### Medtronic

Engineering the extraordinary

Barrx<sup>™</sup> radiofrequency ablation system



The following information is intended as a quick reference. For full details, please refer to this product's Instructions For Use (IFU). Contact customer service or your sales representative for the most in-to-date revision of the package insert.

## Task Basic Troubleshooting

#### Review

#### **Problem: No RF Power Output**

- Energy Generator not plugged in
- Energy Generator not turned on
- Energy Generator in STANDBY mode
- Energy Generator in FAULT mode
- Energy Generator still in ABLATION COMPLETE mode
- Fault in accessory or Footswitch
- Output Cable not connected to the Energy Generator

- No Ablation Catheter Connected
- Defective Ablation Catheter
- Energy Density Parameter Not Set
- Internal Energy Generator failure
- Balloon Inflation Error. The pressure in the Balloon Based Ablation Catheter or Barrx 360 Express RFA Balloon Catheter is less than the target pressure

#### **Operational and Fault Codes**

If a fault condition occurs, the System Status display on the front panel will display an operational code, and all others will be blank. The interpretation of the operational, error and fault codes, as well as possible causes and solutions are listed in Tables 3.A, 3.B, 3.C and 3.D.

In the event of an operational /error or fault code, endoscopic visualization must be used to verify complete balloon deflation if using a Balloon Based Ablation Catheter, Barrx 360 Express RFA Balloon Catheter, or Sizing Balloon.

If the Energy Generator displays an E95 operational code when using a Balloon Based Ablation Catheter, Barrx 360 Express RFA Balloon Catheter, or Sizing Balloon, this is probably due to an air leak within the system. In such situations verify the following connections are secure:

- The pneumatic connector between the Energy Generator and the Output Cable;
- The pneumatic connector between the Output Cable and the Barrx filter;
- The connection between the filter and the Ablation Catheter.

If the E95 operational code is observed again, there may be an air leak in the Ablation Catheter. Under endoscopic visualization, confirm that the balloon is fully deflated and then remove the Ablation Catheter. If the balloon is not deflated by depressing the DEFLATE control button or by depressing the Auto Inflation Foot Pedal, then manually deflate the balloon using a syringe via the pneumatic connector. Remove and replace the Ablation Catheter.

#### **Complaint Filing**

#### Complete the field and technical report form (which includes the information below)

#### 2. Details must be included:

- Date Medtronic employee was first notified of the event/problem
- Initial Reporter: Who informed the sales representative or tech support of the event
- List of all products involved
- Accurate description of the problem
- Issues that the Device problem directly resulted into

#### 3. Retain defective product for return



#### **Troubleshooting Codes**

**Table 3.A. Post Faults (Unrecoverable)** 

Error code	Description	System status messages	Auto deflate function active on error for balloon based catheters
P01	POST CPU Configuration Operational Code	Disconnect Catheter P01 - Cycle Power	N/A
P02	POST ROM Test Operational Code	Disconnect Catheter P02 - Cycle Power	N/A
P03	POST RAM Test Operational Code	Disconnect Catheter P03 - Cycle Power	N/A
P04	POST Power Operational Code	Disconnect Catheter P04 - Cycle Power	N/A
P05	POST Impedance Operational Code	Disconnect Catheter P05 - Cycle Power	N/A
P06	POST Voltage Operational Code	Disconnect Catheter P06 - Cycle Power	N/A
P07	POST Current Operational Code	Disconnect Catheter P07 - Cycle Power	N/A
P08	POST Reference Voltage Operational Code	Disconnect Catheter P08 - Cycle Power	N/A
P09	POST Watchdog Test Operational Code	Disconnect Catheter P09 - Cycle Power	N/A
P010	POST Output Transformer Impedance Operational Code	Disconnect Catheter P10 - Cycle Power	N/A
P011	POST Pressure Sensor Offset Operational Code	Disconnect Catheter P11 - Cycle Power	N/A
P012	POST Pressure Reference Voltage Operational Code	Disconnect Catheter P12 - Cycle Power	N/A
P015	POST Real Time Clock Test Operational Code	Disconnect Catheter P15 - Cycle Power	N/A
P016	POST Real Time Clock Date Operational Code	Disconnect Catheter P16 - Cycle Power	N/A
P017	POST Switch Closed Operational Code	Disconnect Catheter P17 - Cycle Power	N/A



**Table 3.B. Software/Hardware Faults (Unrecoverable)** 

Error code	Description	System status messages	Auto deflate function active on error for balloon based catheters
H10	COP Operational Code	Disconnect Catheter H10 - Cycle Power	Yes
H11	Illegal CPU Instruction	Disconnect Catheter H11 - Cycle Power	Yes
H12	Duplicate Variable Operational Code	Disconnect Catheter H12 - Cycle Power	Yes
H13	Software Operational Code	Disconnect Catheter H13 - Cycle Power	Yes
H15	Reference Voltage Operational Code	Disconnect Catheter H15 - Cycle Power	Yes
H16	Vrms Offset Operational Code	Disconnect Catheter H16 - Cycle Power	Yes
H17	Irms Offset Operational Code	Disconnect Catheter H17 - Cycle Power	Yes
H18	Pmes Offset Operational Code	Disconnect Catheter H18 - Cycle Power	Yes
H19	RF ON Synch Operational Code	Disconnect Catheter H19 - Cycle Power	Yes
H20	Pressure Out of Range Operational Code	Disconnect Catheter H20 - Cycle Power	Yes
H22	Output Transformer Channel Set Operational Code	Disconnect Catheter H22 - Cycle Power	Yes
H23	Duplicate Pressure Operational Code	Disconnect Catheter H23 - Cycle Power	Yes



**Table 3.C. Catheter Errors (Recoverable)** 

Error code	Description	System status messages	Auto deflate function active on error for balloon based catheters	
C50	EEPROM CRC Code	C50 - Reconnect or Discard Catheter	No	
C51	Invalid Catheter ID Code	C51 - Reconnect or Discard Catheter	No	
C52	Expired Catheter Code	C52 - Max Time Reached Discard Catheter	Yes	
		<b>Sizing Balloon:</b> Discard Catheter C53 - Max Use Reached		
	Catheter Use Exceeded Code	nnmm Recommended  Barrx 360 RFA Balloon Catheter: Discard Catheter C53 - Max Use Reached		
		nnn% nnn% nnn% Energy Delivered		
C53		Barrx 360 Express RFA Balloon Catheter: Discard Catheter C53 - Max Use Reached	Yes	
		Energy Delivered		
		Non Balloon Based Ablation Catheter: Discard Catheter C53 - Max Use Reached		
		nn% Energy Delivered		
C55	Catheter Type Code	C55 - Reconnect or Discard Catheter	Yes	
C56	Filter Blocked Code	C56 - Filter Blocked Remove Filter Deflate with Syringe Discard Catheter	No	
C57	EEPROM Setting Code	Unusable Catheter C57 - Discard Catheter	No	



**Table 3.D. Application Operational Codes (Recoverable)** 

Error Code	Description	System Status Messages	Auto deflate function active on error for balloon based catheters	Require Reset Button
E71	Handpiece Communication Loss	Barrx 360 Express RFA Balloon Catheter: E71 - Catheter Communication Error	Yes	Yes
		Press Reset		
E72	IO Expander Readback Error	Barrx 360 Express RFA Balloon Catheter: E72 - Catheter Electronics Fault	Yes	N/A, catheter must be disconnected
		Replace Catheter		and discarded
E73	MOSFET Stuck Error	Barrx 360 Express RFA Balloon Catheter: E73 - Catheter Electronics Fault	Yes	N/A, catheter must be disconnected and discarded
		Replace Catheter		
E81	Low Impedance Error	Barrx 360 RFA Balloon Catheter: E81 - Catheter Too Big Check Sizing Results		No
		Consider Smaller Ablation Catheter	Yes	
		nnn% nnn% nnn% Energy Delivered		
		Barrx 360 Express RFA Balloon Catheter: E81 - Clean Electrode		
		Low Energy Delivered		
		<b>Non Balloon Based Ablation Catheter:</b> E81 - Clean Electrode		
		nn% Energy Delivered		
		n Ablations		



**Table 3.D. Application Operational Codes (Recoverable)** 

Error Code	Description	System Status Messages	Auto deflate function active on error for balloon based catheters	Require Reset Button
E82	High Impedance Error	Barrx 360 RFA Balloon Catheter: E82 - Clean Electrode or Poor Elec Contact		
		nnn% nnn% nnn% Energy Delivered	Yes No	
		Barrx 360 Express RFA Balloon Catheter: E82 - Clean Electrode or Poor Elect Contact		No
		Low Energy Delivered		
		Non Balloon Based Ablation Catheter: E82 - Clean Electrode or Poor Elec Contact		
		nn% Energy Delivered		
		n Ablations		
E83	Voltage Limit Error	Barrx 360 RFA Balloon Catheter: E83 - Clean Electrode or Poor Elec Contact		No
		nnn% nnn% nnn% Energy Delivered		
		Barrx 360 Express RFA Balloon Catheter: E83 - Clean Electrode or Poor Elect Contact	Yes	
		Low Energy Delivered		
		Non Balloon Based Ablation Catheter: E83 - Clean Electrode or Poor Elec Contact		
		nn% Energy Delivered		
		n Ablations		



