Base and Seat. The parts are disassembled for transport.

• Use Environment:

The Cub wheelchair is designed to accommodate both indoor and outdoor use at care facilities, schools, and private residences. The chair is capable of handling different surfaces, including dirty and uneven outdoor surfaces, but performs optimally on firm even surfaces such as concrete, asphalt and indoor flooring.

The Cub is designed to overcome a maximum obstacle height of 3" and operate at a maximum floor incline angle of 11°.

- List of Optional Accessories. For an extensive description of the items, please see the Cub Brochure and support videos participant.life/cub\_support.
  - Flip Down Abductor
  - All Terrain Accessory
  - Jelly Cushion Pressure relief cushion with 25 mm of offloading
  - Ankle Straps
  - Rear Wheel Upgrade Kit: 16" to 24"
  - Long Seat Depth Kit
  - Fit Kit
- Cub Clinical Overview Demonstration Video List of Adjustments. <u>Watch here</u>.
  - Tilt in space
  - Recline
  - Foot Support Height and Angle
  - Headrest Lateral, Height, Depth, Rotation
  - Back Support Height
  - Hip Guide and Lateral Trunk Supports
  - Knee Extension
  - Abductor Depth, Height, Width, Angle
  - Seat Depth
  - Seat to Back Angle
  - Arm Rest Height and Angle
  - Push Handle Height
- Cub Clinical Overview Demo Video List of Quick Release Features. Watch here.
  - Remove Headrest
  - Remove Positioning Shell from the Mobility Base
  - Fold down back support
  - Recline
  - All Terrain Accessory
  - Abductor Flip Down
  - Anti tippers
- Cub Clinical Overview Demo Video Other Feature Explanations. <u>Watch here</u>.
  - Folding for Transport

- Seat Belt Buckle
- Packaging and Logistics Information:
  - One unit per box
  - Box dimensions: 870 x 760 x 520 mm; .34 cubic meters
  - Package Weight / Gross Weight: 29 kg, 63.9 lbs
  - Standard Packaging Included Items. For an extensive description of the items, please see the Cub Brochure and support videos at www.participant.life/cub-support
    - Seat the folding Seat includes seat and back cushions, headrest, footrest, arm rests, lateral and hip postural supports
    - Base the folding Base with 16" rear wheels, 7" casters and anti-tippers
    - Activity Tray
    - User Manual
    - Tool Kit
  - Containerization
    - 40' HC 207 Cub units
    - 20' 84 Cub units
  - The HS Code for manual wheelchairs: 8713.10.0000
  - Level of Assembly:
    - Time required: 10 minutes or less
    - When initially unboxed the setup process for Cub is roughly the same as setting up Cub after transport in a car trunk

		List of Materials Used on the Cub Wheelchai	r	
Component		Details	Material	
Seat		Folds like a U into a suitcase sized unit.	AL*	
Base		X-Brace folding.	AL	
Tilt		Adjustable without tools by the caregiver.	Nylon GF 30, PP, Steel, AL	
Rear Wheel (405mm), St		16" solid rear tire. Wheels have bolt axles and are not adjustable. 0° camber. Plastic mag wheel.		
Parts	Tire	16" x 1 <sup>1</sup> / <sub>4</sub> "	Solid PU	
T dits	Bearing		6202 RS*	
Rear Wheel mm), Optior	•	24" solid rear tire. Wheels have quick release axles and push rims. 0° camber. 3 cross spoke wheels with stainless steel spokes and nipples. Aluminum rim is a standard 504-25 bicycle rim.		
	Tire	24" x 1 <sup>1</sup> / <sub>4</sub> "	Solid PU	
Parts	Bearing		6202 RS*	
Rear Wheel - 24" (504 mm), Optional		24" pneumatic, air rear tire with non-aggressive treads. Wheels have quick release axles and push rims. 0° camber. 3 cross spoke wheels with stainless steel spokes and nipples. Aluminum rim is a standard 504-25 bicycle rim.		
	Tire	24" x 1 <sup><u>1</u></sup>	Pneumatic, Air	
Parts	Bearing		6202 RS*	
Front Caster Wheel - 8", Optional		8" (203 OD x 76 mm) outside diameter, 3" wide. Wheel includes a bearing weather shield.	PU*	
	Tire		PU-type proprietary	
Parts	Hub		Nylon GF30	
	Bearing		6202 RS	
Front Caster Wheel - 7", Standard		7" x 1 3/4" (180 mm Outer Diameter x 45 mm wide tire)	PU*	
	Tire		Natural Rubber	
Parts	Hub		Nylon GF15	
	Bearing		6000RS	
Wheel Lock	S	Foot activated or pull to lock, Adjustable	AL	

List of Materials Used on the Cub Wheelchair			
Seat Pan	Solid, Depth and Angle Adjustable	Nylon GF30	
Seat Cushion	A cushion made from one density of foam. This contoured cushion has an ischial well and troughing bilaterally to aid in neutral femur alignment. The cushion comes with a removable, washable cover made from 4 way stretch material that will help cooling as well as be very durable.	PU Foam and PVC/Polyester fabric cover	
Push Handles	Height adjustable, AL with foam grips	AL	
Arm Support	Angle and height adjustable, removable with tools, clothing guard is integrated into side plate	Texin RXT70A Foam Resin	
Foot Support	Height, angle, depth, and width adjustable. Independent or joined, detachable or folding, lower leg angle is adjustable.	PP*	
Back Support	Rigid, height adjustable, folds forward without tools.	AL	
Back Cushion	A cushion is made from one density of foam. This is a flat cushion without contouring. The design includes slots to make customizations easier. The cushion comes with a removable, washable cover made from 4 way stretch material that will help cooling as well as be very durable.	PU Foam and PVC/Polyester fabric cover	
Lateral PSD	Adjustable depth, width, height	AL frame, PU Foam and PVC/Polyester fabric cover	
Abductor PSD	Adjustable depth and position left to right. Foam shape is modifiable.	PU Foam and PVC/Polyester fabric cover, AL frame, Release latch allows fold down	
Headrest PSD	Adjustable depth, height, left and right, and pivots around a central point in the back of the headrest at the attachment to the bracket.	AL frame, PU Foam and PVC/Polyester fabric cover	
Hip Guide PSD	Adjustable depth, width, height	AL frame, PU Foam and PVC/Polyester fabric cover	
Butterfly Body Harness	Adjustable in height and length.	PU Foam and PVC/Polyester fabric cover, Nylon webbing	
Four Point Seat Belt	Adjustable in height and length.	PU Foam and PVC/Polyester fabric cover, Nylon webbing	

\*AL- aluminum, RS - Rubber Seal, PP - polypropylene, PU - polyurethane, EVA foam - ethylene vinyl SEATacetate, PSD - Postural Support Device

Product Dimensions, Adjustment Ranges, and Product Weight			
Component	Measurements (mm; inches)	Notes	
Seat Width	190 - 365 mm 7 ½ - 14 ⅔ inches	Cub is currently available in one size with a wide range of adjustability to accommodate the user's growth and many different positioning needs.	
Hip Guide Width Range	220-335 mm, 8 11/16 - 13 3/16 inches	Independent left and right brackets are adjustable with tools (included). Can be adjusted up and down to any position and each support can be adjusted for depth. The back cushion foam is designed with slits for easy modification so that the supports can be moved towards the center line without causing bunching or changes in the foam's softness. The Hip Guides can be removed to achieve a maximum width of 365 mm between the side plates.	
Seat Depth Range	225 - 360 mm 8 ¾ - 14 ¼ inches	The rigid seat pan consists of two plates which slide (like a drawer) to easily increase the seat depth. The cushion foam and cushion cover are designed for easy depth adjustment. The Long Seat Depth Kit allows for seat depth up to 450 mm.	
Tilt or Seat Angle Adjustment	- 8°, 0° (Horizontal), 9°, 18°, 27°, 36°, 45°	Tilt is adjusted using a squeeze handle on the back of the chair. This is also used to release the seat from the mobility base.	
Front Seat Height	395 mm 15 ½ inches	Seat height is not adjustable	
Seat Cushion	Cub is equipped with a pre-contoured, molded polyurethane foam cushion with 5 mm loaded contour depth and a thickness of 2" / 50 mm. The cushion and cushion cover allow for insertion of wedges to the sides and back of the cushion to accommodate postural deviations. The cushion cover is a 4 way stretch and waterproof fabric with a velcro closure on the back of the cushion. The cover is easy to remove and wash. The Jelly 25, is a leak proof gel cushion and is also available as an accessory. It is a postural support and pressure relief cushion. To learn more, see the Jelly 25 brochure.		
Backrest Height Range	290 - 560 mm 11 ½ - 22 inches	The rigid back consists of two plates which slide over each other to allow for easy back height adjustment.	

Lower Leg Length Range	140 - 350 mm 5 ½ - 13 ¾ inches	Adjustable by removing a bolt. Additional seat height is achieved by adding a spacer under the seat cushion.	
Produ	ict Dimensions, Adju	istment Ranges, and Product Weight	
Component	Measurements (mm; inches)	Notes	
Back Cushion	Cub is equipped with a flat, molded polyurethane foam cushion. The back cushion foam has markings to assist with modifications so that shorter back heights can be served easily. The back upholstery is designed so that the cover does not need modification to accommodate shorter depths. Additional foam can be added between the back upholstery and the rigid back to accommodate postural deviations. For deep back modifications the user will be seated more forward on the seat pan and may require the Long Seat Depth Kit.		
Lateral Side Trunk Support Height Ranges	50 - 450 mm 2 - 17 ¾ inches	The supports adjust in a continuous slot and can be set at angles from the medial plane. Measurements taken from the middle of the supports.	
Lateral Side Trunk Support Width Range	210 - 370 mm 8 ¼ - 14 <sup>9/16</sup> inches	Independent left and right brackets are adjustable with tools (included) and each support can be adjusted for depth. The back cushion foam is designed with slits for easy modification so that the supports can be moved towards the center line without causing bunching or changes in the foam's softness.	
Lateral Side Trunk and Hip Guide Pads	The support pad has the following dimensions (depth, length, thickness): 140 x 90 x 26 mm. The support pad has a 5 x 4 array of mounting holes which have a vertical and depth spacing of 20 mm. This allows the pad to be set at 5 depth options. The array pattern allows for the pad to be angle adjustable. This also allows the pad to be mounted with the long side in a vertical orientation. The bracket attachment to the back plate is set up so that the pad can be adjusted for angle along the horizontal plane.		
Recline or Seat-to-Back Support Angle Adjustment	-25° to 65° (8 positions)	Recline is adjusted using a squeeze lever on the back of the chair. This is also used to release the back for folding and transport. The maximum recline angle can be set using a stopper, which requires a tool.	

Push Handle Height Range	787 - 1117 mm 31 - 44 inches	Height is adjusted using push buttons. Handles are ergonomic, non-slip, and padded with foam.	
Produ	ct Dimensions, Adju	istment Ranges, and Product Weight	
Component	Measurements (mm; inches)	Notes	
Arm Support	165 - 215 mm 6 ½ - 8 ½	The arm supports are adjustable, using included tools, for height and angle. The Activity Tray attaches to the arm supports.	
Foot Support	Height, Angle, Depth, and Width Adjustable, Independent or Joined, Detachable or Folding, Lower leg angle is adjustable.		
Calf Strap	Adjustable		
Headrest and Bracket	Width: 270 mm; Height: 95 mm; Contour Depth: Adjustable without tools from 0 - 80 mm. For users who need more headrest strength, the Fit Kit includes a steel plate for reinforcement.		
Activity Tray	Cub includes an easy to clean, plastic Activity Tray. The tray has a ridge around the front half and cup holders on each forward corner. The tray attaches to the Arm Supports using screw knobs. The tray is height and depth adjustable independently from the Arm Supports.		
Rear Wheel	Small wheel with a solid tire and plastic mag spokes ( $16 \times 1.75$ ") or optional Big wheel with handrim and solid ( $24 \times 1.3/8$ ") tires or air ( $24$ " x 2") tires on a metal spoke wheel size 540-25, a common bicycle size.		
Anti-Tippers	Includes flip away, Anti-Tippers which are activated with the foot.		
Seat Module	The aluminum seat frame folds like a U. The seat fits into a large backpack for motorcycle transportation. If secured, the flat bottom allows use on typical furniture.		
All Terrain Accessory	200 x 50; 8 x 2		
Wheelbase Length	540; 21 1/4		
Overall Length	787; 31		

\* Parts are standard and included in every box unless marked as Optional

\* Unless otherwise noted, the adjustments are possible using the components included in the standard packaging box, without need to order additional seating, accessories, or other parts.





Tilt/Seat Angle Adjustment

Accessories		
Name and Reference Code	Product Description	Image
Activity tray	The activity tray supports a range of activities like fine motor exercises, playing with friends and family, eating, and education. The design includes two indentations that are great for objects like a cup or blueberries! Also, a perimeter rim prevents objects from rolling off but does not create an uncomfortable area for elbows. The tray is not intended to be a postural support. The polypropylene material is food safe and super easy to clean. The depth and height of the tray is adjustable. The tray is x" wide and the attachment brackets are width adjustable to fit wheelchairs with an armrest pad that has outside edges from X to Y. The tray attaches to the chair with a screw knob clamp mechanism that is under the outside edge of the tray.	
All Terrain	For mixed terrains with uneven and bumpy surfaces, a three wheeler often performs better. This accessory offers that performance advantage without compromising access to small homes, crowded environments, or classrooms. The wheel attaches in seconds without tools	
Flip Down Abductor	The abductor facilitates ideal femur alignment and helps to prevent further complications in the legs and hips. By using the quick release handle the unit flips down to allow easy transfers and prevent loss of the part. Not intended to be a restraint. Easy to clean. Adjustable height, depth, laterally, and width.	
24" Rear Wheels Kit	This kit upgrades a Cub wheelchair with the small 16" rear wheels to 24" rear wheels with a 1.25" solid tire.	

Accessories			
Name and Reference Code	Product Description	Image	
Headrest and Quick Release 4 Axis Bracket	The headrest supports the head by cradling the occipital lobe on the lower rear of the skull. The shape provides a moderate amount of sideways control and has an organic shape that reflects the natural curves of the human body. It is rigid with a medium density foam body. The right and left wings can be bent by a strong person to achieve a more cupped shape.		
	The headrest bracket allows for 4 axis adjustment that mimics the most advanced products available today. The headrest is mounted on a ball and socket joint for rotational positioning. The bracket allows for forward and backward, up and down, and left to right adjustments from the center. The ruggedized bracket includes a quick release mechanism so that the headrest can be removed without tools and returned to the optimized position.		
Hip Guides and Lateral Trunk Supports	The Lateral Trunk Supports and Hip Guides are rigid with a firm foam padding and a removable, washable, and comfortable fabric cover. To accommodate a wide range of needs for supporting the pelvis and torso, each pad is adjustable in width (measuring from the center of the back), height, depth, angle, and has two length options. The support pads are arranged at 90 degrees from the back rest. As with all postural support devices on Cub, the design provides for a rapid provision speed with intuitive adjustments.		
Foot Straps	Foot straps help maintain the position of the user's feet and have easy to use buckles and adjustments.		
Fit Kit	This kit includes foam, glue, tools and rigid plastic for the purpose of customizing wheelchairs.		

Accessories			
Name and Reference Code	Product Description	Image	
Butterfly Body Harness and Four Point Seat Belt	The seat belt greatly increases control of the pelvis, which is the foundation of all posture management. The two sides are joined by a one hand releasable, side squeeze buckle that is secure and durable. Soft padding and comfortable fabric protects the buckle and straps from touching the user and makes an easy to clean and comfortably padded postural support. The design allows for two additional attachment points for a total of 6 mounting points if needed.		
	The butterfly body harness is adjustable at all four connection points so the harness can be positioned up and down the user. The sternum strap is height adjustable so that good placement over the sternum is possible. The curves follow the natural shape of the human form (smae about contact). The upper and lower connection points are quick release to make transfers easier and safer. The Butterfly Body Harness should always be used with a Four Point Seat Belt and should never be used as a restraint.		
Umbrella Holder	An umbrella holder is a simple solution for light protection from sun, rain and wind.		
Fat Tires (2.3" Wide, Pneumatic Tires)	This pair of 2.3" wide tires with wheels gives a softer ride over obstacles and float better on soft surfaces like grass, mud, snow, and mixed terrain with rocks, roots, or broken sidewalks. For our air tires and solid tires, Participant uses standard 24" bicycle rims so that replacing tires is easy and affordable. Be sure to take along an air pump so that tires can be hard for low rolling resistance on hard surfaces or slightly deflated for an even bigger footprint and floatation on the softest of surfaces.		

Cub Spare Parts Kit	The Spare Parts Kit includes:	
	Cable Maintenance 10 Cables for the tilt mechanism (bicycle brake cable) 10 Cable housings for the tilt mechanism (bicycle brake cable housing) 10 End caps (bicycle brake cable housing ferrule) 10 Screws for the cable clamp 10 sets of M6 washers and nylock nuts	
	Wheel Lock Maintenance 10 Wheel lock assemblies for 16" wheel LH and RH 10 screws for wheel lock mount 10 sets of M6 washers and nylock nuts	
	Foot Plate Maintenance 10 Foot Plates 10 sets of M6 washers and nylock nuts	
	Caster Maintenance 10 6" caster wheels 10 replacement bearings, size 6202 RS 10 spacers	
	10 sets of mounting hardware 10 Push handle grips 10 Calf Straps 10 Headrests with Pad, Cover, and mounting screws	
	10 Comfort Cushions with waterproof covers and extra Velcro Tape	
	10 Backrest Cushions with waterproof covers	
	10 Abductor Pads, with waterproof covers and hardware	
	10 Lateral Support Pads with pad, cover, and hardware	
	A variety of screws, washers, nuts, and knob nuts Packaging: 1 Kit	

- Product Labeling:
  - Bottom of Seat (standard layout example)



- Prescription Statement: Cub is an 'Over the Counter' product and no "RX ONLY" label is required.
- Warranty Details

#### **Participant Limited Warranty**

Frame, wearing parts, and consumable parts are guaranteed to be free of defects when the undamaged packing box is first opened. Consumable parts, such as tires and bearings, are not

covered by warranty after first opening of the box. Wearing parts, such as brake levers and various

moving parts in the seat assembly, are covered by warranty for the first 6 months after opening of

the box. The frame is covered for 3 years for folding chairs and 5 years for rigid frame chairs. Modifications to the frame, inadequate storage, abuse, or failure to do maintenance will invalidate the warranty. Parts, not shipping or labor, are covered. Warranty is only valid if Participant receives the following information: Name of user, Service Provider, product serial number. The information can be transmitted by email to: <u>hello@participant.life</u>

- Published field testing:
  - Product Development and Field Testing of the Cub Tilt & Fold Wheelchair
- Sustainability Goals:

Participant Assistive Products is registered as a Benefit Corporation in California and is B Corp with status pending formal review in 2022 after the required quarters of revenue. Participant's founders chose this third party monitoring system and accountability because it contributes to our corporate culture and it shapes the expectations of our investors and workers. Our B Corp commitments help the company stay on track to our intended social mission, as per our formal California registration documents, "to increase the participation in education, work, or social activities of people with disabilities in the United States and abroad by offering affordable assistive products."

Some of our B Corp commitments:

- Our products are evaluated by outside experts and independent test laboratories, not only in-house tests, to confirm that products pass international quality standards and these test reports are publically available.
- We monitor and report the actual efficacy of our products. Our participants tell us if we are succeeding in increasing their participation.
- Our management is evaluated by our board using environmental and social metrics as are all employees.
- People with Disabilities (PWD) and Low and Middle Income Country (LMIC) residents have influence at every level of our organization and we target >50% PWD workers. Currently, we are at 80% PWD workers and 60% LMIC residents.
- All products have lifecycle impact assessments and focus on maximizing participation. Unlike most industry competitors, we do not do 'planned obsolescence'. Our human centered design approach is not an overlay to 'design centered on insurance coding', which maximizes profits from government insurance. Our design process attempts to decrease waste, inventories, packaging, user wait times for assistive products, and our carbon footprint. Our designers seek to improve service speed, days of uninterrupted product performance per user, and days of service per dollar from the health system budget.
- A circular approach and localization are a cornerstone of our vision. Participant is committed to localization of assembly and to a circular approach by assisting substantially with refurbishing activities. We provide upholstery drawings, supply of material, advice on choosing materials locally, local production tools, and other consulting services.
- 5% of our net profits are donated to our non-profit partners, typically local organizations doing service provision training, so they can serve more people.
- We all participate in the company's success. All employees receive a share of company profits as owners, regardless of where they live.
- Recommended storage/ transport conditions:

The recommended use conditions are between -10C - +70 C and 0 - 100% Humidity. The recommended storage conditions are -10C - +70 C. 0 - 90% Humidity.

• Shelf life in months:

The Cub is made of stable materials, primarily aluminum, and has no expected degradation during shelf life. The seat and back cushion are made of polyurethane foam which is sensitive to humidity and temperature. The product is packaged such that the unopened package protects the product from changes in the recommended storage environment. There is no expectation of degradation prior to the beginning of use.

• Recommend safe and responsible method waste disposal:

The foam and upholstery are non-recyclable, household trash. The aluminum frame and steel parts are recyclable metals. The rubber tires are recyclable in some locations.

Regarding Product Lifecycle Management, the frame and metal parts are likely to be reusable by many users as they are overbuilt, for the purpose of reliability use in adverse conditions by very active users. Most users are not so active and the lifespan may serve several users.

• List of supporting items required but not supplied:

No additional supporting items are required.

• Sterilization:

Sterility requirements are not applicable for this product.

• Hazardous goods:

No hazardous goods or materials are in the product or packaging.