CLINICAL IMPLICATIONS

Electrode management during an ablation procedure can be challenging. The new GENius user interface is designed to make it easier to recognize therapeutic and non-therapeutic combinations of power and temperature and take action. Actions may include increasing or decreasing array pressure, deselecting electrode pairs or taking no action at all.

When electrodes are consistently yellow across the array after 10-15 seconds, a pressure change along the array may improve the temperature or power. Slight forward pressure can improve contact to achieve target temperature, whereas a slight decrease in array pressure can increase power delivery.

However, tissue contact along the array can vary resulting in electrode pairs that are green, yellow or green, yellow. These yellow-green electrode combinations highlight where action should be considered.

Figure 10 is an example of yellow/green electrode pairs. Good electrode heating is likely occurring and no action may be needed.

Figure 11 is an example of yellow electrode pairs. In this situation the temperature is low with limited heating or power is low such that a shallower lesion or tissue edema results. Under these circumstances the decision is often made to deselect the electrode pair.

Figure 12 is an example of yellow/green electrode pairs. Good electrode pairs that are green, yellow or green/yellow. These electrode pairs are green, yellow or green/yellow electrode combinations. The result is a new user interface that easily draws the user's attention to electrodes that may not be therapeutic or require action. In vitro and animal testing have demonstrated the importance of achieving good power (≥ 3W) and good temperature (≥ 50 °C) for at least 30 seconds of the 60-second ablation time. GENius with ContactIQ introduces a more precise algorithm for management of power and temperature and a new user interface designed to simplify decision-making and effective ablation assessment.

SUMMARY

GENius with ContactIQ precisely manages power and temperature, incorporating a new user interface designed to simplify decision-making and effective ablation assessment. The power delivery algorithm has been refined to more effectively use the relationship between target temperature and power delivery during ablation to recognize dynamic conditions and adapt energy delivery. Human factor assessment of the user interface combined with pre-clinical research and clinical experience led to widening the target temperature range and integrating both power and temperature to identify therapeutic combinations. The result is a new user interface that easily draws the user’s attention to electrode pairs that may not be therapeutic or require action. In vitro and animal testing have demonstrated the importance of achieving good power (≥ 3W) and good temperature (≥ 50 °C) for at least 30 seconds of the 60-second ablation time. GENius with ContactIQ: Precise energy delivery and simplified data interpretation.

REFERENCES

3. GENius human factors field study – Usability test report. Medtronic document number 10053783DOC Rev 1A.
5. Lab notebook study performed March 21, 2013.
6. PVAC – 4E Test Configuration (4:1, 60 °C).
9. Figure 1. GENius version 14.4 user interface only required temperature for a green bar.
10. Figure 2. GENius with ContactIQ requires temperature ≥ 50 °C to ≤ 65 °C and power ≥ 3 watts for a green bar.
The importance of combined temperature and power information was highlighted in a recent publication by De Greef, et al. This publication demonstrated that parameters of RF biophysics were predictive of both procedural pulmonary vein reconnection (PVR) and 1-year freedom from AF: Pulmonary vein isolation (PVI) plus an adenosine challenge and 1 hour waiting period was used to reveal dominant PVI during the procedure. Post-procedure, the GENius ablation data was analyzed. Acute PVR was less likely to occur when more RF applications had an average temperature > 48°C and power ≥ 3W. Similarly, AF recurrence at 12 months was less likely when more RF applications had average temperature > 48°C and average power > 3W (Figure 4).

Animal and Bench Testing to Verify GENius with ContactIQ

Study Purpose – Lesion Formation at Pre-Determined Contact Times

• Determine correlation between pre-determined contact time and measured Effective Contact seconds
• Lesion depth with increasing contact time

Test Model

The test model consisted of a funnel shape lined with bovine myocardium (5 - 7 mm thickness). Saline flowed through and around the tissue in the simulated vein and the flow rate could be altered to simulate low, normal, and high cardiac flow. The PVAC® GOLD catheter was seated at the “vein annulus.” Post-ablation, the lesion depth was measured and matched with the GENius ablation data to determine average power and temperature. Figure 6 shows a schematic of the PVAC left atrium model and an example of an ablation run.

Study Design

• Catheter contact was stable for 15, 30, 45, and 60 seconds of the 60-second ablation time
• Two (2) ablations were performed for each pre-determined contact time in randomized order
• 4:1 and 2:1 modes were studied
• At the pre-determined contact time the catheter was removed from tissue contact and held above the tissue for the remainder of the ablation
• GENius ablation data, Effective Contact time, and lesion depth under each electrode were recorded

Study Results

Figure 7 shows that Effective Contact as measured by the generator correlates well with the actual contact time in both 4:1 (R = 0.694) and 21 (R = 0.84) modes. Figure 8 shows increasing lesion depth with increasing contact time for both 41 and 21 energy modes and directionally consistent with thermochromic gel testing.

Results Directionally Consistent with Thermochromic Gel and Thigh Muscle Test Methods

The method described in the above study was designed to simulate a pulmonary vein environment and further characterize Phased RF energy delivery. The results from that model were directionally consistent with other in-vitro and more traditional animal models used to characterize Phased RF, including thermochromic gel and thigh muscle. Figure 9 shows the results of pre-determined contact testing conducted in both thigh muscle and thermochromic gel. The results of all 3 models are consistent with prior studies that demonstrate that maximum lesion depth is achieved after 30 to 40 seconds of therapeutic RF delivery.