Instructions for use

The OABC and its accessories can be used only by qualified personnel who has received hands-on training and who has studied the instructions for use and the operational procedures that the center has made for using the OABC and its accessories.

OABC handling

Storage

The OABC is stored vertically on a rolling rack (dolley).

Moving from storage to the CT-simulator couch blade and back

Move the CT-simulator couch blade fully out of the CT-ring. Some types of CT-simulator couches require the use of a couch adaptor frame. Place the couch adaptor frame across the CT-simulator couch blade if applicable using 2 position bars specific for the CT-simulator couch. The OABC is positioned on and locked to the CT-simulation couch, or couch adaptor frame if applicable, using a cranial positioning bar and a caudal fixation bar. Place the positioning bar on the CT-simulator couch or on the couch adaptor frame if applicable. Two operators are recommended for moving the OABC. The OABC has handles on the left and the right lateral sides. To lift the OABC off the storage, one operator stands at each side of the storage rack. Each operator grabs a handle with one hand and the body support component with the other hand. Most of the weight will rest on the handles as these are positioned on both sides of the center of gravity of the device. The OABC is carried horizontally to the room position behind the caudal end of the CT-simulator. Then, it is moved in the cranial direction, one operator at the left and the other operator at the right side of the CT-simulator couch, carrying the OABC above the couch surface. The OABC is lowered and placed on the couch adaptor frame if applicable or directly at the indicated position on the CT-simulator couch. The positioning holes in the bottom surface of the cranial anchorage component of OABC must be docked across the retaining pins on the upper surface of the positioning bar. Verify that both retaining pins pass through the positioning holes. Put the locking clamps on both ends of the fixation bar in their most outward position. The fixation bar is passed through the caudal anchorage component of OABC. The positioning holes of the fixation bar are docked across the retaining pins mounted at the inner bottom surface of the caudal anchorage component. Push both ends of the fixation bar downwards. Verify that the locking clamps pass across the lateral sides of the CT-simulator couch or couch adaptor frame if applicable. Push the locking clamps inwards until the indexing system on both sides engages. Engaging usually causes a clicking sound. Verify that the locking clamps hook under the lateral flanges of the CT-simulator couch or couch adaptor frame if applicable. Verification by a second operator is required. Incorrect positioning of the fixation bar is a major safety hazard. The reverse operation is executed to move OABC back to the storage rack.

Moving from storage to the accelerator couch blade and back

Place the gantry at angle 0°. Place the tabletop and couch isocenter rotation at 0°. Place the couch blade carriage in its neutral position. Dock the positioning bar on the couch according to the couch-specific operational procedures at the radiotherapy department. Retract the EPID and cone-beam CT (CBCT) devices. Two operators are recommended for moving the OABC. The OABC has handles on the left and the right lateral sides. To lift the OABC off the storage, one operator stands at each side of the storage rack or table. Each operator grabs a handle with one hand and the body support component or arm support blade with the other hand. Most of the weight will rest on the handles as these are positioned on both sides of the center of gravity of the OABC. The OABC is carried horizontally. The operators move to the caudal end of the linear accelerator couch and then into the cranial direction, one operator at the left and the other operator at the right side of the linear accelerator couch, carrying the OABC above the couch surface. The positioning holes in the bottom surface of the cranial

anchorage component of OABC must be docked across the retaining pins on the upper surface of the positioning bar. Verify that both retaining pins pass through the positioning holes. Put the locking clamps on both ends of the fixation bar in their most outward position. The fixation bar is passed through the caudal anchorage component of OABC. The positioning holes of the fixation bar are docked across the retaining pins mounted at the inner bottom surface of the caudal anchorage component. Push both ends of the fixation bar downwards. Verify that the locking clamps pass across the lateral sides of the linear accelerator couch. Push the locking clamps inwards until the indexing system on both sides engages. Engaging usually causes a clicking sound. Verify that the locking clamps hook under the lateral flanges of the linear accelerator couch. Verification by a second operator is required. Incorrect positioning of the fixation bar is a major safety hazard. Before allowing the patient to climb on the OABC, the security of the fixation of the caudal anchorage component of OABC and the linear accelerator couch should be controlled by an operator. The reverse operation is executed to move OABC back to the storage rack.

Mounting the Caudal Knee Cushion

Mounting the Caudal Knee Cushion provides comfort for the patient as well as redundant safety regarding the prevention of tilting of OABC. Through its attachments with the linear accelerator couch, CT-simulator couch or Couch Adaptor Frame the Caudal Knee Cushion secures a second connection of the caudal part of OABC with the couch blade on which OABC is positioned. For these reasons, always use OABC with the Caudal Knee Cushion securely mounted to the couch blade or Couch Adaptor Frame below. Position the Caudal Knee Cushion on the caudal end of OABC as shown in figure 19. Dock the Knee Cushion Security Clamps on the lateral flanges of the linear accelerator couch, CT-simulator couch or Couch Adaptor Frame. Fasten the connector bar of the Knee Cushion Security Clamps to the Caudal Knee Cushion using the Clevis-type joint and secure the connection by locking the spring loaded fixing clip. Always fasten the knee cushion to the couch on both sides. Verify if the security clamps are correctly docked on the lateral flanges of the couch. Verify if the fixing clip is correctly fastened.

Patient positioning

Unilateral breast holder to retract the non-treated breast

Fitting the unilateral breast holder is shown in a video made by the breast cancer campaign association Think-Pink. https://vimeo.com/209582806

The video shows between 0'52" and 1'05" the fitting of a unilateral breast holder to retract the non-treated breast away from the radiation beams. It was observed that retracting the breast improved comfort by moving the breast away from the region of highest pressure exerted by the support device near the sternum. The unilateral breast holder is manufactured and distributed by Tricolast NV, Ommegangstraat 53, 9800 Deinze, Belgium.

Patient maneuver for reaching the crawl position

Check if all index pins on the arm and head support components are fully engaged. The couch blade of the CT-simulator or linear accelerator should be set to a low height position. Two operational procedures are commonly used. The first procedure involves climbing directly on the OABC while the second procedure involves climbing first on the CT-simulator or linear accelerator couch and from there on climbing on OABC. Both are knee-hands procedures. It is recommended that the patient is assisted by two operators, on at the left side and one at the right side of the patient. The patient can use any part of the OABC for support, except the cranial end of the arm support blade because it may bend down under load leading to a feeling of unstable grip.

In the first procedure, a step is placed near the couch pedestal to facilitate climbing directly on OABC. In case of left-side treatment, the left hand grasps the caudal region of the arm support blade while the right hand rests on the caudal surface of the OABC (leg supporting region). Then the right knee is placed on the caudal surface of the OABC near the right hand. Next, the left knee is placed on the OABC surface and the patient makes a quarter turn to face towards the direction of the cranial aspects of the

OABC. Next, the right hand is placed more cranially near the right edge of the OABC in order to allow the patient to find sufficient support to reach the prone position. The cranio-caudal position of the patient is iteratively adapted to secure correct positioning of the face against the headrest. With the assistance of an operator, the left arm is placed alongside the body on the arm support blade and the right arm is bended above the head to find rest and hold on the cranial aspects of the head support region of the OABC.
In case of right-side treatment, the procedure mirrors that of the left side described in the previous paragraph.
In the second procedure, the patient climbs first on the part of the CT-simulation or linear accelerator that is exposed behind the CT-simulator or OABC couch blade to reach a knee-hands position facing the OABC. Climbing starts from behind or from aside the couch pedestal, according to the patient's preference. Assisted by an operator on each side, the patient climbs on the OABC on hands and knees. Operators on both sides help the patient reaching the crawl position. As described in the first procedure, the head and the contralateral arm are positioned first, the ipsilateral arm is positioned last.
The reverse operation is executed to help the patient leaving the OABC.

Initial settings of the arm support component
For average-size patients the average position of the LR positioning module (indexed 5) is recommended as start setting. The medial edge of the sloping surface supporting the untreated breast should be at the mid-sternum (mid-sternal position). If the mid-sternal position is off, the LR positioning pedestal should be moved inwards or outwards to reach the mid-sternal position.
The arm support blade is mounted on the LR positioning pedestal by a mechanism that allows changing pitch and yaw. A slightly downward slope (indexed 3) and no yaw (indexed 3) are recommended as start settings. The initial settings are changed to patient-specific setting according to the optimization process described in the operational procedures of each radiotherapy center.

Clinical settings of the head positioning component
The thickness of the wedge and the wedge angle is designed to yield approximately 15° retroflexion (tilt) and 15° rotation (roll) of the face towards the elevated arm when using the 6.5 cm thick Q-fix Prone Headrest. Lateral flexion (yaw) towards the elevated arm involves rotation around an anterior-posterior axis that traverses the cervical spine approximately at C6. As start setting, deadlocking at the position indexed 3C is recommended.
The initial settings are changed to patient-specific setting according to the optimization process described in the operational procedures of each radiotherapy center.

CT-simulation procedure
Using the OABC does not impose specific simulation procedures.

Treatment set-up procedure
Patient set-up during the first fraction uses the standard laser marks and the optimized settings of arm support and head positioning components obtained from CT-simulation. After laser-based set-up, a CBCT scan is acquired and co-registered with the simulation CT to calculate displacement vectors which are used for adjustment of the patient position. After adjustment, laser marks from the floor laser are delineated on the shoulder and breast of the patient. During the second and subsequent fractions, the floor laser is used in combination with the lateral lasers for patient set-up. Using the OABC does not impose specific procedures for treatment delivery.

Precautions for use
Always use OABC on a flat surface. OABC cannot be used on excavated surfaces of diagnostic imaging devices. Always fix the system securely to the treatment couch by means of the positioning and fixation bars. If the OABC is not attached correctly to the treatment couch, it might come loose and fall.

Do not exceed the maximum distributed patient load of 120 kg. Do not apply this force in point loads on the cranial half of the body support component. Do not apply a load of more than 50 kg on the head support part of the device.
The OABC must NOT be used in strong magnetic fields. The OABC cannot be used for MRI imaging.
The diameter of the CT-simulator bore should be minimum 70cm to allow the OABC with a patient to pass without collision.

Maintenance and disinfection

The OABC and its accessories can be cleaned and disinfected by means of an isopropanol or chlorhexidine based disinfectant, applied with a soft cloth. Never use aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents. Do not soak the cushions.
With the novel Corona virus impacting us globally, excellent hygiene has become more important than ever.
Note on COVID-19: the World Health Organization notes that “surfaces in all environments in which COVID-19 patients receive care (treatment units, community care centers) should be cleaned at least once a day and when a patient is discharged.” WHO recommends using a 70% ethyl alcohol solution to disinfect small areas between uses. Sodium hypochlorite at 0.5% (equivalent to 5000 ppm) can be used to disinfect surfaces. Clinell wipes 2% chlorhexidine in 70% alcohol are suitable.
Read the full publication on hygiene by the WHO.
The prone headrest is removable from head support platform. It is recommended to use several prone headrests. After each treatment, remove the prone headrest from the head support platform for disinfection. Place a thoroughly cleaned and disinfected prone headrest on the head support platform before positioning the next patient.
Do not attempt to make repairs yourself. Contact your distributor if there are any questions or concerns about the functioning of the OABC.

Storage

Always store the OABC and its accessories in a safe place to prevent it from getting damaged or falling onto other objects. Prevent hard objects from falling onto the devices. Store the devices in a dry well ventilated room between +10°C and 40°C.