

AN ENERGY PLATFORM TO MEET THE DEMANDS OF SURGEON AND PATIENT.

Valleylab™ FX8 Energy Platform Specification Guide

Introducing the Valleylab™ FX8 energy platform with expanded electrosurgical capabilities ^{1,†}

ADJUSTS ENERGY OUTPUT

The Valleylab™ FX8 energy platform is powered by tissue-sensing technology that adjusts energy output for precision.²⁻⁵ Now, your electrosurgical handpiece will adapt to tissue variability in real time.

INTUITIVE CONTROL PANEL⁶

- Three-section touch screen with enhanced ease of use
- Simple controls and intuitive information displays
- Easy to understand error alerts



VALLEYLAB™ MODE

is available on the Valleylab™ FX8 energy platform when using a ForceTraverse™ electrosurgical pencil.

[†]As compared to Force FX™ generator

General

Output configuration	Isolated output
Cooling	Natural convection and fan
Display	15.7 cm (6.2 in) LCD touchscreen
Enclosure	Magnesium
Mounting	<ul style="list-style-type: none">Valleylab™ universal generator cart (VLFTCRT)Operating room boom systemsAny stable, flat surface such as a table or cart top

Dimensions and Weight

Height	14.6 cm (5.73 in)
Width	33.5 cm (13.18 in)
Length	43.6 cm (17.15 in)
Weight	8.8 kg (19.5 lb)

Audio Tones

Activation Tones	Tone	Duration	Volume
CUT	660 Hz ± 5%	Entire Activation Duration	User adjustable from 45 dBA to 65 dBA (-0/+6 dBA @ 1 m)
COAG	940 Hz ± 5%	Entire Activation Duration	User adjustable from 45 dBA to 65 dBA (-0/+6 dBA @ 1 m)
VALLEYLAB	800 Hz ± 5%	Entire Activation Duration	User adjustable from 45 dBA to 65 dBA (-0/+6 dBA @ 1 m)
BIPOLAR	940 Hz ± 5%	Entire Activation Duration	User adjustable from 45 dBA to 65 dBA (-0/+6 dBA @ 1 m)
SHARED COAG	988 Hz ± 5%	Entire Activation Duration	User adjustable from 45 dBA to 65 dBA (-0/+6 dBA @ 1 m)

Operating Parameters

Ambient temperature range	10°C to 40°C (50°F to 104°F)
Relative humidity	15% to 85% noncondensing
Atmospheric pressure	700 to 1060 millibars

Transport and Storage

Ambient temperature range	-10°C to 60°C (14°F to 140°F)
Relative humidity	15% to 90% noncondensing
Atmospheric pressure	500 to 1060 millibars

Duty Cycle

The Valleylab™ FX8 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	Can be: Lithium CR1620 or CR1632 Battery capacity — 75 mAh minimum
Storage capacity	8 GB

Input Power

	Nominal Line Voltage	
	100–127 VAC	220–240 VAC
Line Ranges		
Line Voltage Full Regulation Range	90–140 VAC	198–264 VAC
Line Frequency	47–63 Hz	47–63 Hz
Max VA Nominal Line Voltage†	660 VA	660 VA
Max Mains Current†	6.6 ARMS	3.0 ARMS
Max Heat Dissipation	180 W	180 W
Fuses	10 A Fuses (2) – 5 mm x 20 mm 10 A, 250 V fast blow	6.3 A Fuses (2) – 5 mm x 20 mm 6.3 A, 250 V fast blow
Power Cord	3-prong hospital-grade connector	

†Max VA and current are based on nominal line voltages.

Output Characteristics

Mode	Rated Load (Ω)	Rated Output Power (W)	Peak Voltage (V) ^ε	Current Nominal Max (A)	Typical Crest Factor†	Duty Cycle
Monopolar CUT						
PURE	300	300	1287	1.25	1.5	100%
BLEND	300	200	2178	1.0	2.3	50%
Valleylab™ mode						
VALLEYLAB	300	200	2783	1.0	3.1	25%
Monopolar COAG						
SOFT	100	120	264	1.55	1.5	100%
FULGURATE	500	120	3448	1.0	5.3	6.25%
SHARED FULGURATE	500 [§]	120	3448	1.0	5.3	6.25%
SPRAY	500	120	3932	1.0	6.1	4.76%
SHARED SPRAY	500 [§]	120	3932	1.0	6.1	4.76%
Bipolar						
PRECISE (1–70 W)	100	70	284	1.8	1.6	100%
STANDARD (1–70 W)	100	70	415	1.8	1.6	100%
MACRO (1–70 W)	100	70	530	1.8	1.8	100%
LOW (1–15 W)	100	15	133	1.0	1.5	100%
MEDIUM (16–40 W)	100	40	214	2.0	1.6	100%
HIGH (45–95 W)	100	95	462	2.0	1.6	100%

^εPer IEC 60601-2-2: 2009 clause 201.7.9.2.2.101(c)(2), whenever the peak voltage is greater than 1600 V, the calculated variable y is less than the actual crest factor. The peak voltage at rated load can be calculated using the equation:

$$V_{peak}(U_{max}) = \text{TypicalCrestFactor} \sqrt{\text{Power-RatedLoad}}$$

‡At rated load.

§Rated load in SHARED COAG modes is the total energy channel load. For SHARED dual activation using two activating instruments, it is the parallel combination of the two loads. For SHARED single activation using one activating instrument, it is the load connected to the activating electrode only.

Output Waveforms

TissueFect™ tissue-sensing technology, an automatic adjustment, controls all modes and effects. 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 minimize sparking.

Bipolar FT Mode

LOW	434 kHz \pm 10% continuous sinusoid
MEDIUM	434 kHz \pm 10% continuous sinusoid
HIGH	434 kHz \pm 10% continuous sinusoid
FX PRECISE	434kHz \pm 10% continuous sinusoid
FX STANDARD	434kHz \pm 10% continuous sinusoid
FX MACRO	434kHz \pm 10% continuous sinusoid

Monopolar CUT

CUT	434 kHz \pm 10% continuous sinusoid
BLEND	434 kHz \pm 10% bursts of sinusoid, recurring at 27.7 kHz \pm 10% intervals 50% duty cycle

VALLEYLAB™ mode

VALLEYLAB	434 kHz \pm 10% bursts of sinusoid, recurring at 27.7 kHz \pm 10% intervals 25% duty cycle
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Monopolar COAG

SOFT	434 kHz \pm 10% continuous sinusoid
FULGURATE	434 kHz \pm 10% damped sinusoidal bursts with a repetition frequency of 27.7 kHz \pm 10% 6.25% duty cycle
SHARED FULGURATE	434 kHz \pm 10% damped sinusoidal bursts with a repetition frequency of 27.7 kHz \pm 10% 6.25% duty cycle
SPRAY	434 kHz \pm 10% damped sinusoidal bursts with a repetition frequency of 21.1 kHz \pm 10% 4.76% duty cycle
SHARED SPRAY	434 kHz \pm 10% damped sinusoidal bursts with a repetition frequency of 21.1 kHz \pm 10% 4.76% duty cycle

Leakage

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

Touch Current	< 100 μ A NC, < 500 μ A SFC
Earth Leakage Current	< 500 μ A NC, < 1000 μ A SFC
Patient Auxiliary Current (< 1kHz)	< 10 μ A NC, < 50 μ A SFC
Patient Auxiliary Current (> 1kHz)	Scaled with frequency per IEC 60601-1:2012, but does not exceed 10 mA NC/SFC
Patient Leakage Current	< 10 μ A NC, < 50 μ A SFC
Total Patient Leakage Current	< 50 μ A NC, < 100 μ 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 (short leads)	< 68.9 mARMS
Monopolar measured directly at the ESU terminals	< 100 mARMS

REM Contact Quality Monitoring System

Interrogation Frequency	64–76 kHz
Interrogation Current	< 100 μ A RMS
Impedance Sense Range	5 Ω to 135 Ω
Impedance Accuracy (RF Not Activated)	\pm 7 Ω
Impedance Accuracy (RF Activated)	Greater of \pm 14 Ω or 20%

Backup Power

The Valleylab™ FX8 energy platform retains all user programmed features, calibration, and statistical data when switched off and unplugged. It also operates within specification when switched over to a supplied-line power by hospital backup systems.

Standards and IEC Classifications

The VLFX8GEN meets all pertinent clauses of the IEC 60601-1 editions 2.0 and 3.1, IEC 60601-2-2 editions 4.0 and 5.0, IEC 60601-1-2 editions 2.1 and 3.0 and 4.0, and IEC 60601-1-8 edition 2.1.

Class I Equipment (IEC 60601-1)

Accessible conductive parts cannot become live in the event of a basic insulation failure because of the way in which they are connected to the protective earth conductor.

Type CF Equipment/Defibrillator Proof (IEC 60601-1, IEC 60601-2-2, and ANSI/AAMI HF18)

The VLFX8GEN provides a high degree of protection against electric shock, particularly regarding allowable leakage currents. It is type CF isolated (floating) output and may be used for procedures involving the heart.



IP21 Liquid Ingress/Spillage (IEC 60601-1 and IEC 60601-2-2)

The VLFX8GEN is constructed so that liquid spillage in normal use does not wet electrical insulation or other components, which when wetted, are likely to adversely affect the safety of the equipment.

Voltage Transients – Energy Platform Mains Transfer (IEC 60601-1, IEC 60601-2-2, and ANSI/AAMI HF18)

The VLFX8GEN continues to operate normally with no errors or system failures when transfer is made between line AC and an emergency system-voltage source. The system may momentarily shut down in a safe mode depending on the switchover time.

CISPR 11 Class A

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment may not offer adequate protection to radio-frequency communication services. The user may need to take mitigation measures, such as relocating or reorienting the equipment.

Electromagnetic Compatibility (IEC 60601-1-2 and IEC 60601-2-2)

The VLFX8GEN complies with the appropriate IEC 60601-1-2 and 60601-2-2 specifications regarding electromagnetic compatibility.

Ordering Information

VLFX8GEN Valleylab™ FX8 Energy Platform
1 per package



References:

1. Based on the Valleylab™ FX8 Service guide: part number PT00046835_A, 2017.
2. Based on internal report #RE00058769 Rev A, Evaluation of the Valleylab™ FX8 energy platform: verification of monopolar power control. June 2017.
3. Based on Verification Report #RE00058773 Rev A, Bipolar Power Control Evaluation of the Valleylab™ FX8 Generator May 2017.
4. Based on internal report #RE00058763 Rev A, Verification of monopolar thermal effect for Valleylab™ FX8 generator. June 2017.
5. Based on the RE00058765 Bipolar Thermal Effect for Valleylab™ FX8 Generator.
6. Based on internal report # RE00077924, Marketing evaluation of the Valleylab™ FX8 energy platform: nurse and surgeon report. June 2017.

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303.530.6100
800.255.8522

medtronic.com/valleylabfx8

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