We help ideas meet the real world

DELTA
Final Report (Technical memorandum)

Separation distance to Motorola RFID FX7400

Performed for Region Midtjylland

Project no.: T201589
Document No: 601100

25 May 2012

DELTA
Danish Electronics,
Light & Acoustics

Venlighedsvej 4
2970 Hørsholm
Denmark

Tel. +45 72 19 40 00
Fax +45 72 19 40 01
www.delta.dk

Title Separation distance to Motorola RFID FX7400

Project no. T201589

Date 25 May 2012

Project manager

Jakob Steensen
Consultant
DELTA Test & Consultancy

Revision Control

Revision No.	Date	Responsible	Change
0.0.0	21 May 2012	JAK	Initial revision
1.0.0	25 May 2012	JAK	Issued version

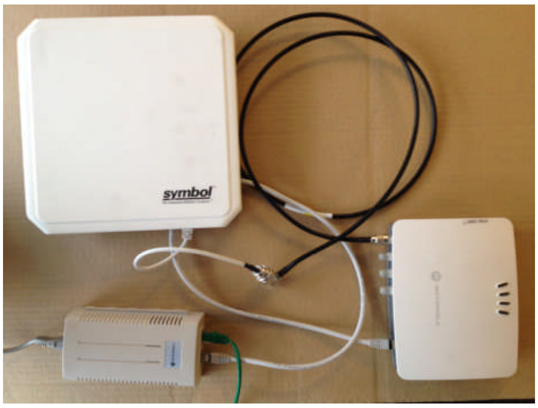
Document Review

Revision No.	Date	Reviewer
1.0.0	25 May 2012	Claus Rømer Andersen, DELTA Anders Mynster, DELTA Lise Korfitzen, DELTA

Table of contents

1. Summary

1.1 Purpose



The purpose of this report is to give Region Midtjylland sufficient data in order to decide the minimum allowable distance between the Motorola FX7400 RFID system and medical electrical equipment, and thereby to act as input to DNU's own risk assessment, if the Motorola FX7400 RFID system should be installed at DNU and if so, with which installation limitations. The data is presented in such way, that both the results from the specific investigations pursuant to this project report as well as general recommendations from the EN/IEC 60601-1-2:2007 3rd edition standard are considered.

1.2 Background investigations

The specific investigations pursuant to this report are constituted primarily by the findings described in the following two documents:

1. Pre-study: Measurement of field strengths of Motorola RFID FX7400.
   (Project doc no. 402003.)

   The pre-study determines the *worst case*[1] electromagnetic field strength of the Motorola FX7400 RFID system as a function of distance from the source. The pre-study also explains how the field can be reproduced in a controlled, semi-anechoic environment with exact reproduction of all other FX7400 field properties, such as frequency, modulation form and B-field.

   It is concluded that no E-field amplitude higher than the ones discovered in the report can occur, except for amplified field strengths as a consequence of constructive interference between an original signal and reflected components of that same signal. The magnitude of such amplification is typically negligible, as the amplification is within field reproduction tolerances and by far within tolerances of immunity of the medical electrical equipment likely to be subject to exposure.

   More precise magnitudes of constructive interference are calculated in the report at hand, and a risk analysis is conducted (Annex 1).

2. Test report: Immunity to emulated Motorola FX7400 RFID fields of selected medical devices. (Project doc no. 503000.)

   The test report determines the level of immunity to fields similar to those coming from the Motorola FX7400 of 11 carefully chosen medical devices, selected by DNU personnel for their ability to represent a more comprehensive group of devices used in typical hospital environments.

[1] All relevant properties of the field are considered. Nothing is left unaddressed.

1.3 Primary findings

Based solely on the two documents described above, the maximum field strength of the signal from the Motorola FX7400 in any receiver position should not exceed 10 V/m, and as a consequence, combinations of system power settings and separation distances between the RFID transmitter antenna and medical electrical equipment giving cause to higher field strengths than 10 V/m should not be allowed in the implementation of the RFID system at DNU.

If it is decided that an additional safety margin is required in order to account for constructive interference phenomena and/or lower immunity levels of exposed medical devices, a 10:3 safety margin could be considered, as this is the general margin used for life-supporting medical devices according to EN/IEC 60601-1-2:2007, 3rd ed.[2]
The 10:3 factor is the difference between minimum immunity levels for life-supporting equipment and for non-life-supporting equipment.

Several factors, however, indicate that a safety margin of less than 10:3 can be used:

- It is unlikely that field strengths as high as those found in the pre-studies will occur where medical equipment is located, as these field strengths are worst case, in terms of conducted power plus antenna gain in any direction.
- It is unlikely that exposed medical electrical equipment is most susceptible to electromagnetic fields at exactly the same frequencies as those used by the Motorola FX7400 RFID system. This general assumption is supported by the fact that most of the tested medical equipment showed higher immunity levels than 10 V/m at the used frequencies (ref: Annex 4).
- If the RFID antennas are installed below the ceilings (facing downwards), the exposed equipment should be located exactly beneath an antenna and all other worst case considerations must be present at the same time in order for the equipment to be exposed to field strengths of 10 V/m.
- Life-supporting medical devices are tested to be compliant to 10 V/m in the frequency band used by the Motorola FX4700 and similar RFID systems.
- The path loss exponent N deviation from free space conditions is not accounted for in the project calculations, but is a factor which will exist in real life surroundings and provide even more margin (refer to Annex 1 for more detailed explanation).

Of course, such speculations are subjective and should be ratified solely by DNU in their cost-benefit analysis.

[2] IEC 60601-1-2:2007, 3rd edition, Annex A, Subclause 5.2.2.2 – Requirements applicable to ME EQUIPMENT and ME SYSTEMS other than those specified for use only in a shielded location.

2. Separation distance illustrated

Section 4.1 in the pre-studies uses the following formula for calculating the E-field strength E_{FF} in the far field region:

$$E_{FF} = \frac{\sqrt{30 \cdot ERP}}{r^N}$$

where

E_{FF} = E-field strength at the specified distance from the antenna (far field) [V/m]. Based only on the immunity tests in the present investigations (project doc no. 503000), we found the maximum allowable field strength to be E_{FF} = 10 V/m.

ERP = Effective radiated power [W].

r = The distance to the antenna [m].

The exponent N to r is set to 1 to assume absolute worst case conditions (refer to Annex 1 for detailed explanation).

Solving for r (with N = 1):

$$r = \frac{\sqrt{30 \cdot ERP}}{10}$$

Example: With ERP = 2 W, r equals 0.77 m.

Annex 1 describes that under the assumption that a perfectly reflecting surface aimed directly at the receiving medical device is mounted no closer to the RFID antenna than twice the direct separation distance r, the worst case scenario for constructive interference is that the resulting total field E_{RES} will be amplified to:

$$E_{RES} = E_{FF} \cdot 123.6\ \%$$

Example: With r = 1.00 m, the total field strength is amplified to 123.6 % times the field strength coming from direct exposure alone.

Therefore, considering constructive interference from a perfectly reflecting surface, the minimum separation distance should be increased accordingly.

If the installation restriction not to have a perfectly reflecting surface closer to the RFID antenna than twice the respect distance of 2* 1.00 meter = 2.00 meter is met, the maximum permissible field strength is reduced to:

$$E_{FF\_REDUCED} = 10 \cdot \frac{100}{123.6} = 8.10\ \text{V/m}$$

Hence, the separation distance can be recalculated:

$$r = \frac{\sqrt{30 \cdot ERP}}{8.10}$$

Example: With ERP = 2 W, r equals 0.96 m.

The minimum separation distances can be calculated in the same way for maximum permissible field strength exposure of 3 V/m with and without considering constructive interference from a perfectly reflecting surface.

From EN/IEC 60601-1-2:2007 3rd edition, Annex C, Table C.6, we find the following calculation formula for minimum separation distance:

$$r = 2.3 \cdot \sqrt{\text{ERP}}$$

Example: With ERP = 2 W, r equals 3.25 m.

The different ways of calculating the separation distance can be graphically illustrated in the following figure:

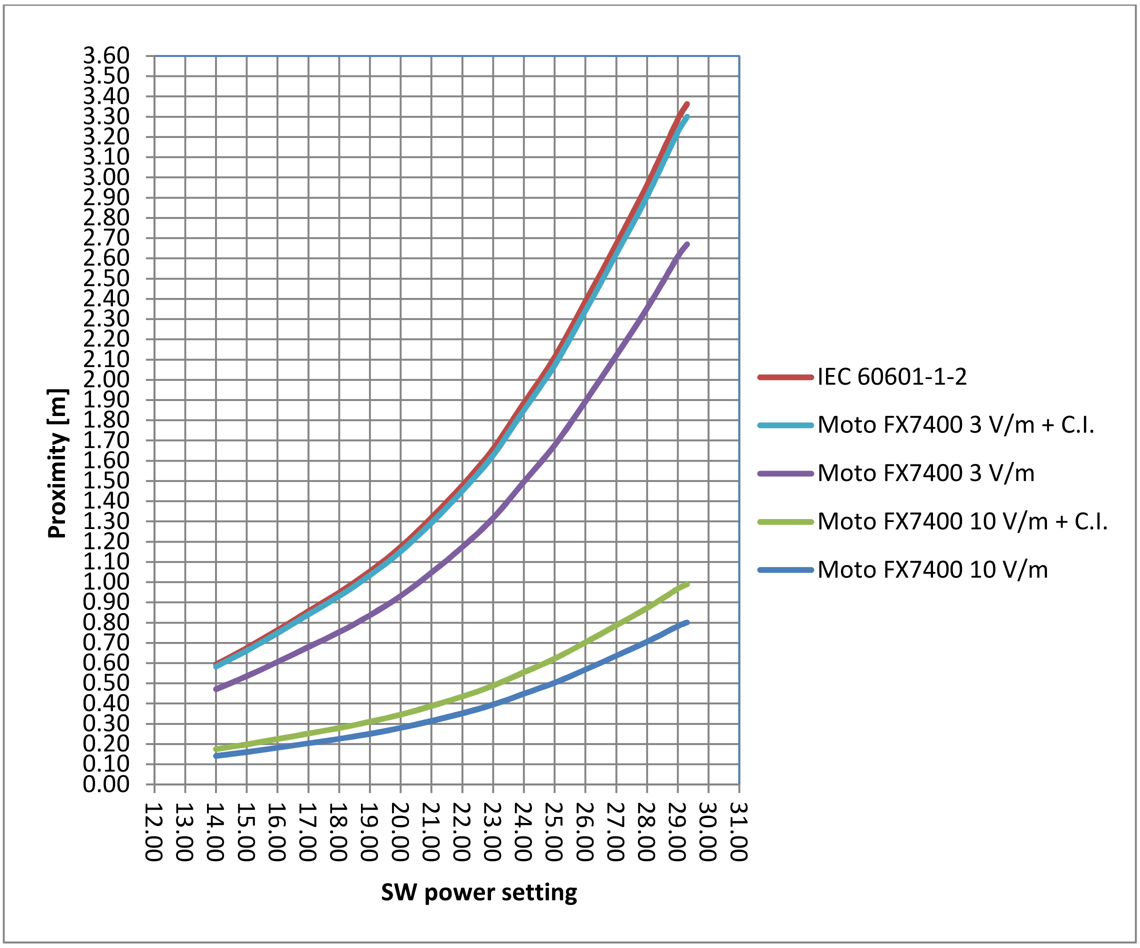


Figure 2.1: Minimum separation distances, calculated the following ways:

a) From the general formula in EN/IEC 60601-1-2:2007 (which considers the general 3 V/m immunity level with additional margin and therefore suggests a greater separation distance).

b) From the project findings, considering a 3 V/m immunity level with an additional margin in respect to constructive interference.

c) From the project findings, considering a general 3 V/m immunity level.

d) From the project findings, considering the tested 10 V/m immunity level with an additional margin in respect to constructive interference.

e) From the project findings, directly considering the 10 V/m immunity level.

The figure illustrates a clear difference between separation distances considering either the 10 V/m level or the 3 V/m level. The minimum separation distance suggested by EN/IEC 60601-1-2 is more restrictive than the separation distance determined by the project investigations, as the IEC standard aims to ensure maximum protection, even for equipment with an immunity level of no more than 3 V/m and with additional margin to this immunity level, whereas this project aims to see how close we can actually go without compromising immunity and safety.

3. Conclusion

This project indicates that a minimum separation distance less than the generally recommended minimum separation distance from IEC 60601-1-2 can be used in the installation of a Motorola FX7400 RFID system at DNU. This, however, only under certain conditions.

Based on the tests, measurements and analysis we have performed during this project, DELTA recommends that a minimum separation distance of 1.00 meter will be sufficient to prevent disturbance and will allow full flexibility in setting the FX7400 system at any power level, even considering the unlikely event that constructive interference will give cause to slightly raised field strength levels. This recommendation is based on the fact that at 2 W RFID system output power, and perfect constructive interference from a single, reflecting surface, the minimum separation distance is calculated to be 0.96 m.

DELTA recommends that Region Midtjylland should use this project to demonstrate and document that shorter separation distances than those recommended by IEC 60601-1-2 can be used. And therefore to proceed onto performing test installations with respect to a minimum separation distance of 1.00 meter. DELTA also recommends that Region Midtjylland specifies not to install reflecting surfaces closer to the RFID antennas than 2 x 1.00 = 2.00 meter (ref: Annex 1), and that the installation specification includes a post installation check of the power level setting in the software. Finally, DELTA recommends only to use the Motorola FX7400 RFID system or a similar system incorporating mitigation techniques such as the Motorola FX7400 RFID system, which ensures that two antennas cabled to the same hub will not transmit simultaneously.

The conditions for the recommendation are:

The installation guide should emphasize not to have reflecting surfaces closer to the RFID antenna than 2.00 meter.

Maximum permissible field strength is 10 V/m.

The 11 devices tested for immunity in the pre-study represent worst case devices.

If the cost-benefit analysis finds that an additional safety margin of 10:3 is required in order to account for any medical device not being disturbed, a separation distance of no less than 3.30 m should be respected if full power from the RFID system is required in order to make the system function to a satisfactory level of operation.

If the 10:3 margin is respected, and it is not possible to obtain more than 1.00 meter of separation distance, the FX7400 system must not be set a power level higher than “18.5 dBm”. Other studies show if this is a sufficient level of power in order for the system to function properly.

This project has addressed the issues initially deemed to be most relevant for installing RFID in the hospital. If it is determined that the residual risks need to be addressed further, the most relevant risk is considered to be related to the potential lower immunity levels of medical devices. Annex 3 addresses this risk further, and identifies the following possible next actions:

A more thorough investigation of the susceptibility level of sensitive equipment, e.g. by rotating the test object.

Statistical analysis of the confidence level related to variation in production of medical devices, as proposed by the standards CISPR 14 and CISPR 22.

Clarification if measures for control of susceptibility level are required on medical equipment that has been subject to maintenance.

Test of medical equipment in additional modes of operation.

Test of additional types of medical equipment.

Annex 1

Quantification of constructive interference

The electromagnetic fields generated by any emitting source may in theory be subject to amplification, if two or more waves of equal frequency and phase interfere, resulting in their mutual reinforcement, hence producing a single amplitude equal to the sum of the amplitudes of the individual waves.

In this project, this phenomena, constructive interference, is excluded from the calculation of field strengths, as both theory, experience and practical measurements show only very little risk of field amplification. However, the phenomena is not disregarded, as this would be a denial of physics, but occurrence is very rare, and areas of constructive interference inside an unknown environment is so difficult to quantify, that it is practically impossible to calculate precisely.

The following parameters are the full sum of potential constructive interference contributors to amplified field strength of the signal coming from the RFID antenna, in the position at which a reception is experienced:

- Constructive interference from standing waves in the surrounding environment.
- Constructive interference from simultaneously transmitting antennas mounted on different RFID controller boxes.
- Constructive interference from simultaneously transmitting antennas mounted on the same RFID controller box.

The risk of each of the contributing parameters actually being present is assessed in the following section.

The conclusion of the risk assessment is, that there is such small risk of amplified fields that it is fair to regard only the fundamental field strengths coming from one RFID antenna.

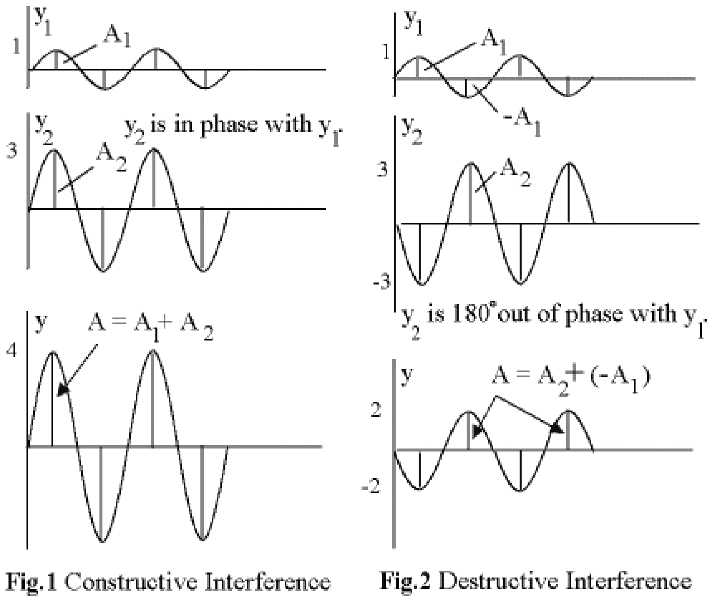
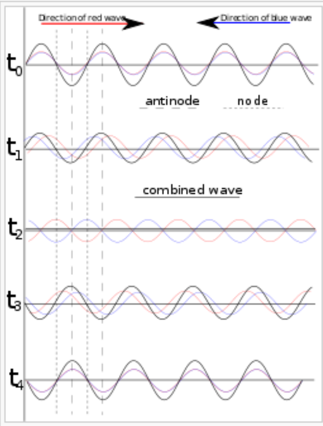


Figure A1.1: Amplification and attenuation of signals as they interfere with each other.

Constructive interference from standing waves in the surrounding environment

When waves hit the reflecting surfaces of the environment, this being walls, ceiling, floor, furniture, equipment and so on, the waves will reflect and waves initially emitted in opposite directions may meet and amplify the signal as a consequence of constructive interference when the phases of the reflected signals are equal to the phase of the direct signal. Likewise, negative interference will occur whenever the signals are out of phase. Absorption will occur when the waves are radiated onto absorbing objects, which may also be walls, curtains, humans and so on. Attenuation will occur as a consequence of distance from the source. Therefore, the signal will quickly “die” out, but before it does, constructive interference may have occurred to a level where field strengths become higher than the maximum permissible level found in this project.



Two opposing waves combine to form a standing wave.

Figure A1.2: Standing waves building up over time t0 to t4.

Standing waves will generate 3D sections of various attenuation and amplification inside a room. The size and position of these areas will change with even the smallest change of room physics, such as the door opening a few degrees more or any object inside the room being moved even slightly. Also, boundaries between attenuated, neutral and amplified sections are not hard, but crossfades. Because of these circumstances, it is extremely difficult to quantify amplification factors precisely even in a mathematical well described environment, and impossible in unknown environments. A pragmatic approach to this problem is to perform measurements in the environments or in similar environments to try and spot constructive interference. This has been done in the pre-study report without finding any positions with problematic field amplification, which is in good harmony with the general expectation, based on DELTA’s vast experience in electromagnetic field measurement practice.

So why are the measured values so much lower than the calculated values, in many cases?

As the real life measurements of this project were intended to search the environment for fields stronger than the ones calculated as worst case direct exposure levels, a worst case formula for field levels were used:

$$E_{FF@r} = \frac{\sqrt{30 \cdot P[\mathrm{Watt}]}}{r}$$

However, in any real life environment, many obstacles contribute in subtracting energy from the original signal, and therefore, especially at longer distances with many obstacles along the path of the signal from its origin to the measurement point, the pass loss exponent N should be considered. That is, if the aim is to calculate more true values (not worst case values):

$$E_{FF@r} = \frac{\sqrt{30 \cdot P[\mathrm{Watt}]}}{r^N}$$

According to many text books on the subject, the pass loss exponent N is typically around 3 in real life office environments. The factor N certainly decreases the "expected" field strength levels of the simulated real life environments. It is tempting to conclude, that N gives one a free ticket to compromise the respect distance, but the operator should remember, that N is for one thing hard to quantify and secondly, N has only relevance at distances, where the field strengths have decreased to levels not of interest to this project.

What is the maximum level of field amplification we should expect?

It is evident, that constructive interference from reflecting surfaces gives a higher contribution to amplification, the smaller the distance d there is from the RFID antenna to the reflecting surface, compared to the separation distance r from the RFID antenna and object subject to potential interference:

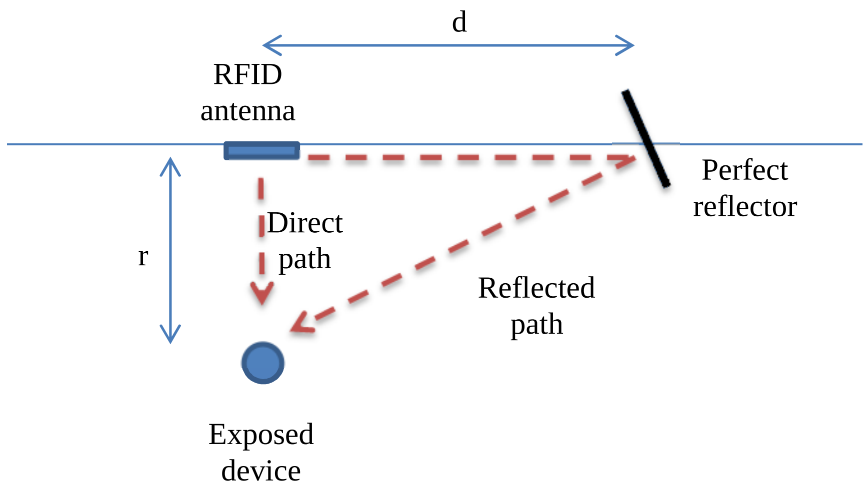


Figure A1.3: Direct and reflected path of a signal. Small direct path compared to the reflected path.

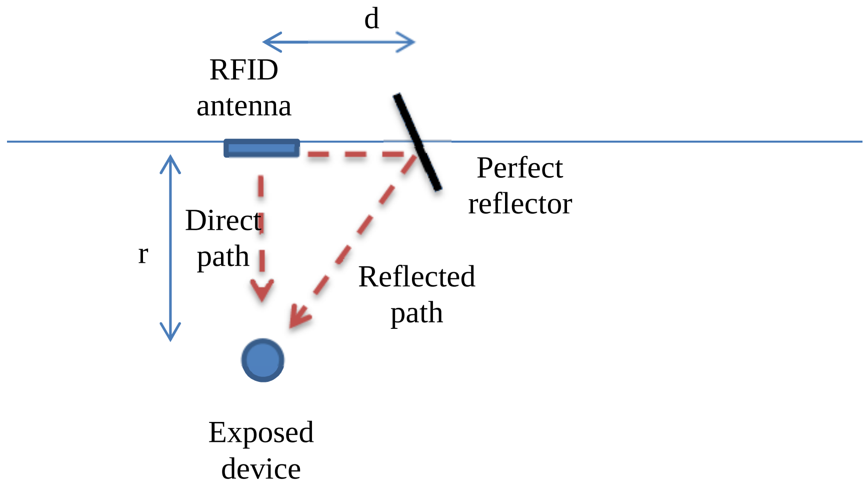


Figure A1.4: Direct and reflected path of a signal. Difference between the direct path and the reflected path is much smaller.

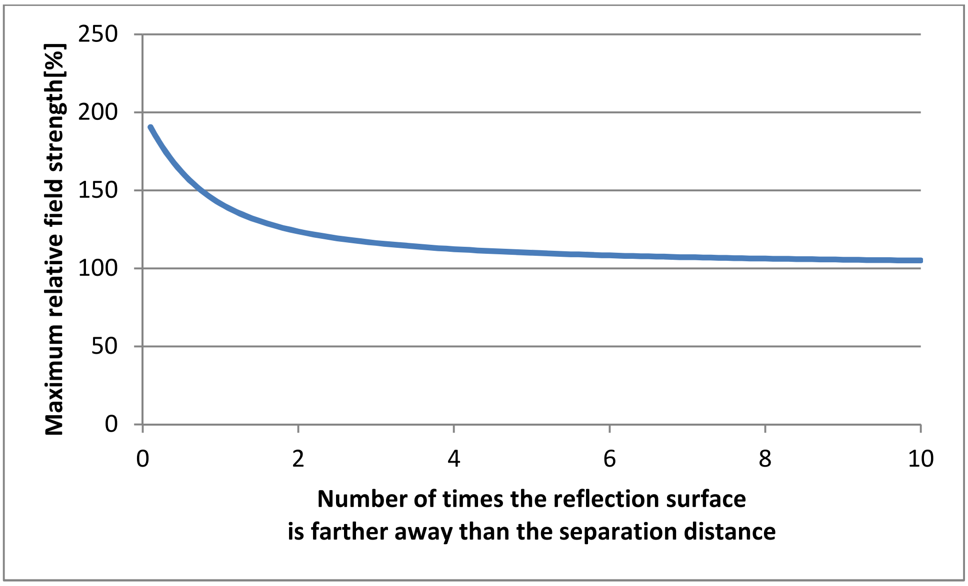


Figure A1.5: Relative maximum field strength due to constructive interference from a single reflector as function of relationship between r and d.

So, at large distances d, the percentage increase of field strength is small, at smaller distances d, the percentage increase approximates 100% (= 6 dB), resulting in double the field strength than that measured alone from the direct exposure.

However, the field strength decreases with a factor of 1/r, which means that the field strength plus margin for constructive interference will never increase as the observation point is moved away from the source! But the field strength in any given distance from the source may still be higher than the level deriving solely from direct exposure. How much higher is a matter of Pythagoras. Say for instance, that d = x * r, the resulting field strength will be:

$$E_{RES} = E_{FF} \cdot (1 + \frac{1}{x + \sqrt{x^2 + 1}})$$

If **d = 2 x r**, the resulting field strength can increase to **123.6 %** of that coming solely from direct exposure. At greater distances r and with the same fixed distance d= 2.00 meter, the field strength may have another size correlation between the direct part and the reflected part, but the total field strength will be smaller. So it is only interesting in this project to look at the percentage increase at the chosen respect distance (farther away = not interesting).

We can conclude, that if a separation distance between the RFID antenna and the medical equipment of no less than 1.00 meter can be sustained, and if no single, perfectly reflecting surface is located within the distance of 2.00 meter from the RFID antenna, then the maximum resulting field strength will be no more than 123.6 % that of direct emission level.

Several arguments oppose a conclusion to reduce the maximum permissible field strength however:

1. The maximum immunity level found is in itself within a calibration tolerance of +/- 1 V/m.
2. We found a failure level of 12 V/m and a pass level of 10 V/m. The actual pass level may hence be 11.9 V/m – we don't know.
3. The probability of having a perfectly reflecting surface exactly at the mentioned proximity and angle is intuitively very small.
4. The values in this project's conclusive separation distance matrix is based on worst case (highest possible) obtainable, direct field reception. It is unlikely, that worst case circumstances are generally present.
5. The pass loss factor gives additional margin but is not accounted for in this project.
6. Other medical equipment than the samples tested in this project may have other immunity levels. One should keep in mind, that the entire project is aimed at reducing risk of critical interference, not to rule out all potential immunity problems by definition.
7. The arguments above explain why DELTA suggest to use the worst case direct emission levels and the respect distances determined as a function only of these. And therefore to disregard constructive interference as respect distance reduction phenomenon.

Constructive interference from simultaneously transmitting sources from different RFID systems

If circumstances are right, two sources will cause constructive interference when the wave tops meet. The pre-study report show what can also be calculated, that field strength is attenuated by 6 dB for each increase in distance by a factor 2. In the current project, equipment is not tested to more than 30 V/m, corresponding to a distance from the RFID antenna of 0.25 m with the highest RFID power setting. This means that the field strengths will have decreased to approximately 15 V/m @ 0.50 meters. To amplify this to 30 V/m would require perfect constructive interference from the original antenna and another antenna positioned 0.50 m away from the target. In this argumentation, the risk of uncontrolled magnitudes of constructive interference can be entirely eliminated if no two RFID antennas from different controller boxes are positioned closer together than 1.00 m.

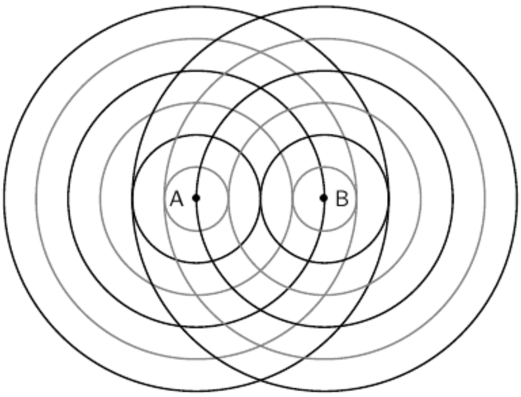


Figure A1.6: Wave tops meeting when the distance between two sources are equal to an integer multiplied with signal wavelength.

Constructive interference from simultaneously transmitting sources (antennas) from the same RFID system

As the pre-study report shows, the Motorola FX7400 RFID system will not allow two antennas to transmit at the same time. The system used a “by-turn” methodology, so the risk of constructive interference from two or more antennas connected to the same controller box can be completely disregarded.

Conclusion to the risk of potential constructive interference

The risk of constructive interference cannot be disregarded, as it is a well-known phenomenon. However, the risk is so small, that it is fair in DELTA’s opinion to disregard field amplification in the scope of the project.

The risk is determined from a general discussion as in this section and by DELTA specialist experience, supported by the simulated real life environment tests performed as part of the project pre-study.

DELTA assess that the risk of constructive interference between electromagnetic waves from any two antennas installed in the future on DNU will be less than 1%.

This risk can be reduced by a simple installation guide:

DELTA assess that field amplification as a consequence of constructive interference between direct emission and a single surface reflected emission originating from the same source, will always be less than an additional 23.6% field strength, if the proximity between RFID antenna and any medical equipment is at least 1.00 meters and the distance between RFID antenna and the reflecting surface is at least twice that distance, in this case at least 2.00 meters.

DELTA furthermore assess that the risk of constructive interference resulting in higher field strengths than the maximum allowable is reduced to less than 1 ppm when medical equipment subject to radiation is positioned further away from the antenna than twice the minimum distance. For instance, if the installation guide dictates a minimum distance of 1 meter between RFID antennas and equipment, the risk of field strengths higher than the highest possible at 1 meter will be reduced to near nothing at 2 meters distance.

Annex 2

List of factors which could potentially contribute to amplified field strength

In DELTA's opinion, these are the only, and all of, the factors which can possibly cause the field strength level to increase to a higher level than the normalized level, in the point of reception:

1. Constructive interference from standing waves in the surrounding environment.
2. Constructive interference from simultaneously transmitting antennas mounted on different RFID controller boxes.
3. Constructive interference from simultaneously transmitting antennas mounted on the same RFID controller box (= firmware malfunction).
4. Faulty setting of the output power level.

Each factor is described in the following subclauses:

Constructive interference from standing waves in the surrounding environment

There will be a small risk of this phenomenon as described in Annex 1.

Constructive interference from simultaneously transmitting antennas mounted on different RFID controller boxes

As described in Annex 1, the risk of constructive interference causing field strength amplification to a level higher than the maximum permissible level can be entirely eliminated if the installation guide ensures that no two antennas from different controllers are positioned closer together than 4 x [separation distance]. Also, any other installation which ensures that medical equipment will not receive more energy than 2 x ½ the initial maximum level will be sufficient to eliminate any risk of unsafe interference levels from two antennas mounted on different controllers. For instance, if the antennas are generally mounted on the ceilings at say, 3 m height, and no equipment is higher than 2 m, smaller distance between two antennas can be allowed.

Another risk eliminating initiative could be to ensure by software, that no two neighboring systems will operate at the same time.

Constructive interference from simultaneously transmitting antennas mounted on the same RFID controller box (= firmware malfunction)

It is ensured by firmware that the Motorola FX7400 RFID system will not output from more than one antenna at a time. This means that only a firmware malfunction will enable the risk of such simultaneous operation. If no two antennas are positioned closer together than 4 x [separation distance], even such firmware malfunctions will not cause filed strength levels higher than the maximum permissible.

Faulty setting of the output power level

If so decided, that the separation distance should be shorter than 1 m, or if the maximum permissible field strength level should be less than 10 V/m, the operator needs to ensure, that the power level is set correctly. If not, greater field strength levels than the maximum permissible may be experienced in the point of reception. Refer to the graphical illustration in Chapter 2 for valid combinations of field strength, power setting and separation distance. Check power setting during installation.

Annex 3

List of factors which could potentially contribute to reduced immunity

In DELTA's opinion, these are the only, and all of, the factors which can possibly influence how susceptible a device exposed to an RFID signal is:

1. Frequencies of the source signal.
2. Modulation form of the source signal.
3. Entry position of the emission into the medical equipment.
4. Duty cycle / duration of the source signal.
5. Susceptible equipment production variations.
6. Physical damage to the susceptible equipment.
7. Susceptible equipment operation mode.
8. Proximity to the emitting source (the RFID antenna).
9. Type of equipment.

Frequencies of the source signal

Typically, any device will be less immune at some frequencies than other due to the trimming of decoupling components, cable lengths and the specific nature of integrated circuits. This is not considered a problem with the devices exposed to the fields from the Motorola FX7400 RFID system, as this system operates only in a very small frequency band. All the devices we tested in this project have been exposed to a sweeped field through the entire frequency band.

Modulation form of the source signal

The actual modulation form of the signal is very relevant for immunity of exposed equipment, as the modulation form defines frequency components and the amplitude of these inside the signal cycle. This will not reveal an undiscovered problem with the devices exposed to the fields from the Motorola FX7400 RFID system, as the immunity test were all conducted with a replica of the exact signal modulation form.

Entry position of the emission into the medical equipment

A severe contributor to immunity variations is the orientation of the exposed equipment towards the source antenna. This project has been using a controlled, calibrated, uniform field and exposure to as many faces of the individual type of equipment, as the circumstances allowed. This will minimize the risk of undiscovered immunity problems, but it will not eliminate the risk, that the most susceptible angle of exposure has not been tested with some or all of the devices.

Next step suggestion: A more thorough susceptibility investigation on particularly sensitive equipment, for instance by using rotation during exposure.

Duty cycle / duration of the source signal

The duration of the exposing signal determines how much energy is stored in various capacitances inside the exposed device, and as such, the duty cycle has much to say. Duty cycle from a macro point of view should not be confused with the modulation form of the signal, but is equally important. This is not a source to undiscovered problems, as the actual Motorola FX7400 signal has been played back in an endless loop, exposing all tested devices to a near 100% duty cycle, whereas the real-life operation mode of the system is closer to 1% duty cycle.

Susceptible equipment production variations

Large variations in decoupling components (such as capacitors) are a common problem in designing immune electronics. Tolerances tune resonance phenomena, so that the best immunity is achieved at different frequencies for one batch of equipment compared to another batch. This means that there is a potential problem that a type of equipment tested to comply to 10 V/m at 865 MHz may have a sister another batch which is less immune at that frequency area. Variations in other components also contribute to different immunity levels, as well as the exact positioning of wires, screws and metal parts.

Next step suggestion: Statistical analysis of confidence level as proposed by the standards CISPR 14 & CISPR 22.

Physical damage to the susceptible equipment

Physical damage, such as break off of decoupling capacitors / inductors inside the device or openings in the shielding chassis may influence how immune a device is to exposure. Other types of relevant physical damage could be emergency shutdown system failures or damaged ferrites or even wires which have shifted position inside the device, making these wires more exposed if for instance, the device has been dropped.

Next step suggestion: Clarification if measures for control of susceptibility level are required on medical equipment that has been subject to maintenance.

Susceptible equipment operation mode

Some equipment may be more susceptible to E- or B-fields in some operating modes than other operating modes. For instance, a less immune subcircuit may be enabled during some type of operation but not during other types of operation. During the immunity tests in this project, the DNU staff has done their utmost to run all devices in worst case modes in terms of immunity, that is, with most functions operating at a time, or with the most essential performance in action.

Next step suggestion: To test medical equipment in additional modes of operation.

Proximity to the emitting source (the RFID antenna)

The exposed object will obviously become easier to disturb, the closer the object is to the source. This issue is covered as the most essential part of the current project.

Type of equipment

The largest risk of this project not having discovered the lowest immunity level of any device used at DNU is the fact that we have only tested 11 types of equipment. The tested devices are carefully chosen for their ability to represent the entire instrument park, and even though we know that any life-supporting equipment is tested to the immunity level of 10 V/m found also in the current project, devices in general are not tested with all sides facing the antenna, and some, non-life-supporting types of devices are only compliant to 3 V/m.

Next step suggestion: To test additional types of medical equipment.

Annex 4

Complete log of test object pass levels

Complete log of pass levels for each type of immunity tested equipment and each surface, recorded by DELTA and by Region Midtjylland during the immunity tests at DELTA Aarhus.

Device type	Infusionspumpe	Sprøjtepumpe	Pacemaker	Assist Pumpe	Overv.udstyr	Dialyseapp
Device manufacturer	B-Braun	Alaris	Medtronic	Arrow	Phillips	Gambro
Device model	8713050 Infusomat Space	TIVA	5388	Autocat 2	M8004A Intellivue MP 50	Prismaflex
Medusa App. Nr.	80734	107280	30529	103394	37121	103844
Formal compliance level	3 V/m	10 V/mm	10 V/m	3 V/m	10 V/mm (?)	3 V/m
Highest pass level [V/m]:						
Front	20	10	30	25	15	25
Back	20	30	30	25	15	25
Left side	20	15	30	25	15	17
Right side	30	20	30	30	25	25
Top	30	20	30	20	15	Not tested
Bottom	30	20	30	25	25	Not tested

Device type	Anæstesiapparat	Respiratorer	Kuvøse	Kuvøse	Respirator	Ekstern Def.
Device manufacturer	Dräger	Maquet	Dräger	Dräger	Dräger	Medtronic
Device model	Primus	Rotaflow	Caleo (O2)	Caleo (fugt+temp)	4 XL	Lifepak 20
Medusa App. Nr.	106382	37855	38608	38608	38985	80009
Formal compliance level	10 V/mm	10V/m (?)	10 V/m	10 V/m	10 V/mm (?)	
Highest pass level [V/m]:						
Front	25	25	30	30	25	30
Back	25	25	30	30	25	25
Left side	25	25	30	30	25	25
Right side	25	25	30	30	25	25
Top	Not tested	25	Not tested	Not tested	25	25
Bottom	Not tested	25	Not tested	Not tested	25	25

Document acceptance

Indkøb og Medicoteknik Jørgen Schmidt IT Konsulent Region Midtjylland, Århus Universitetshospital, Skejby	Date
Executive Sponsor Lars Ganzhorn Knudsen IT Projektchef Region Midtjylland, Projektafdelingen DNU	Date
Project Sponsor Dennis Pedersen Senior Architect Systematic	Date
Jakob Steensen Project Manager DELTA Test & Consultancy	25/5-2012 Date