HIT BY A LASER

Risk Assessments Management at Ziemer Ophthalmic Systems AG

Did you assess the risks correctly?

When your device is a laser for eye surgery, this is a very valid question.

Find out more on how Ziemer structures the risk management file; and integrates device data, post market surveillance information, clinical data and much more in a comprehensive risk assessment approach for a complex medical device.

Reto Sigrist, Project Manager, Ziemer Ophthalmic Systems AG

Content

1. About Ziemer Ophthalmic Systems AG
2. Introduction to Cataract Surgery
3. Content of Ziemers Risk Management File
4. Examples
5. Integration of device data, post market surveillance information and clinical data

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About Ziemer Ophthalmic Systems AG

Key company milestones

Company founded by
Frank Ziemer
1998

Subsidiary
in USA
2007

Subsidiary
in Germany
2012

Rep office
in Taiwan
2014

2001
Launch
Microkeratome
AMADEUS

2007
Launch
Femto LDV
Product line

2010
Launch
Diagnostic
Product line
Galilei

2012
Launch
FEMTO LDV
Z2, Z4, Z6

2013
Launch
Galilei G6

2014
Launch
FEMTO
LDV Z8

About Ziemer Ophthalmic Systems AG

The Ziemer products include a diagnostic and femtosecond laser product line

GALILEI

The GALILEI product line
Unique diagnostic solution

FEMTO LDV Z Models

The FEMTO LDV Z product line
The mobile laser for corneal and cataract surgery

About Ziemer Ophthalmic Systems AG

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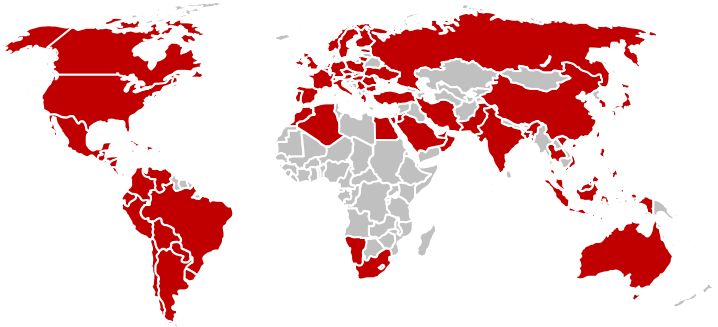
Ziemer today

- **220** employees
- Distribution channels in **40+** countries
- **More than 1000** laser systems installed
- **4 mio** surgeries realized
- **Over 1000** Galilei systems sold



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Types of Surgeries with FEMTO LDV Z8

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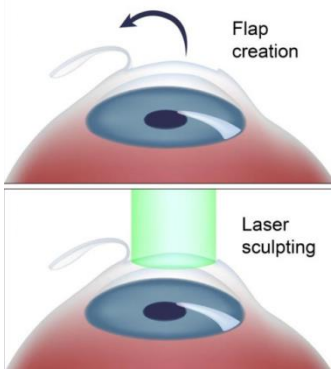
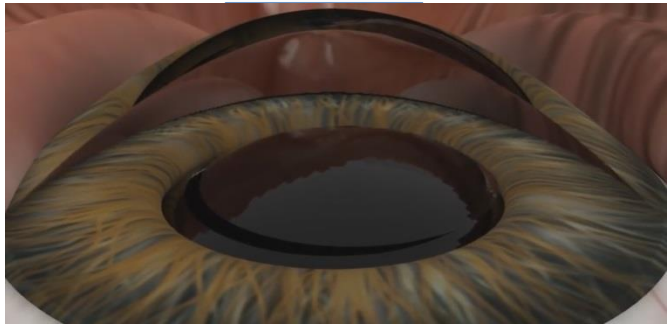
Applications

Refractive Surgery

Cataract Surgery

Therapeutic Surgery





Lamellar keratoplasties

Penetrating keratoplasties

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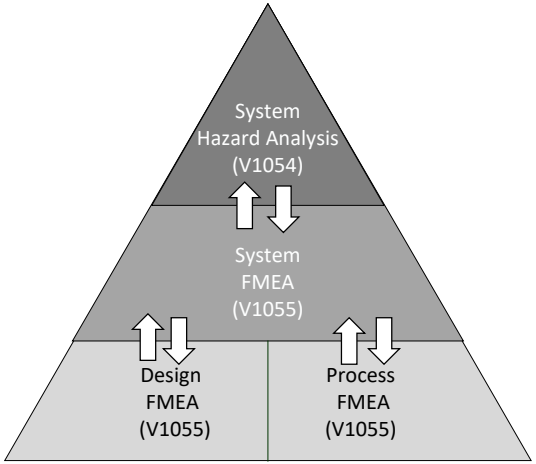
Risk Management File

Risk Management Plan



Software Safety Classification

Cybersecurity documentation

Risk Management Report

Hazard Analysis vs. FMEA

Hazard Analysis

Hazard
Potential Source of Harm

Foreseeable sequences of events
Foreseeable (potential) sequence of events, therewith a harm can occur

Hazardous situation
Circumstance in which people, property, or the environment are exposed to one or more hazard(s)

Harm
Physical injury or damage to the health of people, or damage to property or the environment

Risk estimation
S: Severity of harm
P: Probability of harm occurence

FMEA

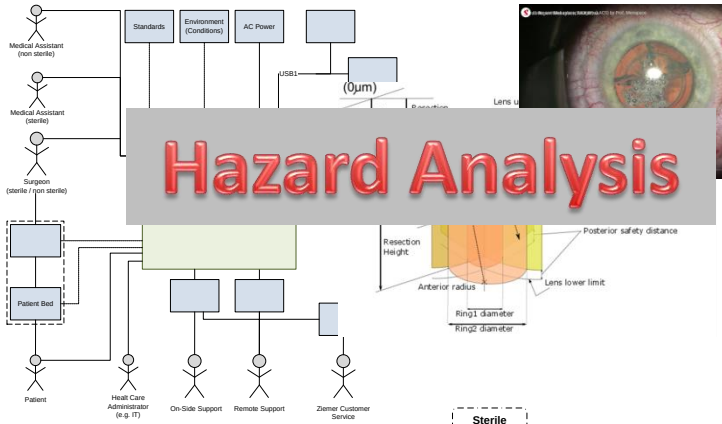
Failure cause
Cause, which leads to the occurence of an Error

Error
Anything that is not intended

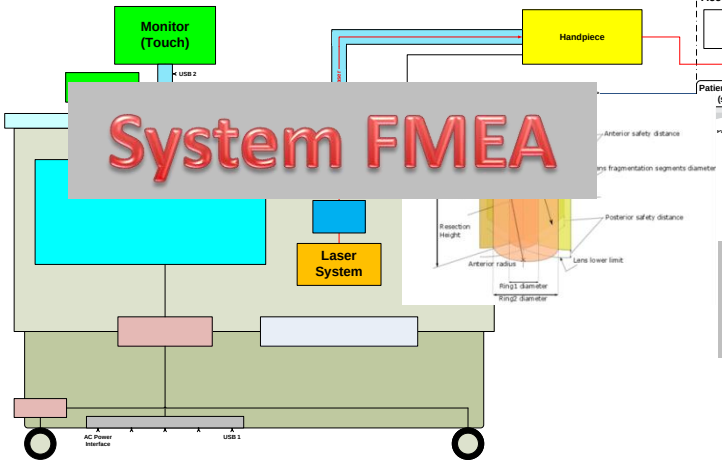
Failure effect
Immediate consequences of an error on safety-relevant characteristics

Error Estimation
S: Severity of the failure effect
O: Probability of **occurrence of the failure cause**
D: the probability that an error is detected and does not lead to the failure effect

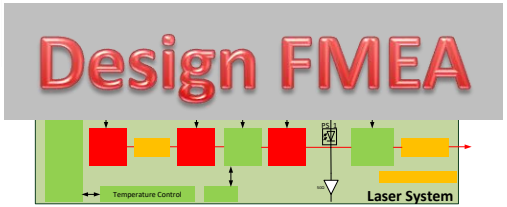
Inputs for Hazard Analysis and FMEA(s)



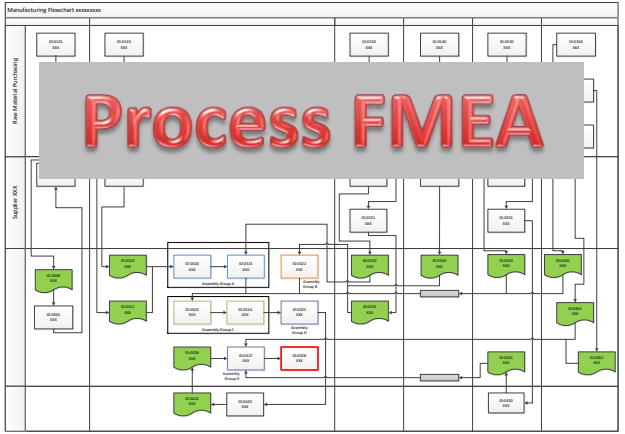
Hazard Analysis



System FMEA



Design FMEA



Process FMEA

Safety Relevant Characteristics (SRC)

Definition:
Characteristics (Features), which are relevant for the safety of the medical device

Hazard Analysis:
Non-compliance with a **Safety Relevant Characteristics → Hazard**

System/Design/Process FMEA:
The FMEA is applied to assess **errors** in system functions, sub-systems/components respectively production-process, which could have an **influence on Safety Relevant Characteristics**.

Examples FEMTO:

SRC ID	Qualitative Description
SRC1	The **performed treatment** in the human eye is adequately for the intended application.
SRC1.1	The **position** of the performed treatment in the human eye is adequately for the intended application.
SRC1.2	The **geometry** of the performed treatment in the human eye is adequately for the intended application.
SRC1.3	The treatment in the human eye is **completely performed**.
SRC1.4	The **quality** of the performed treatment is adequately for the intended application.
SRC2	The device and accessories must guarantee **basic safety and essential performance**.
SRC3	The parts with direct patient contact must adequately fulfil **basic safety** for the intended application.
SRC5.1	The parts with direct patient contact are microbiological decontaminated.
SRC5.2	The parts with direct patient contact are biocompatible.
[…]	[…]

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Example – Hazard Analysis

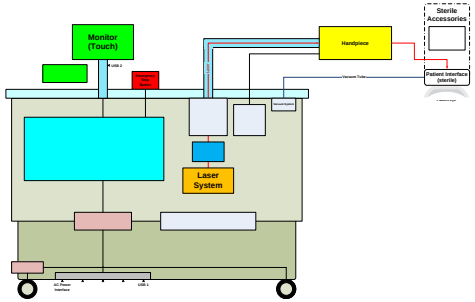
SRC ID	Qualitative Description
SRC1	The **performed treatment** in the human eye is adequately for the intended application.
SRC1.1	…
SRC1.2	…
SRC1.3	The treatment in the human eye is **completely performed**.

Medical knowledge required

				initial risk						current risk		
Hazard ID	Hazard	Foreseeable Sequence of Events including Hazardous Situation	Harm and possible treatment steps	Severity	Probability of Harm Occurence	Risk Level	Remarks to initial Risk assessment (optional)	Risk Control Measures: Description	Risk Control Measures: RC No.	Severity	Probability of Harm Occurence	Risk Level
H5.3.1.2	Incomplete Capsulotomy	1.) Surgeon does not recognize incomplete capsulotomy 2.) Surgeon opens the capsule bag not gently enough (Hazardous Situation)	1.) Big anterior capsule tear evolves to posterior capsule tear 2.) Patient requires Anterior Vitrectomy	III	III	2	n/a	Application Training; The manual contains a description how to check the capsulotomy cut result and how to proceed	[RCM20]; [RCM39]	III	III	2

Example – System FMEA

SRC ID	Qualitative Description
SRC1	The **performed treatment** in the human eye is adequately for the intended application.
SRC1.1	…
SRC1.2	…
SRC1.3	The treatment in the human eye is **completely performed**.



System-Design knowledge required

	Listing of components, their functions and potential errors			Evaluation of the **Severity (S)** of the failure effect		Evaluation of the **probability of occurence (O)** of the failure cause		Evaluation of the **error control measures to detect the error and to prevent the failure effect (D)**			(initial)	Error Control Measures **to detect the error and to prevent the failure effect (D), the probability of occurence of the failure cause (O) and/or to prevent the failure effect (S)**		**Result** *(effect of measure)*				RPN after measures >25:
ID	Component / Process step	Characteristic / function / process step	Error / Deviation / Failure Mode *(Fehler / Abweichung / Fehlzustand)*	Potential Failure Effect if the error is not detected *(Potentielle Fehlerfolge, falls der Fehler nicht detektiert wird)*	S	Potential Failure Cause *(Potentielle Fehlerursache)*	O	Description	RC No.	D	RPN	Description	RC No.	S	O	D	RPN	Escalation: Trace to System Hazard Analysis (Hazard ID)
12.2	Laser System	Laser Pulse generieren	Laser Leistung zu tief	Kein Schnitt oder unvollständiger Schnitt	5	Power loss due to beam clipping, pollution of an optic, external modulator error or optical damage of pump module	2	**Appl. SW Hardware Control Laser-Power to High-/Low-Check with Power-Sensor XY before each Cut.**	FMEA_allg_RC92	1	10	keine	n/a					
12.2	Laser System	Laser Pulse generieren	Laser Leistung zu tief	Kein Schnitt oder unvollständiger Schnitt	5	Power loss due to beam clipping, pollution of an optic, external modulator error or optical damage of pump module	2	**Appl. SW Hardware Control Laser-Power to High-/Low-Check with Power-Sensor XY at every Power-Up.**	FMEA_allg_RC92	2	20	keine	n/a	5	2	2	20	
12.2	Laser System	Laser Pulse generieren	Laser Leistung zu tief	Kein Schnitt oder unvollständiger Schnitt	5	Power loss due to beam clipping, pollution of an optic, external modulator error or optical damage of pump module	2	**keine**	n/a	10	100	keine	n/a	5	2	10	100	**H.5.3.x.x.**

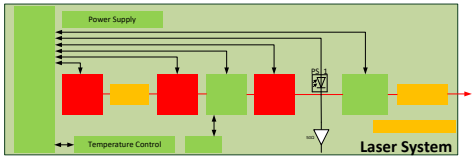
H5.3.1.2 | **Incomplete Capsulotomy** | 1.) Surge… incom… 2.) Surgeon… not gently…

Same example with “weaker” Error Control Measure:

Same example with no Error Control Measure:

Example – Design FMEA

SRC ID	Qualitative Description
SRC1	The **performed treatment** in the human eye is adequately for the intended application.
SRC1.1	…
SRC1.2	…
SRC1.3	The treatment in the human eye is **completely performed**.



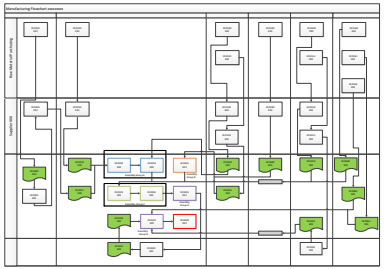
Laser Component knowledge required

	Listing of components, their functions and potential errors			Evaluation of the **Severity (S)** of the failure effect		Evaluation of the **probability of occurence (O)** of the failure cause		Evaluation of the **error control measures to detect the error and to prevent the failure effect (D)**			[initial]	Error Control Measures **to detect the error and to prevent the failure effect (D), the probability of occurence of the failure cause (O) and/or**		**Result** *(effect of measure)*			RPN after measures >25:
ID	Component	Characteristic / function	Error / Deviation / Failure Mode *(Fehler / Abweichung / Fehlzustand)*	Potential Failure Effect if the error is not detected *(Potentielle Fehlerfolge, falls d… Fehler nicht detektiert wird)*	S	Potential Failure Cause *(Potentielle Fehlerursache)*	O	Description	RC No.	D	RPN	D					
3.5.1	XXX Interface	Analog laser output power modulation	Wrong signal amplitude	No laser emission or Wrong laser power	5	Lose cable, signal disturbance	2	None	n/a	5	50	Screw-mount cable connectors for X130B (O)	[FMEA-OneFive RC3]	5	1	5	25	n/a
												EMI Measures - Double-shielded RG-316 cable (O)	[FMEA-OneFive RC4]					
4.11	Temperature Control Module	Laser Diode/Compressor Temperature Control	Loss of power supply	Wrong laser power and/or Wrong (too long) pulse duration	5	Supply cable interruption, blown fuse	2	None	n/a	5	50	None	n/a	5	2	5	50	[5]: ID 12.2

12.2	Laser System	Laser Pulse generieren	Laser Leistung zu tief

Example – Process FMEA

SRC ID	Qualitative Description
SRC3	The parts with direct patient contact must adequately fulfil **basic safety** for the intended application.
SRC5.1	The parts with direct patient contact are microbiological decontaminated.
SRC5.2	The parts with direct patient contact are biocompatible.
[…]	[…]



Production-Process knowledge required

	Listing of components, their functions and potential errors				Evaluation of the **Severity (S)** of the failure effect		Evaluation of the **probability of occurence (O)** of the failure cause		Evaluation of the **error control measures to detect the error and to prevent the failure effect (D)**			(initial)	Error Control Measures **to detect the error and to prevent the failure effect (D), the probability of occurence of the failure cause (O) and/or to prevent the failure effect (S)**		**Result** *(effect of measure)*				RPN after measures >25:
ID	Sub ID	Process step	Description process step	Error / Deviation / Failure Mode *(Fehler / Abweichung / Fehlzustand)*	Potential Failure Effect if the error is not detected *(Potentielle Fehlerfolge, falls der Fehler nicht detektiert wird)*	S	Potential Failure Cause *(Potentielle Fehlerursache)*	O	Description	RC No.	D	RPN	Description	RC No.	S	O	D	RPN	Escalation: Trace to System Hazard Analysis (I
305 320	FL5940-8036 FL5940-8200	Kap. 10 (Schritt 3 & 4) Glas-Membran-Verbund/ Glas in Membran integrieren Kap.10.6/2	Assemblierung, Glas in Membran integrieren	Fehlerhafte Lupenkontrolle (IPC) der gereinigten Gläser welche in die Membran integriert werden	Gläser entsprechen nicht den AK/Qualitätskriterien	5	Menschliches Versagen, Gläser haben Kratzer, Partikel, Verschmutzungen	3	100% Final Inspection mit Lupenlampe	n/a	1	15	Prozess schulen (O)	n/a	5	3	1	15	n/a

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Complaint Handling Inputs

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Person Involved Category	Application / Cut Type	Cases	Cases per Cuts in Percent	Cuts of Category
Capsulotomy insufficient / incomplete	CAPS	62	0.06431%	96403

Kürzel	Bedeutung	Qualitative Beschreibung (produktspezifisch)	Quantitative Definition (produktspezifisch)
V	Häufig		
IV	Wahrscheinlich		
III	Gelegentlich	Der Schaden tritt sporadisch, aber nicht systematisch auf.	1 in 100 bis 1 in 9'999 ≙ 0.01% … 1%
II	Entfernt		
I	Unwahrscheinlich		

Complaint Handling Inputs (V1066) Hazard / Harm	CER Inputs (FL5940-1174)	Hazard ID	Hazard	Deployment of Appl. SW For further information see [7]	Usability relevant (Y, N or N/A)	Foreseeable Sequence of Events including Hazardous Situation	Harm and possible treatment steps	Severity	Probability of Harm Occurence	Risk Level	Remarks to initial Risk assessment (optional)	Risk Control Measures Description	RC No.	Severity	Probability of Harm Occurence	Risk Level
Capsulotomy insufficient / incomplete	Incomplete Capsulotomy	H5.3.1.2	**Incomplete Capsulotomy**	Z8 / Cataract	N/A	1.) Surgeon does not recognize incomplete capsulotomy 2.) Surgeon opens the capsule bag not gently enough (Hazardous Situation)	1.) Big anterior capsule tear evolves to posterior capsule tear 2.) Patient requires Anterior Vitrectomy	III	III	2	n/a	Application Training; The manual contains a description how to check the capsulotomy cut result and how to proceed	[RCM20] [RCM30]	III	III	2
Anterior capsule tear																
Posterior capsule tear																

Clinical Evaluation Report

…
Those typical complications are:

- …
- **Incomplete Capsulotomy**, tag or tears. Minute variations in laser pulse energy and uniformity of exposure of the capsule may produce skip areas and incomplete perforation. This can occur due to folds in Descemet membrane (flattening and distortion of corneal architecture during docking), ….
- …

Complications in case of difficult cases such as white cataract have been studied by Chee [316]. The main complication was **incomplete capsulotomy** which was associated with the type of white cataract and lens thickness. The Morgagnian cataract was identified the predominant type of white cataract at risk of having an **incomplete capsulotomy** …

Complaint Handling Inputs (V1066) Hazard / Harm	CER Inputs (FL5940-1174)	Hazard ID	Hazard	Model / Deployment of Appl. SW For further information see [7]	Usability relevant (Y, N or N/A)	Foreseeable Sequence of Events including Hazardous Situation	Harm and possible treatment steps	Severity	Probability of Harm Occurence	Risk Level	Remarks to initial Risk assessment (optional)	Risk Control Measures		Severity	Probability of Harm Occurence	Risk Level
												Description	RC No.			
Capsulotomy insufficient / incomplete Anterior capsule tear Posterior capsule tear	Incomplete Capsulotomy	H5.3.1.2	**Incomplete Capsulotomy**	Z8 / Cataract	N/A	1.) Surgeon does not recognize incomplete capsulotomy 2.) Surgeon opens the capsule bag not gently enough (Hazardous Situation)	1.) Big anterior capsule tear evolves to posterior capsule tear 2.) Patient requires Anterior Vitrectomy	III	III	2	n/a	Application Training; The manual contains a description how to check the capsulotomy cut result and how to proceed	[RCM20]; [RCM39]	III	III	2

Change Control (Tab in Excel documents)

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Listing of components, their functions and potential errors						Usability relevant (Y, N or N/A)	Evaluation of the **significance (S)** of the failure effect		Evaluation of the **probability of occurence (O)** of the failure cause		Evaluation of the **error control measures to detect the error and to prevent the failure effect (D)**			(initial)	Further Measures **to detect the error and to prevent the failure effect (D), the probability of occurence of the failure cause (O) and/or to prevent the failure effect (S)**		**Result** *(effect of measure)*				RPN after measures >25:	**Trace from**	**changes**
ID	Model	Application	Component / Process step	Characteristic / function / process step	Error / Deviation / Failure Mode *(Fehler / Abweichung / Fehlzustand)*		Potential Failure Effect if the error is not detected *(Potentielle Fehlerfolge, falls der Fehler nicht detektiert wird)*	**S**	Potential Failure Cause *(Potentielle Fehlerursache)*	**O**	Description	RC No.	**D**	**RPN**	Description	RC No.	**S**	**O**	**D**	**RPN**	Escalation: Trace to System Hazard Analysis (ID)		
5.11.2	Z8	Cornea	Procedure Pack - Casing Glas	Casing Glas dient Sterilbariere zwischen Handstück und Humanauge.	XXX	XXX	XXX	5	XXX	2	XXX	XXX	1	10	XXX	XXX	5	2	1	10	n/a	Complaint Nr. 11342	new Error ID
5.11.2	Z8	Cornea	Procedure Pack - Casing Glas	Casing Glas dient Sterilbariere zwischen Handstück und Humanauge.	XXX	XXX	XXX	5	XXX	2	XXX	XXX	1	10	XXX	XXX	5	2	1	10	n/a	F422-2017-12 OCT-Guided Lasik	new Error ID
1.1.8.3	Z8	Cataract Cornea	Lifting Column	Anpassung der Höhe der Basisstation an die untersch. Patientenbetten	XXX	XXX	XXX	5	XXX	2	XXX	XXX	5	50	SW Motion (Z8) schaltet 230V Speisung der Lift-Steuerung ab, wenn E-Stop gedrückt wird (S)	[FMEA_allg_RC89]	2	2	5	20	n/a	CAPA 2017-06	new Error ID

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Thank you for your attention

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