

VšĮ Klaipėdos jūrininkų ligoninei
(Adresatas (perkančioji organizacija))

**PASIŪLYMAS
DĖL MEDICINOS ĮRANGOS PIRKIMO**

2021-04-29 Nr. _____

(Data)

Kaunas

(Sudarymo vieta)

Tiekėjo pavadinimas /Jeigu dalyvauja ūkio subjektų grupė, surašomi visi dalyvių pavadinimai/	UAB „Sorimpeksas“
Tiekėjo adresas /Jeigu dalyvauja ūkio subjektų grupė, surašomi visi dalyvių adresai/	Šiaulių 16 A., Kaunas
Už pasiūlymą atsakingo asmens vardas, pavardė	Daiva Macijauskienė
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El. pašto adresas	daiva@sorimpeksas.com
Tiekėjo (įmonės) kodas	135733248

Vykdam sutartį pasitelksiu šiuos subteikėjus (subteikėjus):

Pastaba. Pildoma, jei tiekėjas ketina pasitelkti subrangovą (-us), subteikėją (-us); ar subteikėją (-us)/

Subteikėjo (-ų) pavadinimas (-ai)	
Subteikėjo (-ų) adresas (-ai)	
Įsipareigojimų dalis (procentais), kuriai ketinama pasitelkti subteikėją (-us)	
Sutarties objekto dalis (-ys), kuriai(-oms) ketinama pasitelkti subteikėją (-us)	

- Šiuo pasiūlymu pažymime, kad sutinkame su visomis pirkimo sąlygomis, nustatytomis:
 - atviro (supaprastinto) konkurso skelbime, paskelbtame Viešųjų pirkimų įstatymo nustatyta tvarka, CVP;
 - atviro(supaprastinto) konkurso sąlygose;
 - kituose pirkimo dokumentuose (jų paaiškinimuose, papildymuose).

2. Mes siūlome šią įrangą ir pateikiame užpildytą pirkimo dokumentų 2 priedo Techninės specifikacijos lentelę. Siūloma įranga visiškai atitinka nurodytus reikalavimus ir jos savybės nurodytos pateikiamoje užpildytoje pirkimo dokumentų 2 priedo techninės specifikacijos lentelėje.

2 pirkimo dalis. Elektrokoagulatorius, 2 kompl.

					Pasiūlymo valiuta: (Eur)	
Eil. Nr.	Prekių pavadinimas (įvardinant tikslų prekių gamintojų ir prekių modelių pavadinimus)	Kiekis	Mato vnt.	Vnt. kaina (be PVM)	Bendra kaina (be PVM)	
1	2	3	4	5	6	
1.	Elektrokoagulatorius Medtronic-Covidien, Valleylab FT10	2	Kompl.	11750,00	23500.00	
				PVM (21 %) suma:	4935.00	
				Bendra pasiūlymo kaina (su PVM)	28435.00	

Bendra pasiūlymo dalies kaina be PVM –	Kaina žodžiais: Dvidešimt trys tūkstančiai penki šimtai eurų 00 ct
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Bendra pasiūlymo dalies kaina su PVM –	Kaina žodžiais: Dvidešimt aštuoni tūkstančiai keturi šimtai trisdešimt penki eurai 00 ct
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Jei suma skaičiais neatitinka sumos žodžiais, teisinga laikoma suma žodžiais.

Į šią kainą įeina visos išlaidos ir visi mokesčiai.

Pastabos:

1) kainos pasiūlyme nurodomos suapvalintos, paliekant du skaitmenis po kablelio;

2) * tiekėjas nurodo PVM dydį procentais. Tais atvejais, kai pagal galiojančius teisės aktus Tiekėjui nereikia mokėti PVM, Tiekėjas atitinkamų skilčių nepildo ir nurodo priežastis, dėl kurių PVM nemoka.

3)** Būtina nurodyti siūlomos įrangos gamintoją ir modelį.

3. Perkančioji organizacija laimėjusio dalyvio pasiūlymą, sudarytą pirkimo sutartį, preliminarią sutartį ir šių sutarčių pakeitimus, išskyrus informaciją, kurios atskleidimas prieštarautų informacijos ir duomenų apsaugą reguliuojantiems teisės aktams arba visuomenės interesams, pažeistų teisėtus konkretaus tiekėjo komercinius interesus arba turėtų neigiamą poveikį tiekėjų konkurencijai, ne vėliau kaip per 15 dienų nuo pirkimo sutarties ar preliminarosios sutarties sudarymo ar jų pakeitimo, bet ne vėliau kaip iki pirmojo mokėjimo pagal ją pradžios Viešųjų pirkimų tarnybos nustatyta tvarka turi paskelbti Centrinėje viešųjų pirkimų informacinėje sistemoje.

Tiekėjai pasiūlyme turi nurodyti, kokia pasiūlyme pateikta informacija yra konfidenciali.

Šiame pasiūlyme pateikta ir **konfidenciali informacija*** (Pildyti tuomet, jei bus pateikiama konfidenciali informacija):

Eil. Nr.	Pateikto dokumento pavadinimas	Dokumentas yra įkeltas pasiūlymo lango eilutėje „Prisegti dokumentai“
1.	Konfidencialu. RC pažyma	Dokumentas yra įkeltas pasiūlymo lango eilutėje „Prisegti dokumentai“

*Konfidencialia informacija gali būti, įskaitant, bet ja neapsiribojant, komercinė (gamybinė) paslaptis ir konfidencialieji pasiūlymų aspektai. Konfidencialia negalima laikyti informacijos nurodytos VPĮ 20 str. 2 d. Tiekėjas neturi teisės nurodyti, kad visa pasiūlyme pateikta informacija yra konfidenciali. Tiekėjas turi aiškiai nurodyti, kokie su pasiūlymu pateikti dokumentai laikytini konfidencialiais. **Jeigu tiekėjas nenurodo konfidencialios informacijos, laikoma, kad tokios tiekėjo pasiūlyme nėra.**

4. Kartu su pasiūlymu pateikiami šie dokumentai (pasirašydamas pasiūlymą elektroniniu parašu patvirtinu, kad dokumentų skaitmeninės kopijos yra tikros):

Eil. Nr.	Pateiktų dokumentų pavadinimas	Dokumento puslapių skaičius
1.	Direktorius įgaliojimas	1
2.	EBVPD pažyma	13
3.	1 Brošiūra	4
4.	1.3, 2.3 pirkimo dalis	76
5.	2 Brošiūra	174
6.	5.1, 5.6 pirkimo dalis	1
7.	5.2 pirkimo dalis	1
8.	5.3 pirkimo dalis	2
9.	8.2 pirkimo dalis	62

10.	8.3 pirkimo dalis	2
11.	Gamintojų įgaliojimai	7
12.	CE sertifikatai	31
13.	Konfidencialu. RC pažyma	2

Pasiūlymas galioja laikotarpį, nurodytą pirkimo dokumentuose.

Viešųjų pirkimų vadybininkė
(Tiekėjo arba jo įgalioto asmens
pareigų pavadinimas)

(Parašas)

Daiva Macijauskienė
(Vardas ir pavardė*)

TECHNINĖ SPECIFIKACIJA

Užpildyta techninės specifikacijos lentelė pateikiama kartu su užpildyta Pasiūlymo forma.

Kartu su įranga pateikiama dokumentacija: naudojimo instrukcijos lietuvių kalba. Pristatant prekes turi būti pateikti CE sertifikatai. Įranga turi būti pristatyta, instaliuota/įdiegta, paleista, apmokytas personalas.

2 pirkimo dalis. Elektrokoagulatorius (2 kompl.)

Eil. Nr.	Parametrai	Reikalaujamos parametrų reikšmės	Tiekėjo siūlomos įrangos parametrai ir jų reikšmės pagal 2 ir 3 stulpelių reikalavimus bei tai patvirtinančio dokumento pavadinimas, psl. Nr., kuriame aprašytas nurodytas parametras
	Elektrokoagulatorius	Medtronic-Covidien, Valleylab FT10	
1.	Monopolinis pjovimas	Monopolinis pjovimas	
1.1	Monopolinio pjovimo režimai:	Monopolinio pjovimo režimai:	
1.1.1	„Pure“ – grynasis pjovimas be koaguliacijos efekto, (ne mažiau 100%)	Būtina	„Pure“ – grynasis pjovimas be koaguliacijos efekto, (100%) <i>1 Brošiūra 4 psl.</i>
1.1.2	„Blend“ – mišrus pjovimas su koaguliacijos efektu (ne mažiau 50%)	Būtina	„Blend“ – mišrus pjovimas su koaguliacijos efektu (50%) <i>1 Brošiūra 4 psl.</i>
1.1.3	Pjovimas su stipriu koaguliacijos efektu (ne mažiau 25%).	Būtina	Pjovimas su stipriu koaguliacijos efektu (25%) <i>1 Brošiūra 4 psl.</i>
1.2.	Maksimalus galingumas/ varža		
1.2.1	„Pure“	Galia ne mažiau 300 W, 300 Ω	„Pure“ : Galia 300 W, 300 Ω <i>1 Brošiūra 4 psl.</i>
1.2.2	„Blend“	Galia ne mažiau 200 W, 300 Ω	„Blend“ Galia 200 W, 300 Ω <i>1 Brošiūra 4 psl.</i>
1.2.3	Pjovimas su stipriu koaguliacijos efektu	Galia ne mažiau 200 W, 300 Ω	Pjovimas su stipriu koaguliacijos efektu: Galia 200 W, 300 Ω <i>1 Brošiūra 4 psl.</i>
1.3	Pjovimo režimų aktyvavimas	Elektrinio peilio rankenėle arba kojine pamina	Pjovimo režimų aktyvavimas: Elektrinio peilio rankenėle arba kojine pamina <i>1.3, 2.3 pirkimo dalis 5 psl.</i>
1.4	Galingumo kontrolė	Dinaminė galios kontrolė, atsižvelgiant į audinių varžą	Galingumo kontrolė: Dinaminė galios kontrolė, atsižvelgiant į audinių varžą <i>1 Brošiūra 4 psl.</i>
2.	Monopolinis koaguliavimas		
2.1	Monopolinio koaguliavimo režimai:		Monopolinio koaguliavimo režimai:

2.1.1	Fulg“ –nekontaktinė , aukštos įtampos koaguliacija	Būtina	Fulg“ –nekontaktinė , aukštos įtampos koaguliacija <i>1 Brošiūra 4 psl.</i>
2.1.2	„Spray“–nekontaktinė , aukštos įtampos koaguliacija	Būtina	„Spray“–nekontaktinė , aukštos įtampos koaguliacija <i>1 Brošiūra 4 psl.</i>
2.1.3	„Soft“– delikati, gilesnės skvarbos koaguliacija	Būtina	„Soft“– delikati, gilesnės skvarbos koaguliacija <i>1 Brošiūra 4 psl.</i>
2.2	Maksimalus galingumas/ varža		Maksimalus galingumas/ varža
2.2.1	„Fulg“	Galia ne mažiau 120 W, 500 Ω	„Fulg“ : Galia 120 W, 500 Ω <i>1 Brošiūra 4 psl.</i>
2.2.2	„Spray“	Galia ne mažiau 120 W, 500 Ω	„Spray“: Galia 120 W, 500 Ω <i>1 Brošiūra 4 psl.</i>
2.2.3	„Soft“	Galia ne mažiau 120 W, 100 Ω	„Soft“: Galia 120 W, 100 Ω <i>1 Brošiūra 4 psl.</i>
2.3	Koaguliacijos režimų aktyvavimas	Elektrinio peilio rankenėle arba kojine pamina	Koaguliacijos režimų aktyvavimas: Elektrinio peilio rankenėle arba kojine pamina <i>1.3, 2.3 pirkimo dalis 5 psl.</i>
2.4	Galingumo kontrolė	Dinaminė galios kontrolė, atsižvelgiant į audinių varžą	Galingumo kontrolė: Dinaminė galios kontrolė, atsižvelgiant į audinių varžą <i>1 Brošiūra 4 psl.</i>
3.	Bipolinė rezekcija		
3.1	Bipolinės rezekcijos režimai	Būtina	Bipolinės rezekcijos režimai <i>1 Brošiūra 4 psl.</i>
3.1.1	Pjovimo režimas „Cut“	Būtina	Pjovimo režimas „Cut“ <i>1 Brošiūra 4 psl.</i>
3.1.2	Koaguliacijos režimas „Coag“	Būtina	Koaguliacijos režimas „Coag“ <i>1 Brošiūra 4 psl.</i>
3.2	Maksimalus galingumas/ varža		
3.2.1	„Cut“	Galia ne mažiau 200 W, 500 Ω	„Cut“: Galia 200 W, 500 Ω <i>1 Brošiūra 4 psl.</i>
3.2.2	„Coag“	Galia ne mažiau 175 W, 100 Ω	„Coag“: Galia 175 W, 100 Ω <i>1 Brošiūra 4 psl.</i>
3.3	Galingumo kontrolė	Dinaminė galios kontrolė, atsižvelgiant į audinių varžą	Galingumo kontrolė: Dinaminė galios kontrolė, atsižvelgiant į audinių varžą <i>1 Brošiūra 4 psl.</i>
4.	Bipolinis režimas		
4.1	Bipoliniai režimai:		
4.1.1	„Low“	Būtina	„Low“ <i>1 Brošiūra 4 psl.</i>

4.1.2	„Medium“	Būtina	„Medium“ <i>1 Brošiūra 4 psl.</i>
4.1.3	„High“	Būtina	„High“ <i>1 Brošiūra 4 psl.</i>
4.2.	Maksimalus galingumas/varža		
4.2.1	„Low“	Galia 1-15 W, 100 Ω	„Low“: Galia 1-15 W, 100 Ω <i>1 Brošiūra 4 psl.</i>
4.2.2	„Medium“	Galia 16-40 W, 100 Ω	„Medium“: Galia 16-40 W, 100 Ω <i>1 Brošiūra 4 psl.</i>
4.2.3	„High“	Galia 45-95 W, 100 Ω	„High“: Galia 45-95 W, 100 Ω <i>1 Brošiūra 4 psl.</i>
4.4.	Galingumo kontrolė		
4.4.1	„Low“, „Medium“, „High“	Dinaminė galios kontrolė, atsižvelgiant į audinių varžą	„Low“, „Medium“, „High“: Dinaminė galios kontrolė, atsižvelgiant į audinių varžą <i>1 Brošiūra 4 psl.</i>
4.5	Bipolinio režimo aktyvavimas	Automatinis arba kojine pamina	Bipolinio režimo aktyvavimas: Automatinis arba kojine pamina <i>2 Brošiūra 79 psl., 150 psl.</i>
5.	Bipolinis audinių sulydymas		
5.1	Automatinis bipolinis audinių sulydymas	Arterijoms, venoms, limfagyslėms ar audiniams ≤ 7 mm diametro	Automatinis bipolinis audinių sulydymas: Arterijoms, venoms, limfagyslėms ar audiniams ≤ 7 mm diametro <i>5.1, 5.6 pirkimo dalis</i>
5.2	Automatinė galios ir slėgio kontrolė sulydymo metu	Būtina	Automatinė galios ir slėgio kontrolė sulydymo metu <i>5.2 pirkimo dalis</i>
5.3	Galimybė prijungti sulydymo rankenas tiek atvirajai, tiek ir laparoskopinei chirurgijai	Būtina	Galimybė prijungti sulydymo rankenas tiek atvirajai, tiek ir laparoskopinei chirurgijai <i>5.3 pirkimo dalis, 1-2 psl.</i>
5.4	Maksimalus galingumas/varža	Galia ne mažiau 350 W, 20 Ω	Maksimalus galingumas/varža: Galia 350 W, 20 Ω
5.5	Audinių sulydymo trukmė	1-4 s	Audinių sulydymo trukmė: 1-4 s <i>1 Brošiūra 1 psl.</i>
5.6	Sulydymo režimo aktyvinimas	Sulydymas rankena arba kojine pamina	Sulydymo režimo aktyvinimas: Sulydymas rankena arba kojine pamina <i>5.1, 5.6 pirkimo dalis</i>
5.7	Galingumo kontrolė	Automatinė galios kontrolė, atsižvelgiant į audinių varžą	Galingumo kontrolė: Automatinė galios kontrolė, atsižvelgiant į audinių varžą <i>1 Brošiūra 4 psl.</i>
6.	Neutralaus elektrodo monitoringo sistema		

	arba paciento kontrolės sistema arba lygiavertė		
6.1	Neutralaus elektrodo kontakto su audinio paviršiumi stebėjimo sistema	Būtina	Neutralaus elektrodo kontakto su audinio paviršiumi stebėjimo sistema <i>1 Brošiūra 3 psl.</i>
6.2	Neutralaus elektrodo monitoringo sistemos dažnis	64-76 kHz	Neutralaus elektrodo monitoringo sistemos dažnis: 64-76 kHz <i>1 Brošiūra 3 psl.</i>
6.3	Audinio paviršiaus stebimos varžos intervalas	Nuo 0 iki 150 Ω	Audinio paviršiaus stebimos varžos intervalas: Nuo 0 iki 150 Ω <i>1 Brošiūra 3 psl.</i>
6.4	Neutralaus elektrodo monitoringo sistemos srovės stipris	< 100 μA RMS	Neutralaus elektrodo monitoringo sistemos srovės stipris: < 100 μA RMS <i>1 Brošiūra 3 psl.</i>
7.	Papildomos prietaiso savybės		
7.1	Išėjimai	Monopoliniai ne mažiau - 2 Bipolinis ne mažiau - 1 Bipoliniai audinių sulydymui ne mažiau - 1 Neutralaus elektrodo - 1	Išėjimai: Monopoliniai - 2 Bipolinis - 1 Bipoliniai audinių sulydymui - 1 Neutralaus elektrodo - 1 <i>1 Brošiūra 1 psl.</i>
7.2	Automatinis instrumentų atpažinimas ir automatinis nominalios galios parinkimas	Būtina	Automatinis instrumentų atpažinimas ir automatinis nominalios galios parinkimas <i>1 Brošiūra 1 psl.</i>
7.3	Įdiegta technologija ypač dideliu dažniu matuojanti audinių varžos pakitimus, tam kad išlaikyti optimalius el. srovės parametrus. Matavimų dažnis 430000 kartų per sekundę	Būtina	Įdiegta technologija ypač dideliu dažniu matuojanti audinių varžos pakitimus, tam kad išlaikyti optimalius el. srovės parametrus. Matavimų dažnis 430000 kartų per sekundę <i>1 Brošiūra 1 psl.</i>
7.4	Ekranas	Ne mažiau 7inc LCD liečiamas ekranas	Ekranas: 7inc LCD liečiamas ekranas <i>1 Brošiūra 2 psl.</i>
7.5	Išmatavimai	180x360x460 mm (±5 mm)	Išmatavimai: 178x358x462 mm (±5 mm) <i>1 Brošiūra 2 psl.</i>
7.6	Svoris	Ne daugiau 10,1 kg	Svoris: 10,1 kg <i>1 Brošiūra 2 psl.</i>
8.	Komplektacija		Komplektacija:
8.1.	Elektrochirurginis generatorius	1 vnt.	Elektrochirurginis generatorius 1 vnt
8.2	Neutralaus elektrodo kabelis, suderinamas su siūlomu generatoriumi.	1 vnt.	Neutralaus elektrodo kabelis, suderinamas su siūlomu generatoriumi. Skirtas naudoti

	Skirtas naudoti su vienkartiniais, skeltais elektrodais.		su vienkartiniais, skeltais elektrodais 1 vnt <i>8.2 pirkimo dalis 55 psl.</i>
8.3	Neutralūs skelti elektrodai	50 vnt.	Neutralūs skelti elektrodai 50 vnt <i>8.3 pirkimo dalis 1-2 psl.</i>
9.	Garantija	Ne mažiau 24 mėnesiai.	Suteikiama garantija 24 mėnesiai

THE NEXT GENERATION ENERGY PLATFORM IS HERE.

Valleylab™ FT10 Energy Platform Specification Guide

For Software Version 1.1.3

The Valleylab™ FT10 energy platform is here with:

- Improved LigaSure™ vessel-sealing technology.¹
- Expanded electrosurgical features.²

5.5 pirkimo dalis

FAST SEALING

Seals vessels in one to four seconds¹

Audinių sulydymo trukmė 1-4s

7.3 pirkimo dalis

TISSUEFACT™ TECHNOLOGY

Consistently responds to changes in tissue — at a speed of 434,000 times per second — as the device seals^{1,3}

Įdiegta technologija ypač dideliu dažniu matuojanti audinių varžos pakitimus, tam kad išlaikyti optimalius el. srovės parametrus. Matavimų dažnis 430000 kartų per sekunde.

TOUCH-SCREEN CONTROL PANEL

- Four-quadrant touch screen with enhanced ease of use^{1,4}
- Quick settings
- Easy to understand error alerts⁵

LIGASURE™ TECHNOLOGY

Improved and enhanced LigaSure™ vessel-sealing performance:

- Faster vessel sealing than ForceTriad™ energy platform⁴
- Minimizes lateral thermal spread to surrounding tissue⁵

7.1 pirkimo dalis

Monopoliniai - 2
Bipolinis - 1
Bipoliniai audinių sulydymui - 1
Neutralaus elektrodo - 1

SMART CONNECTORS

Recognizes the type of instrument used and automatically configures energy output for consistent results

7.2 pirkimo dalis

Automatinis instrumentų atpažinimas ir automatinis nominalios galios parinkimas



Medtronic
Further, Together

VALLEYLAB™ FT10 ENERGY PLATFORM TECHNICAL SPECIFICATIONS²

General

Output configuration	Isolated output
Cooling	Natural convection and fan
Display	7 in. LCD touchscreen
Connector ports	LED illuminated connector reader on the LigaSure™/Bipolar receptacle
Enclosure	Magnesium
Mounting	<ul style="list-style-type: none">Valleylab™ universal generator cart (VLFTCRT)OR boom systemsAny stable, flat surface such as a table or cart top

Dimensions and Weight

Height	7.0 in. (17.8 cm)
Width	14.5 in. (35.8 cm)
Length	18.2 in. (46.2 cm)
Weight	22.3 lb. (10.1 kg)

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)
LIGASURE	440 Hz ± 5%	Entire Activation Duration	User adjustable from 45 dBA to 65 dBA (-0/+6 dBA @ 1 m)

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 140 F (-10 to +60 C)
Relative humidity	25% to 85% non-condensing
Atmospheric pressure	500 to 1060 millibars

Duty Cycle

The Valleylab™ 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	Battery type - Lithium CR1620 or CR1632; Battery capacity - 75 mAh
Storage capacity	8 GB



Radio Frequency Identification (RFID)²

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)²

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	WPA2
Type of Antenna	Internal Antenna (1T1R)
Contains Module FCC ID	NDD9578111008
Contains IC ID	4701A-78111306

Leakage²

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

Touch Current	< 100 µA NC, < 500 µA SFC
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

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 at the ESU terminals	< 100 mARMS

REM Contact Quality Monitoring System²

Interrogation frequency	64-76 kHz
Interrogation current	< 100 µA
Impedance Sense Range	0 Ω to 150 Ω
Impedance Accuracy (RF not activated)	± 7 Ω
Impedance Accuracy (RF Activated)	Greater of ± 14 Ω or 20%

Backup Power²

The Valleylab™ FT10 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.

Output Waveforms²

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 minimize sparking.

Output Characteristics²

Mode	Rated Load (Ω)	Rated Output Power (W)	Peak Voltage	Current RMS Max	Typical Crest Factor*	Duty Cycle
Monopolar CUT						
PURE	300	300	1287	1.25	1.6	100%
BLEND	300	200	2178	1	2.2	50%
VALLEYLAB	300	200	2783	1	3.2	25%
Monopolar COAG						
FULGURATE	500	120	3448	2.1.1 pirkimo dalis	5.4	6.25%
SPRAY	500	120	3932	2.1.2 pirkimo dalis	6.2	4.76%
SOFT	100	120	264	2.1.3 pirkimo dalis	1.5	100%
Bipolar						
LOW (1-15 W) in that row	100	15	133	1	1.8	100%
MEDIUM (16-40 W)	100	40	214	2	1.8	100%
HIGH (45-95 W)	100	95	462	2	1.7	100%
LigaSure™ Technology						
LIGASURE	20	350	244	5.5	1.9	N/A
Bipolar Resection						
CUT	500	200**	742	2.4	1.4	100%
COAG	100	175	318	3.2	1.6	100%

*At rated load

**Bipolar Resection CUT maximum power is 432W

ORDERING INFORMATION

VLFT10GEN Valleylab™ FT10 Energy Platform
1 per package



1. Based on internal test report #RE00025819 Rev A, LigaSure™ data sources for VLFT10 white papers, September 2015.
2. Based on the Valleylab™ FT10 energy platform users guide: part number 1073652, REV 12/2014 and ForceTriad™ energy platform user's manual: part number 1004175 (soft coag mode not included in ForceTriad™ energy platform)
3. Valleylab™ FT10 energy platform [package insert]. Minneapolis, MN: Medtronic, 2015.
4. Based on Covidien product validation report: "Product Validation of Valleylab™ FT10 Surgeon & Nurse Evaluation in Simulated Use" January - February, 2015; RE00005401
5. Based on internal test report #RE00016807, Product introduction Valleylab™ FT10 energy platform. April 2016.
6. Based on internal test report #RE00005503, Verification – report – GLP acute animal lab – LigaSure™ preclinical evaluation of Valleylab™ FT10. May 19, 2015.

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User's Guide

Valleylab™ FT10

FT Series Energy Platform

For use with software version 1.1x

Part Number: PT00016328

Preface

This guide and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the Covidien Valleylab FT10 FT Series Energy Platform only. Additional technical information, such as circuit diagrams, component part lists, descriptions, calibration instructions, component-replacement instructions, and software-update instructions, is available in the *Valleylab FT10 FT Series Energy Platform Service Manual*.

The latest version of the FT10 service manual is available at www.BioMedConnect.com. Call these numbers to request a hardcopy of the service manual

- USA and Canada: 1-800-255-8522 Option 2
- International: 1-303-476-7996

Equipment covered in this manual

Valleylab FT10 FT Series Energy Platform (VLFT10GEN) with software version 1.1x

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Valleylab™ FT10 FT Series Energy Platform One year from date of shipping

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Chapter 1

Overview and General Features

This chapter provides an overview of the features and functions of the Valleylab FT10 FT Series Energy Platform.

Precaution

Read the instructions, warnings, and precautions provided with this energy platform and associated accessories before using. Specific instructions for electro-surgical instruments are not included in this manual.

The Valleylab FT10 Energy Platform

Introduction

The Valleylab FT10 FT Series Energy Platform (VLFT10GEN) provides RF energy for monopolar and bipolar surgical applications, and tissue-fusion and vessel-sealing applications. It features a touchscreen divided into four sections for viewing and user input of settings and options available for any application. The energy platform automatically detects coded handsets and configures the energy platform accordingly. Safety and diagnostic functionality include automatic fail-safe functions.

The VLFT10GEN, applied parts (patient return electrodes and active instruments) are designed to work as a system. Covidien offers a selection of patient return electrodes and active instruments that are fully compatible with this energy platform.

- Refer to each instrument's instructions for use (IFU) for indications, warnings, and specific contraindications.
- When considering other manufacturers' patient return electrodes and/or active instruments, customers should seek detailed user instructions and warning information from the manufacturer.

The generator is intended for use in general surgery and such surgical specialties as urologic, vascular, thoracic, plastic, gynecologic, reconstructive, and colorectal surgery.

Indications for Use

The Valleylab FT10 is a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue. When used with compatible sealing devices, it is indicated for sealing vessels up to and including 7 mm, tissue bundles, and lymphatics.

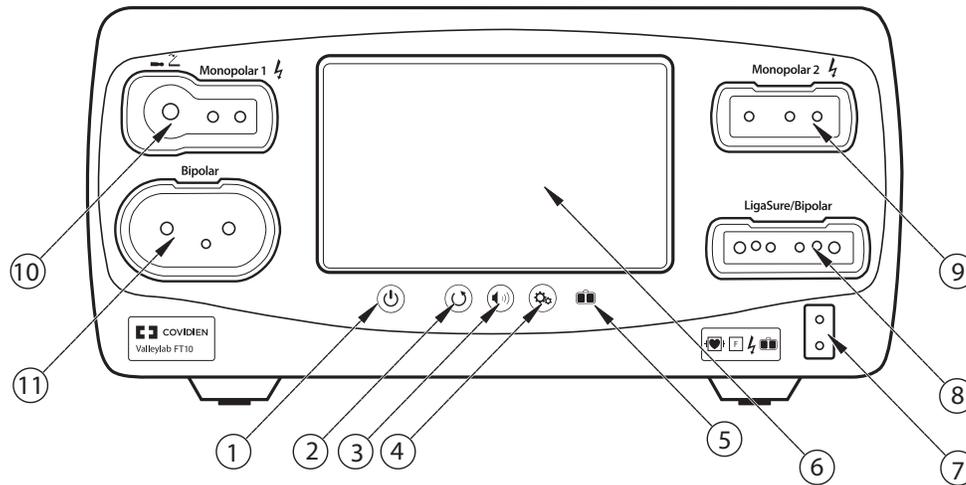
The generator can also be used with compatible resectoscopes for endoscopically controlled removal or coagulation of tissue using 0.9% NaCl solution as the irrigation medium.

The tissue fusion function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

Contraindications

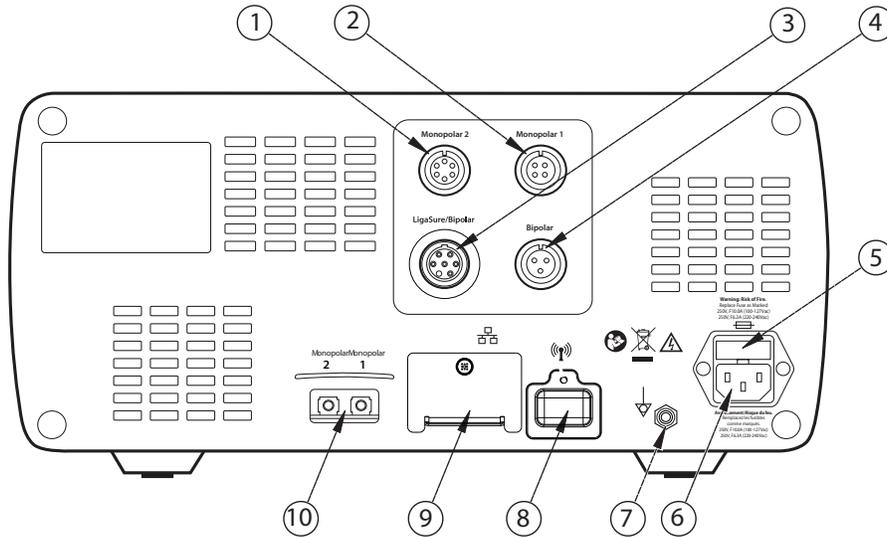
None known.

Front Panel



- ① On/Off button
- ② Restore Settings button
- ③ Audio Volume control button
- ④ Service/Settings button
- ⑤ REM (Return Electrode Monitoring) indicator
- ⑥ Interface touchscreen
- ⑦ REM patient return electrode receptacle
- ⑧ LigaSure™/Bipolar receptacle
- ⑨ Monopolar 2 instrument receptacle
- ⑩ Monopolar 1 Universal Foot Pedal Port (UFP) receptacle
- ⑪ Bipolar instrument receptacle

Rear Panel



- ① Monopolar 2 foot-pedal receptacle (requires included adapter to connect standard four-pin monopolar foot pedal)
- ② Monopolar 1 foot-pedal receptacle
- ③ LigaSure/Bipolar foot-pedal receptacle (requires included adapter to connect Bipolar Resection foot pedal)
- ④ Bipolar foot-pedal receptacle
- ⑤ Fuse drawer
- ⑥ Power cord receptacle
- ⑦ Equipotential grounding lug
- ⑧ WiFi antenna (Covered. For service only.)
- ⑨ Ethernet receptacle (Covered. For service only.)
- ⑩ Interlink cable receptacles for EKG blanking and smoke-evacuation control

Modes & Settings

The VLFT10GEN provides the following modes and settings for a variety of surgical procedures:

Monopolar modes	Power-Setting Ranges	Peak Voltage
• CUT		
- PURE	Off, 1–300 W	1287 V
- BLEND	Off, 1–200 W	2178 V
• VALLEYLAB	5–85 W	2783 V
• COAG		
- SOFT	Off, 1–120 W	264 V
- FULGURATE	Off, 1–120 W	3449 V
- SPRAY	Off, 1–120 W	3933 V
Bipolar effects		
• LOW	Off, 1–15 W	133 V
• MEDIUM	16–40 W	214 V
• HIGH	45–95 W	462 V
LigaSure (tissue fusion)	No power settings	244 V
Bipolar Resection effect		
• CUT	1–6	742 V
• COAG	1–6	318 V

Monopolar Modes

The system produces six modes of monopolar power output.

Precaution

To provide expected functionality from a hand piece, proper insertion is required. Refer to the alignment dots below the receptacles for proper insertion orientation.

CUT Modes

1.1.1 pirkimo dalis

PURE CUT provides a clean, precise cut in any tissue with little or no hemostasis.

Pure“ - grynasis pjovimas be koaguliacijos efekto.

1.1.2 pirkimo dalis

BLEND CUT is a conventional blended waveform that provides slower cutting with simultaneous hemostasis.

„Blend“ - mišrus pjovimas su koaguliacijos efektu

VALLEYLAB Mode

1.1.3 pirkimo dalis

VALLEYLAB mode is a unique combination of hemostasis and dissection that allows the user to slow down for more hemostasis and speed up for faster dissection. Thermal spread is equal to or less than CUT or BLEND modes.

Pjovimas su stipriu koaguliacijos efektu

COAG Modes

1.2.3 pirkimo dalis

SOFT desiccates tissue at a relatively slower rate with deeper thermal penetration. It is typically performed with a ball electrode.

Delikati, gilesnės skvarbos koaguliacija

1.2.1 pirkimo dalis

FULGURATE coagulates tissue by sparking from the active electrode, through air, to the patient tissue.

Fulg“ -nekontaktinė, aukštos įtampos koaguliacija

1.2.2 pirkimo dalis

SPRAY delivers wider fulguration; penetration is shallower and the affected tissue area is larger than with the FULGURATE mode.

„Spray“-nekontaktinė, aukštos įtampos koaguliacija

Compatible Monopolar Instruments & Devices

The following Covidien catalog numbers for monopolar surgical instruments, return electrodes, foot pedals, and adapters are fully compatible with the VLFT10GEN.

UFP-Receptacle Adapter (connect only to Monopolar 1)

E05021 Monopolar Adapter

E050212 Monopolar Adapter

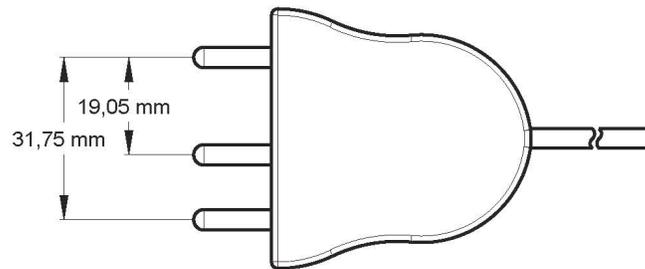
Instruments (connect only to Monopolar 2 receptacle)

FT3000DB Force TriVerse™ Electrosurgical Device

FT3000 Force TriVerse Electrosurgical Device

Instruments (connect to either Monopolar 1 or Monopolar 2)

This generator is designed for use with Covidien monopolar instruments. However, monopolar instruments are compatible with the VLFT10GEN if they have a connector that matches the following figure and are rated for peak voltages of at least 3933 V.

Monopolar

Utilizes 4 mm banana pins

Return Electrodes (Monitoring)

E0560 Valleylab REM™ Patient Return Electrode Cord
E7507 REM Polyhesive™ Adult Patient Return Electrode
E7507DB REM Polyhesive Adult Patient Return Electrode
E7508 REM Polyhesive Adult Cordless Patient Return Electrode
E7509 REM Polyhesive Adult Cordless Patient Return Electrode
E7509B REM Polyhesive Adult Cordless Patient Return Electrode
E7510-25 REM Polyhesive Infant Patient Return Electrode
E7510-25DB REM Polyhesive Infant Patient Return Electrode
E7512 REM Polyhesive Neonatal Patient Return Electrode

Return Electrodes (Non-Monitoring, for use in DEMO mode only. Not for clinical use.)

E7506 Non-REM Polyhesive Patient Return Electrode

REM Connector

E0507B Valleylab Multiple Return/S Cord Adapter

Foot Pedals

FT6003 ForceTriad Three-Pedal Footswitch (Monopolar 2 only)
E6008 Valleylab Monopolar Footswitch (Monopolar 1, Monopolar 2 with adapter)
E6008B Valleylab Monopolar Footswitch (Monopolar 1, Monopolar 2 with adapter)
1017577 6-Pin to 4-Pin Monopolar Footswitch Adapter (Monopolar 2 only)

Bipolar Effects

Selection of Bipolar effects and power settings is dependent on surgeon preferences, tissue characteristics, accessories selection, and the intended clinical application.

LOW effect is for power selections of 1–15 watts. It delivers low-voltage output for precision and fine control of the amount of desiccation typically used with small-surface area instruments.

MEDIUM effect is for power selections of 16–40 watts. It is a conventional bipolar output typically used with medium surface-area electrodes.

HIGH effect is for power selections 45–95 watts. Power remains constant over a wide range of tissue types and may be used for large electrodes.

Effect Setting	Power Setting Range	Optimized Instrumentation
LOW	1—15 watts	<ul style="list-style-type: none"> • Small surface-area instruments • Micro-tip forceps (0.4—2.2 mm)
MEDIUM	16—40 watts	<ul style="list-style-type: none"> • Medium surface-area instruments • Micro-tip forceps (1.0—2.2 mm) • Small paddle lap forceps • Bipolar scissors
HIGH	45—95 watts (5 watt increments)	<ul style="list-style-type: none"> • Large surface-area instruments • Large paddle lap forceps

Auto Bipolar

The Auto Bipolar feature senses tissue impedance between the two bipolar electrodes, then uses the impedance information to automatically start or stop bipolar RF energy delivery. Optionally, the user may select a timed activation delay for auto start and RF activation.

Note: When using Auto Bipolar, the tissue in the grasp of the bipolar device must have an impedance less than 2200 Ω . The activation impedance safety feature will not deliver RF power to the tissue if it is not within the specified range. This is a factory-set value that cannot be reset by the user.

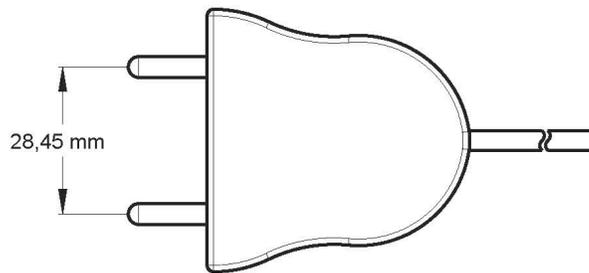
Precaution

Do not use the FT0501 ForceTriad Bipolar Adapter with Auto Bipolar on the VLFT10GEN.

Compatible Bipolar Instruments & Devices

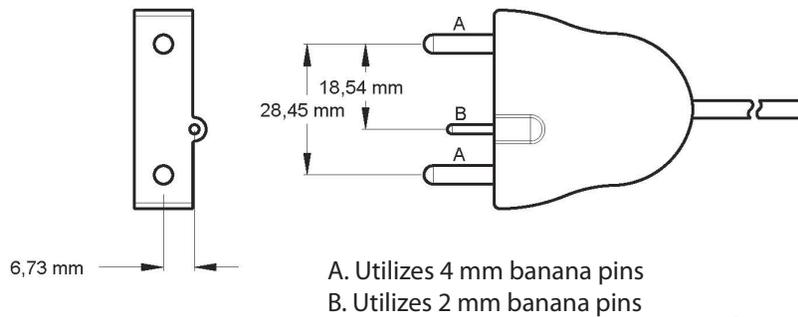
The VLFT10GEN is designed for use with Covidien bipolar instruments. However, other bipolar instruments are compatible with the FT10 if their connectors match the following illustration and are rated for peak voltages of at least 531 V.

Bipolar



Utilizes 4 mm banana pins

Bipolar with Switching



A. Utilizes 4 mm banana pins
B. Utilizes 2 mm banana pins

The following Covidien catalog numbers for bipolar foot pedals are fully compatible with the VLFT10GEN.

Foot Pedals

E6009 Valleylab Bipolar Standard Footswitch
E6009B Valleylab Bipolar Standard Footswitch
E6019 Valleylab Bipolar Dome Footswitch

Bipolar Resection

Bipolar Resection configures the LigaSure/Bipolar receptacle to use bipolar-resection resectoscopes.

Accessories

FT0021S ForceTriad Bipolar Resection Cord
FT0022W ForceTriad Bipolar Resection Cord
FT6009 ForceTriad FT Series Bipolar Resection Footswitch (with adapter)
1060355 Valleylab TR Bipolar Resection Footswitch Adapter

Effect-Settings Reference Chart

Effect Setting	Initiation Current Setting (amps)	CUT (watts)	COAG (volts)
1	1.8	80	25
2	1.8	120	50
3	2.1	120	75
4	2.4	120	100
5	2.4	160	125
6	2.4	200	150

LigaSure

LigaSure tissue fusion can be used on arteries, veins, pulmonary vasculature, and lymphatics—up to and including 7 mm in diameter—and tissue bundles. When used with compatible instruments, the system provides precise energy delivery and electrode pressure to vessels for a controlled time period to achieve a complete and permanent fusion of the vessel lumen. The system has been designed to produce minimal sticking, charring, and thermal spread to adjacent tissue.

Warning

The tissue fusion function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

LigaSure Instruments

The LigaSure instruments that complete the VLFT10GEN tissue-fusion system include reusable and single-use instruments for open and laparoscopic procedures. Each reusable instrument requires a corresponding single-use electrode. The LigaSure function is only available when using compatible instruments.

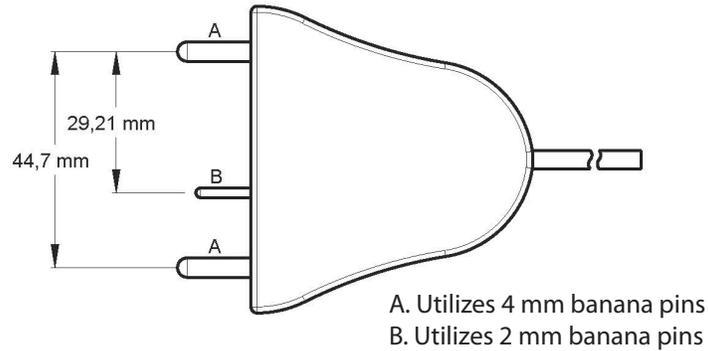
Compatible LigaSure Instruments & Devices

This generator is designed for use with Covidien LigaSure instruments that have a connector that matches the following figures and are rated for peak voltages of at least 244 V. However, it does not recognize all LigaSure instruments. Please refer to the cover of the instructions for use to confirm if a specific LigaSure catalog number is compatible with the VLFT10GEN.



Utilizes 4 mm banana pins

LigaSure with Switching



The following LigaSure foot pedal is fully compatible with the VLFT10GEN.

Foot Pedal

LS0300 Tissue Fusion Footswitch, Purple

Connection to External Systems

The VLFT10GEN can be connected to an external system. For example, connections can be made to enable smoke evacuation or EKG blanking during monopolar activation, or provide argon-enhanced coagulation. There are two external system receptacles on the back of the VLFT10GEN that can signal RF activation—one that is associated with the Monopolar 1 receptacle (labeled Monopolar 1) and one with the Monopolar 2 receptacle (labeled Monopolar 2). Refer to the external system user's guide for detailed instructions regarding how to connect it to the generator.

External Systems Compatible with the FT10 Energy Platform

SEA3730 RapidVac™ Smoke Evacuator Interlink Cable
SE3690 RapidVac Smoke Evacuator
Force™ Argon II-20 Argon Gas Delivery Unit II

Warning

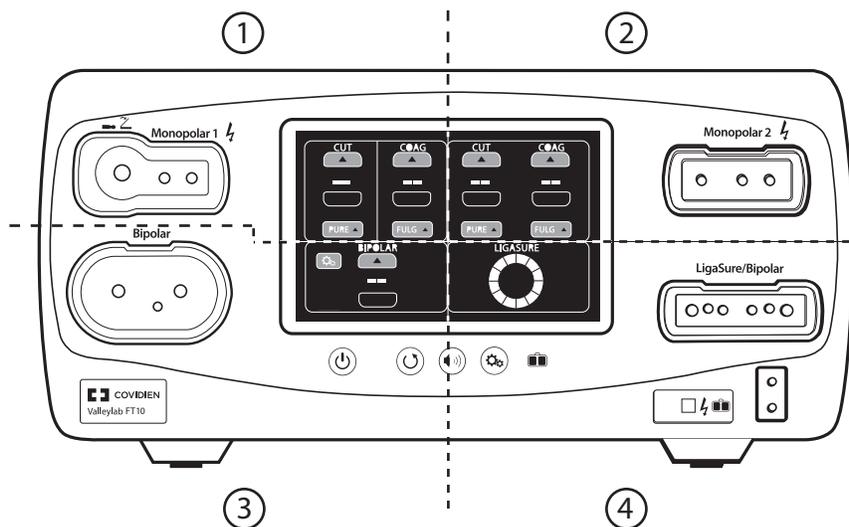
The use of any external system connected to the VLFT10GEN should be evaluated by qualified personnel.

System Conventions

The Touchscreen

The VLFT10GEN features a user-friendly touchscreen interface to control system functions. The touchscreen is divided into quadrants; each of the four sections is associated with an adjacent instrument receptacle.

- **Quadrant 1**—Settings entered in the touchscreen control an instrument attached to the Monopolar 1 receptacle.
- **Quadrant 2**—Settings entered in the touchscreen control an instrument attached to the Monopolar 2 receptacle.
- **Quadrant 3**—Settings entered in the touchscreen control an instrument attached to the Bipolar receptacle.
- **Quadrant 4**—The touchscreen displays instrument-specific options and activation of LigaSure and Bipolar Resection devices.



Generator States

The appearance of touchscreen components indicates one of the three states of the system.

Edit

When the system is powered on and no instrument is attached, the instrument controls in the monopolar and bipolar sections can be preset. The following illustration shows monopolar controls edited prior to inserting an instrument.



Inserted

The controls change from the edit stage's flat gray to a brightly illuminated color when an instrument is inserted into the associated receptacle. The following illustration shows the monopolar controls when a two-button pencil is inserted.



Activation

The black background illuminates brightly when the instrument is activated. The following illustration shows the two-button pencil is currently delivering energy for PURE CUT. The mode controls are locked during activation preventing any change in the mode. Power settings can be changed during activation.



System Buttons

There are four buttons on the energy platform's front panel:



On/Off

Turns system power on and off. To turn power on, hold the button for 0.25 seconds. To turn off, hold the button for 1 second. To reset a non-responsive system, hold for 10 seconds.



Restore Settings

Restores settings from the last time the system was powered down using the On/Off button.



Audio Volume

Displays the volume pop-up menu to adjust sound levels.



Service/Settings

Displays the service/settings menu.

Interface Conventions

Interface Element	Name	Description
	<p>Pop-up window/ menu</p>	<p>Pop-up windows and menus appear on screen when user input is needed or requested. Pop-ups close if the user touches anywhere outside of the pop-up window.</p>
	<p>Up/Down arrows</p>	<p>Up and down arrows indicate additional values or selections are available for the current setting.</p> <p>For numeric values, press the up or down arrow to increase or decrease the displayed value. When the value is at its maximum or minimum available setting, the appropriate arrow button becomes inactive.</p> <p>Menu selections (such as the up arrow on PURE) presents other available settings.</p>
	<p>Software Buttons</p>	<p>Options and confirmations are represented by virtual buttons on the touchscreen. Touch on-screen buttons to select preference.</p>
	<p>Toggle Switches</p>	<p>Touch the virtual toggle switches to enable (ON) or disable (OFF) options or functions.</p>

Chapter 2

Warnings and Precautions for Patient and Operating Room Safety

The safe and effective use of electrosurgery depends to a large degree upon factors solely under the control of the operator. There is no substitute for a properly trained and vigilant surgical team. It is important that the operating instructions supplied with this or any electrosurgical equipment be read, understood, and followed.

Electrosurgery has been used safely in millions of procedures. Before starting any surgical procedure, the surgeon should be trained in the particular technique and surgical procedure to be performed, should be familiar with the medical literature related to the procedure and potential complications, and should be familiar with the risks versus the benefits of utilizing electrosurgery in the procedure.

Conventions Used in this Guide

Warning

Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

Precaution

Indicates a hazardous situation which, if not avoided, may result in minor or moderate injury.

Notice

Indicates a hazard which may result in product damage.

Important

Indicates an operating tip or maintenance suggestion.

General Warnings and Precautions

Fire/Explosion Hazards

Warning

Danger - Explosion Hazard Do not use electrosurgery in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N₂O) and oxygen) or in close proximity of to volatile solvents (such as ether or alcohol).

Fire Hazard Do not place active instruments near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical instruments that are activated or hot from use can cause a fire. When not in use, place electrosurgical instruments in a safety holster or safely away from patients, the surgical team, and flammable materials.

Sparking and heating associated with electrosurgery can be an ignition source. Keep gauze and sponges wet. Keep electrosurgical electrodes away from flammable materials and oxygen (O₂) enriched environments.

Use of electrosurgery in O₂ rich environments increases the risk of fire. Therefore, take measures to reduce the O₂ concentration at the surgical site.

If possible, stop supplemental oxygen at least one minute before and during use of electrosurgery.

The use of non-flammable agents is recommended for cleaning and disinfecting wherever possible. If flammable agents are used, do not activate the energy platform until flammable vapors from skin-preparation solutions and tinctures have dissipated.

There is a risk of pooling of flammable solutions under the patient or in body depressions, such as the umbilicus, and in body cavities, such as the vagina. Any fluid pooled in these areas should be removed before activating the energy platform.

Avoid the accumulation of naturally occurring flammable gases that may accumulate in body cavities such as the bowel.

Prevent the accumulation of flammable or oxidizing gases or vapors under surgical drapes or near the surgical site.

Tissue buildup (eschar) on the tip of an active electrode may create embers that pose a fire hazard, especially in oxygen-enriched environments. Keep the electrode clean and free of all debris.

Facial and other body hair is flammable. Water soluble surgical lubricating jelly may be used to cover hair close to the surgical site to decrease flammability.

Verify that all anesthesia circuit connections are leak free before and during use of electrosurgery.

Fire Hazard During Oropharyngeal Surgery

Verify endotracheal tubes are leak free and that the cuff seals properly to prevent oxygen leaks.

If an uncuffed tube is in use, pack the throat with wet sponges around the uncuffed tube, and be sure to keep sponges wet throughout the procedure.

Question the need for 100% O₂ during oropharyngeal or head and neck surgery.

If necessary, scavenge excess O₂ with separate suction.

Do not attempt to recharge the generator's lithium battery. This can cause the battery to explode.

System Setup Warnings and Precautions

Warning

Electric Shock Hazard Connect the system power cord to a properly grounded power receptacle. Do not use power plug adapters.

Electric Shock Hazard When taking measurements or troubleshooting the system, take appropriate precautions, such as using isolated tools and equipment, using the “one hand rule,” etc.

Electric Shock Hazard Do not touch any exposed wiring or conductive surfaces while the system is disassembled and energized. Never wear a grounding strap when working on an energized system.

Electric Shock Hazard To allow stored energy to dissipate after power is disconnected, wait at least 5 minutes before replacing parts.

Position the generator where it can be easily unplugged in an emergency.

Fire Hazard Do not plug into a power strip or extension cord.

Patient Safety Use the energy platform only if the power-on self-test has been completed as described in this manual, otherwise inaccurate power outputs may result.

Hazardous Electrical Output This equipment is for use only by trained, licensed physicians. Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Use of this equipment without such training can result in serious, unintended patient injury, including bowel perforation and unintended, irreversible tissue necrosis.

Do not touch the patient while touching a connector or fuse contact at the same time. Simultaneous contact can cause electric shock or burns.

Do not wrap the instrument cords or patient-return-electrode cords around metal objects. This may induce currents (capacitive coupling) that could lead to shocks, fires, or injury to the patient or surgical team.

Electric Shock Hazard Do not connect wet instruments to the energy platform. Ensure that all instruments and adapters are correctly connected and that no metal is exposed at any connection points.

Confirm proper power settings before proceeding with surgery. If the proper power settings are not known, set the power to a low setting and cautiously increase the power until the desired effect is achieved. If increased power settings are requested, check the patient return electrode and all instrument connections before major power-setting adjustments.

Contact between the active electrode and any metal will greatly increase current flow and can result in unintended surgical effect.

Warning

While using electrosurgery, the user and patient should not be allowed to come into direct contact with grounded metal objects (e.g., surgical-table frame, instrument table, etc.). If this is not possible during certain procedures (e.g., those in which noninsulated head frames are used), use extreme caution to maximize patient safety:

- Use the lowest power setting that achieves the desired effect.
- Place the patient return electrode as close to the surgical site as possible.
- Place dry gauze between the patient and the grounded object if possible.
- Continually monitor the contact point(s).
- Do not use metal needle monitoring electrodes.

Precaution

Read the instructions, warnings, and precautions provided with this energy platform and associated accessories before using. Specific instructions for electrosurgical instruments are not included in this manual.

Read the instructions, warnings, and precautions provided with electrosurgical instruments before using. Specific instructions for electrosurgical instruments are not included in this manual.

Always use the lowest power setting that achieves the desired surgical effect. The active electrode should be utilized only for the minimum time necessary in order to lessen the possibility of unintended burn injury. Accidental and unintended burn injury has occurred during procedures in small surgical fields and on small appendages. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small structures.

For surgical procedures where the current could flow through delicate parts of the body, the use of bipolar techniques may be desirable in order to avoid unwanted coagulation.

Connect only Covidien-approved devices. Using devices from other manufacturers may cause equipment malfunction or patient injury.

Examine all instruments and connections to the system before using. Improper connection may result in arcs, sparks, instrument malfunction, or unintended surgical effects.

Do not operate the generator for clinical use while cables are connected to the utility WiFi receptacle or Ethernet receptacles on the back of the generator. This may cause a system error that would halt the procedure and require restarting the generator.

Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when the energy platform is delivering RF energy.

When using a smoke evacuator in conjunction with the VLFT10GEN, set the system volume control at a level that ensures the activation tones can be heard.

A non-functioning VLFT10GEN may cause an interruption of surgery. A backup system should be available for use.

Precaution

Inadvertent activation may occur while installing, removing, or bending electrodes. Ensure that the instrument cord is not connected to the VLFT10GEN or that the system is off.

Leads connected to the patient should be positioned in such a way that contact with the patient or other leads is avoided because the capacitance between the electrode cable and the patient may result in some local high current densities.

Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and the surgical team. These studies recommend adequately ventilating the smoke by using a surgical-smoke evacuator or other means.¹

1. U.S. Department of Health and Human Services. National Institute for Occupational Safety and Health (NIOSH). Control of Smoke from Laser/Electric Surgical Procedures. HAZARD CONTROLS, Publication No. 96-128, September, 1996

Notice

Connect the power cord to a properly grounded power receptacle having the correct voltage. Otherwise, product damage may result.

The VLFT10GEN requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the *Valleylab FT10 Energy Platform Service Manual*.

Portable and mobile RF communications equipment can affect the VLFT10GEN. Refer to the EMC information provided in the *Valleylab FT10 Energy Platform Service Manual*.

The system should not be used adjacent to or stacked with equipment other than specified in the *Valleylab FT10 Energy Platform User Guide and Service Manual*. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

The system intentionally applies RF energy for diagnosis or treatment during activation. Observe other electronic medical equipment in the vicinity during the system activation for any possible adverse electromagnetic effects. Ensure adequate separation of electronic medical equipment based on observed reactions.

The use of accessories, other than specified in the *Valleylab FT10 Energy Platform User Guide and Service Manual*, may result in increased emissions or decreased immunity of the system.

Calibration must be performed on a non-conductive surface. Do not use antistatic bench-top mats. When performed on a conductive surface, calibration values may not be accurate.

After completing calibration, the system will reboot to the clinical screen to save the values or abort the calibration.

Important

The VLFT10GEN is intended for use in a hospital environment.

Important

If required by local codes, connect the energy platform to the hospital potential equalization system with an equipotential cable.

The operator of the generator may be as far away from the generator as 2 feet (direct product interaction), 5 feet (inside the sterile field), and 13 feet (across the room working with other equipment).

RFID and WiFi function may be interfered with by other equipment even if that other equipment complies with CISPR emission requirements.

Log files are maintained when the system is powered down. The time when the system was powered down or experiences a total loss of power is also logged.

When log files reach capacity, the earliest log is deleted to make room for the newest log.

Warnings and Precautions for the Energy Platform

Warning

Each instrument receptacle on this energy platform is designed to accept only one instrument at a time. Follow the instructions provided with electrosurgical instruments for proper connection and use.

Failure of the generator could result in an unintended increase of output power or activation.

The use of any external system connected to the VLFT10GEN should be evaluated by qualified personnel.

Precaution

Do not stack equipment on top of the energy platform or place the energy platform on top of electrical equipment. This is an unstable configuration and does not allow for adequate cooling.

Provide at least 4" to 6" (10 to 15 cm) of unobstructed space round the top and sides of the generator to ensure proper cooling.

Provide as much distance as possible between the energy platform and other electronic equipment (such as monitors). Do not cross or bundle cords from electronic devices. This energy platform may cause interference with other electronic equipment.

The use of monitoring systems that incorporate high-frequency current-limiting devices is recommended to reduce interference with the monitoring device.

The system contains electrostatic-sensitive components. When repairing the system, work at a static-control workstation. Wear a grounding strap when handling electrostatic-sensitive components, except when working on an energized system. Handle Printed Circuit Board Assemblies (PCBA) by their non-conductive edges. Use an antistatic container for transport of electrostatic-sensitive components and PCBAs.

Notice

Make no modifications to the energy platform. Any modifications to the system will void the warranty.

When testing RF equipment, follow these test procedures. Keep test leads to the minimum length usable; lead inductance and stray capacitance can adversely affect readings. Carefully select suitable ground points to avoid ground loop error in measurements.

The accuracy of most RF instruments is approximately 1%–5% of full scale. Using uncompensated scope probes causes large errors when measuring high-voltage RF waveforms.

Warnings and Precautions for Active Instruments**Warning**

Energy applied to an electro-surgical instrument can convert liquids to steam. The thermal energy of steam may cause unintended injury in close proximity to the tip of the instrument. Care should be taken in surgical procedures occurring in confined spaces in anticipation of this possibility.

Do not activate the energy platform in an open-circuit condition. To reduce the chances of unintended burns, activate the energy platform only when the active electrode is near or touching the target tissue.

Use the lowest power setting that achieves the desired surgical effect and use a low-voltage waveform (PURE CUT, BLEND, or Valleylab mode) to lessen the potential for the creation of capacitive currents.

If energy delivery from the generator cannot be stopped, disconnect the handpiece or power cord.

Do not activate the instrument when not in contact with target tissue as this may cause injuries due to capacitive coupling.

The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.

Keep the active electrodes clear. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.

Precaution

Read the instructions, warnings, and precautions provided with electro-surgical instruments before using. Specific instructions for electro-surgical instruments are not included in this manual.

Inspect instruments and cords—especially for laparoscopic/endoscopic instruments—for breaks, cracks, nicks, and other damage before every use. If damaged, do not use. Damaged instruments or cords may result in injury or electrical shock to the patient or surgical team.

Precaution

Use only instruments that can withstand the maximum output (peak) voltage for each output mode as listed in Chapter 10, *Technical Specifications*. Using an instrument with a voltage rating that is lower than the maximum output voltage may result in injury to the patient or the operator, or damage to the instrument.

Information on voltage ratings for non-Covidien instruments should be obtained from the instrument's manufacturer.

Notice

All Covidien instruments have voltage ratings that are greater than the maximum output voltages in the VLFT10GEN and are thus fully compatible.

Inspect instrument plugs for wear before every use. Worn plugs may result in a loose or stuck connection to the generator.

Warnings for Implanted Electronic Devices (IEDs)

IEDs include, but are not limited to, pacemakers, neurostimulators, implantable cardioverter defibrillators (ICDs), ventricular assist devices (VAD), spinal cord stimulators, cochlear implants, infusion pumps, and bone growth stimulators.

Warning

Use the system with caution in the presence of internal or external pacemakers or other implanted devices. Interference produced by electrosurgical equipment can cause a pacemaker or other device to enter an unsafe mode or permanently damage the device. Consult the device manufacturer or responsible hospital department for further information when use is planned in patients with implanted medical devices.

Post Surgery Safety Issues

Warning

Shock Hazard Before cleaning or servicing the unit, disconnect the power plug from the power outlet in order to completely isolate the generator from mains power.

Notice

Do not clean the energy platform with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the energy platform.

Warnings and Precautions for Monopolar Procedures

Warning

Simultaneously activating suction/irrigation and electrosurgical current may result in increased arcing at the electrode tip, burns to unintended tissues, or shocks and burns to the surgical team.

Power output of a two- or three-button pencil (CUT and COAG selections) can change during use when another foot pedal is pressed.

Some surgeons may elect to “buzz the hemostat” during surgical procedures. It is not recommended, and the hazards of such a practice probably cannot be eliminated. Burns to the surgeon’s hands are possible. To minimize the risk take these precautions:

- Do not buzz the hemostat with a needle electrode.
- Do not lean on the patient, the table, or the retractors while buzzing the hemostat.
- Activate CUT rather than COAG. CUT has a lower voltage than COAG.
- Firmly grasp as much of the hemostat as possible before activating the energy platform. This disperses the current over a larger area and minimizes the current concentration at the finger tips.
- Buzz the hemostat below hand level (as close as possible to the patient) to reduce the opportunity for current to follow alternate paths through the surgeon’s hands.
- Use the lowest power setting possible for the minimum time necessary to achieve hemostasis.
- Activate the energy platform after the instrument makes contact with the hemostat. Do not arc to the hemostat.
- When using a coated- or nonstick-blade electrode, place the edge of the electrode against the hemostat or other metal instrument.

DEMO mode delivers monopolar energy without the use of a patient return electrode, and is intended for demonstration purposes only. Chance of burns to the patient significantly increase when DEMO mode is used for clinical procedures.

Precaution

To provide expected functionality from a hand piece, proper insertion is required. Refer to the orientation drawing near the receptacles for proper insertion orientation.

Warnings and Precautions for Patient Return Electrodes

Warning

It is not possible to foresee what combination of current and duty cycle may be safely used in every situation—for example, when higher currents and/or longer duty cycles are used on procedures such as tissue lesioning, tissue ablation, tissue vaporization; and procedures where conductive fluid is introduced into the surgical site. Under these conditions a greater risk may exist that the heating under a fully applied return electrode may be high enough to injure the patient.

When using a Covidien energy platform or a patient return electrode during these types of surgical procedures, the user should seek written guidance in the form of detailed user instructions from the manufacturer of the active accessory regarding the currents and duty cycles that can be expected. In some instances, the application of additional patient return electrodes may help mitigate the increased risk.

Do not attempt to use patient return electrodes that disable the Return Electrode Monitoring (REM) system. The VLFT10GEN REM system will function correctly only with contact quality monitoring (CQM) split-style patient return electrodes. Other patient-return-electrode products may cause patient injury or product damage.

The safe use of monopolar electrosurgery requires proper placement of the patient return electrode. To avoid electrosurgical burns beneath the patient return electrode, follow all directions provided with the product.

Do not cut a patient return electrode to reduce its size. Patient burns due to high current density may result.

To avoid patient burns, ensure that the patient return electrode makes firm and complete contact with the skin. Always check the patient return electrode periodically, after the patient is repositioned, and during procedures involving long periods of activation.

Use of duty cycles greater than 25% (10 seconds active followed by 30 seconds inactive) will increase the risk that heat build-up under a return electrode may be high enough to injure the patient. Do not continuously activate for longer than one minute.

Apparent low-power output at the normal operating settings may indicate faulty application of the return electrode. Verify the return electrode is correctly placed and attached to the patient as described in the electrode's instructions for use. Verify the connection between the electrode and the generator.

Use of a non-REM return electrode while in DEMO mode does not monitor the quality of pad contact with the patient. No warning will be issued from the generator when a non-REM return electrode's pad-to-patient contact degrades when in DEMO mode.

Precaution

Covidien REM Polyhesive patient return electrodes are recommended for use with the FT10. Return electrodes from other manufacturers may not provide proper impedance to work correctly with the energy platform.

Important

A statement of compatibility from the CQM patient return electrode manufacturer should be obtained prior to the use of a non-Covidien CQM patient return electrode.

A patient return electrode is not necessary in bipolar or LigaSure procedures.

Inadvertent Radio Frequency (RF) Burns**Warning**

Electrodes and probes used with monitoring, stimulation, and imaging devices (or similar equipment) can provide a path for high frequency current even if the electrodes or probes are isolated at 50 –60 Hz, insulated, and/or battery operated.

Do not use needles as monitoring electrodes during electrosurgical procedures. Inadvertent electrosurgical burns may result.

To reduce the risk of an inadvertent electrosurgical burn at the monitoring electrode or probe site, place the electrode and/or probe as far away as possible from the electrosurgical site and/or patient return electrode. Protective impedances (resistors or RF inductors) installed in the monitoring leads may reduce the risk of such burns. Consult the hospital biomedical engineer for further information.

In some circumstances, the potential exists for alternate site burns at points of skin contact (e.g., between the arm and the side of the body). This occurs when electrosurgical current seeks a path to the patient return electrode that includes the skin-to-skin contact point. Current passing through small skin-to-skin contact points is concentrated and may cause a burn. This is true for ground referenced and isolated output electrosurgical energy systems.

To reduce the potential for alternate site burns, do one or more of the following:

- Avoid skin-to-skin contact points, such as fingers touching leg or knee touching knee when positioning the patient.
- Place insulation, such as dry gauze or towel, between contact points to ensure that contact does not occur.
- Position the patient return electrode to provide a direct current route between the surgical site and the return electrode which avoids skin-to-skin contact areas.
- In addition, place patient return electrodes according to the manufacturer's instructions.

Warnings and Cautions for Laparoscopic Procedures

Warning

For laparoscopic procedures, be alert to these potential hazards:

- Laparoscopic surgery may result in gas embolism due to insufflation of gas in the abdomen.
- The electrode tip or LigaSure jaws may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of the activated instrument electrode or jaws outside of the field of vision may result in injury to the patient.
- Localized burns to the patient or physician may result from electrical currents carried through conductive objects (such as other instrument, cannulas, or scopes). Electrical current may be generated in conductive objects through direct contact with the active electrode or jaws, capacitive coupling, or by the active instrument (electrode or cable) being in close proximity to the conductive object. Localized burns to the patient or physician may occur.
- Do not use hybrid trocars that have a non-conductive locking anchor placed over a conductive sleeve. For the operative channel, use all-metal or all-plastic systems. At no time should electrical energy pass through hybrid systems. Capacitive coupling of RF current may cause unintended burns.
- When using laparoscopic instrumentation with metal cannulas, the potential exists for burns to the abdominal wall due to direct electrode contact or capacitive coupling of RF current. This is most likely to occur in instances where the energy platform is activated for extended periods at high power levels inducing high current levels in the cannula.
- Carefully insert and withdraw LigaSure instruments from cannulas to avoid possible damage to the devices and/or injury to the patient.
- Ensure that the insulation of single-use and reusable laparoscopic instrumentation is intact and uncompromised. Compromised insulation may lead to inadvertent metal-to-metal sparking and neuromuscular stimulation and/or inadvertent sparking to adjacent tissue.
- Do not activate the LigaSure function in an open-circuit condition. Activate the energy platform only when the instrument is near or in direct contact with the target tissue to reduce the possibility of unintended burns.

Covidien recommends against the use of laparoscopic surgery on pregnant patients.

Warnings and Precautions for Bipolar Procedures

Warning

Use of different Covidien cord models or cords from other manufacturers may not achieve proper electrical output for this device, thereby failing to produce the desired clinical effect. For example, Auto Bipolar activation/deactivation settings may not work properly using cords other than those specified by Covidien.

In the Auto Bipolar setting, activation may occur with contact of any material. When not in use, place electrosurgical instruments in a safety holster or safely away from patients, the surgical team, and flammable materials

Precaution

Bipolar instruments must be connected to the bipolar instrument receptacle only. Improper connection may result in inadvertent system activation.

Do not use the FT0501 ForceTriad™ Bipolar Adapter with Auto Bipolar on the VLFT10GEN.

Bipolar forceps should not be set down while Autobipolar is active. Contact with any material may cause activation. Turn off Autobipolar before releasing an instrument.

Warnings and Precautions for LigaSure Procedures

Warning

LigaSure instruments are intended for use only with compatible Covidien generators and energy platforms. See the front cover of the instrument's instructions for a list of compatible generators. Use of these instruments with other generators may not result in electrical output that they were designed for, and may not result in the desired clinical effect.

The tissue fusion function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

Tissue fusion requires the application of RF energy and pressure from the instrument. Ensure grasping pressure is maintained until the seal cycle is complete. Tissue to be sealed must be firmly grasped between the instrument jaw electrodes. Tissue in the jaw hinge or outside the instrument jaw may not be sealed even if thermal blanching occurs.

If the seal-cycle-complete tone has not sounded, an optimal seal may not have been achieved. Reactivate the RF energy until a seal-cycle-complete tone is heard.

Do not activate the energy platform in LigaSure until the tissue-fusion instrument has been applied with the proper pressure. Do not release the pressure on the tissue until the end tone has sounded. Activating the energy platform under these conditions may result in an improper seal and may increase thermal spread to tissue outside the surgical site.

Warning

Fluid in the body cavity should be kept to a minimum during treatment. Conductive fluids (e.g., blood or saline) in direct contact with, or in close proximity to, the instrument may carry electrical current or heat, which may cause unintended burns to the patient. Aspirate fluid from around the instrument jaws before activating the instrument.

Do not attempt to seal or cut over clips or staples as incomplete seals may be formed.

Precaution

Energy-based devices, such as electro-surgical pencils or ultrasonic scalpels, that are associated with thermal spread should not be used to transect seals.

Warnings and Precautions for Bipolar Resection

Warning

Bipolar Resection mode is intended to be used only with compatible resectoscopes for endoscopically controlled removal (resection) or coagulation of tissue using 0.9% NaCl solution (saline) as the irrigation medium

Precaution

Bipolar Resection mode is supported only if a Covidien-specified Bipolar Resection instrument is connected to the LigaSure/Bipolar receptacle with a Covidien Bipolar Resection cord. In addition, Bipolar Resection mode can be activated only with the Covidien Bipolar Resection foot pedal connected to the LigaSure/Bipolar foot-pedal receptacle. See the cords IFU listed in *Accessories* on page 1-10 for the list of supported Bipolar Resection instruments and cords.

Servicing

Warning

Electric Shock Hazard Do not remove the energy platform cover. Contact qualified personnel for service.



Do not dispose of electrical appliances as unsorted municipal waste. Use separate collection facilities.

Electrical appliances that are incorrectly disposed in dumps or landfills can leach dangerous substances causing contamination of soil and groundwater, and damaging the environment.

Contact your local government, or point of sale for information regarding the collection of waste electrical appliances

Notice

Refer to this system's service manual for maintenance recommendations, and function and output-power verification procedures.

Do not spray cleaning fluids directly on the generator as damage to the generator may occur.

The latest version of the *Valleylab FT10 Energy Platform Service Manual* is available at www.BioMedConnect.com.

Call these numbers to request a hardcopy of the service manual

- USA and Canada: 1-800-255-8522 Option 2
- International: 1-303-476-7996

Shunt Cords

Warning

Some surgical instruments (e.g., colonoscopes) may allow substantial leakage current that could burn the surgeon. If the instrument manufacturer recommends the use of a shunt cord (s-cord) to direct the current back to the energy platform, an E0507-B adaptor must also be used. To avoid a REM alarm, a REM Polyhesive patient return electrode with the E0507-B adaptor must be used.

Conductive Fluid In the Surgical Site

Warning

When this energy platform is used in monopolar procedures where conductive fluid (including, but not limited to saline or lactated Ringer's) is introduced into the surgical site for distention or to conduct RF current, higher than normal currents (greater than one amp) may be produced. In this situation, use one or more adult-size return electrode. Do not use return electrodes labeled for children, infants, babies, neonatal use, or pediatric use.

Use of duty cycles greater than 25% (10 seconds active followed by 30 seconds inactive) will increase the risk that heat build-up under a return electrode may be high enough to injure the patient. Do not continuously activate for longer than one minute.

Chapter 3

System Setup

This chapter describes how to set up the energy platform, turn it on, and configure system settings.

Precaution

Read the instructions, warnings, and precautions provided with this energy platform and associated accessories before using. Specific instructions for electro-surgical instruments are not included in this manual.

Setup

Unpacking the System

Carefully unpack the contents of the shipping container. The container contains the following items:

- Valleylab FT10 FT Series Energy Platform
- Power cord
- First-time setup guide
- Quick reference card
- User's guide
- DVD with user's guide translations and service manual
- Ethernet cable
- Monopolar foot-pedal adapter
- Bipolar Resection foot-pedal adapter

Before Starting the System

Important

The VLFT10GEN is intended for use in a hospital environment.

The operator of the generator may be as far away from the generator as 2 ft. (60 cm) [direct product interaction], 5 ft. (1.5 m) [inside the sterile field], and 13 ft. (4 m) [across the room working with other equipment].

1. Verify the system is off and the power cord is unplugged.
2. Place the energy platform on a flat, stable surface such as a table, platform, boom system, or Valleylab Universal Generator Cart (VLFTCRT). Refer to the procedures for the local institution or local codes.
3. If necessary, connect the equipotential grounding lug to a ground source.
4. Plug the system power cord into the rear panel receptacle.
5. Plug the system power cord into a grounded power receptacle. The On/Off button illuminates yellow.

Precaution

Do not plug the system power cord into a power strip or extension cord.

Turning On the VLFT10GEN

1. Turn on the system by depressing the On/Off button on the front panel. Observe the following during the power-on self-test (POST):
 - The Covidien logo appears on screen.
 - A status bar indicates authentication activity.
 - The system revision code appears.
 - A tone sounds upon completion of the power-on self-test (POST).
 - The REM (Return Electrode Monitoring) indicator appears on the touchscreen: red if a REM-alarm condition exists; green if no REM-alarm condition.
 - If the system does not pass the power-on self-test and an error code is displayed, refer to *Correcting a REM-Alarm Condition* on page 8-2.
2. If the self-test is not successful, an alarm tone sounds. An error screen appears on the touchscreen. Note the information on the display and refer to Chapter 8, *Troubleshooting*

Warning

Patient Safety Use the energy platform only if the power-on self-test has been completed as described in this manual, otherwise inaccurate power outputs may result.

3. **Required for initial start up**—The generator must be set up using the Valleylab Exchange Remote Software System. For instructions, refer to the *First-Time Setup Guide* and the *Valleylab Exchange Remote Software System User's Guide*.

These documents are available online at www.covidien.com/valleylabexchange.

Turning Off the VLFT10GEN (Normal Power-off)

1. Turn off the system by depressing the On/Off button (illuminated green) on the front panel for at least 1 second. Observe the following during the power-off:
 - The system exits the screen.
 - The screen displays the power-down sequence.
 - Once the power-down is complete, the screen turns off and the On/Off button illuminates yellow.
 - Power-down is complete.
2. If the system was powered up but non-responsive, press and hold the On/Off button for at least 10 seconds and observe the following:
 - The screen turns off and the On/Off button illuminates yellow.
 - Power-down is complete.

System Functions

The VLFT10GEN system functions are accessed from buttons on the front panel: On/Off, Restore, Audio Volume, and Service and Settings.

On/Off



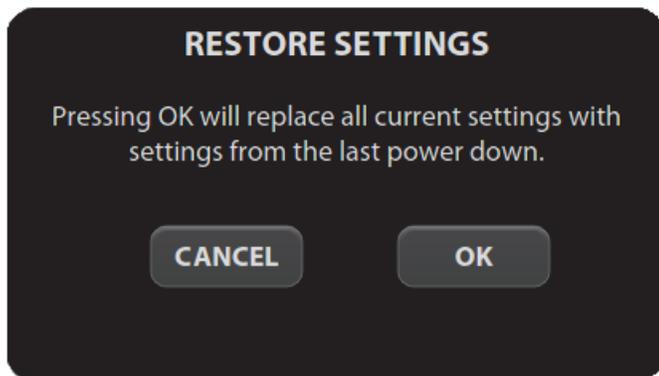
When the system is plugged into a power source, the On/Off button appears yellow. Turn on power to the energy platform by pressing and holding the On/Off button for 0.25 seconds. After a successful power-on self-test, the On/Off button illuminates green. A tone sounds to signal a successful system power up.

Press and hold the button for 1 second to turn power off. The button illuminates yellow when the system is powered down. If a system is non-responsive, holding the button for 10 seconds will power down the system.

Restore



Select the restore button on the front panel to reset the system to the settings in use when the system was last powered down using the On/Off button. Accepting the prompt in the dialog box will reset all quadrants to their last setting. All modes and values are reset with the exception of volume and Auto Bipolar setting.

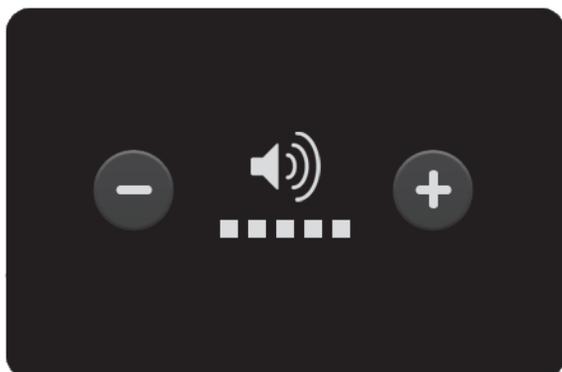


Touch **OK** and the touchscreen will display the last settings entered into each of the quadrants prior to shutting off the system.

Audio Volume



The VLFT10GEN has five levels of audio volume. Press the audio-volume button on the front panel to view the volume-select menu.



The factory setting is as shown with the volume set at it's highest level. Adjust the volume using the + or - buttons. Dismiss the dialog box by touching the screen outside of the volume menu.

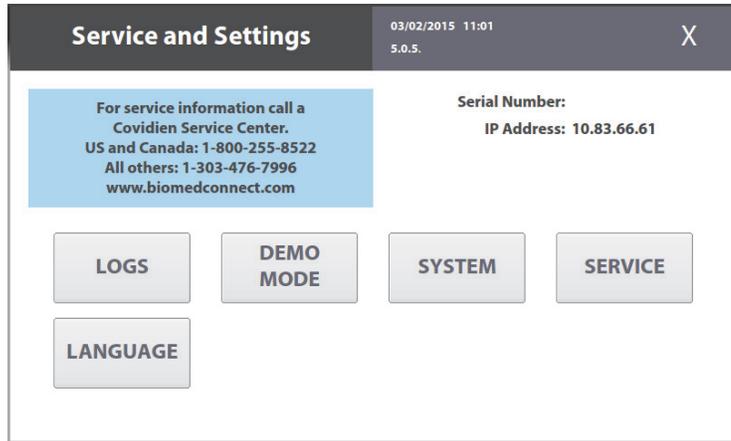
Language Selection Menu

The Language Selection menu presents 25 buttons; each labeled with a language available for all software screens and options in the software interface. To change the language, select the button labeled with the desired language. The software interface changes the non-service windows to the selected language after the language button is selected. Some service screens are not translated.

Service and Settings



The *Service and Settings* menu is accessed by pressing the gears button on the front panel.



The *Service and Settings* menu displays the generator serial number, IP address (if connected to the network), software version number, and contact information for the Covidien Service Center.

It provides available options for

- Viewing logs
 - Events Log
 - Error Log
 - Error Histogram
- Enabling DEMO Mode
- Selecting system settings
 - System Config
 - Diagnostics
 - Network
 - Time Zone
 - Calibration Info
- Accessing system service functions
 - Qualified service personnel can access service functions from a password-protected menu. Refer to the *Valleylab FT10 Energy Platform Service Manual* for service instructions.
- Selecting a language

Logs

The LOGS button displays the LOGS menu with three options.

1. Touch the **LOGS** button to view the Logs menu:
 - EVENTS—A detailed display of all user actions and generator events on the VLFT10GEN
 - ERROR—A display of all recorded system errors with details
 - ERROR HISTOGRAM—A summary of how often an error has occurred
2. Touch entries to view available details:
 - EVENTS—Touch an event entry to view details. Touch **BACK** to return to the EVENTS screen.
 - ERROR LOG—Touch an error to view its details in the *Error Details* dialog box. Touch the **SHOW EVENTS** button to view related events in the Events log entries. Touch **BACK** to return to the *Error Log* screen.
 - ERROR HISTOGRAM—Entries in the *Error Histogram* dialog box are not linked to other logs.

Important

Log files are maintained when the system is powered down. The time when the system was powered down or experiences a total loss of power is also logged.

When log files reach capacity, the earliest log is deleted to make room for the newest log.

DEMO Mode

DEMO mode is used for demonstration of the generator and accessories only. DEMO mode enables monopolar activation through an attached instrument without the use of a REM patient return electrode. When the monopolar surgery is performed clinically, the required return electrode provides a safe path for the current introduced to the patient's body.

Warning

DEMO mode delivers monopolar energy without the use of a patient return electrode, and is intended for demonstration purposes only. Chance of burns to the patient significantly increase when DEMO mode is used for clinical procedures.

The use of a non-REM return electrode while in DEMO mode will prevent the generator from warning the user if the return electrode is peeling.

Enable DEMO Mode

1. Touch **DEMO MODE** in the *Service and Settings* screen.
2. Click the **Enable DEMO MODE** button to place the monopolar quadrant in DEMO mode. A reminder is posted: "NOT FOR CLINICAL USE."



3. Touch the screen anywhere outside the EXIT DEMO MODE BUTTON to temporarily remove the message, allowing full access to the controls.
4. Proceed with any practice or demonstration scenarios. While in DEMO mode, the REM alarm is deactivated, but RF power is still delivered.

Note: The energy platform does not sense instrument type while in DEMO mode. The appropriate mode setting must be selected manually for the connected instrument.

Warning

Use of a non-REM return electrode while in DEMO mode does not monitor the quality of pad contact with the patient. Therefore, no warning will be issued from the generator when pad-to-patient contact degrades.

5. Touch **EXIT DEMO** to close DEMO mode and return to the functional monopolar screen. This will enable REM.

System Menu

The System button accesses settings for

- System Config
- Diagnostics
- Network
- Time Zone
- Calibration Info

System Configuration

System Configuration displays the hardware, software, and firmware components of the VLFT10GEN. This information is for reference only. No changes to the configuration can be performed from this screen.

Diagnostics

- **Instrument Bar Code Reader**—Insert a Covidien device with a scannable bar code. When the SCAN button is touched, the bar-code reader displays the current view from the reader's camera to verify it is working properly.
- **Self Test**—Runs the same system test as the power-on self-test when the system is turned on. Current power and mode settings in each quadrant will be lost as the system is reset to run the power-on self-test. These settings can be retrieved by pressing the Restore Settings button on the front panel. If the self-test is successful, a tone sounds.

Network

The Network button allows the technician to select a network connection to the Valleylab Exchange server for service operations. There are 4 ways to connect to the IT network:

- Wired Point-to-Point
- Wired Automatic
- Wired Manual
- Wireless

Wired Point-to-Point

This selection allows the generator to communicate directly with another computer through an Ethernet cable that is connected from the generator to the computer.

Wired Automatic

This selection allows the generator to communicate on the IT network through an Ethernet cable that is connected from the generator to a router or the facility's DHCP server. The generator is automatically assigned an IP address by the facility's DHCP server.

Wired Manual

This selection allows the generator to communicate on the IT network through an Ethernet cable that is connected from the generator to a router or the facility's DHCP server. The technician can manually set a static IP address, network mask, and default gateway address.

Wireless

This selection allows a wireless connection from the generator to a router or to a DHCP server via a WiFi access point broadcasting a non-hidden SSID. The technician selects which SSID to connect to and enters a WPA2 password to enable the connection. The generator is automatically assigned an IP address by the facility's DHCP server.

Time Zone

Select a region from the drop-down menu to set the time zone used by the system clock. The time and date are originally set during the initial connection to Valleylab Exchange (see page 3-3).

Calibration Info

Calibration Info displays all of the energy calibration values stored in the VLFT10GEN. This information is for reference only. No changes to the calibration values can be performed from this screen.

Service Menu

Items in the Covidien Service menu are specifically for qualified service personnel and are password protected. The password is 423213. The Service Menu button accesses settings for

- RF Output Test
- Touchscreen Calibration
- Energy Calibration
- Country Setup
- RFID Antenna Control

RF Output Test

The *RF Output Test Screen* is used to test the RF output of the generator. It allows a technician to output RF in a specified mode, to a specified energy channel, at a specified power level. While RF is output, the *RF Output Test Screen* displays the internal sensor readings of average power, RMS voltage, RMS current, impedance magnitude, impedance phase angle, REM impedance magnitude, and REM impedance phase angle.

Touchscreen Calibration

The Touchscreen Calibration screen allows the technician to calibrate the touchscreen. See the *Valleylab FT10 Energy Platform Service Manual* for more information.

Energy Calibration

The Energy Calibration screen allows the technician to calibrate the RF output. See the *Valleylab FT10 Energy Platform Service Manual* for more information.

Country Setup

The Country Setup screen allows the technician to identify in which country the generator is set up to operate. If this is the first time using the generator, the country code needs to be selected before the LigaSure/Bipolar energy channel will function. See the *First Time Setup Guide* for instructions on how to set the country code.

RFID Antenna Control

The RFID Antenna Control screen allows the technician to manually initiate an RFID scan of an instrument connected to the LigaSure receptacle.

Chapter 4

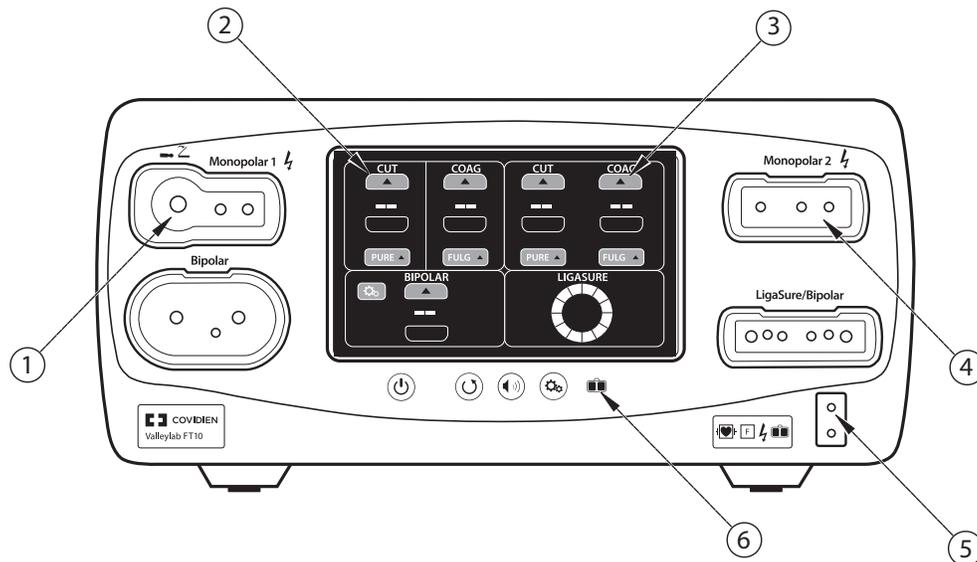
Monopolar

This chapter describes the Monopolar function of the VLFT10GEN.

Precaution

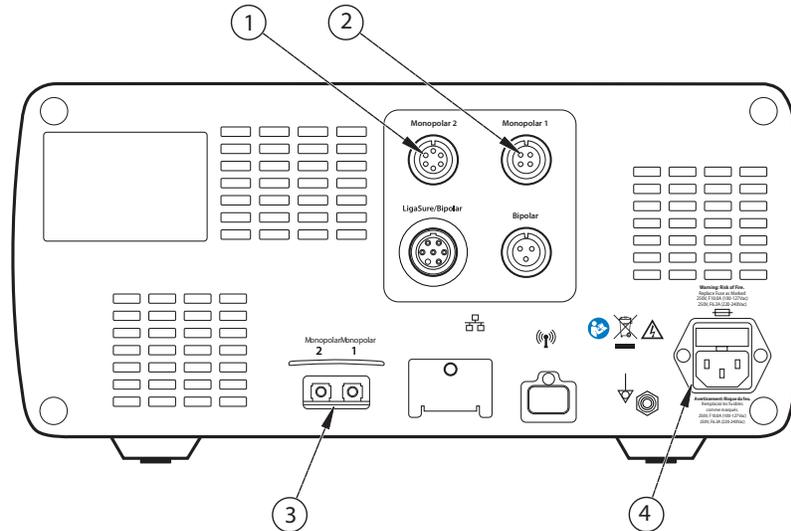
Read the instructions, warnings, and precautions provided with this energy platform and associated accessories before using. Specific instructions for electro-surgical instruments are not included in this manual.

Front Panel Monopolar Features



- ① Monopolar 1 Universal Foot Pedal Port (UFP) receptacle
- ② Monopolar 1 touchscreen quadrant
- ③ Monopolar 2 touchscreen quadrant
- ④ Monopolar 2 instrument receptacle
- ⑤ REM Patient return electrode receptacle
- ⑥ Return electrode monitoring (REM) indicator

Rear Panel Monopolar Features



- ① Monopolar 2 foot-pedal receptacle (requires adapter to connect standard four-pin monopolar foot pedal)
- ② Monopolar 1 foot-pedal receptacle
- ③ Interlink cable receptacle for EKG smoke-evacuation control devices
- ④ Power cord receptacle

Monopolar Quick Setup Instructions

If familiar with the VLFT10GEN, follow this abbreviated procedure to set up the system for monopolar surgery.

If more detailed instructions are required, refer to the following sections in this chapter for detailed instructions.

1. Plug the system power cord into the rear panel receptacle.
2. Plug the system power cord into a grounded power outlet.

Important

Do not plug the system power cord into a power strip or extension cord.

3. Turn on the energy platform and verify that the power-on self-test is successfully completed.
4. If using a foot pedal, connect it to a monopolar foot-pedal receptacle on the rear panel. The Monopolar 2 receptacle requires an adapter to connect a standard 4-pin monopolar foot pedal.

Warning

Use only Covidien foot pedals. Use of other manufacturer's foot pedals is not recommended; unexpected output may occur.

5. Apply the patient return electrode to the patient and connect it to the patient return electrode receptacle on the generator's front panel.
6. Connect the instrument to the appropriate instrument receptacle on the front panel. Align the connector pins with the dots below each Monopolar receptacle to ensure full functionality of the instrument. Inserting an instrument into the Monopolar 1 receptacle will require additional force.
7. Verify or change the mode and power settings in the corresponding quadrant of the touchscreen.

Monopolar Function Overview

Monopolar Power Output Modes

The monopolar energy channels can be configured to these modes: PURE CUT, BLEND, VALLEYLAB, SOFT, FULGURATE, and SPRAY.

Warning

Electric Shock Hazard

- Do not connect wet instruments to the system.
- Ensure that all instruments and adapters are correctly connected and that no metal is exposed at any connection point.

Connect instruments to the proper receptacle. Improper connection may result in inadvertent instrument activation or other potentially hazardous conditions. Follow the instructions provided with electro-surgical instruments for proper connection and use.

Each instrument receptacle on this energy platform is designed to accept only one instrument at a time. Follow the instructions provided with electro-surgical instruments for proper connection and use.

Precaution

Read the instructions, warnings, and precautions provided with electro-surgical instruments before use. Specific instructions are not included in this manual.

Inspect instruments and cords—especially for laparoscopic/endoscopic instruments—for breaks, cracks, nicks, and other damage before every use. If damaged, do not use. Damaged instruments or cords may result in injury or electrical shock to the patient or surgical team.

Important

Avoid switching rapidly between CUT and COAG with the monopolar handpiece controls as this may cause the generator to temporarily ignore the handpiece control. Release the handpiece control momentarily and then press it again to rectify this situation.

Foot Pedal

Monopolar foot pedals connect to the rear panel and correspond to either the Monopolar 1 or Monopolar 2 receptacles on the front panel.

Standard foot-pedal devices attached to the Monopolar 1 Universal Foot Pedal Port receptacle on the front panel can be controlled with a Covidien foot pedal attached to the Monopolar 1 foot-pedal receptacle on the back panel.

Precaution

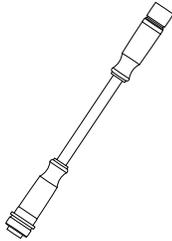
Connect only Covidien foot pedals. Using foot pedals from other manufacturers may cause equipment malfunction or patient injury. See the list of compatible Covidien foot pedals on page 1-8.

Monopolar Foot-Pedal Activation

All devices attached to the Monopolar 1 or Monopolar 2 receptacle—whether handswitching or foot-pedal-activated accessories—can be controlled with a foot pedal.

Standard monopolar foot pedals can be set up using compatible accessories:

- Pedal-activated instrument
- Two- or three-pedal foot pedal
- Foot-pedal adapter 1017577 for Monopolar 2 (shown below)



Setup:

1. Plug the two-pedal foot-pedal connector into the Monopolar 1 foot-pedal receptacle on the rear panel.
2. Plug a two-button pencil into the Monopolar 1 receptacle, or plug a pedal-activated instrument cord into the Universal Foot Pedal Port (UFP) portion of the Monopolar 1 receptacle (identified by a blue ring). A UFP adapter is required for UFP-instrument connectors that have a plug diameter less than 4 mm.
3. Attach a FT6003 three-pedal foot pedal or standard foot pedal with 6-pin-to-4-pin adapter 1017577 to the Monopolar 2 foot-pedal receptacle on the back panel.

Important

CUT and COAG foot-pedal activation is also available at this point for Force TriVerse™ instruments controlled by a two-pedal foot pedal.

4. Plug the two-button pencil or a Force TriVerse instrument into the Monopolar 2 receptacle.
5. Select settings for the procedure.
6. Step on the appropriate pedal to deliver monopolar power.

Return Electrodes – REM Contact Quality Monitoring System

Notice

Only contact-quality-monitoring-system patient return electrodes can be used with the VLFT10GEN.

Patient Return Electrode Considerations

Warning

It is not possible to foresee what combination of current and duty cycle may be safely used in every situation—for example, when higher currents and/or longer duty cycles are used on procedures such as tissue lesioning, tissue ablation, tissue vaporization; and procedures where conductive fluid is introduced into the surgical site. Under these conditions a greater risk may exist that the heating under a fully applied return electrode may be high enough to injure the patient.

When using a Covidien energy platform or a patient return electrode during these types of surgical procedures, the user should seek written guidance in the form of detailed user instructions from the manufacturer of the active accessory regarding the currents and duty cycles that can be expected. In some instances, the application of additional patient return electrodes may help mitigate the increased risk.

During monopolar electrosurgery, a patient return electrode is always required to safely recover the current that flows through the patient's body and return it to the energy platform. A reduction in surface area contact or poor conductivity between the patient and the return electrode can cause the current to become concentrated, potentially resulting in burns at the return-electrode site.

During a surgical procedure, the amount of current delivered in a given time determines the amount of heating that occurs under the return electrode. REM Polyhesive patient return electrodes are designed for use during conventional electrosurgical procedures and duty cycles (on time compared to off time). Users should consult Chapter 10, *Technical Specifications* for the recommended maximum duty cycle specifications.

How the REM System Works

The VLFT10GEN uses the REM contact-quality monitoring system to monitor the quality of electrical contact between the patient return electrode and the patient. The REM system is designed to reduce the risk of burns at the return electrode site. A non-REM return electrode is not to be used with the VLFT10GEN.

The REM system continuously measures the resistance at the return electrode site and compares it to a standard range of safe resistance (between 5 Ω and 135 Ω), thus eliminating intermittent false alarms that could result from small changes in resistance.

The REM system also adapts to individual patients by measuring the initial contact resistance between the patient and the patient return electrode and lowering the baseline resistance if the contact resistance drops.

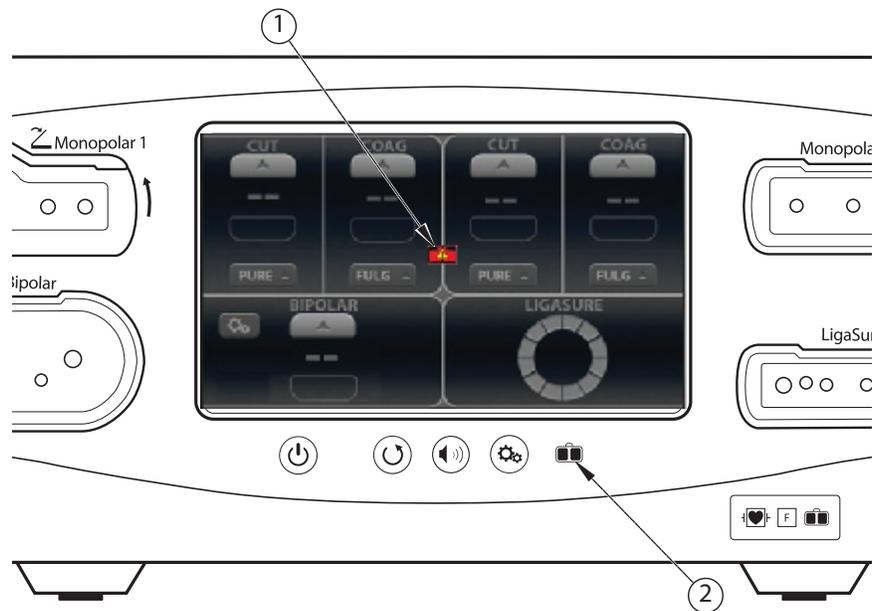
A REM alarm sounds and the system stops producing output power when **either** of the following occurs:

- The measured resistance is below 5 Ω or above 135 Ω , the limits of the standard range of safe resistance.
- An increase in contact resistance is greater than 40% from the baseline measurement.

Patient Return Electrode Setup



The REM icon appears on the main screen each time the FT10 system is started. When the power-on self-test is complete, the icon remains if a REM return electrode is not connected to the energy platform or incorrectly attached to a patient. The icon is removed when the return electrode is correctly attached to the system and patient.



① REM icon

② REM LED indicator

A REM indicator, located below the touchscreen also displays the status of the return electrode by illuminating red when not connected or improperly applied to the patient.

The REM indicator illuminates green when the system senses that the patient return electrode is properly connected to the energy platform and patient.

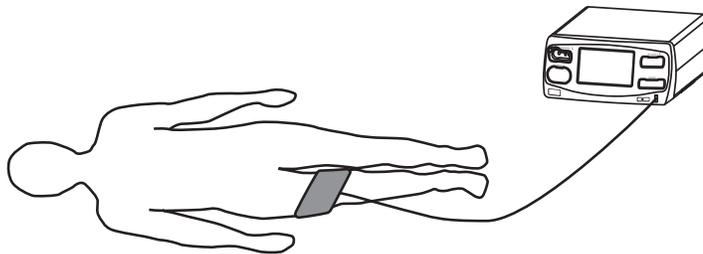
Warning

The safe use of monopolar electrosurgery requires proper placement of the patient return electrode. To avoid electrosurgical burns beneath the patient return electrode, follow all directions on the product package and the instructions for use for proper return electrode placement and use.

Warning

Do not cut a patient return electrode to reduce its size. Patient burns due to high-current density may result.

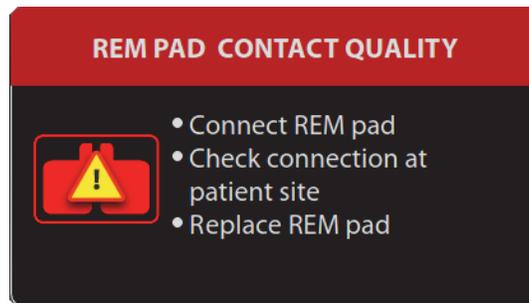
1. Select a well vascularized, convex area in close proximity to the surgical site for electrode application. Avoid scar tissue, bony prominences, excessive adipose tissue, and areas where fluid may pool.
2. The patient return electrode site should be free of excessive hair. Remove hair from the selected application site in accordance with the policies and procedures of your facility.
3. Clean and dry the application site as needed. The application site must be free of oils, lotions, and other topically applied products to ensure secure contact between the patient's skin and the return electrode.
4. Remove the return electrode from its pouch.
5. Remove the liner from the electrode and apply it to the patient.
6. Turn on the generator and allow it to complete the self test.
7. Insert the return-electrode connector into the REM patient return electrode receptacle on the front panel. See page 4-2 for the receptacle location.



REM Alarm (Visual and Audible)

If the REM system senses an alarm condition during the activation of an instrument, RF power delivery stops. An error message is displayed on the touchscreen and two audible warnings sound. The indicator below the screen illuminates red.

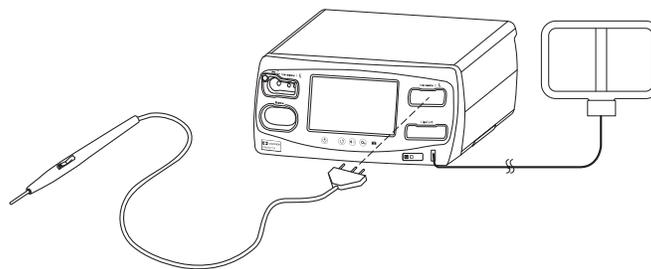
When the alarm condition has been corrected, the error message closes and the REM LED illuminates green.



For instructions to correct REM alarms, refer to Chapter 8, *Troubleshooting* and the troubleshooting flow chart in the REM Polyhesive patient return electrode instructions for use.

Monopolar Electrodes

Connect a monopolar instrument to the Monopolar 1 or Monopolar 2 instrument receptacle on the front of the energy platform. See the Covidien instrument's instructions for use for recommendations on which receptacle to use.



The Monopolar 1 UFP receptacle, identified by a blue ring, accepts connectors of various sizes when coupled with the E05021 and E050212 UFP adapters. UFP connectors can vary in diameter from 3 mm to 8 mm plugs. UFP plugs with diameters less than 4 mm require an adapter to connect to the Monopolar 1 UFP receptacle.

If a two-button instrument is connected to the energy platform, proceed to the *Standard Monopolar Mode Functionality* section that follows.

If a VALLEYLAB-mode enabled three-button instrument is connected to the energy platform, proceed to *VALLEYLAB Mode Functionality* on page 4-12.

Standard Monopolar Mode Functionality

Monopolar settings can be selected for an instrument by three methods:

- **User Input** - Modes and power levels are selected before attaching the instrument.
- **Automatic** - Settings are selected by the system when an attached instrument is identified. Most Automatic settings override Preset settings.
- **Restore Settings** - Using the Restore Settings button to reset the system to the settings in use when the system was last powered down.

User Input Instrument Settings

Monopolar settings can be preset on the main screen of the energy platform before or after inserting an instrument. The settings will be in effect when the instrument is attached to the Monopolar 2 receptacle unless the FT10 detects an instrument type that includes automatic settings.

1. Place the energy platform in the edit state (power on, no instrument attached).
2. Manually select a mode and power-output level for a monopolar instrument from the touch screen.
3. Attach an instrument to the monopolar receptacle that corresponds to the edited quadrant (left for Monopolar 1 and right for Monopolar 2). Inserting an instrument into the Monopolar 1 receptacle will require additional force.

The pre-set settings are active for the attached instrument only if the instrument does not include automatic settings.

Automatic Settings for a Recognized Instrument

Some Covidien instruments compatible with the FT10 have an identification that is recognized by the system when attached to the Monopolar 2 receptacle. The energy platform automatically sets the default mode and power level assigned to the instrument. These settings are displayed on screen. Settings can be changed prior to activation.

Note: Inserting a monopolar instrument that is not recognized by the system will result in the existing settings for a two-button pencil. If the settings have been manually changed prior to insertion or the Restore Settings button was used, those settings remain in effect.

Monopolar Default Settings

Monopolar Instrument	Default
Two-button Pencil	PURE CUT (CUT mode) and FULGURATE (COAG mode)
	Power setting defaults to disabled (-)
Force TriVerse	PURE CUT, VALLEYLAB, COAG
	Power setting is 1 power bar
	CUT mode is on (enabled)

Restore to the Last Settings Used

Use the Restore button to enter the settings when the system was last powered down. The Restore button can be used prior to and after insertion of the instrument.

1. Press the **Restore** button. A dialog box appears indicating the current settings will be replaced with those from the last time the energy platform was powered down.
 - All quadrants are populated with previous settings for each.
2. Press **OK** to confirm the use of the last settings
 - Inserting an instrument highlights the corresponding quadrant.

VALLEYLAB Mode Functionality

Covidien instruments featuring the VALLEYLAB mode—a unique combination of hemostasis and dissection—are specialty devices providing output control from the sterile field. Some have a sliding power control on the instrument that enables direct adjustments to power output during surgery.

These output modes, if available on the instrument, are selected at the handset with the following buttons:

- The yellow CUT button enables a cutting function.
- The clear VALLEYLAB button enables a hemostasis function while providing dissection.
- The blue COAG button enables a coagulation function.

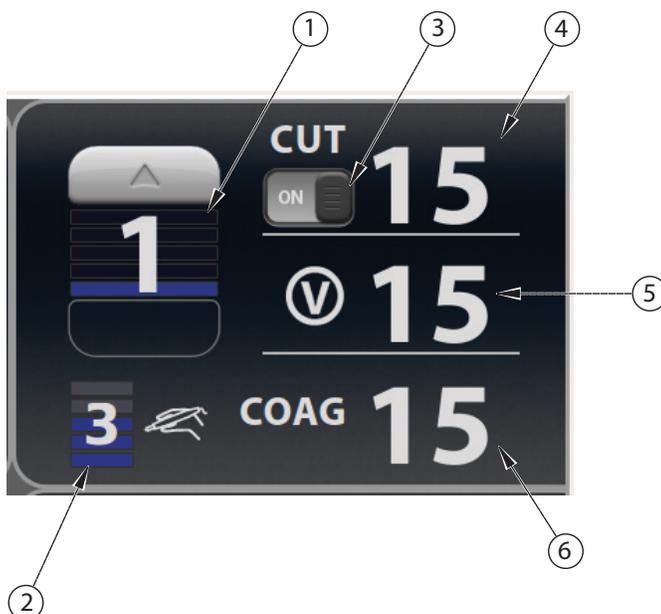
If available on the instrument, a dual slider control adjusts power output in all available modes.

Note: Monopolar 1 does not support VALLEYLAB mode and Force TriVerse.

Note: When a Force TriVerse instrument is inserted, the screen changes from the default two-button instrument display to the Force TriVerse edit state in which the screen brightens and controls are highlighted.

When an instrument with VALLEYLAB-mode capability is attached to the Monopolar 2 receptacle, the energy platform detects the instrument type and changes the screen from the default two-button to the corresponding screen.

Force TriVerse Screen



- ① Power bar indicator
- ② Slider position indicator
- ③ CUT mode ON/OFF switch
- ④ CUT mode power indicator (watts)
- ⑤ VALLEYLAB mode power indicator (watts)
- ⑥ COAG mode power indicator (watts)

Power Bars—The five power bars represent the range of power available for the instrument attached to the energy platform receptacle. The system automatically identifies the instrument and selects the default power-bar setting. The power bars represent power *available* to the instrument and can be set independently from the slider bars indicated in the slider-position indicator. Power bars can only be changed at the touchscreen interface on the energy platform.

Note: Refer to the individual instrument instructions for power-bar output in watts.

ON/OFF Switch for CUT—Enable or disable CUT. CUT will not be available from the yellow button on the instrument when disabled on the touchscreen.

Slider Position (if available on the instrument)—The energy platform detects the position of the instrument's slider switch, and the slider position indicator displays this position. Slider position can only be changed by the instrument user in the sterile field.

Using a VALLEYLAB-Mode Instrument

1. Select the desired power level by touching the up and down arrows on the power-output mode. A brief double tone sounds. Power output is displayed in watts. The power level cannot be changed during instrument activation.

Warning

The power-selecting slider, if available on the instrument, increases and decreases power output. Verify the slider position prior to activation.

2. Activate power output by pressing the desired button on the instrument.
 - Activate the CUT mode by pressing the yellow button on the electro-surgical instrument. The CUT display illuminates yellow and a tone sounds for the duration of the activation.
Note: CUT mode is not available when disabled on the touchscreen with the ON/OFF switch.
 - Activate the VALLEYLAB mode by pressing the clear button on the electro-surgical instrument. The VALLEYLAB display illuminates white and a tone sounds for the duration of the activation. VALLEYLAB mode can also be activated with the middle (white) pedal of the FT6003 Three-Pedal Footswitch.
 - Activate the COAG mode by pressing the blue button on the electro-surgical instrument. The COAG display illuminates blue and a tone sounds for the duration of the activation.
3. If the instrument has a slider, the power output can be changed while in the sterile field by adjusting the slider position on the electro-surgical instrument. A double tone will sound when slider position is changed. Slider position cannot be changed while RF energy is being delivered.

CUT Mode Disable (Force TriVerse only)

Power output can be disabled in the CUT mode using the ON/OFF switch.

1. Disable the CUT mode by touching the screen ON/OFF selector below CUT. The power level is grayed out when disabled.
2. Enable the CUT mode by touching the ON/OFF switch below CUT on the screen. The CUT box will display the power setting of the instrument slider position. The CUT mode is also re-enabled when the energy platform is restarted.

After Surgery

Disconnect the instruments

1. Turn off the energy platform.
2. Disconnect all instruments from the front panel.
3. Dispose of the instrument according to the procedures for your institution.
4. Disconnect and store any foot pedals used.
5. Disconnect the power plug from the wall receptacle by pulling the plug, not the cable.

Chapter 5

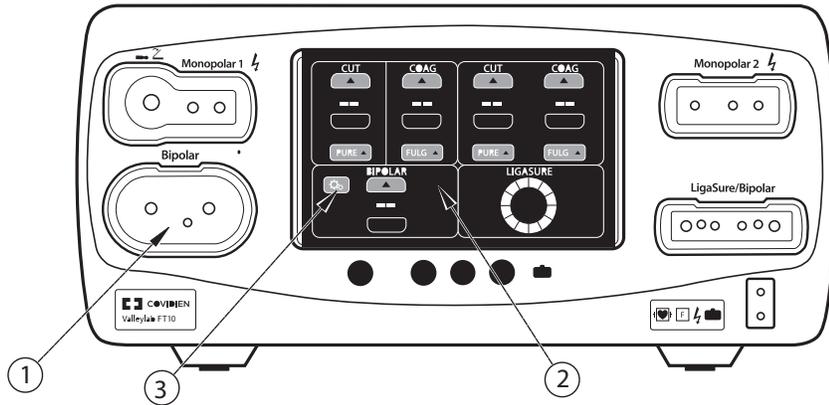
Bipolar

This chapter describes the Bipolar function of the VLFT10GEN.

Precaution

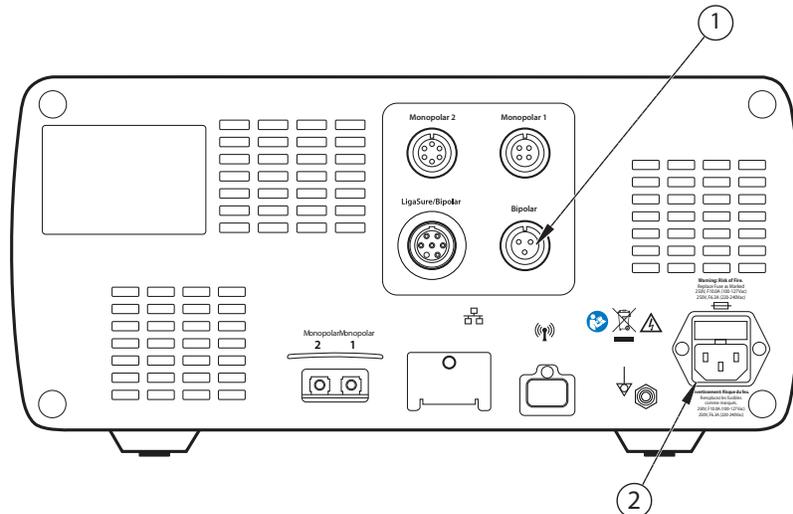
Read the instructions, warnings, and precautions provided with this energy platform and associated accessories before using. Specific instructions for electro-surgical instruments are not included in this manual.

Front Panel Bipolar Features



- ① Bipolar receptacle
- ② Bipolar touchscreen quadrant
- ③ Bipolar settings button

Rear Panel Bipolar Features



- ① Bipolar foot-pedal receptacle
- ② Power cord receptacle

Bipolar Quick Setup Instructions

If you are familiar with the VLFT10GEN, follow this abbreviated procedure to set up the system for bipolar surgery.

If you are not familiar with the VLFT10GEN, refer to the following sections in this chapter for detailed instructions.

1. Plug the system power cord into the rear panel receptacle.
2. Plug the system power cord into a grounded wall receptacle.

Important

Do not plug the system power cord into a power strip or extension cord.

3. Turn on the system and verify that the power-on self-test successfully completes.
4. If using a foot pedal, connect it to the Bipolar foot-pedal receptacle on the rear panel.

Warning

Use only Covidien foot pedals. Use of other manufacturer's foot pedals is not recommended; unexpected output may occur.

5. Connect the instrument to the Bipolar instrument receptacle on the front panel.
6. Verify or change the mode and power settings.

Bipolar Function Overview

Delicate tissue requires less energy to desiccate. The VLFT10GEN provides low-voltage, continuous current for faster desiccation without sparking.

The possibility of sparking increases as desiccated tissue becomes more resistant to energy flow. The system protects against sparking by limiting the bipolar voltage at relatively high levels of tissue impedance.

Bipolar Power Output Modes

The VLFT10GEN produces one Bipolar mode with three possible effects: LOW (1-15 watts), MEDIUM (15–40 watts), and HIGH (45-95 watts).

Warning

Electric Shock Hazard

- Do not connect wet instruments to the energy platform.
- Ensure that all instruments and adapters are correctly connected and that no metal is exposed at any connection point.

Connect instruments to the proper receptacle. Improper connection may result in inadvertent instrument activation or other potentially hazardous conditions. Follow the instructions provided with electro-surgical instruments for proper connection and use.

The instrument receptacles on this system are designed to accept only one instrument at a time.

Precaution

Read the instructions, warnings, and precautions provided with electro-surgical instruments before use. Specific instructions are not included in this manual.

Inspect instruments and cords—especially for laparoscopic/endoscopic instruments—for breaks, cracks, nicks, and other damage before every use. If damaged, do not use. Damaged instruments or cords may result in injury or electrical shock to the patient or surgical team.

Bipolar Default Settings

Output	Default
Bipolar	<ul style="list-style-type: none">• LOW effect• Power—disabled (--)• Ammeter—off

Foot Pedal

The VLFT10GEN in Bipolar mode can accommodate a three-pin, single-pedal bipolar foot pedal.

If pedal activation is to be used with a bipolar instrument, attach the bipolar foot-pedal connector to the Bipolar foot-pedal receptacle on the rear panel.

Warning

Use only Covidien foot pedals. Use of other manufacturer's foot pedals is not recommended; unexpected output may occur.

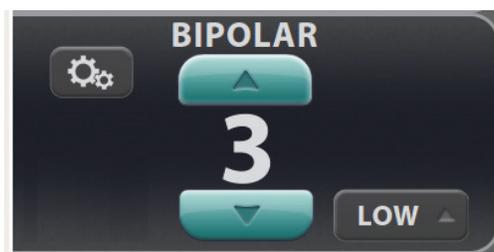
Virtual Ammeter

The virtual ammeter on the bipolar quadrant displays the current delivered during bipolar-instrument activation. The ammeter registers current between 1 and 1,000 milliamps. An audio tone sounds to indicate increases and decreases in current delivery.

Setting the Ammeter

To setup the ammeter to display during Bipolar procedures:

1. Access Bipolar settings by touching the settings button in the Bipolar quadrant. The Bipolar Settings window appears with the ammeter default setting OFF.



2. Touch the ammeter **ON/OFF** switch to enable the visual ammeter and audio ammeter tones for Bipolar procedures.



3. Touch **OK** to close the ammeter settings window and retain any changes. The visual ammeter is added to the Bipolar screen and the audio and visual feedback is in use during Bipolar activation.

Ammeter settings are retained in the Bipolar quadrant until the system is powered down.

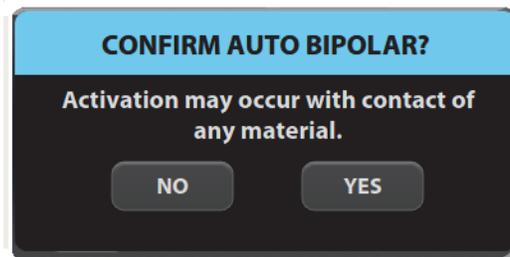
Auto Bipolar Function

The VLFT10GEN is equipped with an Auto Bipolar feature that configures the system for automatic activation and cessation of bipolar energy.

Auto Bipolar must be enabled in the feature menu before the Auto Bipolar function can be used as the default setting is OFF.

Enable/Disable Auto Bipolar

1. Access Bipolar settings by touching the settings button in the Bipolar quadrant. The Bipolar settings appear with the default Auto Bipolar setting OFF
2. Touch the AUTO **ON/OFF** switch.
3. A confirmation screen appears over the Bipolar quadrant. Touch **Yes** to enable, or **No** to reject.

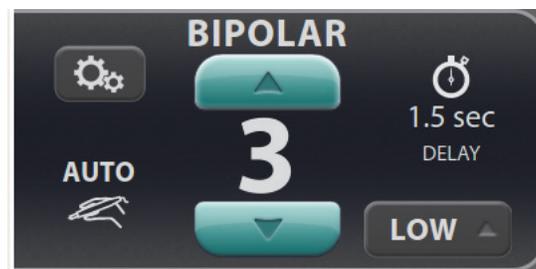


When confirmed, the Bipolar settings reappear with Auto Bipolar set to ON.

Important

When Auto Bipolar is turned ON, the ammeter setting option disappears. If the ammeter was ON before, it will automatically be turned OFF.

4. Set the Auto Bipolar activation delay and touch **OK**. The Bipolar quadrant shows the Auto Bipolar symbol and the delay time (if greater than 0 seconds) to indicate that Auto Bipolar is ON.



Auto Bipolar Activation Impedance

The impedance of the tissue grasped by the bipolar device must be within a factory-set range of up to 2200 Ω to activate. If impedance during activation increases to greater than 4000 Ω , RF energy will deactivate. The activation impedance range is a safety feature that prevents power delivery if the grasped tissue is not within the anticipated range.

Tissues such as scar tissue, moles, and others with low blood flow are likely to have impedance greater than 2200 Ω . While grasping high-impedance tissue, the Valleylab FT10 will not activate regardless of customer-set preferences.

Warning

Use of different Covidien cord models or cords from other manufacturers may not achieve proper electrical output for this device, thereby failing to produce the desired clinical effect. For example, Auto Bipolar activation/deactivation settings may not work properly using cords other than those specified by Covidien.

Setting the Auto Bipolar Activation Delay

Specify a delay between the instrument's initial contact with tissue and delivery of bipolar energy.

1. When Auto Bipolar is ON, access the activation delay settings by touching the settings button in the Bipolar quadrant
2. Use the up or down arrows to set the activation delay time (in seconds). Delay selections are 0.0 (default), 0.5, 1.0, 1.5, 2.0, and 2.5 sec.



3. Touch **OK** to close the window and save the delay setting. If the delay selected is greater than 0.0 seconds, the delay time will be displayed in the bipolar quadrant.

Precaution

Do not use the FT0501 ForceTriad Bipolar Adapter with Auto Bipolar on the VLFT10GEN.

Important

The tines of the bipolar instrument must be removed from the tissue between each Auto Bipolar activation.

Shutting Down Bipolar Functions

The Auto Bipolar settings can be exited quickly to change non-setting controls in response to the surgeon's needs. Any of the following actions closes the window and reopens it with the last saved settings.

- Touch the screen outside the settings window
- Activate RF energy by an instrument
- Select **Cancel**
- Select a system control
- Time out after 10 seconds
- Activate any mode
- Connect a bipolar instrument
- Remove a bipolar instrument

When an instrument is unplugged from the Bipolar receptacle, the display reverts to the last set values.

After Surgery

Disconnect the instruments

1. Turn off the energy platform.
2. Disconnect all instruments from the front panel.
3. Dispose of the instrument according to the procedures for your institution.
4. Disconnect and store any foot pedals used.
5. Disconnect the power plug from the wall receptacle by pulling the plug, not the cable.

Chapter 6

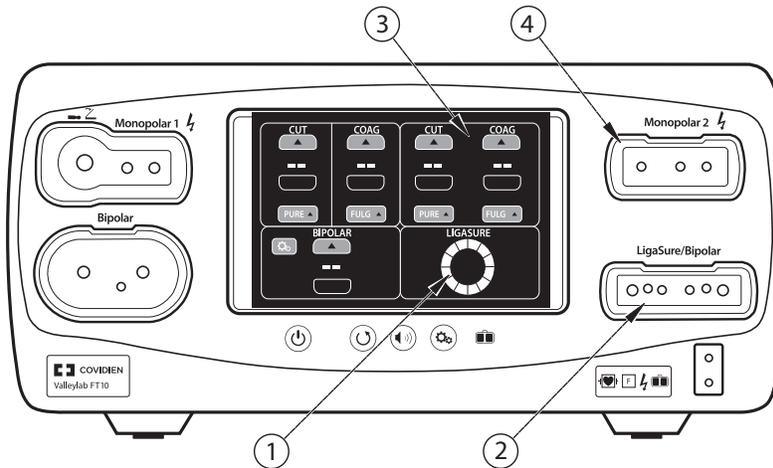
LigaSure

This chapter describes how to set up and operate the LigaSure tissue-fusion function of the VLFT10GEN.

Precaution

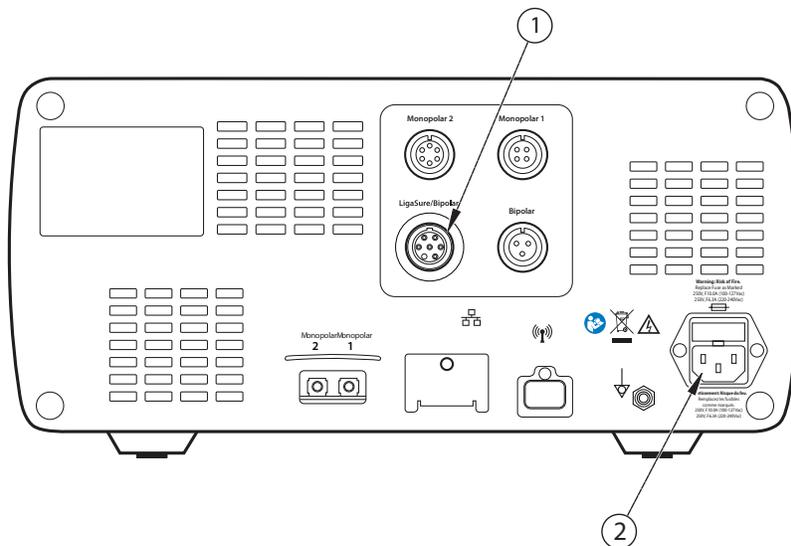
Read the instructions, warnings, and precautions provided with this energy platform and associated accessories before using. Specific instructions for electro-surgical instruments are not included in this manual.

Front Panel LigaSure Features



- ① LigaSure quadrant
- ② LigaSure/Bipolar receptacle
- ③ Monopolar 2 quadrant (for LigaSure dual-plug instruments)
- ④ Monopolar 2 receptacle (for LigaSure dual-plug instruments)

Rear Panel LigaSure Features



- ① LigaSure/Bipolar foot-pedal receptacle
- ② Power cord receptacle

LigaSure Quick Setup Instructions

If you are familiar with the VLFT10GEN, follow this abbreviated procedure to setup the system for LigaSure tissue fusion.

The following instructions are for a single-plug instrument, which covers most LigaSure devices. For devices that have two plugs and provide both LigaSure and monopolar functionality, see *Connecting Dual-Plug LigaSure Instruments* on page 6-8.

If you are not familiar with the VLFT10GEN, refer to the following sections in this chapter for detailed instructions.

1. Plug the system power cord into the rear panel receptacle.
2. Plug the system power cord into a grounded wall receptacle.

Important

Do not plug the system power cord into a power strip or extension cord.

3. Turn on the system and verify that the power-on self-test has successfully completed.
4. If using a foot pedal, connect it to the LigaSure/Bipolar foot-pedal receptacle on the rear panel.
5. Connect the instrument to the LigaSure/Bipolar instrument receptacle on the front panel.

LigaSure Function Overview

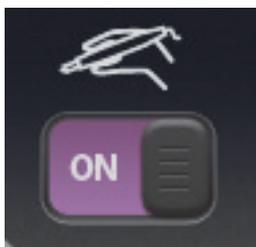
LigaSure tissue fusion can be used on arteries, veins, and lymphatics, up to and including, 7 mm in diameter and tissue bundles. This system provides precise energy delivery and electrode pressure to tissues for a controlled time period to achieve a complete and permanent fusion of tissues and vessel lumens. The system has been designed to produce minimal sticking, charring, or thermal spread to adjacent tissue.

There are no editable parameters in the LigaSure quadrant.



During instrument activation, the progress wheel in the LigaSure display control panel illuminates, and a tone sounds for the duration of energy delivery.

Some instruments cause the hand-activation ON/OFF switch to appear on the control panel when the instrument is recognized.



Important

If using an instrument that causes the hand-activation button to appear on the LigaSure control panel, see *Hand-Activation ON/OFF Switch* on page 6-9.

LigaSure Default Settings

Output or Instrument	Default
LigaSure	Handswitching—enabled (On)
LF5544 Pistol Grip	<ul style="list-style-type: none"> • MONOPOLAR mode—VALLEYLAB <ul style="list-style-type: none"> – 15 W
LF5637 and LF5644	<ul style="list-style-type: none"> • MONOPOLAR mode—VALLEYLAB • Monopolar power <ul style="list-style-type: none"> – CUT—15 W – VALLEYLAB—15 W – COAG—15 W

LigaSure/Bipolar Receptacle

The LigaSure/Bipolar receptacle is located adjacent to the lower-right quadrant of the screen. This receptacle accepts LigaSure instruments and can read bar codes on the RFID chip or the LigaSure connector.

Warning

Electric Shock Hazard

- Do not connect wet instruments to the energy platform.
- Ensure that all instruments are correctly connected and that no metal is exposed at any connection point.

Connect instruments to the proper receptacle. Improper connection may result in inadvertent instrument activation or other potentially hazardous conditions. Follow the instructions provided with LigaSure instruments for proper connection and use.

Each instrument receptacle on the energy platform is designed to accept only one instrument at a time. Follow the instructions provided with electro-surgical instruments for proper connection and use.

Precaution

Read the instructions, warnings, and precautions provided with LigaSure instruments before use. Specific instructions are not included in this manual.

Inspect instruments and cords—especially for laparoscopic/endoscopic instruments—for breaks, cracks, nicks, and other damage before every use. If damaged, do not use. Damaged instruments or cords may result in injury or electrical shock to the patient or surgical team.

Foot Pedal

A single-pedal LigaSure foot pedal can be used when the energy platform is using the LigaSure quadrant.

LigaSure Instruments

Reusable-Instrument Assembly

To prepare the reusable LigaSure instruments for use in a procedure, refer to the following steps for the general preparation. To find detailed directions for each instrument, refer to the individual instrument instructions that accompany the instrument electrode.

1. Slip the base of the disposable electrode's white shaft onto the retaining post on the instrument ring handle.
2. Attach the body of the electrode shaft to the instrument handle. The white shaft of the electrode must be completely flush with the reusable-instrument shaft.
3. Attach each electrode to the appropriate instrument jaw, matching electrode curvature to jaw curvature. Insert the proximal pin first. Verify that there is no gap between the electrode and the instrument jaw.

Important

Bent or broken electrode pins will not function properly and may result in an alert situation. In this case, the electrode must be discarded.

4. Gently ratchet the instrument closed on a folded 4" x 4" gauze pad to ensure the electrodes are properly seated in the instrument jaws.

Connecting LigaSure Instruments to the Energy Platform

Connect the LigaSure instrument's purple connector to the LigaSure/Bipolar receptacle on the front panel of the VLFT10GEN. The system detects and sets the appropriate settings.

Other than the handswitching ON/OFF switch, there are no editable settings in the LigaSure quadrant.

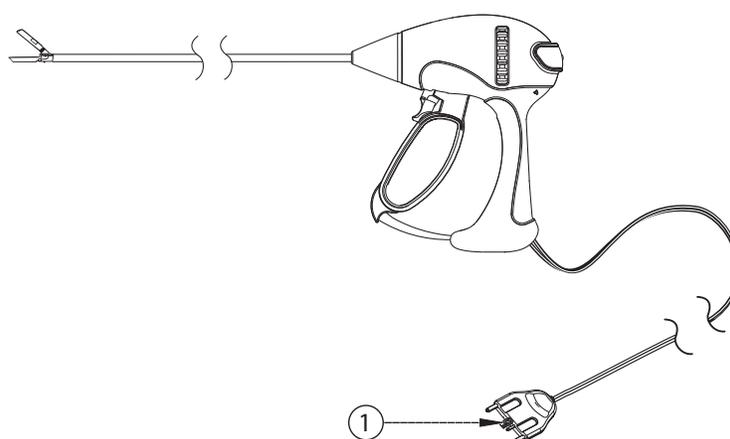
If applicable, refer to the following sections:

- *Hand-Activation ON/OFF Switch* on page 6-9
- *Invalid Instrument* on page 6-9

Connecting Single-Plug LigaSure Instruments

There are multiple instrument designs, but the general LigaSure-instrument connection process is the same for LigaSure instruments with a single purple LigaSure connector. For devices that have two plugs and provide both LigaSure and monopolar functionality, see *Connecting Dual-Plug LigaSure Instruments* on page 6-8.

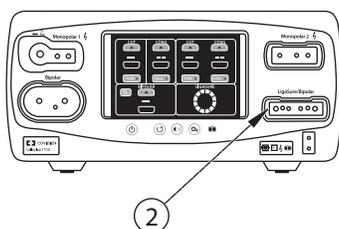
Setup for LigaSure Instruments with a Single Connector



- ① LigaSure purple connector

Setup

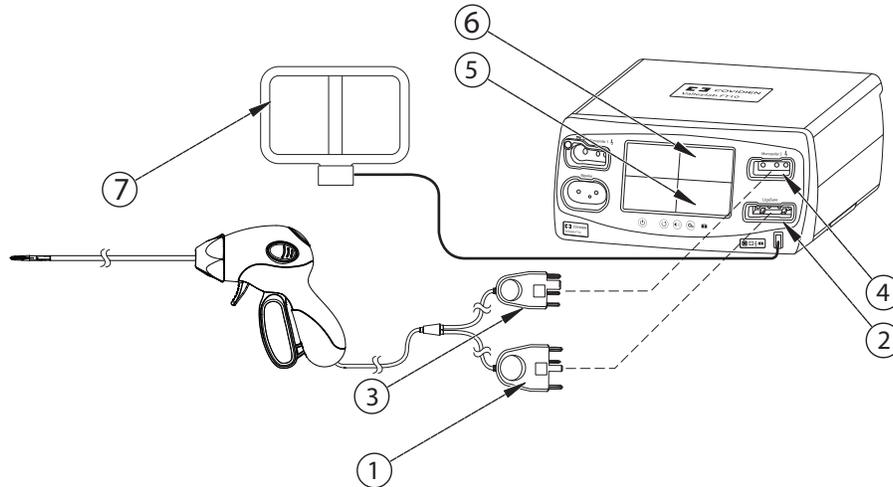
1. With the bar code on the purple connector **(1)** facing up, firmly insert it into the LigaSure/Bipolar receptacle **(2)** on the energy platform front panel.



- ② LigaSure/Bipolar receptacle

2. The energy platform detects the instrument type and selects the intensity setting. The settings cannot be changed.

Connecting Dual-Plug LigaSure Instruments



- ① LigaSure connector (purple)
- ② LigaSure/Bipolar instrument receptacle
- ③ Monopolar connector (blue)
- ④ Monopolar 2 instrument receptacle
- ⑤ LigaSure touchscreen quadrant
- ⑥ Monopolar 2 touchscreen quadrant
- ⑦ REM patient return electrode

Setup

1. With the bar code on the purple LigaSure connector **(1)** facing up, firmly insert it into the LigaSure/Bipolar receptacle **(2)** next to the LigaSure touchscreen quadrant **(5)**.
2. With the bar code on the blue Monopolar connector **(3)** facing up, firmly insert it into the Monopolar 2 receptacle **(4)** next to the Monopolar 2 quadrant **(6)**.

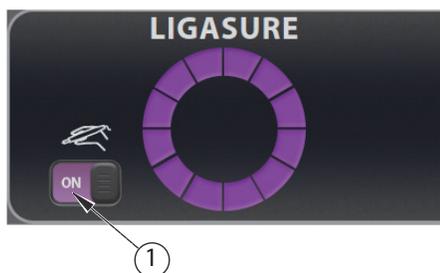
The energy platform reads the information from the two connectors and sets the power output accordingly:

- **LigaSure** – Power output is selected automatically and cannot be changed from the LigaSure touchscreen.
- **Monopolar** – Power output is set to the default values and can be edited in the Monopolar 2 quadrant.

Hand-Activation ON/OFF Switch

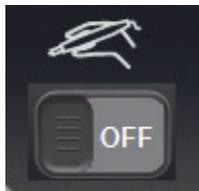
Some LigaSure instruments cause the hand-activation icon to appear in the lower left corner of the LigaSure control panel. The hand-activation switch toggles between the ON and OFF setting.

For example, the LF1212 Curved, Small Jaw, Open Sealer/Divider, is a LigaSure instrument that can be used with hand-activation on or off. When hand-activation is off, a foot pedal is used to initiate energy delivery.



① Hand activation enabled

In this example, the enabled hand activation appears in the lower-left corner of the LigaSure quadrant. Touching the **ON/OFF** switch turns off the hand activation, requiring the use of a foot pedal.



Invalid Instrument

If the VLFT10GEN does not recognize the attached instrument, a pop-up will display the words "INVALID INSTRUMENT." Refer to the following steps to resolve the issue.

1. Confirm that a LigaSure instrument is in use.
2. Reconnect the instrument using firm pressure to insert the instrument into the LigaSure/Bipolar instrument receptacle.
3. If "INVALID INSTRUMENT" continues to appear in the status bar, use a new LigaSure instrument or electrode.

Activating the LigaSure Instrument

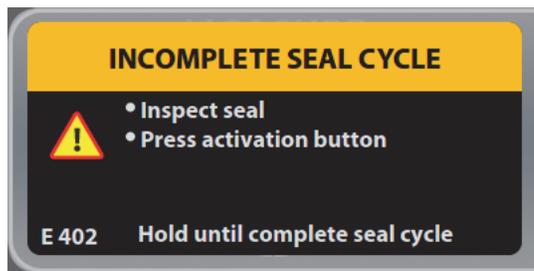
1. Fully grasp the target tissue in accordance with the LigaSure instrument's IFU.
2. Activate the LigaSure instrument either by pressing and holding the activation button on the instrument or by depressing the foot pedal. During instrument activation, the LigaSure quadrant of the display illuminates purple and rotates clockwise, and an activation tone sounds for the duration of energy delivery.
3. When the end tone sounds, release the activation button or foot pedal. In the case of an alert condition, refer to the following section.
4. Inspect the vessel or tissue prior to cutting by releasing the tissue from between the instrument jaws.

Alert Situations

A four-pulsed tone will sound when an alert condition occurs, and the LigaSure quadrant will display an alert message with a list of corrective actions. When an alert condition occurs, energy delivery is interrupted, but is available immediately after correcting the alert condition.

Incomplete Seal Cycle - Interrupted

The seal cycle was interrupted before completion. The handswitch or foot pedal was released before the end tone activated.



If this message appears the user should

1. Release the foot pedal or handswitch button.
2. Open the instrument jaws and inspect for a successful seal.
3. If the seal is incomplete, regrasp the tissue (with the jaws in the same position or overlapping the first seal, if possible).
4. Reactivate the seal cycle.

Incomplete Seal Cycle - Short

The generator detected a short circuit between the LigaSure jaws—possibly due to contact with a metal object or excess fluid around the surgical site.



If this message appears the user should

1. Release the foot pedal or handswitch button.
2. Check for metal clips or staples.
3. Reposition the instrument to avoid contact with metal.
4. Remove excess fluids from the surgical site.
5. Reactivate the seal cycle.

Incomplete Seal Cycle - Open Circuit

The LigaSure jaws were not fully closed or the grasped tissue was too thin.



If this message appears, the user should

1. Release the foot pedal or activation button.
2. Open the instrument jaws and inspect for a successful seal.
3. Clean and dry the LigaSure jaws.
4. If possible, regrasp thicker tissue.
5. Fully close the instrument jaws.
6. Reactivate the seal cycle.

Incomplete Seal Cycle - Time Out

Additional time and energy are needed to complete the seal cycle.



If this message appears, the user should

1. Release the foot pedal or activation button.
2. Open the instrument jaws and inspect for a successful seal.
3. Remove excess fluids from the surgical site.
4. Clean and dry the LigaSure jaws.
5. Regrasp the tissue.
6. Reactivate the seal cycle.

After Surgery

Disconnect the instruments

1. Turn off the energy platform.
2. Disconnect all instrument cords from the front panel.
 - If the instrument is single-use only (disposable), dispose of it according to the procedures for your institution.
 - If the instrument is reusable, clean and sterilize it according to the manufacturer's instructions for use.
3. Disconnect and clean the foot pedal (if used) according to the instructions for use.
4. Disconnect the power plug from the wall receptacle by pulling the plug, not the cable.

Chapter 7

Bipolar Resection

This chapter describes how to set up and operate the Bipolar Resection application on the energy platform.

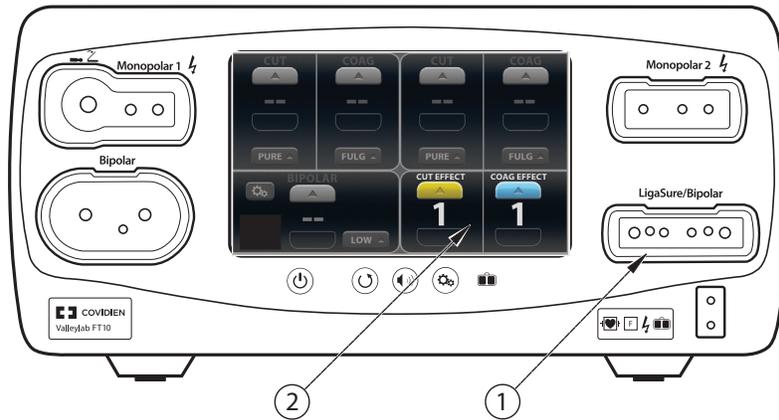
For information about setting up and using the Bipolar Resection application, refer to these documents:

- This chapter.
- *ForceTriad Bipolar Resection Footswitch Instructions for Use* (FT6009) - Instructions for the only foot pedal that supports Bipolar Resection mode.
- *ForceTriad Bipolar Resection Cord Instructions for Use* (FT0021S or FT0022W) - Instructions for the two types of cords supported for use with supported Bipolar Resection instruments. Also contains a list of supported Bipolar Resection instruments.

Precaution

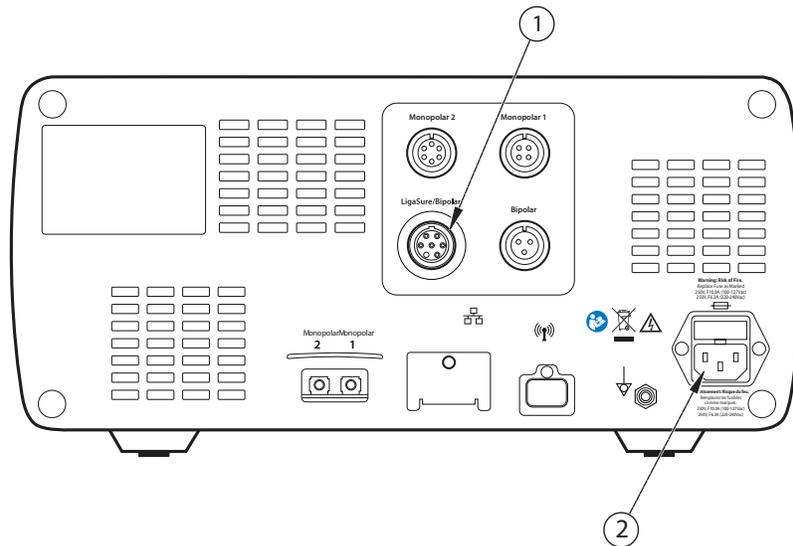
Read the instructions, warnings, and precautions provided with this energy platform and associated accessories before using. Specific instructions for electro-surgical instruments are not included in this manual.

Front Panel Bipolar Resection Features



- ① LigaSure/Bipolar receptacle
- ② Bipolar Resection quadrant (appears upon insertion of Bipolar Resection instrument)

Rear Panel Bipolar Resection Features



- ① LigaSure/Bipolar foot-pedal receptacle
- ② Power cord receptacle

Bipolar Resection Function Overview

Certain urology and gynecology procedures use resection electrodes in a saline environment requiring high bipolar-power outputs to obtain resection and hemostasis performance.

Bipolar Resection function provides two different effect modes:

- CUT effect for resection, activated by the yellow (left) foot pedal
- COAG effect for desiccation, activated by the blue (right) foot pedal

When a compatible Bipolar Resection cord is plugged into the LigaSure/Bipolar receptacle on the front panel, the Bipolar Resection screen appears in the LigaSure quadrant.



The Bipolar Resection screen has controls for both CUT and COAG modes. The effect setting may be adjusted for either mode from 1 to 6—1 being the minimum effect for the selected mode. During instrument activation, the Bipolar Resection screen illuminates brightly as yellow for CUT and blue for COAG. A tone sounds for the duration of energy delivery.

LigaSure/Bipolar Receptacle

The LigaSure/Bipolar receptacle accepts both LigaSure and Bipolar Resection instruments. The connector recognizes codes from an instrument's RFID chip or bar codes printed on the connector.

Bipolar Resection Default Settings

Output or Instrument	Default
Bipolar Resection	<ul style="list-style-type: none">• CUT effect—1• COAG effect—1

Warning

Electric Shock Hazard

- Do not connect wet instruments to the energy platform.
- Ensure that all instruments are correctly connected and that no metal is exposed at any connection point.

Connect instruments to the proper receptacle. Improper connection may result in inadvertent instrument activation or other potentially hazardous conditions. Follow the instructions provided with Bipolar Resection instruments for proper connection and use.

The instrument receptacles on this system are designed to accept only one instrument at a time.

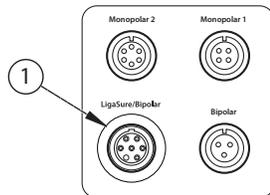
Precaution

Read the instructions, warnings, and precautions provided with Bipolar Resection instruments before use. Instrument instructions are not included in this manual.

Inspect instruments and cords—especially for laparoscopic/endoscopic instruments—for breaks, cracks, nicks, and other damage before every use. If damaged, do not use. Damaged instruments or cords may result in injury or electrical shock to the patient or surgical team.

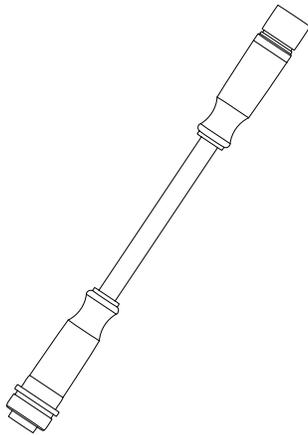
Foot Pedal

The LigaSure/Bipolar foot-pedal receptacle is located on the rear panel of the energy platform.



① LigaSure/Bipolar foot-pedal receptacle

When Bipolar Resection is in use, a single dual-pedal Bipolar Resection Footswitch can be attached to the LigaSure/Bipolar foot-pedal receptacle using a 1060355 adapter. The foot pedal is used to activate a Bipolar Resection instrument attached to the LigaSure/Bipolar receptacle on the front panel.



1060355 adapter

The purple end of the adapter connects to the energy platform. The orange end of the adapter connects to the foot pedal

Connecting Bipolar Resection Instruments to the Energy Platform

Warning

Malfunction may be caused by a loose or incorrect connection of the cord to the energy platform or instrument. Worn cords cannot be repaired. Replace cords on a routine basis to maintain optimum functionality and reliability in operating-room use.

Connect accessories to the proper receptacle. Improper connection of accessories may result in potentially hazardous conditions.

Inspect the cord insulation before and after each use for cracks, nicks, cuts, dents, or depressions which may decrease the insulation effectiveness. If the cord is compromised, do not use. Unintended thermal injury could occur.

Precaution

Always disconnect the cord from the instrument or energy platform by gripping the connector. Do not pull on the cord when disconnecting from the instrument and energy platform. Improper disconnection may damage the cord insulation.

1. Plug the system power cord into the rear panel receptacle.
2. Plug the system power cord into a grounded wall receptacle.

Notice

Do not plug the system power cord into a power strip or extension cord.

3. Turn on the system and verify the power-on self-test successfully completes.
4. Connect a Bipolar Resection cord (FT0021S or FT0022W) to the LigaSure/Bipolar receptacle on the front panel.
5. Connect a supported Bipolar Resection instrument to the Bipolar Resection cord used in the previous step.
6. Connect the Bipolar Resection Footswitch (FT6009) with adapter (1060355) to the LigaSure/Bipolar foot-pedal receptacle on the rear panel.
7. Adjust the Bipolar Resection CUT or COAG effect setting to values between 1 and 6 from the lower-right quadrant of the touchscreen.

Bipolar Resection Settings

Changing the Energy-Delivery Setting

Warning

Confirm proper power or intensity settings before proceeding with surgery.

Touch either the up or down arrows to increase or decrease the effect setting by one. The effect setting does not advance from 6 to 1 when touching the up arrow or from 1 to 6 when touching the down arrow. Instead a warning tone sounds indicating the minimum or maximum effect setting has been reached.

Activating a Bipolar Resection Instrument

Supported Bipolar Resection instruments may be used on the energy platform once the required accessories are connected.

1. Activate the Bipolar Resection instrument by stepping on and holding the pedal for the desired mode. During instrument activation, the Bipolar Resection touchscreen controls illuminate brightly.
2. To deactivate the mode and stop energy delivery, release the foot pedal.

Incorrect Foot-Pedal Error

If a warning tone is heard when depressing a foot pedal and no energy is delivered, an incorrect foot pedal may be installed.

To correct this situation

1. Confirm that a Bipolar Resection Footswitch with adapter 1060355 is plugged into the LigaSure/Bipolar foot-pedal receptacle on the rear panel of the energy platform.
2. If there is no foot pedal connected, locate the proper foot pedal and connect it to the LigaSure/Bipolar foot-pedal receptacle.
3. If there is a foot pedal connected to the LigaSure/Bipolar foot-pedal receptacle, but it is not a Bipolar Resection Footswitch, disconnect the foot pedal. Locate the proper foot pedal and connect it to the receptacle.

After Surgery

Disconnect the Instruments

1. Turn off the energy platform.
2. Disconnect the Bipolar Resection cord from the LigaSure/Bipolar receptacle from the front panel.
3. Disconnect the instrument from the cord.
 - If the instrument is single-use only (disposable), dispose of it according to the procedures for your institution.
 - If the instrument is reusable, clean and sterilize it according to the manufacturer's instructions for use.
 - Clean and sterilize the cord according to the instructions for use.
4. Disconnect and clean the foot pedal according to the instructions for use.
5. Disconnect the power plug from the wall receptacle by pulling the plug, not the cable.

Chapter 8

Troubleshooting

Precaution

Read the instructions, warnings, and precautions provided with this energy platform and associated accessories before using. Specific instructions for electro-surgical instruments are not included in this manual.

General Troubleshooting Guidelines

If the VLFT10GEN malfunctions, check for obvious conditions that may have caused the problem:

- Check the system for visible signs of physical damage.
- Make sure the fuse drawer is tightly closed.
- Verify that all cords are connected and attached properly.
- If an error code is displayed on the touchscreens, note the code along with all information on the error screen and use the information in this chapter to proceed.
- If the problem is still unclear, turn the VLFT10GEN off, wait two minutes before turning on again.

If the malfunction persists, the system may require service. Contact your institution's biomedical engineering department. Covidien Technical Service contact information is listed on page 9-6.

REM Alarms

If the VLFT10GEN does not sense the correct impedance for the connected REM Polyhesive patient return electrode, monopolar energy is disabled, the REM indicator on the front panel illuminates red, the REM symbol appears and enlarges on the touchscreen, and an alarm tone sounds twice. The REM symbol on the screen returns to its smaller size but remains red, and RF energy remains disabled until the REM alarm is corrected.

When you correct a REM-alarm condition, the system is enabled and the REM-alarm indicator on the front panel illuminates green.

Precaution

Covidien REM Polyhesive patient return electrodes are recommended for use with the VLFT10GEN. Return electrodes from other manufacturers may not provide proper impedance to work correctly with the energy platform.

Notice

Alarm characteristics cannot be changed.

Correcting a REM-Alarm Condition

To correct a REM-alarm condition, follow these steps:

1. Inspect the return-electrode plug and cord. If there is evidence of cracks, breaks, or other visible damage, replace the return electrode and/or the cord.
2. Verify that the patient-return-electrode cord is correctly connected to the energy platform.

3. Verify that there is full contact between the patient and return electrode. Follow the instructions for use provided with the REM Polyheseive patient return electrode to ensure proper attachment.
4. If the REM alarm persists, it may be necessary to use more than one patient return electrode. Refer to the troubleshooting flow chart in the REM Polyheseive patient return electrode instructions for use for more detail.

Correcting Malfunctions

If a solution is not readily apparent, use the table below to help identify and correct specific malfunctions. After you correct the malfunction, verify that the system completes the self-test as described in Chapter 3, *System Setup*.

Situation	Possible Cause	Solution
Abnormal neuromuscular stimulation (<i>stop surgery immediately</i>).	Metal-to-metal sparking.	Check all connections to the energy platform, patient return electrode, and active electrodes.
	Can occur during COAG.	Use a lower power setting for the FULGURATE and the SPRAY modes.
	Abnormal 50–60 Hz leakage currents.	Contact your biomedical engineering department or a Covidien technical service representative for assistance.
Energy platform does not respond when turned on.	Disconnected power cord or faulty wall outlet.	Check power cord connections (energy platform and wall outlet). Connect the power cord to a functional outlet.
	Faulty power cord.	Replace the power cord.
	Fuse drawer is open or fuses are blown.	Replace the blown fuse(s). Close the fuse drawer. See Chapter 10, <i>Technical Specifications</i> .
	Internal component malfunction.	Use a backup energy platform. Contact your biomedical engineering department or a Covidien technical service representative for assistance.

Situation	Possible Cause	Solution
System is on, but did not complete the self-test.	Software malfunction.	Turn off the energy platform, then turn on.
	Internal component malfunction.	<p>Note the code along with all information on the error screen. Note the number and refer to <i>System Alarms</i> on page 8-9.</p> <p>Use a backup energy platform. Contact your biomedical engineering department or a Covidien technical service representative for assistance.</p>
Energy platform is on and instrument is activated, but system does not deliver output.	Malfunctioning foot pedal or handswitching instrument.	<p>Turn off the energy platform. Check and correct all instrument connections.</p> <p>Turn on the energy platform. Replace the instrument if it continues to malfunction.</p>
	Power is set too low or turned off.	Increase the power setting.
	An alarm condition exists.	<p>Note the code along with all information on the error screen. Note the number and refer to <i>System Alarms</i> on page 8-9.</p> <p>In case of a REM alarm, refer to <i>Correcting a REM-Alarm Condition</i> on page 8-2.</p>
	Internal component malfunction.	Contact your biomedical engineering department or a Covidien technical service representative for assistance.
System does not detect tissue-fusion instrument.		Firmly insert the LigaSmart connector into the appropriate receptacle on the energy platform front panel. Ensure the LigaSure quadrant indicates that it has detected the instrument.

Situation	Possible Cause	Solution
	System does not detect monopolar instrument.	Firmly insert the monopolar connector into the appropriate receptacle on the energy platform front panel. Ensure the associated monopolar quadrant indicates that it has detected the instrument.
	System does not detect bipolar instrument.	Firmly insert the bipolar connector into the appropriate receptacle on the energy platform front panel. Ensure the Bipolar quadrant indicates that it has detected the instrument.
<p><i>CHECK LIGASURE INSTRUMENT</i> pop-up screen appears, a four-pulsed tone sounds, and RF output is disabled.</p>	Excessive tissue/eschar on electrode tips or jaws.	Clean electrode tips and jaws with a wet gauze pad.
	<p>Electrodes have come loose from the instrument jaws.</p> <p>Electrode pins may have been compromised or bent during assembly to the instrument and may need to be replaced.</p>	Re-insert the electrode into the instrument jaws making sure that all the electrode pins are firmly seated.
	Metal or other foreign object is grasped within jaws.	Avoid grasping objects, such as staples, clips, or encapsulated sutures in the jaws of the instrument.
	Tissue grasped within jaws is too thin.	Open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the amount of tissue and repeat the procedure.
	Pooled fluids around instrument tip.	Minimize or remove excess fluids.

Situation	Possible Cause	Solution
<p><i>REACTIVATE LIGASURE</i> pop-up screen appears, a four-pulsed tone sounds, and RF output is disabled.</p>	<p>The seal cycle was interrupted before completion.</p> <p>The handswitch or foot pedal was released before the end tone activated.</p> <p>The jaws were opened before the end tone activated.</p> <p>Additional time and energy are needed to complete the fusion cycle.</p>	<p>Reactivate the seal cycle without removing or repositioning the instrument.</p>
<p>Continuous monitor interference.</p>	<p>Malfunctioning monitor.</p>	<p>Replace the monitor.</p>
	<p>Faulty chassis-to-ground connections.</p>	<p>Check and correct the chassis ground connections for the monitor and for the energy platform.</p> <p>Check other electrical equipment in the room for defective grounds.</p>
	<p>Electrical equipment is grounded to different objects rather than a common ground. The energy platform may respond to the resulting voltage differences between grounded objects.</p>	<p>Plug all electrical equipment into line power at the same location. Contact your biomedical engineering department or a Covidien technical service representative for assistance.</p>

Situation	Possible Cause	Solution
Interference with other devices only when the energy platform is activated.	Metal-to-metal sparking.	Check all connections to the energy platform, patient return electrode, and instruments.
	High settings used for FULGURATION.	Use lower power settings for FULGURATION.
	Electrically inconsistent ground wires in the operating room.	Verify that all ground wires are as short as possible and go to the same grounded metal.
	If interference continues when the energy platform is activated, the monitor is responding to radiated frequencies.	<p>Ask your biomedical engineering department to check with the manufacturer of the monitor.</p> <p>Some manufacturers offer RF choke filters for use in monitor leads. The filters reduce interference when the energy platform is activated and minimize the potential for an electrosurgical burn at the site of the monitor electrode.</p>

Situation	Possible Cause	Solution
Pacemaker interference.	Intermittent connections or metal-to-metal sparking.	<p>Check the active and patient return electrode cord connections.</p> <p>It may be necessary to reprogram the pacemaker.</p>
	<p>Current traveling from active to return electrode during monopolar electrosurgery is passing too close to pacemaker.</p>	<p>Consult the pacemaker manufacturer or hospital cardiology department for further information when use of electrosurgical appliances is planned in patients with cardiac pacemakers.</p> <p>Use bipolar instruments, if possible.</p> <p>If you must use a monopolar instrument, place the patient return electrode as close as possible to the surgical site. Make sure the current path from the surgical site to the patient return electrode does not pass through the vicinity of the heart or the site where the pacemaker is implanted.</p> <p>Always monitor patients with pacemakers during surgery and keep a defibrillator available.</p>
Internal Cardiac Defibrillator (ICD) activation.	ICD is activated by energy platform.	Stop the procedure and contact the ICD manufacturer for instructions.

System Alarms

Most system alarms require some action on the user's part to correct the condition; however, some are corrected automatically. Use the following list to determine how to correct an alarm condition.

After correcting the alarm condition, verify that the system completes the self-test as described in Chapter 3, *System Setup*.

Error Codes

Error Code	Error Title	Description	Alarm Type	Clearing Condition
E101	SYSTEM ERROR	FPGA Failure	Safe Mode	Power on reboot, successful Power-On Self-Test (POST)
E102	SYSTEM ERROR	CPLD Failure	Safe Mode	Power on reboot, successful POST
E103	SYSTEM ERROR	FPGA Failure	Safe Mode	Power on reboot, successful POST
E104	SYSTEM ERROR	Boot Sector Failure	Safe Mode	Power on reboot, successful POST
E105	SYSTEM ERROR	RAM Test Failure	Safe Mode	Power on reboot, successful POST
E106	SYSTEM ERROR	Processor Exception	Safe Mode	Power on reboot, successful POST
E107	SYSTEM ERROR	Unexpected Interrupt	Safe Mode	Power on reboot, successful POST
E201	SYSTEM ERROR	Storage Failure	High Alarm	Power on reboot, successful POST
E202	SYSTEM ERROR	RTOS Failure	High Alarm	Power on reboot, successful POST
E203	SYSTEM ERROR	OS Failure	High Alarm	Power on reboot, successful POST
E204	SYSTEM ERROR	Assert Error	High Alarm	Power on reboot, successful POST
E205	SYSTEM ERROR	Null Pointer Error	High Alarm	Power on reboot, successful POST
E206	SYSTEM ERROR	Database Error	High Alarm	Power on reboot, successful POST
E207	SYSTEM ERROR	Mem Allocate Error	High Alarm	Power on reboot, successful POST

Error Code	Error Title	Description	Alarm Type	Clearing Condition
E208	SYSTEM ERROR	Stack Overflow	High Alarm	Power on reboot, successful POST
E209	SYSTEM ERROR	DMA Failure	High Alarm	Power on reboot, successful POST
E210	SYSTEM ERROR	Thread Limit Error	High Alarm	Power on reboot, successful POST
E211	SYSTEM ERROR	Internal Messaging Error	High Alarm	Power on reboot, successful POST
E212	SYSTEM ERROR	PCBA Failure	High Alarm	Power on reboot, successful POST
E213	SYSTEM ERROR	SR PCBA Failure	High Alarm	Power on reboot, successful POST
E214	SYSTEM ERROR	RF PCBA Failure	High Alarm	Power on reboot, successful POST
E215	SYSTEM ERROR	Software State Error	High Alarm	Power on reboot, successful POST
E216	SYSTEM ERROR	Low Voltage Rail Failure	High Alarm	Power on reboot, successful POST
E217	SYSTEM ERROR	High Voltage Rail Failure	High Alarm	Power on reboot, successful POST
E218	SYSTEM ERROR	Display Driver Error	High Alarm	Power on reboot, successful POST
E219	SYSTEM ERROR	Audio Circuit Failure	High Alarm	Power on reboot, successful POST
E220	SYSTEM ERROR	Multi-tasking Error	High Alarm	Power on reboot, successful POST
E221	SYSTEM ERROR	Processor Timebase Error	High Alarm	Power on reboot, successful POST
E222	SYSTEM ERROR	Processor Timebase Error	High Alarm	Power on reboot, successful POST
E223	SYSTEM ERROR	FPGA Timebase Error	High Alarm	Power on reboot, successful POST
E224	SYSTEM ERROR	System Timebase Error	High Alarm	Power on reboot, successful POST

Error Code	Error Title	Description	Alarm Type	Clearing Condition
E225	SYSTEM ERROR	Processor Watchdog Error	High Alarm	Power on reboot, successful POST
E226	SYSTEM ERROR	FPCA Comm Error	High Alarm	Power on reboot, successful POST
E227	SYSTEM ERROR	REM Circuit Failure	High Alarm	Power on reboot, successful POST
E228	SYSTEM ERROR	Relay Feedback Failure	High Alarm	Power on reboot, successful POST
E229	SYSTEM ERROR	Connector Diagnostic Failure	High Alarm	Power on reboot, successful POST
E230	SYSTEM ERROR	Critical Data Failure	High Alarm	Power on reboot, successful POST
E231	SYSTEM ERROR	Security Access Error	High Alarm	Power on reboot, successful POST
E232	CONFIGURATION MISMATCH	Invalid System Configuration	High Alarm	Power on reboot, successful POST
E233	CONFIGURATION MISMATCH	Field Replaceable Unit Updated	High Alarm	Requires redock, FRU replacement, successful POST
E234	SYSTEM ERROR	Processor Comm Failure	High Alarm	Power on reboot, successful POST
E235	(NONE)	REM Pad Contact Quality	REM Alarm	Split pad balanced impedance (REM ok), Enter Demo
E236	SYSTEM ERROR	Processor Watchdog Error	High Alarm	Power on reboot, successful POST
E237	SYSTEM ERROR	Processor Watchdog Error	High Alarm	Power on reboot, successful POST
E238	SYSTEM ERROR	Software Failure	High Alarm	Power on reboot, successful POST
E239	SYSTEM ERROR	Software Failure	High Alarm	Power on reboot, successful POST
E240	SYSTEM ERROR	Thread Check Failure	High Alarm	Power on reboot, successful POST
E241	SYSTEM ERROR	RF Data Error	High Alarm	Power on reboot, successful POST

Error Code	Error Title	Description	Alarm Type	Clearing Condition
E242	SYSTEM ERROR	RF Data Timing Error	High Alarm	Power on reboot, successful POST
E243	SYSTEM ERROR	RF Data Delay Error	High Alarm	Power on reboot, successful POST
E244	SYSTEM ERROR	RF Interrupt Error	High Alarm	Power on reboot, successful POST
E246	SYSTEM ERROR	HWC Control Selection Error	High Alarm	Power on reboot, successful POST
E247	SYSTEM ERROR	PS PCBA Failure	High alarm	Power on reboot, successful POST
E248	SYSTEM ERROR	FP PCBA Failure	High Alarm	Power on reboot, successful POST
E301	INTERNAL CHECK	Network Diagnostic Issue	Medium Alarm	User acknowledge, Enter Service
E302	INTERNAL CHECK	Mono 1 Port Comm Issue	Medium Alarm	Comm status ok, User acknowledge, Enter Service
E303	INTERNAL CHECK	Mono 2 Port Comm Issue	Medium Alarm	Comm status ok, User acknowledge, Enter Service
E304	INTERNAL CHECK	Bipolar Port Comm Issue	Medium Alarm	Comm status ok, User acknowledge, Enter Service
E305	INTERNAL CHECK	LigaSure Port Comm Issue	Medium Alarm	Comm status ok, User acknowledge, Enter Service
E306	INTERNAL CHECK	Instrument Scanner Issue	Medium Alarm	VIBE status ok, User acknowledge, Enter Service
E307	INTERNAL CHECK	Unsupported Command	Medium Alarm	User acknowledge, Enter Service
E308	INTERNAL CHECK	Software Timeout Issue	Medium Alarm	User acknowledge, Enter Service
E309	INTERNAL CHECK	Activation Timing Issue	Medium Alarm	Condition clears and reactivation, User acknowledge, Enter Service

Error Code	Error Title	Description	Alarm Type	Clearing Condition
E310	TOUCHSCREEN ERROR	Unintentional Screen Input	Medium Alarm	Condition clears
E312	INTERNAL CHECK	Absolute Integrated Error	Medium Alarm	Reactivation, User acknowledge, Enter Service
E313	INTERNAL CHECK	Voltage Sensor Compare Error	Medium Alarm	Reactivation, User acknowledge, Enter Service
E314	INTERNAL CHECK	Current Sensor Compare Error	Medium Alarm	Reactivation, User acknowledge, Enter Service
E315	INTERNAL CHECK	Power Sensor Compare Error	Medium Alarm	Reactivation, User acknowledge, Enter Service
E316	INTERNAL CHECK	Power Compare Error	Medium Alarm	Reactivation, User acknowledge, Enter Service
E317	INTERNAL CHECK	PVI Curve Compare Error	Medium Alarm	Reactivation, User acknowledge, Enter Service
E318	INTERNAL CHECK	Voltage Sensor Clip Error	Medium Alarm	Reactivation, User acknowledge, Enter Service
E319	INTERNAL CHECK	Current Sensor Clip Error	Medium Alarm	Reactivation, User acknowledge, Enter Service
E320	CHECK INSTRUMENT	N/A	Medium Alarm	Switch release, Remove instrument
E321	CHECK FOOT PEDAL	N/A	Medium Alarm	Pedal release
E322	CHECK INSTRUMENT	N/A	Medium Alarm	Switch release, Remove instrument
E323	CHECK FOOT PEDAL	N/A	Medium Alarm	Pedal release
E324	CHECK INSTRUMENT	N/A	Medium Alarm	Switch release, Remove instrument
E325	CHECK FOOT PEDAL	N/A	Medium Alarm	Pedal release

Error Code	Error Title	Description	Alarm Type	Clearing Condition
E326	CHECK INSTRUMENT	N/A	Medium Alarm	Switch release, Remove instrument
E327	CHECK FOOT PEDAL	N/a	Medium Alarm	Pedal release
E328	UNINTENTIONAL INPUT	Panel Button Error	Medium Alarm	Button release
E329	CHECK FOOT PEDAL	Invalid Foot Pedal Input	Medium Alarm	Condition clears
E330	PROLONGED ACTIVATION	Prolonged Activation	Medium Alarm	User acknowledge, Enter Service, Reactivation
E331	INVALID INSTRUMENT	Invalid Instrument	Medium Alarm	Instrument removal
E332	SYSTEM ISSUE	Unit Overtemp Detected	Medium Alarm	User acknowledge, Enter Service
E333	SYSTEM ISSUE	Cooling Fan Issue	Medium Alarm	User acknowledge, Enter Service
E334	REM CHECK ISSUE	REM Automated Check Error	Medium Alarm	Successful completion of REM check, User acknowledge, Enter Service
E335	SYSTEM ISSUE	Driver Comm Issue	Medium Alarm	User acknowledge, Enter Service
E336	INTERNAL CHECK	ADC Sync Issue	Medium Alarm	Start RF activation, User acknowledge, Enter Service
E337	INTERNAL CHECK	Real Time Clock Issue	Medium Alarm	User acknowledge, Enter Service
E339	INTERNAL CHECK	RF Control Limit Check Issue	Medium Alarm	Start RF activation, User acknowledge, Enter Service
E340	CONFIGURATION MISMATCH	Invalid Country Code	Medium Alarm	Connect to VLEX
E341	INTERNAL CHECK	Panel Comm Issue	Medium Alarm	Condition clears, User acknowledge, Enter Service

Error Code	Error Title	Description	Alarm Type	Clearing Condition
E342	INTERNAL CHECK	Foot Pedal Comm Issue	Medium Alarm	Condition clears, User acknowledge, Enter Service
E343	INTERNAL CHECK	REM Comm Issue	Medium Alarm	Condition clears, User acknowledge, Enter Service
E344	INTERNAL CHECK	REM Comm Issue	Medium Alarm	Condition clears, User acknowledge, Enter Service
E345	INTERNAL CHECK	REM Comm Issue	Medium Alarm	User Acknowledge, Enter Service
E346	INTERNAL CHECK	REM Comm Issue	Medium Alarm	User Acknowledge, Enter Service
E347	INTERNAL CHECK	REM Data Issue	Medium Alarm	User Acknowledge, Enter Service
E348	INTERNAL CHECK	Software Assert Issue	Medium Alarm	Start RF activation, User Acknowledge, Enter Service
E349	INTERNAL CHECK	Thread Check Issue	Medium Alarm	Start RF activation, User Acknowledge, Enter Service
E350	INTERNAL CHECK	Return Electrode Overtemp	Medium Alarm	Condition clears, User acknowledge, Enter Service
E351	SYSTEM ISSUE	Processor Watchdog Error	Low Alarm	User acknowledge, Enter Service
E352	INTERNAL CHECK	Software Update Issue	Medium Alarm	Reload software
E353	SYSTEM ISSUE	Touchscreen Calibration Reset	Medium Alarm	User acknowledge, Enter Service
E354	INTERNAL CHECK	SWC Target Variance	Medium Alarm	Start RF activation, User Acknowledge, Enter Service
E355	INVALID ACTIVATION	Foot pedal Not Supported	Medium Alarm	Start RF Activation, User Acknowledge, Enter Service

Error Code	Error Title	Description	Alarm Type	Clearing Condition
E401	AUTHORIZATION ISSUE	Invalid Pairing Code	Low Alarm	User acknowledge, Enter Service
E402	INCOMPLETE SEAL CYCLE	N/A	LigaSure Alarm	Reactivation, Remove instrument, User acknowledge, Enter Service, Install instrument
E403	INCOMPLETE SEAL CYCLE	N/A	LigaSure Alarm	Reactivation, Remove instrument, User acknowledge, Enter Service
E404	INCOMPLETE SEAL CYCLE	N/A	LigaSure Alarm	Reactivation, Remove instrument, User acknowledge, Enter Service
E405	INCOMPLETE SEAL CYCLE	N/A	LigaSure Alarm	Reactivation, Remove instrument, User acknowledge, Enter Service
E407	INSTRUMENT NOT READY	N/A	Medium Alarm	Other plug on instrument inserted into LigaSure port, Remove instrument
E408	INSTRUMENT NOT READY	N/A	Medium Alarm	Other plug on instrument inserted into Mono 2 port, Remove instrument
E411	INVALID ACTIVATION ATTEMPT	N/A	Medium Alarm	Insert other half of plug into LigaSure port, Remove instrument
E412	INVALID ACTIVATION ATTEMPT	N/A	Medium Alarm	Insert other half of plug into Mono 2 port, Remove instrument
E413	INVALID COMBINATION	N/A	Medium Alarm	Remove instrument. Insert other half of plug into LigaSure port
E414	INVALID COMBINATION	N/A	Medium Alarm	Remove instrument. Insert other half of plug into Mono 2 port

Error Code	Error Title	Description	Alarm Type	Clearing Condition
E415	FEATURE NOT ENABLED	N/A	Medium Alarm	Remove instrument, Enter Service, Dismiss message (select Okay or Cancel)
E416	UNKNOWN INSTRUMENT	N/A	Medium Alarm	Remove instrument
E417	INVALID INSTRUMENT	N/A	Medium Alarm	Remove instrument
E419	Incomplete Setup	N/A	Low Alarm	Remove instrument. Enter Service, EM clearing message, RF activation
E420	Usage Limit	N/A	Medium Alarm	Replace instrument
E421	Usage Limit	N/A	Medium Alarm	User acknowledge, RF activation
E422	Incomplete Setup	N/A	Low Alarm	Remove instrument, Enter Service, EM clearing message, RF activation
E424	Activation Time Exceeded	N/A	Medium Alert	Remove instrument. Enter Service. EM clearing message (open circuit or open circuit timeout), RF activation
E425	Contact time Exceeded	N/A	Medium Alert	Remove instrument, Enter Service, EM clearing message (open circuit), RF activation

Chapter 9

Maintenance and Repair

This chapter presents the following information:

- The manufacturer's responsibility
- Routine maintenance and safety checks
- Cleaning the energy platform
- Product service
- Service manual copies and updates
- Returning the energy platform for service
- Software updates
- Covidien Technical Service
- Training and education

Precaution

Read the instructions, warnings, and precautions provided with this energy platform and associated accessories before using. Specific instructions for electrosurgical instruments are not included in this manual.

Responsibility of the Manufacturer

Covidien is responsible for the safety, reliability, and performance of the energy platform only if all of the following conditions have been met:

- Installation and setup procedures in this manual are followed.
- Assembly, operation, readjustments, modifications, or repairs are carried out by persons authorized by Covidien.
- The electrical installation of the relevant room complies with local codes and regulatory requirements, such as IEC and BSI.
- The equipment is used in accordance with the Covidien instructions for use.

For warranty information, refer to the *Limited Warranty* section in this manual.

Routine Maintenance and Periodic Safety Checks

Notice

Refer to the energy platform service manual for maintenance recommendations and function and output-power verification procedures.

When should the energy platform be checked or serviced?

Covidien recommends that the energy platform be inspected by qualified service personnel at least once a year. This inspection should include adjusting the system to factory specifications.

When should the power cord be checked or replaced?

Check the power cord before each use of the system or at the intervals recommended by your institution. Check the power cord for exposed wires, cracks, frayed edges, or a damaged connector. Replace damaged cords.

When should the fuses be replaced?

An internal component malfunction can damage the fuses. The system fuses may need to be replaced if the system fails the power-on self-test or if the system stops functioning, even though it is receiving power from a wall outlet.

Cleaning

Warning

Shock Hazard Before cleaning or servicing the unit, disconnect the power plug from the power outlet in order to completely isolate the generator from mains power.

Notice

Do not clean the energy platform with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the energy platform.

Do not spray cleaning fluids directly on the generator as damage to the generator may occur.

1. Turn off the system and unplug the power cord from the wall outlet.
2. Thoroughly wipe all surfaces of the energy platform and power cord with a damp cloth and mild cleaning solution or disinfectant. The energy platform will withstand the effects of cleaning over time without degrading the enclosure or display quality.

Product Service

Covidien recommends that all VLFT10GEN systems be returned to the manufacturer for all service requirements. If any service is required without returning the system to the manufacturer, Covidien recommends that only qualified personnel service the VLFT10GEN system.

Covidien defines qualified personnel as a person with electrosurgical equipment repair experience, such as biomedical personnel, and/or individuals who have taken official Covidien training courses.

Returning the Energy Platform for Service

Before returning the energy platform, call a Covidien sales representative for assistance. If the energy platform is to be sent to Covidien, do the following:

1. Obtain a return authorization number.

Call the Covidien Technical Service Center (see page 9-6) to obtain a Return Authorization Number. Have the following information ready before calling:

- Hospital/clinic name/customer number
- Telephone number
- Department/address, city, state, and zip code
- Model number
- Serial number
- Description of the problem
- Type of repair to be done

2. Clean the energy platform.

See the previous section, *Cleaning*.

3. Ship the energy platform.

- a. Attach a tag to the energy platform that includes the return authorization number and the information (hospital, phone number, etc.) listed in step 1.
- b. Be sure the energy platform is completely dry before packing it for shipment. Package it in its original shipping container, if available.
- c. Ship the energy platform, prepaid, to the Covidien Service Center.

Software Updates

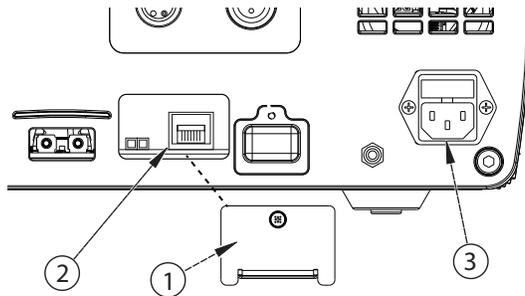
Software updates are available directly from Covidien by using the Valleylab Exchange Remote Software System application. Go to www.covidien.com/valleylabexchange to download and install the latest version of the Valleylab Exchange application. For additional information, the *Valleylab Exchange Remote Software System User's Guide* is available on the Valleylab Exchange website.

Updating Energy Platform Software

Once the Valleylab Exchange application has been installed on the computer to be used for the update, follow these brief instructions. Refer to the *Valleylab Exchange Remote Software System User's Guide* for more extensive information if needed.

To remotely update software on a VLFT10GEN Energy Platform:

1. Turn on the facility computer that has Valleylab Exchange installed,
2. Remove cover on back of generator to expose the data ports.



- ① Ethernet receptacle cover
- ② Ethernet receptacle
- ③ Power cord receptacle

3. Connect Ethernet cable to the Ethernet receptacle on the back of the energy platform.
4. Connect the other end of the cable to a LAN connector on the facility computer.
5. Plug the system power cord into the power cord receptacle.
6. Plug the other end of the cord into a grounded power receptacle.
7. Turn on the generator by pressing the On/Off button and wait for the power-on self-test to complete.
8. Touch the Service/Settings button on the front panel of the generator to view the *Service and Settings* menu.
9. Touch the **System** button from the menu to view the *System Menu*.
10. Touch **Network**.
11. Select **Enable Network Default Pt. to Pt.**

12. On the facility computer, open the Valleylab Exchange application. Valleylab Exchange prompts the user to put the energy platform in service mode.
13. Select the software version from Valleylab Exchange to be installed on the energy platform. The software upgrade will start.
14. Confirm the start of the software upgrade on the generator touchscreen. A progress bar on the generator will inform you that the software update is in process.
15. After the successful completion of the software update, the generator will automatically restart.
16. When Valleylab Exchange indicates the upgrade is complete, turn off the generator by depressing the On/Off button for 3 seconds.
17. Unplug the system power cord from the wall receptacle.
18. Unplug the system power cord from the rear panel receptacle.
19. Disconnect the Ethernet cable from the facility's LAN connector.
20. Disconnect the Ethernet cable from the back of the generator.
21. Replace cover on back of generator to cover the data ports.

Service Manual Copies and Updates

The latest version of this service manual is available at www.BioMedConnect.com.

To request a hard copy of the service manual, call the telephone numbers listed in the next section.

Covidien Technical Service

For service, contact Covidien Technical Service or your VLFT10GEN sales representative. Contact a Covidien technical-service representative by telephone, email, or through the Internet:

- USA and Canada: 1-800-255-8522 Option 2
- International: 1-303-476-7996
- Email— valleylab.technicalservice@covidien.com
- Internet—<http://surgical.covidien.com/service-centers>

or

www.BioMedConnect.com

Training/Education

For clinical professionals and service training options, please refer to the Covidien web site:
<http://www.covidien.com/education>

Chapter 10

Technical Specifications

Precaution

Read the instructions, warnings, and precautions provided with this energy platform and associated accessories before using. Specific instructions for electro-surgical instruments are not included in this manual.

VLFT10GEN Specifications

General

Output configuration	Isolated output
Cooling	Natural convection and fan
Display	7 in. LCD touchscreen
Connector receptacles	LED illuminated connector readers on the LigaSure/Bipolar receptacle
Enclosure	Magnesium
Mounting	<ul style="list-style-type: none"> • Valleylab Universal Generator Cart (VLFCRT) • Operating-room boom systems • Any stable, flat surface such as a table or cart top
Operating System	Linux™*

Dimensions and Weight

Height	7.0 in. (17.78 cm)
Width	14.5 in. (35.8 cm)
Length	18.2 in. (46.2 cm)
Weight	22.3 lb. (10.1 kg)

Environmental Parameters

	Operation	Transport and Storage ^{1,2}
Ambient temperature range	50 to 104 °F (10 to 40 °C)	14 to 140 °F (-10 to +60 °C)
Relative humidity	30% to 75% non-condensing	25% to 85% non-condensing
Atmospheric pressure	700 to 1060 millibars	500 to 1060 millibars

1. The system can be stored for up to one year without performance degradation upon use.

2. If the generator is stored at a temperature outside the normal operating range of 10 to 40 °C, the system is ready for use after at least one hour at ambient temperature 20 °C ± 5 °C.

Input Power

	100–120 VAC	200–240 VAC	Units
Line Ranges			
Line Voltage Full Regulation Range	90–132	180–264	VAC
Line Frequency	47–63	47–63	Hz
Max VA nominal line Voltage	950	950	VA
Max Mains Current	10	6	A
Max Heat Dissipation	180	180	W
Fuses	10	6	A
	Fuses (2) – 5 mm x 20 mm 10 A, 250 V fast blow	Fuses (2) – 5 mm x 20 mm 6.3 A, 250 V fast blow	
Power Cord	NEMA 3-prong hospital-grade connector		

Power Cord Specifications

This system is factory equipped with a 110 VAC hospital grade NEMA 5-15 power cord. Should the AC power cord need to be replaced to match another plug configuration, the replacement plug/cable/receptacle configuration must meet or exceed the following specifications:

- **100-120 VAC**

Cable - SJT16/3, IEC color code, maximum length 15 ft. (5 m)

Plug - minimum 10 A - 125 VAC

Unit receptacle - IEC female, minimum 10 A - 125 VAC

- **220-240 VAC**

Cable - H05VVF3G1.0 VDE, maximum length 15 ft. (5 m)

Plug - minimum 6 A - 250 VAC

Unit receptacle - IEC female, minimum 6 A - 250 VAC

Important

Contact your local Covidien representative for alternative internationally approved power-cord options.

Backup Power

The VLFT10GEN retains all user programmed features, calibration, and statistical data when switched off and unplugged. The VLFT10GEN operates within specification when switched over to a supplied-line power by hospital backup systems.

Real time clock battery	Battery type – Lithium CR1620 or CR1632
	Battery life – 75 mAh minimum

Equipotential Ground Connection

An equipotential ground connection is provided to allow connection of the VLFT10GEN to ground.

EKG Blanking and Smoke Evacuation

Interlink cable receptacles are provided to signal other devices, such as an EKG or smoke evacuator, that the VLFT10GEN is active. The receptacle is a 2.5 mm mono jack. It is electrically isolated from the internal ground referenced electronics with the shell electrically connected to the chassis for ESD protection.

Internal Memory

Storage capacity	8 GB
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Duty Cycle

The VLFT10GEN 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 four hours.

Precaution

Use of duty cycles greater than 25% (10 seconds active followed by 30 seconds inactive) will increase the risk that heat build-up under a return electrode may be high enough to injure the patient. Do not continuously activate for longer than one minute.

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 10mA 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 mA _{RMS}
Monopolar measured directly at the ESU terminals	< 100 mA _{RMS}
LigaSure/BPR measured directly at the ESU terminals	< 100 mA

Radio Frequency Identification (RFID)

The RFID module is located above the LigaSure/Bipolar receptacle. The intended use of the RFID module is to identify the inserted LigaSure instrument and configure the generator with the data included in the RFID tag.

Transmit/Receive Frequency Range	13.56MHz
RF Output Power	68.17 dBu V/m @3 meter
Type of Antenna	Integral Loop Antenna
Modulation	Modulation: Amplitude-shift keying (ASK)
Mode of Operation (Simplex / Duplex)	Duplex
Contains Module FCC ID	2AAVI-JDK1901
Contains IC ID	11355A-JDK1901

Wireless Fidelity (WiFi)

The WiFi module is located on the back of the generator. The intended use of the WiFi module is to perform service operations on the generator.

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	WPA2
Type of Antenna	Internal Antenna (1T1R)
Contains Module FCC ID	NDD9578111008
Contains IC ID	4701A-78111306

IFETEL Radio Standards Warning Statement

The operation of radios within this equipment is subject to the following two conditions:

- 1) They shall not cause harmful interference, and
- 2) They must accept any interference received, including interference that may cause undesired operation.

Industry Canada Statement

This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following conditions:

- 1) This device may not cause interference; and
- 2) This device must accept any interference, including interference that may cause undesired operation of the device.

RF Exposure Statement

This device meets the requirements for RF exposure when operated at a minimum distance of 20 cm from the user or nearby persons.

EU Declaration of Conformity

Hereby, Covidien llc, declares that this wireless LAN and RFID are in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

WiFi Device Installation Guide

The translated Quick Installation Guide (QIG) for the WiFi device (EW-7811Un) is available on the Edimax™* website in many languages. It is at the following location:

http://www.edimax.com/edimax/download/download/data/edimax/global/download/for_home/wireless_adapters/wireless_adapters_n150/ew-7811un

Ethernet

The Ethernet connection is located on the back of the generator. The intended use of the Ethernet connection is to perform service operations on the generator.

Connected Speed	10/100/1000Base-T
Standards	IEEE 802.3, IPv4
Protocols	SFTP (for file transfer through port 22), UDP (non-file transfer), TCP/IP

Symbols Used



For prescription use only



Consult instructions for use



Follow instructions for use (blue)



Caution: Consult accompanying documents



The energy platform output is floating (isolated) with respect to ground.



Defibrillation proof



DANGER

Explosion risk if used with flammable anesthetics



To reduce the risk of electric shock, do not remove the cover. Refer servicing to qualified service personnel.



- 1) Unit produces non-ionizing radiation
- 2) Unit includes RFID



Unit includes WiFi



Classified with respect to electrical shock, fire, and mechanical hazards only in accordance with AAMI ES standard 60601-1; certified to CSA standard C22.2 60601-1:2008.

IP21

Liquid Ingress/Spillage Classification



On/Off



Settings restore



Volume



Service/Settings



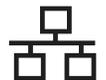
High voltage



REM patient return electrode



Monopolar 1 Universal Foot Pedal Port (UFP)



Ethernet



Fuse



Foot pedal



Volume adjustment for activation tones



Equipotential grounding point



Equipment should not be disposed in trash



Do not reuse (Single use only)

Standards and IEC Classifications

The VLFT10GEN 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)



This VLFT10GEN 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 VLFT10GEN 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 VLFT10GEN 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 re-orienting the equipment.

Important

RFID and WiFi function may be interfered with by other equipment even if that other equipment complies with CISPR emission requirements.

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

The VLFT10GEN complies with the appropriate IEC 60601-1-2 and 60601-2-2 specifications regarding electromagnetic compatibility.

Notice

The VLFT10GEN requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the *Valleylab FT10 Energy Platform Service Manual*.

Portable and mobile RF communications equipment can affect the VLFT10GEN. Refer to the EMC information provided in the *Valleylab FT10 Energy Platform Service Manual*.

The system should not be used adjacent to or stacked with equipment other than specified in the *Valleylab FT10 Energy Platform User Guide and Service Manual*. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

Notice

The system intentionally applies RF energy for diagnosis or treatment during activation. Observe other electronic medical equipment in the vicinity during the system activation for any possible adverse electromagnetic effects. Ensure adequate separation of electronic medical equipment based on observed reactions.

The use of accessories, other than specified in the *Valleylab FT10 Energy Platform User Guide and Service Manual*, may result in increased emissions or decreased immunity of the system.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Valleylab FT10 FT Series Energy Platform is intended for use in the electromagnetic environment specified below. The customer or the user of the Valleylab FT10 FT Series Energy Platform should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The Valleylab FT10 FT Series Energy Platform must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The Valleylab FT10 FT Series Energy Platform is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

The essential performance requirement per IEC60601-1 does not apply to VLFT10GEN. Basic safety is the performance requirement used during immunity testing.

Guidance and manufacturer's declaration - electromagnetic immunity			
The Valleylab FT10 FT Series Energy Platform is intended for use in the electromagnetic environment specified below. The customer or the user of the Valleylab FT10 FT Series Energy Platform should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle ^a < 40% U_T (> 60% dip in U_T) for 5 cycles < 70% U_T (> 30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec 0% U_T for 1 cycle	< 5% U_T (> 95% dip in U_T) for 0.5 cycle < 40% U_T (> 60% dip in U_T) for 5 cycles < 70% U_T (> 30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec 0% U_T for 1 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Continued			

Guidance and manufacturer's declaration - electromagnetic immunity
<p>a. 1 cycle is at 50 Hz or 20 ms</p> <p>NOTE: U_T is the a.c. mains voltage prior to the application of the test level.</p>

Guidance and manufacturer's declaration - electromagnetic immunity			
<p>The Valleylab FT10 FT Series Energy Platform is intended for use in the electromagnetic environment specified below. The customer or the user of the Valleylab FT10 FT Series Energy Platform should assure that it is used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	$3 V_{rms}$ 150 kHz to 80 MHz	$3 V_{rms}$	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Valleylab FT10 FT Series Energy Platform, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d=1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	$3 V/m$ 80 MHz to 2.7 GHz	$3 V/m$	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol. 
Continued			

Guidance and manufacturer's declaration - electromagnetic immunity
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
<p>a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Valleylab FT10 FT Series Energy Platform is used exceeds the applicable RF compliance level above, the Valleylab FT10 FT Series Energy Platform should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Valleylab FT10 FT Series Energy Platform.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>

Recommended separation distances between portable and mobile RF communication equipment and the Valleylab FT10 FT Series Energy Platform			
<p>The VLFT10GEN is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.</p>			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2 \times \sqrt{P}$	80 MHz to 800 MHz $d=1.2 \times \sqrt{P}$	800 MHz to 2.5 GHz $d=2.7 \times \sqrt{P}$
0.01	0.12	0.12 ^a	0.23 ^a
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p>			
<p>a. For frequencies listed in the following table, use a separation distance of 0.3 m.</p>			
Continued			

Recommended separation distances between portable and mobile RF communication equipment and the Valleylab FT10 FT Series Energy Platform			
Frequency ranges and test condition on transmitter bands			
Bands (MHz)	Test Frequencies (MHz)	Modulation	Claimed Compliance Level V/m
380 – 390	385	Pulse ^a – 18 Hz	27
430 – 470	450	FM \pm 5 kHz Deviation or Pulse ^a – 18 Hz	28
704 – 787	710, 745, 780	Pulse ^a – 217 Hz	9
800 – 960	810, 870, 930	Pulse ^a – 18 Hz	28
1700 – 1990	1720, 1845, 1970	Pulse ^a – 217 Hz	28
2400 – 2570	2450	Pulse ^a – 217 Hz	28
5100 – 5800	5240, 5500, 5785	Pulse ^a – 217 Hz	9

a. Pulse Modulation is defined as a square wave input with a 50% duty cycle at the listed frequency.

NOTE 1 The minimum dwell time during test is 7 s.

NOTE 2 A minimum separation distance of 0.3 meters should be maintained between any device transmitting in this band and the VLFT10GEN. This includes devices such as mobile phones, PDAs, Wireless LANs, RFID and Bluetooth™.

Cables Used for EMC Compliance Testing

The following cables, lengths, and instruments were used to determine compliance levels.

Model No.	Description	Shielded	Length	Location	Classification	Tests Included
207002060	A/C cable	No	15 ft. (4.6 m)	Rear panel	AC	Emissions/ Immunity
1017178	Equipotential cable	No	15 ft. (4.6 m)	Rear panel	EQ	Emissions/ Immunity
E2450HDB	2-button pencil	No	15 ft. (4.6 m)	Front panel Mono 1	Patient	Emissions/ Immunity
FT3000DB	Force TriVerse pencil	No	15 ft. (4.6 m)	Front panel Mono 2	Patient	Emissions/ Immunity
E7507DB	Adult REM pad	No	15 ft. (4.6 m)	Front panel REM	Patient	Emissions/ Immunity
E0020V/ E4073CT	Foot switching Bipolar cord/ bayonet forceps	No	15 ft. (4.6 m)	Front panel Bipolar	Patient	Emissions/ Immunity
LF1644	LigaSure	No	10 ft. (3 m)	Front panel LigaSure	Patient	Immunity
FT0021S/ FT27050SL	Cord Storz/ Storz Resectoscope	No	15 ft. (4.6 m)/ NA	Front panel Adv. Energy	Patient	Emissions
E6008B	Monopolar footswitch	No	15 ft. (4.6 m)	Rear panel Mono 1	SIP/SOP	Emissions/ Immunity
E6019	Dome Bipolar footswitch	No	15 ft. (4.6 m)	Rear panel Bipolar	SIP/SOP	Emissions/ Immunity
LS0300	LigaSure footswitch	No	15 ft. (4.6 m)	Rear panel LigaSure	SIP/SOP	Emissions/ Immunity
Continued						

Model No.	Description	Shielded	Length	Location	Classification	Tests Included
Any	Ethernet	No	15 ft. (4.6 m) min.	Rear panel	SIP/SOP	Emissions/ Immunity
SEA3730	Coax	No	10 ft. (3 m)	Rear panel smoke2 evac.	SIP/SOP	Emissions/ Immunity
SEA3730	Coax	No	10 ft. (3 m)	Rear panel ECG blank	SIP/SOP	Emissions/ Immunity

Return Electrode Monitor (REM)

REM Specification

Interrogation Frequency	64–76 kHz
Interrogation Current	< 100 μ A
Interrogation Voltage	\leq 12 V_{RMS}
Impedance Sense Range	0 Ω to 150 Ω
Impedance Accuracy (RF not activated)	\pm 7 Ω
Impedance Accuracy (RF Activated)	Greater of \pm 14 Ω or 20%

REM Alarm Activation

REM patient return electrode: When the measured resistance exceeds the standard range of safe resistance (below 5 ohms or above 135 ohms) or when the initial measured contact resistance increases by 40% (whichever is less), the REM alarm is activated and RF output is disabled.

Auto Bipolar

The VLFT10GEN is equipped with an Auto Bipolar feature that allows for automatic activation of bipolar energy.

Warning

Use of different Covidien cord models or cords from other manufacturers may not achieve proper electrical output for this device, thereby failing to produce the desired clinical effect. For example, Auto Bipolar activation/deactivation settings may not work properly using cords other than those specified by Covidien.

In the Auto Bipolar setting, activation may occur with contact of any material. When not in use, place electro-surgical instruments in a safety holster or safely away from patients, the surgical team, and flammable materials

Auto Bipolar Specifications	Duration
Interrogation Frequency	434 kHz
Interrogation Current	< 10 μA_{RMS} averaged over 1 second
Interrogation Voltage	< 12 V_{RMS}
Activation Impedance	$\leq 2200 \Omega \pm 20\%$
Deactivation Impedance	$> 4000 \Omega \pm 20\%$
Keying Delay	User selectable in 0.5 second increments from 0 sec. to 2.5 sec.
Minimum Power	1 W

Audio Tones

Activation Tones

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

Alarm Tones

Alarm Tones	Tone(s)	Duration	Volume
REM	660 Hz ± 5%	Two 500 msec. tones separated by 500 msec. of silence	65 dBA (-0/+6 dBA @ 1 m)
Regrasp/ Reactivate	High 784 Hz ± 5% Low 587 Hz ± 5%	Four 175 msec. tones (high, low, high, low)	
Seal Cycle Complete	988 Hz ± 5%	Two 175 msec. tones separated by 175 msec. of silence	
High System Alarm	Simultaneously play the following tones: 784 Hz ± 5% 1568Hz ± 5% 2352 Hz ± 5% 3136 Hz ± 5%	Ten 138 msec. tones separated by 88, 88, 312, 88, 825, 88, 88, 312, and 88 msec. of silence	
Medium System Alarm	Simultaneously play the following tones: 784 Hz ± 5% 1568Hz ± 5% 2352 Hz ± 5% 3136 Hz ± 5%	Three 188 msec. tones separated 188 msec. of silence	
Low System Alarm	Simultaneously play the following tones: 784 Hz ± 5% 1568Hz ± 5% 2352 Hz ± 5% 3136 Hz ± 5%	One 188 msec. tone	

Notice

Alarm characteristics cannot be changed.

Alarm response time is less than one second.

Energy Output Characteristics

The VLFT10GEN automatically senses the tissue resistance and adjusts the output voltage to maintain a consistent effect across different tissue density. The adjustment is based on the selected mode or effect, power setting, and the level of tissue resistance. The maximum output voltage is controlled to reduce capacitive coupling and video interference and to minimize undesired sparking. The following table outlines the maximum power, peak voltages, and maximum output current for a given modality.

	Rated Load (Ω)	Rated Output Power (W)	Peak Voltage	Current RMS Max	Typical Crest Factor	Duty Cycle
Monopolar CUT						
PURE	300	300	1287	1.25	1.42	100%
BLEND	300	200	2178	1	2.5	50%
VALLEYLAB	300	200	2783	1	3.8	25%
Monopolar COAG						
SOFT	100	120	264	1.55	1.42	100%
FULGURATE	500	120	3449	1	5.7	6.25%
SPRAY	500	120	3933	1	6.5	4.76%
Bipolar						
LOW (1–15 W)	100	15	133	1	1.42	100%
MEDIUM (16–40 W)	100	40	214	2	1.42	100%
HIGH (45–95 W)	100	95	462	2	1.42	100%
LigaSure						
LIGASURE	20	350	244	5.5	1.42	100%
BIPOLAR RESECTION						
• CUT	500	200	742	2.4	1.42	100%
• COAG	100	175	318	3.2	1.42	100%

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

LOW	434 kHz sinusoid continuous
MEDIUM	434 kHz sinusoid continuous
HIGH	434 kHz sinusoid continuous

Monopolar CUT

CUT	434 kHz sinusoid continuous
BLEND	434 kHz bursts of sinusoid, recurring at 27.13 kHz intervals 50% duty cycle

VALLEYLAB

VALLEYLAB	434 kHz bursts of sinusoid, recurring at 27.13 kHz intervals 25% duty cycle
------------------	--

Monopolar COAG

SOFT	434 kHz sinusoid continuous
FULGURATE	434 kHz damped sinusoidal bursts with a repetition frequency of 27.13 kHz 6.25% duty cycle
SPRAY	434 kHz damped sinusoidal bursts with a randomized repetition centered at 20.67 kHz 4.76% duty cycle

LigaSure

LIGASURE	434 kHz sinusoid continuous
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Bipolar Resection

BIPOLAR RESECTION	434 kHz sinusoid continuous
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Output Power vs. Resistance Graphs

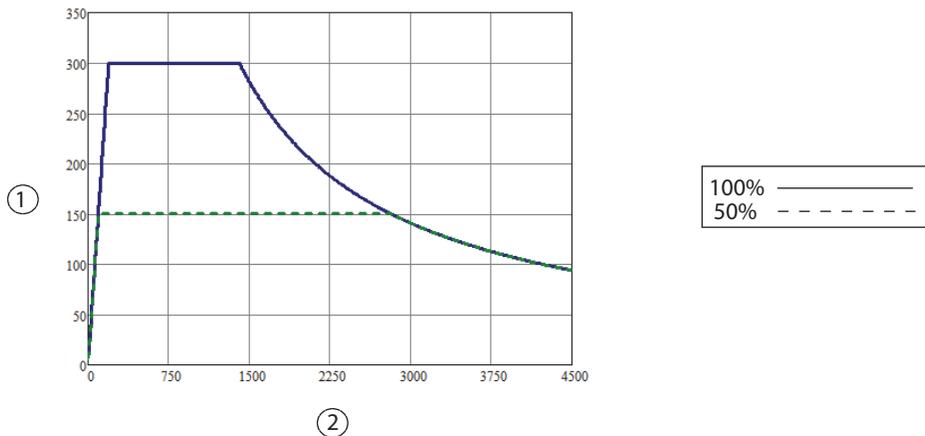
For the values stated in the graphs provided in this section:

- Output power is within the greater of 15% or 8 W.
- Peak voltage includes tolerances.

Monopolar Graphs

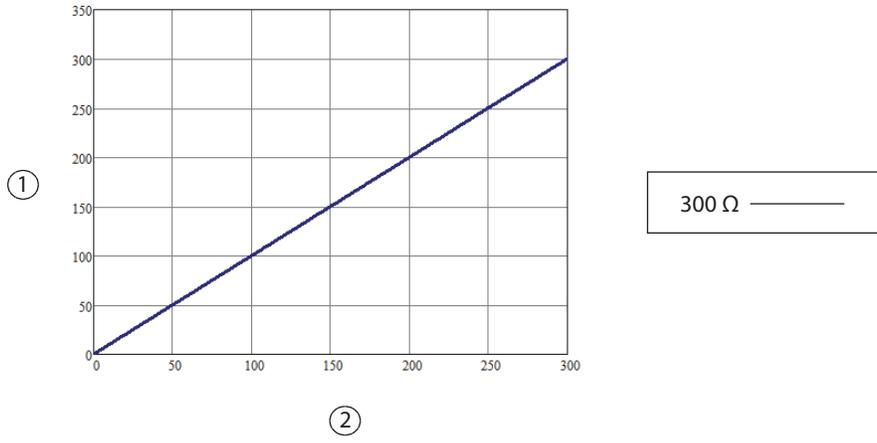
PURE CUT

Output power versus impedance for Pure CUT power



- ① Output power (watts)
- ② Load impedance (ohms)

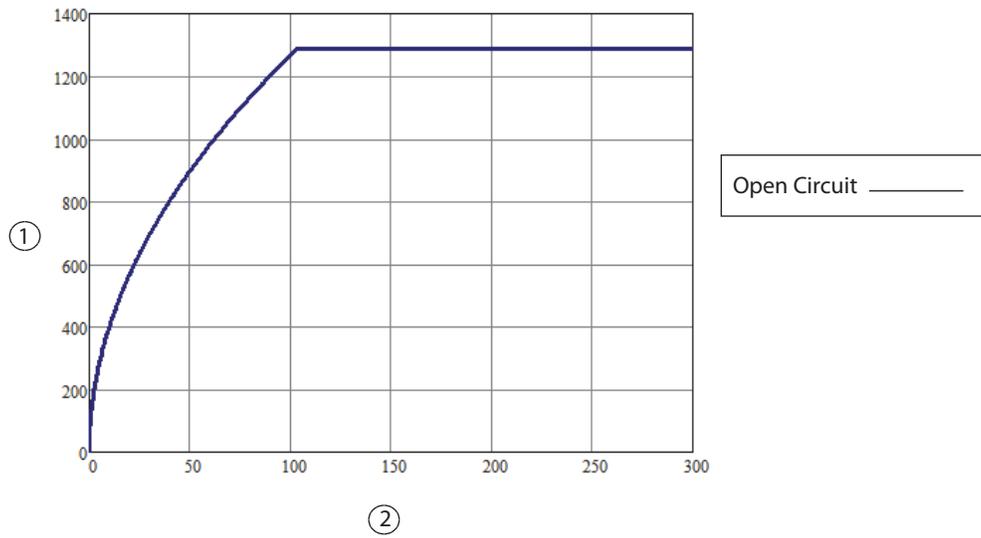
Output power versus power setting for Pure CUT power



① Output power (watts)

② Power setting

Peak voltage versus power setting for Pure CUT power

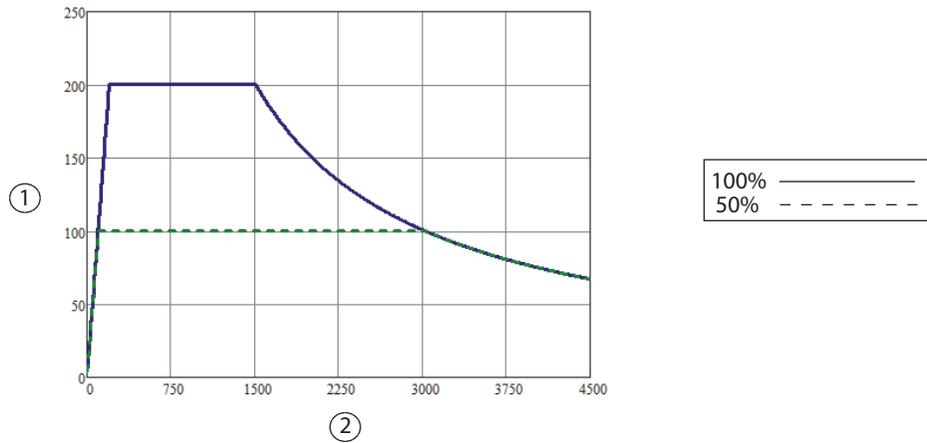


① Peak voltage

② Power setting

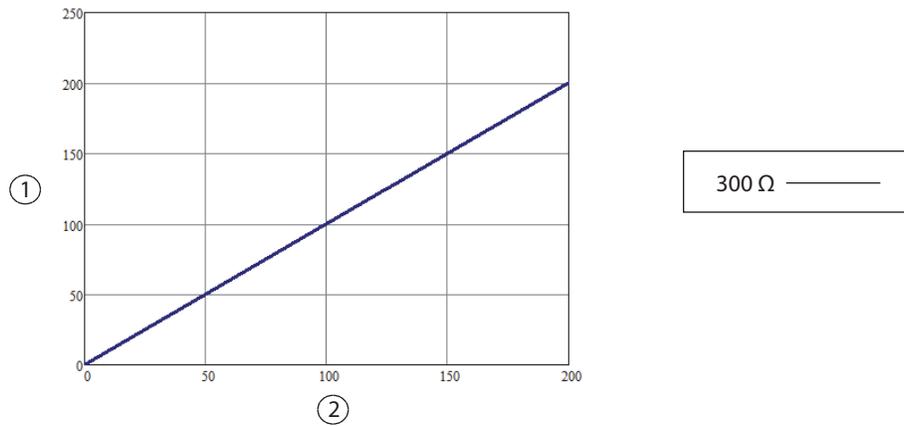
BLEND

Output power versus impedance for BLEND power



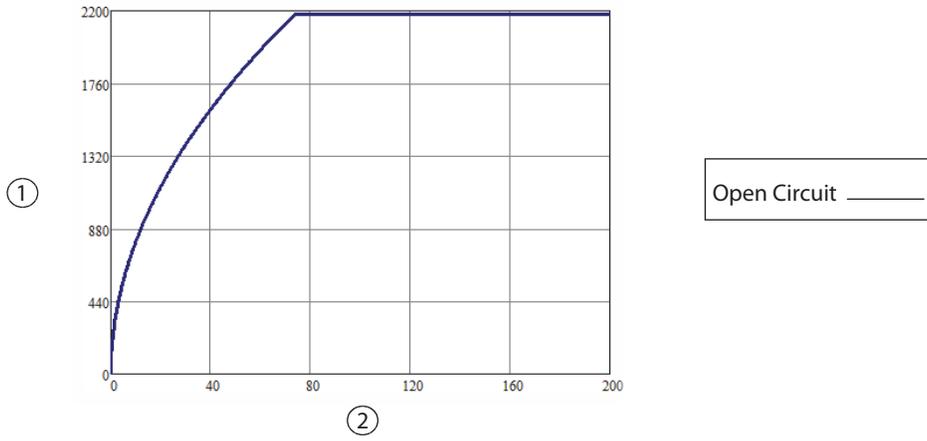
- ① Output power (watts)
- ② Load impedance (ohms)

Output power versus power setting for BLEND power



- ① Output power (watts)
- ② Power setting

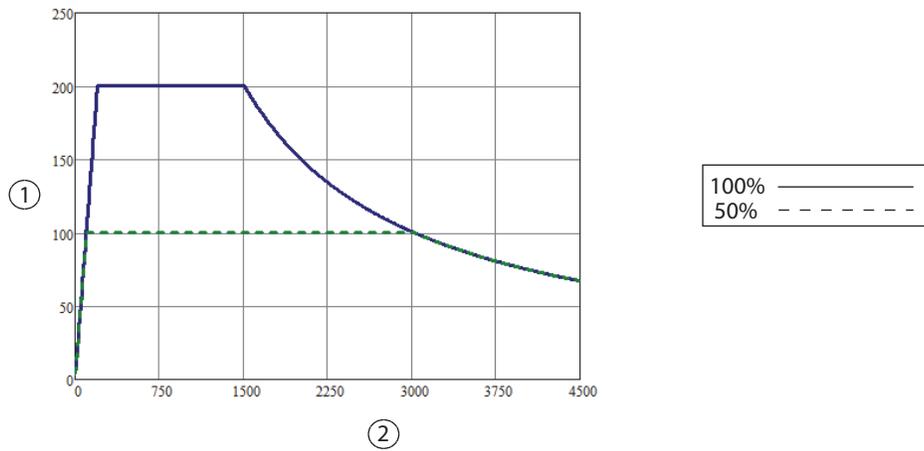
Peak voltage versus power setting for BLEND power



- ① Peak voltage
- ② Power setting

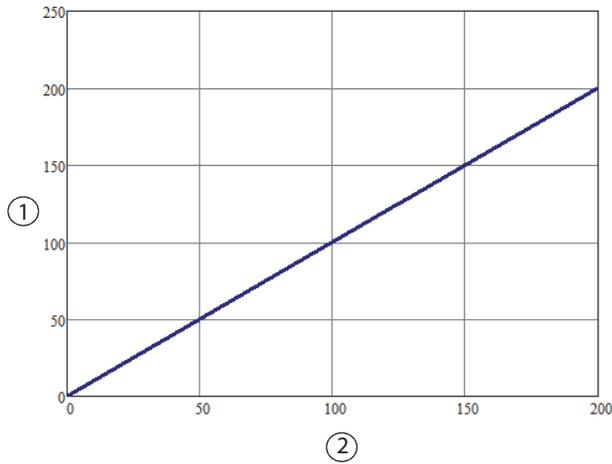
VALLEYLAB

Output power versus impedance for VALLEYLAB power



- ① Output power (watts)
- ② Load impedance (ohms)

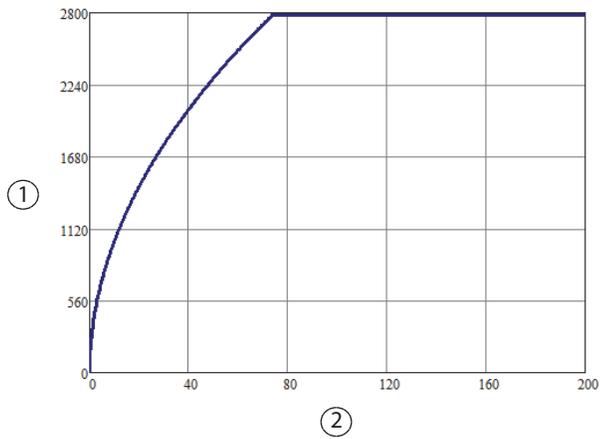
Output power versus power setting for VALLEYLAB power



300 Ω _____

- ① Output power (watts)
- ② Power setting

Peak voltage versus power setting for VALLEYLAB power

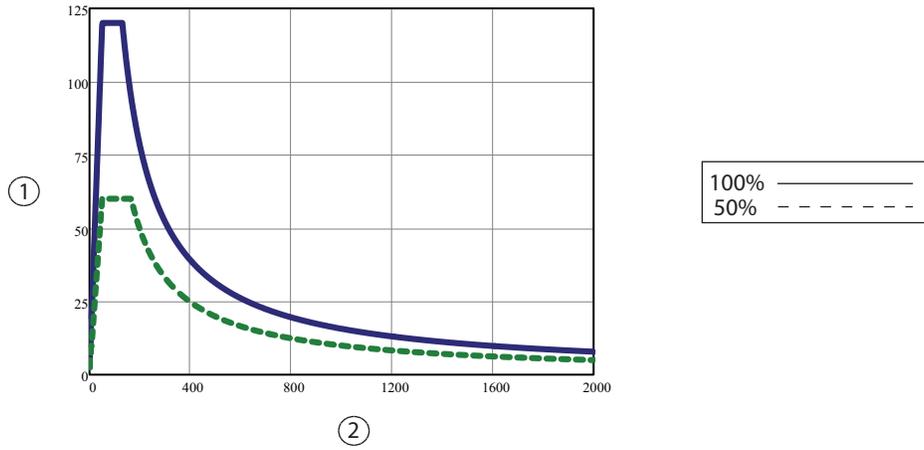


Open Circuit _____

- ① Peak voltage
- ② Power setting

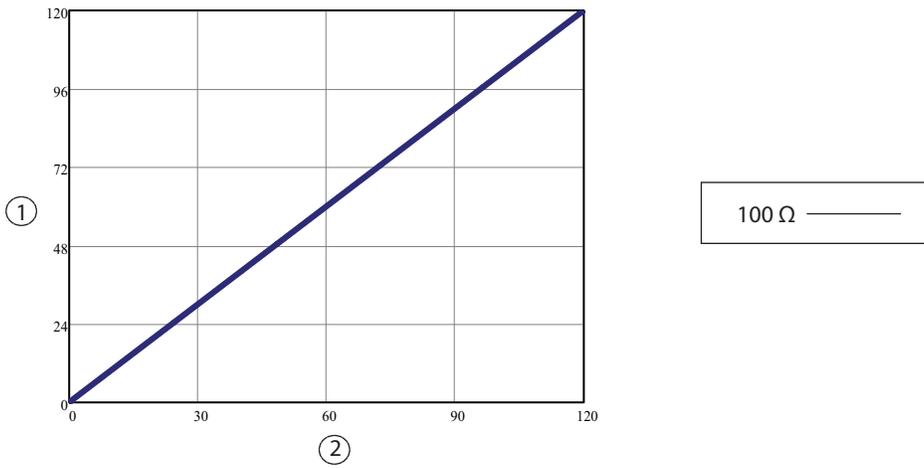
SOFT COAG

Output power versus impedance for SOFT COAG power



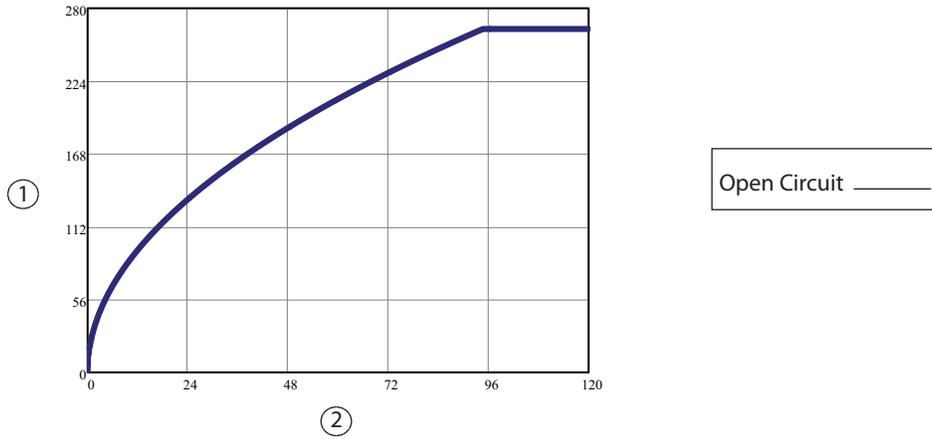
- ① Output power (watts)
- ② Load impedance (ohms)

Output power versus power setting for SOFT COAG power



- ① Output power (watts)
- ② Power setting

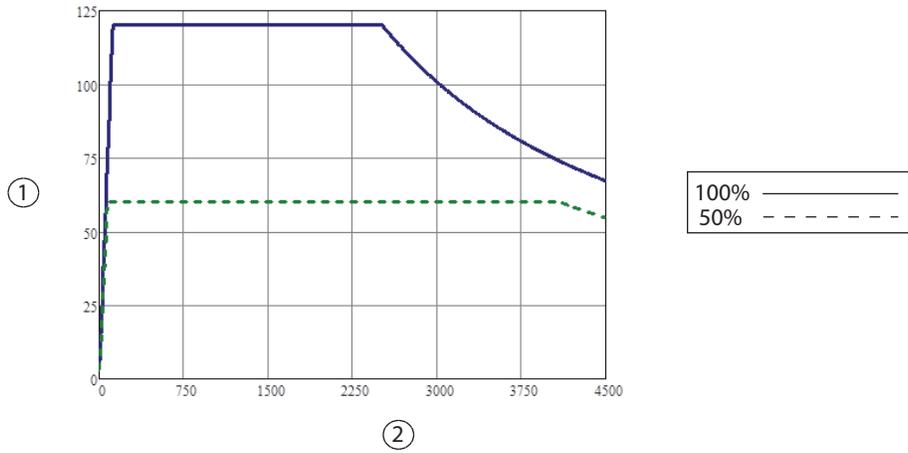
Peak voltage versus power setting for SOFT COAG power



- ① Peak voltage
- ② Power setting

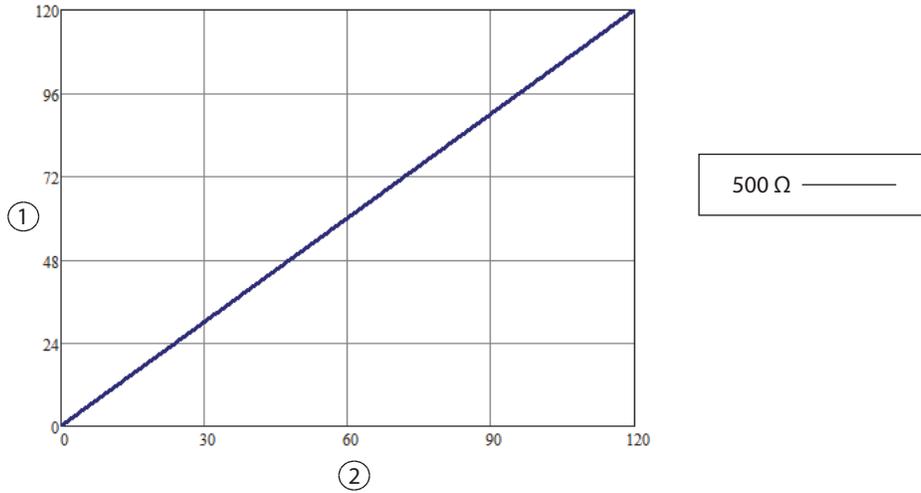
FULGURATE

Output power versus impedance for FULGURATE power



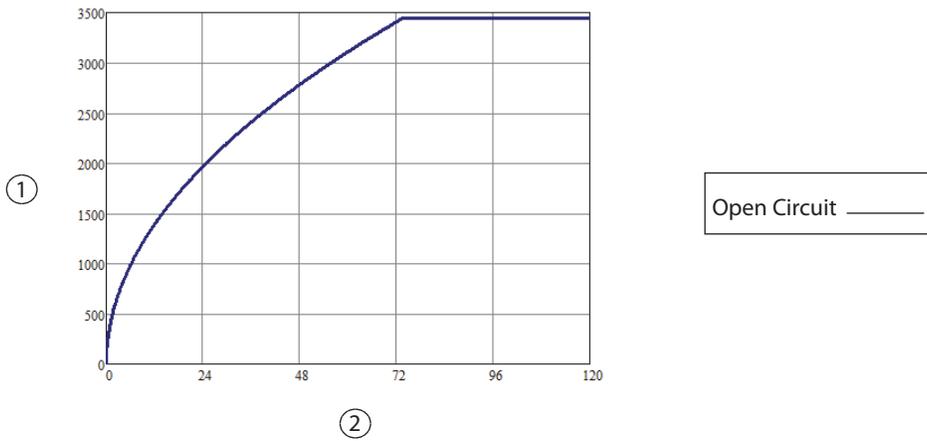
- ① Output power (watts)
- ② Load impedance (ohms)

Output power versus power setting for FULGURATE power



- ① Output power (watts)
- ② Power setting

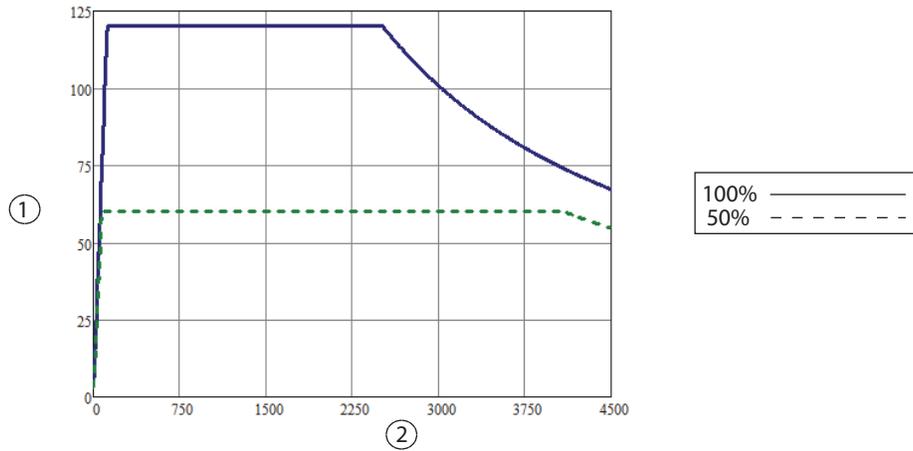
Peak voltage versus power setting for FULGURATE power



- ① Peak voltage
- ② Power setting

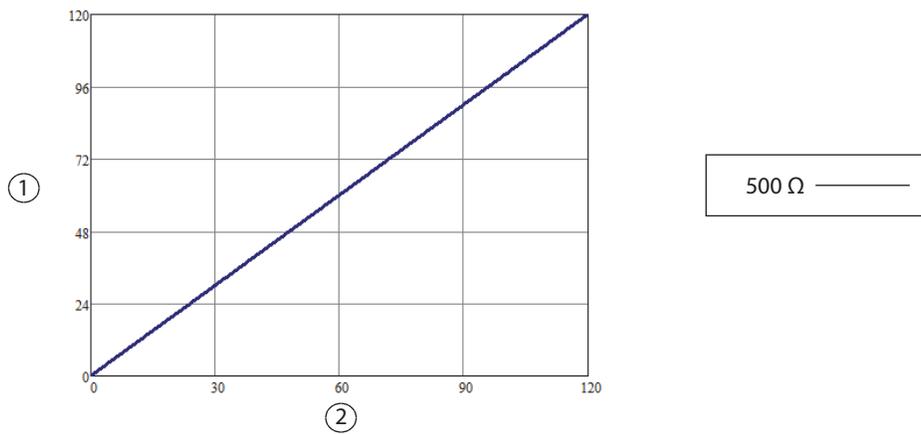
SPRAY

Output power versus impedance for SPRAY power



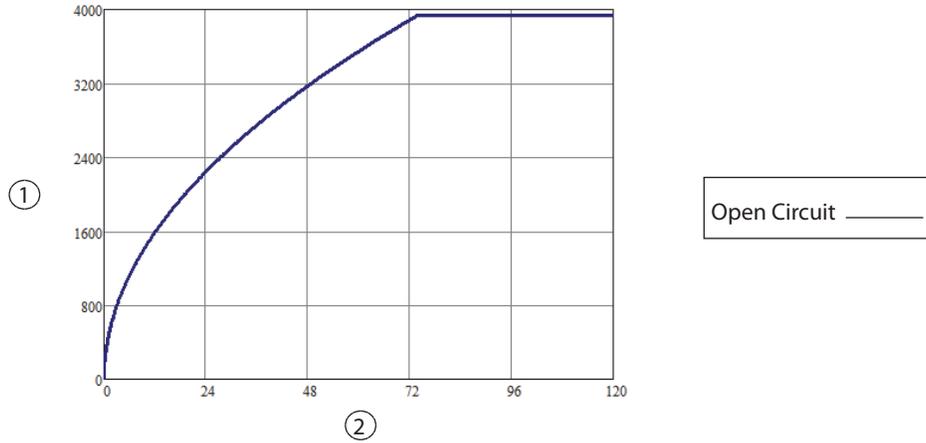
- ① Output power (watts)
- ② Load impedance (ohms)

Output power versus power setting for SPRAY power



- ① Output power (watts)
- ② Power setting

Peak voltage versus power setting for SPRAY power

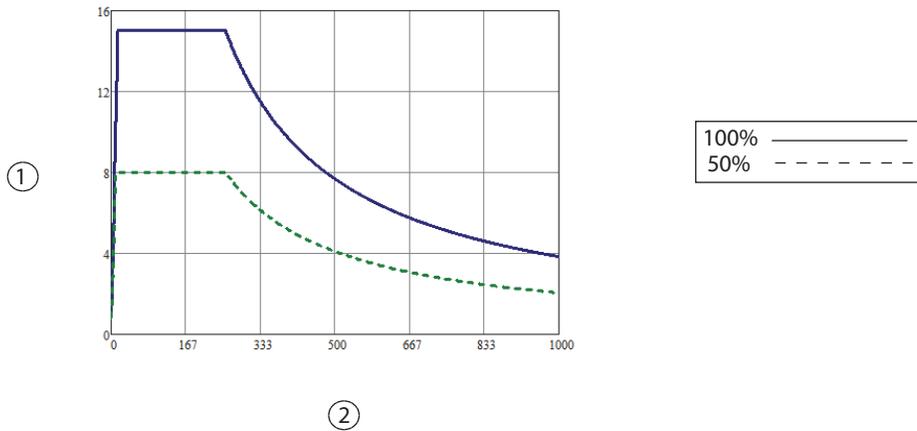


- ① Peak voltage
- ② Power setting

Bipolar Graphs

Bipolar LOW Effect

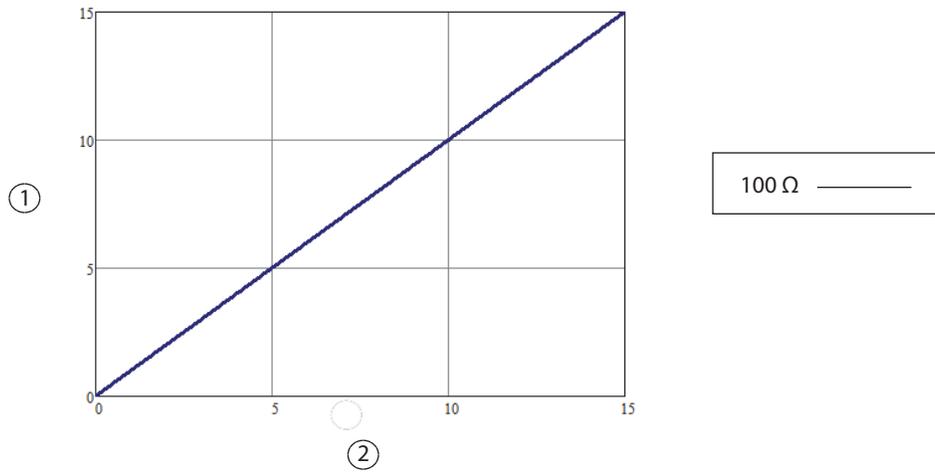
Output power versus impedance for Bipolar LOW power



- ① Output power (watts)
- ② Load impedance (ohms)

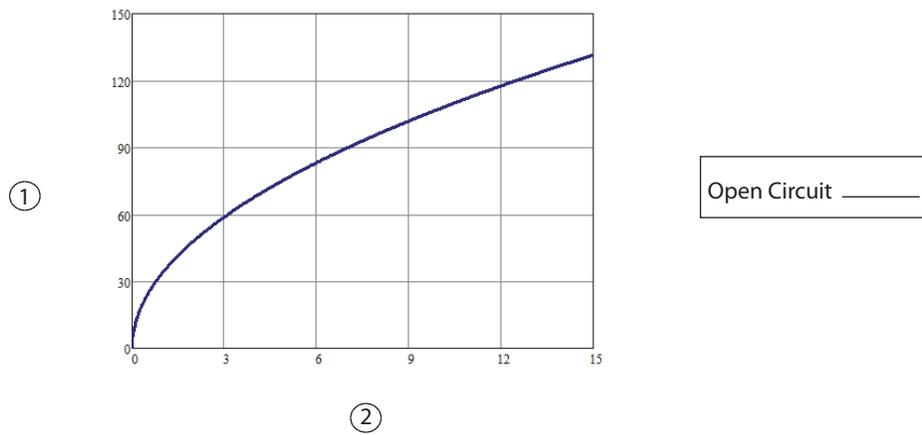
Note: Bipolar LOW effect is utilized for power settings of Off, 1–15 W inclusive within Bipolar mode (1–95 W).

Output power versus power setting for Bipolar LOW power



- ① Output power (watts)
- ② Power setting

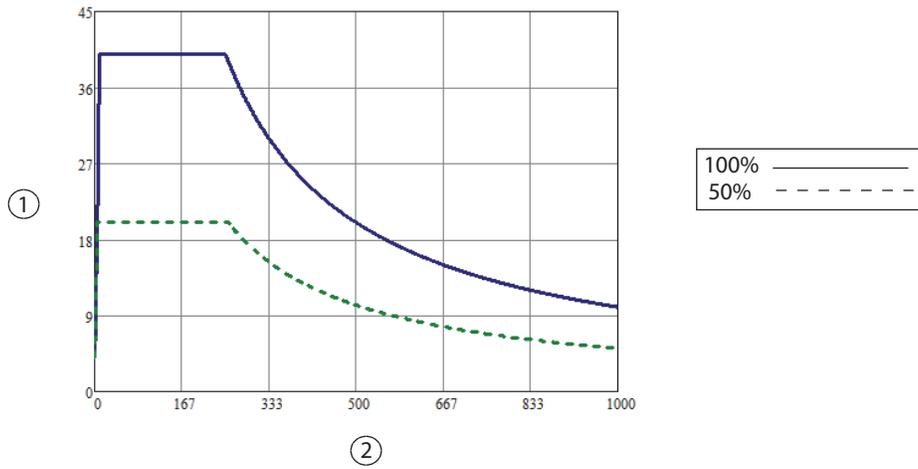
Peak voltage versus power setting for Bipolar LOW power



- ① Peak voltage
- ② Power setting

Bipolar MEDIUM Effect

Output power versus impedance for Bipolar MEDIUM power

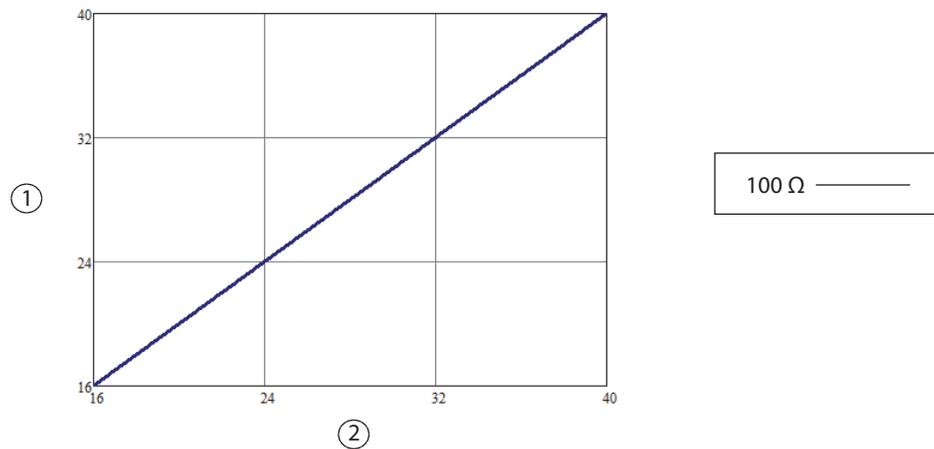


① Output power (watts)

② Load impedance (ohms)

Note: Bipolar MEDIUM effect is utilized for power settings of 16–40 W inclusive within Bipolar mode (1-95 W).

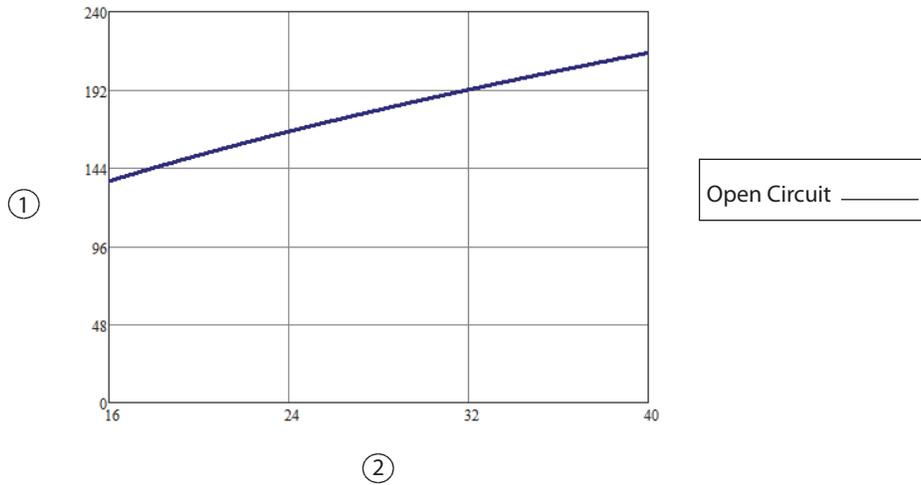
Output power versus power setting for Bipolar MEDIUM power



① Output power (watts)

② Power setting

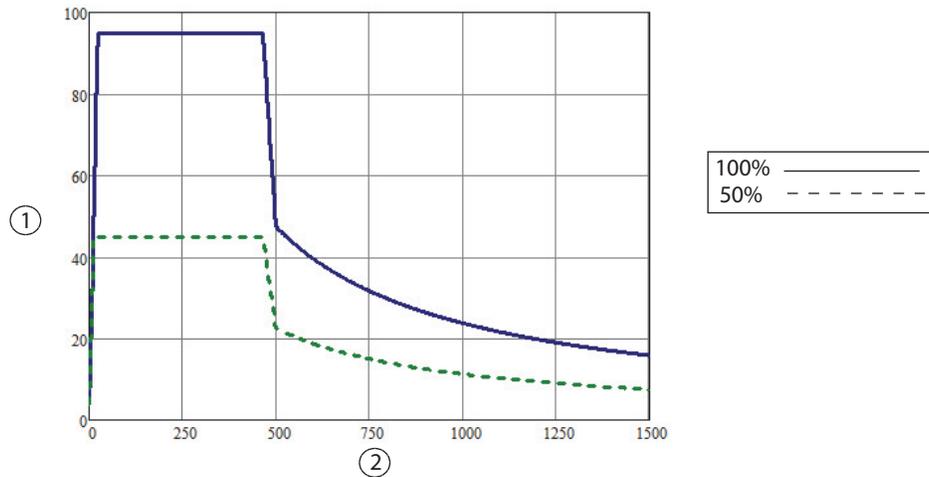
Peak voltage versus power setting for Bipolar MEDIUM power



- ① Peak voltage
- ② Power setting

Bipolar HIGH Effect

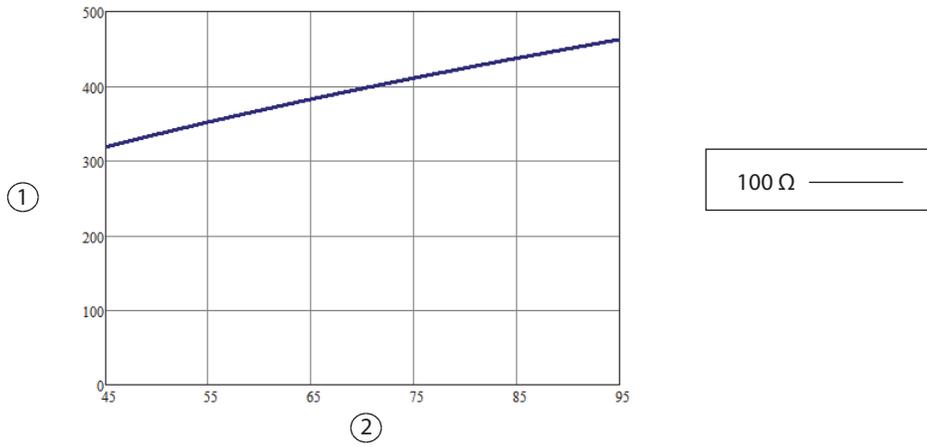
Output power versus impedance for Bipolar HIGH power



- ① Output power (watts)
- ② Load impedance (ohms)

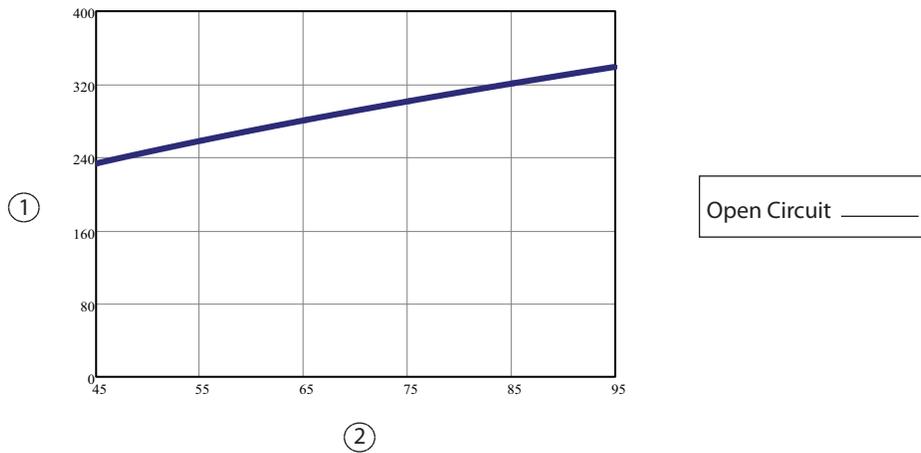
Note: Bipolar HIGH Effect is utilized for power settings of 45–95 W inclusive within Bipolar mode (1–95 W).

Output power versus power setting for Bipolar HIGH power



- ① Output power (watts)
- ② Power setting

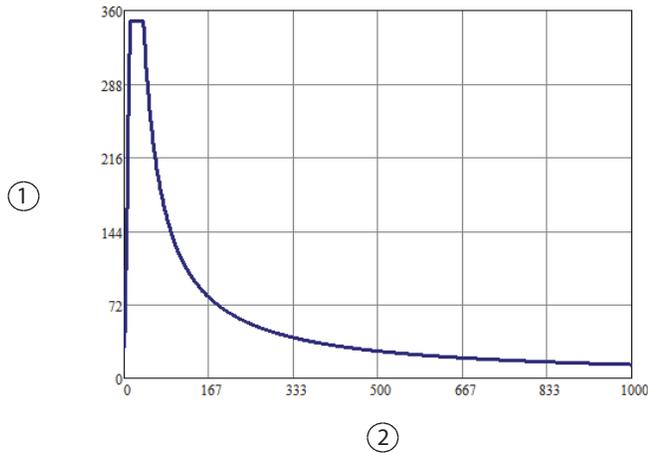
Peak voltage versus power setting for Bipolar HIGH power



- ① Peak voltage
- ② Power setting

LigaSure

Output power versus impedance for LigaSure power

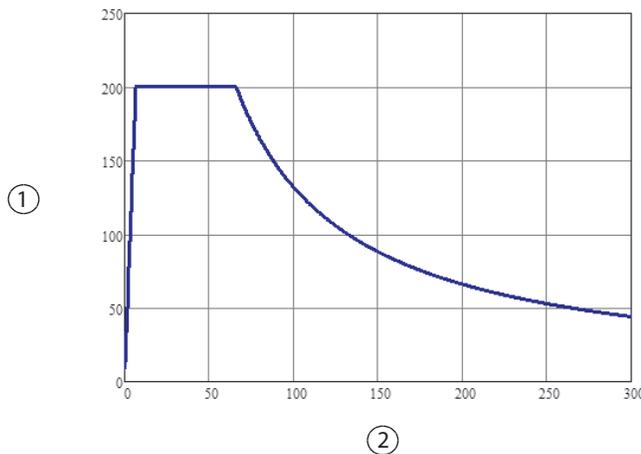


① Output power (watts)

② Load impedance (ohms)

Note: The LigaSure Vessel Sealing algorithm is a vessel adaptive algorithm. The LigaSure Vessel Sealing algorithm only requests the power it needs to optimally seal vessels; the power requested will be within the confines of the output power capability curve.

Output power versus impedance for representative LigaSure instruments

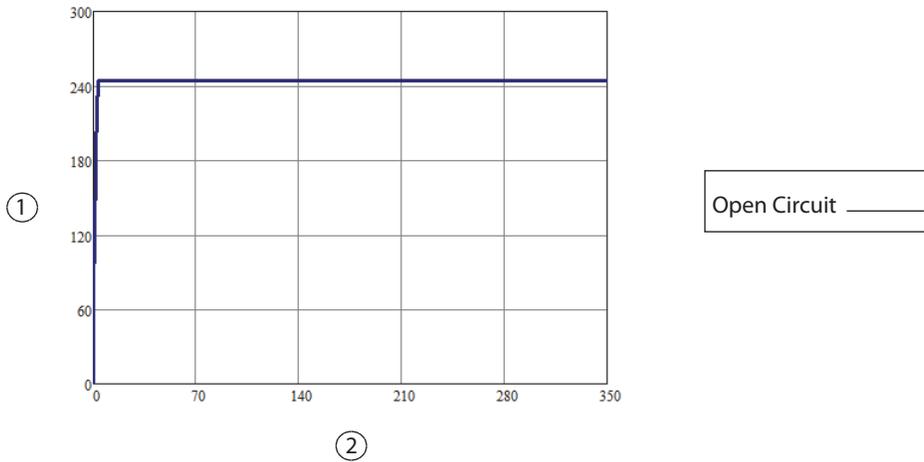


① Output power (watts)

② Load impedance (ohms)

Note: The LigaSure algorithm limits the power to 200 watts for the representative LigaSure instruments including LF1537, LF1544, LF5544, LF1212, LF1212A, LF4200, LF4200T, LF1520, LF1723, LF1737, LF1744, LF1637, LF1623, LF1644, LF3225, LS1020, LS1037, LF4318, LF5637, and LF5644.

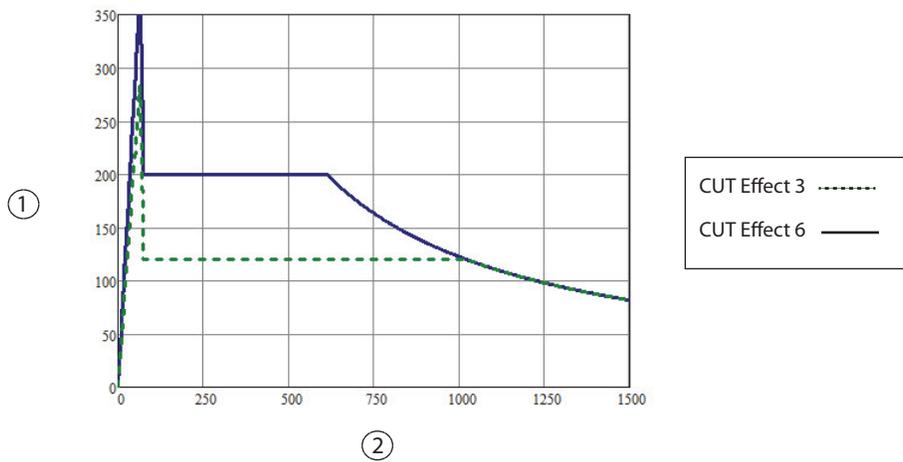
Peak voltage versus output power for LigaSure power



- ① Peak voltage
- ② Output power (watts)

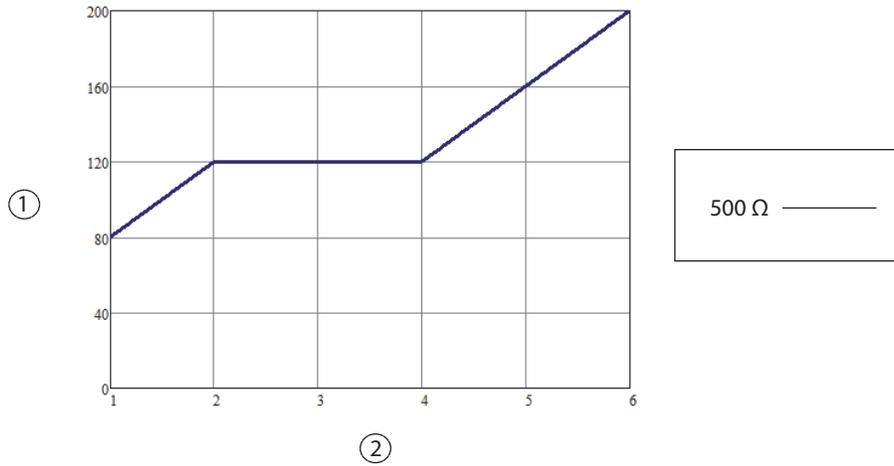
Bipolar Resection CUT

Output power versus impedance for Bipolar Resection CUT effect setting



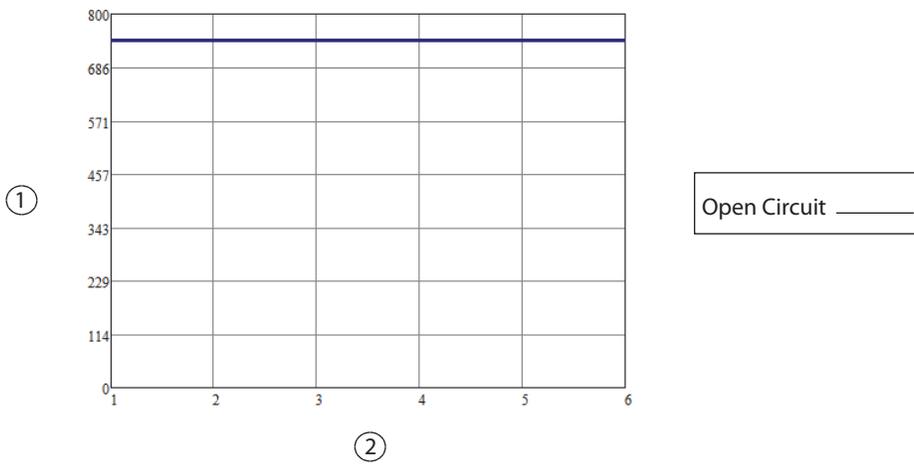
- ① Output power (watts)
- ② Load impedance (ohms)

Output power versus Bipolar Resection CUT effect setting



- ① Peak voltage
- ② Effect setting

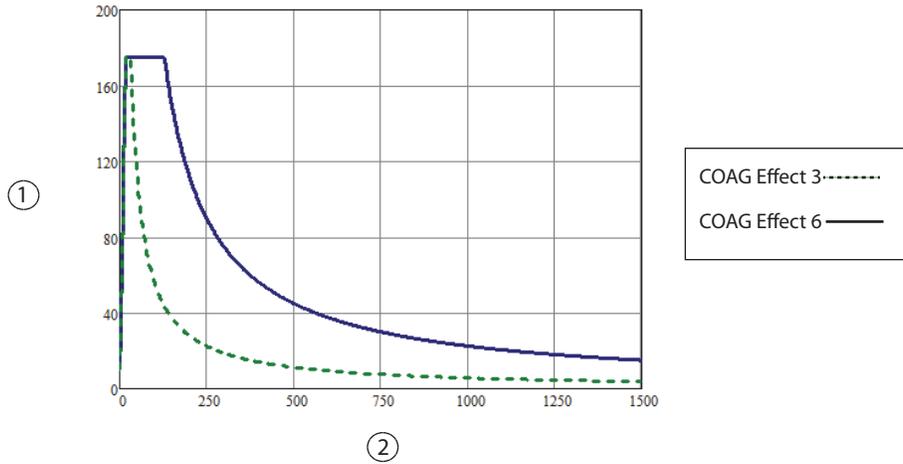
Peak voltage versus Bipolar Resection CUT effect setting



- ① Peak voltage
- ② Effect setting

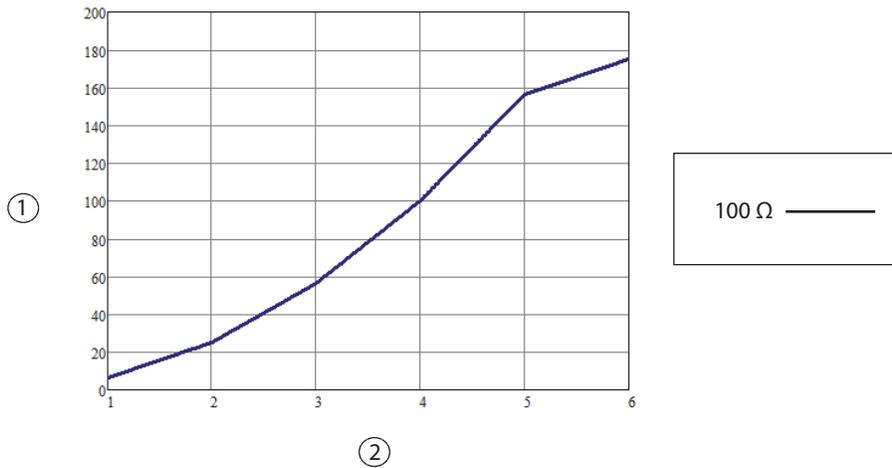
Bipolar Resection COAG

Output power versus impedance for Bipolar Resection COAG setting



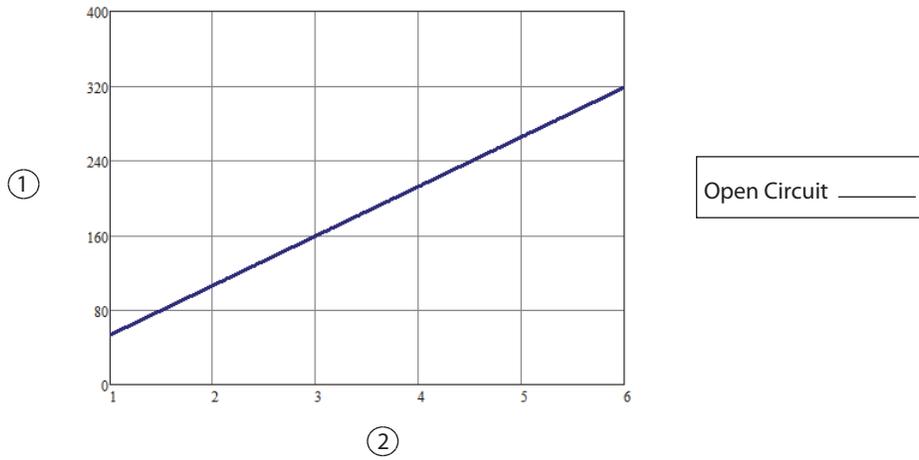
- ① Output power (watts)
- ② Load impedance (ohms)

Output power versus Bipolar Resection COAG effect setting



- ① Peak voltage
- ② Effect setting

Peak voltage versus Bipolar Resection COAG effect setting



- ① Peak voltage
- ② Effect setting

Europos bendrasis viešųjų pirkimų dokumentas (EBVPD)

I dalis. Informacija apie pirkimo procedūrą ir perkančiąją organizaciją ar perkantįjį subjektą

Informacija apie paskelbimą

Skelbimo numeris OL S (tik tarptautiniams pirkimams):

-

Skelbimo numeris CVP IS (kur rasti?)

542359

Perkančiosios organizacijos / Perkančiojo subjekto tapatybė

Oficialus pavadinimas:

Viešoji įstaiga Klaipėdos jūrininkų ligoninė

Šalis:

Lietuva

Informacija apie pirkimo procedūrą

Procedūros tipas

Atvira

Pavadinimas:

Medicinos įranga (hemodializės, EKG aparatai, elektrokoagulatoriai))

Trumpas aprašymas:

Medicinos įranga (hemodializės, EKG aparatai, elektrokoagulatoriai))

Perkančiosios organizacijos ar perkančiojo subjekto (jei taikoma) priskirtas dokumento numeris:

542359

II dalis. Informacija apie ekonominės veiklos vykdytoją

A. Informacija apie ekonominės veiklos vykdytoją

Tiekėjo pavadinimas arba vardas ir pavardė (jei fizinis asmuo):

UAB "Sorimpeksas"

Gatvė ir namo numeris:

Šiaulių 16a.

Pašto kodas:

LT44353

Miestas:

Kaunas

Šalis:

Lietuva

Interneto adresas (jei yra):

-

E. paštas:

daiva@sorimpeksas.com

Telefonas:

+370 37 361766

Asmuo ar asmenys ryšiams:

Daiva Macijauskienė

PVM mokėtojo kodas, jei yra:

LT357332412

Jei PVM mokėtojo kodo nėra, nurodykite kitą nacionalinį identifikacinį numerį (Lietuvoje - įmonės kodą)

-

Ar ekonominės veiklos vykdytojas yra labai maža, mažoji ar vidutinė įmonė?

Taip

Ne

Tik tuo atveju, kai pirkimas rezervuotas: ar ekonominės veiklos vykdytojas yra globojama darbo grupė (neįgaliųjų socialinė įmonė), socialinė įmonė? Ar jis vykdys sutartį pagal globojamų darbo grupių (neįgaliųjų socialinių įmonių) užimtumo programas?

Taip

Ne

Jei taikoma, ar ekonominės veiklos vykdytojas įtrauktas į oficialų patvirtintų ekonominės veiklos vykdytojų sąrašą arba ar jis turi lygiavertį sertifikatą (pvz., pagal nacionalinę (išankstinę) kvalifikacijos vertinimo sistemą)? Lietuvos tiekėjai renkasi „ne“

Taip

Ne

- Be to, užpildykite trūkstamą informaciją IV dalies A, B, C arba D skirsniuose, atsižvelgdami į konkretų atvejį TIK jei to reikalaujama atitinkamame skelbime arba pirkimo dokumentuose:

e) Ar ekonominės veiklos vykdytojas galės pateikti sertifikatą dėl socialinio draudimo įmokų ir mokesčių mokėjimo arba pateikti informaciją, kuri leistų perkančiajai organizacijai ar perkančiajam subjektui jį gauti tiesiogiai naudojantis prieiga prie bet kurios iš valstybių narių nemokamos nacionalinės duomenų bazės?

Taip

Ne

Jei atitinkami dokumentai prieinami elektroniniu būdu, nurodykite:

https://draudejai.sodra.lt/draudeju_viesi_duomenys/

Ar ekonominės veiklos vykdytojas pirkimo procedūroje dalyvauja kartu su kitais? Žymima TAIP, jei pasiūlymą teikia ūkio subjektų grupė (konsorciumas) pagal jungtinės veiklos sutartį

Taip

Ne

Jei pirkimas padalintas į dalis, nuoroda į pirkimo dalį (-is), dėl kurios (-ių) ekonominės veiklos vykdytojas nori dalyvauti konkurse:

2 PIRKIMO DALIS

B. Informacija apie ekonominės veiklos vykdytojo teisinius atstovus #1

- Šis skirsnis pildomas, jeigu tiekėjo vadovas įgalioja kitą asmenį pasirašyti pasiūlymą, bendrauti su pirkimo vykdytoju, įgalioja atstovauti ir pasirašyti EBVPD, bendrauti su pirkimo vykdytoju dėl EBVPD pateiktos informacijos, teikiamų kvalifikaciją ir pašalinimo pagrindų nebuvimą pagrindžiančių dokumentų, dėl pasiūlymo ir pan.

Jeif taikytina, nurodykite asmens (-ų), įgalioto (-ų) atstovauti ekonominės veiklos vykdytojui šios pirkimo procedūros tikslais, vardą ir pavardę ir adresą:

Vardas

Daiva

Pavardė

Macijauskienė

Gimimo data

-

Gimimo vieta

-

Gatvė ir namo numeris:

Šiaulių 16 a.

Pašto kodas:

LT44353

Miestas:

Kaunas

Šalis:

Lietuva

E. paštas:

-

Telefonas:

-

Pareigos arba statusas:

-

Prireikus pateikite išsamią informaciją apie atstovavimą (formą, aprėptį, paskirtį ir t. t.):

-

C. Informacija apie rėmimąsi kitų subjektų pajėgumais

Ar siekdamas patenkinti IV dalyje nurodytus atrankos kriterijus ir V dalyje nurodytus kriterijus bei taisykles (jei tokių yra) ekonominės veiklos vykdytojas remiasi kitų subjektų pajėgumais?

Taip

Ne

D. Informacija apie subrangovus, kurių pajėgumais ekonominės veiklos vykdytojas nesiremia

- (Skirsnį reikia pildyti, tik jei šios informacijos aiškiai reikalauja perkančioji organizacija ar perkantysis subjektas.)

Ar ekonominės veiklos vykdytojas ketina kurias nors sutarties dalis subrangos sutartimi pavesti atlikti trečiosioms šalims?

Taip

Ne

- Jei perkančioji organizacija ar perkantysis subjektas aiškiai prašo šios informacijos, šalia informacijos pagal šį skirsnį, pateikite pagal šios dalies A ir B skirsnius ir III dalį reikalaujamą informaciją apie kiekvieną susijusį subrangovą (subrangovų kategorijas).

III dalis. Pašalinimo pagrindai

A. Su baudžiamaisiais nuosprendžiais susiję pagrindai

Direktyvos 2014/24/ES 57 straipsnio 1 dalyje nustatyti šie pašalinimo pagrindai

Dalyvavimas nusikalstamos organizacijos veikloje (VPĮ 46 str. 1 d. 1 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už dalyvavimą nusikalstamos organizacijos veikloje, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2008 m. spalio 24 d. Tarybos pamatinio sprendimo 2008/841/TVR dėl kovos su organizuotu nusikalstamumu 2 straipsnyje (OL L 300, 2008 11 11, p. 42).

Jūsų atsakymas

Taip

Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

Taip

Ne

Korupcija (VPĮ 46 str. 1 d. 2 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už korupciją, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta Konvencijos dėl kovos su korupcija, susijusia

su Europos Bendrijų pareigūnais ar Europos Sąjungos valstybių narių pareigūnais, 3 straipsnyje (OL C 195, 1997 6 25, p. 1) ir 2003 m. liepos 22 d. Tarybos pamatinio sprendimo 2003/568/TVR dėl kovos su korupcija privačiame sektoriuje 2 straipsnio 1 dalyje (OL L 192, 2003 7 31, p. 54). Į pašalinimo pagrindus taip pat įtraukta korupcija, kaip apibrėžta perkančiosios organizacijos (perkančiojo subjekto) arba ekonominės veiklos vykdytojo nacionalinėje teisėje.

Jūsų atsakymas

Taip

Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

Taip

Ne

Sukčiavimas (VPĮ 46 str. 1 d. 3 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už sukčiavimą, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Pagal Europos Bendrijų finansinių interesų apsaugos konvencijos 1 straipsnį (OL C 316, 1995 11 27, p. 48).

Jūsų atsakymas

Taip

Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

Taip

Ne

Teroristiniai nusikaltimai arba su teroristine veikla susiję nusikaltimai (VPĮ 46 str. 1 d. 5 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už teroristinius nusikaltimus arba su teroristine veikla susijusius nusikaltimus, o nuosprendis priimtas prieš ne

daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2002 m. birželio 13 d. Tarybos pamatinio sprendimo dėl kovos su terorizmu 1 ir 3 straipsniuose (OL L 164, 2002 6 22, p. 3). Į pašalinimo pagrindus taip pat įtrauktas nusikalstamos veikos kurstymas, pagalba ar bendrininkavimas ją vykdant arba kėsintis ją įvykdyti, kaip nurodyta to pamatinio sprendimo 4 straipsnyje.

Jūsų atsakymas

Taip

Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

Taip

Ne

Pinigų plovimas arba teroristų finansavimas (VPĮ 46 str. 1 d. 6 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už pinigų plovimą arba teroristų finansavimą, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2005 m. spalio 26 d. Europos Parlamento ir Tarybos direktyvos 2005/60/EB dėl finansų sistemos apsaugos nuo jos panaudojimo pinigų plovimui ir teroristų finansavimui 1 straipsnyje (OL L 309, 2005 11 25, p. 15).

Jūsų atsakymas

Taip

Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

Taip

Ne

Vaikų darbas ir kitos prekybos žmonėmis formos (VPĮ 46 str. 1 d. 7 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už vaikų darbą arba kitas prekybos

žmonėmis formos, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2011 m. balandžio 5 d. Europos Parlamento ir Tarybos direktyvos 2011/36/ES dėl prekybos žmonėmis prevencijos, kovos su ja ir aukų apsaugos, pakeičiančios Tarybos pamatinį sprendimą 2002/629/TVR, 2 straipsnyje (OL L 101, 2011 4 15, p. 1).

Jūsų atsakymas

Taip

Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

Taip

Ne

B. Su mokesčių ar socialinio draudimo įmokų mokėjimu susiję pagrindai **Direktyvos 2014/24/ES 57 straipsnio 2 dalyje nustatytos šios pašalinimo priemonės**

Mokesčių mokėjimas VPĮ 46 str. 3 d.

Ar ekonominės veiklos vykdytojas pažeidė savo pareigas, susijusias su mokesčių mokėjimu, tiek šalyje, kurioje yra įsisteigęs, tiek perkančiosios organizacijos ar perkančiojo subjekto valstybėje narėje, jei tai nėra jo įsisteigimo šalis?

Jūsų atsakymas

Taip

Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

Taip

Ne

Socialinio draudimo įmokų mokėjimas VPĮ 46 str. 3 d.

Ar ekonominės veiklos vykdytojas pažeidė savo pareigas, susijusias su socialinio draudimo įmokų mokėjimu, tiek šalyje, kurioje yra įsisteigęs, tiek perkančiosios organizacijos ar perkančiojo subjekto valstybėje narėje, jei tai nėra jo įsisteigimo šalis?

Jūsų atsakymas

Taip

Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

Taip

Ne

URL

https://draudejai.sodra.lt/draudeju_viesi_duomenys/

Kodas

-

Emitentas

Valstybinio socialinio draudimo fondo valdyba prie Socialinės apsaugos ir darbo ministerijos

C. Su nemokumu, interesų konfliktu ar profesiniais nusižengimais susiję pagrindai

Direktyvos 2014/24/ES 57 straipsnio 4 dalyje nustatyti šie pašalinimo pagrindai

Su kitais ekonominės veiklos vykdytojais sudaryti susitarimai, kuriais siekta iškraipyti konkurenciją (VPĮ 46 str. 4 d. 1 p.)

Ar ekonominės veiklos vykdytojas su kitais ekonominės veiklos vykdytojais yra sudaręs susitarimų, kuriais siekta iškraipyti konkurenciją?

Jūsų atsakymas

Taip

Ne

Pripažinimas kaltu dėl sunkaus profesinio nusižengimo VPĮ 46 str. 4 d. 7 p., VPĮ 46 str. 6 d. 3 p.

Ar ekonominės veiklos vykdytojas yra pripažintas kaltu dėl sunkaus profesinio nusižengimo kaip nurodyta žemiau?

I. ar ekonominės veiklos vykdytojas yra padaręs profesinį pažeidimą, kai už finansinės atskaitomybės ir audito teisės aktų pažeidimus ekonominės veiklos vykdytojui ar jo vadovui paskirta administracinė nuobauda ar ekonominė sankcija, nustatytos Lietuvos Respublikos įstatymuose ar kitų valstybių teisės aktuose, ir nuo sprendimo, kuriuo buvo paskirta ši sankcija, įsiteisėjimo dienos arba nuo dienos, kai asmuo įvykdė administracinį nurodymą, praėjo mažiau kaip vieni metai?

II. Ar ekonominės veiklos vykdytojas yra padaręs kurį nors vieną iš žemiau nurodytų rimtų profesinių pažeidimų(taikoma tik tada kai, ir tik tiek, kiek apibrėžta kituose pirkimo dokumentuose):

a) profesinės etikos pažeidimas, kai nuo ekonominės veiklos vykdytojo pripažinimo nesilaikančiu profesinės etikos normų momento praėjo mažiau kaip vieni metai;

b) konkurencijos, darbuotojų saugos ir sveikatos, informacijos apsaugos, intelektinės nuosavybės apsaugos pažeidimas, už kurį ekonominės veiklos vykdytojui ar jo vadovui yra paskirta administracinė nuobauda ar ekonominė sankcija, nustatytos Lietuvos Respublikos ar kitų valstybių įstatymuose, kai nuo sprendimo, kuriuo buvo paskirta ši sankcija, arba nuo dienos, kai asmuo įvykdė administracinį nurodymą, įsiteisėjimo dienos praėjo mažiau kaip vieni metai;

c) draudimo sudaryti draudžiamus susitarimus, įtvirtinto Lietuvos Respublikos konkurencijos įstatyme ar panašaus pobūdžio kitos valstybės teisės akte, pažeidimas, kai nuo sprendimo paskirti Konkurencijos įstatyme ar kitos valstybės teisės akte nustatytą ekonominę sankciją įsiteisėjimo dienos praėjo mažiau kaip 3 metai;

d) ekonominės veiklos vykdytojas, kuris yra fizinis asmuo, arba ekonominės veiklos vykdytojo, kuris yra juridinis asmuo, kita organizacija ar jos padalinys, vadovas, kitas valdymo ar priežiūros organo narys ar kitas asmuo, turintis (turintys) teisę atstovauti ekonominės veiklos vykdytojui ar jį kontroliuoti, jo vardu priimti sprendimą, sudaryti sandorį, arba dalyvis, turintis balsų daugumą juridinio asmens dalyvių susirinkime, yra pripažintas kaltu dėl tyčinio bankroto, kaip jis apibrėžtas Lietuvos Respublikos įmonių bankroto įstatyme ar panašaus pobūdžio kitų valstybių teisės aktuose, kai nuo teismo sprendimo įsiteisėjimo dienos praėjo mažiau kaip 3 metai?

Jūsų atsakymas

Taip

Ne

Interesų konfliktas dėl dalyvavimo pirkimo procedūroje (VPĮ 46 str. 4 d. 2 p.)

Ar ekonominės veiklos vykdytojas žino apie kokius nors [interesų konfliktus](#), kaip nurodyta nacionalinėje teisėje, atitinkamame skelbime ar pirkimo dokumentuose, kylančius dėl jo dalyvavimo pirkimo procedūroje?

Jūsų atsakymas

Taip

Ne

Tiesioginis arba netiesioginis dalyvavimas rengiant šią pirkimo procedūrą (46 str. 4 d. 3 p.)

Ar ekonominės veiklos vykdytojas arba su juo susijusi įmonė konsultavo perkančiąją organizaciją ar perkantįjį subjektą arba kitaip dalyvavo rengiant pirkimo procedūrą?

Jūsų atsakymas

Taip

Ne

Sutarties nutraukimas anksčiau laiko, žala ar kitos panašios sankcijos (VPĮ 46 str. 4 d. 6 p.)

Ar ekonominės veiklos vykdytojas turėjo tokios patirties: ankstesnė viešoji sutartis, ankstesnė sutartis su perkančiuoju subjektu arba ankstesnė koncesijos sutartis buvo nutraukta anksčiau laiko; arba buvo pareikalauta atlyginti su ankstesne sutartimi susijusią žalą ar skirtos kitos panašios sankcijos?

Lietuvoje (be kita ko) - ar ekonominės veiklos vykdytojas yra įtrauktas į nepatikimų tiekėjų sąrašą ?

Jūsų atsakymas

Taip

Ne

Pripažinimas kaltu dėl faktų iškraipymo, informacijos nuslėpimo, negalėjimas pateikti reikalaujamų dokumentų ir su šia procedūra susijusios konfidencialios informacijos gavimas (46 str. 4 d. 4 p. ir 46 str. 4 d. 5 p.)

Ar ekonominės veiklos vykdytojas yra susijęs su vienu iš šių atvejų, kai jis :

a) buvo labai iškreipęs faktus pateikdamas informaciją (**pateikęs melagingą informaciją**), reikalingą patikrinti, ar nėra pagrindų pašalinti, arba patikrinti atitiktį atrankos kriterijams;

b) slėpė tokią informaciją;

c) delsė pateikti patvirtinamuosius dokumentus, kurių reikalavo perkančioji organizacija ar perkantysis subjektas,

d) siekė daryti neteisėtą įtaką perkančiosios organizacijos ar perkančiojo subjekto sprendimų priėmimo procesui, kad gautų konfidencialios informacijos, dėl kurios per pirkimo procedūrą įgytų nepagrįstą pranašumą, arba tyčia teikti klaidinančios informacijos, kuri gali turėti esminės įtakos sprendimams dėl pašalinimo, atrankos ar sutarties skyrimo?

Jūsų atsakymas

Taip

Ne

D. Išimtinai nacionaliniai pašalinimo pagrindai

Išimtinai nacionaliniai pašalinimo pagrindai, nurodyti atitinkamame skelbime ar pirkimo dokumentuose.

Išimtinai nacionaliniai pašalinimo pagrindai (VPĮ 46 str. 1 d. 4 p., 46 str. 4 d. 8 p.)

Ar ekonominės veiklos vykdytojas yra susijęs su vienu iš šių atvejų, kai:

a) jis **neatitinka minimalių patikimo mokesčių mokėtojo kriterijų**, nustatytų Lietuvos Respublikos mokesčių administravimo įstatymo 40¹ straipsnio 1 dalyje ir dėl to laikomas padariusiu šiurkštų profesinį pažeidimą.

b) pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo **nuteistas galutiniu teismo sprendimu už nusikalstamą bankrotą**, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsias?

Jūsų atsakymas

Taip

Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

Taip

Ne

URL

[http://www.vmi.lt/cms/informacija-apie-mokesciu-moketojus?](http://www.vmi.lt/cms/informacija-apie-mokesciu-moketojus?fbclid=IwAR3_ZWzap0oP9j3fDM1JhXkS8LhLW_7I6KyA_h6gHzdEwsl7UbsG7ySKyPk)

[fbclid=IwAR3_ZWzap0oP9j3fDM1JhXkS8LhLW_7I6KyA_h6gHzdEwsl7UbsG7ySKyPk](http://www.vmi.lt/cms/informacija-apie-mokesciu-moketojus?fbclid=IwAR3_ZWzap0oP9j3fDM1JhXkS8LhLW_7I6KyA_h6gHzdEwsl7UbsG7ySKyPk)

Kodas

-

Emitentas

Valstybinė mokesčių inspekcija

IV dalis. Atrankos kriterijai

α. Visų atrankos kriterijų bendra nuoroda

Dėl atrankos kriterijų ekonominės veiklos vykdytojas pareiškia, kad

Jis atitinka visus reikalaujamus atrankos kriterijus

Jūsų atsakymas

Taip

Ne

Baigti

IV dalis. Baigiamieji pareiškimai

Ekonominės veiklos vykdytojai oficialiai pareiškia, kad II–V dalyse pateikta informacija yra tiksli ir teisinga ir kad ji pateikta visiškai suvokiant didelio faktų iškreipimo padarinius.

Ekonominės veiklos vykdytojai oficialiai pareiškia, kad pareikalavus gali nedelsdami pateikti nurodytus sertifikatus ir kitų formų įrodomuosius dokumentus, išskyrus tuos atvejus, kai:

- a) perkančioji organizacija ar perkantysis subjektas turi galimybę atitinkamus patvirtinamuosius dokumentus tiesiogiai gauti naudodamiesi prieiga prie bet kurios iš valstybių narių nemokamos nacionalinės duomenų bazės (su sąlyga, kad ekonominės veiklos vykdytojas pateikė reikalingą informaciją (interneto adresą, išduodančiąją instituciją ar įstaigą, tikslias dokumentų nuorodas), kuri perkančiajai organizacijai ar perkančiajam subjektui leidžia tai padaryti (pareikalavus dėl tokios prieigos turi būti pridėtas atitinkamas sutikimas), arba
- b) perkančioji organizacija ar perkantysis subjektas yra gavusi ir turi aktualius susijusius dokumentus iš ankstesnių (kitų) pirkimo procedūrų.

Ekonominės veiklos vykdytojai oficialiai sutinka perkančiajai organizacijai ar perkančiajam subjektui, nurodytam I dalyje, leisti susipažinti su dokumentais, kuriais patvirtinama informacija, pateikta šio Europos bendrojo viešųjų pirkimų dokumento III ir IV dalyse, kiek tai susiję su pirkimu, nurodytu I dalyje.

Data, vieta ir, jei reikia ar būtina, parašas (-ai):

Data

29-04-2021

Vieta

Kaunas

Parašas