

# Usability evaluations of COVID-19 rapid tests

With Prof. Dr. Christian Johner

## Transcript

00:00:05 Speaker 1

Medical Device Insights, a podcast by the Johner Institute for medical device manufacturers, authorities and notified bodies.

00:00:17 Speaker 2

Welcome to the next podcast.

00:00:21 Speaker 2

Usually, the podcast is mainly about

00:00:24 Speaker 2

Discuss disputes or conflicts that manufacturers have with the authorities, find solutions and clarify regulatory requirements.

00:00:35 Speaker 2

But sometimes there are disputes not between authorities or notified bodies and manufacturers, but for example between manufacturers and their customers, i.e. the operators, the hospitals.

00:00:48 Speaker 2

And there you often move in the area of trade disputes.

00:00:53 Speaker 2

Today I have someone here on the phone who has been dealing with such trade disputes for many, many years.

00:01:00 Speaker 2

Now Dr.

00:01:01 Speaker 2

Reith, who was head of development for 17 years and later managing director of a medium-sized medical device manufacturer.

00:01:09 Speaker 2

Mr. Reith, could you introduce yourself very briefly, please.

00:01:12 Speaker 3

I had been publicly appointed as an expert for X-ray diagnostic systems since 1987.

00:01:19 Speaker 3

and had carried out this expert activity until 2017, mainly on behalf of courts in commercial disputes between different parties.

00:01:33 Speaker 3

Often, however, they were also commissioned by private operators of X-ray systems or for insurance companies when it came to claims for compensation for damage that were to be compensated by the insurance.

00:01:47 Speaker 2

You have already given us the first examples just now on the subject of trade disputes.

00:01:53 Speaker 2

Could you give us any more?

00:01:54 Speaker 2

In other words, who argued with whom about what.

00:01:58 Speaker 3

In most cases, the operators of X-ray systems have come into dispute with their suppliers or with their service companies if:

00:02:11 Speaker 3

The systems have not worked as expected, if there were faults, or if the repairs were not carried out properly or as expected.

00:02:24 Speaker 3

This was the main group of disputes, but even people who were not involved in the original commercial transaction could get into disputes with the operators of these systems.

00:02:38 Speaker 3

If you have unexpectedly caused damage to the system during another job, this can be done by transport or by other work in the same room, which then caused damage to the X-ray system.

00:02:54 Speaker 3

In such cases, the liability insurance of the injuring party usually kicked in.

00:03:00 Speaker 3

The amount of damage was then disputed.

00:03:04 Speaker 2

You have just finished the

00:03:06 Speaker 2

had addressed the matter of liability insurance.

00:03:10 Speaker 2

What exactly happened here?

00:03:11 Speaker 2

What exactly happened there and what was the dispute?

00:03:15 Speaker 3

I can give you an example.

00:03:17 Speaker 3

A computer tomograph has been newly installed in a hospital.

00:03:23 Speaker 3

At the same time, however, a cooling system was installed in the ceiling and a pipe was leaking from this cooling system.

00:03:34 Speaker 3

As a result, several liters of coolant leaked and unfortunately ran into the ventilation slots of the computer tomograph.

00:03:42 Speaker 3

And then, of course, the dispute was, how great is the damage that has been caused to the computer tomograph as a result?

00:03:50 Speaker 3

Is it a total loss or can it be repaired somehow?

00:03:53 Speaker 3

And there it was definitely about amounts in dispute of a little over 1000000.

00:03:59 Speaker 2

This is a very high case, I guess, or are these typical sums that are at stake?

00:04:04 Speaker 3

No, these are exceptions, at least in the cases I have worked on.

00:04:09 Speaker 3

Most disputes are in the range of 50,000 to 100,000 or 200,000 euros.

00:04:16 Speaker 3

Of course, this also depends on the usual prices of the systems, and these are in these orders of magnitude for radiological technology.

00:04:26 Speaker 2

Now there are these quarrels.

00:04:27 Speaker 2

Of course, it would be best if you could avoid them from the outset.

00:04:31 Speaker 2

Is that even possible?

00:04:33 Speaker 3

I don't think that disputes can be avoided here, because they lie in the human inadequacy of both the person of the supplier and the operator.

00:04:46 Speaker 3

Mistakes can happen on both sides, which then ultimately lead to arguments.

00:04:52 Speaker 3

It is not really about avoiding the dispute, but about settling the dispute as quickly and cheaply as possible.

00:05:01 Speaker 2

Now you have already talked about the settlement.

00:05:04 Speaker 2

So, what options do you have at all if it comes to a dispute?

00:05:08 Speaker 2

And which of these options would you particularly recommend?

00:05:12 Speaker 3

If you have a tangible, serious dispute with another person or company, of a commercial nature, then in most cases there will be nothing left but

00:05:27 Speaker 3

going to court and filing a lawsuit is something you have to do in order not to let your claims become statute-barred.

00:05:36 Speaker 3

All these claims are lost depending on the type of demand.

00:05:40 Speaker 3

But that's not all, because the court proceedings drag on for a long, long time, over many years, which you probably don't expect from the outset.

00:05:51 Speaker 3

And that's why you have to see that these procedures are

00:05:56 Speaker 3

and this can only be done through an out-of-court settlement with the opposing party.

00:06:02 Speaker 3

And I advise you to take this step in any case, because fighting out the court cases to the bitter end is very lengthy and costly for both sides.

00:06:14 Speaker 2

This means that, on the one hand, you advise that you may already go to court in order to be able to comply with statutes of limitations, but on the other hand, you also have a parallel

00:06:25 Speaker 2

to reach an out-of-court settlement.

00:06:29 Speaker 2

How do you go about getting the two parties to the dispute to reach an out-of-court settlement?

00:06:37 Speaker 3

It makes a difference whether both parties are already willing to reach an out-of-court settlement.

00:06:44 Speaker 3

If this is the case, then a so-called mediation procedure can begin, where

00:06:51 Speaker 3

a mediator, in my case an expert mediator, guides the parties to come to an agreement.

00:06:59 Speaker 3

But it can also be that this effort to reach an agreement comes from a single party and then this party can instruct me to find an agreement with the other party in its interest and on its behalf.

00:07:16 Speaker 3

In any case, it has to start with

00:07:20 Speaker 3

That the technical points of contention are thoroughly discussed with each other, so that both parties to the dispute understand exactly who did what wrong or who is more right on which point.

00:07:34 Speaker 3

And in this way, a better starting point is created to come to a reasonable financial agreement.

00:07:44 Speaker 2

You are talking about a financial agreement right now.

00:07:47 Speaker 2

So is it always just a matter of who pays whom how much, so to speak, or can other parameters also be included in this equation?

00:07:55 Speaker 3

Of course, trade disputes are always about a certain amount of money that one party demands from

the other.

00:08:05 Speaker 3

So, the plaintiff demands something from the other party, which it must name in a sum of money.

00:08:12 Speaker 3

But such an agreement, which takes place out of court, is not only a

00:08:17 Speaker 3

To find the amount of money that is ultimately to be paid from one party to the other, but there are even more things that can be included in the agreement that cannot be expressed directly in money, such as the continuation of a business relationship, the purchase of a new system, the repurchase of an old plant

00:08:45 Speaker 3

Or the extension of warranty periods, all of this can be included in such an agreement and that is then of course advantageous for both parties.

00:08:58 Speaker 2

How long does such an agreement process take?

00:09:00 Speaker 2

How, for example, how often do they meet with you until you come to the conclusion that both sides accept it?

00:09:07 Speaker 3

The total time it takes to reach an agreement is much shorter.

00:09:14 Speaker 3

than the time it takes to get through a court case to the end.

00:09:19 Speaker 3

Court proceedings in these areas usually take five, six to ten years or more, whereas such an attempt at settlement out of court with a mediator or mediator can be completed in a few months.

00:09:37 Speaker 3

I would guess three, four months.

00:09:40 Speaker 3

If nothing is possible after this time, really none

00:09:44 Speaker 3

agreement, then you have to give up the matter.

00:09:47 Speaker 3

Then it just didn't work out.

00:09:49 Speaker 2

Now you have already talked about the duration.

00:09:52 Speaker 2

Another question that arises in this context: How much does something like this cost?

00:09:56 Speaker 2

So, how do you pay a mediator like you in such disputes?

00:10:01 Speaker 2

Is it possible per time you spend?

00:10:04 Speaker 2

Is it related to the amount in dispute?

00:10:07 Speaker 2

Is there any kind of profit-sharing?

00:10:10 Speaker 3

It is common for the intermediary or facilitator to charge for their time spent.

00:10:18 Speaker 3

Similar to what an expert for the preparation of expert reports does.

00:10:23 Speaker 3

So I charge an amount per hour, in the region of 100 euros.

00:10:28 Speaker 3

And this sentence is of the value of the dispute

00:10:33 Speaker 3

but it is customary to charge a so-called settlement fee in the event of an agreement, as lawyers have to do in their remuneration regulations.

00:10:47 Speaker 3

And this settlement fee depends on the amount in dispute, but by no means proportionally, but to a very small extent it increases with the amount in dispute.

00:10:58 Speaker 3

Logarithmic, for example.

00:11:00 Speaker 2

Now we have just discussed the conciliation fee

00:11:02 Speaker 2

How many times do you manage to get these two parties to come to an agreement?

00:11:09 Speaker 3

If the order for mediation is given at all, then the willingness is already there, at least on the part of one party.

00:11:18 Speaker 3

Then the probability is about 50%.

00:11:22 Speaker 3

When mediation is commissioned, i.e. when both parties

00:11:28 Speaker 3

seek an out-of-court settlement, then there is good will on the part of both parties.

00:11:34 Speaker 3

And then the probability of an actual agreement is much higher.

00:11:38 Speaker 3

I would estimate 80, 90 percent.

00:11:41 Speaker 2

Herr Dr.

00:11:41 Speaker 2

Reith, thank you very much for this interview.

00:11:44 Speaker 3

Thank you.

