Output Characteristics

Mode	Rated Load (Ω)	Rated Output Power (W)	Peak Voltage	Current RMS Max	Crest Factor*	Duty Cycle
Monopolar CUT						
PURE	300	300	910	1.25	1.42	100%
BLEND	300	200	1100	1	2.5	50%
VALLEYLAB	300	200	1549	1	3.8	25%
Monopolar COAG						
FULGURATE	500	120	3135	1	5.7	6.25%
SPRAY	500	120	3575	1	6.5	4.76%
SOFT	100	120	240	1.55	1.42	100%
Bipolar						
LOW (1-15 W)	100	15	88	1	1.42	100%
MEDIUM (16-40 W)	100	40	143	2	1.42	100%
HIGH (45-95 W)	100	95	310	2	1.42	100%
LigaSure™						
LIGASURE	20	350	163	5.5	1.42	N/A
Bipolar Resection						
CUT	500	375	495	2.4	1.42	100%
COAG	100	175	212	3.2	1.42	100%

Output Waveforms

TissueFect[™] Tissue Sensing Technology, an automatic adjustment, controls all modes. As tissue resistance increases from zero, the energy platform outputs constant current followed by constant power followed by constant voltage. The maximum output voltage is controlled to reduce capacitive coupling and video interference and to minimise sparking.

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- 3. Based on Covidien In-vivo GLP Acute report: "Verification Report GLP Acute Animal Lab LigaSure™ Preclinical Evaluation of Valleylab™ FT10." May 19, 2015: RE00005503; Report page 4, Attachment pg. 33-39
- $4. \ Based on product validation testing. Covidien report, "Product Validation of Valleylab" FT10 Surgeon \& Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation in Simulated Use." May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation In Simulated Use. May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation In Simulated Use. May 26, 2015; RE00005401 Rev A; pg. 11 Surgeon & Nurse Evaluation In Simulated Use. May 26, 2015; RE00005401 Rev A; pg. 201$

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VALLEYLAB™ FT10 **ENERGY PLATFORM SPECIFICATION GUIDE**



Valleylab[™] FT10 energy platform -

our next generation advanced energy platform with improved LigaSure[™] vessel sealing technology and expanded electrosurgical features.

Be the first to see how over 2 million devices sold annually will see performance enhancements.



VALLEYLAB™ FT10 ENERGY PLATFORM TECHNICAL SPECIFICATIONS

General

Output configuration	Isolated output
Cooling	Natural convection and fan
Display	7 in. LCD touchscreen
Connector ports	LED illuminated Smart [™] connector readers on the LigaSure [™] /Bipolar receptacle
Enclosure	Magnesium
Mounting	• Valleylab™ Universal Generator Cart (VLFTCRT)
	Operating-room boom systems

• Any stable, flat surface such as a

Dimensions and Weight

Height	6.7 in. (17.0 cm)	
Width	14.5 in. (35.8 cm)	
Length	18.2 in. (46.2 cm)	
Weight	22.3 lb. (10.1 kg)	

table or cart top

Operating Parameters

Ambient temperature range	50 to 104 °F (10 to 40 °C)
Relative humidity	30% to 75% non-condensing
Atmospheric pressure	700 to 1060 millibars

Transport and Storage

Ambient temperature range	14 to 149 °F (-10 to +65 °C)
Relative humidity	25% to 85% non-condensing
Atmospheric pressure	500 to 1060 millibars

Duty Cycle

The Valleylab^{$^{\circ}$} FT10 energy platform is capable of operating a duty cycle of 25%, defined as 10 seconds active and 30 seconds inactive, in any mode for a period of 4 hours.

Internal Memory

Real-time clock	Battery type - Lithium CR1620;	
battery	Battery capacity - 75 mAh	
Storage capacity	4 GB	

Audio Tones

Activation			
Tones	Tone	Duration	Volume
		Entire Activation	
CUT	660 Hz ± 5%	Duration	User adjustable from 45 dBA to 65 dBA (-0/+6 dBA @ 1 m)
		Entire Activation	
COAG	940 Hz ± 5%	Duration	User adjustable from 45 dBA to 65 dBA (-0/+6 dBA @ 1 m)
		Entire Activation	
VALLEYLAB	800 Hz ± 5%	Duration	User adjustable from 45 dBA to 65 dBA (-0/+6 dBA @ 1 m)
		Entire Activation	
BIPOLAR	940 Hz ± 5%	Duration	User adjustable from 45 dBA to 65 dBA (-0/+6 dBA @ 1 m)
	·	Entire Activation	
LIGASURE	440 Hz ± 5%	Duration	User adjustable from 45 dBA to 65 dBA (-0/+6 dBA @ 1 m)

Radio Frequency Identification (RFID)

Frequency Range	13.56 MHz
RF Output Power	68.17 dBuV/m @ 3 meters
Type of Antenna	Integral Loop Antenna
Modulation	Amplitude-shift Keying (ASK)
Mode of Operation (Simplex/Duplex)	Duplex
Contains Transmitter Module FCC ID	2AAVI-JDK1901
Contains IC ID	11355A-JDK1901

Wireless Fidelity (WiFi)

Transmit/Receive Frequency Range	2.4000 ~ 2.4835 GHz (Industrial Scientific Medical Band)
Standards	IEEE 802.11b, 802.11g, 802.11n
RF Output Power	11b: 17 ± 1.5 dBm
	11g: 15 ± 1.5 dBm
	11n: 14 ± 1.5 dBm
Data Rate	11b: 1/2/5.5/11 Mbps
	11g: 6/9/12/24/36/48/54 Mbps
	11n: (20 MHz): MCSO-7 (Up to 72 Mbps)
	11n: (40 MHz): MCSO-7 (Up to 150 Mbps)
Securities	WEP 64/128, WPA, WPA2, and IEEE 802.1x
Type of Antenna	Internal Antenna (1T1R)
Contains Module FCC ID	NDD9578111008
Contains IC ID	4701A-78111306

Leakag

Touch Current

Leakage Currents and Patient Auxiliary Currents (IEC 60601-1:2012)

Earth Leakage Current	< 500 μA NC, < 1000 μA SFC
Patient Auxiliary Current (< 1kHz)	< 10 μA NC, < 50 μA SFC
Patient Auxiliary Current (> 1kHz)	Scaled with frequency per IEC 60601-1:2012, but does not exceed 10mA NC/SFC
Patient Leakage Current	< 10 μA NC, < 50 μA SFC
Total Patient Leakage Current	< 50 μA NC, < 100 μA SFC

 $< 100 \,\mu\text{A}$ NC, $< 500 \,\mu\text{A}$ SFC

NC - Normal Condition

SFC – Single Fault Condition (as defined in IEC 60601-1:2012)

Total Patient Leakage Current – Measurement of patient leakage current with all patient outputs connected together

High Frequency Leakage (IEC 60601-2-2)

Bipolar	< 68.9 mARMS	
Monopolar measured directly at the ESU terminals	< 100 mARMS	
LigaSure [™] /BPR measured directly	< 100 mARMS	

at the ESU terminals

REM Contact Quality Monitoring System

Interrogation frequency	68–75 kHz
Interrogation current	< 100 µA RMS
Interrogation Voltage	< 12 VRMS
Impedance Sense Range	5 Ω to 135 Ω
Impedance Accuracy (RF not activated)	±7Ω
Impedance Accuracy (RF Activated)	Greater of \pm 14 Ω

or 20%

Backup Power

The Valleylab™ FT10 energy platform retains all user programmed features, calibration, and statistical data when switched off and unplugged. The Valleylab™ FT10 energy platform operates within specification when switched over to a supplied-line power by hospital backup systems.

