



PROCEDURE # 945.8012

**MEDTRONIC AUTOMATED COAGULATION TIMER II—
 WHOLE BLOOD ACTIVATED CLOTTING TIME (ACT)**

PREPARED BY	DATE ADOPTED	SUPERSEDES PROCEDURE #
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REVIEW DATE	REVISION DATE	SIGNATURE

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PURPOSE:

To provide a standard P&P for use of the Medtronic ACT II coagulation instrument in determining ACT's.

PRINCIPLE:

Upon initiation of a test, the reagent is injected into the reaction chamber. The plunger assembly is lifted and allowed to fall through the unclotted sample and as a fibrin web is formed during clotting. The fall rate of the assembly is impeded. The instrument detects this decrease in the fall rate by a photo-optical system located in the cover of the instrument.

SPECIMEN:

Patient Prep:

Patient is identified using the name and date of birth.

Sample Requirements:

1. Syringe sample must contain 0.4 cc's of blood
2. Sample syringes must not be anticoagulated, must be free of air and other contaminants.
3. Samples can be either venous or arterial blood.

GENERAL DESCRIPTION OF PROCESS:

1. Each operating room has it's own Medtronic ACT II analyzer designated to that particular room.
2. Samples are drawn from the patient/Heart-Lung machine, and are then immediately run in the specified analyzer.
3. Analysis is performed solely by Clinical Perfusionist.
4. Results are recorded on the patient's Perfusion Record, and verbally reported to the attending surgeon and anesthesiologist. All recorded results are checked against the visual display to ensure accurate recording.
5. If, after systemic heparinization but prior to cardiopulmonary bypass, the ACT is < 400 seconds, additional heparin will be administered by the anesthesiologist. If deemed appropriate, the ACT will be repeated.
6. If the Clinical Perfusionist or physician questions the ACT results, repeat the ACT
7. If any analytical errors are detected, repeat the ACT.
8. Daily Quality Controls are performed prior to analyzing the first patient blood sample of the day by the Clinical Perfusionist responsible for the instrument.

INSTRUMENTATION:

1. Sample to sample calibration is not required.
2. The Medtronic ACT II machine poses a linear value limit of 999 seconds.
3. **Error Codes:**
 - 01 Pull cover forward.
 - 02 Call service department
 - 03 Call service department
 - 04-07 Remove cartridge. Clean light path holes in actuator cover. If error is not corrected, call service department.
 - 08 Turn instrument OFF. Remove the cartridge and restart the instrument.
 - 09 See 4 above.
 - 10 Call service department.



MAINTENANCE AND TROUBLESHOOTING:

1. Monthly routine cleaning is performed monthly and documented on the ROUTINE CLEANING LOG.
2. Monthly temperature measurements of each well is checked and recorded on the HEAT BLOCK TEMPERATURE VERIFICATION LOG.
3. Timer accuracy is checked monthly and documented on the TIMER ACCURACY LOG.
4. Troubleshooting is performed by Biomedical Engineering.
5. Biannual maintenance is performed by Biomedical Engineering. When the system is down, Biomedical Engineering is responsible for repairs to the Medtronic ACT II machine.

CHARTING AND REPORTING:

Time of analysis and results are recorded on the patient Perfusion Record.

QUALITY CONTROL:

1. Medtronic CLOTrac Controls for the Automated Coagulation Timer consist of sheep plasma and red blood cells. When reconstituted, they behave like a fresh whole blood patient sample.
2. Normal and abnormal controls (electronic and wet) are used to represent the entire range of expected values.
3. Electronic controls (normal—98 sec to 102 sec and abnormal—490 sec to 510 sec) are performed for 6 days and on the 7th day, wet controls are performed.

“Wet” Control procedure:

- a. Allow “normal” and “abnormal” CLOTrac Coagulation Control and deionized water vials to stand at room temperature for at least 10 minutes.
- b. Add 1.8 ml of deionized water to each control vial (“normal” and “abnormal”).
- c. After allowing 10 minutes for rehydration, shake the control vials vigorously to complete rehydration.
- d. Aspirate 0.4 ml of “normal” control into each channel of the ACT cartridge.
- e. Place the cartridge into the Automated Coagulation Timer (warmed up) and turn the incubate switch to the “ON” position. Push the sample block back into its closed position and the test will automatically initiate after 5 minutes (300 sec).
- f. Aspirate 0.4 ml of “abnormal” control into each channel of the ACT cartridge.
- g. Place the cartridge into the Automated Coagulation Timer (warmed up) and turn the incubate switch to the “ON” position. Push the sample block back into its closed position and the test will automatically initiate after 5 minutes (300 sec).

RESULTS:

1. Within the same lot of controls, there should be less than a 15% variation.
2. Within the same cartridge, there should be less than a 12% variation from one channel to the other.
3. Clotting ranges are printed on control vials.

Reporting Format:

1. Record the results on the ACT Quality Assurance Record. Include: date, time, temp, cartridge lot #, normal or abnormal, lot #, specified range, clotting times for channel 1 and 2 and average, indicate whether results were OK, who performed sample, and comments.
2. If the results obtained do not meet the above criteria, repeat the process. After two failed attempts, notify the Chief Perfusionist or his/her designee.



STORAGE AND STABILITY OF CONTROLS:

1. Store refrigerated between 2° C and 10° C until use.
2. Once reconstituted, the control is stable for 2 hours at room temperature (15 to 25° C).
3. DO NOT use the controls past the indicated expiration date.

PROCEDURE—STEPWISE:

1. Warm the cartridge to 37° +/- 0.5° C for 3-5 minutes in the instrument heat block.
2. Tap the cartridge to suspend the reagent.
3. For HRACT—add 400 µl sample to each cartridge channel; to between the fill lines.
4. Insert cartridge into instrument.
5. Rotate the actuator to the closed position to start the test.
6. Test completion is indicated by an audible alert. The average and difference of the determinants are displayed by depressing the Display switch.

HEAT BLOCK TEMPERATURE VERIFICATION:

1. The temperature of the heat block is verified once a month.
2. Turn the Automated Coagulation Timer on and allow the instrument to warm up for 5-10 minutes.
3. Place a calibrated thermometer (Temperature Verification Cartridge provided by Medtronic) in one of the cartridge reaction chambers.
4. Wait for temperature equilibration to occur (less than 15 minutes) and read thermometer. Record results on the TEMPERATURE VERIFICATION LOG.
5. The instrument temperature and measured temperature are required to read within 36.5 to 37.5° C. The measured temperature is required to read within +/- 0.5° C of the instrument temperature.
6. If heat block temperature lies outside this range, adjust with a screwdriver using the bottom panel temperature adjustment.

TIMER ACCURACY:

1. Insert unused ACT cartridge into instrument and activate test. Simultaneously depress the start button of a stopwatch.
2. After 3 minutes of run time, stop the stopwatch and simultaneously record the elapsed time on the ACT counter.
3. The instrument timer and the stopwatch elapsed time are recorded.
4. If a difference of more than 1 second is recorded, repeat procedure until less than a 1 second discrepancy exists or remove the instrument from use and call for service.

ACT TESTING IS CLASSIFIED BY CLIA ASD MODERATELY COMPLEX:

1. Moderate complex testing can be performed by a trained individual with a minimum of a high school degree and appropriate clinical training in testing procedures.

ROUTINE CLEANING:

1. In order to ensure proper performance, it is important to clean the instrument once every 30 days or more as required.
2. Dip the swab, in the Liqui-Nox Solution or peroxide.
3. Swab flag lifters, removing all blood.
4. Swab inside of actuator cover, especially the detector and lamp area (photo-optical system).
5. Remove excess Liqui-Nox, or peroxide, with a dry swab.
6. If blood should get into the detector or lamp area and cannot be removed with a swab, error code 4, 5, 6, or 7 may be displayed. If this occurs, contact Biomedical Engineering.



7. Document your routine cleaning by recording appropriate information on the temperature, cleaning and dispenser log.

INTERPRETATION OF RESULTS:

1. Acceptable limits for each parameter is listed on record sheet.
2. "Accept" the control run if all parameters fall within established parameters.
3. "Repeat" the control run of any level whose results do not fall in the established parameters.
4. If the repeat run(s) fails to demonstrate values in acceptable parameters **do not** use to report any patient results. Consider the equipment "**DOWN**" and notify Biomedical Engineering Department

REFERENCES:

1. Department of Health and Human Services. "42 CFR Part 405, et al. Clinical Laboratory Improvement Amendments of 1988; Final Rule." Federal Register. 57(40), 2/28/92, page 7003.
2. Brzys, Karen; "CLIA '88: Hopefully the Final Update" Perfusion Life, June 1992, pages 40-46.