MONARCH CHAPTERED PROCEDURE GUIDE NOTES

About chapter notes: this is a high-level summary of each chaptered video. Notes preceded by numbers emphasize the importance of the order, while the information preceded by letters/bullet points are not specific to an order

1 Plan Case

The MONARCH planning laptop (or "laptop") is set up with a connected mouse *(00:10)*

- Requirements for login: username and password *(00:14)*

To load patient's DICOM study: *(00:20)*

1. Insert a disc and select *Import*
2. CT imaging data is auto-populated
3. Select the data set to be loaded
4. The software builds the airway segmentation

- The laptop software shows four windows/views of the CT scan: *(00:40)*
    1. Coronal
    2. Sagittal
    3. Axial
    4. Segmentation

- Navigating with the mouse *(00:49)*
    a. **Double click** a window to enlarge it to a single window view
    b. **Scroll** to examine anatomy and nodules
    c. **Right click** to zoom in and out on CT Images (slide forward or backward with the mouse to increase or decrease zoom)
    d. **Left click** on the nodule to place cross hairs
    e. **Click the [+] icon** to add a target
        - Targets appear as volumetric shapes and can be changed to a sphere
        - Move the sizing handles to change sphere shapes
        - Check the target in all three views
        - Name your target by clicking on the edit pencil and click the check mark to save

- Segmentation view *(02:20)*
    a. **Left button** to rotate
    b. **Right button** to zoom
    c. **Click** *Approve Case* to save plan
    d. **Insert** the MONARCH USB and **click** *Export* to save plan case onto the MONARCH system

2 Room Set up

- The MONARCH Tower (or “Tower”) and Cart *(00:17)*
    a. Usually positioned at foot of patient’s bed
    b. Should not be moved once the procedure is underway
    c. Position the suction canister nearby

- Imaging monitors *(00:40)*
    a. Place in the physician’s line of sight when standing in front of the Tower to allow simultaneous visibility of all screens

- The C-Arm *(00:50)*
    a. Use for targeting confirmation and positioned 4 ft or more away from the table to allow swinging in/out during the procedure
    b. The C-Arm Tower and C-Arm: positioned on one side of the patient/opposite side of the MONARCH platform

- Beds *(01:14)*
    a. Important: fix bed rails onto the bed on both sides
    b. Can use fluoro and floating beds and most procedural beds

- Carts *(01:28)*
    a. **Anesthesia Cart**: typically placed at one of the patient's shoulders and close to the head
    b. **MONARCH Cart**: usually positioned on the opposite side of the bed from the anesthesia Cart at the patient's head

- Position the **bronchoscopy Tower** near the bed easily accessible by the physician/assistant *(01:47)*

- Where to put biopsy instruments *(01:56)*
    a. Bronch tower on top of a chuck or cloth
    b. Back table near the bronch tower

- ROSE (Rapid On-Site Evaluation) table should be accessible to the physician or the assistant for passing specimens *(02:10)*

3 MONARCH System Prep

Powering up

1. Plug in the umbilical cord from the Tower to the Cart *(00:09)*
    a. Line up the red dots at 12 o'clock
2. Plug in the Tower and Cart to dedicated power outlets.
    a. Use a generator backup outlet whenever possible
    b. Do **not** plug the Tower or Cart into the same electrical outlet as the C-arm
3. To turn on entire system, press power button on the Tower or Cart
    a. While the MONARCH powers up, put a chuck on the storage shelf

Storage Compartment *(01:00)*

4. Open the drawer and place the navigation field generator on back left quadrant of shelf
5. Place the three patient sensor patches on the front left quadrant of the shelf
6. Remove the patient sensor cable from storage compartment (L- side of the Tower)
    a. Place cable on the back right quadrant of the shelf
7. Remove the field generator mount and the patient introducer mount
    a. Place them on the right side of the shelf
8. Close the door of the storage compartment

USB *(02:00)*

9. Physician hands off the MONARCH USB with the planned case
10. Log in to the Tower and insert the USB
11. Import + open the planned case to identify the white dot showing the primary lesion
12. Start setup and follow the prompts until you reach the navigation screen
    a. Verify that controller is plugged into the controller port in the drawer

Scope (2:06)

13. Remove the scope package from the box and peel back the first quarter of the sleeve
14. Hang the sleeve and clamshell of the scope on the hook on the side of Tower
15. Place the disposable Sheath Valve on the sheath in the scope pouch

Fluidics *(03:43)*

16. Remove the fluidics tubing from the package and connect to the MONARCH scope
17. Attach the blue striped tubing to the irrigation pump between the arrow labels and close the pump cover (all three labels point in the same direction)
18. Attach the VAC line of tubing from suction into the Tower Pinch valve
19. Attach vacuum tubing from room suction to the VAC line of the fluidics tubing
20. Spike then hang the saline bag on the hook on the left-side of the Tower
21. Prime the fluidics tubing using the controller until saline just short of entering scope

Finishing setup *(04:53)*

22. Plug in the bronchoscope camera cable to the MONARCH Tower (line thumb pad at 12 o'clock)
23. Verify a live image by gently moving the packaging sleeve
24. Insert the Field Generator cable into the port on the Tower (line up red dot at 12 o'clock)
25. Insert the patient sensor cable into the port on the Tower
26. Attach the three patient sensor patches to the ends of the patient sensor cables
27. Drape the patient sensor cords over the top of the Tower under the monitor in preparation for patient entry

4 Patient Prep

Note: belts with metal buckles/components may disrupt navigation

1. **Position patient** *(00:08)*
    1. Supine at the center of the table with the head at the top of the bed and secure with straps or sheets
    2. Anesthesia uses a 7.5mm ET tube or larger and bite block

2. **Apply sensors** *(00:30)*
    1. MONARCH patient sensors→ patient's chest
    2. Gray middle sensor→ patient's sternal notch
    3. Left blue sensor and right white sensor → eighth rib at the midaxillary line

3. **Install mounts** *(00:45)*
    1. Install field generator mount to the bed rail (same side of the table as the lesion)
    2. Install patient introducer mount on the other side of bed, in line with the ET tube
    3. After intubation, replace the patient pillow with a gel doughnut
    4. Attach field generator to the mount
    5. Attach patient introducer to the mount

4. Physician performs a manual clean out and quick airway survey with the standard bronchoscope *(01:45)*

5. **ET tube** *(02:02)*
    1. Verify position of the ET tube: minimum of 4 cm from the main carina
    2. Tape down ET tube
    3. Cut the ET tube at nose height or 3-4 cm protruding from the mouth
    4. Replace swivel adapter with MONARCH swivel adapter

6. **Ventilation**

   Visualization and biopsy of lesions in or near the peripheral airways can be challenging. Optimal distention and visualization of the airways will give the best chances of success. Discuss with your anesthesia staff the safest way to achieve these goals with your specific patient.

7. **Completing patient prep** *(03:38)*
   a. Cables should be laying flat on the ground and not looped
   b. Swipe left until the sensor screen appears
   c. Field generator mount: adjust until all three sensors are green
   d. Attach the patient introducer to the MONARCH swivel adapter while supporting the distal end of the patient introducer mount
   e. Verify patient introducer angle. Should not be tilted towards the feet, head, or off the axial line. Make sure ET tube remains in place; avoid pushing the ET tube into the patient

5 MONARCH System Prep Completion

1. Select side of patient where the Cart will be placed *(00:13)*
2. **MONARCH Cart** *(00:19)*
   a. Press “Unstow Arms” (“Stop” button will freeze robotic arms during unstowing)
   b. Immobilize then move the Cart. Arm should be within 2 inches of the patient introducer. A second team member stands at the patient’s head to protect the patient introducer and assist with introducer alignment
   c. Base should be parallel to the top edge of the bed
   d. Once Cart and table are parallel, hold the Cart firmly by the handles and pump the foot pedal until the circle indicator on the Cart screen turns green, and then pump 7 more full pumps
3. **Align the arms** *(01:09)*
   a. Use the Emittance button on the arm closest to the patient for alignment
   b. Press and hold, applying directional force to (1) lower the arms to the appropriate height and (2) to make lateral movements towards the patient introducer, (3) to align blue markers on the Instrument Device Manipulator (IDM) and those on the Patient introducer
   c. Make slight adjustments by (1) supporting the distal end of the patient introducer mount with one hand, (2) loosening the patient introducer mount, (3) making the adjustment and then (4) re-tightening the mount
   d. Confirm correct alignment by looking across the white arm caps into the patient introducer opening

4. On the Cart, swipe to the next screen *(02:14)*

5. Press Next→ Retract Arms to position the arms into the loading pose *(01:17)*
    a. Another team member finishes the scope preparation by lubricating the MONARCH scope with 4x4's and silicone spray
    b. The scope is lubricated as it is pulled out of the package (do not lubricate tip)

6. **Load the Scope** *(03:00)*
    a. Insert the scope into the sheath while retracted from the clam shell
    b. Remove clam shell and set aside
    c. Insert the scope into the patient introducer
7. Open the seal on the swivel adapter *(03:40)*
8. Slide the scope & sheath into the ET tube and set handles onto the robotic arms *(03:44)*
9. Support underside of arm and press down on the scope handle to click it into place *(03:55)*
10. Support underside of arm and press down on the sheath handle to click it into place *(04:02)*

6 Navigation Initialization

- **Before navigation** *(00:09)*
    1. Ensure that the C-arm is 70 cm away to avoid electromagnetic interference with navigation
    2. Press the "Start Procedure" button on the MONARCH Tower

- **Navigation** *(00:25)*
    3. Press the Play and Pause button to activate the controller
        - Physician action: Drive into the ET tube
        - Assistant action: Apply gentle pressure on the sheath and scope to prevent buckling, maintaining pressure and alignment until the murphy eye is visualized
    4. Drive in the lumen's center during registration
    5. To roll correct, press the menu button and use the arrows to select "Roll Correction"
    6. Use the L and R buttons on the pad to achieve a proper roll, to ensure the main carina is vertical on screen and the left and right main stem bronchi are horizontal. Press "SET"
    7. Touch the main carina to set robotic insertion depth. Press "SET"
    Retract 40mm and press "SET" on the controller

6. **Completing navigation** *(02:10)*
    8. Teach the robot left and right by driving into the contralateral main stem bronchus until the system tells you to retract to a specified distance (different for every

patient and will vary for the right or left mainstem based on the length of the airway)

9. Once retracted to the specified distance, the navigation screen will appear

7 Drive to Target

- **Quick action features** *(00:09)*
    a. To see a virtual flythrough of the path to target at any time throughout the case, use the directional pad to move white box to the virtual bronchoscope. Press and hold quick action button
    b. Other useful quick action features on the navigation screen: CT area, 3D map, local, view tip and orbit view. To activate, highlight preferred view and press the quick action button
    c. Zoom in or out on the Tower touch screen by double-tapping and sliding your finger up and down

- **Driving (slow is fast)** *(01:05)*
    1. Follow the virtual view to approach the target and maintain the center of the airway by repeatedly advancing and then steering
    2. Drive in paired mode for as long as possible
    3. Use a deliberate technique to ensure the system has enough time to register each carina as it passes using “Optical Pattern Recognition” and Computer Vision
    4. Dock the sheath and continue driving the scope alone

    Driving tips & tricks *(01:45)*
    5. Drive 25-30 mm away from your target and switch from the navigation screen to the targeting screens - local, orbital, or tip view
        - **Local view** has enhanced spatial awareness of the scope relative to the target and may be the best alternative if virtual bronchoscope does not show a pathway. To utilize local view, press and hold the Quick Action Button and watch the target come to the center screen
        - **Orbital view** is used to rotate the image in the 3D plane to see the cone in the most optimal perspective. When the cone is red, the working channel is not oriented on the target. As it turns green, the scope and working channel are now aligned to the planned target

- **Tip View** or the **Call of Duty** view is employed to align the scope to the target or a specific location in the target
    - Toggle back and forth between these views to ensure the target remains aligned throughout the respiratory cycle
    - Don't sacrifice vision for distance and avoid burying the scope
- The sweet spot for biopsy is around 20mm

6. Once in place, press the play/pause button to pause and set down the controller
7. The physician can now use the radial probe and fluoroscopy to confirm the location

8 Confirm Target Location

- **Confirm target** *(00:08)*
    1. Insert radial probe into the working channel via the fluidics hub
        - **Important**: mark non-MONARCH tools like the radial probe to know when they will exit the working channel during insertion
    2. Once you see the radial probe on the MONARCH scope view, assistant should unfreeze the radial probe. Make micro adjustments to your position if necessary. A concentric view is ideal *(00:30)*
- **Positioning** *(01:05)*
    3 Use fluoroscopy imaging for position confirmation. Place white tape on the patient where the C-arm laser targeting appears to move the C-arm more efficiently. Take a fluoro shot and use this as a reference image. You can also make a manual mark on the fluoroscopy screen with a sharpie or your C-ARM may have the capability of marking a point
    4 Continue to use fluoroscopy in this manner while taking specimens via needle aspiration, cytology brush, or forceps

9 Biopsy

- **Biopsy** *(00:09)*
    1. Remove the radial probe and insert a needle into the working channel
    2. Advance the needle to the desired location under fluoroscopy with the stylette in place
    3. Remove the stylette then apply suction. You should feel resistance
    4. Take another radial image through the otomy while the first pass is being looked at by rapid onsite. Note the concentric signature
    5. Reposition if necessary, with the controller and use fluoro to confirm location

6. Pathology confirms there is sufficient tissue for diagnosis.

- **Biopsy Tips and Tricks** *(04:12)*
    1. Avoid insertion and retraction of the scope while the C-arm is near the field generator. The system can handle **small articulations** in the scope tip, but major movements will reset the compensation algorithm
    2. Use the forcep following the needle otomy. Open the forceps, advance, close and pull
    3. Continue biopsy using needle aspiration, forceps, or cytology brush as necessary
    4. One or samples from each instrument can be used to make a slide for ROSE evaluation. Remainder can go into formalin or cytology medium

10 Procedure Completion and Documentation

- **Procedure completion** *(00:09)*
    1. Drive the scope back towards the main carina by staying in the center of the airway as much as possible
    2. Auto relax will occur after 25mm of uninterrupted retraction
    3. The scope and sheath will pair as you continue to drive back
    4. Once in the ET tube, press the Play/pause button to pause the robot and set the controller on the shelf
    5. Press the menu icon on the touch screen and select “Stop Procedure” and “Confirm”

- **Documentation** *(00:55)*
    1. Document the radial image and ROSE findings and press “Submit”
    2. Press “Export Media to USB”

11 Case Tear Down and Clean Up

- **Tear down** *(00:08)*
    1. Press the release tabs on both handles of the scope and lift them from the arms, sweeping away from the patient
    2. Remove the fluidics tubing (untangle if necessary) so it can be hung on the Tower hook with the saline bag. Unspike bag over a sink and leave to drain. Discard in a bio receptacle once empty
    3. Unplug the camera and place the scope and cord, handles down, into the packaging sleeve to be cleaned later
    4. Mobilize the Cart by lifting up on the foot pedal and then rotate the Cart away from the patient. Press “Clean Arms” on the Cart and watch for potential collision

5. Detach the swivel adapter from the patient introducer
6. Loosen the patient introducer mount and remove from the field. Remove the patient introducer from the mount and discard. The mount is placed on the Tower shelf
7. The field generator is removed from the mount and placed on the shelf. The field generator mount is placed on the Tower shelf

- **Cleaning guidelines** *(01:40)*
    a. **Remaining cords on the front of the Tower**: unplug, coil and place on the shelf
    b. **Controller and field generator**: wiped down with disinfectant wipes and placed in the drawer
    c. **Both mounts**: wiped down and put back in the side storage compartment
    d. **Patient sensors**: removed and cleaned with disinfectant wipes. Place in the pouch in the side storage compartment
    e. **Chuck:** removed to wipe down the shelf and internal walls in the shelf area
    f. **Sleeve containing the scope:** removed from the Tower and set to one side
    g. **Cart**: wipe down all surfaces, including the screen
    h. **Arms**: stow by pressing “Stow Arms” on the Cart screen
    i. **The Tower**: wiped down with disinfectant, using an alcohol pad to remove buildup as necessary

- **Powering down** *(04:10)*
    1. Push the power button on the Tower touch screen to power down the Tower and Cart
    2. Remove USB
    3. After the blue lights on the Tower and Cart go out, unplug the umbilical and power cables, wipe down and coil in their appropriate locations for storage.
        - Tip: wrap the power cord first, then the umbilical cord to ready the cords for the next set up.

12 Scope Cleaning

- **Scope** *(00:08)*
    1. The scope is cleaned and returned to the company for sterilization and reprocessing
    2. Remove all components from the original box and arrange on a working surface
    3. Remove scope and sheath from packaging sleeve and discard sleeve
    4. Remove sheath valve and discard

- **Decontamination** *(00:30)*
    1. Decontaminate MONARCH Bronchoscope using a First Step pouch or other enzymatic cleaner
    2. Using the enzymatic pouch and sponge, wipe the entire surface of the scope
    3. Tubing may need to be cut so that the actual tube is fitted over the scope luer fitting. Attach the suction tubing to the scope luer lock and aspirate 200 ml of enzymatic solution through the working channel
    4. Remove the scope from the solution while continuing to aspirate for 10-15 seconds until dry
    5. Remove suction tubing
    6. Using the sponge and enzymatic solution, wipe the entire surface of sheath and cord
    7. Attach the sheath luer lock to the house suction to aspirate 200 ml of enzymatic solution through the channel
    8. Remove sheath from solution while continuing to aspirate 10-15 seconds to dry

- **Packaging** *(02:07)*
    1. Dry the scope and sheath with a 4x4 or lap sponge and place in the clamshell
    2. Coil and insert camera cord into the clamshell (secure the camera connector)
    3. Hang the clamshell on the hook on the side of the Tower and change gloves
    4. Slide the red biohazard bag over the clamshell and seal
    5. Try to remove as much air as possible prior to sealing to prevent ballooning
    6. Place the biohazard bag in the box and use the adhesive strips to seal for shipment
    7. Place the box in the prepaid FEDEX shipping bag and seal
    8. Send back to Auris within 48 hours

13 Emergent Conversion

- **Urgent access to patient's airway** *(00:13)*
    1. Press the release tabs on the Scope and Sheath handles and lift up and away from the patient. As the handles are removed, all articulation will be released, creating a flexible sheath and scope
    2. Detach the (blue) swivel adapter from the (white) patient introducer while the nurse hands the physician the manual bronchoscope
    3. Push the patient introducer mount away using hand-strength
    4. Lift up the immobilization pedal on the Cart and rotate the Cart to move it away from the working area

Safety and Disclaimers

If you have any questions, please reach out to MONARCH™ Support: T: (800) 434-0032 | E: monarchsupport@its.jnj.com

This guide is provided for informational and educational purposes only and does not provide medical advice. It is not intended to be used as a surgical training guide. This information is an adjunct to, but not a substitute for, robust surgical training and formal clinical training in bronchoscopy or otherwise. It is the responsibility of operating physicians to determine and utilize the appropriate medical device use and techniques according to their own clinical judgement for each of their individual patients. Before performing any procedure on a patient and using any medical device, including those referenced in this material, you should get appropriate accredited surgical training and review the MONARCH™ User Manual, with particular attention to the indications, contraindications, warnings, precautions and steps for use of the device.

Safety Information Disclaimer

Complications from bronchoscopy are rare and most often minor, but if they occur, may include breathing difficulty, vocal cord spasm, hoarseness, slight fever, vomiting, dizziness, bronchial spasm, infection, low blood oxygen, bleeding from biopsied site, or an allergic reaction to medications. Only rarely do patients experience other more serious complications (for example, collapsed lung, respiratory failure, heart attack and/or cardiac arrhythmia).

Indications for Use

The MONARCH™ Platform and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.