Liability

In the context of this proposal and any future studies and achievements, the Customer agrees that it is his responsibility to check, or to have checked, before using the device on the human body or in any way presenting risks for the human body, that the whole system (including the transducer, the electronics, the order processor, the mechanical positioning elements, etc) functions in a way that is safe for the patient and the user. This responsibility includes taking account of the statutory requirements of the countries concerned and the translation of these regulations into requirements applicable to transducers, taking into account the specificities of the system (for example, the electric structure of the system: insulation and grounding choices, etc) and the integration and operating conditions of the transducer.

IMASONIC shall not be liable for:

- The performance of the system, in particular possible failures of the system or the consequences of such failures to patients,
- The system's non-compliance with legal requirements through insufficient information or an incorrect translation by the Customer of the legal requirements into requirements applicable to transducers,
- The consequences of any use of the transducers that does not comply with the using conditions defined in the present document.

In this context, IMASONIC proposes that its responsibilities are as follows:

- To analyze the requests and needs expressed by the customer and to seek solutions for these requirements,
- To make IMASONIC's expertise and resources available to meet requirements and to guarantee compliance with the agreed specifications,
- To ensure the appropriateness and the performance of the methods and manufacturing processes used in executing the orders,
- To alert the customer if a doubt arises concerning the relevance or the reliability of a study or a manufacturing process with a potential link with the safety of the device.

The current proposal takes into account the customer's requirements that IMASONIC is aware of to date.
Other actions may be proposed by IMASONIC, if required and on the customer's request, for additional projects or to follow up future developments.

OVERVIEW - APPLICATION

The current document presents the specifications of a 256-element array transducer that will be incorporated into a device developed by the customer. This device is also composed of an optical source, a mechanical positioning system, a computing system for the image construction and the user interface.

The device will be used for experimental developments and not yet a clinical stage.

NORMATIVE ASPECTS

Considering the experimental laboratory use without any use on the human body, we have considered that the system including the transducer is not required to comply with any standard. Hence, no specific action has been taken into account neither in the design nor in the testing plan.

Normative requirements can be taken into account on request (see also § "Liability").

IMASONIC reference: cdc9420-8 dated July 1st 2021

Technical Characteristics

ACOUSTICAL CHARACTERISTICS:

Array type:	2D array of square elements distributed over a circular aperture with center hole
Mechanical focusing:	spherical, 40 mm (+1/-2 mm) radius of curvature
Element number:	256
Element dimensions:	See table in Appendix 2
Element numbering:	According drawing in Appendix 3
Centre frequency (-6dB):	4 MHz ± 10% (*) (**)
Acoustical impedance matching:	water (1.5 MRayl)
Bandwidth (-6dB):	≥ 45 % in Transmit/Receive mode (*) (**)
Homogeneity in sensibility:	± 5 dB in T/R mode (*) (**) *Taking into account only the elements with equal area*
Number of non working elements:	6 maximum (adjacent or not)

These elements will not be taken into account in the determination of the mean values of the parameters.

(*) *average value for all the measured elements*
(**) *measured in conditions described in "Final control" chapter.*

Note: the transducer structure has been chosen to be a trade-off between bandwidth and sensitivity. However, regarding the difficulty to predict the sensitivity, no commitment can be taken on its value. Consequently, the transducer design shall be validated by the customer regarding the expected performance and image.

MECHANICAL CHARACTERISTICS

Material:	Stainless steel
Geometry and dimensions:	According to drawing 9420D0100000 in Appendix
Output cable:	2 outputs, on rear side of transducer
Probe holder interface:	According to drawing 9420D0100000 in Appendix

INTERCONNEXIONS

Cable:	2 x multi-coaxial cables with overall shielding (85Ω)
Cable protection:	none (external jacket: PVC)
Cable length:	1.5 meters ± 0.1m
Connector and wiring diagram:	2x ITT DLM5-260 compatible VERASONICS (see appendix for details)
Ground connection:	Shielding of the cables, shell of the connectors, transducer's housing are all connected together and not connected to the electrical ground.

Recommended using conditions****

Integration of the transducer in the system
- Avoid any mechanical shocks on the front face
- **Avoid any mechanical stress on housing and cable bundle when integrating the transducer in the mechanical set-up.**
- **Avoid any mechanical stress on internal tube. This could damage the active part.**
- Do not handle the probe by the cables
- Do not strain the cable more than the radius of curvature (ROC) below
  Minimum static ROC: 32 mm
  Minimum Dynamic ROC: 64 mm

Storage, transport and maintenance
- Transducer is fragile, manipulate with care.
- Storage temperature : 0°C to +50°C
- Storage humidity : 10 to 75%
- Cleaning conditions: wiped with a tissue and 75° isopropyl alcohol taking care of not wearing the front face with particles between the front face and the tissue
- The box supplied with the transducer shall be used for any transportation of the transducer.

Utilization
- Continuous immersion in water
- Pressure: under 0.5 m of water
- Temperature : 10 to 40°C
- Excitation: The transducer is used in receive mode mainly and detection sensitivity and smooth band are the parameters to be privileged in the acoustical design of the transducer.
- The transducer will be connected to a Verasonics electronics (input impedance adjustable from 115 Ohms to 3kOhms)

(****) *Other using conditions are not taken into account by IMASONIC*

Engraving

On housing
4 MHz – 256 elts
Serial number
Index marking (see drawing in Appendix 1 for description)

On connectors
1→ 128 (for connector 1), 129→256 (for connector 2)

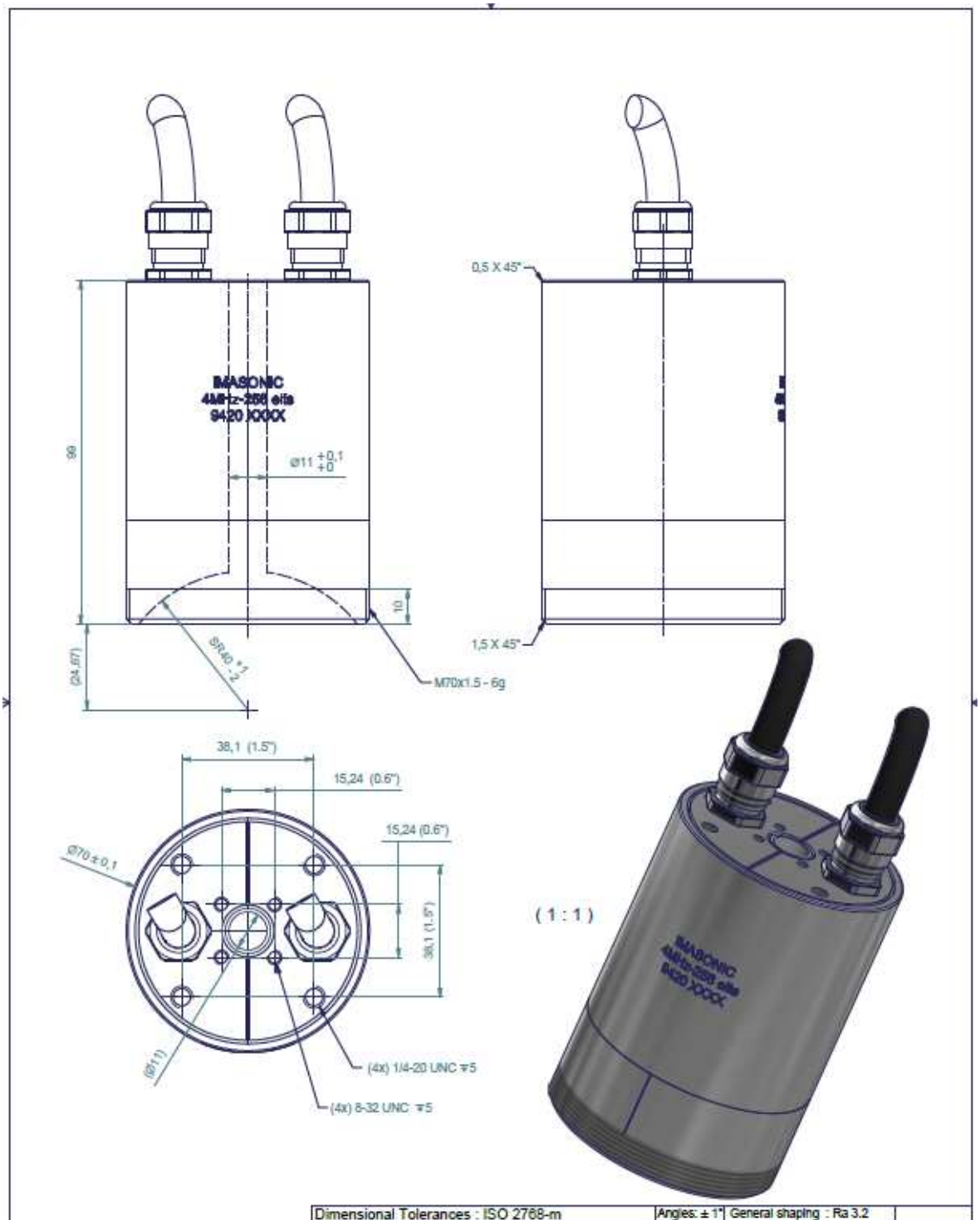
Final Control

Temporal response & frequency spectrum measurement (IMASONIC procedure INP413)
Performed in water in T/R mode, on a concentric spherical target
Excitation signal: 1 negative square, T/2, at the nominal frequency

Warranty

12 months in the above-mentioned using conditions.

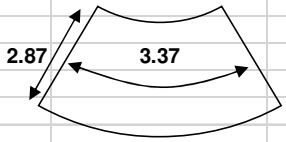
APPENDIX 1
General Drawing



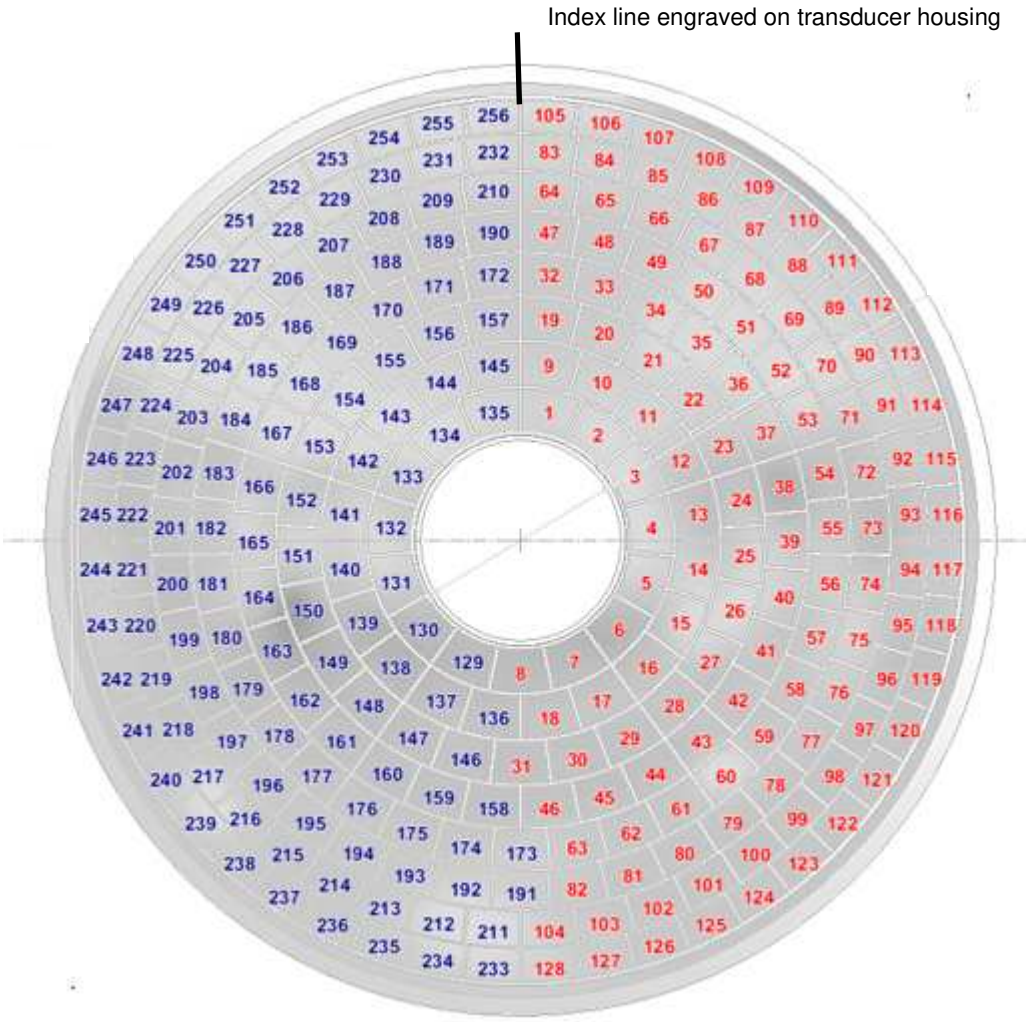
Appendix 2
Elements dimensions

Dimensions from the front-face point of view

			ring #	number of elements	elementary area (mm²) *	intra-ring pitch (mm)	angular position relative to the vertical axis (°)
			1	15	9.54	3.52	12.1
			2	20	9.70	3.58	16.5
			3	25	9.74	3.59	20.9
			4	30	9.72	3.59	25.3
			5	35	9.66	3.56	29.7
			6	39	9.81	3.62	34.1
			7	44	9.65	3.56	38.5
			8	48	9.67	3.57	42.9
mean value	=>				9.69	3.57	
total number of active elements	=>			256			
total angular aperture	90	°					
active ID (chord)	14.00	mm					
active OD (chord)	56.57	mm					
inter-element spacing	0.2	mm					
max difference between areas *	3%						
developped pitch between rings	3.07	mm					
or	4.40	°					
(*) approximate values							



Appendix 3
Element Numbering



View from transducer rear face

Appendix 4
Pinout diagram

Connector # 1 : elements 1 to 128
Connector #2 : elements 129 to 256

Pin	1	2	3	4	5	6	7	8	9	10	Pin
A	GND	GND						GND	GND	GND	A
B	GND									GND	B
C	GND									GND	C
D	GND									GND	D
E	GND									GND	E
F	GND									GND	F
G	GND									GND	G
H	GND									GND	H
J	GND									GND	J
K	GND	El 93	El 94	El 95	El 96	El 97	El 98	El 99	El 100	GND	K
L	GND	El 92	El 91	El 90	El 89	El 104	El 103	El 102	El 101	GND	L
M	GND	El 85	El 86	El 87	El 88	El 105	El 106	El 107	El 108	GND	M
N	GND	El 84	El 83	El 82	El 81	El 112	El 111	El 110	El 109	GND	N
	Space for Connector Latch Mechanism										
P	GND	El 77	El 78	El 79	El 80	El 113	El 114	El 115	El 116	GND	P
R	GND	El 76	El 75	El 74	El 73	El 120	El 119	El 118	El 117	GND	R
S	GND	El 69	El 70	El 71	El 72	El 121	El 122	El 123	El 124	GND	S
T	GND	El 68	El 67	El 66	El 65	EL 128	El 127	El 126	El 125	GND	T
U	GND	El 4	El 3	El 2	El 1	El 64	El 63	El 62	El 61	GND	U
V	GND	El 5	El 6	El 7	El 8	El 57	El 58	El 59	El 60	GND	V
W	GND	El 12	El 11	El 10	El 9	El 56	El 55	El 54	El 53	GND	W
X	GND	El 13	El 14	El 15	El 16	El 49	El 50	El 51	El 52	GND	X
Y	GND	El 20	El 19	El 18	El 17	El 48	El 47	El 46	El 45	GND	Y
Z	GND	El 21	El 22	El 23	El 24	El 41	El 42	El 43	El 44	GND	Z
AA	GND	El 28	El 27	El 26	El 25	El 40	El 39	El 38	El 37	GND	AA
BB	GND	EL 29	El 30	El 31	El 32	El 33	El 34	El 35	El 36	GND	BB
CC	GND	GND						GND	GND	GND	CC
Pin	1	2	3	4	5	6	7	8	9	10	Pin