Publishable Summary for 17IND01 MIMAS
Procedures allowing medical implant manufacturers to demonstrate compliance with MRI safety regulations

Overview

Medical implants represent a multi-billion market across Europe. A majority of the 50 million EU citizens carrying a medical implant will likely need a magnetic resonance imaging (MRI) scan during the lifetime of their device. However, the powerful electromagnetic fields of MRI systems in these cases represented a unique hazard for patient safety. Therefore, it was vital for both patient wellbeing and the success of a medical implant on the market that implant manufacturers could demonstrate safety compliance for their device in an MRI environment. This project improved the competitiveness of European implant manufacturers by providing innovative, metrologically sound and legally safe methods to demonstrate the compatibility of their products with MRI safety regulations.

New, high resolution anatomical models of implant carriers were developed, using virtual surgery techniques to position the device in the patient. A comparison to the less accurate, but simpler and cheaper state-of-the art techniques to create a computer of an implant patient is given. Researchers and implant manufacturers are, for the first time, to choose the proper approach to meet their specific requirements. A new *Medical Device Development Tools* was developed and regulatorily approved during the project. It is commercially available and provides implant manufacturers with a clear and legally safe pathway to obtain regulatory approval for their innovative devices. Beyond solutions for today, also completely new, and potentially disruptive approaches towards *personalised* implant safety assessments were investigated. On a proof-of-concept level it was demonstrated, how sensor-equipped implants interfaced to parallel-transmit capable MR scanners could not only combine patient safety with optimised image quality, but simultaneously make manufacturers more and clinical personnel less responsible for safety of an implant carrying patient. A complete assessment of the patient hazards due to gradient-induced heating of large implants in MRI was achieved and possible test procedures and simplified analyses were described. The ground is thus prepared for standardisation bodies to include this hitherto uncovered subject into their normative documents and for test laboratories to offer the relevant test procedures and equipment.

Need

With more than 30 million MRI scans per year across European countries, safety for patients with medical implants was a concern with some carriers having suffered fatal accidents due to the interference of their device with the electromagnetic fields (EMF) from the MRI scanner. MRI compatibility of an implant thus represented a key factor for the competitiveness of a manufacturer. This was exemplified in 2011 when Medtronic Inc. achieved the first ever MRI approval for a cardiac pacemaker and within a few years virtually all non-compatible devices disappeared from the market. However, the recently applied procedures to demonstrate MRI compatibility were either outdated (ASTM F2182) or incomplete (ISO/TS 10974). Additionally, large producers of high-end active implantable medical devices were facing technological challenges to demonstrate MRI compatibility, and SMEs manufacturing passive medical implants were overburdened by the necessity to demonstrate MRI safety for each new size and shape of a particular device, therefore limiting their innovation potential.

The established state of the art technique was and still is the numerical modelling of field distributions in human subjects. However, even though this technique has been used to include the presence of metallic implants, an experimental verification of the results was limited as mostly generic or simplified implants with non-detailed features were modelled. Parallel-transmit (pTx) radiofrequency systems can be used to steer, within certain limits, the electromagnetic field in MRI scanners as well as temperature distributions in and around the implant. The use of pTx for risk mitigation has an enormous potential to ensure safety for a wide range of different

implants and boundary conditions. These systems can be combined with sensor-equipped implants to provide real-time feedback. However, this concept was still in an early stage of development and further work was needed to prove its usefulness.

The EMRP project 'HLT06 MRI safety' discovered that heating of metallic implants due to switched magnetic-field gradients was an underestimated hazard in MRI. As some normative documents ignored this effect completely, whilst others mentioned the possibility of such effects only in the context of protecting the device rather than the patient, this specific hazard was investigated in the project.

Objectives

To enable manufacturers of medical implants to demonstrate that patients carrying their products can safely undergo an MRI scan, the project aimed to achieve the following objectives:

1. To develop **anatomical models of human subjects with realistic medical implants** and millimetre resolution. The models to be sufficiently detailed for use with *in silico* medicine concepts, with resolution to be determined according to image analysis needs.
2. To develop validated computational tools for the **numerical simulation of electromagnetic fields (EMF) and temperature distributions** in a virtual human subject **during MRI exposure**. The computational tools should be able to process high-resolution anatomical models.
3. To develop validated methods and sensor-equipped reference implants for quantifying real-time implant-induced hazards during MRI exposure. This should include an assessment of parallel transmit (pTx) radiofrequency (RF) systems in MRI with real-time feedback and the **development of appropriate mitigation strategies**.
4. To investigate numerically and experimentally the hazards associated with **the interaction between bulk metallic implants and switched magnetic fields** in the kilohertz regime. In addition, to develop a reference set-up for testing metallic implant heating, using switched magnetic-field gradients of a few mT/m with a target gradient uncertainty below 5 %.
5. To develop and apply a **suitable statistical method to demonstrate MRI compliance** for small (< 10 cm) orthopaedic implants without extensive testing or numerical modelling, by determining an upper limit for the hazard associated with the new implant by comparison with a similar surrogate implant, which has already been fully assessed, thus enabling small manufacturers of a large variety of similar small metallic implants to dramatically reduce their costs for compliance demonstration.
6. To **interact closely with manufacturers of implants, MRI and test equipment and with standards developing organisations** (e.g., ISO/TS 10974, IEC TC/SC 62B and ASTM Subcommittee F04.15 on Material Test Methods) to align the project and facilitate the take up of the technology and measurement infrastructure developed in the project.

Progress beyond the state of the art

Safety testing of metallic implants for MRI was until recently largely based on unreliable phantom measurements. The project improved this unsatisfactory state of the art by applying more meaningful numerical modelling of realistic virtual models. High precision numerical models were developed and subsequently used as an input to electromagnetic field (EMF) simulations. While the utilisation of EMF modelling in this context is becoming more and more accepted as the adequate approach to the problem in the scientific community, it has still not fully arrived at the level of small manufacturers and test houses. Still unique to this project was the use of calibrated sensor measurements to validate those simulation results with metrological rigour.

The project went even further by exploring technical means to actively mitigate metallic-implant related hazards in MRI. This was achieved by steering the RF electric field (E-field) away from the implant by using pTx technology, an approach with a high potential for ensuring safety for a wide range of implants and scan conditions. In contrast to some recently published work, where this E-field steering approach has been pursued using the regular RF transmit coil ("body coil") driven as a two-channel coil, the present project exploited the much larger parameter space of true parallel transmission with at up to eight independent channels.

Compared to RF heating, the potential heating of an implant by the switched gradient fields of an MRI scanner was a largely unexplored field. While preliminary results had already convincingly demonstrated the existence of the problem, this project was the first ever to systematically investigate this issue and propose practical

approaches to manage it. Most of the existing knowledge in this young field results from the MIMAS project and the consortium members aim to continue this work even beyond the project.

Finally, the goal was to develop a procedure for demonstrating MRI compliance, allowing the manufacturers of small implants, e.g., screws, clips, or fixation devices, to reduce their costs by simplified safety assessments. Instead of performing numerical simulations and heating experiments for each and every new item, simple scaling laws can be applied to infer a valid safety assessment for their new product from previous, extensive investigations of similar devices. This attempt was only partly successful; a stochastic procedure was indeed developed, however, the uncertainties of this approach turned out to be much larger than anticipated. As a result, the practical application of such a stochastic approach is not currently feasible.

Results

Objective 1

The project developed virtual models of human subjects carrying a metallic implant. For the first time, precision planning tools from a virtual surgery were applied to position the implants with sub-mm accuracy.

Data on main orthopaedic implants, one-dimensional implants, and small stand-alone implants was sourced and analysed. Implant types, implant materials, most relevant locations in the body and human types were defined. Implant samples for experimental validation were collected and for certain orthopaedic implants CAD models for virtual surgery could be obtained from manufacturers. CAD models of small implants were created by uniting data from catalogues with measurements made using a combination of micro-scale CMM and optical scanning probes. The geometric tools within the simulation software Sim4Life were used to manipulate the virtual implants to ensure that they reflected the real-world usage of the devices.

This objective was successfully achieved.

Objective 2

A large selection of different human body types, implant positions and RF transmit coils was investigated via validated computational tools developed by ZMT with the IT'IS Foundation, in particular IMAnalytics with MRIxViP and BCLib, which were qualified by the FDA as part of the Medical Device Development Tool (MDDT) program. General conclusions were derived from a systematic exploration of the parameter space for implant related RF hazards in MRI. This approach was further extended, and also FDA-qualified, to support the scaling of experimental *E*-fields to the in vivo situation in a given region of interest, to support evaluations according to ISO 10974 Tier 2 and ASTM F2182-19e2. This was especially important for the latter, where earlier revisions represented the human body directly by a saline-filled phantom. The project output underpins the ambitious concepts of the new ISO/TS 10974 standard with specific and validated procedures and thus contribute to advancing this document from its present state (a *Technical Specification)* to a full standard.

Existing methods to assess MRI safety of metallic implants were adjusted, enhanced, and tailored for the specific needs of this project. The joint effort in identifying and categorising relevant medical implants allowed all relevant safety assessments at and beyond the state of the art to be performed. Methods for simplified and accurate estimations were developed, including an iso-electric exposure scenario within tissues of different relative permittivity (e.g., water-like, fatty, bone) and on their interface (e.g., orthopaedic implants on the bone-muscle interface).

To complement the verified solvers and validated measurements, a general and comprehensive uncertainty budget of the ISO 10974 Tier 3 evaluation of RF-heating of elongated medical implants, compliant with the GUM, was developed. Predictions with meaningful confidence intervals can now be made and validation success or failure can be defined. Additionally, a new annex was added to ISO 10974 focusing on measurement system validation with the SAIMD-U, a fully characterised leaded generic implant which simulates the key elements of an active implantable medical device (AIMD), enabling the verification and validation of instrumentation and procedures of AIMD model generation, assessment of deposited power and induced voltages.

This objective was successfully achieved.

Objective 3

A safety concept to control and mitigate RF heating of metallic implants during an MRI scan was developed. The central idea is to combine the information from ex-ante simulations and in situ sensor measurements to assess and quantify the momentary safety hazard for the patient. A new RF setting for the MRI scanner is then

calculated ensuring that implant heating is reduced to an acceptable level. If the scanner is parallel transmit (pTx) capable, an optimisation algorithm is used to find the setting which combines patient safety with the best possible image quality.

In the next step, a simulation approach was developed to relate *steady-state* temperature at the implant tip, i.e., the true but not directly accessible hazard parameter, to different surrogate parameters that can be measured by sensors. Various sensor types were investigated, and it was found that time-averaged *E*-field (E_{rms}) and point SAR (without spatial averaging) are most suitable as sensor-measurable safety surrogates. The approach allows to actually calibrate the surrogate signals in terms of the true hazard parameters. The sensor can thus be used to monitor compliance with established safety limits in real time which gives implant manufacturers the incentive to develop such sensor-equipped devices.

A procedure was subsequently developed and tested, using pTx to optimise the distribution of the RF *B*-field, determining the image quality, while keeping the maximum tip-SAR below a predefined limit. Compared to the standard method used in most clinical scanners today, the optimised approach produced 2.5 times higher RF B-field without any compromise in tip-SAR or image homogeneity. This is a significant progress underlining the power of the pTx approach to mitigate implant-related risks in MRI.

For a systematic exploration of this approach, a comprehensive 'Parallel Transmission Implant Safety Testbed' was developed, a compact setup allowing to investigate different sensor feedback methods, perform validation measurements and assess the safety of a variety of implants for a wide range of MR settings (from 1.5 T to 7 T) and implant locations.

Sensor-equipped implants were constructed with rms sensors embedded either at the implant tip or in the implant casing. It was demonstrated that the measured rms signals are sufficient to assess implant safety and perform a mitigation of the RF heating hazard by a pTx system applying the sensor Qs-matrix approach developed in this project. It was furthermore demonstrated that the so-called "orthogonal projection" method, also developed in this project, is capable to mitigate the RF heating threat based on the sensor signal alone while at the same time imaging quality could be maintained in the target region. Furthermore, this methodology was tested in realistic but complex proof of concept experiments applying realistic deep brain stimulator (DBS) lead trajectories, wireless transmission protocols and multiple implant locations and orientations. These results indicate that a safety concept based on sensor-equipped medical implants that communicate with a pTx capable MRI system is principally feasible.

This objective was successfully achieved.

Objective 4

For a long time, the possible heating of an implant by the switched gradient fields in MRI was overlooked as a safety issue. For a systematic investigation of this problem, this research project combined modelling results with validating measurements. Real-life implants, e.g. hip, knee and shoulder prostheses, were investigated in a clinical MRI scanner under real-life imaging conditions, while simultaneously a test stand was built and utilised for systematic experiments in a precisely controlled environment.

A wide database containing the magnetic field distributions from different gradient-coil designs (both conventional and special-purpose scanners) was created. In parallel, an extensive examination of clinical sequences was performed, to select the most relevant cases.

New computational tools, specifically designed to simulate the exposure to MRI gradient fields of a patient carrying a prosthesis, were implemented. In parallel, the new gradient testbed was utilised to investigate thermal effects of gradient coils on real metallic implants under controlled conditions. The experimental data collected in this laboratory (together with the corresponding data obtained in a clinical scanner) was used to provide a validation of the computational tools, obtaining an excellent agreement. The facilities set up in this laboratory can now be used to offer a service to customers interested in checking the heating of implants when exposed to gradient fields (but also the behaviour of magnetic field meters in a given and characterised spatial gradient).

A large number of simulations of implants, embedded in phantoms or realistically implanted in digital human models, was performed, exposing such models to realistic field distributions and imaging sequences. For the first time, the thermal effects of RF and gradient fields around a bulky implant were compared and superposed to obtain the total heating. Moreover, a pragmatic approach to rate the risk associated with both RF- and gradient-induced heating of knee/hip/shoulder implants during a given imaging protocol was developed and a software package to classify this risk based on dosimetric data provided by the user was made publicly

available. The stability of the numerical results was assessed with respect to the variability of some physical parameters (e.g., thermal properties, blood perfusion) and for different versions of the “virtual surgery” applied to the digital human models.

Based on the collected data, a standardised and versatile procedure was designed to test gradient-induced heating of implants (including implants with complex shape, where the geometrical anisotropy plays a crucial role) avoiding over-conservative assumptions. When combined with some a priori information, the outcomes of this procedure allow predicting the heating of a given implant placed in a given position within a specific MRI scanner and exposed to a specific imaging sequence.

Finally, the possible enhancement in the magnitude of the electric field induced in tissues by gradient fields, in the presence of an orthopaedic implant, was investigated.

This objective was successfully achieved.

Objective 5

A statistical approach was employed to assess the MRI safety for small metallic implants like screws or fixation parts, i.e., groups of devices with a large variety of sizes and shapes within each group. A few reference implants of a given type were investigated in detail and it was attempted to derive scaling laws to transfer this knowledge, including its uncertainties, to a whole class of similar devices.

Mathematical models of parameterised implants were used to explore how shape factors, field strength scan sequence, and orientation affect the heating of implants during scanning. Extensive simulations of simplified orthopaedic implants in gradient fields showed a strong correlation between maximum temperature rise and deposited power per unit surface area, and a parametric model was developed to describe these correlations.

The physical processes behind the heating of tissue around a medical implant are quite different for gradient induced vs. RF induced heating. A first version of unified description, linking and comparing the simulation results for both mechanisms was nevertheless developed. To this end, a set of parameterised models of idealised and realistic implants has been created and compared. The different physical effects that dominate each heating model can be linked to physical properties of the implants, enabling enhanced clinical guidelines.

A more detailed analysis of the simulation results was performed with the goal to develop parameterised models to predict heating from implant properties. Combining all the developed evidence to assess the possibility of a stochastic approach to MRI safety for small implants, it had to be concluded, however, that such a type of approach is not currently feasible because its uncertainties could not be reliably established. This is because i) many sources of uncertainty were not sufficiently quantifiable, ii) parametric models to predict implant heating did not work accurately enough even for simple cases, while iii) the models that could indeed predict implant heating accurately were “black box” and computationally expensive, and therefore not suitable for an uncertainty evaluation.

The effects of variability of humans on MRI-induced *E*-fields was studied and the results published. Data was generated that represented the *E*-field occurring during MRI scanning in six regions within the human body where implants are commonly placed. A large number of implant locations and scanner configurations were investigated, and an initial analysis identified which factors have the strongest effect on the *E*-field. The *E*-field exposure was then linked to the electromagnetic properties of the tissue in that region, providing a method to account for person-to-person variability when assessing exposure risk.

This objective was successfully achieved. New approaches were applied, lots of new insight was gained and published. Still the ultimate goal, to provide an easier and cheaper safety assessment for small implants was not reached.

Impact

MIMAS results have led to several journal papers, most notably an invited review paper and a book chapter on implant safety co-authored by multiple consortium members. Project findings were disseminated in 51 conference contributions, about one third of which were invited oral presentations. Lectures on gradient-induced heating of implants were given for PhD students in Engineering and for students of a Health Physics course.

In September 2021, an international stakeholder workshop was organised with 200 registrants from five continents and a strong (42 %) participation by industry. At this workshop, convenors and spokespersons for the most important MR safety standards ISO/TS 10974, IEC 60601-2-33, and ASTM F2182, as well as industry

representatives from major manufacturers or academic researchers, gave presentations. A broad stakeholder community learned about project results and discussed the consecutive needs for the ongoing current standardization work.

Impact on industrial and other user communities

In December 2019, ZMT's in-vivo RF-exposure libraries *MRIxVIP 1.5* and *MRIxVIP 3.0T* and the standardised evaluation tool *IMAnalytics* were qualified, as the first computational tool ever, by the U.S. Food and Drug Administration (FDA) as a Medical Device Development Tool (MDDT). This is a major success, since the MDDT label certified that evaluations of the health risk posed by medical implants to patients undergoing MRI were traceable, easy-to-conduct, and standardised at the most comprehensive level. The combination of *IMAnalytics* and *MRIxViP* data libraries enables the medical device industry to accelerate their approval processes with standardised risk evaluations of approved, high quality.

At the end of 2019, IMAnalytics v3.0 was released. In addition to Tier 3 (mostly for active implants), this new update now also supports Tier 2 evaluations (mostly for passive implants) with a workflow for extracting field data from the MRIxViP libraries in customised regions of interest, with derivation of all statistics necessary for Tier 2 of ISO/TS 10974. The development of this functionality enabled the quantification of worst-case *E*-fields in the human body in implant regions, which played a key part in MIMAS deliverables. IMAnalytics v3.0 and MRIxViP v2.1 have been qualified by the FDA in May 2021.

The new laboratory devoted to gradient-induced heating is now available to offer to third parties a measurement service for heating of implants exposed to gradient fields. More in general, the same facilities can be exploited to check the behaviour of magnetic field meters in a given and characterised field spatial gradient, possibly leading to the development of a new CMC in the near future.

Impact on the metrology and scientific communities

The successful cooperation within the MIMAS project and the deeper insight into mutual research interests and capacities led consortium members to join forces in a different research field, too. MIMAS partners were the key drivers in conceiving and procuring a new joint research project on quantitative imaging which will be coordinated by a MIMAS consortium member.

The scientific community learned about the newly developed methodologies through journal publications and conference presentations. For the first time ever, numerical models of tissue and implant heating in MRI, which were already in widespread use in the research community, are supported by a metrological underpinning.

A software package that allows the user to classify the risk associated with the exposure of bulky implants to RF and gradient fields, based on dosimetric data provided by the user himself, was made freely available to the scientific and clinical community.

Impact on relevant standards

The Technical Specification ISO/TS 10974 on MRI safety of active medical implants is still lacking key procedures necessary for progression to a standard. The project developed specific procedures and validated tools for the safety assessment of implants and provided a metrological underpinning to ensure that ISO/TS 10974 will i) become a full standard and ii) be continuously developed and improved. This will also contribute to the future development of IEC 60601-2-33, the international standard on MRI equipment and safety, since a complementary co-development of both the MRI and the implants standard was agreed upon by a joint ISO/IEC working group.

The procedure specifically developed in the project to test, in a standardised way, the heating of bulky implants exposed to gradient-fields was circulated and, in particular, disseminated towards the FDA and members of the committees that maintain standards ISO/TS 10974, ASTM F2182 and IEC 60601-2-33.

Longer-term economic, social, and environmental impacts

European implant manufacturers benefit from a faster market introduction of their innovative products as metrologically approved methods to assess the MRI safety of medical implants are now available. This holds particularly for the simulation-based assessment of active implanted medical devices (AIMD) with long electrodes or leads since these are the most hazardous implants in MRI for which new *Medical Device Development Tools* were developed and approved.

In addition, an independent, novel safety concept towards a personalised safety assessment for AIMD carriers in MRI was developed within MIMAS and the proof-of-principle was given. This approach utilises the

information from sensors on the implant to adjust the RF settings of a parallel-transmit capable MR scanner. No longer the MRI operators in the clinics but rather the implant and scanner manufacturers would be chiefly responsible for the safety of implant carriers, then. The concept assigns new responsibilities, and it requires technical changes to both implants and MRI scanners. Manufacturers may be reluctant to adopt it, therefore, and even after the concept was developed and its principal feasibility demonstrated within MIMAS, the route towards formal approval and practical implementation may still be a long and tedious one. Once it is adopted, however, it will change the MR scanning of implant patients forever.

List of publications

[1] *In silico evaluation of the thermal stress induced by MRI switched gradient fields in patients with metallic hip implant.* Arduino A, Bottauscio O, Brühl R, Chiampi M, Zilberti L. Phys Med Biol. 2019. https://doi.org/10.1088/1361-6560/ab5428

[2] *RF-induced heating of metallic implants simulated as PEC: Is there something missing?* Zilberti L., Zanovello U., Arduino A., Bottauscio O., Chiampi M. Magn Reson Med 2020. https://doi.org/10.1002/mrm.28512

[3] *MRI-Related Heating of Implants and Devices: A Review. Winter* L, Seifert F, Zilberti L, Murbach M, Ittermann B. J Magn Reson Imaging 2020. https://doi.org/10.1002/jmri.27194

[4] *Parallel transmission medical implant safety testbed: Real-time mitigation of RF induced tip heating using time-domain E-field sensors.* Winter L, Silemek B, Petzold J, Pfeiffer H, Hoffmann W, Seifert F, Ittermann B. Magn Reson Med 2020. https://doi.org/10.1002/mrm.28379

[5] *Heating of hip joint implants in MRI: The combined effect of RF and switched-gradient fields.* Arduino A, Zanovello U, Hand J, Zilberti L, Brühl R, Chiampi M, Bottauscio M. Magn Reson Med 2021. https://doi.org/10.1002/mrm.28666

[6] *Rapid safety assessment and mitigation of radiofrequency induced implant heating using small root mean square sensors and the sensor matrix Qs.* Silemek B, Seifert F, Petzold J, Hoffmann W, Pfeiffer H, Speck O, Rose G, Ittermann B, Winter L. Magn Reson Med 2022. https://doi.org/10.1002/mrm.28968

[7] *Gradient coil and radiofrequency induced heating of orthopaedic implants in MRI: influencing factors. Wooldridge* J, Arduino A, Zilberti L, Zanovello U, Chiampi M, Clementi V, Bottauscio O. Phys Med Biol 2021. https://doi.org/10.1088/1361-6560/ac3eab

[8] *Statistical analysis of temperature rise in passive medical implants in a magnetic resonance imaging environment.* Cox MG, Jagan K, Rajan S. NPL Report MS28, 2021. https://doi.org/10.47120/npl.MS28

[9] *Radiofrequency-induced heating of broken and abandoned implant leads during magnetic resonance examinations.* Yao A, Goren T, Samaras T, Kuster N, Kainz W. Magn Reason Med 2021. https://doi.org/10.1002/mrm.28836

[10] *Experimental and numerical optimization modelling to reduce radiofrequency-induced risks of magnetic resonance examinations on leaded implants.* Córcoles J, Yao A, Kuster N. Appl Math Modelling 2021. https://doi.org/10.1016/j.apm.2021.02.036

[11] *Induced radiofrequency fields in patients undergoing MR examinations: insights for risk assessment.* Yao A, Murbach M, Goren T, Zastrow E, Kainz W, Kuster N. Phys Med Biol 2021. https://doi.org\10.1088/1361-6560/ac212d

This list is also available here: https://www.euramet.org/repository/research-publications-repository-link/

17IND01 MIMAS

Project start date and duration:	01 June 2018, 40 months	
Coordinator: Bernd Ittermann, PTB Tel: +49-30-3481-7303 E-mail: bernd.ittermann@ptb.de Project website address: https://www.ptb.de/mimas/home		
Internal Funded Partners: 1 PTB, Germany 2 INRIM, Italy 3 NPL, United Kingdom	External Funded Partners: 4 IOR, Italy 5 ZMT, Switzerland	Unfunded Partners: –
RMG1: INRIM, Italy (Employing organisation); PTB, Germany (Guestworking organisation)		