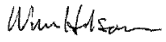
CDRH 21 CFR Part 1040 Informative Laser Report

21 CFR Part 1040 (*2013-04-01*): Performance Standards for Light-Emitting Products

Total number of pages……..:	8
Report Reference No……:	4786277698
Date of issue……..:	2014-03-14
Product……..:	Rescue Laser Flare / Rescue Laser Light
Model/type Tested……..:	RLL013-xx (Rescue Laser Light), RLFAA024-xx (Rescue Laser Flare Magnum), GLF032-xx (Green Rescue Laser Flare), where 'xx' may be numeric digits.
Rating……:	3.0Vdc (optional – no direct connection to mains)
Notes: Powered by batteries.	
Applicant……:	Greatland Laser PO Box 792 Willow, AK 99688 USA
Testing Laboratory……..:	UL LLC 12 Laboratory Dr. Research Triangle Park, NC 27709 USA

Tested by……..:	Winn Henderson	
Approved by..……..:	Benjamin Cribb	

SECTION A: PREFACE AND GENERAL PRODUCT INFORMATION

This report is designed to evaluate the product to the requirements of CDRH 21CFR Part 1040. UL LLC has prepared this report with information provided in part from Greatland Laser.

The issuance of this report in no way implies Listing, Classification or Recognition by UL and does not authorize the use of UL Listing, Classification or Recognition Marks or any other reference to UL on or in connection with the product or system. You cannot use UL's name or marks in connection with any product, packaging, advertising, promotion or marketing without UL's prior written permission.

Please be informed that UL LLC neither selected the sample nor determined whether the sample was representative of production samples. The test results apply only to the actual samples tested.

CDRH Laser Notice 50 is used for this evaluation, which allows for portions of IEC 60825-1 to be used in lieu of the corresponding CDRH 21CFR requirements. The Edition of IEC 60825-1 used was Ed. 2 (2007).

The products are rescue flare/lights.

The purpose of this report is to test and evaluate a sample provided by the applicant. As a result, detailed information such as the laser component manufacturer/part no., schematics, component layouts, diffuser materials, etc. are not documented by this report. However, schematics were reviewed and analyzed so that the laser powers could be measured under applicable single faults per the requirements of IEC 60825-1.

The two models tested for this report were: RLFAA024-01 (Rescue Laser Flare Magnum) and GLF032-01 (Green Rescue Laser Flare). Based on similarities, testing of Model RLFAA024-01 (Rescue Laser Flare Magnum) was considered representative of Model RLL013-xx (Rescue Laser Light), as well as RLFAA024-xx and GLF032-xx, where 'xx' may be numeric digits.

Model Differences – the 'xx' variables in the model number represent enclosure color.

SECTION B: TEST RESULTS

B.1 Photographs of Products

FIGURE 1 – Model RLL013-01 (Rescue Laser Light)

FIGURE 2 – Model RLFAA024-01 (Rescue Laser Flare Magnum)

FIGURE 3 – Model GLF032-01 (Green Rescue Laser Flare)

B.2 Wavelength Measurement

- RLFAA024-01 (Rescue Laser Flare Magnum) Measured Wavelength: 660 nm (see **FIGURE 4**)
- GLF032-01 (Green Rescue Laser Flare): 532nm (see **FIGURE 5**)

FIGURE 4 – Wavelength Plot for RLFAA024-01 (Rescue Laser Flare Magnum)

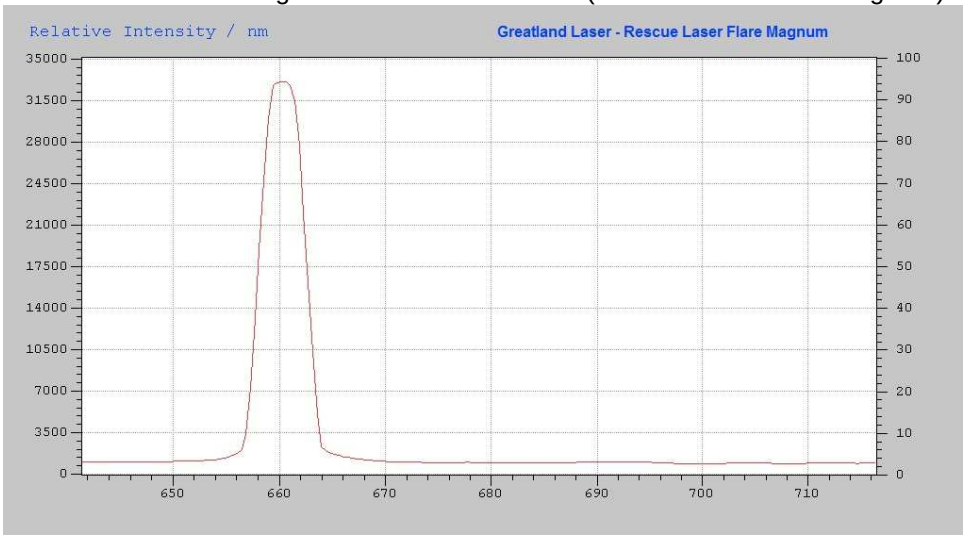
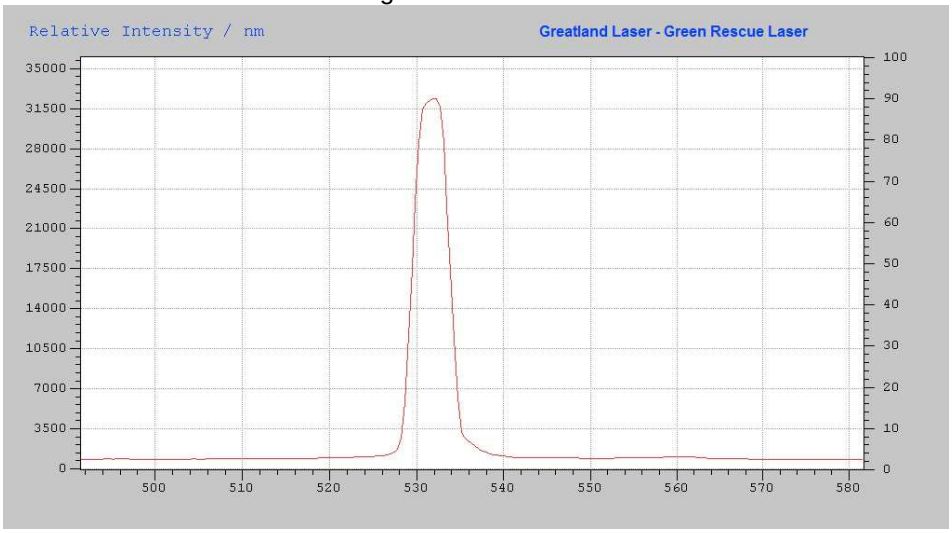


FIGURE 5 – Wavelength Plot for Green Rescue Laser Flare



*NOTE: No other significant wavelength peaks, including in the IR region, were observed via spectrometer measurement.

B.3 Optical Output Power Measurements

CDRH 21 CFR Test Conditions (using IEC 60825-1 per CDRH Laser Notice 50):

Model	Operating Condition NOTE 1 NOTE 2	Reference Point for Apparent Source Location	Aperture Stop Diameter Size (mm)	Measurement Distance from Apparent Source Location to Aperture Stop (mm)	Measured Average Output Power (mW)
RLFAA024-01 (Rescue Laser Flare Magnum)	Normal Operation	Laser aperture	50	2000	1.95
	Normal Operation	Laser aperture	7	70	4.41
	Normal Operation	Laser aperture	7	100	4.38
	Normal Operation	Laser aperture	None	0	4.71 NOTE 3
	Fault Operation – Short Vout to Vin on SOT-23 chip	Laser aperture	7	70	0.89uW NOTE 4
GLF032-01 (Green Rescue Laser Flare)	Normal Operation	Laser aperture	50	2000	2.92
	Normal Operation	Laser aperture	7	70	4.04
	Normal Operation	Laser aperture	7	100	3.95
	Normal Operation	Laser aperture	None	0	4.11 NOTE 3
	Fault Operation – Short Q1 C-E	Laser aperture	7	70	1.5uW NOTE 4
	Fault Operation – Open R5	Laser aperture	7	70	0.3uW NOTE 4

Testing Notes:

NOTE 1 In lieu of batteries, an external calibrated DC power supply supplied 3.0Vdc to the battery terminals.

NOTE2 Model Rescue Laser Flare Magnum employs a variable resistor that can be adjusted during production to control the laser power. Once adjusted, the unit is capped and glued to prevent access after production. The SOP for this process was reviewed during this assessment. As a result, adjustment of the variable resistor was not considered during this testing.

NOTE 3 Reference measurement only – not a required measurement per the CDRH 21CFR / IEC 60825-1.

NOTE 4 Output of laser effectively shuts down.

SECTION C: LASER RADIATION CLASSIFICATION

Model Rescue Laser Flare Magnum

PARAMETERS:
Wavelength = 660nm
C6=1 (assumed worst case)
CW radiation

Exposure Time	MEASURED RESULTS	CALCULATED AEL	Class
100s	IEC60825 Condition 1 = 1.95mW IEC60825 Condition 2 = 4.41mW IEC60825 Condition 3 = 4.38mW	3.9E-04W =0.39mW	>1 >1M
100s	IEC60825 Condition 1 = 1.95mW IEC60825 Condition 2 = 4.41mW IEC60825 Condition 3 = 4.38mW	C6E-03W =1mW	>2 >2M
100s	IEC60825 Condition 1 = 1.95mW IEC60825 Condition 2 = 4.41mW IEC60825 Condition 3 = 4.38mW	5E-03W =5mW	3R
Therefore, the radiation emitted is Class 3R.			

Model Green Rescue Laser Flare

PARAMETERS:
Wavelength = 532nm
C6=1 (assumed worst case)
CW radiation

Exposure Time	MEASURED RESULTS	CALCULATED AEL	Class
100s	IEC60825 Condition 1 = 2.92mW IEC60825 Condition 2 = 4.04mW IEC60825 Condition 3 = 3.95mW	3.9E-04W =0.39mW	>1 >1M
100s	IEC60825 Condition 1 = 2.92mW IEC60825 Condition 2 = 4.04mW IEC60825 Condition 3 = 3.95mW	C6E-03W =1mW	>2 >2M
100s	IEC60825 Condition 1 = 2.92mW IEC60825 Condition 2 = 4.04mW IEC60825 Condition 3 = 3.95mW	5E-03W =5mW	3R
Therefore, the radiation emitted is Class 3R.			

SECTION D: EVALUATION TO CDRH 21CFR REQUIREMENTS

NOTE: Where allowed by CDRH Laser Notice 50, IEC 60825-1 Ed. 2 (2001) requirements are used.

REQUIREMENT	CLAUSE	VERDICT	COMMENTS
PERFORMANCE REQUIREMENTS			
Protective Housing	1040.10(f)(1)	PASS	--
Safety Interlocks	1040.10(f)(2)	N/A	--
Remote Interlock Connector	1040.10(f)(3)	N/A	--
Key Control	1040.10(f)(4)	N/A	--
Laser Radiation Emission Indicator	1040.10(f)(5)	N/A	N/A per IEC 60825-1 via LN50.
Beam Attenuator	1040.10(f)(6)	N/A	--
Location of Controls	1040.10(f)(7)	PASS	--
Viewing Optics	1040.10(f)(8)	N/A	--
Scanning Safeguard	1040.10(f)(9)	N/A	--
Manual Reset Mechanism	1040.10(f)(10)	N/A	--
LABELING REQUIREMENTS			
Laser Label Designation and Warnings	1040.10(g)(1-3)	PASS	IEC60825-1 labeling used per CDRH Laser Notice 50. 'LASER RADIATION AVOID DIRECT EYE EXPOSURE CLASS 3R LASER PRODUCTS' provided on rectangle Explanatory Label; Triangle Warning Label with starburst symbol provided
Radiation Output Information	1040.10(g)(4)	PASS	'530-680nm, 5mW cw max' provided
Aperture Label	1040.10(g)(5)	PASS	'LASER APERTURE' label provided with arrows pointing to aperture.
Label for Noninterlocked Protective Housing	1040.10(g)(6)	N/A	--
Label for Defeatably Interlocked Protective Housing	1040.10(g)(7)	N/A	--
Warning for Visible and/or Invisible Laser Radiation	1040.10(g)(8)	N/A	--
Positioning of Labels	1040.10(g)(9)	PASS	Labels positioned so as not to require unnecessary exposure to radiation.
Label Specifications	1040.10(g)(10)	PASS	Labels appear to be reliably secured.
INFORMATIONAL REQUIREMENTS – USER INFORMATION ONLY*			
Adequate Instructions	1040.10(h)(1)(i)	PASS	Provided.
Pulse duration, maximum radiant power/energy	1040.10(h)(1)(ii)	PASS	Provided. NOTE: Beam divergence provided on web site in various locations and will be added in the future to printed materials, per the applicant.
Legible reproductions of labeling and corresponding positions on unit	1040.10(h)(1)(iii)	PASS	Legible reproduction provided and photograph of product with label also provided showing position.
Listing of controls including CAUTION statement	1040.10(h)(1)(iv)	PASS	Provided.
Laser energy source information	1040.10(h)(1)(v)	PASS	Battery information provided.
Optical instrument CAUTION statement	1040.10(h)(1)(vi)	N/A	--

*CDRH 21CFR Part 1040 Purchasing and Servicing Information Requirements are not addressed by this report.

SECTION E: CONCLUSION

The determined laser class emitted by the product was Class 3R.

The determined laser class emitted by the product was under the CDRH's 5.0mW / Class 3R limit.

There were no compliance issues found with the CDRH 21CFR requirements.