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Datasheet for the decision
of 22 January 2013

Case Number: T 0609/09 - 3.5.05

Application Number: 00943124.8

Publication Number: 1200924

IPC: G06F 19/00

Language of the proceedings: EN

Title of invention:
Telemedical expert service provision for intensive care units

Applicant:
Visicu, Inc.

Headword:
Telemedical expert service provision/VISICU

Relevant legal provisions:
EPC Art. 52(1), 56, 84, 123(2)

Keyword:
"Clarity - (yes, after amendment)"
"Extension of subject-matter - (no, after amendment)"
"Inventive step - (yes, after amendment)"

Decisions cited:
–

Catchword:
–

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C8594.D

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Case Number: T 0609/09 - 3.5.05

D E C I S I O N
of the Technical Board of Appeal 3.5.05
of 22 January 2013

Appellant:	Visicu, Inc.
(Applicant)	2400 Boston Street
	Suite 302
	Baltimore, MD 21224 (US)

Representative:	van Iersel, Hannie
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Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted 10 November 2008 refusing European patent application No. 00943124.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair:	A. Ritzka
Members:	P. Corcoran
	F. Blumer

C8594.D

Summary of Facts and Submissions

I.   The present appeal is against the decision of the
        examining division to refuse the European patent
        application no. 00 943 124.8, published as
        international application no. WO 00/79466 A2.
        The decision was announced during oral proceedings on
        29 October 2008 and the written reasons were dispatched
        on 10 November 2008.

II.   The decision under appeal was based on a main request
        and five auxiliary requests filed with the letter of
        29 September 2008. In the decision it was found that
        the independent claims of the main request did not
        involve an inventive step in the light of the following
        document:

        D1: H. Lee et al.: "Remote Patient Monitoring Service
             Through World-Wide Web", ANNUAL INTERNATIONAL
             CONFERENCE OF THE IEEE ENGINEERING IN MEDICINE AND
             BIOLOGY SOCIETY, IEEE, 30 October 1997, pp.928-
             931, ISBN: 0-7803-4263-1.

III.   Notice of appeal was received at the EPO on 19 December
        2008 with the appropriate fee being paid on the same
        date. A statement setting out the grounds of appeal was
        received at the EPO on 9 March 2009. With the statement
        setting out the grounds of appeal the appellant filed a
        new main request comprising claims 1 to 18 and an
        auxiliary request.

IV.   In a communication accompanying a summons to oral
        proceedings to be held on 22 January 2013, the board
        gave its preliminary opinion that the appellant's
        requests were not allowable.

        In particular, the board expressed reservations as to
        whether the independent claims of the main request
        complied with the requirements of Articles 84 and 123(2)
        EPC. The board further noted that it had not been
        convinced by the appellant's submissions that the
        subject-matter of said independent claims involved an
        inventive step over D1.

        In its discussion of D1, the board also referred, *inter
        alia*, to the following document which is an article co-
        authored by Brian Rosenfeld and Michael Breslow, the
        inventors designated with respect to the present
        application:

D7:   B. Rosenfeld et al., "Remote Management Improves
        ICU Outcomes", CRITICAL CARE MEDICINE, Vol. 27,
        No. 1, (Suppl.), January 1999, p.153a, Society of
        Critical Care Medicine, 28th Educational and
        Scientific Symposium, California, US, January 23-
        27 1999, Poster Presentations, ISSN: 0090-3493.

V.   The board's communication additionally made reference
        to the prior art pertaining to patient monitoring
        systems acknowledged in the first paragraph of the
        introductory section of D1. The following document,
        inter alia, was cited by the board of its own motion as
        an example of a patient monitoring system for an
        intensive care unit:

D12: V. Moret-Bonillo et al., "Integration of data,
      information and knowledge in intelligent patient
      monitoring", Expert Systems with Applications,
      Vol. 15 No. 2, August 1998, pp.155-163, Elsevier,
       ISSN 0957-4174.

The board noted that the disclosure of D12 appeared to
be prejudicial to the novelty or at least the inventive
step of the independent claims of the main request.

In its discussion of D12, the board referred, *inter
alia*, to the following document:

D10: A. Berson, "Client/Server Architecture", Chapter 6
      "Local Area Networking", pp.157-180, 2nd Edition,
      1996, McGraw-Hill, ISBN: 0-07-005664-1.

D10 is a textbook extract cited as evidence of the
common general knowledge of the skilled person in
relation to local and wide area networks.

VI.   The board's communication also expressed the
       preliminary opinion that the independent claims of the
       auxiliary request were not allowable for reasons
       substantially similar to those set forth in relation to
       the main request.

VII.   With a letter of reply dated 20 December 2012, the
       appellant filed a new main request and four auxiliary
       requests.

VIII. Oral proceedings were held as scheduled on 22 January
       2013. During the oral proceedings the appellant
       submitted an amended main request.

IX.   The appellant requested that the decision under appeal
       be set aside and that a patent be granted on the basis
       of the main request (claims 1 to 13) filed during oral
       proceedings before the board or, subsidiarily, on the
       basis of any of the four auxiliary requests filed with
       the letter of 20 December 2012.

X.   Claim 1 of the main request reads as follows:

       "A system for providing continuous, expert network
       health care services to a plurality of patients in a
       plurality of intensive care units from a remote
       location, the system comprising:

       a wide area network;

       a plurality of intensive care units comprising patient
       monitoring equipment for collecting physiological
       variable data of the patients at predetermined time
       intervals and means for transmitting the collected
       physiological variable data to a remote command center
       by the wide area network;

       wherein the remote command center is connected to the
       wide area network and comprises:

           a database for storing patient data of the
           plurality of patients, the patient data including
           the collected physiological variable data; and

           a computerized patient care management system
           arranged for:

receiving and storing in the database the collected physiological variable data of the patients, transmitted from the plurality of intensive care units;

constantly monitoring the database for each individual patient and applying rules to the physiological variable data of each patient to automate detection of problems before a condition reaches a crisis state, wherein by means of the rules changes in the physiological variable data over time are detected using thresholds applied to the physiological variable data, the detected changes being indicative of preconfigured alarming conditions,

> wherein the rules comprise at least one rule providing a threshold adapted to the respective patient and/or at least one rule which is responsive to simultaneous changes of at least two physiological variables of a patient indicative of an alarming condition; and

providing an alarm to an intensivist at the remote command center, if a change of the physiological variable data indicative of a preconfigured alarming condition is detected based on the rules; and

wherein the remote command center provides continuous intensivist monitoring of the plurality of intensive care units."

Claim 8 seeks protection for a method corresponding to the system of claim 1.

Claim 13 seeks protection for a remote command center corresponding to the remote command center of the system of claim 1.

XI.   Insofar as they are relevant to the present decision, the written and oral submissions made with respect to the main request by the appellant during the present appeal proceedings, may be summarised as follows:

(i)   The invention as defined in claim 1 of the main request relates to a system comprising a command center, which is connected to multiple intensive care units at various locations remote from the command center. The connection between the command center/remote location and the ICUs is via a wide-area network as disclosed on p.8 l.1-8 of the published application. The remote command center includes a patient care management system which provides automated monitoring of the plurality of ICUs such that a single intensivist can manage the care of a large number of patients.

(ii) The patient care management system of the remote command center of claim 1 comprises a centralised alarm generating function which is defined by the following feature group:
"constantly monitoring the database for each individual patient and applying rules to the physiological variable data of each patient to automate detection of problems before a

condition reaches a crisis state, wherein by
means of the rules changes in the physiological
variable data over time are detected using
thresholds applied to the physiological variable
data, the detected changes being indicative of
preconfigured alarming conditions,

wherein the rules comprise at least one rule
providing a threshold adapted to the
respective patient and/or at least one rule
which is responsive to simultaneous changes
of at least two physiological variables of a
patient indicative of an alarming condition;
and

providing an alarm to an intensivist at the
remote command center, if a change of the
physiological variable data indicative of a
preconfigured alarming condition is detected
based on the rules."

(iii) The alarm generating function is responsible for
automatically generating alarms on the basis of a
continuous evaluation of patient-specific
physiological variable data collected using
patient monitoring equipment. Claim 1 specifies
that the patient care management system is
arranged for "constantly monitoring the database
for each individual patient and applying rules to
the physiological variable data of each patient"
which means that each time a new physiological
variable value is stored in the database, the
rules are applied to the data including the new
value in order to determine whether an alarming
condition is fulfilled.

(iv)   The rules use thresholds to determine changes in
       the physiological variable data which are
       indicative of alarming conditions. The claim
       refers to two specific families of rules.
       One family uses thresholds which are adapted to
       the respective patient whose physiological
       variable data is being evaluated using the rules.
       A further family of rules looks for simultaneous
       changes in multiple physiological variables. Such
       rules are based on associations between
       simultaneous changes in multiple physiological
       variables and adverse clinical events. The rules
       are implemented such that alarms are generated
       before a condition reaches a crisis state.

 (v)   The claim features defining the alarm generating
       function find support in the passages of the
       description relating to the vital signs monitoring
       system and smart alarms system as disclosed
       respectively on p.26 l.14 - p.27 l.3 and p.30 l.28
       - p.31 l.29 of the published application. On this
       basis, the amendments to claim 1 of the main
       request are compliant with the requirements of
       Articles 84 EPC 1973 and 123(2) EPC.

(vi)   Dl discloses a system in which remote monitoring
       clients, i.e. PCs with conventional web browser
       software, can access the local network of an
       intensive care unit through the Internet as
       depicted in Fig. 1 of Dl. Dl thus discloses a
       system allowing a remote site to connect to a
       monitoring server of a single ICU rather than a
       command center connected to a plurality of ICUs as
       specified in claim 1 of the main request. The

remote site of D1 does not have a database for persistently storing patient data nor does it include a system for analysing physiological variable data acquired from the patients and generating alarms based on such an analysis.

(vii) D7 refers to the provision of ICU care by remote intensivists using "telemedical methodologies" to provide patient monitoring. However, it does not provide any specific technical teaching in this regard and it neither discloses nor suggests a system having a central alarming function within the meaning of claim 1.

(viii) D12 discloses a system in which ICU stations comprising bedside monitors equipped with a front-end computer are connected to a central control station via a local area network in the form of an Ethernet network (D12: p.157, left-hand col., last line - right-hand col., third line). D12 does not disclose that patient monitoring equipment is connected to a central station/command center via a wide-area network.

(ix) The system of D12 allows for "the formulation of diagnoses and therapeutic suggestions" which is done by the central station using the information received from the local stations (cf. D12: 4.3 Heuristic handling, p.158-159). However, the task of formulation of diagnosis and therapeutic suggestions is a significantly different task than the generation of alarms based on changes in physiological variable data.

(x)   In the system of D12, the task of alarm generation
      is allocated to the local stations, i.e. the
      bedside monitor and the front-end computer
      connected to it, (cf. D12: p.161, left-hand col.,
      in particular item 5):

      "PATRICIA 's Deterministic Module is located in
      the local station (Fig. 8). Its main element is
      a control procedure that guides the execution of
      the following tasks:

      ...

      5. Warning the server module about possible
      non-inferential alarm or pre-alarm situations
      (i.e. those numerical values that are beyond or
      near the thresholds established)."

      The alarm messages coming from a local station are
      transmitted to the central server and displayed
      together with "inferential alarms" generated in
      the central server (cf. D12: p.161, right-hand
      column, last sentence).

(xi) D12 does not provide a further explanation of the
      term "inferential alarms" and, in particular does
      not disclose that such alarms are generated by
      continuously monitoring physiological data of a
      patient as recited in claim 1 of the main request.
      Rather, these alarms appear to be closely related
      to the diagnosis and therapeutic suggestions
      generated in the central station. Typically, such
      diagnosis is done once on the basis of a
      collection of information and this seems to apply
      to the inferential alarms. Otherwise, there would
      be no difference between the inferential alarms
      generated in the central station and the non-
      inferential alarms generated in the local station.

(xii)   Thus, D12 does not disclose a central alarm
        generating function corresponding to that of
        claim 1. Rather, it teaches the skilled person to
        implement the alarming functions in the local
        stations at each intensive care unit and to
        forward the locally generated alarms to the
        central station.

(xiii) The effect achieved by the central alarm
        generating function of claim 1 of the main request
        is an improved standardisation of ICU patient care
        (cf. published application p.7 l.15-19). From a
        technical point of view, the provision of a
        central alarm generating function means that the
        data processing associated with alarm generation
        is carried out in a standardised and consistent
        manner for all patients.

(xiv)   The skilled person attempting to achieve an
        improved standardisation of ICU patient care in
        the system of D12 would try to ensure that the
        local stations were standardised but he would have
        no discernible motivation to migrate the alarm
        generating functionality of the local stations to
        the central station. Thus starting from D12, the
        subject-matter of claim 1 can only be arrived at
        using hindsight.

XII.   At the end of the oral proceedings the chair announced
       the board's decision.

Reasons for the Decision

1.   The appeal is admissible. The board also finds that the
        appeal is allowable for the reasons which follow.

Main request

2.   *Claim 1*

2.1   Claim 1 of the main request is directed towards a
        system for providing continuous, expert network health
        care services to a plurality of patients in a plurality
        of intensive care units from a remote location. The
        claimed system comprises a wide area network, a
        plurality of intensive care units (ICUs) comprising
        patient monitoring equipment and a remote command
        center connected to the wide area network.

2.2   The claim defines an arrangement according to which the
        physiological variable data of the patients are
        collected at predetermined time intervals by the
        patient monitoring equipment at the ICUs and are
        transmitted to the remote command center via the wide
        area network.

2.3   The remote command center comprises a database and a
        computerized patient care management system which
        automates the detection of problems relating to a
        patient's clinical condition and it includes an alarm
        generating function (cf. Facts and Submissions, item
        XI(ii)-(iv) above) for generating an alarm which is
        provided to an intensivist at the remote command center.

3.   *Articles 84 and 123(2) EPC*

3.1   Having regard to the appellant's submissions concerning
        support for the amendments to claim 1 of the main
        request (cf. Facts and Submissions, item XI (i) and (v)
        above), the board is satisfied that the aforementioned
        amendments, in particular those relating to the alarm
        generating function, are supported by the description
        and provide a definition of the matter for which
        protection is sought which complies with the
        requirements of Article 84 EPC.

3.2   As the passages of the description providing support
        for the aforementioned amendments, form part of the
        originally filed application documents, the board is
        also satisfied that the requirements of Article 123(2)
        EPC are complied with.

4.   *Determination of closest prior art*

4.1   D1, which was cited as the closest prior art in the
        decision under appeal, discloses a remote patient
        monitoring service via the World Wide Web (WWW)
        according to which a bedside monitoring server collects
        patient-specific physiological variable data and
        transmits this data through the Internet to a
        monitoring client at a remote site in real-time (D1:
        p.929, first paragraph).

4.2   The monitoring client at the remote site of D1 is a
        computer provided with an Internet connection which is
        used to receive and present a data stream provided by
        an ICU system. In this way, a physician at a remote
        site may observe a stream of vital sign data generated

by an ICU monitoring system using conventional Web
browser software (cf. D1: Abstract; p.928, right-hand
col., first paragraph).

4.3   The board judges that it is implicit in the disclosure
        of D1 that the data stream provided to the remote site
        is only stored in a transient form, i.e. only for as
        long as it is required for display purposes.

4.4   D1 is thus essentially concerned with displaying a
        transient stream of ICU data to a physician at a remote
        location whereas the present application is concerned
        with providing a physician at a remote location with
        computerised patient care management facilities
        including the persistent storage of patient-specific
        physiological variable data in a database and the
        automated rule-based analysis of this data to detect
        situations in which an alarm is to be generated and
        provided to a physician at the remote site.

4.5   There is no disclosure or suggestion in D1 to the
        effect that the remote site is provided with database
        facilities to support the persistent storage of the ICU
        data or that it is to be provided with a computerised
        patient care management system to perform automated
        analysis of this data. For this reason, the board
        judges that D1 is too remote from the subject-matter of
        the present application to provide a realistic starting
        point for an inventive step objection.

4.6   D12, which the board introduced into the proceedings
        pursuant to Article 114(1) EPC, discloses a patient
        monitoring system having a hardware infrastructure
        which includes a plurality of ICUs comprising patient

monitoring equipment ("local bedside monitoring equipment") and a remote command center ("central control station") connected to the local ICUs by way of a network (cf. D12: Abstract; 4. Methods and materials, in particular first paragraph thereof).

4.7   In view of the foregoing, the board concludes that the system of D12, both in terms of its hardware infrastructure and its intended function, is substantially closer to the subject-matter of claim 1 than the system of D1. Consequently, D12 is judged to represent the closest available prior art to the invention according to said claim 1.

5.   *Differences over D12*

5.1   The board concurs with the appellant's submissions to the effect that claim 1 of the main request is distinguished from the disclosure of D12 in the following respects:

        (i)   Claim 1 specifies that a wide area network (WAN) is used to connect the remote command center to the patient monitoring equipment in the ICUs whereas in D12 a local area network (LAN) in the form of an Ethernet network is used to connect the ICU stations and the central monitoring station (cf. Facts and Submissions, item XI(viii) above).

        (ii)   The remote command center of claim 1 is provided with a computerised patient care management system which includes an alarm generation function whereby a rule-based analysis of the

patient-specific physiological variable data
provided by the ICU monitoring equipment is
performed centrally at the remote command center.
D12 discloses that such alarms are generated
locally at an ICU station from where they are
forwarded to the central station (cf. Facts and
Submissions, item XI(xii) above).

5.2   With respect to the difference identified under 5.1(i)
above, the board judges that although the system of D12
relies on a local area network (LAN) in the form of an
Ethernet network to connect the ICU stations and the
central monitoring station, the replacement of the LAN
by a WAN as specified in claim 1 merely results in an
extension of the geographical area covered by the
system and would not require the exercise of inventive
skill.

In this regard it is noted that, D12 makes an explicit
reference to "telemedicine" which, in the board's
judgement, is a direct hint to extend the geographical
area covered by the system (cf. D12: 6. Discussion,
p.162, left-hand col., item 3.). At the claimed
priority date, it was generally known in the context of
supporting interconnection over larger geographical
areas to use WANs to overcome the traditional distance
limitations of LANs (cf. D10: section 6.1.1).

6.   *Inventive step*

6.1   With respect to the difference identified under 5.1(ii)
above, the board judges that the feature group of claim
1 defining the central alarm generation function (cf.
Facts and Submissions, item XI(ii) above) provides an

inventive contribution to the claimed subject-matter
for the reasons which follow.

6.2   Although D12 discloses the persistent storage of
        patient-specific physiological data at the central
        station in the form of a "historic repository" (cf. D12:
        paragraph bridging pp. 157 and 158), it does not
        contain any hint or suggestion to the effect that this
        repository should be used to provide a central alarm
        generating function as specified in claim 1.

6.3   According to D12, the bedside monitoring equipment
        receives data relating to the physiological variables
        of the patient in the form of signals and incorporates
        alarm facilities triggered when specified thresholds on
        the signals have been crossed (cf. D12: p.157, right-
        hand col., l.4-19). Extra facilities such as dynamic
        modification of the alarm thresholds and analysis of
        trends are provided by a front-end computer connected
        to the physiological monitor at the local station.

6.4   D12 further states that one of the tasks of the
        software executing on the local station, i.e. the so-
        called "Deterministic Module", is to forward locally
        generated alarms indicative of numerical values that
        are beyond or near the established thresholds to the
        server at the central station (cf. 5. Application of
        client-server architecture to the clinical problem, in
        particular p.161, left-hand col., item 5). The software
        executing on the central station, i.e. the so-called
        "Server Module", is arranged to display alarm messages
        coming from local stations (cf. D12: p.161, last
        paragraph).

6.5   D12 mentions that the Server Module includes an expert
        system having an inference engine, i.e. the so-called
        "Heuristic Module", which may generate information
        including "inferential alarms" (cf. D12: 4.3 Heuristic
        handling, p.158; p.161, last paragraph). However, D12
        provides no further information about this type of
        alarm. In the given context, the board judges that the
        term "inferential alarms" must be interpreted as
        denoting some kind of additional information generated
        by the inference engine in response to requests from
        local stations (cf. D12: p.161, left-hand col., item 7).
        Based on this interpretation, the board concurs with
        the appellant's submissions to the effect that the
        aforementioned "inferential alarms" cannot be
        considered as alarms of the type specified in claim 1
        (cf. Facts and Submissions, item XI(xi) above).

6.6   Insofar as D12 discloses alarms of the type specified
        in claim 1, it teaches that such alarms are generated
        locally at ICU stations and then forwarded to the
        central station which is arranged to display the
        corresponding alarm messages. It provides no hint or
        suggestion to the effect that these alarms can or
        should be generated centrally by monitoring a central
        database of physiological variable data and by applying
        rules to said data as specified in claim 1.

6.7   Inasmuch as claim 1 requires the physiological variable
        data monitoring and associated alarm generation to be
        performed in one central location within the system and
        thus in substantially the same manner for all patients,
        the board accepts the appellant's submissions to the
        effect that generating alarms in a centralised manner
        according to claim 1 of the main request achieves the

effect of standardising the data processing relating to
ICU patient care (cf. Facts and Submissions, item
XI(xiii) above).

6.8   The board further concurs with the appellant's
        submissions to the effect that, starting from D12, the
        skilled person attempting to achieve a standardisation
        of the data processing would try to ensure that the
        local stations were standardised and he would have no
        discernible motivation to migrate the alarm generating
        functionality of the local stations to the central
        station (cf. Facts and Submissions, item XI(xiv) above).

6.9   For the sake of completeness, the document D7 to which
        the board referred in its communication, is briefly
        considered. Although D7 refers in general terms to the
        provision of ICU care by remote intensivists using
        "telemedical methodologies", said document contains no
        specific details as to how the technical infrastructure
        to provide remote ICU management should be configured.
        In the board's judgement, D7 neither teaches nor
        suggests providing a centralised alarm generating
        function as specified in claim 1 of the main request.

6.10   Although, from a technical point of view, the
        modifications to the disclosure of D12 required to
        arrive at the subject-matter of claim 1 of the main
        request could arguably have been carried out by the
        skilled person without undue difficulty, the question
        of obviousness has to be decided, not by considering
        what the skilled person could hypothetically have done
        but rather what he would have done.

6.11   In the absence of any clearly identifiable motivation
        to migrate the alarm generating function of the local
        stations of D12 to the central station, the board
        judges that the skilled person starting from D12 would
        not have arrived at the claimed invention without the
        use of hindsight.

Conclusions

7.   In view of the foregoing, the board concludes that the
        subject-matter of claim 1 of the main request involves
        an inventive step over D12. A similar finding applies
        to the further independent claims of the request.

8.   Having regard to its findings concerning the main
        request, it is not necessary for the board to consider
        the appellant's auxiliary requests.

Order

For these reasons it is decided that:

1.   The decision under appeal is set aside.

2.   The case is remitted to the department of first instance
       with the order to grant a patent on the basis of the
       main request (claims 1 to 13) as filed during the oral
       proceedings before the board and a description yet to be
       adapted.

The Registrar: The Chair:

K. Götz   A. Ritzka