I Dispositivi Impiantabili Attivi RM Conditional nella pratica Clinica.

Neurochirurgia

U.O. Neurochirurgia Modena

Neurochirurgia

- Clips vascolari
- Viti
- Cage
- Valvole ventricolo perotineali
- Deep brain stimulation
- Protesi craniche
- Neurostimolatori

YASARGIL Aneurysm Clip System

Clips for microsurgical treatment of cerebral aneurysms

Description

Then decades of intensive cooperation with leading neurosurgeons all over the world from the foundation for Aesculap´s technical and scientific experience.
YASARGIL Aneurysm Clips are the world's leading clips for the treatment of cerebral aneurysms. Since their introduction, over2 million clips have been implantedin more than 80 countries. A milestone in the history of neurosurgery.
The surgical treatment of cerebral aneurysms will continue to represent an important and indispensable therapy option into the future.
The product range of Aesculap is the widest one, including more than 320 different clip designs and55 appliers (Phynox, titanium, mini, standard, permanent, temporary and fenestrated).

Advantages

▪Atraumatic blade profile
▪Atraumatic surface
▪Sterile packaging
▪Patented guidance mechanism
▪Individual serial number

Indication

▪Surgical treatment of cerebral aneurysms

Properties

▪MRI examinations using magnetic fields of 1.5 and 3.0 Tesla do not present an additional risk to implant wearers

Note

The clip production has approximately 30 production steps and 70% ofthose aredone by hand. The below movie offers an impressive glance behind the scenes of aneurysm clipproduction ofAesculap which is located at the Aesculap headquarters in Tuttlingen, Germany.

CranioFix®2

The generation of titanium clamps for quicker application

Description

Since its market introduction in 1997, the titanium clamp system CranioFix® by Aesculap has been an outstanding success. CranioFix® revolutionized bone flap fixation in neurosurgery. The numbers speak for themselves: Over 3.5 million successfully implanted clamps helped patients in over 60 countries. Today, CranioFix®2, the second generation is established worldwide. With even improved speed, ease of use, reliability and efficiency, CranioFix®2 exceeded the success of CranioFix®.

Advantages

▪Fast and easy application
▪Excellent reliability
▪Brilliant stability
▪Extraordinary smooth and safe operation

Indication

▪Fixation of craniotomized cranial bone flaps
▪Fixation of fractures at the brain skull

Properties

▪Well-known implant-material (Titanium alloy)
▪High bio-compatibility
▪MRI examinations using magnetic fields of 1.5 and 3.0 Tesla do not present an additional risk to implant wearers

Brochure CranioFix® 2 Cranial fixation system

Codman **Hakim** programmable valve (CHPV, Codman & Shurtleff Inc., USA)

Strata valve (Medtronic Neurosurgery, Goelta, CA, USA)

GAV (Aesculap-Miesthke, Tuttlingen/Postdam, Germany)

programmable valve (ProGAV) with a gravitational unit (Aesculap-Miesthke, Tuttlingen/Postdam, Germany)

ProGAV without a gravitational unit (Aesculap-Miesthke, Tuttlingen/Postdam, Germany)

Pudenz (Heyer-Schulte® Pudenz Flushing valves, Integra™)

Novus valves (Novus™ valve system, Integra™)

Le fonti normative:
La direttiva europea sui Dispositivi Medici Impiantabili Attivi
La normativa italiana sull'uso dei sistemi a Risonanza Magnetica
Le linee guida internazionali:
American College of Radiology
European Society of Cardiology
Il consensus document ISS-AIAC-SIRM-FIC-AIFM-AIIC

AHA Scientific Statement: Safety of Magnetic Resonance Imaging in Patients with Cardiovascular Device (2007)

The presence of a pacemaker or ICD should still be considered a strong relative contraindication to routine MR examination, which is therefore discouraged. MR imaging should only be considered in cases in which the potential benefit to the patient clearly outweighs the risks to the patient.

Risks to the patient are likely increased in centers without highly experienced personnel in both function and programming of the device and operations/pulse sequences of the MR scanner.

Thus, scanning should only be performed at extremely experienced centers with expertise in MR imaging and electrophysiology.

The patient's heart rhythm and vital signs should be monitored throughout the MR examination.

A physician with pacemaker/ICD expertise should be in attendance during scanning, and a "crash cart," including a defibrillator, must be available throughout the procedure to address any adverse events.

A person with expertise in MR physics and safety should be involved with the scan to optimally plan the scan to minimize risk. The pacemaker/ICD should be interrogated before and after the procedure.

ACR: Guidance Document for Safe MR Practices: 2013

Amongst the patients with MR unsafe CIEDs, many have conditions that would ordinarily be assessed with MRI. While many can have their medical conditions managed without MRI, in some instances, specific clinical circumstances may present compelling reasons for undergoing an MR examination.

Should MRI be considered, it should be evaluated on a case-by-case and site-bysite basis and only if the site is manned with individuals with the appropriate radiology and cardiology knowledge and expertise on hand.

Consent: The patient with a pacemaker or ICD that is not labeled as MR Conditional should be apprised of the risks associated with MRI and should provide informed consent.

Si distingue tra device MR conditional e device convenzionali

- Si riconosce a possibilità di eseguire esami su pazienti con PM/ICD convenzionali, se sussistono importanti indicazioni cliniche (“compelling reasons)
- Si sottolinea l’importanza di un consenso informato specifico

Addendum, Strata®-type Valves, 3.0 Tesla

Tilføjelse, Strata-type ventiler 3,0 Tesla
Addendum, kleppen van het Strata-type, 3,0 Tesla
Addenda, valves du type Strata, 3,0 Tesla
Ergänzung, Ventile vom Typ Strata, 3,0 Tesla
Παραρτημα, βαλβιδες τυπου Strata, 3,0 Tesla
Kiegészítés, Strata típusú szelepek, 3,0 Tesla
Appendice, valvole di tipo Strata, 3,0 Tesla
Tillegg, Strata-type ventiler, 3,0 Tesla
Dodatek, zastawki Strata, 3,0 Tesla
Adenda, válvulas do tipo Strata, 3,0 Tesla
Anexo, válvulas tipo Strata, 3 teslas
Tillägg, ventiler av Strata-typ, 3,0 Tesla
Ek, Strata Tipi Valfler, 3,0 Tesla

Medtronic

y). This symbol means that the device fully complies with European Directive 93/42/EEC.
emmelse). Dette symbol angiver, at anordningen er i fuld overensstemmelse med EU-direktivet 93/42/EØF.
nt). Dit symbool betekent dat het apparaat voldoet aan Europese richtlijn 93/42/EEC.
ue le dispositif est entièrement conforme aux exigences de la directive 93/42 de la CEE.
hlält). Dieses Symbol bedeutet, dass die Vorrichtung vollständig mit der europäischen Direktive 93/42/EWG in Einklang steht.
ιωση). Αυτό το σύμβολο σημαίνει ότι η ιατρική συμπορεύεται πλήρως προς την Ευρωπαϊκή Κατευθυντήρια Οδηγία 93/42/ΕΟΚ.
g). Ez a jel azt jelenti, hogy az eszköz teljes mértékben megfelel a 93/42/EEC európai irányelvnek.
). Questo simbolo indica che il dispositivo aderisce pienamente ai termini della Direttiva europea 93/42/CEE.
et). Dette symbolet angir at enheten oppfyller europeisk direktiv 93/42/EØS.
o). Symbol oznaczający, że urządzenie spełnia w całości wymogi Dyrektywy Rady nr 93/42/EEC.
eia). Este símbolo significa que o dispositivo cumpre na íntegra a Directiva Europeia 93/42/CEE.
a). Este símbolo significa que el dispositivo cumple totalmente con la disguesta en la Directiva Europea 93/42/EEC.
et). Denna symbol anger att anordningen uppfyller kraven i EU-direktivet 93/42/EEC.
şaret cihazın Avrupa Direktifi 93/42/EEC ile tam uyumlu olduğunu göstermektedir.

	Προσοχή: Συμβουλευτείτε τα συνοδευτικά έντυπα	Atenção: consulte as instruções para uso
	Figyelem: Lásd a használati utasítást	Atención: consulte las instrucciones de uso
	Attenzione: vedere le istruzioni per l'uso	Obs! Se bruksanvisningen
	Obs! Se dokumentasjonen som følger med	Dikkat: Beraberindeki Belgelere Bakınız
	Uwaga: Zobacz dokumenty towarzyszące	

	Επηρεάζεται σε περιβάλλον μαγνητικού συντονισμού	Condicional de ressonância magnética
	Mágneses rezonancia alkalmazása feltételhez kötött	Resonancia magnética condicional
	Condizionato dalla risonanza magnetica	Villkor för magnetresonans
	Magnetisk resonans betinget	Manyetik Rezonans Koşullu
	Zależne od Magnetycznego Rezonansu	

	Gyártó	Wytwórca	Tillverkare
	Producttoe	Fabricante	Üretici
ατής	Produsent	Fabricante	

Warnings and Precautions - MRI Information

MR

Valves

The Strata®, Strata® NSC, and Strata® II valves are considered Magnetic Resonance Conditional in accordance with ASTM F2503.

MRI systems of up to 3.0 Tesla may be used any time after implantation and will not damage the Strata, Strata NSC, or Strata II valve mechanisms, but can change the performance level setting. The performance level setting should always be checked before and after MRI exposure.

The results of the tests performed to assess magnetic field interactions, artifacts, and heating, indicated the presence of the valves evaluated should present no substantial risk to a patient undergoing an MRI procedure using the following conditions:

- Static magnetic field of **3.0 Tesla** or less
- Spatial Gradient of 720 G/cm or less
- Radio Frequency (RF) Fields with an average Specific Absorption Rate (SAR) of 3 W/kg for 15 minutes.

Using the GE 3.0T Excite® HD Magnetic Resonance Imaging System, the valve experienced a maximum temperature change of 0.4°C over a 15 minute exposure period.

The table provides maximum signal voids (artifact sizes) for standard imaging pulse sequences at **3.0 Tesla** per ASTM F2119.

Valve	Pulse Sequence	Plane Imaging	Max. Signal Void (Artifact), cm^2
Strata-type	T1-SE	Parallel	35.16
	T1-SE	Perpendicular	33.03
	GRE	Parallel	73.91
	GRE	Perpendicular	66.55

Adjustment Kits

Do **NOT** take the Adjustment Tool into an MRI facility as these magnets could potentially be a safety hazard to the patient and/or user.

Proximity to MRI suite may impede the mechanism in the Indicator Tool due to the field strength of an MRI magnet. Move out of the vicinity prior to attempting to verify a valve setting.

Prosepective Study to Evaluate Rate and Frequency of Perturbations of Implanted Programmable Hakim Codman® Valve after 1,5-Tesla MRI.

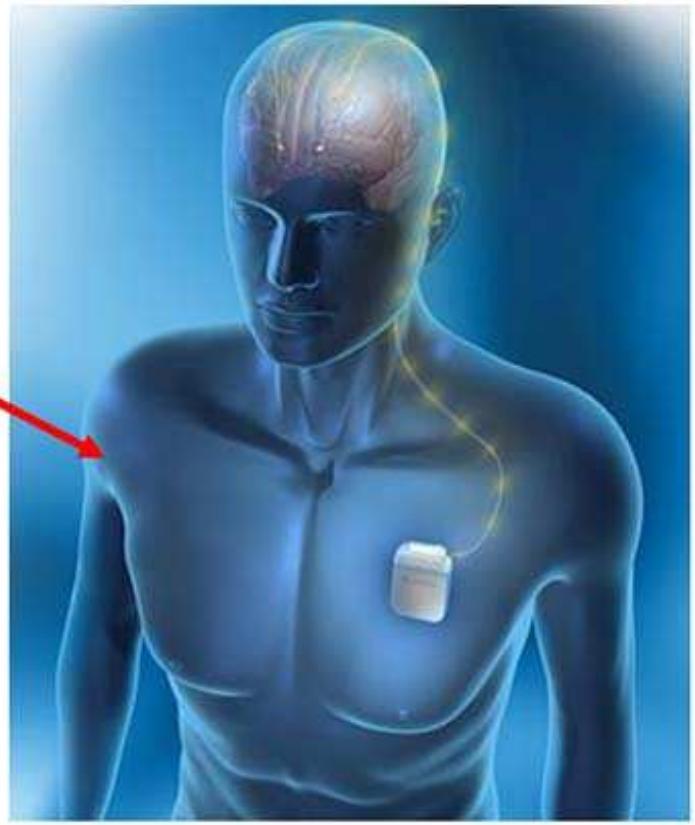
Capitanio JF, Venier A, Mazzeo LA, Barzaghi LR, Acerno S, Mortini P.

World Neurosurg**. 2015 Oct 5. pii: S1878-8750(15)01250-4. doi: 10.1016/j.wneu.2015.09.082. [Epub ahead of print]**

PMID:

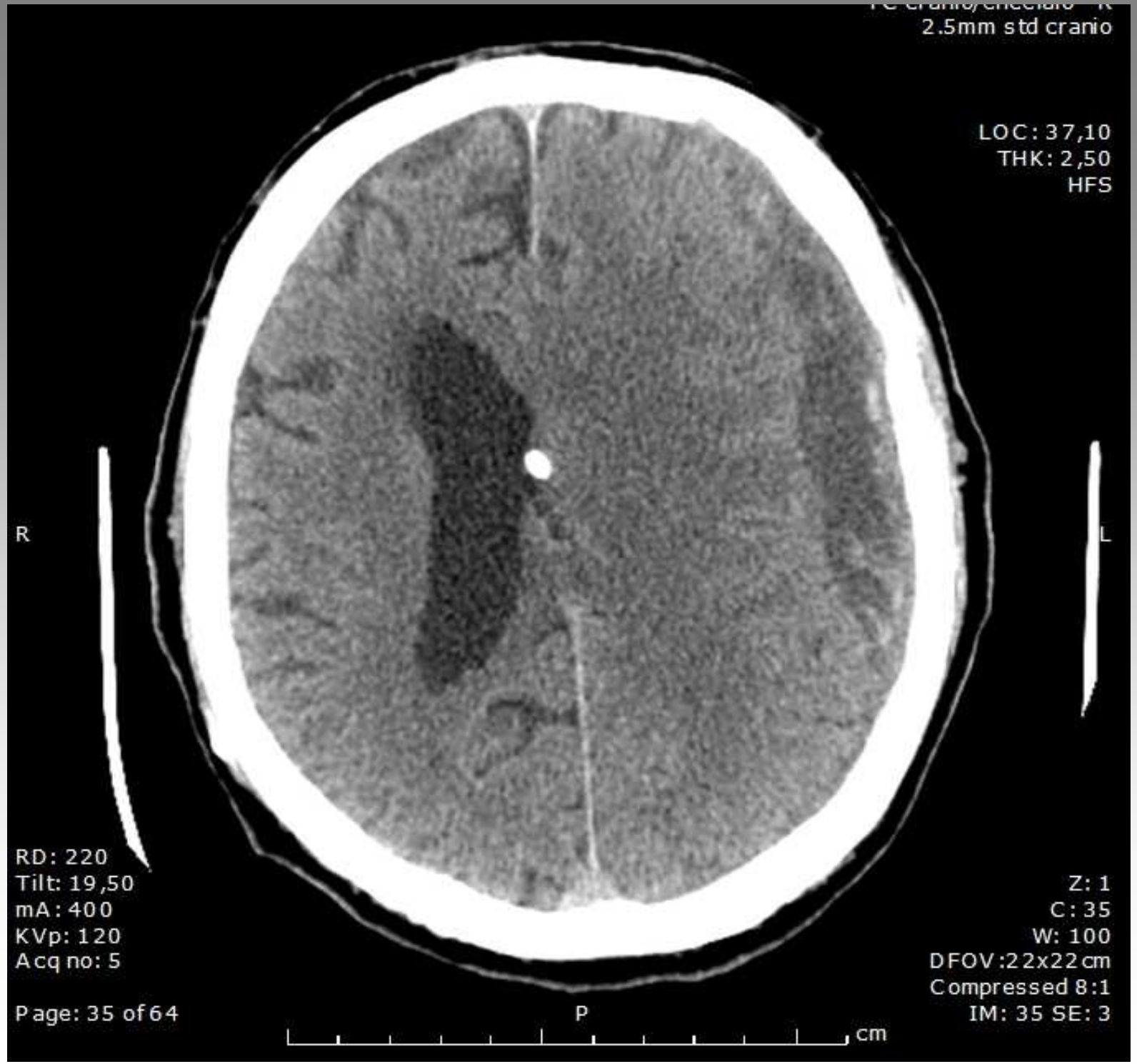
26455768

Deep brain stimulation device

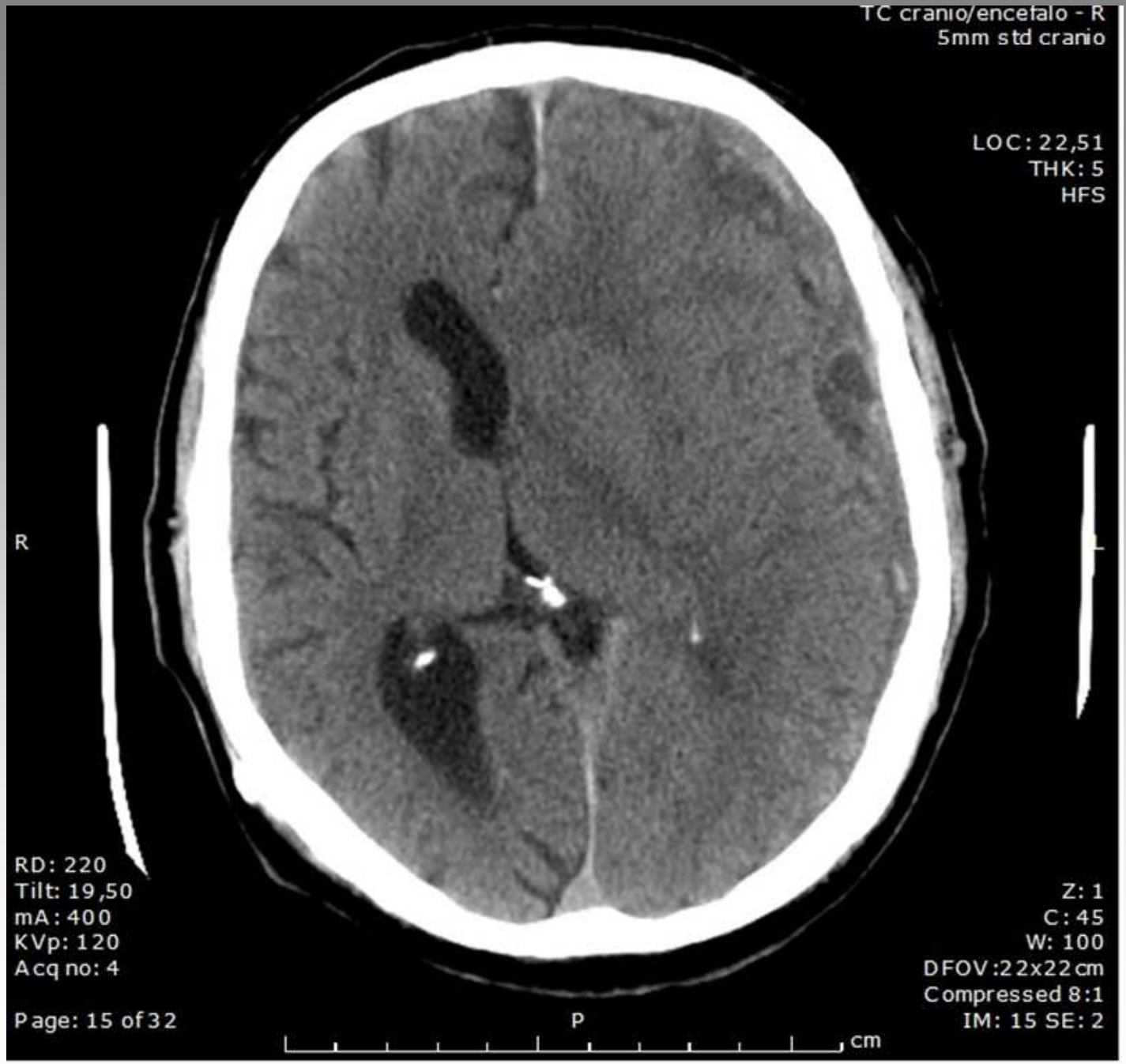


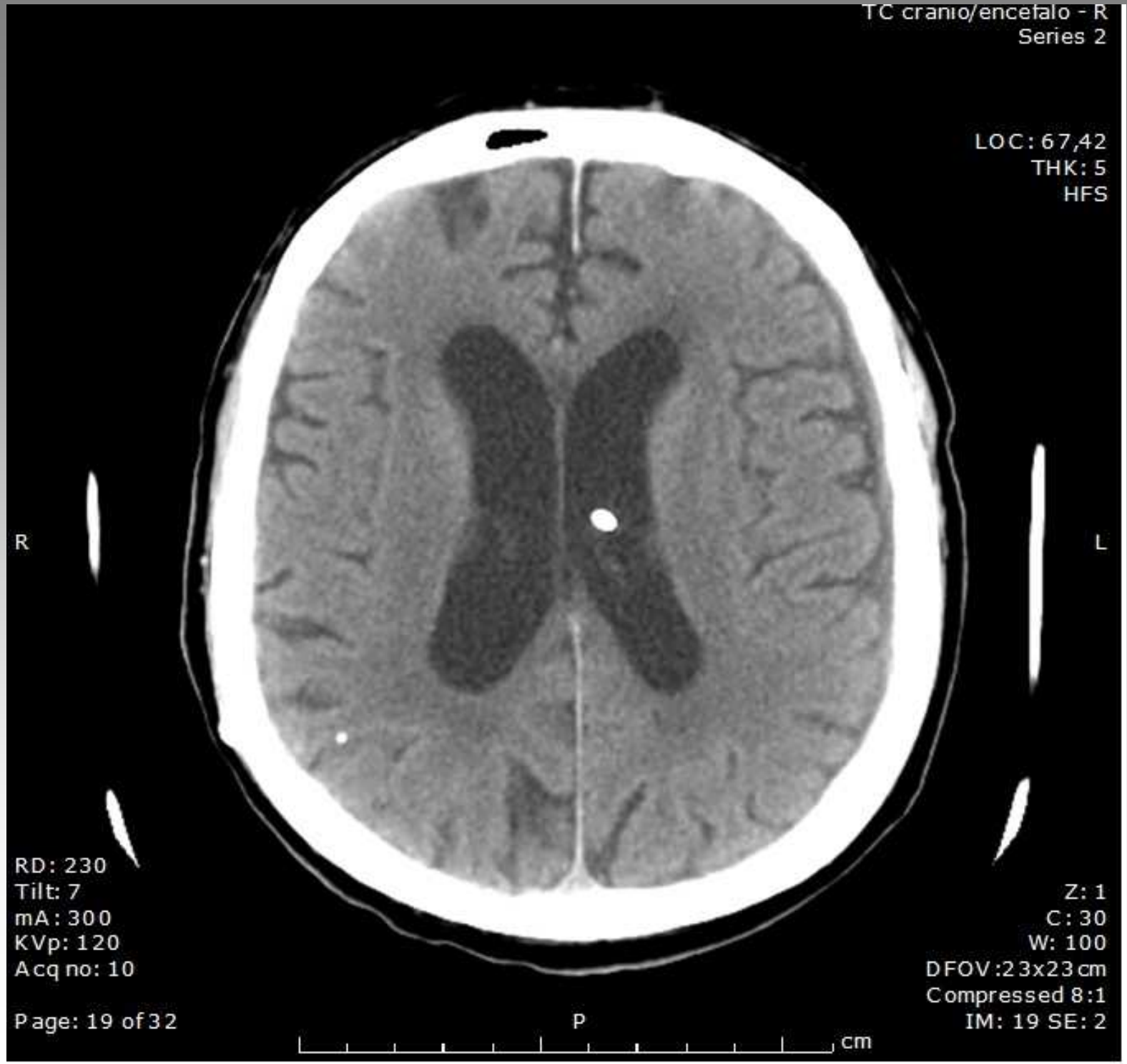
Spinal cord stimulation device

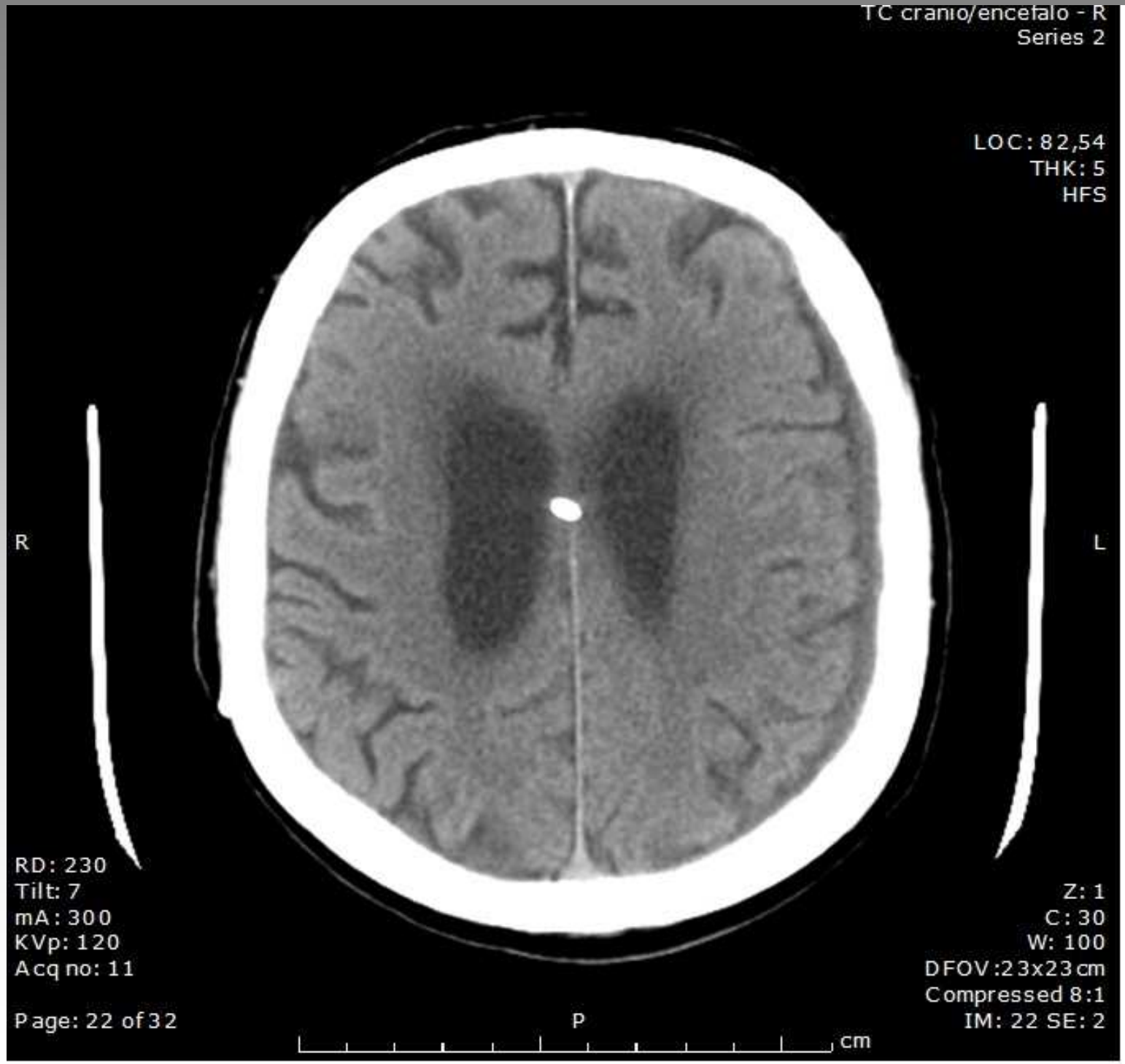
Maschio, 83 anni
DVP valvola strata per idrocefalo normoteso
TAO per fibrillazione atriale
RM per controllo


2.5mm std cranio
LOC: 37,10
THK: 2,50
HFS
R
L
RD: 220
Tilt: 19,50
mA: 400
KVp: 120
Acq no: 5
Page: 35 of 64
P
cm
Z: 1
C: 35
W: 100
DFOV: 22x22 cm
Compressed 8:1
IM: 35 SE: 3

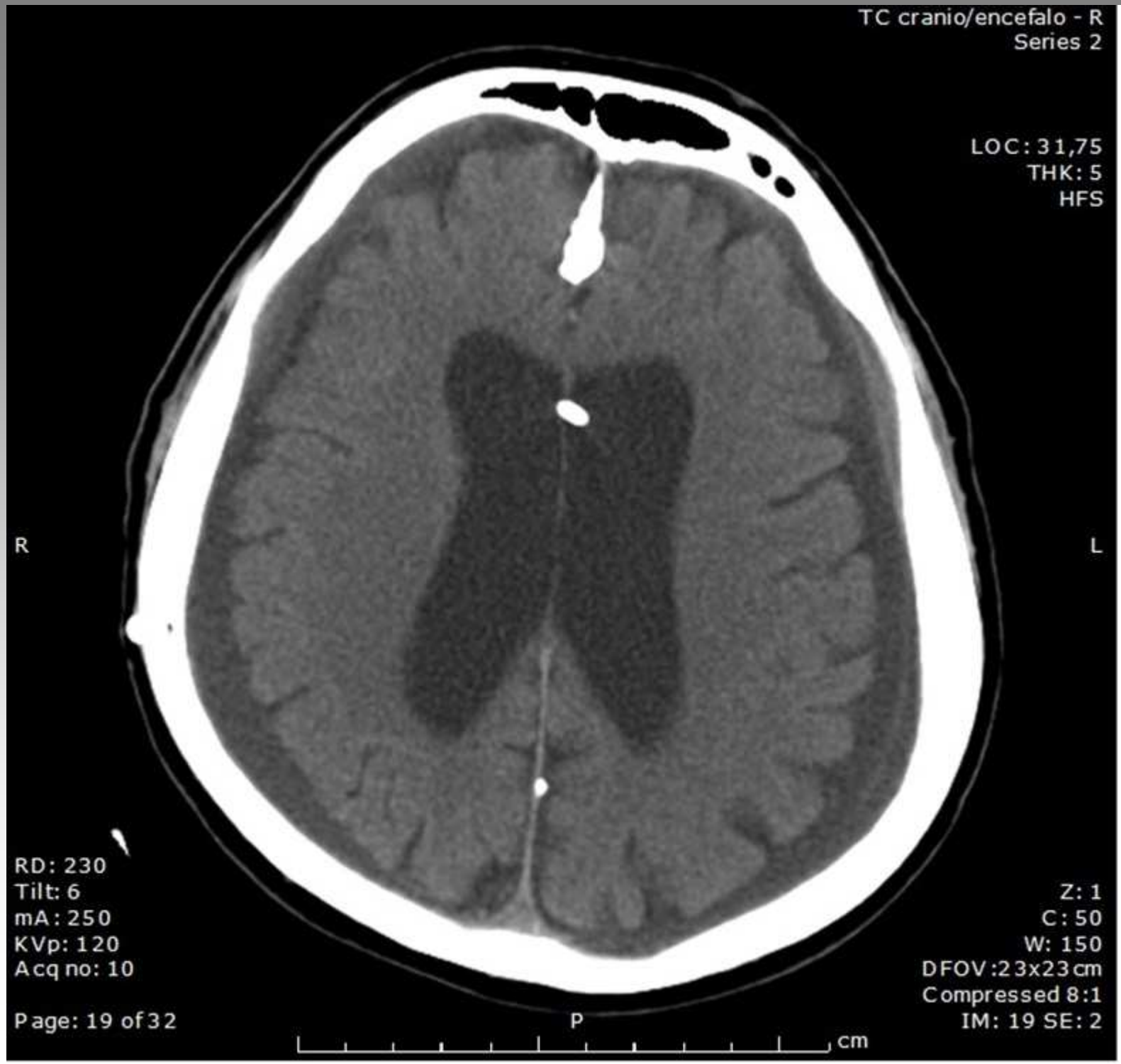

TC cranio/encefalo - R
5mm std cranio
LOC: 59,64
THK: 5
HFS
R
L
20,55mm
RD: 220
Tilt: 19,50
mA: 400
KVp: 120
Acq no: 6
Page: 22 of 32
P
cm
Z: 1
C: 45
W: 100
DFOV: 22x22 cm
Compressed 8:1
IM: 22 SE: 2

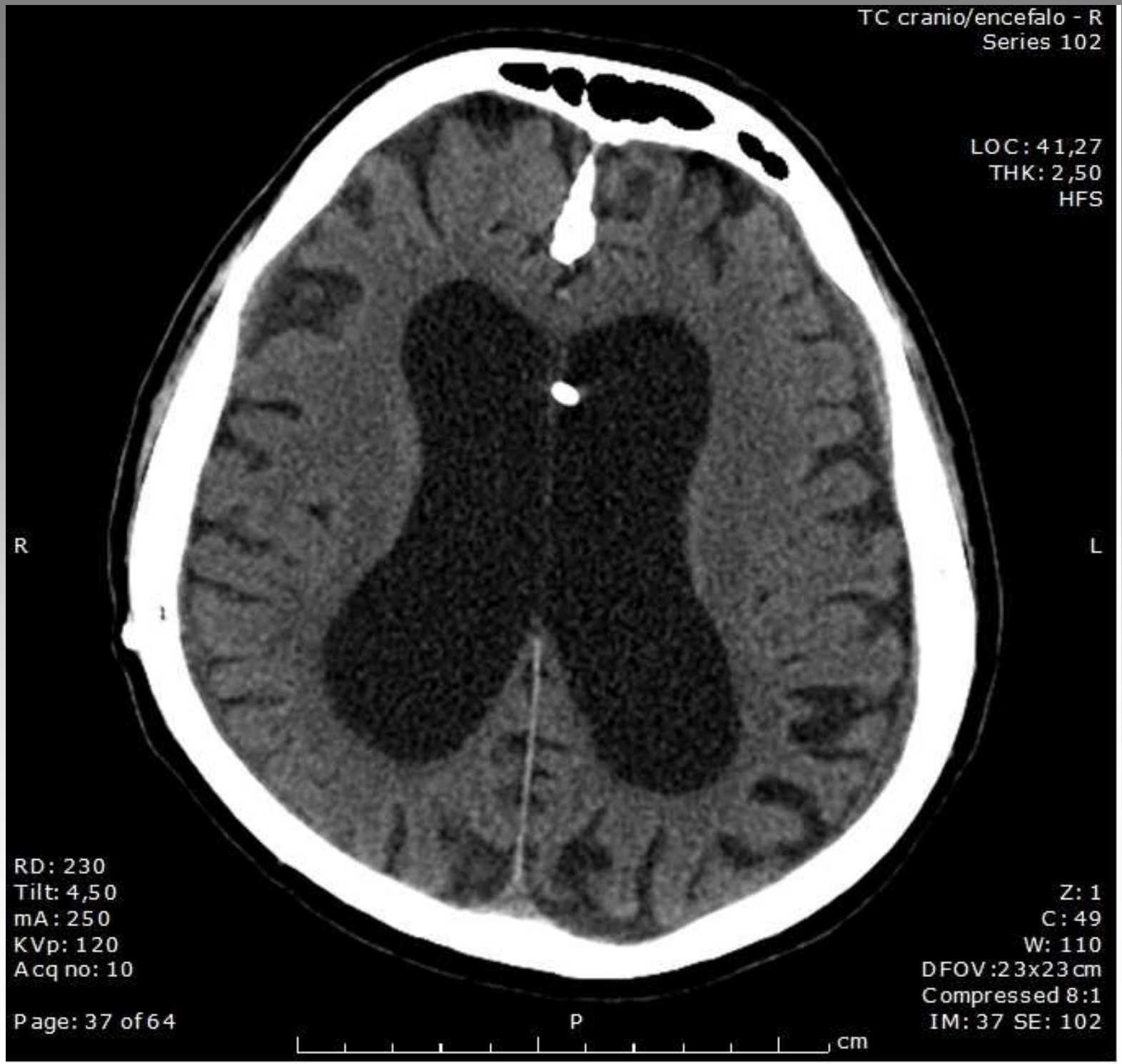

TC cranio/encefalo - R
5mm std cranio
LOC: 22,51
THK: 5
HFS
R
RD: 220
Tilt: 19,50
mA: 400
KVp: 120
Acq no: 4
Page: 15 of 32
P
cm
Z: 1
C: 45
W: 100
DFOV: 22x22 cm
Compressed 8:1
IM: 15 SE: 2


TC cranio/encefalo - R
Series 2
LOC: 67,42
THK: 5
HFS
R
L
RD: 230
Tilt: 7
mA: 300
KVp: 120
Acq no: 10
Page: 19 of 32
P
cm
Z: 1
C: 30
W: 100
DFOV: 23x23 cm
Compressed 8:1
IM: 19 SE: 2


TC cranio/encefalo - R
Series 2
LOC: 82,54
THK: 5
HFS
R
L
RD: 230
Tilt: 7
mA: 300
KVp: 120
Acq no: 11
Page: 22 of 32
P
cm
Z: 1
C: 30
W: 100
DFOV: 23x23 cm
Compressed 8:1
IM: 22 SE: 2

Maschio 71 anni
DVP valvola strata per idrocefalo normoteso
RM osteoarticolare


TC cranio/encefalo - R
Series 2
LOC: 31,75
THK: 5
HFS
R
L
RD: 230
Tilt: 6
mA: 250
KVp: 120
Acq no: 10
Page: 19 of 32
Z: 1
C: 50
W: 150
DFOV: 23x23cm
Compressed 8:1
IM: 19 SE: 2
P
cm

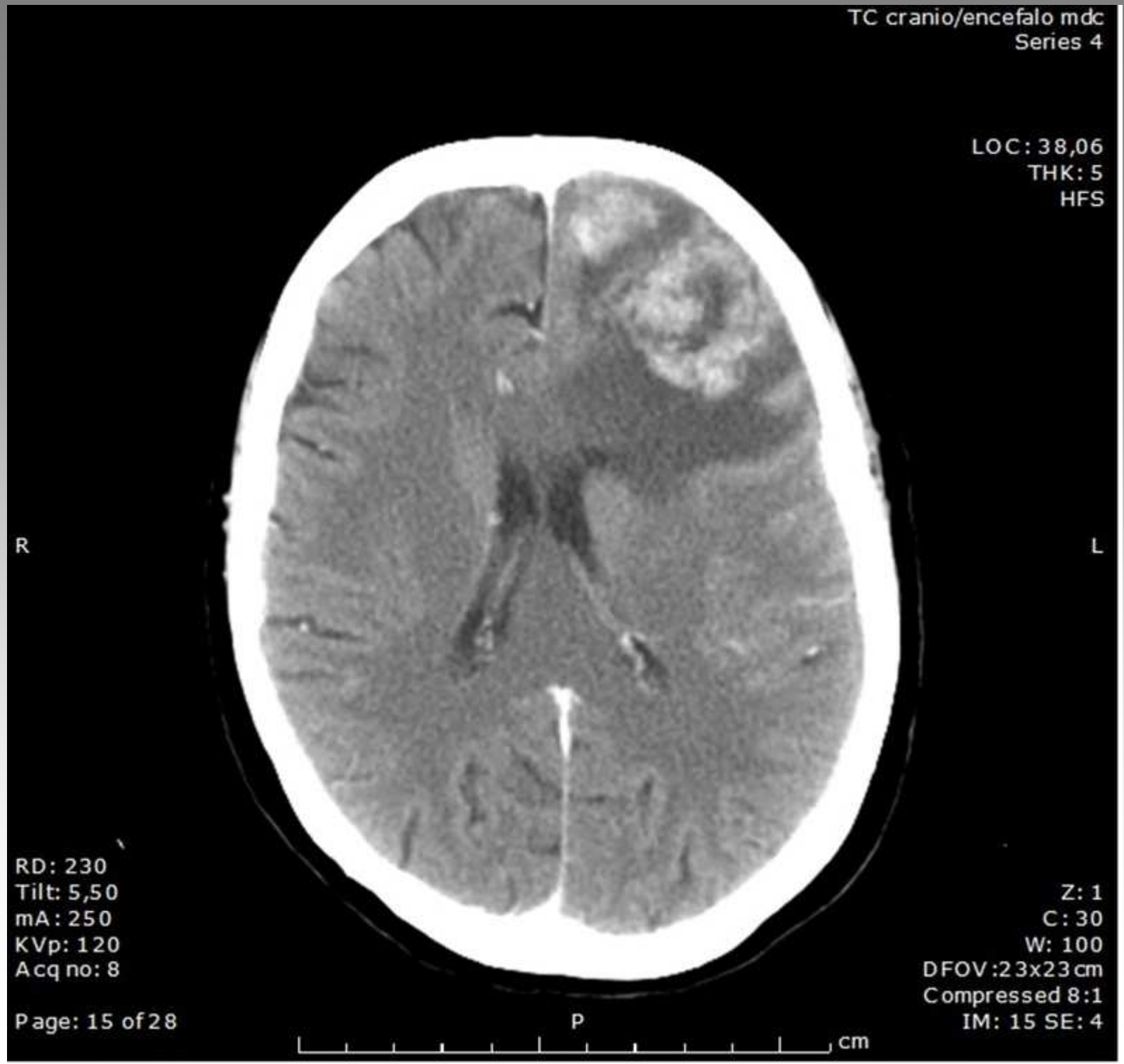

TC cranio/encefalo - R
Series 102
LOC: 41,27
THK: 2,50
HFS
R
L
RD: 230
Tilt: 4,50
mA: 250
KVp: 120
Acq no: 10
Page: 37 of 64
P
cm
Z: 1
C: 49
W: 110
DFOV: 23x23 cm
Compressed 8:1
IM: 37 SE: 102

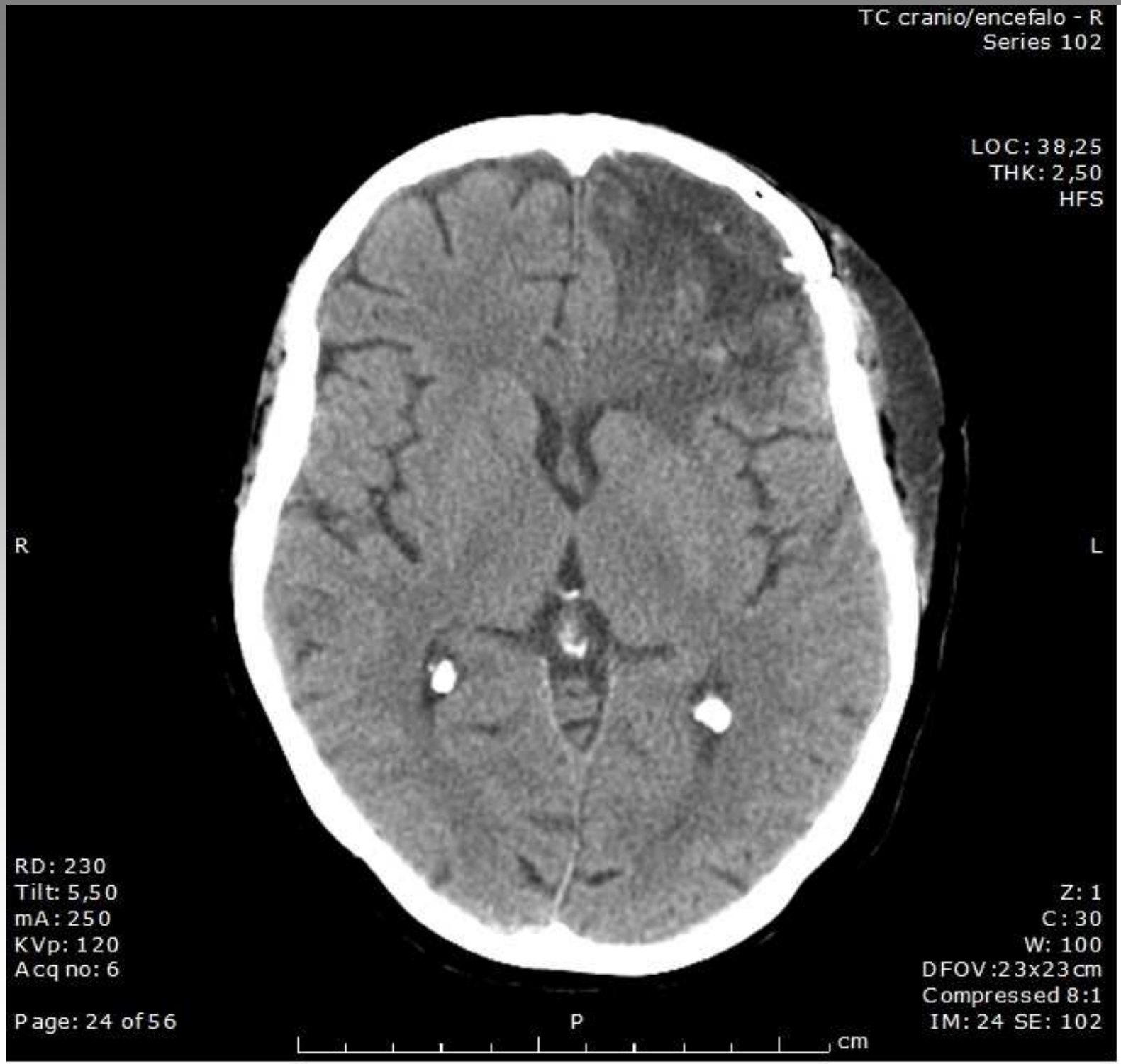
Femmina 78 anni
Da 2 settimane confusione, rallentamento
Nel 1987 protesi staffa AU Dx
Anacusia Dx


Series 4
LOC: -12,16
THK: 5
HFS
R
L
RD: 230
Tilt: 5,50
mA: 250
KVp: 120
Acq no: 3
Page: 5 of 28
P
cm
Z: 1
C: 400
W: 2000
DFOV: 23x23cm
Compressed 8:1
IM: 5 SE: 4


Series 4
LOC: -17,18
THK: 5
HFS
R
L
RD: 230
Tilt: 5,50
mA: 250
KVp: 120
Acq no: 2
Page: 4 of 28
P
cm
Z: 1
C: 400
W: 2000
DFOV: 23x23 cm
Compressed 8:1
IM: 4 SE: 4

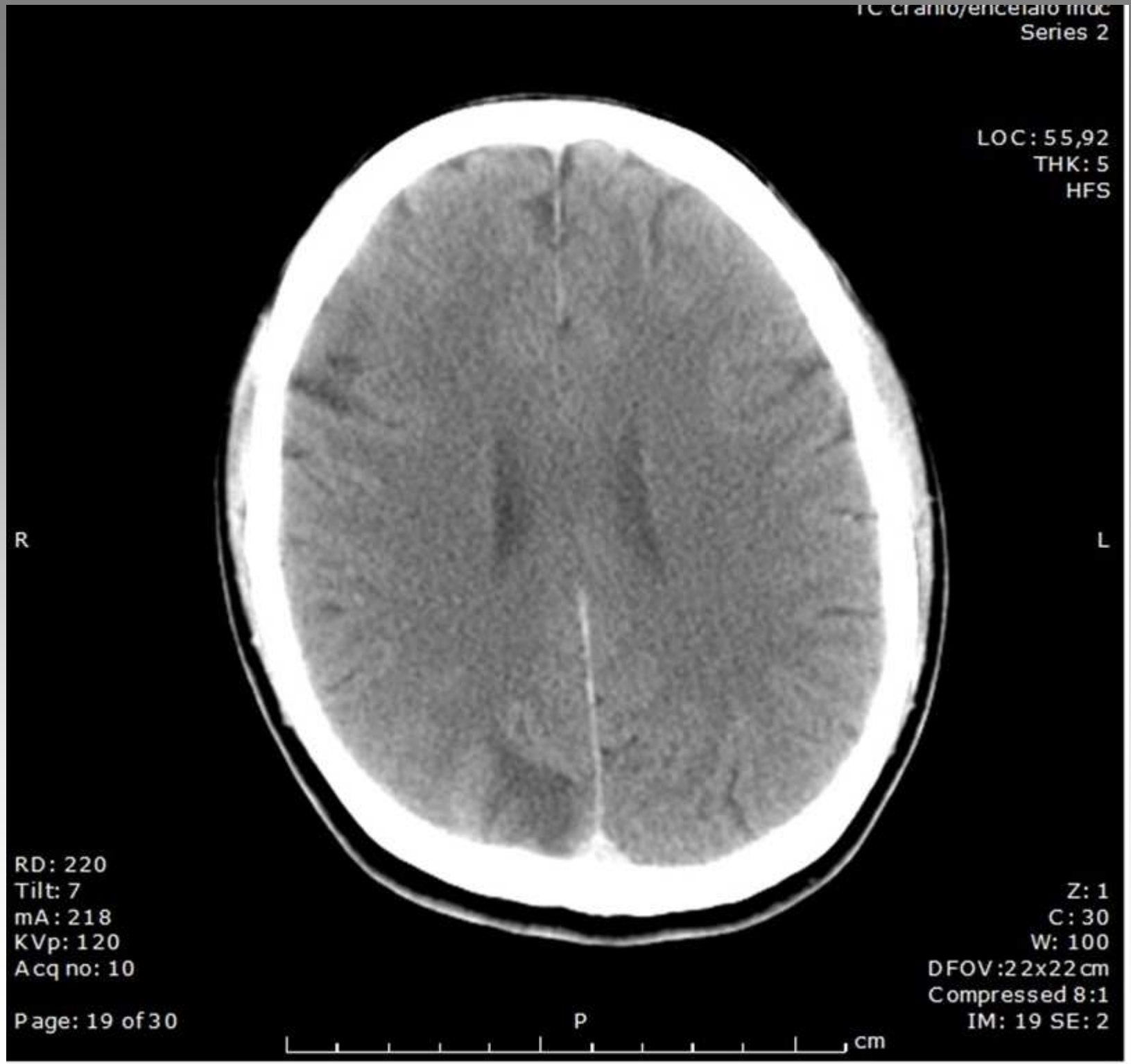

TC cranio/encefalo mdc
Series 4
LOC: 23
THK: 5
HFS
R
L
RD: 230
Tilt: 5,50
mA: 250
KVp: 120
Acq no: 6
Page: 12 of 28
P
cm
Z: 1
C: 30
W: 100
DFOV: 23x23 cm
Compressed 8:1
IM: 12 SE: 4

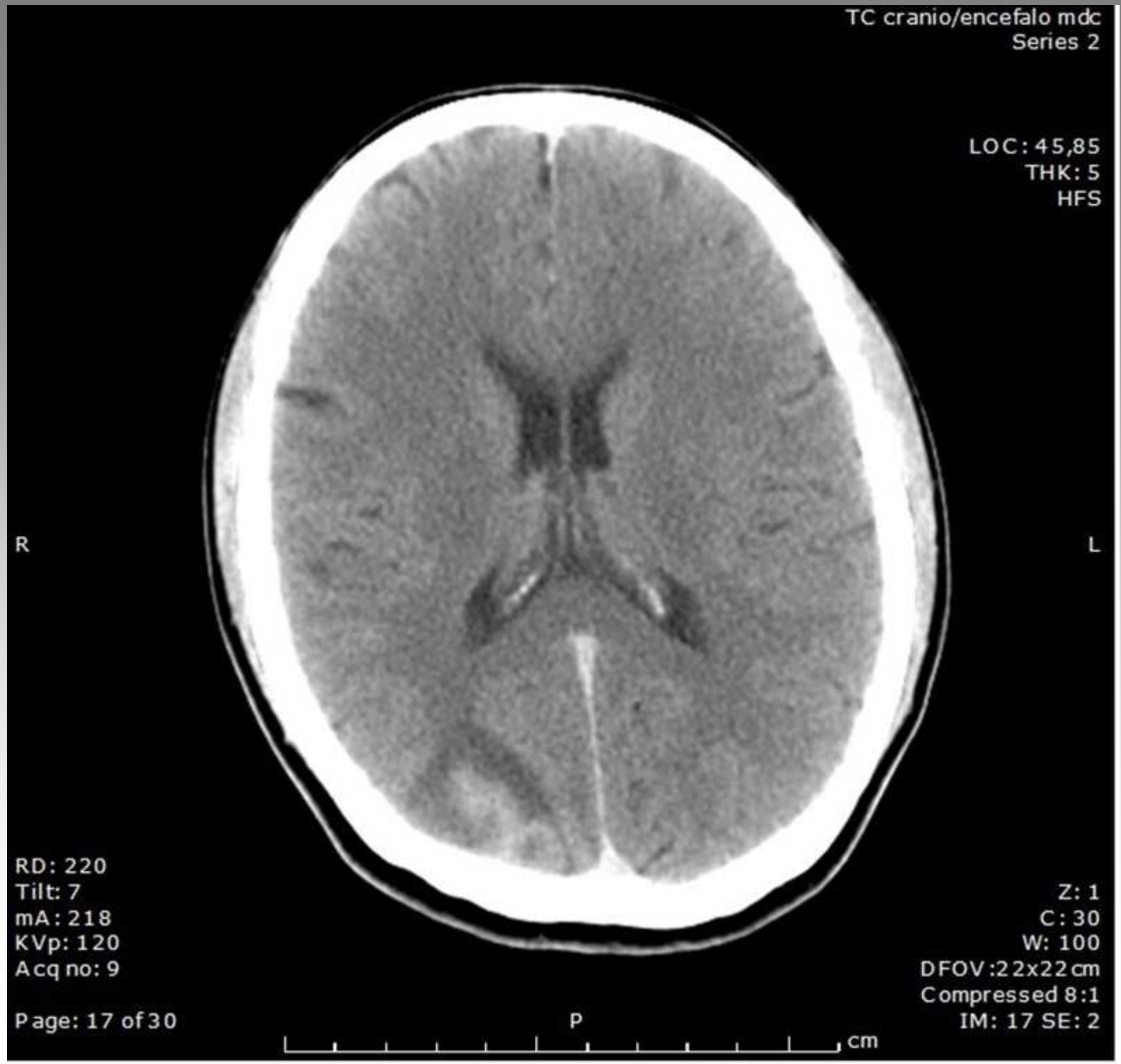

TC cranio/encefalo mdc
Series 4
LOC: 38,06
THK: 5
HFS
R
L
RD: 230
Tilt: 5,50
mA: 250
KVp: 120
Acq no: 8
Page: 15 of 28
P
cm
Z: 1
C: 30
W: 100
DFOV: 23x23 cm
Compressed 8:1
IM: 15 SE: 4

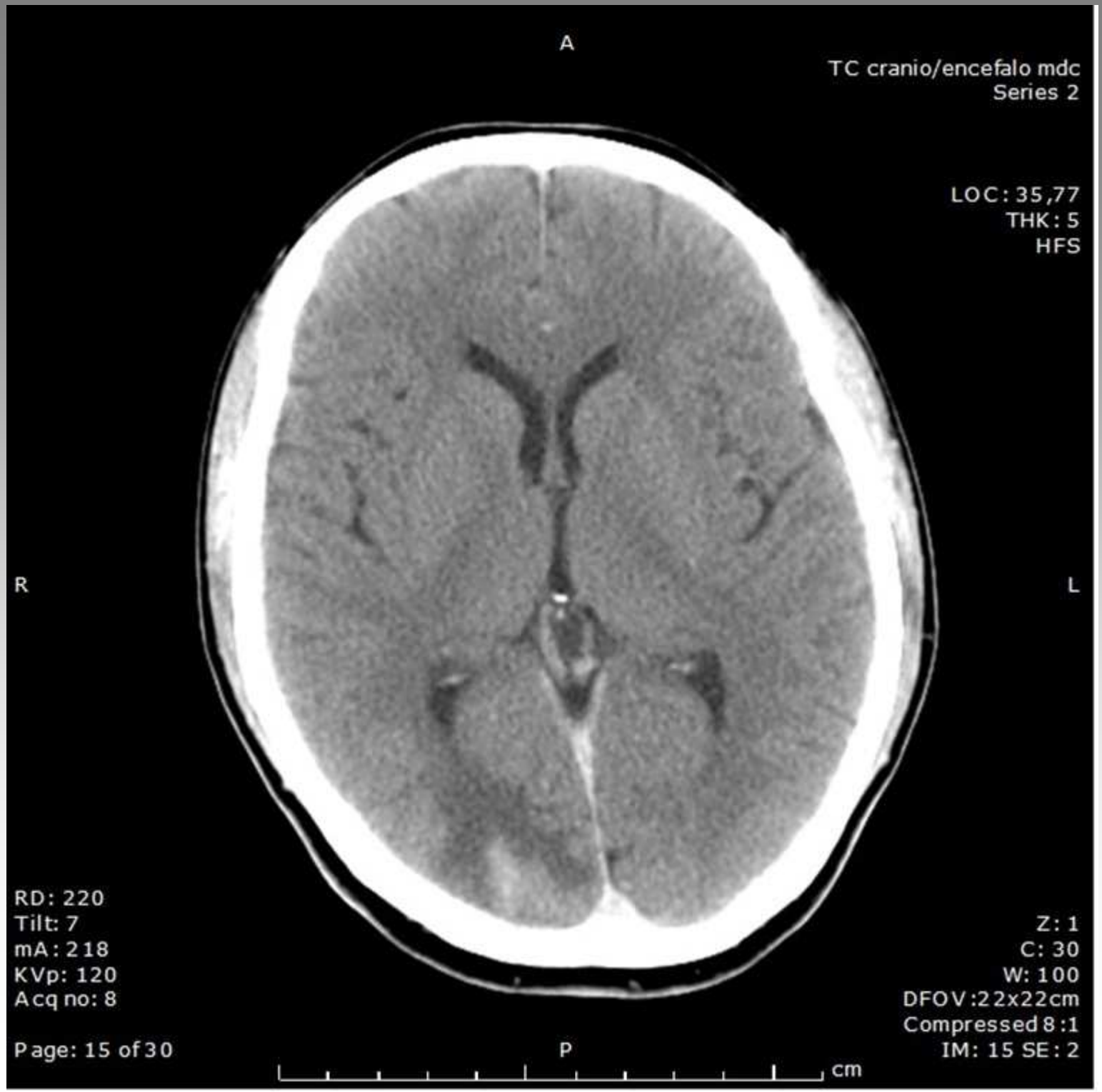

TC cranio/encefalo - R
Series 102
LOC: 38,25
THK: 2,50
HFS
R
L
RD: 230
Tilt: 5,50
mA: 250
KVp: 120
Acq no: 6
Page: 24 of 56
P
cm
Z: 1
C: 30
W: 100
DFOV: 23x23 cm
Compressed 8:1
IM: 24 SE: 102

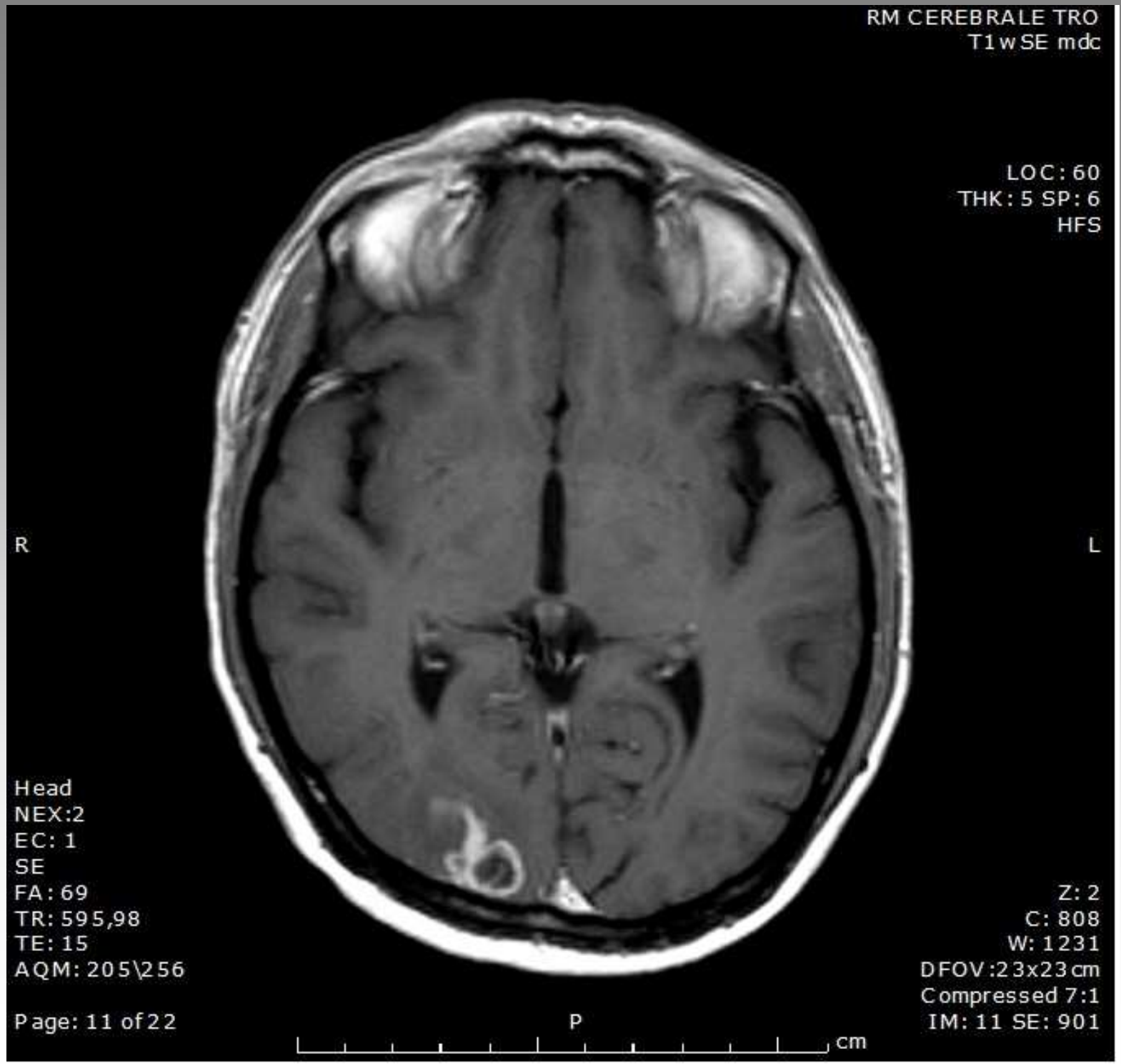

Series 102
LOC: 25,70
THK: 2,50
HFS
R
L
RD: 230
Tilt: 5,50
mA: 250
KVp: 120
Acq no: 5
Page: 19 of 56
P
cm
Z: 1
C: 30
W: 100
DFOV: 23x23 cm
Compressed 8:1
IM: 19 SE: 102

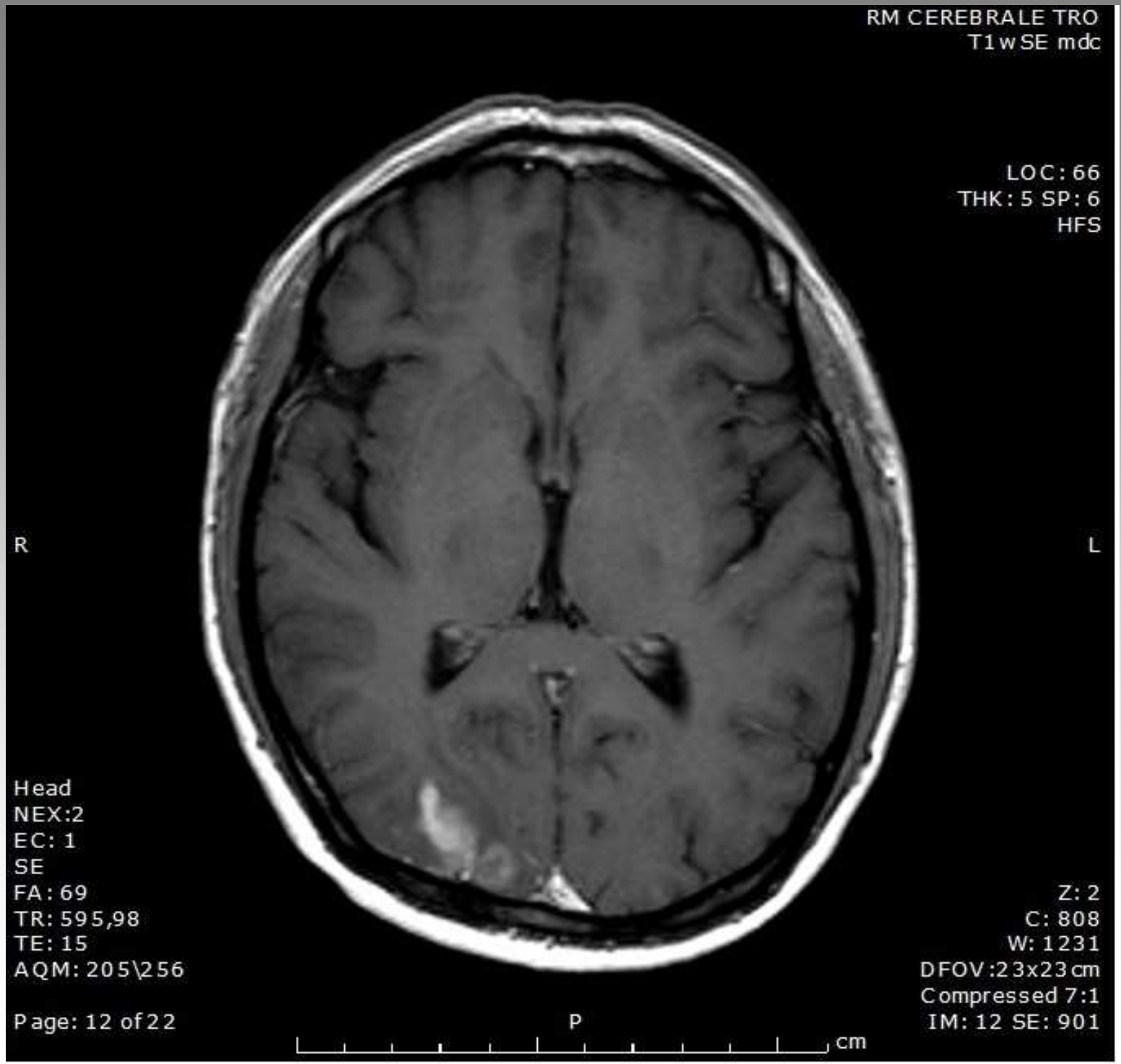
Femmina 38 anni
K mammella maggio 2014
Espansori mammari no RM compatibili
Gennaio 2015 TIA?


TC cranio/encefalo ridc
Series 2
LOC: 55,92
THK: 5
HFS
R
L
RD: 220
Tilt: 7
mA: 218
KVp: 120
Acq no: 10
Page: 19 of 30
P
cm
Z: 1
C: 30
W: 100
DFOV: 22x22 cm
Compressed 8:1
IM: 19 SE: 2


TC cranio/encefalo mdc
Series 2
LOC: 45,85
THK: 5
HFS
R
L
RD: 220
Tilt: 7
mA: 218
KVp: 120
Acq no: 9
Page: 17 of 30
P
cm
Z: 1
C: 30
W: 100
DFOV: 22x22 cm
Compressed 8:1
IM: 17 SE: 2


A
TC cranio/encefalo mdc
Series 2
LOC: 35,77
THK: 5
HFS
R
L
RD: 220
Tilt: 7
mA: 218
KVp: 120
Acq no: 8
Page: 15 of 30
P
cm
Z: 1
C: 30
W: 100
DFOV: 22x22cm
Compressed 8:1
IM: 15 SE: 2


RM CEREBRALE TRO
T1wSE mdc
LOC: 60
THK: 5 SP: 6
HFS
R
L
Head
NEX:2
EC: 1
SE
FA: 69
TR: 595,98
TE: 15
AQM: 205\256
Page: 11 of 22
P
cm
Z: 2
C: 808
W: 1231
DFOV: 23x23 cm
Compressed 7:1
IM: 11 SE: 901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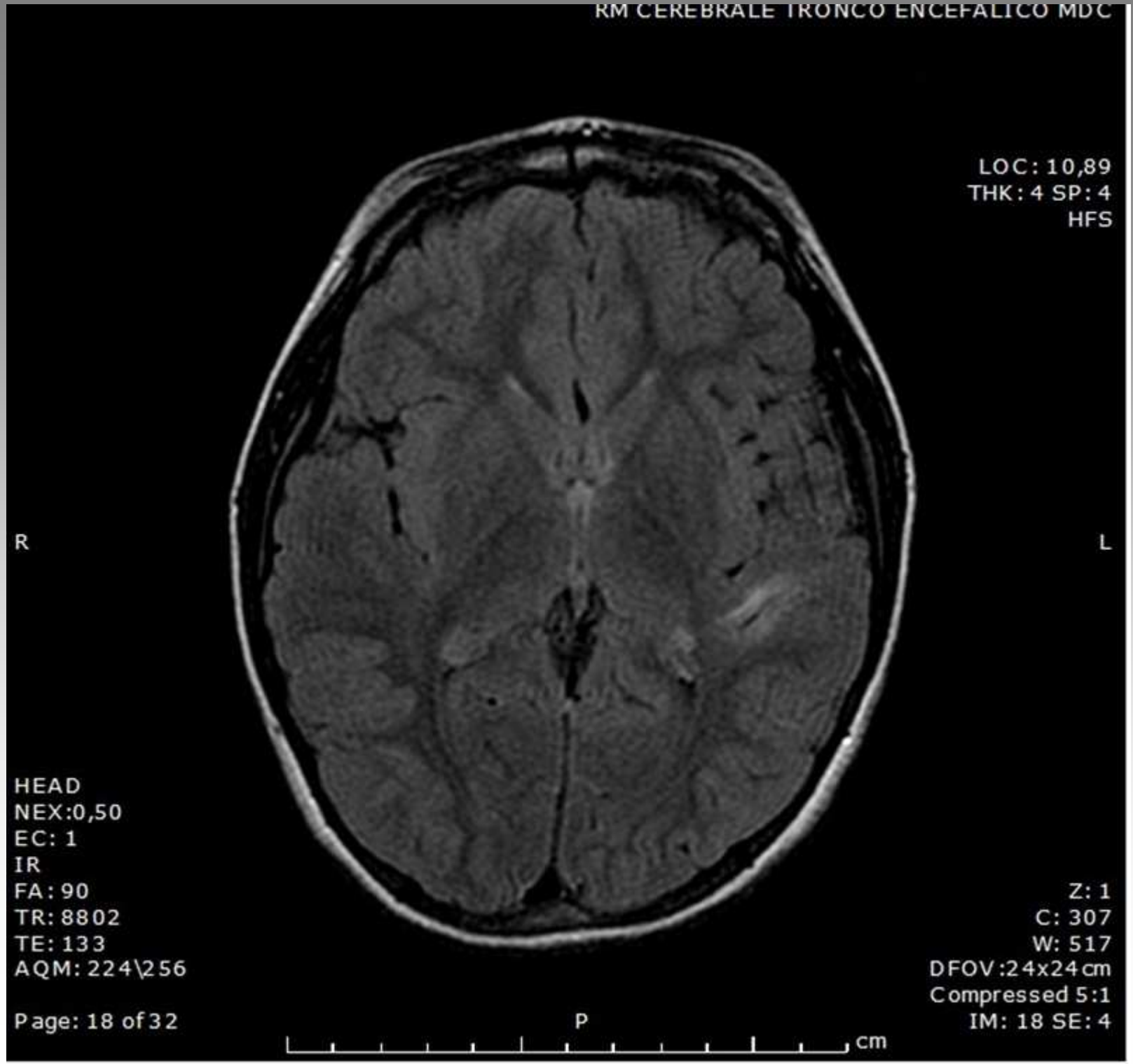
T1wSE mdc
LOC: 66
THK: 5 SP: 6
HFS
R
L
Head
NEX:2
EC: 1
SE
FA: 69
TR: 595,98
TE: 15
AQM: 205\256
Page: 12 of 22
P
cm
Z: 2
C: 808
W: 1231
DFOV: 23x23 cm
Compressed 7:1
IM: 12 SE: 901


RM CEREBRALE TRO
T1wSE mdc
LOC: 132
THK: 5 SP: 6
HFS
R
L
Head
NEX:2
EC: 1
SE
FA: 67
TR: 623,86
TE: 15
AQM: 169\212
Page: 1 of 23
F
cm
Z: 2,29
C: 1192
W: 2072
DFOV:19x19cm
Compressed 7:1
IM: 1 SE: 1001

Maschio 17 anni
A 7 anni diagnosi di epilessia temporale
Gravi difficoltàapprendimento, dislessia
A 12 anni cambio di mano nello scrivere
A 17 aa coma,emiplegia dx

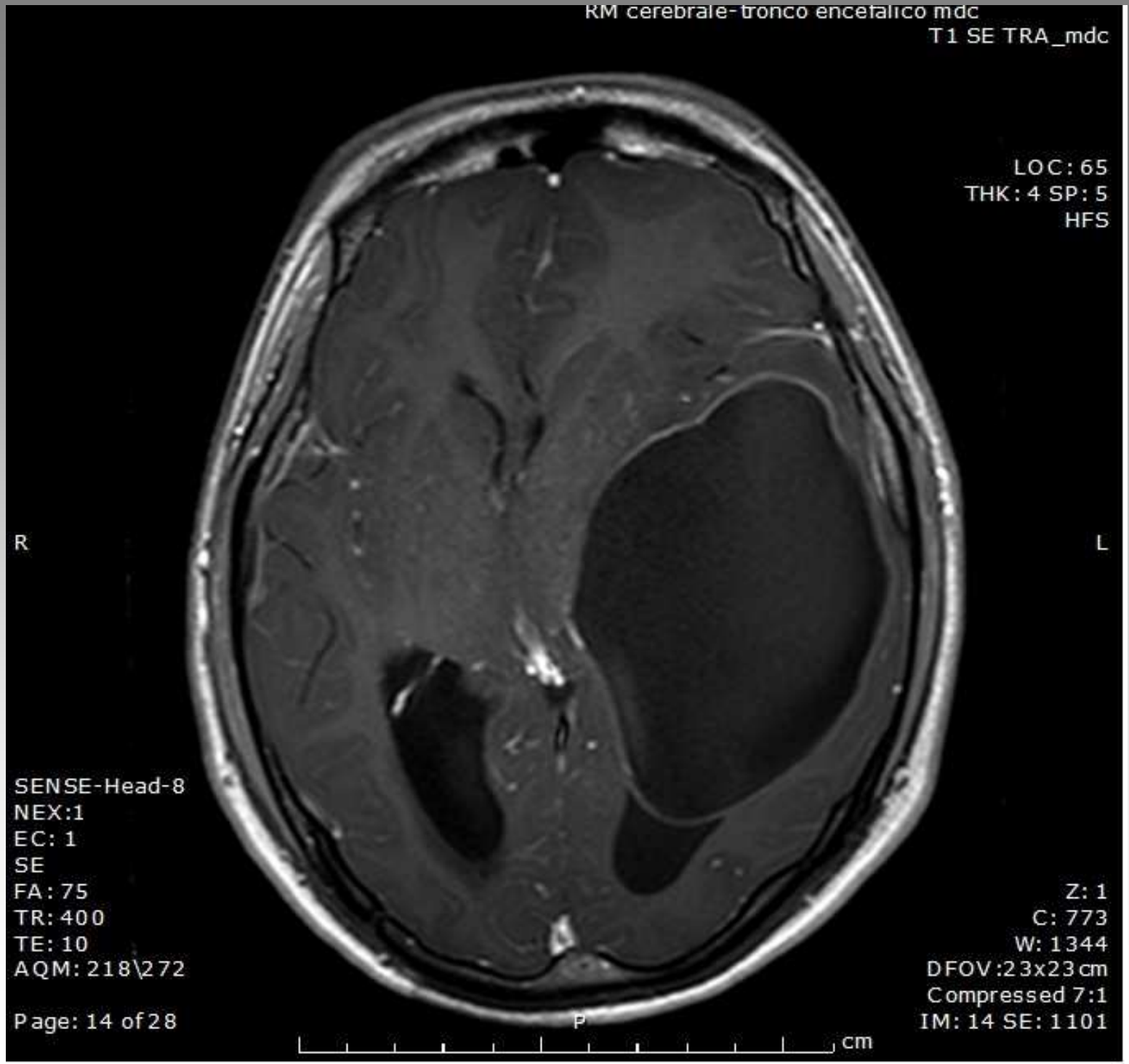

RM CEREBRALE TRONCO ENCEFALICO MDC
LOC: 10,89
THK: 4 SP: 4
HFS
R
L
HEAD
NEX:0,50
EC: 1
IR
FA: 90
TR: 8802
TE: 133
AQM: 224\256
Page: 18 of 32
P
cm
Z: 1
C: 307
W: 517
DFOV:24x24cm
Compressed 5:1
IM: 18 SE: 4


H
RM CEREBRALE TRONCO ENCEFALICO MDC
LOC: -29,33
THK: 4 SP: 5
HFS
R
L
HEAD
NEX: 1
EC: 1
IR
FA: 90
TR: 6000
TE: 20
AQM: 224\512
Page: 8 of 14
F
cm
Z: 1
C: 453
W: 907
DFOV: 24x24cm
Compressed 5:1
IM: 8 SE: 3


TC cranio/encefalo - R
Series 102
LOC: 50,93
THK: 2,50
HFS
R
L
RD: 220
Tilt: 4,50
mA: 218
KVp: 120
Acq no: 7
Page: 26 of 56
P
cm
Z: 1
C: 47
W: 80
DFOV: 22x22 cm
Compressed 8:1
IM: 26 SE: 102


TC cranio/encefalo - R
Series 102
LOC: 68,49
THK: 2,50
HFS
R
L
RD: 220
Tilt: 4,50
mA: 218
KVp: 120
Acq no: 9
Page: 33 of 56
P
cm
Z: 1
C: 47
W: 80
DFOV: 22x22 cm
Compressed 8:1
IM: 33 SE: 102


RM cerebrale-tronco encefalico mdc
T1 SE TRA_mdc
LOC: 90
THK: 4 SP: 5
HFS
R
L
SENSE-Head-8
NEX:1
EC: 1
SE
FA: 75
TR: 400
TE: 10
AQM: 218\272
Page: 19 of 28
P
cm
Z: 1
C: 660
W: 1147
DFOV: 23x23 cm
Compressed 7:1
IM: 19 SE: 1101


RM cerebrale-tronco encefalico mdc
T1 SE TRA_mdc
LOC: 65
THK: 4 SP: 5
HFS
R
L
SENSE-Head-8
NEX:1
EC: 1
SE
FA: 75
TR: 400
TE: 10
AQM: 218\272
Page: 14 of 28
Z: 1
C: 773
W: 1344
DFOV: 23x23 cm
Compressed 7:1
IM: 14 SE: 1101
P
cm


H
RM cerebrale-tronco encefalico mdc -
T1 SE COR_mdc
LOC: 95
THK: 4 SP: 5
HFS
R
L
SENSE-Head-8
NEX:1
EC: 1
SE
FA: 75
TR: 400
TE: 10
AQM: 218\272
Page: 17 of 36
F
cm
Z: 1
C: 1229
W: 2136
DFOV:23x23cm
Compressed 7:1
IM: 17 SE: 1201

Take home message

1. controllo valvole DVP dopo RMI

2. eseguire RMI encefalo in pazienti con lesioni intracraniche