

ACE BLADE 700 and ZIP-PEN™ Smoke Evacuation Pencil Design Validation Discussion Guide

Instrument Set-up: Circulating Nurse or Equivalent

Nurse Representative Signature: [Signature] **Date:** 12.1.17

Moderator Signature: [Signature] **Date:** 12.1.17

Device Used: 2330 - LOT 175730

Set-up:

After being provided with the IFU (attachment 2 of the protocol) The participant will be asked to connect the In-Line filter to the wall vacuum and the suction canister per the protocol.

1. Rate the ability to connect the In-Line filter to the wall and suction canister:
- ☒ Acceptable
- ☐ Acceptable with Comments
- ☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
- Comments:

The participant will be asked to connect the C connector on the Zip-Pen to the canister using a 2145 connector and surgical tubing per the protocol.

2. Rate the ability to connect the Zip-pen to the suction canister:
- ☒ Acceptable
- ☐ Acceptable with Comments
- ☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
- Comments:

Instrument Use and Evaluation: Surgeon

Surgeon Signature: Houston #4 **Date:** 12.1.17

Device Used: ME7251E LOT - S170326

Surgeon Information is captured in Hurricane Discussion Guide and will be referenced in the report corresponding to this protocol.

Greeting (2 min):

I will be the moderator of today's session....

Provide Surgeon with IFU of the device being used

Ex-Vivo Model:

In this portion of the lab I'd like to give you the chance to use the device for a period of time to assess the overall performance.

Do you use monopolar electrosurgical devices in your practice?

☒ Yes ☐ No

If no, thank and dismiss.

Describe device (monopolar with smoke evacuation).

- Demonstrate how the tube zips from the handle for a more different hand positioning.
- Ask surgeon to use most comfortable configuration.
- Ask surgeon to use cut and coag functions of the device on the tissue model

3. Did the device monopolar functionality perform as expected:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

4. Rate the ability to evacuate smoke away from the surgical site:

- ☐ Acceptable
☒ Acceptable with Comments *BETTER THAN NOT HAVING - 7 OUT 10, ODR IS LESS*
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

5. Rate the ability to visualize the active electrode during the procedure:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

6. Rate the ergonomics of the device:

- ☐ Acceptable
☒ Acceptable with Comments *HEAVY, DRAG FROM HOSE - BRIST*
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

7. Rate the amount of drag on your hand from the tubing:

- ☐ Acceptable
☒ Acceptable with Comments *AGAINST UNACCEPTABLE*
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

HEAVY DRAG.

8. Rate the tactile feel of the buttons:

- ☒ Acceptable *BEST*
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Ask the surgeon to clean electrode with gauze or 4x4 sponge.

9. Rate the security of the active electrode when cleaning:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Thank and dismiss Surgeon.

Instrument Use and Evaluation: Scrub Nurse or Equivalent (only applicable if testing the Zip-Pen)

This device has the ability to change active electrodes. For example if you needed a longer active electrode you could change during the procedure. Ask the scrub nurse to remove electrode.

10. Rate the ability to remove the active electrode:

(If the scrub nurse has difficulty, demonstrate technique to remove.) If scrub nurse still has difficulty ask if they would use a tool (Hemostat?) to remove.

- N/A
- ☐ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
Comments:

Hand the scrub nurse the long electrode and ask to insert into device. Hand the scrub nurse the long nozzle and ask to insert over nozzle.

11. Rate the ability to insert the active electrode into the collet:

- N/A
- ☐ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
Comments:

Instrument Clean-up: Circulating Nurse or Equivalent**Clean-up:**

The participant will be asked to disconnect the In-Line filter to the wall vacuum and the suction canister per the protocol.

12. Rate the ability to disconnect the In-Line filter to the wall and suction canister:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
Comments:

The participant will be asked to disconnect the ACE BLADE 700 or Zip-Pen from the canister.

13. Rate the ability to disconnect the ACE BLADE 700 or Zip-pen to the suction canister:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
Comments:

Thank and dismiss.

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Instrument Set-up: Circulating Nurse or Equivalent

Nurse Representative Signature: [Signature]

Date: 11/30/17

Moderator Signature: [Signature]

Date: 11.30.17

Device Used: 2337 - LOT 175730

Set-up:

After being provided with the IFU (attachment 2 of the protocol) The participant will be asked to connect the In-Line filter to the wall vacuum and the suction canister per the protocol.

1. Rate the ability to connect the In-Line filter to the wall and suction canister:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
 Comments:

The participant will be asked to connect the C connector on the Zip-Pen to the canister using a 2145 connector and surgical tubing per the protocol.

2. Rate the ability to connect the Zip-pen to the suction canister:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
 Comments:

Instrument Use and Evaluation: Surgeon

Surgeon Signature: HOUSTON #3

Date: 11.30.17

Device Used: ME7251E LOT-S170326

Surgeon Information is captured in Hurricane Discussion Guide and will be referenced in the report corresponding to this protocol.

Greeting (2 min):

I will be the moderator of today's session....

Provide Surgeon with IFU of the device being used

Ex-Vivo Model:

In this portion of the lab I'd like to give you the chance to use the device for a period of time to assess the overall performance.

Do you use monopolar electrosurgical devices in your practice?

☒ Yes ☐ No

If no, thank and dismiss.

Describe device (monopolar with smoke evacuation).

- Demonstrate how the tube zips from the handle for a more different hand positioning.
- Ask surgeon to use most comfortable configuration.
- Ask surgeon to use cut and coag functions of the device on the tissue model

3. Did the device monopolar functionality perform as expected:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
 Comments:

4. Rate the ability to evacuate smoke away from the surgical site:

- ☐ Acceptable
☒ Acceptable with Comments – IMPROVE BY CLOSER TO TIP
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
 Comments: ADD ANOTHER SUCTION

5. Rate the ability to visualize the active electrode during the procedure:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
 Comments:

6. Rate the ergonomics of the device:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
 Comments:

7. Rate the amount of drag on your hand from the tubing:

- ☐ Acceptable
☒ Acceptable with Comments – TRIGGER METHOD IS EXCELLENT, TRADITIONAL HAS A LITTLE MORE DRAG
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
 Comments:

8. Rate the tactile feel of the buttons:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
 Comments:

Ask the surgeon to clean electrode with gauze or 4x4 sponge.

9. Rate the security of the active electrode when cleaning:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
 Comments:

Thank and dismiss Surgeon.

Instrument Use and Evaluation: Scrub Nurse or Equivalent (only applicable if testing the Zip-Pen)

This device has the ability to change active electrodes. For example if you needed a longer active electrode you could change during the procedure. Ask the scrub nurse to remove electrode.

10. Rate the ability to remove the active electrode:

(If the scrub nurse has difficulty, demonstrate technique to remove.) If scrub nurse still has difficulty ask if they would use a tool (Hemostat?) to remove.

N/A

- ☐ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Hand the scrub nurse the long electrode and ask to insert into device. Hand the scrub nurse the long nozzle and ask to insert over nozzle.

11. Rate the ability to insert the active electrode into the collet:

N/A

- ☐ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Instrument Clean-up: Circulating Nurse or Equivalent**Clean-up:**

The participant will be asked to disconnect the In-Line filter to the wall vacuum and the suction canister per the protocol.

12. Rate the ability to disconnect the In-Line filter to the wall and suction canister:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

The participant will be asked to disconnect the ACE BLADE 700 or Zip-Pen from the canister.

13. Rate the ability to disconnect the ACE BLADE 700 or Zip-pen to the suction canister:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Thank and dismiss.

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Instrument Set-up: Circulating Nurse or Equivalent

Nurse Representative Signature: _____

Date: 29 NOV 17

Moderator Signature: _____

Date: 11.29.17

Device Used: 2145 - LOT 174369 2330 - LOT 175730

Set-up:

After being provided with the IFU (attachment 2 of the protocol) The participant will be asked to connect the In-Line filter to the wall vacuum and the suction canister per the protocol.

1. Rate the ability to connect the In-Line filter to the wall and suction canister:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

The participant will be asked to connect the C connector on the Zip-Pen to the canister using a 2145 connector and surgical tubing per the protocol.

2. Rate the ability to connect the Zip-pen to the suction canister:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Instrument Use and Evaluation: Surgeon

Surgeon Signature: #2 Houston

Date: 11.29.17

Device Used: ME7251E - LOT 5170326

Surgeon Information is captured in Hurricane Discussion Guide and will be referenced in the report corresponding to this protocol.

Greeting (2 min):

I will be the moderator of today's session....

Provide Surgeon with IFU of the device being used

Ex-Vivo Model:

In this portion of the lab I'd like to give you the chance to use the device for a period of time to assess the overall performance.

Do you use monopolar electrosurgical devices in your practice?

☒ Yes ☐ No

If no, thank and dismiss.

Describe device (monopolar with smoke evacuation).

- Demonstrate how the tube zips from the handle for a more different hand positioning.
- Ask surgeon to use most comfortable configuration.
- Ask surgeon to use cut and coag functions of the device on the tissue model

3. Did the device monopolar functionality perform as expected:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

4. Rate the ability to evacuate smoke away from the surgical site:

- ☐ Acceptable
☒ Acceptable with Comments *COULD USE A LITTLE STRONGER, BUT BETTER THAN WITHOUT IT*
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

5. Rate the ability to visualize the active electrode during the procedure:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

6. Rate the ergonomics of the device:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

7. Rate the amount of drag on your hand from the tubing:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

8. Rate the tactile feel of the buttons:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Ask the surgeon to clean electrode with gauze or 4x4 sponge.

9. Rate the security of the active electrode when cleaning:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Thank and dismiss Surgeon.

Instrument Use and Evaluation: Scrub Nurse or Equivalent (only applicable if testing the Zip-Pen)

This device has the ability to change active electrodes. For example if you needed a longer active electrode you could change during the procedure. Ask the scrub nurse to remove electrode.

10. Rate the ability to remove the active electrode:

(If the scrub nurse has difficulty, demonstrate technique to remove.) If scrub nurse still has difficulty ask if they would use a tool (Hemostat?) to remove.

N/A

- ☐ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Hand the scrub nurse the long electrode and ask to insert into device. Hand the scrub nurse the long nozzle and ask to insert over nozzle.

11. Rate the ability to insert the active electrode into the collet:

N/A

- ☐ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Instrument Clean-up: Circulating Nurse or Equivalent**Clean-up:**

The participant will be asked to disconnect the In-Line filter to the wall vacuum and the suction canister per the protocol.

12. Rate the ability to disconnect the In-Line filter to the wall and suction canister:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

The participant will be asked to disconnect the ACE BLADE 700 or Zip-Pen from the canister.

13. Rate the ability to disconnect the ACE BLADE 700 or Zip-pen to the suction canister:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Thank and dismiss.

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Instrument Set-up: Circulating Nurse or Equivalent

Nurse Representative Signature: A Ray **Date:** 11.29.17

Moderator Signature: [Signature] **Date:** 11.29.17

Device Used: 2145 - LOT 174369 2330 - LOT 175730

Set-up:

After being provided with the IFU (attachment 2 of the protocol) The participant will be asked to connect the In-Line filter to the wall vacuum and the suction canister per the protocol.

1. Rate the ability to connect the In-Line filter to the wall and suction canister:
 - ☒ Acceptable
 - ☐ Acceptable with Comments
 - ☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
 Comments:

The participant will be asked to connect the C connector on the Zip-Pen to the canister using a 2145 connector and surgical tubing per the protocol.

2. Rate the ability to connect the Zip-pen to the suction canister:
 - ☒ Acceptable
 - ☐ Acceptable with Comments
 - ☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)
 Comments:

Instrument Use and Evaluation: Surgeon

Surgeon Signature: #1 Houston **Date:** 11.29.17

Device Used: ME7251E - LOT S170326

Surgeon Information is captured in Hurricane Discussion Guide and will be referenced in the report corresponding to this protocol.

Greeting (2 min):

I will be the moderator of today's session....

Provide Surgeon with IFU of the device being used

Ex-Vivo Model:

In this portion of the lab I'd like to give you the chance to use the device for a period of time to assess the overall performance.

Do you use monopolar electrosurgical devices in your practice?

☒ Yes ☐ No

If no, thank and dismiss.

Describe device (monopolar with smoke evacuation).

- Demonstrate how the tube zips from the handle for a more different hand positioning.
- Ask surgeon to use most comfortable configuration.
- Ask surgeon to use cut and coag functions of the device on the tissue model

3. Did the device monopolar functionality perform as expected:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

4. Rate the ability to evacuate smoke away from the surgical site:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

5. Rate the ability to visualize the active electrode during the procedure:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

6. Rate the ergonomics of the device:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

7. Rate the amount of drag on your hand from the tubing:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

8. Rate the tactile feel of the buttons:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Ask the surgeon to clean electrode with gauze or 4x4 sponge.

9. Rate the security of the active electrode when cleaning:

- ☒ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Thank and dismiss Surgeon.

Instrument Use and Evaluation: Scrub Nurse or Equivalent (only applicable if testing the Zip-Pen)

This device has the ability to change active electrodes. For example if you needed a longer active electrode you could change during the procedure. Ask the scrub nurse to remove electrode.

10. Rate the ability to remove the active electrode:

(If the scrub nurse has difficulty, demonstrate technique to remove.) If scrub nurse still has difficulty ask if they would use a tool (Hemostat?) to remove.

- ☐ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Hand the scrub nurse the long electrode and ask to insert into device. Hand the scrub nurse the long nozzle and ask to insert over nozzle.

11. Rate the ability to insert the active electrode into the collet:

- ☐ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Instrument Clean-up: Circulating Nurse or Equivalent**Clean-up:**

The participant will be asked to disconnect the In-Line filter to the wall vacuum and the suction canister per the protocol.

12. Rate the ability to disconnect the In-Line filter to the wall and suction canister:

- ☐ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

The participant will be asked to disconnect the ACE BLADE 700 or Zip-Pen from the canister.

13. Rate the ability to disconnect the ACE BLADE 700 or Zip-pen to the suction canister:

- ☐ Acceptable
☐ Acceptable with Comments
☐ Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

Thank and dismiss.