ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			findings.) Diagnostic technologies may also have effects on relatives; not only genetic tests, but all diagnoses of hereditary disorders, also provide knowledge of relatives. Diagnostic information may also affect social relations (e.g. STD)"						
F0004	Autonomy	Does the implementation or use of the technology challenge patient autonomy?	Patients have in most cases a right to autonomy, i.e. right to be self-governing agents. This requires the right to decide about things of importance to oneself on one hand, but also relevant information and a capability to understand the information, consider it in relation to personal values and decide accordingly. Thus, technologies and health systems may interfere with patient's right to autonomy directly or indirectly by influencing the decisional capacity. For example, a technology that does not allow itself to be understandably explained to the patient (e.g. diagnostic procedures for dementia) is potentially problematic, as are treatments that require patients to behave in a certain way (e.g. to abstain from alcohol prior to investigations). The practical challenge with diagnostic tests is that in order to be fully autonomous, the patient should understand not just direct risks of testing, but also all alternatives following different test results.	3	2	Literature search. Expert opinion. Stakesholder hearing	Miller 2004		Yes
F0005	Autonomy	Is the technology used for patients/people that are especially vulnerable?	The right and justification to use the technology for persons who are vulnerable (critically ill or have otherwise reduced decision making capacity, like children, mentally retarded, patients that have due to their illness/state limited decision making capacity, pregnant women etc) has to be clarified. Who has the right to balance the benefit against possible harm in these situations? On what grounds can these decisions be made? Is the technology so valuable, as to justify its use on people who can not give informed consent to it?	3	3	Literature search. Expert opinion. Stakeholder hearing	Miller 2004		Yes
F0006	Autonomy	Can the technology entail special challenges/risk that the patient/person needs to be informed of?	Is the common professional practice of discussing the technology with patients enough, or is special care needed with this technology? Should the patient be explicitly informed, for example, that false positive results may lead unnecessary further investigations and treatments with serious harms? The technology to be used in life-threatening situations may have life-threatening side effects (e.g. invasive techniques). Technology used to get exact information may have unexpected severe side-effects (e.g. miscarriage due to amniocentesis).	3	3	Literature search. Expert opinion. Registers	Miller 2004	Safety	Yes
F0007	Autonomy	Does the implementation challenge or change	Technologies may change the relationship between physician and patient, challenge professional autonomy or otherwise interfere with professional ethics and values. The patient-physician relationship is	3	2	Expert opinion	Hofmann 2005b. Medical Professionalism	Organisational. Technology description	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		professional values, ethics or traditional roles?	traditionally based on mutual trust, confidentiality and professional autonomy so that individual treatment decisions can be made in the best interest of the patient. Technologies that interfere with core virtues and principles of medical and professional ethics challenge the professional integrity of the physicians or other health care professionals. Technologies that align with professional ethics are more likely to be implemented successfully. For example, people may require diagnostic tests for many reasons, even if the professionals think them unnecessary and potentially harmful.				Project 2002		
F0008	Human Dignity	Does the implementation or use of the technology affect human dignity?	"Especially technologies that are applied for persons with reduced autonomy may violate a person's dignity (children, mentally impaired, severely ill), i.e. challenge the idea that all human beings have intrinsic moral value, and should thus not be seen as means to others ends. Labelling people may also threaten their dignity; for example predictive tests may label healthy people as sick or otherwise less worthy; handicapped people may be labelled by prenatal diagnostics which imply that their handicap is an indication for abortion."	3	2	Literature search. Expert opinion. Stakeholder hearing	Kilner 2004		Yes
F0009	Human integrity	Does the implementation or use of the technology affect human integrity?	"Technology can challenge human integrity by preventing (or even tempting) people (patients or professionals) to live according their moral convictions, preferences or commitments. This is especially important for vulnerable patient groups. Integrity can also be seen as a coherent image or identity of oneself. Thus, for example, prenatal diagnostics might challenge the integrity of people who value new life as gift; cochlear implants are problematic for those, who do not see deafness as a disability. Institutions that discourage honesty or ethical conduct more generally are detrimental to integrity (for example, systems where lying about ones health state might lead to better treatment than being honest). "	3	2	Literature search. Expert opinion. Stakeholder hearing	Kilner 2004		Yes
F0010	Beneficence/nonmaleficence	What are the benefits and harms for patients, and what is the balance between the benefits and harms when implementing and when not implementing the technology? Who will balance the risks and benefits in practice and	The decision to implement new diagnostic technology requires careful decision on the balance between benefit and harm, cost-effectiveness, reallocation of resources etc. When this decision has been made on the system level, the decision on individual patient level rests on both the professional who offers the technology and the patient who autonomously accepts the use of technology in her/his situation. The individual decision has to be based on objective information on possible benefit and risks. Risks are only justified to the extent they are needed to create benefits. If not proven otherwise, the individual patient is generally to be seen	3	2	Literature search. Expert opinion. Stakeholder hearing	Autti-Rämö 2007	safety. Effectiveness	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		how?	as the best judge of risks and benefits for her/himself.						
F0011	Beneficence/nonmaleficence	Can the technology harm any other stakeholders? What are the potential benefits and harms for other stakeholders, what is the balance between them? Who will balance the risks and benefits in practice and how?	Some technologies have the potential to unfold unwanted or harmful effects not only on the patients that the technology is directly applied to but also indirectly on other stakeholders (relatives, other patients, organisations, commercial entities, society etc.) Benefits and harms to individuals must be balanced with benefits and harms that can befall society as a whole (social utility, maximizing public health). These harmful effects may manifest in the physical, social, financial or even other domains of life. For example results of genetic tests may negatively interfere with the family planning and social life of not only the individual being tested but also of his or her relatives. Changes in the availability of diagnostic tests may significantly alter the requirements placed on the health care system.Table 2 in the process description can be used to describe benefits and harms.	3	2	Literature search. Expert opinion. Stakeholder hearing	Autti-Rämö 2007 Beauchamp and Childress 2001	Organisational. Social	Yes
F0012	Justice and Equity	What are the consequences of implementing / not implementing the technology on justice in the health care system? Are principles of fairness, justness and solidarity respected?	A new intervention may require reallocation of human resources, funding and training. A large reallocation of resources may seriously jeopardize other patient groups (e.g. new diagnostic technology that uncovers a large pool of unmet needs for treatment). How this reallocation affects the existing health care system has to be studied for all stakeholders? Can the technology be applied in a way that there is equal access to those in equal need? How can this be guaranteed? Could potential discrimination or other inequalities (geographic, gender, ethnic, religious, employment, insurance) prevent access? Diagnostic technologies sometimes acquire significant symbolic value (e.g. fetal ultrasound, PSA) that may create demands for tests that are not justified on health grounds. Are specific safeguards needed? How will possible caregivers' burden and well-being be influenced? Potential inequalities and discrimination should be justified.	3	2	Literature search. Expert opinion. Stakeholder hearing	Sterba 2004 Daniels 2001	Cost-effectiveness. Organisational. Social	Yes
F0013	Justice and Equity	How are technologies presenting with relevantly similar (ethical) problems treated in health care system?	Clearly presenting how relevantly similar technologies are treated in a health care system may help to adopt coherent and just health policies, either by applying past precedents to current cases, or showing that past cases need reconsideration. Similarity is to be defined individually for each technology. The idea is to concentrate only on the similarities relevant for solving the ethical problems found important for the current HTA project. The similarity may be, for example, of medical, technological, economical, ethical, social, organisational or legal nature.	3	2	Littrature search. Expert opinion	Hofmann 2005b		Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
F0014	Rights	Does the implementation or use of the technology affect the realisation of basic human rights?	Human rights exist both in ethics and legislation, most notably in the United Nations declarations and related statements, like the European Council Biomedicine convention. Basic human rights are universal and consider the most important goods, protections and freedoms. Classes of rights are civil and political rights, social rights, minority and group rights and environmental rights. For HTA, perhaps the most relevant are the rights to equality, non-discrimination, safety, adequate standard of living and health care. For example: -Right to life, liberty and security of person. -Right to a standard of living adequate for the health and well-being of himself and of his family, including medical care and necessary social services, and the right to security in the event of sickness, disability or old age. -Right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. For diagnostic tests, issues of access to tests and treatments as well as labelling and potential discrimination of diagnosed persons may be relevant issues.	3	3	Literature search. Law, rules and regulations. Expert opinion. Stakeholder hearing	Marks 2004	Social. Legal	Yes
F0016	Legislation	Is legislation and regulation to use the technology fair and adequate?	Technology may lead to ethical problems that make current regulation inadequate. Diagnostic technologies are commonly differently regulated than treatments, especially medications. Ethical reflection is needed when considering what kind of regulation is needed. This consideration is done on the basis and in combination with the legal domain. Emphasis should be put on considering the ethically relevant aspects and consequences of current law, needs for legal regulation that have arisen from the ethical analysis, and a global assesment of the adequacy of the legislation based on all available information. For example, who has a right to get the results and for what purposes?	2	1	Law, rules and regulations. Stakeholder hearing. Expert opinion	Capron 2004	Legal	No
F0017	Questions about effectiveness and accuracy	What are the proper end-points for assessment and how should they be investigated?	"For diagnostic tests, clinical effectiveness should ideally be directly investigated, but this is not always fully possible so other endpoints may have to be used. In addition, diagnostic tests may have several aims (e.g. those related to knowledge without expected health effects). The acceptable and feasible endpoints (possibly several) for assessing diagnostic technologies must be carefully consireded early in the analysis. The context-specificity of diagnostic technologies must be especially considered; for example, results of diagnostic technologies are rarely in practice interpreted without knowing the clinical and organisational situation of the patient, some technologies require extensive interpretative	3	2	Other domains of analysis: accuracy, safety, effectiveness. Expert opinion			Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			skills, and the practical consequences of diagnostic tests will depend on the population tested. The importanve of context relates to what kinds of studies are deemed acceptable. "						
F0018	Questions about effectiveness and accuracy	Are the accuracy measures decided and balanced on a transparent and acceptable way?	Are the accuracy measures chosen so that they accord with the purpose of the HTA? How and by whom are cut-off values decided? How and by whom has balancing sensitivity and specificity been done? This should be done considering the moral value of different results – for example, high specificity is required if false positives have serious consequences.	3	3	Other domains of analysis: accuracy, safety, effectiveness. Expert opinion			Yes

7 Organisational aspects

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
G0001	Process	What kind of work flow and patient flow processes are needed?	A new technology could change current work tasks and processes (including also quality control). Work and patient processes should be described, and it should be explained what kind of activities a new technology might replace or reduce in the target organisation. Patient flow and changes required in patient path should be taken to account when implementing new technology. It is essential to know the change the use of the new technology generates to the performance of care.	3	2	Systematic reviews (and other studies), annual reports and statistics of the hospital, other qualitative research methods	Kristensen 2001, Kristensen 2007	(Current use)	Yes
G0002	Process	What kind of patient and relative involvement in treatment or care has to be mobilized?	A new technology may require changes in the distribution of tasks among the people involved in the treatment and care. Patients and their important others may be more actively involved in own care and treatment – or tasks they used to carry out may be taken over by health professionals.	2	1		Kristensen 2007		No
G0003	Process	What kind of staff, training and other human resources is required?	It has to be clarified what kind of staff is needed, and whether the existing staff can be trained or extra staff must be brought in. A new technology can bring along the need for extra staff when extending the ongoing activities in the organisation or when there is a demand for special expert knowledge. It must be considered if there will be a need to increase or decrease the amount of the staff. The implementation of a new innovation can mean change in job satisfaction. It could make some tasks monotonous or bring along new boring job descriptions. It is crucial that there is not just one person familiar with the new technology. If just one person has been trained for a new technology, there is a risk of loosing know-how when he/she leaves the organisation (or moves to other tasks).	3	2	Systematic reviews (and other studies), reports of the hospital or hospital districts and other qualitative research methods	Busse 2002, Kristensen 2001, Kristensen 2007	Description	Yes
G0004	Process	What kind of co-operation and communication of activities have to be mobilised?	The use of technology can presume new co-operation and communication with other parts of the structure (e.g. other units) or outside the structure (e.g. other hospitals, pharmacies). The type of technology 'determines' the frequency of need for information exchange between different actors. Also interaction and communication with patients and their important others will change.	2	2	Systematic reviews (and other studies), reports of the hospital or hospital districts and other qualitative research methods	Kristensen 2001, Kristensen 2007, Senter för Medisinsk metodevurdering (SMM) 2003		Yes
G0005	Structure	What consequences the implementation of the new technology will have in respect of decentralisation or centralisation?	The location of use of the technology (primary - secondary - tertiary care) could vary between different countries depending on the system of organisational systems. (De)centralisation could have some economical and qualitative benefits. Centralisation could make a new technology more difficult to access. For example some expensive technologies are centralized to tertiary care units.	3	2	Systematic reviews (and other studies), reports of the hospital or hospital districts and other qualitative research methods	Busse 2002, Kristensen 2001, Kristensen 2007, Senter för Medisinsk metodevurdering (SMM) 2003	Current use, Description	Yes
G0006	Structure	What kinds of investments are needed (material or premises)?	The new technology could require many changes in the organisation e.g. premises must be according to the directions of the manufacturer. This could be very costly for the organisation. High costs of the new technology	3	2	Systematic reviews (and other studies), reports of the hospital or hospital	Kristensen 2007	Description	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			can influence the decision of purchasing the new technology. It is important to know which organisation(s) participate in the investments of a new technology and to what extent the other organisations take part in the running costs.			districts and other qualitative research methods. Information from manufacturers			
G0007	Structure	What is the likely budget impact of the implementation of the technology for the payers (e.g. government)?	When a new technology is introduced, the question about reimbursement quickly arises. Whenever a technology is reimbursed, there will be an impact on the health care budget. Budget impact analysis examines the likely impact of the reimbursement of a new technology on financial outlays from the perspective of the payers (e.g. government).	3	1	Systematic reviews (and other studies), reports of the hospital or hospital districts and other qualitative research methods			Yes
G0008	Management	What management problems and opportunities are attached to the new technology?	The issue concerns the administrative / managerial questions of the new technology: management of resources (e.g. investments), co-ordination (in relation to different levels), establishment of objectives, monitoring and control, evaluation and sanctioning.	2	2		Kristensen 2007		Yes
G0009	Management	Who decides which patients are to undergo a treatment and on what basis?	Procedurals about decisions about the patients who receive care could vary.	3	2	Systematic reviews (and other studies), reports of the hospital or hospital districts and other qualitative research methods	Kristensen 2007		Yes
G0010	Culture	How is the new technology accepted?	Acceptance should bee looked at by different perspectives: by organisation, by personnel and by patients. A new technology could consist of elements which don't suit the image of the organisation. Also, the alternative ways to introduce a new technology into the organisation could influence problems e.g. resistance among staff and dysfunction of processes. Patients are usually very technologically-oriented. However, patients can resist a new technology itself or its implementation. Objective and understandable information on a new technology is important.	2	2	Systematic reviews (and other studies), qualitative research methods	Finohta's EUnetHTA workshop 2006, Kristensen 2007	Ethical, Social	Yes
G0011	Culture	How will the other interest groups of the new technology be taken into account in the planning / implementation of the new technology?	It may be useful to know who are the possible stakeholders of the particular technology, as well as what kind of co-operation there has been and what kind of interaction is needed. The stakeholders could be e.g. the pharmaceutical industry and companies offering new technologies, authorities (national / regional), administrative parties, municipalities, policy makers / decision makers, staff groups and patient organisation. One can also ask: Has the patient organisation taken part into the process? Has it been involved from the beginning (in the planning) or in the later stages for example as commentator? Furthermore, it is interesting to figure out what kind of co-operation exists between hospitals and companies offering new technologies and what kind of co-operation is needed.	3	1	Systematic reviews (and other studies), qualitative research methods	Kristensen 2001, Kristensen 2007, Senter för Medisinsk metodevurdering (SMM) 2003	Ethical	Yes

8 Social aspects

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
H0001	Major life areas	Which social areas does the use of the technology influence?	Map the major life areas of the patient and the important others (family life, day care, school, work, leisure time, lifestyle, or other daily activities), where the technology is going to be used or where its use may have a direct or indirect influence.	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.	-1		Yes
H0002	Major life areas	Who are the important others that the use of the technology may affect in addition to the patient?	Describe who are the important other people that are involved in the use of technology in addition to the patients (parents, children, friends, people at work place etc)	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.			Yes
H0003	Major life areas	What kind of support and resources are needed or might be released as the technology is put to use?	This issue is about any kind of support and resources (practical, physical, emotional, personal social, nurturing, financial etc.) that need to be mobilized, and organized - or might be released - in order for the patient to use the technology with satisfactory results. It covers all arrangements or adjustments that may be needed in the major life areas (e.g. alteration of special tasks, working time, adjustments in the physical environment, emotional support).	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.	"ICF(32) environmental factors: support and relationships (chapter 3: e310-399); " activities and participation, chapter 6: d698, structural arrangements of patient's environment (10, 12, 13)	Organisational	Yes
H0004	Major life areas	What kinds of changes does the use of the technology generate in the patient's role in the major life areas?	This issue is about the patient's social roles and ability to manage and maintain relations with other people in a socially appropriate manner in major life areas.	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.	ICF(32) activities and participation, interpersonal interactions and relationships (chapter 7, d710-779), community, social and civic life (chapter 9:d910-d999), (5, 7, 33, 34)	Ethical. Effectiveness, safety	Yes
H0005	Major life areas	What kind of changes does the implementation and use of the technology mean for the patients physical and	This issue is about the physical and psychological consequences the use of the technology may generate in the patient's main life areas e.g. on person's body functions and structures, activities on daily living, or	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no	ICF(32),(15)	Effectiveness. Safety	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		psychological functioning in his or her major life areas?	performance at work, school, home or leisure time. This issue covers whether, from a patient perspective, the technology leads to improvements or harms (a cross reference to effectiveness, safety domain issues), or generates any other unexpected effects on functioning.			time for primary study, the opinion of health care professionals and content experts can be consulted.			
H0006	Individual	How do patients and important others react and act upon the technology?	This issue is about the patients and her important others' attitudes, perceptions, preferences, satisfaction and relations to the technology. This covers whether, from a patient perspective, any positive or negative issues arise as a consequence of using the technology e.g. feelings of unity or empowerment and existential experiences (e.g. insecurity, worries, hope, anxiety, stigmatisation, person's value as a human being or social status, courage to face life, satisfaction, changes in self-conception).	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.	ICF(32) body functions: mental functions (chapter 1:b110-b199) environmental factors: attitudes (chapter 4:, e410-499) , (3)	Effectiveness	Yes
H0007	Communication	What is patients' and important others' knowledge and understanding of the technology?	This issue explores the patient's and important others' understanding of the technology in order to describe and decide what guidance and help (e.g. patient information leaflets, counselling processes, need of follow up consultation or help from other professionals) they need before, during and after the use of the technology.	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.		Current use. Safety	Yes
H0008	Communication	How is the information regarding the use of the technology processed and exchanged?	This issue is about the exchange of information from a patient's perspective. What are patients' and significant others' questions? How do they receive answers? How is information provided and received?	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.		Organisational	Yes
H0009	Communication	What are the consequences in decision making?	This issue clarifies the possible implications from the patient's perspective to decision making e.g. limitations (dependent, passive user) and possibilities (empowered, active user) as a consequence of using the technology.	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.		Organisational. Ethical	Yes

9 Legal aspects

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
I0002	Autonomy of the patient	Can patients understand the implications of using/not using the technology?	It is important to provide information on the (evermore complex) technologies in such a manner that the patient can truly understand it.	3	2	Explanatory report to Biomedicine convention	Biomedicince Convention Art 5		Yes
I0003	Autonomy of the patient	Are there relevant optional technologies that future patients should be allowed to consider?	The concept of informed consent includes also the possibility to consider other therapeutic options, if these are available.	3	2	Explanatory report to Biomedicine convention	Biomed conv Art 5		Yes
I0004	Autonomy of the patient	Is it possible to give future patients enough time to consider their decisions?	It is usually advised that the patient is given some time to think over the treatment decision, especially if the decision involves assimilating complex technical information or a tough weighing of risks and benefits of the procedure. It should be assessed beforehand if a given technology allows such time for consideration.	2	2				Yes
I0005	Autonomy of the patient	Is it possible to obtain an advance directive on the use of the technology?	If it is expected that the technology may be used in an emergency situation in the future it is advised that the patient is consulted beforehand and her opinion is recorded to the medical file as an advance directive on the use of a given technology.	2	1				No
I0009	Privacy of the patient	Can the access to the patient data secured properly?	At the era of computer-based patient records it is crucial that the health care unit has taken appropriate measures to secure the patient databases. Negligence may lead to liability.	2	1		Directive 95/46/EC	Organisational aspects	No
I0010	Privacy of the patient	What levels of access to which kind of patient information exist in the chain of care?	During the therapeutic process many people may either need to get access or semi-accidentally get access to the personal medical data of patients. The delicacy of the information depends on the technology in question. Health care unit must be organised so that it minimises the number of people having access to patient data. Also other measures to minimise the risk of information leakage from health care unit must be taken.	1	1			Organisational aspects	No
I0011	Equality in health care	Is the technology equally accessible to all needing members in a given society?	This topic operates both at national and international level. In general, equality in health care is spoken out in the EU Charter of Fundamental Rights and it is also one of the central principles of the Biomedicine Convention. In many Constitutions equality of citizens covers also access to health care.	3	2		EU FR Charter Art 35, Biomedicine Convention Article 3, CM RecommendationR (2006) 18	Social domain	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
I0012	Equality in health care	Is the technology subsidized by the society?	Governmental interventions or the lack of them may affect to the expected number of patients.	2	1			Social, organisational, economical aspects	No
I0013	Equality in health care	Is there a wide variation in the acceptability of the technology across Europe?	Varying legal regimes may lead to health-care tourism across the borders, especially if the technology in question is controversial.	3	3	Europe-wide legal comparison		Social domain	Yes
I0014	Equality in health care	Is health-care tourism expected from/to other European countries?	Varying legal regimes may lead to health-care tourism across the borders.	2	3	C-158/96 (ECJ), C-372/04 (ECJ), Europe-wide legal comparison		Social domain	Yes
I0015	Authorisation & safety	Has the technology national/EU level authorisation?	Patient safety as expressed in product safety is one domain of health care technology assessment which clearly falls under the mandate of the European Union	3	3			Safety aspects	Yes
I0016	Authorisation & safety	Does the technology need to be listed in a national/EU register?	A European database of medical devices (EUDAMED) is under construction.	2	2			Safety aspects	Yes
I0017	Authorisation & safety	Does the technology fulfil product safety requirements?	The implication of findings in the safety domain should be discussed against the relevant European or national legal frameworks to ensure patient safety from using the technology:	3	3		Directive 93/42/EEC, Directive 95/2001/EC	Safety aspects	Yes
I0018	Authorisation & safety	Does the technology fulfil tissue safety requirements?	Many novel health technologies may utilise human cells or tissue (so called advanced therapy medicinal products). These products must fulfil the safety requirements issued by EC Directive 2004/23/EC.	3	3	COM 567 (2005) final	Directive 2004/23/EC	Safety aspects	Yes
I0019	Ownership & liability	Does the technology infringe some intellectual property right?	Issues in this topic are to be considered by the health care unit when considering the acquisition of a new technology. The wording of acquisition contract may affect liability sharing between the manufacturer and health care unit.	2	3	Manufacturer, patent data bases, EPO Web site	European patent convention (EPC), Directive 98/44/EC, national legislation		Yes
I0020	Ownership & liability	Does the introduction of the technology presume some additional licensing fees to be paid?	As novel technologies build up on existing knowledge, the use of the technology may involve the payment of some additional fees to additional patent holders etc. In principle, the manufacturer should be able to clarify this to the health care unit/health care system in question.	2	2	Manufacturer, patent data bases			Yes
I0021	Ownership & liability	What are the width, depth and length of the manufacturers guarantee?	The terms of the manufacturers guarantee are of importance to the health care unit as well as to the society's health care sector when considering whether it is economically and/or liabilitywise advantageous to	3	3	Manufacturer			Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			introduce the technology or not.						
I0022	Ownership & liability	Is the user guide of the technology comprehensive enough?	The wording and clarity of the user guide of the technology can have legal effects on the liability issues in case the technology is not working as expected.	3	3	Manufacturer			Yes
I0023	Regulation of the market	Is the technology subject to price control?	As health care technology is essential to everyone at some point in their lives, its pricing may be regulated.	3	2	C-317/05 (ECJ), C-283/03 (ECJ)	Directive 1989/105/EEC		Yes
I0024	Regulation of the market	Is the technology subject to acquisition regulation?	Expensive technology is subject to acquisition regulation.	3	2		Directive 2004/18/EC		Yes
I0025	Regulation of the market	Is the marketing of the technology to the patients restricted?	As health care technology is essential to everyone at some point in their lives, the way by which it can be marketed to consumers may be regulated.	3	2	T-179/00 (ECJ)	Directive 1989/105/EEC, directive 1992/27/EEC		Yes
I0026	Legal regulation of novel/experimental techniques	Is the technology so novel existing legislation was not designed to cover its regulation?	Modern biomedical sciences produce novel technologies which may not always be unambiguously covered by existing provisions.	3	1				Yes
I0027	Legal regulation of novel/experimental techniques	How the liability issues are solved according to existing legislation?	If the current law does not provide a straightforward answer to the liability issues it may be advisible to consult a legal expert on the interpretation of the existing provisions with regard to the technology in question. This way the health care unit can prepare itself for the possible future legal proceedings.	3	1				Yes
I0028	Legal regulation of novel/experimental techniques	Are new legislative measures needed?	If the existing legislation is not satisfactory the introduction of a novel technology may require new legislative measures. At the level of a health care unit this may slow down the introduction, whereas at the level of the society it implies a need to use resources for preparing new laws.	2	1				No
I0029	Legal regulation of novel/experimental techniques	Is the voluntary participation of patients guaranteed properly?	Use of experimental technologies may not compromise patient safety. Patients must not be pressured into such treatments.	3	1		Biomedicine Convention Article 16		Yes
I0007	Privacy of the patient	Does the use of the technology produce some additional (i.e. diagnostically or therapeutically irrelevant) information on the patient?	The protection of sensitive personal data is secured at the EU level. Privacy protection is a modern expression of the ancient ethical principle of confidentiality in doctor-patient relationship. The use of computerised patient record databases and modern genetic diagnostics means further challenges to this principle.	3	3	Z vs. Finland (ECHR February 25, 1997); M.S. vs. Sweden (ECHR August 28, 1997); national legislation; legal literature	Directive 95/46/EC, EU FR Charter Art 8, Biomedicine Convention Art 10, CM Recommendation R (97) 5	Ethical aspects	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
I0008	Privacy of the patient	Does the use of the technology produce information that would be relevant for the relatives of the patient?	The results of a given diagnostic technology may indicate that the relatives of a patient may have a medical condition that would need to be addressed.The issue is on what conditions (if any) can the privacy of the original patient be broken in order to inform the relatives of their situation.	2	2				Yes
I0033	Privacy of the patient	Does the use of the technology produce such information on the patient that is not directly relevant to the current disease/condition?	Modern biomedicine may produce (genetic) information from the relatives of the patient as well as on patient herself. If this can be foreseen, appropriate procedures, according with the existing legislation, must be thought through beforehand: is the information to be revealed to or withheld from the relatives in question.	3	1				Yes
I0030	End-user	Who is the intended end-user of the technology?	Different requirements may apply depending on the answer. E.g. consumer Information, CE-marks, easiness of use, exactness of the results etc. are to be evaluated differently if the technology is intended to laymen's use.	3	3	"In vitro diag. directive 98/79/EC; " Council of Europe Gen testing protocol 2008	"Directive 98/79/EC; " Council of Europe Gen testing protocol 2008		Yes
I0031	End-user	Is the use of the technology limited in legislation?	Some countries may have restricted the use of some diagnostic technologies.	3	1			Ethical aspects	Yes
I0032	End-user	Is the health care personnel using the technology according the professional standards?	Health care personnel are obliged to follow professional standards and apply methods that are generally approved. When considering their professional liability towards patients it is very important that they know the limits and possibilities of diagnostical methods.	3	2			Ethical aspects	Yes