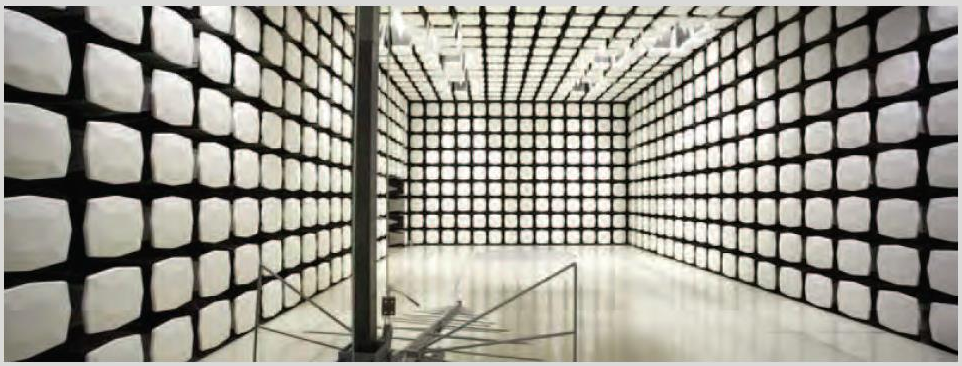
Ventana Medical Systems, Inc.

HE600

FCC 2.1093:2023

RFID

Report: VENT0079.6, Issue Date: May 16, 2023



CERTIFICATE OF EVALUATION

Last Date of Evaluation: May 16, 2023
Ventana Medical Systems, Inc.
EUT: HE600

RF Exposure Evaluation

Standards

Specification	Method
FCC 2.1093:2023	FCC 447498 D01 General RF Exposure Guidance v06

Results

Method Clause	Description	Applied	Results	Comments
4.3.2	SAR Test Exclusion	Yes	Pass	Both a conducted rated and measured radiated output power were assessed to show SAR test exclusion.

Deviations From Evaluation Standards

None

Approved By:

Donald Facteau, Process Architect

Product compliance is the responsibility of the client; therefore, the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. The results of this test pertain only to the sample(s) tested. The specific description is noted in each of the individual sections of the test report supporting this certificate of test. This report reflects only those tests from the referenced standards shown in the certificate of test. It does not include inspection or verification of labels, identification, marking or user information. As indicated in the Statement of Work sent with the quotation, Element's standard process is to always use the latest published version of the test methods even when earlier versions are cited in the test specification. Issuance of a purchase order was de facto acceptance of this approach. Otherwise, the client would have advised Element in writing of the specific version of the test methods they wanted applied to the subject testing

REVISION HISTORY

Revision Number	Description	Date (yyyy-mm-dd)	Page Number
00	None		

ACCREDITATIONS AND AUTHORIZATIONS

element
2021.09.01

United States

FCC - Designated by the FCC as a Telecommunications Certification Body (TCB). Certification chambers, Open Area Test Sites, and conducted measurement facilities are listed with the FCC.

A2LA - Each laboratory is accredited by A2LA to ISO / IEC 17025, and as a product certifier to ISO / IEC 17065 which allows Element to certify transmitters to FCC and IC specifications.

Canada

ISED - Recognized by Innovation, Science and Economic Development Canada as a Certification Body (CB) and as a CAB for the acceptance of test data.

European Union

European Commission – Recognized as an EU Notified Body validated for the EMCD and RED Directives.

United Kingdom

BEIS – Recognized by the UK as an Approved Body under the UK Radio Equipment and UK EMC Regulations.

Australia/New Zealand

ACMA - Recognized by ACMA as a CAB for the acceptance of test data.

Korea

MSIT / RRA - Recognized by KCC's RRA as a CAB for the acceptance of test data.

Japan

VCCI - Associate Member of the VCCI. Conducted and radiated measurement facilities are registered.

Taiwan

BSMI – Recognized by BSMI as a CAB for the acceptance of test data.

NCC - Recognized by NCC as a CAB for the acceptance of test data.

Singapore

IDA – Recognized by IDA as a CAB for the acceptance of test data.

Israel

MOC – Recognized by MOC as a CAB for the acceptance of test data.

Hong Kong

OFCA – Recognized by OFCA as a CAB for the acceptance of test data.

Vietnam

MIC – Recognized by MIC as a CAB for the acceptance of test data.

SCOPE

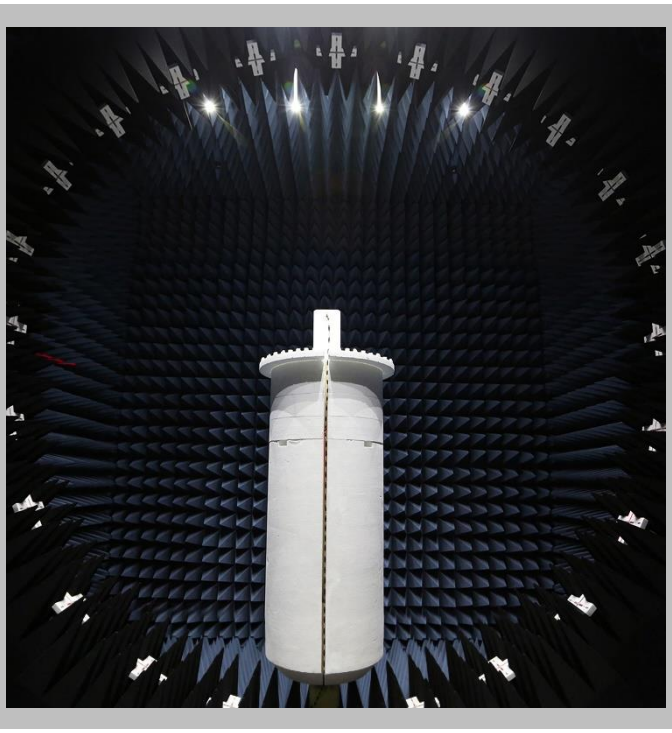
For details on the Scopes of our Accreditations, please visit:

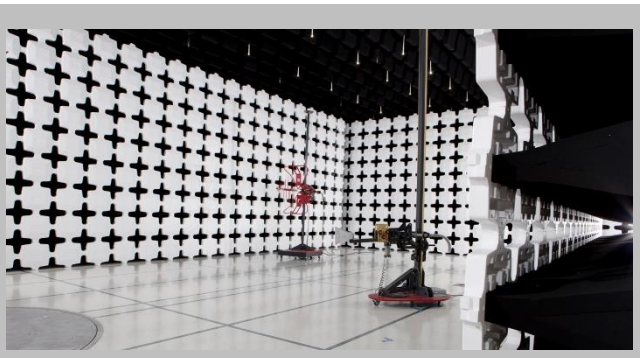
California Minnesota Oregon Texas Washington

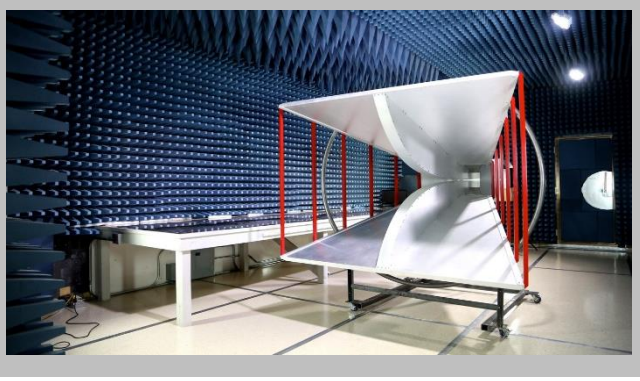
FACILITIES

element
2020.12.15

California	Minnesota	Oregon	Texas	Washington
Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	Labs MN01-11 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612) 638-5136	Labs EV01-12 6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	Labs TX01-09 3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	Labs NC01-05 19201 120th Ave NE Bothell, WA 98011 (425) 984-6600
A2LA				
Lab Code: 3310.04	Lab Code: 3310.05	Lab Code: 3310.02	Lab Code: 3310.03	Lab Code: 3310.06
Innovation, Science and Economic Development Canada				
2834B-1, 2834B-3	2834E-1, 2834E-3	2834D-1	2834G-1	2834F-1
BSMI				
SL2-IN-E-1154R	SL2-IN-E-1152R	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
VCCI				
A-0029	A-0109	A-0108	A-0201	A-0110
Recognized Phase I CAB for ISED, ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA				
US0158	US0175	US0017	US0191	US0157







PRODUCT DESCRIPTION

Client and Equipment Under Evaluation Information

Company Name:	Ventana Medical Systems, Inc.
Address:	1910 E Innovation Park Dr
City, State, Zip:	Tucson, AZ 85755
Evaluation Requested By:	Connor Creitz
EUT:	HE600
Date of Evaluation:	5/16/2023

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

VENTANA HE 600 system is a platform consisting of instrument, software, and reagents, used for hematoxylin and eosin staining of histologic sections from formalin- fixed, paraffin-embedded tissues.

Two RFID readers are present in the system:
a) monitors the content and expiration date for reagents
b) monitors the content and expiration date for glass coverslips

80" tall x 29" deep x 57" wide

Objective:

To demonstrate compliance with FCC RF exposure requirements for 2.1093 portable devices.

RF EXPOSURE CONDITION

The following RF Exposure conditions were used for the assessment documented in this report:	
Intended Use	Portable
Location on Body (if applicable)	Limb
How is the Device Used	The HE600 is used at a distance of less than 20 cm from the user
Radios Contained in the Same Host Device	2 x RFID
Simultaneous Transmitting Radios	RFID, RFID
Body Worn Accessories	N/A
Environment	General Population/Uncontrolled Exposure

SAR TEST EXCLUSION

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OVERVIEW

Human exposure to RF emissions from portable devices (47 CFR §2.1093) used with the radiating antenna closer than 20 cm to the user requires Specific Absorption Rate (SAR) to evaluate the environmental impact of human exposure to radiofrequency (RF) radiation.

COMPLIANCE WITH FCC 2.1093

47 CFR §1.1307
"(b)(1) Requirements. (i) With respect to the limits on human exposure to RF provided in §1.1310 of this chapter, applicants to the Commission for the grant or modification of construction permits, licenses or renewals thereof, temporary authorities, equipment authorizations, or any other authorizations for radiofrequency sources must either:

(A) Determine that they qualify for an exemption pursuant to §1.1307(b)(3);

(B) Prepare an evaluation of the human exposure to RF radiation pursuant to §1.1310 and include in the application a statement confirming compliance with the limits in §1.1310; or

(C) Prepare an Environmental Assessment if those RF sources would cause human exposure to levels of RF radiation in excess of the limits in §1.1310.

The EUT will be used with a separation distance of less than 20 centimeters between the radiating antenna and the body of the user or nearby persons and must therefore be considered a portable transmitter per 47 CFR 2.1093(b).

47 CFR §2.1093
"(*b) For purposes of this section, the definitions in §1.1307(b)(2) of this chapter shall apply. A portable device is defined as a transmitting device designed to be used in other than fixed locations and to generally be used in such a way that the RF source's radiating structure(s) is/are within 20 centimeters of the body of the user."*

COMPLIANCE WITH FCC KDB 447498 D01 General RF Exposure Guidance v06

"KDB 447498 D01 General RF Exposure Guidance v06" provides the procedures, requirements, and authorization policies for mobile and portable devices.

Standalone radio SAR test exclusion is covered under section 4.3.1. Unless specifically required by the published RF exposure KDB procedures, standalone 1-g head or body and 10-g extremity SAR evaluation for general population exposure conditions, by measurement or numerical simulation, is not required when the corresponding SAR Test Exclusion Thresholds are met as shown in the Limits section below.

Simultaneous transmission SAR test exclusion is covered under section 4.3.2. SAR test exclusion is determined for each operating configuration and exposure condition according to the reported standalone SAR of each applicable simultaneously transmitting antenna. When the sum of 1-g or 10-g SAR of all simultaneously transmitting antennas in an operating mode and exposure condition combination is within the SAR limit, SAR test exclusion applies to that simultaneous transmission configuration.

SAR TEST EXCLUSION

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LIMITS

Limits for General Population /Uncontrolled Exposure: 47 CFR 1.1310 (c)

The SAR limits for general population/uncontrolled exposure are 0.08 W/kg, as averaged over the whole body, and a peak spatial-average SAR of 1.6 W/kg, averaged over any 1 gram of tissue (defined as a tissue volume in the shape of a cube). Exceptions are the parts of the human body treated as extremities, such as hands, wrists, feet, ankles, and pinnae, where the peak spatial-average SAR limit is 4 W/kg, averaged over any 10 grams of tissue (defined as a tissue volume in the shape of a cube). Exposure may be averaged over a time period not to exceed 30 minutes to determine compliance with general population/uncontrolled SAR limits.

For 100 kHz to 6 GHz and test separation distances ≤ 50 mm, the SAR test exclusion thresholds are 1-g for head and body SAR and 10-g SAR for extremity SAR.

ASSESSMENT (KDB 447498 D01 GENERAL RF EXPOSURE GUIDANCE V06)

For 100 MHz to 6 GHz and test separation distances ≤ 50 mm, the 1-g and 10-g SAR test exclusion thresholds are determined by the following:

$$\left[\frac{(\text{max. power of channel, including tune-up tolerance, mW})}{(\text{min. test separation distance, mm})}\right] \cdot \left[\sqrt{f(GHz)}\right] = \begin{matrix}3.0 \text{ for 1-g SAR} \\ 7.5 \text{ for 10-g extremity SAR}\end{matrix}$$

Where:

- *f(GHz)* is the RF channel transmit frequency in GHz
- Power and distance are rounded to the nearest mW and mm before calculation
- The result is rounded to one decimal place for comparison
- 3.0 and 7.5 are referred to as the numeric thresholds

The test exclusions are applicable only when the minimum test separation distance is ≤ 50 mm and for transmission frequencies between 100 MHz and 6 GHz. When the minimum test separation distance is < 5 mm, a distance of 5 mm according to 4.1f) is applied to determine SAR test exclusion.

When the transmitted power is measured as a field strength value (dBµV/m), this value is converted to a power level using the following derivation (assuming the field strength value has been distance corrected to 3 m, see notes below table):

Step 1 – Per ANSI C63.10:2013 section 10.3.9 equation (34), the relationship between EIRP and field strength is as follows:

$$EIRP_{meas} = E_{meas} - 95.3$$

Where:
$EIRP_{meas}$ is the equivalent isotropically radiated power in dBm as converted from a measured value
E_{meas} is the field strength at a 3 m measurement distance in dBµV/m. To convert from the specification measurement distance to 3m, a 40 dB/decade adjustment was applied.

Step 2 – If a power tolerance or a tune-up value is provided, the reported power should be scaled accordingly:

$$EIRP = EIRP_{meas} + Tolerance$$

Where:
EIRP is the maximum equivalent isotropically radiated power in dBm
$EIRP_{meas}$ is the equivalent isotropically radiated power in dBm as converted from a measured value
Tolerance is either the tolerance provided in dB or the positive tune-up tolerance range in dB

Step 3 – Convert the EIRP value to linear terms

$$EIRP(mW) = 10^{\frac{EIRP\ (dBm)}{10}}$$

Where:
EIRP is the maximum equivalent isotropically radiated power, in terms of either mW or dBm

This value can then be compared against the limit to determine compliance.

The SAR Test Exclusion Threshold is summarized in the following table(s):

Radio	Transmit Frequency (MHz)	Conducted Output Power (mW)	Power Tolerance (dB)	Duty Cycle	Minimum Separation Distance (mm)	Exclusion Threshold	Limit	Compliant
RFID	13.56	400	1.0	100.0%	76.2	503.6	6088.2	Yes

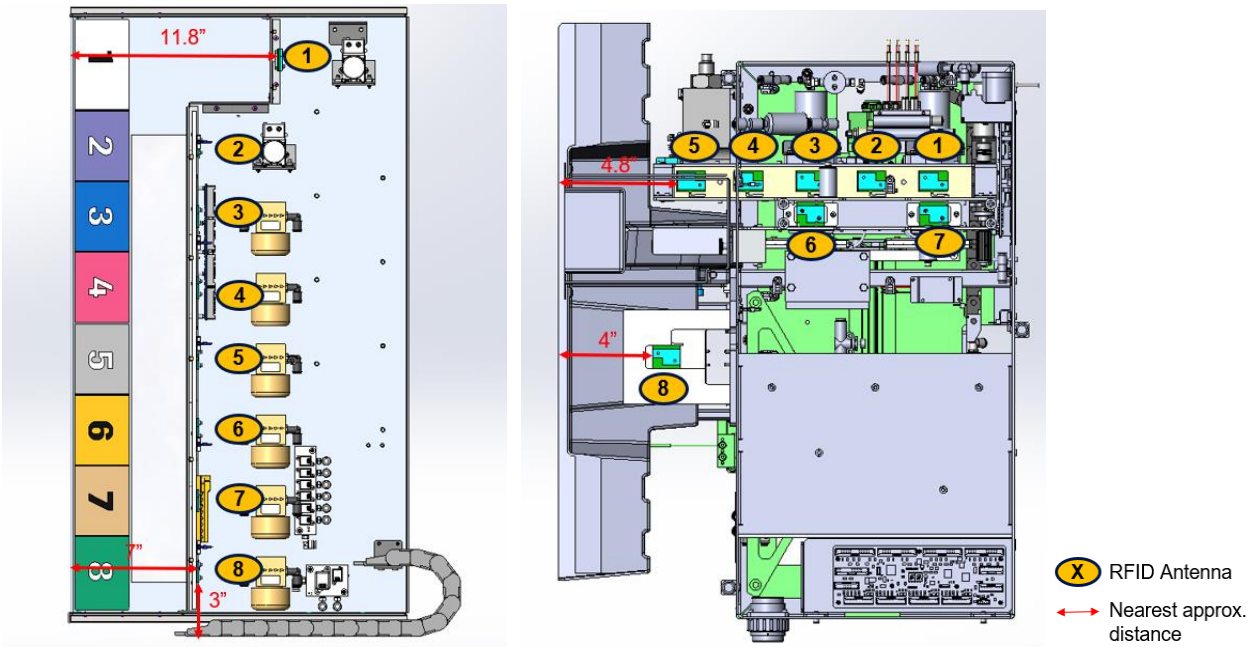
Radio	Transmit Frequency (MHz)	Radiated Output Power (mW) EIRP	Power Tolerance (dB)	Duty Cycle	Minimum Separation Distance (mm)	Exclusion Threshold	Limit	Compliant
RFID	13.56	1.50882E-05	1.0	100.0%	76.2	0.0	6088.2	Yes

The information in the table above was obtained from:

A rated and measured value was used in these calculations. Client provided a rated conducted power of 200 mW per radio. The system contains 2 radios for a total of 400 mW of rated conducted output power (2 x 200 mW = 400 mW). Assessment at 400mW is considered worst case as radios are more than 20 cm away from one another.

The radiated output power was also assessed and is based on field strength of 26.1 dBuV/m taken at 10m from VENT0079.0 test report. A 40dB/decade distance correction was applied to convert the data to 3m. An apparent power conversion was then used to convert field strength to radiated power (EIRP) as outlined in Steps 1-3 above.

Minimum separation distance of 76.2 mm (3 inches) based on diagrams below:



Evaluator: Mark Baytan

ESTIMATED SAR

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METHOD OF EVALUATION – SIMULTANEOUS TRANSMISSION CONFIGURATION

KDB 447498 D01 General RF Exposure Guidance v06, Section 4.3.2(b)

"When an antenna qualifies for the standalone SAR test exclusion of 4.3.1 and also transmits simultaneously with other antennas, the standalone SAR value must be estimated according to the following to determine the simultaneous transmission SAR test exclusion criteria:

1) *[(max. power of channel, including tune-up tolerance, mW)/(min. test separation distance, mm)] · [$\sqrt{f(GHz)}/x$], for test separation distances ≤ 50mm;*

   where x = 7.5 for 1-g SAR and x = 18.75 for 10-g SAR.

2) *0.4 W/kg for 1-g SAR and 1.0 W/kg for 10-g SAR, when the test separation distance is > 50 mm.*

This SAR estimation formula has been considered in conjunction with the SAR Test Exclusion Thresholds to result in substantially conservative SAR values of = 0.4 W/kg. When SAR is estimated, the peak SAR location is assumed to be at the feed-point or geometric center of the antenna, whichever provides a smaller antenna separation distance, and this location must be clearly identified in test reports. The estimated SAR is used only to determine simultaneous transmission SAR test exclusion; it should not be reported as the standalone SAR. When SAR is estimated, it must be applied to determine the sum of 1-g SAR test exclusion. When SAR to peak location separation ratio test exclusion is applied, the highest reported SAR for simultaneous transmission can be an estimated standalone SAR if the estimated SAR is the highest among the simultaneously transmitting antennas (see also KDB Publication 690783 D01). For situations where the estimated SAR is overly conservative for certain conditions, the test lab may choose to perform standalone SAR measurements, then use the measured SAR to determine simultaneous transmission SAR test exclusion. Estimated SAR values at selected frequencies, distances, and power levels are illustrated in Appendix D.

In the table below, the estimated stand-alone SAR for the radio(s) capable of simultaneous transmission is listed. The estimated values have been summed and compared to the SAR limit. The result of the calculation is well below the limit therefore the unit is excluded from simultaneous SAR evaluation and deemed compliant with FCC RF exposure requirements.

ESTIMATED SAR

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Radio	Band	Transmit Frequency (GHz)	Test Separation (mm)	Output Power (mW)	Duty Cycle	Estimated SAR (W/kg)	Specification (W/kg)
RFID	13.56 MHz	0.01356	76.2	251.8	1	1	4
RFID #2	13.56 MHz	0.01356	76.2	251.8	1	1	4
					Estimated Summed SAR	2	4

The information in the table above was obtained from:
Element test report VENT0079.0 Rev. 0.

End of Test Report