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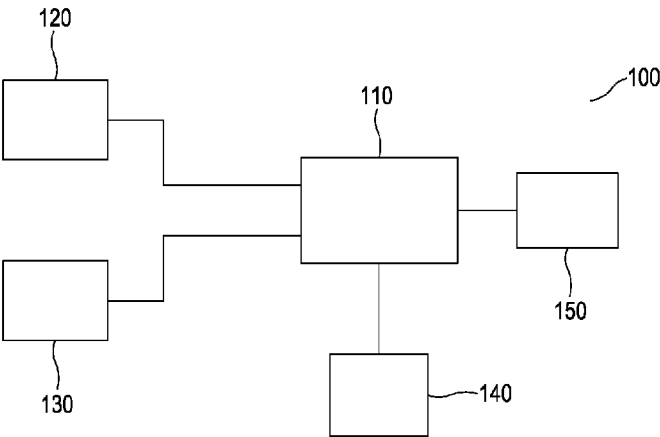


Fig. 1

(57) Abstract: Figure 1 shows generally at (100) an apparatus for analysing ultrasound images of a patient. The apparatus comprises a processor (110) having a first input (120). The first input (120) is arranged to receive ultrasound image data from an ultrasound scan of a patient's abdomen. A second input (130) is arranged to receive one or more items of metadata relating to the patient (not shown). The processor (110) uses a trained, machine learning model (140) to predict the probability that the ultrasound images depict one or more conditions present in the liver of the patient, and the calculated probabilities are output at (150).

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RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ,
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5 Apparatus for Analysing Medical Images

The present invention relates to apparatus for analysing medical images, and is concerned particularly, though not exclusively, with an apparatus for identifying a probability
10 of the existence of a medical condition from an analysis of ultrasound images of a patient's abdomen.

Metabolic Associated Fatty Liver Disease (MAFLD) is a very common disease in which fat accumulates in the liver in
15 people who do not have an excessive intake of alcohol. Around 30% of the population worldwide are thought to have MAFLD. Most have simple fatty infiltration (steatosis). Non-alcoholic steatohepatitis, or metabolic-associated steatohepatitis (known as MASH) is a less common (2.5% of
20 population) but aggressive form of MALFD in which the liver cells become inflamed and damaged. It may eventually lead to scarring (fibrosis/cirrhosis) or liver cancer.

Currently, the most reliable way of distinguishing MASH from
25 MAFLD is to perform a liver biopsy on the patient. However, this can be painful and can have significant side effects, including a risk of mortality of around 0.2%. While non-invasive techniques for measuring some components of MASH have been developed, such as Magnetic Resonance Imaging
30 Proton Density Fat Fraction (MRI-PDFF) for steatosis, and transient elastography [Fibroscan] or shear wave propagation for fibrosis, these imaging modalities are slow, expensive and cannot currently distinguish MASH from MAFLD.

35 There is currently no inexpensive, fast, and reliable method to screen a large proportion of the population to determine

5 who is likely to have MASH. One potential imaging medium
that could be deployed at scale is ultrasound. Unfortunately,
ultrasound is not commonly used in diagnosis or monitoring
fatty liver conditions at present as it is challenging to
accurately assess fatty infiltration, inflammation (MASH)
10 and scarring by human interpretation of ultrasound images.

Embodiments of the present invention aim to provide a system
to distinguish MASH from MAFLD using ultrasound and deep
learning.

15

The present invention is defined in the attached independent
claims, to which reference should now be made. Further,
preferred features may be found in the sub-claims appended
thereto.

20

According to a first aspect of the present invention there
is provided apparatus for analysing ultrasound images of a
patient's abdomen, the apparatus comprising:

25 a first input arranged to receive at least one
ultrasound image of the abdomen of a patient; and

a processor arranged to process the data from the
first input using a trained machine learning model;

wherein the processor is arranged to determine a
30 probability that the, or each, ultrasound image of the
patient exhibits one or more medical conditions.

In a preferred arrangement, the apparatus comprises
a second input arranged to receive at least one item of
35 metadata related to the patient. The apparatus may be
arranged to process the data from the second input.

- 5 The first input may be arranged to receive data of a plurality of ultrasound images of the patient's abdomen. Preferably, the second input is arranged to receive a plurality of items of metadata related to the patient.
- 10 In a preferred arrangement, the trained model comprises a machine learning model trained using both supervised and unsupervised machine learning techniques, respectively in an unsupervised phase and a supervised phase.
- 15 By a supervised learning phase, we mean the process of training a machine learning by supplying to it a quantity of example inputs along with their classifications (often referred to as "ground-truths") and then using optimisation methods to encourage the model to emit predictions that
- 20 correspond as closely as possible to those classifications.

By an unsupervised learning phase, we mean a process of training a machine learning model in which no ground-truth data is present in the training data, and instead the

25 optimisation task is crafted in such a way that the resulting model has some desired properties. Methods for doing this include contrastive learning, de-noising autoencoders and self-distillation, for example.

- 30 While the descriptions above were framed in terms of a classification task, the skilled practitioner will recognise that they any be easily adapted to equivalently describe other prediction types, including, for example, regression tasks.

5 Unsupervised techniques may be used to generate generic features of ultrasound images from ultrasound data, more preferably from unannotated ultrasound data, and still more preferably from a large amount of such data. The supervised learning phase may take features found during the
10 unsupervised phase and may use them together with the metadata and appropriate ground-truth to produce models that predict various clinical indications. This two-phase process allows an effective model to be developed from the very limited quantity of labelled data that is available.

15

Preferably, the unsupervised techniques are used to generate features of a large quantity of unannotated ultrasound data.

In a preferred arrangement the supervised learning
20 techniques are arranged to take features found during the unsupervised phase and use them, optionally together with patient metadata, to make a model that predicts a clinical indication.

25 The apparatus is preferably arranged to produce a probability density function for one or more of the following:

- the degree of steatosis,
- the probability that the non-alcoholic fatty liver activity score [NAS] is greater than or equal to 4
30 [whether the patient has MASH or not],
- the degree of liver fibrosis, as a probability distribution over the following bands:
 - o F0/F1: No fibrosis or Zone 3 mild/moderate
35 perisinusoidal or portal fibrosis,

- 5 o F2: Zone 3 and portal/periportal fibrosis,
 o F3: Bridging fibrosis,
 o F4: Cirrhosis.

10 According to another aspect of the present invention, there is provided a method of analysing ultrasound images of a patient, the method comprising:

 receiving at least one ultrasound image of the
15 abdomen of a patient;
 processing the data using a trained machine learning model; and
 determining a probability that the, or each,
ultrasound image of the patient's abdomen exhibits one or
20 more medical conditions.

 In a preferred arrangement, the method includes receiving at least one item of metadata related to the patient. The method may include processing the meta data.

25

 The method may comprise training the machine learning model using both supervised and unsupervised learning techniques. The unsupervised techniques may be used to generate generic features of ultrasound images from ultrasound data, more
30 preferably from unannotated data, still more preferably from a large amount of such data. The supervised learning phase may take features found during the unsupervised phase and may use them together with the metadata and appropriate ground-truth to produce models that predict the various
35 clinical indications listed above. This two-phase process

5 allows an effective model to developed from the very limited quantity of labelled data that is available.

The method may include incorporating proxy ground-truth data from several associated indicators. These may include MRI-
10 PDFF results which may be used to measure the degree of steatosis; shear wave or other elastography results which may be used to measure the degree of fibrosis; or blood test results for biomarkers specific to fibrosis, steatosis and/or MASH.

15

In a further aspect, the invention provides a computer programme product on a computer readable medium, comprising instructions that, when executed by a computer, cause the computer to perform a method of analysing ultrasound images
20 of a patient, the method comprising:

receiving at least one ultrasound image of the abdomen of a patient; and

processing the data from the first input using a
25 trained machine learning model;

determine a probability that the, or each, ultrasound image of the patient exhibits one or more medical conditions.

30 The method may include receiving at least one item of metadata related to the patient. The method may include processing the metadata from the second input.

5 The invention also comprises a program for causing a device to perform a method of analysing ultrasound images of a patient, the method comprising:

receiving at least one ultrasound image of the
10 abdomen of a patient; and
processing the data from the first input using a trained machine learning model;
determine a probability that the, or each,
ultrasound image of the patient exhibits one or more medical
15 conditions.

The method may include receiving at least one item of metadata related to the patient. The method may include processing the metadata from the second input.

20

The invention may include any combination of the features or limitations referred to herein, except such a combination of features as are mutually exclusive, or mutually inconsistent.

25

A preferred embodiment of the present invention will now be described, by way of example only, with reference to the accompanying diagrammatic drawings, in which:

30 Figure 1 shows schematically an apparatus for analysing ultrasound images of a patient, according to an embodiment of the present invention; and

Figure 2 shows schematically a method for analysing
35 ultrasound images of a patient according to an embodiment of the present invention.

5 Some recent studies have suggested that machine learning techniques applied to ultrasound images of the liver can reliably predict the degree of steatosis and fibrosis. If ultrasound could also be used to distinguish MASH from MALFD, this could enable large-scale screening of the population
10 for MASH.

In some implementations, embodiments of the present invention include a system to distinguish MASH from MAFLD using ultrasound and deep learning. The inputs to the system
15 are ultrasound images of the abdomen and easily obtained metadata about the patient (for example, but not limited to: BMI, age, liver function test results, alcohol intake etc.).

The system uses machine learning to analyse the images and
20 metadata to produce the following outputs:

- The degree of steatosis (the percentage of fat in the liver)
- 25 • The probability that the non-alcoholic fatty liver activity score (NAS) is greater than or equal to 4 (does the patient have MASH or not)
- The degree of liver fibrosis, as a probability
30 distribution over the following bands:
 - o F0/F1: no fibrosis or Zone 3 mild/moderate perisinusoidal or portal fibrosis
 - 35 o F2: Zone 3 and portal/perportal fibrosis

5

- o F3: Bridging fibrosis
- o F4: Cirrhosis

10 These outputs cover the key clinical markers that describe the health of the liver.

Supervised model training requires suitable ground-truth corresponding to the desired clinical indications. The
15 "gold-standard" for measuring steatosis, fibrosis and the presence of MASH is liver biopsy, so the ideal ground truth data would consist of abdominal ultrasound images with contemporaneous liver biopsy results. However, because liver biopsies carry a degree of risk, obtaining large numbers of
20 biopsy results for model training may be difficult.

To obtain adequate model performance, it is preferable to incorporate proxy ground-truth data from several associated indicators. These may include MRI-PDFF results which may be
25 used to measure the degree of steatosis; shear wave results which may be used to measure the degree of fibrosis; or blood test results for biomarkers specific to fibrosis, steatosis and/or MASH. Data for these is more readily available. While this may only act as a weak signal of the outcome of interest
30 (MASH), it is nevertheless helpful in boosting the effectiveness of the model for a given quantity of labelled data for that outcome.

Additionally, the system is trained using both supervised
35 and unsupervised learning techniques. The unsupervised

5 techniques are used to generate generic features of
ultrasound images from a large amount of unannotated
ultrasound data. In a typical example (but not exclusively),
the quantity of available unannotated data will exceed that
of annotated data by at least an order of magnitude, and
10 sometimes by several orders of magnitude. The supervised
learning phase takes features found during the unsupervised
phase and uses them together with the metadata and
appropriate ground-truth to produce models that predict the
various clinical indications listed above. This two-phase
15 process allows an effective model to be developed from the
very limited quantity of labelled data that is available.

Turning to Figure 1, this shows generally at 100 an apparatus
for analysing ultrasound images of a patient. The apparatus
20 comprises a processor 110 having a first input 120. The first
input 120 is arranged to receive ultrasound image data from
an ultrasound scan of a patient's abdomen. A second input
130 is arranged to receive one or more items of metadata
relating to the patient (not shown). The processor 110 uses
25 a trained, machine learning model 140 to predict the
probability that the ultrasound images depict one or more
conditions present in the liver of the patient, and the
calculated probabilities are output at 150.

30 Figure 2 shows schematically a method of analysing the image
data of a patient. At step S1 the ultrasound image data of
the patient's abdomen is acquired. At step S2 one or more
items of metadata relating to the patient are acquired. At
Step S3 a processor uses a trained machine learning model to
35 predict the probability that the image(s) acquired at step

- 5 S1 depicts one or more medical conditions, and at step S4
the or each probability is output.

Whilst endeavouring in the foregoing specification to draw
attention to those features of the invention believed to be
10 of particular importance, it should be understood that the
applicant claims protection in respect of any patentable
feature or combination of features referred to herein, and/or
shown in the drawings, whether or not particular emphasis
has been placed thereon.

15

5 CLAIMS

1. Apparatus for analysing ultrasound images of a patient,
the apparatus comprising:
- 10 a first input arranged to receive data of at least one
ultrasound image of a patient; and
a processor arranged to process the data from the first input
using a trained machine learning model;
- wherein the processor is arranged to determine a
15 probability that the or each ultrasound image of the
patient exhibits one or more medical conditions, wherein
the apparatus includes a second input arranged to receive
at least one item of metadata related to the patient, and
the apparatus is arranged to process data from the second
20 input and wherein the apparatus is arranged to produce a
probability density function for one or more of the
following:
- the degree of steatosis,
 - 25 • the probability that the non-alcoholic fatty liver
activity score [NAS] is greater than or equal to 4
[whether the patient has MASH or not],
 - the degree of liver fibrosis, as a probability
distribution over the following bands:
 - 30 o F0/F1: No fibrosis or Zone 3 mild/ moderate
perisinusoidal or portal fibrosis,
 - o F2: Zone 3 and portal/periportal fibrosis,
 - o F3: Bridging fibrosis,
 - o F4: Cirrhosis.

35

- 5 2. Apparatus according to Claim 1, wherein the machine learning model is trained using both supervised and unsupervised machine learning techniques, respectively in an unsupervised phase and a supervised phase.
- 10 3. Apparatus according to Claim 2, wherein the unsupervised techniques are used to generate features of a large quantity of unannotated ultrasound data.
- 15 4. Apparatus according to Claim 2 or 3, wherein the apparatus is arranged to incorporate proxy ground-truth data from a number of associated indicators into the training of the model.
- 20 5. Apparatus according to Claim 2, wherein the supervised learning techniques are arranged to take features found during the unsupervised phase and use them, together with the or each item of patient metadata, to make a model that predicts a clinical indication.
- 25 6. A method of analysing ultrasound images of a patient, the method comprising:
- receiving data of at least one ultrasound image of a patient;
- 30 processing the data using a trained machine learning model; and
- determining a probability that the or each ultrasound image of the patient exhibits one or more medical conditions, wherein the method includes receiving at least
- 35 one item of metadata related to the patient and processing the metadata, and wherein the method comprises producing

5 a probability density function for one or more of the following:

- the degree of steatosis,
- the probability that the non-alcoholic fatty liver activity score [NAS] is greater than or equal to 4
10 [whether the patient has MASH or not],
- the degree of liver fibrosis, as a probability distribution over the following bands:
 - o F0/F1: No fibrosis or Zone 3 mild/ moderate
15 perisinusoidal or portal fibrosis,
 - o F2: Zone 3 and portal/periportal fibrosis,
 - o F3: Bridging fibrosis,
 - o F4: Cirrhosis.

20 7. A method according to Claim 6, comprising training the machine learning model using both supervised and unsupervised learning techniques.

25 8. A method according to Claim 7 wherein the unsupervised techniques are used to generate generic features of ultrasound images from unannotated ultrasound data.

30 9. A method according to Claim 7 or 8, wherein the supervised learning phase comprises taking features found during the unsupervised phase and using them together with the metadata and appropriate ground-truth to produce models that predict the various clinical indications listed above.

35 10. A method according to any of Claims 7 - 9, wherein the method includes incorporating proxy ground-truth data

5 from a number of associated indicators into the training
of the model.

11. A method according to Claim 10, wherein the proxy
ground-truth data include MRI-PDFF results which may be
10 used to measure the degree of steatosis.

12. A method according to Claim 10 or 11, wherein the proxy
ground-truth data includes shear wave or other
15 elastography results to measure the degree of fibrosis.

13. A method according to any of Claims 10-12, wherein the
proxy ground-truth data includes one or more of: MRI-
PDFF results which may be used to measure the degree of
20 steatosis; shear wave results which may be used to
measure the degree of fibrosis; or blood test results
for biomarkers specific to fibrosis, steatosis and/or
MASH.

25 14. A computer programme product on a computer readable
medium, comprising instructions that, when executed by
a computer, cause the computer to perform a method of
analysing ultrasound images of a patient's liver, the
method being in accordance with any of Claims 6-13.

30 15. A program for causing a device to perform a method of
analysing ultrasound images of a patient, the method
being in accordance with any of Claims 6-13.

35

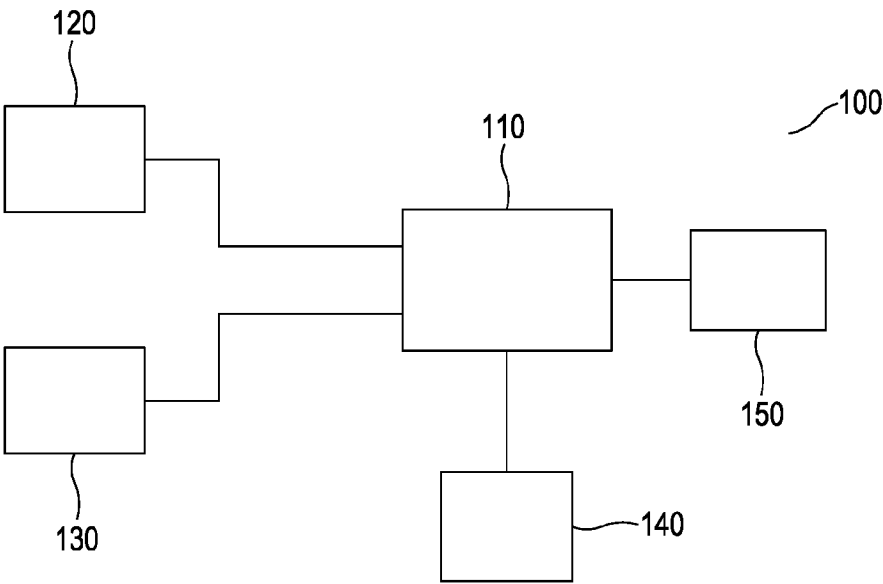


Fig. 1

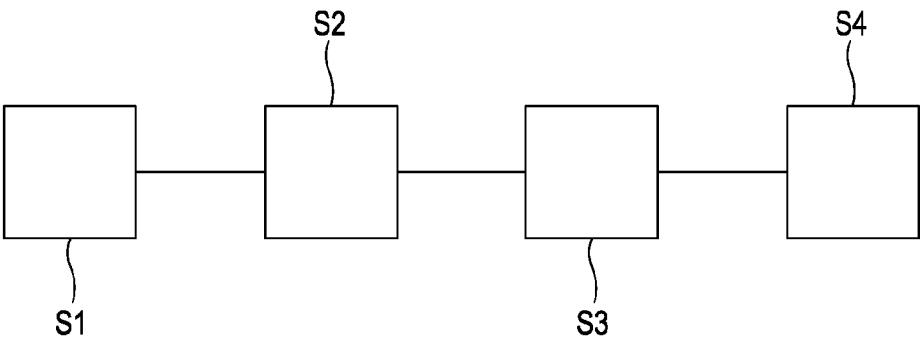


Fig. 2

INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER				
INV.	G16H50/20 A61B5/00 G06N20/00	A61B8/08 G16H10/60	G06N3/088 G16H30/40	G06N3/09 G16H50/70
ADD.				
According to International Patent Classification (IPC) or to both national classification and IPC				
B. FIELDS SEARCHED				
Minimum documentation searched (classification system followed by classification symbols) G16H A61B G06N G06T				
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the relevant passages			Relevant to claim No.
Y	XUE LI-YUN ET AL: "Transfer learning radiomics based on multimodal ultrasound imaging for staging liver fibrosis", EUROPEAN RADIOLOGY, SPRINGER BERLIN HEIDELBERG, BERLIN/HEIDELBERG, vol. 30, no. 5, 21 January 2020 (2020-01-21), pages 2973-2983, XP037092530, ISSN: 0938-7994, DOI: 10.1007/S00330-019-06595-W [retrieved on 2020-01-21] The whole document, in particular: "Abstract" on Page 2973, "Transfer learning" and "Pathological examination" on Page 2975, "Patient characteristics" on Page 2977; Figures 1, 2; Table 1. ----- -/-			1 - 15
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.				
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family				
Date of the actual completion of the international search 12 September 2024		Date of mailing of the international search report 24/09/2024		
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Ruschke, Stefan		

INTERNATIONAL SEARCH REPORT

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	LEE JEONG HYUN ET AL: "Deep learning with ultrasonography: automated classification of liver fibrosis using a deep convolutional neural network", EUROPEAN RADIOLOGY, SPRINGER BERLIN HEIDELBERG, BERLIN/HEIDELBERG, vol. 30, no. 2, 2 September 2019 (2019-09-02), pages 1264-1273, XP036986870, ISSN: 0938-7994, DOI: 10.1007/s00330-019-06407-1 [retrieved on 2019-09-02] The whole document, in particular: Pages 1264 - 1271; Figures 2 - 4. -----	1-15
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Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members

International application No

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