CARDIOMEDICS

Model 3000 ECP System *Clinical Troubleshooting Q and A*

Status Post MI

Q – The patient had a recent heart attack (MI). How long should I wait until I can start him/her on ECP?

A – There is no current clinical data to guide the use of ECP post MI. However, the current common practice is to wait 4-6 weeks post MI dependent on the patient's condition.
Concern: Make sure there are no clots post MI. Patients are usually on blood thinners such as Plavix post MI.

Leg Stents

Q – The patient has had stents placed in his leg. Can I treat him with ECP?

A – How long ago did he have the stents placed? As long as it's been more than 6-8 months post stenting, he can be treated with ECP.

Aneurysms

Q – The patient has an aneurysm larger than 3.0cm. Can I treat him?

A – It is up to the treating physician. It is the physician's medical discretion whether to treat the patient or not. Cardiomedics cannot recommend treatment if the aneurysm is greater than 3.0cm in size.

Poor Augmentation

Q – The patient is not augmenting, what should I do?

A – There are many reasons why some people may not augment. Some reasons are:

- Peripheral vascular disease
- History of smoking

It may take up to 3-4 weeks for some people to get therapeutic augmentation, which leads to the following questions:

1. How many ECP treatments has the patient had?
2. Does he have PVD?
3. Is there a history of smoking?

It is also possible that the delay/duration settings are not appropriate for the patient such as:

- If the delay timing is not appropriate with the patient's ECG/HR, the PPG waveform will look shallow and won't have a distinct separation from systolic to diastolic. If this occurs, increase the delay until more of a distinct notch separation is seen. Early delay is usually 100-145ms. The green marker will appear too early, starting closer to the S wave.

- The delay is too late if the green marker is starting after the T wave and the PPG waveform has a deep transition like a "U" wave or longer transition from systolic to diastolic (late delay is usually 220-300ms).

- The delay should be set appropriately for patients on an individual basis.

- A correct delay is when the PPG waveform appears with a distinct separation from systolic to diastolic looking like a check mark or "V" transition from D/S ratio. The green marker will appear to start just before the peak of the T wave. Correct delay is usually 160-250ms depending on the patient's ECG and heart rate. Patients with wider QRS, bundle branch block or with pacemakers will usually have a longer delay setting for appropriate timing.

Machine shutting down from high/low HR

Q – The heart rate on the machine indicates 23bpm up to128bpm. It is all over the place and the green marker keeps dropping in and out.

A – There are three reasons this may occur:

1. The duration is set too long for the patient's heart rate. If HR is 80bpm or higher, drop the duration to 300ms.
2. The minimum or maximum adjustment of the QRS is not set appropriately for the patient's QRS width. Does the patient have a pacemaker or a bundle branch block (a wide or skinny QRS)?

    - If the QRS is wider than the factory default of 30ms, the adjustment of the QRS will have to be widened out up to 80,120 or 180 depending on the measurement of the QRS.
    - If the QRS is smaller than the factory default of 18ms, the minimum width of the QRS will have to be decreased to 8 or 11ms depending on the measurement.

3. Poor conduction or lead placement: The solution is to re-prep with alcohol first, then Nu-prep, and reapply the electrodes. Check the patient's 12-lead ECG to find the most prominent upright T wave and hook-up following the pictures found within the operator's manual. Remember that the machine software is looking for the upright R wave for the green marker to conduct. If the T wave is as strong as the R wave the system will double count and shut off at the factory safety default of 120bpm. The solution is to find a better lead placement if this occurs.

Two ECP treatments per day

Q – Can patients be treated with double treatments (twice per day)?

A – If the patient is being treated for Angina and his ejection fraction is >40%, he can be treated with 2 sessions per day with a 20-minute break between sessions. If the patient has CHF and the ejection fraction is less than 40%, do not treat the patient more than one time per day.

Lower extremity numbness

Q – Some patient's lower extremities (calves) are going numb 20-30 minutes into treatment. Is this normal and what can be done to prevent it?

A – This may occur in patients with peripheral vascular disease, diabetes and neuropathy. It would be considered normal due to the patient's poor vascular compliance. To resolve the issue, 20-30 minutes into treatment when the patient starts to get the numbing sensation, stop treatment and disconnect the calf cuffs from the patient and place something such as a towel or small pillow inside the calf cuffs and wrap them like fake legs. Only the thighs and buttocks cuffs will be functional, which will eliminate the uncomfortable feeling of numbness during ECP. Clinically the patient only gets 10-15% of blood supply from the calves and thus only minimal augmentation will be sacrificed.

Poor PPG signal

Q – I am getting very poor PPG waveform on the ECP screen, what can I do to increase the amplitude of the waveform?

A –

1. Warm the patient's fingers with a warm, wet towel or a heating pad to increase the amount of blood flow to the fingers for better amplitude.
2. Make sure the PPG cable is in working order. Check to see that it is plugged in all the way within the back of the ECP system.
3. Increase the PPG amplitude on the ECP screen by touching Adjust PPG. The amplitude can be increased by pressing up at this point. Increase or decrease the off-set to get the waveform to appear in the proper position on the screen. This is not real time; the print out of a waveform strip may be small and hard to read. To get the real time waveform to appear larger, warm the patient's fingers up to increase blood flow or move the PPG to another finger that may have better blood flow.
4. If the waveform is flat on all your patients the PPG cable may need to be replaced.

Missed ECP treatments

Q – The patient has missed more than 5 treatments consistently, should he be discharged from treatment?

A – If the patient has missed 5 days within the first 2 weeks, the patient will have to re-start treatment from the beginning. If the patient has not missed any treatments until after 3 weeks of consistent treatments and they were missed with a good excuse, just add them to the end of his treatments. The first 2 weeks are the most important. The patient may feel tired or fatigued the first few weeks of treatments, which is a normal response.

Skin chafing

Q – The patient has formed a blister on his right/left calf, what should I do?

A – Patients that are diabetic tend to have skin chafing with ECP.

- First, all diabetic patients should wear nylon knee highs or TED hose underneath their leggings to prevent skin chafing.
- Second, make sure the calf cuffs are wrapped very snug to prevent rubbing and chafing.
- Third, send your patient to wound care if blisters appear. Continue treatment but do not wrap that calf (or calves) until the wound has healed.

Pacemaker Issue

Q – The patient has a pacemaker and when I treat him with ECP his heart rate increases and shuts down the system. What should I do?

A – Patients with pacemakers may have a rate response in their device. Rate response is a physiological response to increase the patient's HR during movement such as exercise and ECP. First, find out what kind of pacemaker the patient has. Is it in a DDDR or VVIR mode? If so, ask the pacemaker rep to turn off the rate response for ECP. The mode should be changed to a DDD or VVI mode during treatment. The patient's HR will stay at their set rate of 60-70bpm during ECP.

It is recommend that the pacer rep leave the pacemaker programmer for the 7-week treatment cycle and educate the ECP staff how to interrogate the pacemaker and turn on/off rate response before and after ECP therapy. This will provide a much better outcome for the patient. If the patient rate response is turned off for the 7 weeks, the patient will not be able to exercise or walk up stairs at home without getting short of breath.

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Coumadin therapy

Q – The patient is on Coumadin therapy with an INR level of 3.4, are there any precautions?

A – This depends on the patient's diagnosis and the reason for taking Coumadin.

- If they are taking Coumadin for A-Fibrillation the INR should be from 2-3 INR.
- If on Coumadin for valve replacement the INR should be from 2-4 INR depending on the physician's personal guidelines. It should be safe to treat patients with ECP with an INR of 3.4, but the patient should have a PT-INR level within 3-4 days. ECP will not increase or decrease their INR levels.

Check for signs and symptoms during therapy such as:

- Bruising
- Blood shot eyes
- Blood in stool